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How to Improve a Production Flow within the Medical Device Sector Using Lean Methods

- A case study at Astra Tech

Master of Science Thesis in Production Engineering

ANNA BERGDAHL
GUSTAV BLANK

Department of Technology Management and Economics
Division of Logistics and Transportation
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Master's Thesis E2012:071
Department of Technology Management and Economics
Division of Logistics and Transportation
Chalmers University of Technology
SE-412 96 Gothenburg
Sweden
Telephone: + 46 (0)31-772 1000

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Abstract

This Master's Thesis was based on a case study at Astra Tech, a company operating in the Medical Device Sector. What distinct this sector is the requirements for high quality and cleanliness. Lately Astra Tech had experienced problems with high scrap rate, low resource efficiency, and long throughput times in the production flow of one of their product families.

The purpose of this Master's Thesis is to understand how to improve a production flow within the Medical Device Sector using Lean methods. Three methods were selected to study the effects Lean methods could have on the production flow, i.e. Value Stream Mapping, Seven plus One Wastes, and Overall Equipment Efficiency.

Initially an understanding of the production area and the organisation as a whole was gained through observations and interviews. Value Stream Maps of the current state were made for the three characteristic production flows that were considered in the study. The production flows were analyzed using the Seven plus One Wastes. The efficiency of the flows was then measured by the throughput time. Based on this, future states were developed and compared to the current state of the flow. The measurements for Overall Equipment Efficiency was gathered as secondary data and analyzed to see what influence it has on the production flow.

The study showed that the used methods were useful in order to get an understanding of how to improve a production flow within the Medical Device Sector. By using the methods, the throughput time could theoretically be decreased for all three production flows (by 89%, 90% and 99.4% respectively) and thereby making them more efficient.

Keywords: Lean Production, Production Flow, Value Stream Mapping, Seven plus One Wastes, Overall Equipment Efficiency, Medical Device Sector.

Preface

This report is the result of a Master's Thesis performed at Chalmers University of Technology during the period from January to June 2012, at the division of Logistics and Transportation. The thesis was conducted in cooperation with Astra Tech in Mölndal, where a case study was performed. The Master's Thesis comprises 30 credits and implies an exam in Mechanical Engineering after five years of completed studies.

The authors would like to point out their acknowledgements to the persons to whom this Master's Thesis would not have been possible without.

The authors would like to say thanks to the involved people at Astra Tech, which have helped making this achievable, for their nice treatment and positive attitude to the collaboration. Especially thanks to Sara Prince, for her great support and knowledge as a supervisor during the whole project, and Ann-Charlotte Ryrman for realizing the cooperation. Further, thanks to the coordination group, interviewees and other persons who have shared their valuable knowledge and experiences with us.

Thanks to Agneta Larsson, supervisor at Chalmers University of Technology, for her guidance in the initial phase of the project. Further, thanks to Carl Wänström, supervisor and examiner at Chalmers University of Technology, for supervision and great advices during the Master's Thesis.

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Abbreviations and Concepts

Short explanations of abbreviations and Japanese concepts, mentioned in the report, will be presented here.

Andon	Signal system for help to fix a problem
FIFO	First-In/ First-Out
Jidoka	Principle of built in quality
JIT	Just In Time
Kaizen	Continuous Improvements
Kanban	A form of Pull system
MPS	Master Production Scheduling
Muda	Waste
Mura	Unevenness
Muri	Overburden
OEE	Overall Equipment Effectiveness
Poka-Yoke	Mistake-proof
TIA	Tillverkning Inom Astra Tech (English: Manufacturing Within Astra Tech)
TPM	Total Productive Maintenance
TPS	Toyota Production System
VSM	Value Stream Mapping
WIP	Work In Process

1 Introduction

This chapter will present the background of this Master's Thesis which leads to the main purpose. Followed by the formulated research questions which are the subparts of the purpose which are to be answered in this report. Further, the scope and limitations are presented, and finally the overall outline of the report.

1.1 Background

Lean is a business strategy based on the Japanese car manufacturer Toyota's production system (TPS). The basic core values in Lean are respect, teamwork, and to put focus on customer needs above all else. These are the guidelines that define how the organisation should act in all situations (Modig, N., Åhlström, P., 2011). The customers are the most important thing and they need to be prioritised because without them the company can not grow and prosper (Liker, J.K., 2004).

There are two principles that define how a Lean organisation should think to uphold the core values, i.e. Just-In-Time (JIT) and Jidoka (Modig, N. and Åhlström P., 2011). JIT is a focus on creating continuous and efficient flow that delivers what the customer wants, instead of the more traditional thinking of effectively utilizing the resources (Forza, C., 1996). It is impossible to achieve a perfect state of a production process, where all products in the flow are built to order, i.e. the company only produce exactly what is ordered, while at the same time utilize the resources to maximum capacity (Modig, N. and Åhlström P., 2011). However, by always improving an organization can continuously move closer to the perfect state. Once an efficient flow has been achieved by eliminating non-value adding activities, the focus can be shifted towards making the resources more efficient to further approach the perfect state (Modig, N. and Åhlström, P., 2011). To create an efficient flow the throughput time needs to be short, which is achieved by minimizing the number of products in the flow, shorten cycle time and have a low variety of products. Eliminating non value adding activities from the process and increasing the value adding activities leads to a more efficient flow (Bicheno, J. et al., 1993).

To enable an efficient flow it is important that all activities are performed with high quality. If there is a problem with the products or if there is something that obstructs the flow, it is vital that it is fixed right away, otherwise it will cause more trouble later on (Liker, J.K., 2004). This is what the second of Toyota's principles, Jidoka, is about. Jidoka acts as a complement to JIT by making the flow visual so that problems can be detected. The essence of Jidoka is that quality should be built in to the process and whenever a problem occurs it should be handled right away and not passed on to the next process down the line (Modig, N. and Åhlström, P., 2011). Jidoka promotes problems to be brought to the surface, when an error occurs the problem shall be identified, analyzed and eliminated right away. Doing so continuously improves the process and enables an efficient flow (Liker, J.K., 2004).

When working towards a Lean production flow there are many methods that can be used to fulfil the two principles. These methods define what an organisation should do in order to become Lean and they can facilitate the work with finding and eliminating waste and assuring quality. When working with the methods it is important to always keep the two principles in mind (Modig, N., Åhlström, P., 2011). Companies in different industrial sectors have tried to take advantage of the methods, but with mixed results. A reason why many fail is that they forget to promote long term thinking and adaptation of the methods, which is fundamental for success. Instead they simply try to use it as a quick-fix and implement tools without a true understanding of them (Schonberger, R. J., 2007). Lean Production can not become a goal in itself, instead the needs of the production process should lead the way (Womack, J.P., Jones, D.T., 2003).

A problem some companies fail to realize is that the Lean principles and methods were developed by, and for, the automotive industry. Though many methods are universal, there are requirements that differ between industrial sectors, meaning that every sector has its own preconditions for which the methods have to be adapted (Jina, J. et al., 1997). It is common to believe that Lean is just a tool-box for production efficiency and fast results are expected. However, having a long-term perspective is a vital part of Lean and it is important to understand that change does not happen overnight. Liker, J.K. (2004) states the factors for success as:

> *"The most important factors for success are patience, a focus on long-term rather that short-term results, reinvestment in people, product, and plant, and an unforgiving commitment to quality"* (Liker, J.K., 2004, pp. 71).

There are companies in most manufacturing sectors who have at least attempted to introduce Lean into their manufacturing process in some way, but the general perception is that it is still hard to transfer Lean production into other sectors than the automotive industry (Crute, V., et al., 2003).

An industrial sector that is different from the automotive industry is the Medical Device Sector. The products have to be of high quality, clean and safe to use (World Health Organization, 2003). This contributes to special requirements, which makes it an interesting sector to look further into and see how Lean methods can improve the production flow.

1.2 Purpose

The purpose of this Master's Thesis is to understand how to improve a production flow within the Medical Device Sector using Lean methods.

1.3 Research Questions

In order to answer to the stated purpose, it was divided into three different research questions. These will be presented in this section, with related motivation.

To understand how to improve a production flow, it is vital to start at the current state and get an overview and understand the current situation, since it is important to know what to improve. Recognizing the current state of the company is the first step towards creating a Lean environment (Feld, W.M., 2001). A useful method to accomplishing this is Value Stream Mapping (VSM). A value stream is a flow that includes all actions currently required in a production flow. The perspective of the value stream is to study on the whole rather than focusing on a specific process (Rother, M. and Shook, J., 2003). Thus, VSM is a tool used to illustrate and map the value stream in the production flow from raw material to finished product (Jones, D. and Womack, J., 2003). It is used to visualize and analyze the current, as well as future, state of the production flow. It is a useful method in many ways as it can help visualize the entire flow instead of only the single process, which gives more of an overview of where problems occur. Not only does it help with locating Non Value adding activities, it also aid in locating the source of that waste, so that action can be taken where it is truly needed. VSM provides a common language regarding manufacturing processes and the visualization makes decisions about the flow more apparent. Thereby enabling discussions of changes and avoiding decisions to take place at the shop floor by default (Rother, M. and Shook, J., 2003). However, is VSM a suitable method to use in this sector with its specific requirements? This results in the first research question:

RQ 1: How can the use of Value Stream Mapping ease the understanding of how to improve a production flow with the special requirements of the Medical Device Sector?

In the production process there are different types of activities that disturb the production flow, which referred to as wastes since they counteract the possibility of a smooth production flow. Toyota has divided these into three categories, all beginning with the letter M. The categories are all important in Lean and they are; Muda (Waste), Muri (Overburden) and Mura (Unevenness) (Liker, J.K., 2004). These three M's work together as a system and complement each other to achieve a smooth and continuous production flow. The first "M", Muda, refers to non-value-adding work. The second "M", Muri, is overburdening of people and equipment. This is important to pay attention to since the result of overburdening of people can result in safety problems and poor product quality, and overburdening of equipment can result in breakdowns and defects. The third "M", Mura, is unevenness in the production and an unleveled production schedule. This is of significance because the result of Mura is Muda, since an unleveled production most often refers to a need of a planned production on the highest level even if the current demand is lower (Dennis, P., 2007). To succeed with Lean attention needs to be payed to all three M's when improving the production process. However, it is common to start to focus on identify and eliminate Muda. To be able to improve a production flow it is also vital to identify the problems with the current state. According to Lean, one of the most relevant factors to achieve continuous flow within the production is to reduce activities that do not add value to the product, referred to as waste, where Seven plus One general wastes have been identified. This leads to the second research question:

RQ 2: How can an analysis with the Seven plus One Wastes ease the understanding and identification of problem areas in a production flow within the Medical Device Sector?

OEE is a vital part of Total Productive Maintenance (TPM), which is a concept that intends to improve the production performance (Nakajima, S., 1988). Andersson, C. and Bellgran, M. (2011) states that OEE is one of the most commonly used operational measure, and also that it is a good measure to indicate improvements in a production environment. Within a production environment the OEE measure can be used on different levels, with different intentions. Dal, B. et al. (2000) categorize these in three levels; manufacturing plant, manufacturing line and machine process. Thereby, OEE can e.g. be used in order to evaluate improvements of a manufacturing plant by compare OEE for initial and future state, identify weak lines by compare OEE for different lines within the plant, and identify the weakest machine performance within a machine process (Dal, B. et al., 2000). Further, it is relevant to measure the efficiency of the production flow due the fact that an improvement of it is mostly coupled to an increased efficiency. However, there is a difference of opinion regarding the suitability to use OEE measures, due to the fact that a strict focus on a high OEE value might obstruct the general flow. Thereby, the third and last research question handles this subject, in the following way:

RQ 3: How does the OEE value affect the production flow?

1.4 Scope and Limitations

The scope of this Master's Thesis is to focus on the area of the Medical Device Sector, and is limited to the preconditions of this sector.

This Master's Thesis has been based on the study of one case. Within the specific case, the area is limited to only one product family of catheters. In order to get a manageable scope of the case study, the focus within the production flow is limited to a section where only the chosen product family is taken into consideration. This means the production flow between the warehouse and the packaging stations. Thus, three sub flows will be considered, with the condition that the current shift structure shall be preserved. By these means, the effect on the extended production flow (before the warehouse and after the packaging) will not be included in the scope.

The Lean methods which will be handled in order to fulfill the purpose are limited to three main methods which are handled by the research questions. These methods are; VSM, Seven plus one wastes, and OEE.

1.5 Outline

This section will present the overall outline of this report, which will give an overview of the structure and an insight in what it is that will come.

Chapter 2 – Frame of References
Description of the theoretical base used in this Master's Thesis.

Chapter 3 – Method
Describes how the task was approached and what has been done to reach results.

Chapter 4 – Empirical Settings
Description of the overall company background which includes the company's corporate philosophy, and the specific conditions and circumstances of hygiene regulations.

Chapter 5 – Empirical Data
This chapter describes the chosen product family, the current state of the studied production flow, and the company's current work with Lean methods.

Chapter 6 – Analysis
The findings in the empirical data are compared and analyzed based on the frame of references.

Chapter 7 – Recommendations to the Company
Ideal future states and recommendations for what the company should do to improve the production flow.

Chapter 8 – Discussion and Conclusion
In this chapter there are discussions and conclusions regarding the results, the applicability of the chosen Lean methods. Followed by a general discussion on the company's Lean progress and how this Master's Thesis contributes to a sustainable development.

2 Frame of References

This chapter will present the theory acting as a base for this Master's Thesis. At first a short overview of the structure will be presented in this introduction. Where the coming subchapters will handle each of the different divisions of the structure; the fundamental values, principles, methods and tools of Lean production.

Modig, N. and Åhlstöm, P. (2011) argue that the concept of Lean needs to be clarified, they states that Lean is a business strategy with a goal of high flow efficiency. They have structured an overview of what assets can be used to reach the goals of Lean, these assets are defined at different levels which can be seen in figure 1.

The whole concept rest on a base of fundamental values, which defines how an organization shall be. The fundamental values of Lean thinking are the customer, respect and teamwork. Thereby the customer shall always be the centre of attention, the most vital goal is to meet the customers' demand. This by integrating the philosophy of respect and teamwork among the employees, which are preconditions to be able to create an efficient flow (Modig, N. and Åhlström P., 2011).

The principles define how an organization shall think, where the two principles Just-In-Time and Jidoka is the nucleus in the context. Just-In-Time means to create an efficient flow through the organization, while Jidoka means to create a conscious organization that prevent, identify and eliminate what disturbs the flow. Basically, the two principles complement each other; Jidoka is a precondition in order to succeed with Just-In-Time (Modig, N. and Åhlström P., 2011).

The methods define what an organization shall do, i.e. what they shall do to improve the efficiency of the flow. There are many different methods available and they need to be matched with the purpose of the improvement. In order to complement the methods there are tools and activities, which are used within the methods, they define what an organization shall have to ease the performance (Modig, N. and Åhlström, P., 2011).

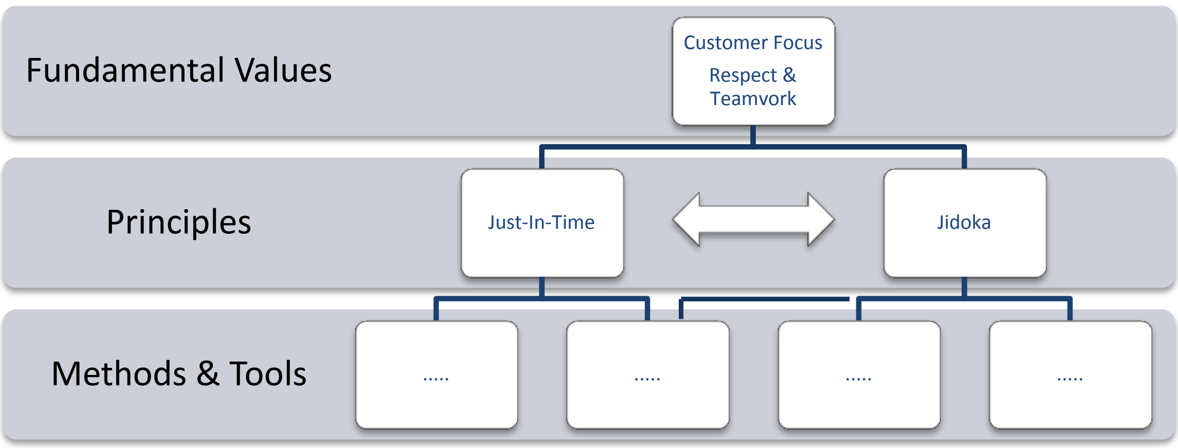

Figure 1 Conditions for an efficient flow, structured in three levels according to Lean production (inspired by Modig, N. and Åhlström, P., 2011)

2.1 Fundamental Values

To assure that the entire organization works towards the same goal, some basic fundamental values have been defined, which explain what is important and what the organization's main purposes are. In Lean these values are respect, teamwork, and most important; customer needs. In Lean production, the customer need is the most important fundamental value. This because the company can only exist if it has customers, and customer return only if they are satisfied. Therefore, this is of top priority for the company and valued above anything else (Modig, N. and Åhlström, P., 2011).

In order to satisfy the customers the most important resource in the company is the employees, that is why it is so important to build trust and mutual respect with the employees. It is the employees who drives the company forward and makes it possible to satisfy the customers. E.g. when times are bad it is not an option to just fire employees to save money. If the workforce has been doing what they are asked and then get laid off when times are tough, it would not only be a betrayal to society and the unemployed but also send out a wrong message to the other employees. It is vital to act as you speak, and really show that you mean it when you say that the employees are the most important asset. Thereby, keep employees and respect them, and do not fire employees but find other work tasks (Liker, J.K., 2004).

Teamwork is of help when solving problems, people often complement each other and drive others to perform better. It encourages people to come up with new ideas and teamwork is also important as it enables people's development (Modig, N. and Åhlström, P., 2011). Teamwork also encouraged cooperation between different departments in the organization to get a holistic view and involve people so that everyone pulls in the same direction. It is not only within the organisation that teamwork and cooperation is important, the same goes for dealing with outside partners. Mutual respect and helping people and partners grow are two fundamental aspects for success in this case as well. The best way to ensure that partners live up to expectations is to have constant interaction with them. If the companies understand each other's processes and needs they become easier to accommodate. In order to gain a deeper level of understanding and involvement in a supplier's operation there has to be trust and respect, which can only be achieved over time. Long term partnerships can be mutually beneficial for both the supplier and parent company (Liker, J.K., 2004).

It is vital to have a holistic point of view and have a focus on long-term decisions. This does not concern the pure profit of the company itself, but rather mainly the customers, employees and society. The basic mission for the company shall be to always do the right thing, with a wide perspective; *"for the company, its employees, the customer, and society as a whole"* (Liker, J.K., 2004, pp. 72). This is the key to Lean, and act as a foundation for the whole concept. With this common mission, everyone within the company can identify to a purpose regarding this mission (Liker, J.K., 2004).

2.2 Just-In-Time Principle

JIT means that Lean focuses on creating efficient flow, instead of the more traditional thinking of effectively utilizing the resources. All equipment and people who are involved should work together to find the best way to deliver what the customers want, when they want it, and in the right amount. To create an efficient continuous flow, only actions that are necessary for delivering a finished product to the customer should be included. Therefore, the non-value adding activities should be eliminated from the process while the value adding activities are increased. Creating a more efficient flow helps bring problems to the surface, forcing immediate action in order to solve the problem which builds in quality to the process (Modig, N. and Åhlström, P., 2011).

There are different ways to organize the equipment in the plant to attain a well-functioning flow. The optimal layout of a production process is to have the equipment placed in the same order as the flow of material, in order for it to follow the flow. Common ways to organize the equipment is in a U-shaped or L-shaped layout, or in a straight line. The most efficient layout is in most cases to have the equipment structured in a U-shaped layout, which will enable good communication and a smooth and easy movement of people and material (Liker, J.K., 2004).

Even though the ideal way to produce products from a flow efficiency perspective is to "build to order", it is usually not practical to achieve (Modig, N. and Åhlström, P., 2011). To produce in this way requires the use of a pull flow, meaning that when the customer sends an order it should trigger the whole production process in reversed order, with start at the customer and all the way back to the raw material. However, since customer demand often vary in reality, resulting in an uneven flow, it is hard to know how much to order from suppliers. Therefore, inventory to cover the highest amount of needed material is usually required, which will create unnecessary inventory. A strict culture of "build to order" will most likely lead to inventory and hidden problems, which will create poorer quality and in the long run a growing lead time because the plant is disorganized and messy. Instead the production should be leveled out in of respect to the employees and to achieve a stable production flow (Liker, J.K., 2004).

2.3 Jidoka Principle

The essence of Jidoka is that quality should be built in to the process and whenever a problem occurs it should be handled right away and not passed on to the next process down the line (Modig, N. and Åhlström, P., 2011).

Responsibility of quality is put on the employees, who shall stop the production every time something deviates from the standard. This challenges the employees and credits the employee empowerment since they do not only get responsibility, but also a feeling of the fact that they actually matter. Jidoka also refers to autonomation (machines with human intelligence) that should stop itself automatically when a problem occurs (Womack J.P. and Jones D.T., 2003).

In a Lean production environment, the inventory level should be as low as possible, therefore it is extra important to get quality right the first time. Otherwise if a quality problem occurs at the end, there is not much security in inventory to fall back on. According to Liker J.K. (2004), this part is the one that has often been the hardest one to implement in western countries, due to cultural differences. This since there in the western world has been a fundamental culture and unwritten rule that if production is stopped, the plant is not performing well. Therefore many people rather produce too many products than the other way around. But in Lean thinking it is important to be aware of the fact that all plants have problems, therefore it is also important to deal with the problems in order to improve and get the best possible quality. Hence, it is a bad thing if production is never shut down, since that means that problems are hidden somewhere (Liker, J.K., 2004).

2.4 Lean Methods and Tools

This section will handle the Lean methods which are used in this Master's Thesis. As mentioned above in the introduction to the frame of references, the two principles complement each other. Thereby, most of the methods are meant for both JIT and Jidoka.

The methods and tools which will be presented are firstly; VSM, Seven plus one wastes and OEE. This since, the three of them are handling the research questions of this Master's Thesis. This is followed by general Lean methods and tools which affect the production flow, and which will be handled in this Master's Thesis in order to give a holistic view to the company. These are; Kanban, Standardized work, Kaizen, Poka-Yoke, Andon, Five Whys, Visualization, 5S and Ergonomics.

2.4.1 Value Stream Mapping

VSM is a tool used to illustrate and map the value stream in the production flow from raw material to finished product (Jones, D. and Womack, J., 2003). It is used to visualize and analyze the current, as well as future, state of the production flow. It also helps to visualize the entire flow instead of only a single process, which gives an overview of where problems occur (Rother, M. and Shook, J., 2003). According to Rother, M. and Shook, J. (2003) it makes sense when performing a VSM to do it for one particular product or product family. This because the customers most likely does not care about all products, only their specific products are of interest to them.

Rother, M. and Shook, J. (2003) describes the steps that shall be taken when performing a VSM, and once a product family is chosen, it begins with a quick walkthrough of the entire flow is needed to get a sense of it. At this stage it is enough to draw a simple map of the products' way through the production area, only stating the processes they pass through without describing the steps within each process. When an overview of the flow is attained, a new visit to the processes will take place to gather information. It is important that each participant collects information while walking along the actual path of the flow and that they always maps the whole value stream and collect data by themself, otherwise a full understanding of the flow will not be attained. If the flow is divided up amongst the team, no one will know the entire flow. Standard times or information that has been given from other sources are not reliable, only times that have been personally obtained by observing the process are useful during the mapping. The data of interest for the VSM includes cycle time, setup time, number of operators, transportation distance, and volume. Once all the data is collected it is time to draw the map, for which there is a set of symbols used to illustrate the different activities in the flow, they can be found in Appendix A. Both the material and information flows should be considered. Based on the VSM, conclusions can be drawn on whether the flow and its processes are exhibiting wasteful behaviour (Rother, M. and Shook, J., 2003).

The standard approach to VSM is to describe the flow as it is perceived at one point in time and thereby it does not regard variability in the processes, something that needs be taken into consideration when making a VSM (Braglia, M. et al., 2009). According to Braglia, M. et al. (2009) this is a shortcoming of VSM since variability has significant impact on costs and Non Value Adding activities.

2.4.2 Seven Plus One Wastes

In Lean production effort is supposed to be put in to constantly reduce wastes (muda), with the common goal to create continuous flow. Toyota has identified seven categories wastes, they are; overproduction, waiting, unnecessary transport, overprocessing, excess inventory, unnecessary movement, and defects (Lewis, J., 2005). In addition to these seven wastes it is common to include an eighth waste as well - Unused employee creativity (Liker, J.K., 2004). The categories are defined as:

1. **Overproduction**

   Producing more than what is necessary to meet customer demand is considered to be the fundamental waste, which leads to the other types of waste. It can be difficult to detect because the process can appear to be running efficiently since it is continually producing. When producing more than current demand, the resources can not be used for other products that might need it. Creating process flexibility can eliminate this type of waste (Lewis, J., 2005).

2. **Waiting**

   Waiting is when the time on hand is wasted, for example when workers simply watch an automated machine, waiting because there is a stop somewhere else in the flow, or stand around waiting for the next processing step (Lewis, J., 2005).

3. **Unnecessary transport**

   The ideal state is to have minimal or no transportation of material between process steps. If a process has multiple customers some transportation may be required, using a kanban (see section 2.4.4) at the supplier so that all customers are ensured an uninterrupted flow of material can be a solution to minimize transportation in this case (Lewis, J., 2005).

4. **Overprocessing**

   Performing unnecessary steps in production is to overprocess the products. Poor tool, fixture, and equipment design and maintenance can cause processing to be inefficient (Liker, J.K., 2004). Malfunctioning tools, fixtures and equipment can go unnoticed by managers because operators have figured out how to overcome deficiencies. The product design and choice of material is also of importance since this can affect whether or not tools, fixtures and equipment needs to be changed. Designing products using standardized material will decrease inventory (Lewis, J., 2005).

5. **Excess inventory**

   Inventory becomes a waste when there is more raw material, Work In Process (WIP), or finished goods available than is in demand. It can hide problems such as production imbalance and requires storage space (Liker, J.K., 2004).

6. **Unnecessary movement**

   Any movement that workers do that is not necessary to perform the work task is waste. It can be caused by poor layout, inconsistency in the placement of materials in the work area, or equipment that is larger than necessary for the process. Assembly parts should not be placed outside reaching distance from operators (Lewis, J., 2005).

7. **Defects**
Defected products that are scrapped or receive rework is costly and requires time (Liker, J.K., 2004). Often scrapped material is not recorded, which means that no one will be aware of the reason and that is has even occurred at all. If problems are not reported it is a good chance that the same problem will occur again in the future (Lewis, J., 2005).

8. **Unused employee creativity**
The knowledge of employees should be used to the company's benefit instead of overlooking it and missing ideas from the people who work with the processes every day (Liker, J.K., 2004).

2.4.3 Overall Equipment Efficiency

OEE is mainly a measurement of the efficiency of the equipment. However it can be used on different levels as well. Dal, B. et al. (2000) categorize these in three levels; manufacturing plant, manufacturing line and machine process. OEE is one of the most commonly used operational measure, and it is a suitable measure to indicate improvements in a production environment (Andersson, C. and Bellgran, M. 2011).

Dal, B. et al. (2000) argues that both expected and unexpected disturbances have negative impact on a manufacturing process, since they do not add any value to the final product, and that OEE have a purpose to identify these losses. Nakajima, S. (1989) defined six big losses, which should be eliminated in order to achieve overall equipment effectiveness, these are:

1. Breakdowns due to equipment failure
2. Setup and adjustment (e.g., exchange of die in injection molding machines, etc.)
3. Idling and minor stoppages (abnormal operation of sensors, blockage of work on chutes, etc.)
4. Reduced speed (discrepancies between designed and actual speed of equipment)
5. Defects in process and rework (scrap and quality defects requiring repair)
6. Reduced yield between machine startup and stable production

Where number 1 and 2 represent downtime, number 3 and 4 represent speed losses, and number 5 and 6 represent defects (Nakajima, S., 1989).

OEE is a measure which is a function of three different terms; availability, performance rate and quality rate of a plant, line or machine, see formulae 1 (Dal, B. et al., 2000).

$$\boldsymbol{OEE}\ [\%] = Availability\ [\%] \cdot Performance\ [\%] \cdot Quality[\%] \qquad (1)$$

In the OEE measure, availability is connected to the downtime part of the six big losses. The availability of a machine or a process is calculated by the proportion of the actual operating time to the planned operating time, see formulae 2. This will point out unplanned downtime. The actual operating time is calculated by subtrahend unplanned maintenance, minor stoppages, and setup & changeover from the planned operating time, see formulae 3. While the planned operating time is the total shift time minus the planned maintenance, see formulae 4 (Dal, B. et al., 2000).

$$\boldsymbol{Availability}\ [\%] = \frac{Actual\ operating\ time\ [s]}{Planned\ operating\ time\ [s]} \cdot 100[\%] \qquad (2)$$

where

$$Actual\ operating\ time\ [s] = Planned\ operating\ time\ [s] - Unplanned\ maintenance\ [s] - Minor\ stoppages\ [s] - Setup\ \&\ changeover\ [s] \quad (3)$$

and

$$Planned\ operating\ time\ [s] = Total\ shift\ time\ [s] - Planned\ maintenance\ [s] \quad (4)$$

The Performance part of the OEE measure is connected to the “six big losses” by terms of the speed losses part. The performance rate basically measures the actual quantity of production, where the net operating speed rate and the operating speed rate are considered, see formulae 5. Further, the net operating rate calculate minor stoppages by considering rate of accomplishment of a stable processing speed in relation to a certain time period, see formulae 6. While the operating speed rate considers the difference between the theoretical and the actual cycle time, see formulae 7 (Dal, B. et al., 2000).

$$\boldsymbol{Performance}\ [\%] = (Net\ operating\ rate\ [\%] \cdot Operating\ speed\ rate\ [\%]) \cdot 100\ [\%] \quad (5)$$

where

$$Net\ operating\ rate\ [\%] = \frac{No.produced \cdot Actual\ cycle\ time\ [s]}{Operation\ time\ [s]} \quad (6)$$

and

$$Operating\ speed\ rate\ [\%] = \frac{Theoretical\ cycle\ time\ [s]}{Actual\ cycle\ time\ [s]} \quad (7)$$

The last element of the OEE measure, quality, is connected to the defect part of the “six big losses”. The quality rate represents the amount of defect products in relation to the total amount of produced products, see formulae 8. However, it is vital to only consider the defects that occur in the selected area of the production, e.g. a specific plant, line or machine (Dal, B. et al., 2000).

$$\boldsymbol{Quality}\ [\%] = \frac{Total\ no.produced - No.scrapped}{Total\ no.\ produced} \cdot 100\ [\%] \quad (8)$$

A high value of OEE indicates a high effectiveness, and the optimal value of OEE is, according to Nakajima, S. (1988), approximately 85%. However, Dal, B. et al. (2000) discuss the fact that there is a difference of opinion in this question, where different studies have resulted in different ideal OEE values. Thereby, due to different preconditions various industries, the ideal OEE value would vary with it (Dal, B. et al, 2000).

2.4.4 Kanban

There are many methods used for achieving a pull system, one such method is the kanban system. It is a form of pull mechanism which sends an order for new delivery up-streams in the production flow when the current process is finished. However, before introducing a kanban system, some other issues has to be sorted out first, i.e. reducing demand amplification, reducing changeover, reducing defect rate, introduce standardized work, and reducing disruptions (Bicheno, J., 2004). According to Feld, W.M. (2001) there is a set of rules that all kanban systems needs to follow, and in doing so becomes an effective method to reduce the three M's:

1. A kanban demand signal is the authorization to begin work
2. No job is to be released without demand from the customer
3. The kanban control the amount of work in process allowed in the flow
4. the number of kanbans will control the manufacturing lead-time through queue management
5. Do not pass known defects on
6. Utilize First-In/First-Out (FIFO) material flow

Kanban can be used in a production system in different forms, e.g. a two-bin system, where an empty bin symbolize the need for production of a specific number of products, or a card system , where a card tells the information of what is needs to be produced. The kanban thereby triggers the production in a visual way, which is both simple and effective (Liker, J.K., 2004). The type of kanban system deployed depends on the manufacturing environment, the interest in change in the organization's culture, and how motivated the supplier/customer is to participate (Feld, W.M., 2001).

2.4.5 Standardized Work

The impression of standardized work is often that it is a limitation of creativity and that it is only used in order to control the employees, and is thereby connected to something negative. This could be the true result, if used in the wrong way. However, there is a great importance of standardized work in order to assure quality and improve. If the work is not stable and standardized, how do one know what and how to improve? Liker, J.K. (2004) states:

> *"…it is impossible to improve any process until it is standardized."* (Liker, J.K., 2004, pp. 142)

and

> *"Using standardization…is the foundation for continuous improvement, innovation, and employee growth."* (Liker, J.K., 2004, pp. 148)

When establishing the standard for a work task, the one best way is supposed to be found, or rather the currently best way of doing that specific work task (Whitmore, T., 2008). Then specific and detailed standardized work sheets are made, which will instruct the operator and then he or she should do the work without it. It is the responsibility of the team leaders to follow up and see if the standards are being followed. Even if the standard is established, it is not written in stone, since it is only the one best way know right know. Then there is room for improvements, which anyone can influence and come with suggestions of better ways of doing the task (Liker, J.K., 2004).

In Lean thinking the concept “enabling bureaucracy” should be followed, which is a mix of structure and employee involvement. Liker, J.K. (2004) describes the view of standardized work in enabling systems as:

> *“…enabling systems are simply the best practice methods, designed and improved upon with the participation of the work force. The standards actually help people control their work.”* (Liker, J.K., 2004, pp. 145)

Employee empowerment is encouraged and standards are made for the employees own wellbeing. This differs from “coercive bureaucracy”, which is the most common way of using standardized work, which is used to control the employees (Liker, J.K., 2004).

Liker, J.K. (2004) argues that the challenge when implementing standardization is to find a balance between firm instruction which shall be followed and enable the liberty to be creative. He also says that the solution to this is depending on who develops the standards and on who contribute to them. The standards have to be specific in order to act as a good instruction but at the same time leave some room for flexibility. Improvements of the standards have to be done by the operators, while documentation maintenance of the standard is the responsibility of the cell leader when improvements are made (Whitmore, T., 2008).

2.4.6 Kaizen

Kaizen means continuous improvement, which is also a fundamental concept in Lean. It means that all processes can, and should, constantly be improved. To make this possible there needs to be a standardized way of working, otherwise it is impossible to know if an improvement actually has occurred when there is no former procedure to compare to. It is also unnecessary to improve a process where everyone does things differently (Liker, J.K., 2004).

To encourage employee involvement in the improvement process and generation of improvement suggestions can be difficult. The traditional approach is to offer bonuses in the form of money for extra effort. However, money is not a motivating force for most people to push their limits. Instead there are other factors that are more important; such as the ability to set challenging goals, the ability to get emotionally engaged in work, and the ability to focus (Freifeld, L., 2011). To get them involved in continuous improvements it is beneficial to set time aside for employees to think up ideas, analyze and discuss amongst each other (Cameron, K.S., Quinn, R.E., 2011). In the short term external motivators such as incentives can be useful, but in the long run it is not. Often fun things are more appreciated, such as trips, dinners or experiences (Freifeld, L., 2011). Incentives should be used to encourage teamwork and groups taking responsibility, instead of a focus on individual achievements (Liker, J.K., 2004).

2.4.7 Poka-Yoke

A countermeasure to prevent problems leading to defects and other quality issues is Poka-Yoke, which means mistake-proofing. Both the product and the workstation should be designed to eliminate or reduce the risk of making mistakes. A form of Poka-Yoke is to use the same material for different products, because it reduces the risk of using the wrong material by mistake. It is also vital to keep the controls of quality simple and involve the employees in this work. Poka-Yoke is a good method to keep scrap rate down since the process should be designed to avoid problems. The most fundamental mistake-proofing is to work in a standardized way, which is necessary to reach and sustain quality (Liker, J.K., 2004).

There are three types of mistake-proofing devices that can be used for either control or warning, they are; contact, fixed value, and motion step. A contact system physically makes contact with every product or has a shape that prevents mistakes from occurring. Fixed value method is a design that makes it clear when a part is missing or not used, this is often combined with a contact system. The motion step method automatically ensures that the correct steps have been taken, e.g. a checklist. The best Poka-Yoke system is fully automatic where no human interaction is needed, thereby eliminating the human factor (Bicheno, J., 2004).

2.4.8 Andon

Andon is basically a signal system for help. An andon system should be used in different steps, as the andon button is pushed a yellow light for that station is showing and the line is still moving. It is first when the product reaches the zone of the next station that the andon turns red and the line stops, during the time the light is yellow the team leader should respond to the problem. The team leader should fix the problem directly, or decide if the problem can be fixed as the product moves on or if the line should stop. If this is the case, it is vital to be aware of the fact that the whole line or factory should stop (Liker, J.K., 2004).

To avoid stopping the whole line it can be split into sections, with small buffers in-between. Thereby a short stop in the upstream process does not affect the flow later on (Bicheno, J., 2004). Team leaders should be well trained in handling andon calls, and use a standardized method of the handling it. Using andon systems helps keep the scrap rate and rework down since problems are detected early on, before too many products are affected by it (Liker, J.K., 2004).

2.4.9 Five Whys

The Five Whys is a method which is used in order to get to the bottom of the problem, finding the causes and thereby be able to solve the actual problem and prevent it from happening again (Bicheno J., 2004). The basic principle of the method is to ask the question “why” five times and not accept the first reason that comes to surface, since there is most often underlying reasons which actually causes the problem. Thereby the actual root cause can be established and it is possible to solve it (Murugaiah, U., et al., 2010).

To visualize the meaning and use of the Five Whys method Bicheno J. (2004) demonstrated an simplified example:

> *“A door does not appear to close as well as it should. Why? Because the alignment is not perfect. Why? Because the hinges are not always located in exactly the right place. Why? Because, although the robot that locates the hinges has high consistency, the frame onto which it is fixed is not always resting in exactly the same place. Why? Because the overall unit containing the frame is not stiff enough. Why? Because stiffness of the unit during manufacture does not appear to have been fully accounted for. So the real solution is to look at the redesign of the support unit.”* (Bicheno J., 2004, pp. 152).

2.4.10 Visualization

It is, according to Lean production, important to clean up and visualize the work place in order to ease the work task and help people to be easily determined if the standard is followed or not, and thereby detect problems. The main reason of using visual control is to be able to improve the flow. Liker, J.K. (2004) states some examples of what visual control can show:

> *"It might show where items belong, how many items belong there, what the standard procedure is for doing something, the status of work in process…"* (Liker, J.K., 2004, pp. 152).

A good visual system is, according to Lean production, to try to make an as simple design as possible at the actual workplace. In addition to this the visual aids should not force the operator to change focus away from the workplace. Basically, the visualization should only help and support the operator to do a good work. Liker, J.K. (2004) states that the reason why visualization is so successful is:

> *"…visual management complements humans because we are visually, tactilely, and audibly oriented."* (Liker, J.K., 2004, pp.158).

2.4.11 5S

A common tool within Lean production is to use "5S programs" in order to visualize the work station. The 5S programs refer to cleaning up and organize the work station, and thereby eliminate waste and stands for continuous improvements of the work environment. Liker, J.K. (2004) states:

> *"Lean systems use 5S to support a smooth flow to takt time. 5S is also a tool to help make problems visible and, if used in a sophisticated way, can be part of the process of visual control of a well-planned Lean system."* (Liker, J.K., 2004, pp. 152).

The fundamental idea of the 5S tool is that everything has a place, and that is where it should to be located. It is a tool used to eliminate waste by only having relevant material in the work area and making sure that it is at its proper place at all time, all other material has no reason to take up space on the shop floor and is therefore disposed of. 5S refers to five Japanese words beginning with the letter "S" (Seiri, Seiton, Seiso, Seiketsu, Shitsuke) describing the steps taken with tool (Feld, W.M., 2001). The English translation is listed below with a description of each step (Liker, J.K., 2004):

1. **Sort**
   Sort through items and keep only what is needed while disposing of what is not used. Red tag with a date the items which are not used regularly, if the item haven't been used by the date the item can be removed or stored at another location.

2. **Straighten**
   Organize and label a place for everything, "A place for everything and everything in its place". The item shall be placed in order to ease the work, e.g. close to where they are used in a standardized way. Labelling can be in form of e.g. shadow boards, colour matching with tools and inventory footprints. Thereby, if e.g. a tool is not used and not in its place this indicates a problem.

3. **Shine**
   Keeping the work area clean works as an inspection that exposes flawed conditions. It is vital to identify a standard and name who is responsible for what, in order to minimize the risk of misunderstandings.

4. **Standardize**
   Develop systems and procedures to maintain the first three S's. Clear standards shall be established in order to ensure a continuous work with 5S.

5. **Sustain**
   Maintain a stabilized workplace by using regular management audits to stay disciplined

Using the five S's prohibits covering up problems, and instead brings them to the surface where they need to be dealt with. Following the five steps creates a continuous process of improving the work environment and will support a smooth flow to takt time (Liker, J.K., 2004). Thereby, the method is not a onetime effort, it is a continuous process which should be a natural part of the everyday work (see figure 2).

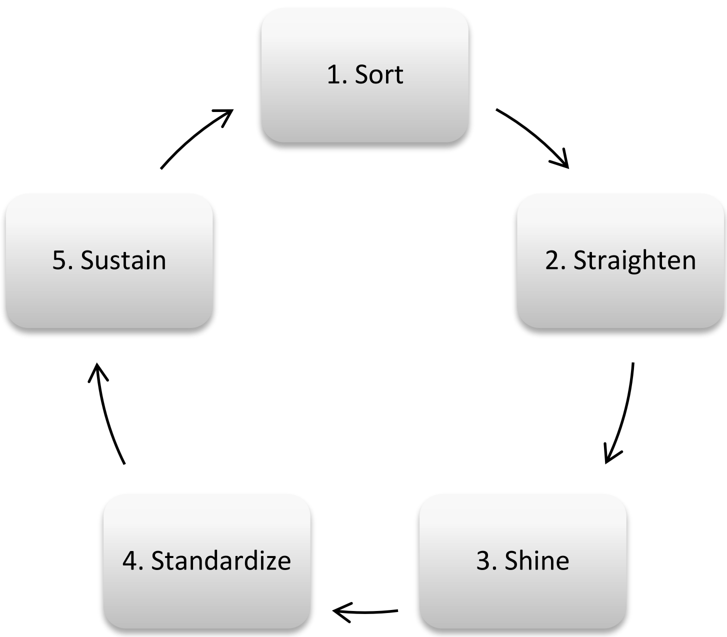

Figure 2 The five S's

2.4.12 Ergonomics

One of the fundamental values of Lean production is, as mentioned before, that the employees are the company's most valuable resource. This connects to the fact that it is important to keep the employees satisfied, which requires a safe and ergonomic work environment. Thereby, it is vital to assure that the removal of waste do not create new waste in the form of overburden of workers (Walder J. and Karlin J., 2007).

Walder J. and Karlin J. (2007) states that an implementation of Lean production requires effective ergonomics. A well-designed workplace allows the worker to work in natural postures most of the working day, an upright position with relaxed shoulders and arms close to the body. Work positions which increase the risk of injury is; sharply bent, stretched or twisted body postures. The human body can perform most work postures and movements without getting injured, with the precondition that work is not repetitive or continues for a long period of time (Arbetsmiljöverket's homepage, 2011). By using Lean analysis, the ergonomic problem areas can be brought to the surface and thereby solved (Walder J. and Karlin J., 2007).

Wong Y. C. et al. (2009) argues that ergonomics is important since it reduce injuries and fatigues, but that it also enables employees to improve the productivity. Further, an ergonomically well designed work environment decreases; unnecessary movements and mistakes caused by human errors, thus the product quality is improved (Wong Y.C., et al., 2009).

3 Method

This chapter will present the work method which has been used in order to fulfil the purpose of this Master's Thesis. The work was based on the foundation of literature studies and an empirical part in form of a case study. The first section explains the research approach, which is a case study, followed by the literature review. The third section present the methods of data collection, which are; observations, interviews and secondary data, and in the fourth section the realisation of VSM is explained. Further, the data analysis is described, followed by the reliability and validity of the collected data.

3.1 Case Study

The chosen research approach of this Master's Thesis was in the form of a case study. Due to the purpose of the thesis, a company within the Medical Device Sector was selected, namely Astra Tech that manufactures dental implants and advanced medical devices used in the fields of urology and surgery. Astra Tech was chosen since it is a characteristic company for the specific sector. The focus at Astra Tech was at the production flow for one product family of catheters.

According to Denscombe, M. (2007) the performance of a case study helps the understanding of the relationships between processes but also to get a holistic view. Further the research questions of this Master's Thesis aims at explaining the current state as a first step. In these circumstances Yin, R. (2009) states that it is relevant to have a case study approach, especially when there is a social phenomenon in the picture. Denscombe, M. (2007) states that the case study approach works best when:

> *"the researcher wants to investigate an issue in depth and provide an explanation that can cope with the complexity and subtlety of real life situation"* (Denscombe, M., 2007, pp.38).

As a part of the case study, a field study was performed at a co-working company in order to get familiar with the part of the production flow that is outsourced. At this point observations acted as a source of information in combination with a guide that explained the work.

3.2 Literature Review

The initial stage included a thorough theoretical research of Lean production and of earlier studies in the area of the subject. This in order to get a deeper knowledge in the area, and to learn how to use related methods and tools in a correct way. The literature study was performed in a structured way with standardized notations during the reviews. A variation in types of references was used and different references were compared with each other in order to get different point of views.

According to Backman, J. (1998) it is a necessity to study literature in the specific area when performing a scientific project. A literature review gives a background of information, which is needed in e.g. the problem definition, choice of method and choice of analyze technique (Patel, R. and Davidson, B., 2003).

There are mainly three different ways of gathering information in a literature review; consultation, seeking manually and data based method (Backman, J., 1998). Consultation means receiving information by communication with e.g. experts or colleagues. Further, seeking manually basically means to gather information by using e.g. libraries, book and articles. While data based method means using e.g. internet or scientific databases (Backman, J., 1998). In this Master's Thesis, all three types of information gathering were used. This in order to combine different type of sources to get a trustworthy information base. During the Master Thesis, consultation was made with experts at both Chalmers University of Technology and Astra Tech. The manual seeking were mainly done at the library at Chalmers University of Technology, and complemented at the local library at Astra Tech. Further, the internet and scientific databases has been widely used, examples of used scientific data bases are; Millennium web catalogue, ScienceDirect, and Emerald. Where common search words, or key words, was; Lean, Lean Production, Medical Device Sector, Value Stream Mapping, VSM, Overall Equipment Efficiency, OEE, Waste, Muda, etc.

3.3 Data Collection

In order to collect data for this Master's Thesis both observations and interviews was used, which was complemented with secondary data. This section will describe the different types of methods which have been used to collect data and how they were used.

3.3.1 Observation

Observation can be used to see how the operators act in a real situation, how the work is performed, how machines and products are handled, and how problems are handled (Denscombe M., 2007).Therefore, was this method used to collect data, with the purpose to get an insight in how the work is done in its natural environment without influencing the work process. This resulted in information regarding what the operator actually does, not what he or she say and think he or she does.

Osvalder A.L. et al. (2010) states that observation is a method which is most suitable to use in an initial stage of a study, and should preferable be complemented with interviews. Further they also states the following main advantages and disadvantages as the one in table 1.

Table 1 Advantages and disadvantages of observations (Osvalder A.L. et al., 2010)

Advantages	Disadvantages
• Gives good understanding of the specific situation.	• Do not give knowledge of reasons to specific behavior which obstruct the interpretation of the result.
• See real behavior and natural preconditions.	• Gives no information of how the operator thinks when performing a specific task.
• No disturbance of the operators with e.g. questions and measuring.	• Operators might change behavior, and become more aware of their behavior, if they know they are being studied.

According to Denscombe M. (2007) observations can be either systematic or unsystematic. Systematic observations are performed after a pre-determined schedule, which are used when the observer already know the events and actions that will be relevant for the study. Unsystematic observation on the other hand is usually used in an early stage of the investigation in order to collect information, where everything of interest is notated and "nothing specific" is observed. This Master's

Thesis used unstructured interviews in an initial stage in order to get familiar with the work environment, the work procedure and the production flow. Further when specific information was needed structured observation was used in order to get a focused insight in the processes that were of interest.

Osvalder A.L. et al. (2010) states that there is overall two different types of observations; direct or indirect. When using direct observation the observer is present all the time and reflects on the situation. Further, the meaning of indirect observation is that the observer is not present and notations are made by e.g. continual filming. However, in this Master's Thesis only direct observations were made with two observers present. During the observations notations was done in form of e.g. simple notes, checklists and protocol. The observations were held at several different times during a period of ten weeks, at different times of the day (both day and evening shift), and five different shift teams were observed as well. This in order to cover eventual differences and deviations.

3.3.2 Interviews

In order to get information and data regarding what people think and what their opinion is, interviews were used. This method is suitable to use in order to get knowledge regarding people's experiences, knowledge, opinions, values and how they reason (Patel R. and Davidson B., 2003). Osvalder A.L. et al. (2010) states that interviews are suitable to use in order to get specific information from chosen key-persons, but that it should be combined with observations in order to see if people actually act as they say they do.

There are in general three different levels of interviews; unstructured, structured, and semi-structured (Denscombe M., 2007). Osvalder A.L. et al. (2010) define the three different levels of interviews as:

Unstructured interview

In an unstructured interview there are question which allows for an open conversation, thereby is it possible for the interviewed person to speak freely about what he or she find important. This allows expert knowledge in areas where the interviewer does not have any deeper knowledge. Thereby this type of interview is most suitable in cases where the interviewer only have basic knowledge and the wanted results are qualitative. When performing this, it is suitable to use it on a smaller number of persons, e.g. three to six persons. The weakness of unstructured interviews is that the results are hard to compile and compare.

Structured interview

In a structured interview the questions are direct and structured which means that the interviewed person can answer them shortly with words or by choosing out of a predetermined grading of answers. To be able to prepare a structured interview, a rather deep knowledge of the specific area is needed. The questions have to be straightforward in order to minimize the risk of misinterpretation of them. The result is quantitative and easy to analyze and compare. This type of interview is suitable to use on a larger number of persons, and are usually rather short, maximum 20 minutes.

Semi-structured interview

This type of interview is a crossing between unstructured and structured interviews. In a semi-structured interview has the interviewer prepared a structure of what areas that will be handled and questions can be both open and prepared, further the areas do not have any rang of order and follow up questions are allowed. By these means, the result are given a certain structure which ease the analysis, but there are also the benefits of a deeper knowledge in some areas due to the interviewed person's possibility to partly speak freely.

The choice of interview form is dependent on what results is wanted and on what the purpose of the interview is. In this Master's Thesis both unstructured and semi-structured interviews was used when interviews with key people at both organizational level and production level was held. The interviews was unstructured on the organizational level, since it was desirable to let people with e.g. expertise knowledge to be able to speak freely, and semi-structural on the production level, since it is desirable to be able to compare answers. Interviews were held with several different persons, at the organizational level were interviews held with approximately ten persons and at the production level were the interviews held with operators from five different shift teams. This in order to cover eventual differences and deviations.

The main advantages and disadvantages of interviews are according to Osvalder A.L. et al. (2010) is listed in table 2.

Table 2 Advantages and disadvantages of interviews (Osvalder A.L et al., 2010)

Advantages	Disadvantages
• Subjective and flexible.	• The constant presents of the interviewer might influence the person.
• Knowledge of what the person's opinion of specific subjects.	• The answers might be adapted to satisfy the interviewer (called *"interview effects*").
• Possibility to ask for explanations and to as follow-up questions which reduce the risk of misinterpretation of the result.	• Does not give an general result, result only represent the specific persons opinion
• Choice of suitable persons with key-knowledge gives representative material.	• What a person say does not always correspond to reality (what an operator say he or she do might not be equal to what he or she actually do).

At the beginning of the interviews the interviewed persons was informed of what the purpose of the interview was and of how the results was meant to be used. The interviews were held in Swedish to ease the communication and the questions were prepared in advance (see Appendix B), the order of the question was adapted to the specific conversation. Further, in the end the interview was summarized and coupled back in order to see if the answers had been interpreted in the right way.

3.3.3 Secondary Data

Secondary data from the company's data base was used in order to get a basic knowledge of the company itself and their principles. This source of information was also used to get familiar with the product family of interest and the standards for its processes.

Documented information regarding OEE values was given as secondary data from the company's data base, this in combination with documented history of stop times and scrap rates. This information was used, since it was of interest to see trends by getting a broader range and a wider time span than what would have been possible to gather during this Master's Thesis.

3.4 Value Stream Mapping

VSM was used in this Master's Thesis as a method to visualize the production flow, of both current state and possible future state. By mapping the current state, areas of improvements could be identified.

It is suitable when performing a VSM to do it for one particular product or product family (Jones, D.T. et al., 1997). This because the customers does not care about all products, only their specific products are of interest to them. Thus, in this Master's Thesis, one specific product family of catheters was selected, and more specifically three characteristic products within this product family. Further, three different flows was considered, one for each characteristic product. The production flow is specific for this product family from the warehouse to the dispatch, therefore was the warehouse defined as the supplier and the dispatch was defined as the customer.

As an initiating stage the researchers were getting familiar with the production flow by gathering basic information while walking along the production flow together with the work manager. This followed by a walk along the flow alone, asking questions and observing. Rother, M. and Shook, J. (2003) argues that it is important to collect information while walking along the production flow and individually creating the VSM, this in order to get a full understanding of the flow. However, due to the fact that the flow was not a continuous flow, and some steps where infrequent, the data collection for the VSMs had to be made at several different occasions.

The VSMs were made by hand in different drafts, which were updated three times before the final version was established and documented in computer form. This in order to assure that the information in the VSMs was inconsistent with reality. To assure this, additional observations and interviews were held, where the maps were verified by the work manager of the specific product family.

With the analysis and evaluation of the current state as a starting point, future states were developed, with the goal to find a more efficient production flow from a Lean perspective. However, due to the specific requirements of the Medical Device Sector, an adaption of Lean was needed. Suggestions were given on two different levels.

The first level, one ideal state of the three production flows was suggested, with developed layouts and with future state VSMs. This to be able to evaluate and compare the current and the future state with each other, which then acted as an indication of improvement. The second level, alternative suggestions were presented to the second and third flow, to enable the company to consider smaller changes which could improve the production flows in a nearby future.

The development of the future states was based on the foundation of the frame of references, in combination with influences of the information given in the observations and, mainly, the interviews. Where the interviews with the operators was of importance, since it was of interest to involve the employees in the improvement process, as well as getting information that need experience. The development of future states was made in order to indicate how Lean improvements can be used at a production flow in the Medical Device Sector.

3.5 Data Analysis

Analysis of the collected data was made with both quantitative and qualitative methods. Numeric data e.g. data for OEE values was analyzed by quantitative methods in the form of graphs, which present possible trends within the collected data. On the other hand, qualitative methods were used for data collected from e.g. interviews and observations which were structured and summarized. It is most common that the result of the observations is qualitative, which explain and give a deeper understanding of the situation (Osvalder A.L. et al., 2010).

The collected data was used in order to evaluate the current state in the case study. Further the situation was analyzed and evaluated out of respect to the frame of references, especially with the seven plus one wastes.

3.6 Reliability and Validity of Data

The interviews were held with different persons in order to assure the reliability of the data. Longer interviews were recorded, which enabled the interviewers to double check the gathered information. When the interviews had been summarized they were also, in specific cases, coupled back to the interviewed person for feedback if it had been reflected correctly.

In order to assure the reliability of the data collected from the observations, two persons performed the observations which gave a broader chance to capture information and two different perspectives. The observations were also held at different occasions during a period of ten weeks in order to get a representative distribution of the actual situation and to cover eventual deviations from the planned production flow.

Triangulation was used by combining different types of sources of the data. Bryman, A. and Bell, E. (2007) explain that triangulation is to rely on more than one source of information, they states that it improves the assurance of the results. By the means of triangulation, findings are compared and balanced with each other. In this Master's Thesis, different persons were interviewed in combination with observations, in order to assure that the given information was consistent. Triangulation was also used in the literature findings, where different sources of information were used.

The authors' previous level of education in the field and former experience through similar projects, combined with thorough literature studies, provided insight in what approach was suitable to use for gathering relevant information. The questions for the interviews were based on literature and aimed at only covering aspects that were relevant for this Master's Thesis, this to assure the validity of the gathered information.

4 Empirical Settings

This chapter will present the empirical settings of the case study. The first section will present the overall company background and its corporate philosophy, in order to get familiar with the specific conditions and circumstances. The second section will present the specific hygiene regulations, which are specific requirements of the company and the Medical Device Sector.

4.1 Company Background

Astra Tech is a part of Dentsply International Inc. who develops, manufactures, and markets dental implants as well as advanced medical devices in the field of urology and surgery. Astra Tech was founded in 1948 and today they employ 2200 people with the headquarters located in Mölndal, Sweden. They deliver products all over the world and they have 16 subsidiary locations where they are present outside of Sweden and in countries where they are not present they use local distributors to reach customers (Astra Tech's homepage, 2012).

The study of this Master's Thesis was conducted at Astra Tech's headquarter in Mölndal, focusing on the production of devices used in the field of urology. They deal with a demand for low cost products that needs to be available at an instance when customers need them. Many times the products are high volume products that are used once and then thrown away. It is a competitive market where the profit margin per product is sometimes low, therefore it is important to keep manufacturing costs down to reach leading positions (Ryrman, A.C., 2012).

The production of catheters at the headquarters includes both dry and wet products (with or without water already added in the catheters package), where the wet products are the newest addition to the line of products. Because the dry products has been around for a long time, the manufacturing process has become reliable and stable, which is why the company has mainly focused on developing the production lines for newer products in recent years. Since the production of dry products has not been in focus lately it is interesting to study how Lean can improve this flow.

Astra Tech's Production System

In 2004 Astra Tech introduced the concept of Lean in their operations, therefore they have developed their own version of TPS, named Tillverkning Inom Astra Tech (TIA) which means Manufacturing Within Astra Tech. This in order to have a common corporate philosophy that everyone can identify themselves with. The two main values are waste elimination and costumer focus, whereas the base of TIA is Standardized work, Commitment and Continuous Improvements. The goal is Zero defects and Just In Time, and in centre of it all is the employees (Mullins, T., 2012). The TIA model is visualized below in figure 3.

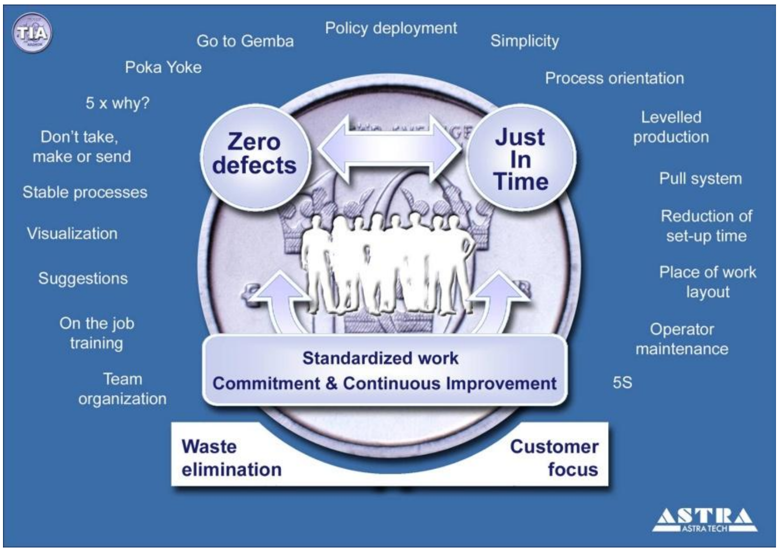

Figure 3 Astra Tech's TIA model (Mullins T., 2012)

Overall, the concept of TIA is common to the one in TPS, however it have been adapted to Astra Tech and their demands. The TIA model served as a complement to the Lean principles in this Master's Thesis, since it is vital to take into consideration the company's philosophy when performing the case study. It is also interesting to investigate how their work with adapting the Lean philosophy to their company has worked out.

4.2 Hygiene Regulations

Due to the fact that Astra Tech produce product which are medical devices that are used in the body, the hygiene regulations are strict. This since it is of greatest importance to minimize the risk of infections and more damage. Thereby is the production area regulated with cleanroom conditions, which should fulfill Astra Tech's quality policy. There are three aspects of their quality policy that affect dress and hygiene regulations:

- *"Quality is about fulfilling our customers' needs and expectations, but also to live up to our own."*
- *"In all research, development and manufacturing we shall follow international regulations."*
- *"Through continuous improvements we shall strive to further increase our quality level."*

Products

Products or components without wrapping which are not yet sterilized are only allowed to be handled in cleanrooms. Bulk material is too handled after regulations in airlocks.

Products in primary package (meaning the products inner package, which is closest to the product) shall at all times be protected from impurities as e.g. dirt, textile fiber and hair.

Personnel

The personnel are the company's most important resource, but it is also the most common source of impurity of the products. Therefore it is of great importance to keep a good hygiene (especially regarding hands and hair), wear the right cloths and an overall correct behavior, in order to minimize the risk of impurity.

Facilities
The facilities or the production areas are adapted to general regulations regarding manufacturing of medical devices. This put high requirements on ventilation and hygiene.

In this case there are two main types of facilities; cleanroom and dispatch facilities. Further there are two types of entrances to the clean room in form of airlocks; airlocks for personnel and visitors and material airlocks (one in and one out).

Cleanroom conditions
In order to reach and sustain a clean and correct production environment the production is done in a cleanroom, where good ventilation and hygiene are required. There are airlocks which are regulated with air pressure when entering or exiting a cleanroom. Doors provided with light and sound signals, and shall only be opened when the light is green and when there are no sound. The doors are not to be opened unnecessarily.

When working or visiting a cleanroom it is extremely important with the right clothing. There is special cleanroom clothing which used above regular cloths, and they are only to be used in cleanrooms and on the "clean side" at the airlocks. White working shoes or shoe covers shall be used, and hairnet shall be used regardless hair length. Bare feet, arms or legs are strictly forbidden, as well as watches, rings, bracelets and visible jewelry. When entering a cleanroom the hands shall be washed carefully followed by hand sanitizer. Every time before starting the work with product shall the hands disinfected, as well as every time during the work when touched anything else than the products.

Bulk materials are to be passed through in material airlocks, where the outer package shall be removed. Corresponding regulation is for semi-finished products which shall leave the cleanroom area, the products shall then get plastic binding before exiting the out material airlock.

5 Empirical Data

This chapter will present the empirical data which is data collected during the case study, that summarizes and explain the current state. First there is a brief introduction of the studied product family with product specifications. This followed by a clarification of the studied production flow, with details on the three different characteristic production flows with results from the current state VSMs. This followed by the OEE and finally other Lean methods and tools used are presented, which are general observations that also affect the production flow.

5.1 Product Specifications

The market is stable with a levelled demand that is hardly affected by the current state of the economy, however, there are other competing companies present in the same market. The customer demand of catheters is rather even due to the fact that the people who use this type of products (the end customers) have an even need for it, since it is usually a part of their everyday life. There are two main reason to why it is necessary to use intermittent catheterization; common urinary issues and problems due to illness or injury (LoFric's homepage, 2012). Regarding common urinary issues, the most common urinary complications is; Urinary tract infections, Incontinence and Retention. These are all problems which are probably more common than one can imagine, and they are all complications where intermittent catheterization can be a part of the treatment solution. Further, problems due to illness or injury refer to conditions that affect the bladder, e.g. MS, Spinal cord injury, Diabetes and Enlarged prostate. In these cases the catheterization shall help to manage the bladder disorder, in a safe, comfortable and easy way (LoFric's homepage, 2012).

The chosen product family in this case study is the one of dry catheters, Lofric Classic. Lofric stands for low-friction catheter, and this product family is Astra Tech's original catheter, which have been around since 1983. This makes LoFric catheters the most well tested and documented catheter. Astra Tech where the first company to introduce hydrophilic catheters, meaning catheters that only use water as a lubricant, more specific with the Urotonic™ Surface Technology (LoFric's homepage, 2012). This surface technology is based on a chemical process which makes the surface isotonic to urine (the salt content is the same as in the urine). Thereby, when water is added to the catheter the salt will make the water stay on the moist surface the whole catheterization. The catheterization is then smoother, easier and gentler to use (LoFric's homepage, 2012).

Within the product family of LoFric catheters, this Master's Thesis have focused on three characteristic catheters which are in this Master's Thesis named; Product A, Product B and Product C. Product A is the basic version with a rounded tip (see figure 4), which is used for general usage (both in hospitals and at home). Product B is quite similar to Product A, but with a tapered tip (see figure 5), which is used for men in order to be able to turn it during catheterization in cases of enlarged prostate (both in hospitals and at home). Product C has the same shape as Product A or Product B but with the exception regarding the connector, which is a special connector that prevents spills or leaks (see figure 6). Product C is used to inject pharmaceuticals directly into the bladder (only at hospitals).

Figure 4 Principal picture of Lofric, Product A with rounded tip (LoFric's homepage, 2012)

Figure 5 Principal picture of Lofric, Product B with tapered tip (LoFric's homepage, 2012)

Figure 6 Principal picture of LoFric Product C with special connector (LoFric's homepage, 2012)

Each product type in the product family is available in different sizes (both different lengths, given in centimeters, and diameters, given in charrière value), in order to suit women, men and children, but also in different materials. This leads to a large product variety, see table 3.

Table 3 Different product types in the chosen product family, shows the variety in length, diameters and material (LoFric's homepage, 2012)

		Product A					**Product B**		**Product C**		
Length [cm], (Material)		15, (PVC-neutral)	20, (PVC-neutral)	30, (PVC-neutral)	40, (PVC-neutral)	40	40, (PVC-neutral)	40	20 Product A attributes, (PVC-neutral)	40 Product A attributes, (PVC-neutral)	40 Product B attributes
Diameter [Charrière value]	CH06		X	X							
	CH08	X	X	X	X	X			X	X	
	CH10	X	X	X	X	X	X	X	X	X	X
	CH12	X	X		X	X	X	X	X	X	X
	CH14	X	X		X	X	X	X	X	X	X
	CH16		X		X	X	X	X			
	CH18		X		X	X	X	X			
	CH20				X	X	X	X			
	CH22				X	X					
	CH24					X					

5.2 Production Flow

The LoFric Classic products follow one of three characteristic flows through the manufacturing process depending on their specifications. The company use five shifts so that production is continuous and does not have to be interrupted during night or weekends. The customer in the in this case study, which is the dispatch, delivers to bulk storage and not the final users.

In the field of medical devices it is vital that the products are of the highest quality and that they are handled in a hygienic way to avoid risks for the end user. If flaws occur in a product it is important with traceability to make sure that there is not something wrong with the entire order, therefore the orders can not be separated during the manufacturing process. All material, i.e. raw materials, products in process, and finished products are identified with a lot number. This is done so it is possible to trace errors and minimize the risk of bad products reaching customers and thereby assure quality.

The overall production planning is based on a Master Production Scheduling (MPS), which is based on sales from earlier years in combination with a predicted change factor in demand. The demand in the bulk storage is not considered in the flows, instead the production is triggered by a production plan which is based on a MPS. The plan is introduced into the company's production system PING, by the local production planner who plans the specific production for each process. Thereby, the MPS generates a prediction of the need of products in PING and at the production plant. This generates an order and production structure in PING for each process.

All three flows begin at the warehouse and end when the products are packed and placed in the airlock outside the cleanroom. The products are initially located on a load carrier and the production is triggered in PING, which is the production plan that the operators follow in the production. Outside the production area, in the dispatch, another information system, MOVEX, is used.

Figure 7 visualize the parts of the plant which are considered. Number 1 refers to the production area and number 2 to the packaging area. Number 3 and 5 are the airlocks, and number 4 is the dispatch.

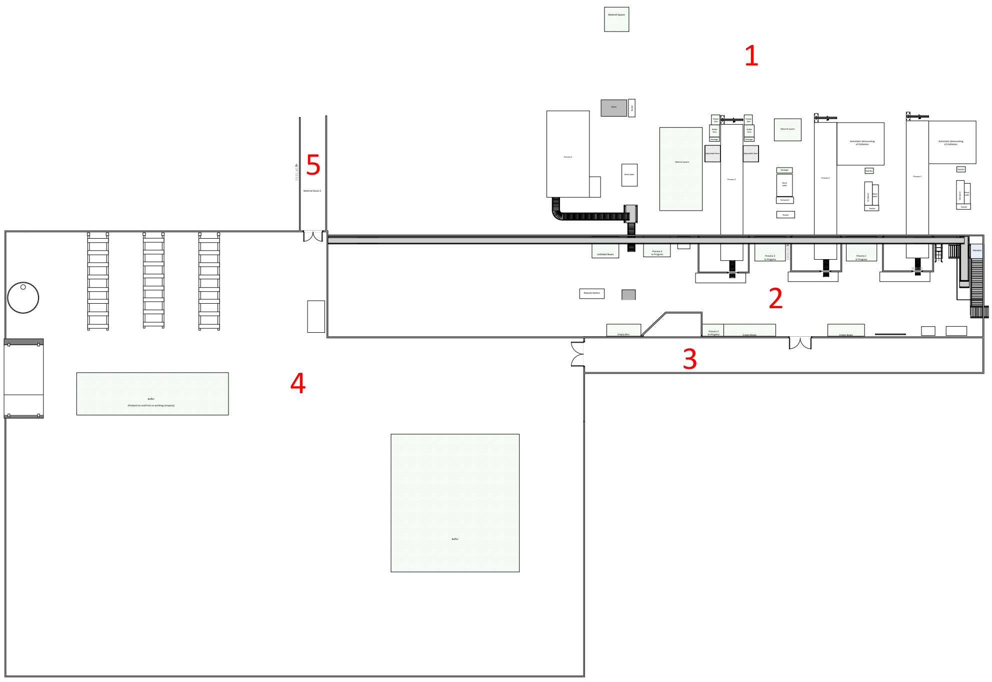

Figure 7 Principal sketch of the considered part of the plant, current state

5.2.1 Flow 1

The flow is initiated when an operator places an order to either Process 1 or 2. Process 1 and 2 are automatic processes where catheters are demounted (1 in figure 8) from the load carriers and placed into individually moulded plastic packages (2 in figure 8), ten at a time, before being welded shut with a paper top (3 in figure 8). There is one operator per machine overseeing the operation.

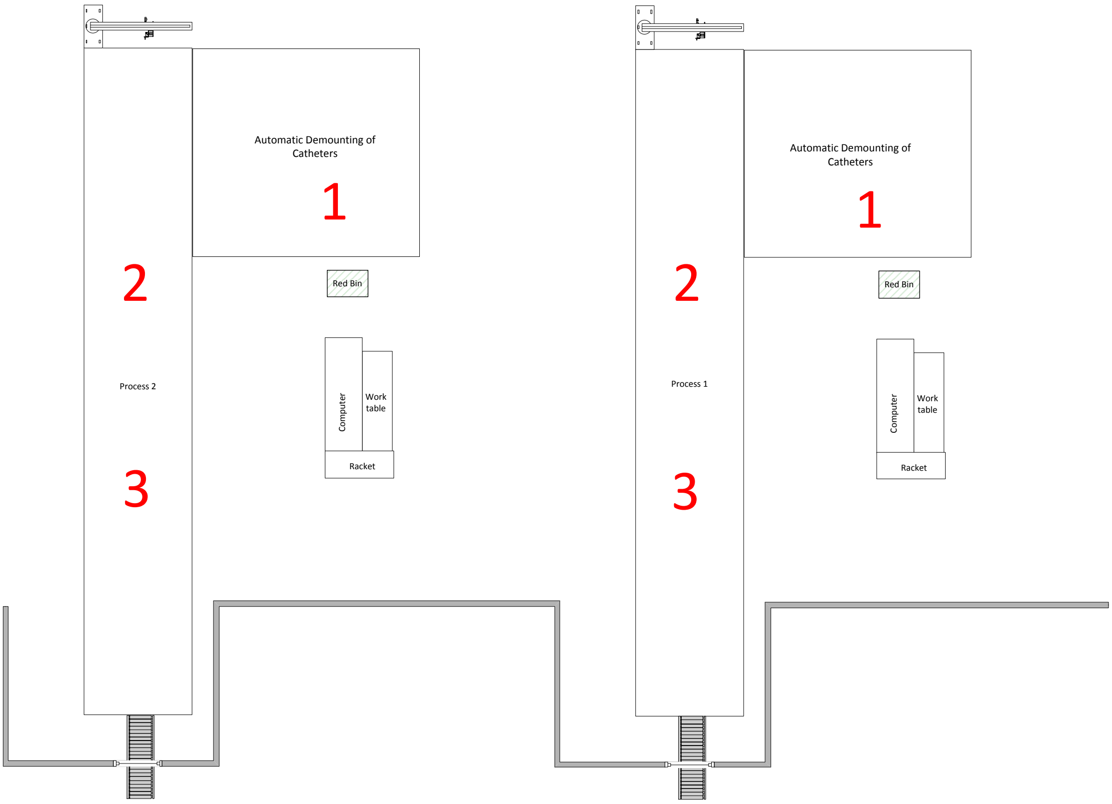

Figure 8 Principal sketch of the production area at Process 1 and Process 2, current state flow 1

The packages follow a conveyor to a packaging station where two operators manually count and inspect them. Quality inspections are performed for the packages before packaging them into larger cardboard boxes, which are wrapped in plastic in order to pass the requirements for the cleanroom (1 in figure 9). When a cardboard box is full it is placed in a buffer next to the packaging station (2 in figure 9) until either 20 cardboard boxes are filled or when the entire order is finished, at that time they are transported to a buffer in the airlock outside the cleanroom for the dispatch personnel to pick up (3 in figure 9).

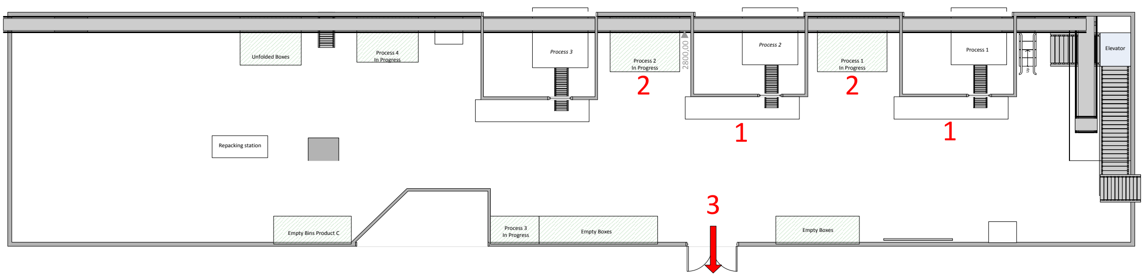

Figure 9 Principal sketch of the packaging area, current state flow 1

5.2.2 Flow 2

The second flow is basically the same as the first, however, it only passes through Process 2 and instead of paper, plastic is used to seal up the package. The most significant differences to the flow are found in the packaging process where this type of products needs to be handled differently than the others because it uses a sterilization process that the others do not. Currently the packaging procedure for this product is to pack the finished products into bins at the packaging station behind Process 2 (1 in figure 10) and then move them to another packaging station at the other end of the packaging area (2 in figure 10), where the products are packed into boxes. When all boxes are filled they are moved back to the opposite end of the packaging area (3 in figure 10) where they are placed on a conveyor that transports it to the sterilization process.

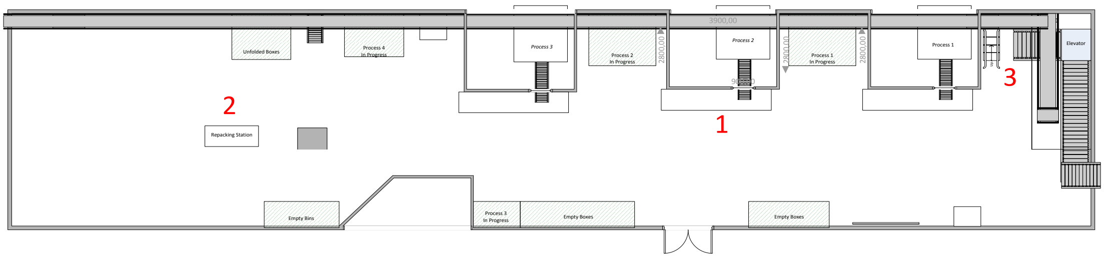

Figure 10 Principal sketch of the packaging area, current state flow 2

5.2.3 Flow 3

The third flow is handling products that are punched manually due to their design or choice of material, therefore they are sent to a co-working company who perform this task. When ordered from the warehouse by an operator they are transported to Process 4 by conveyor, where they are demounted from the load carrier and automatically placed into plastic bins (1 in figure 11). The full bin is transported manually on a conveyor (2 in figure 11) to a wrapping station where the bin is wrapped in plastic (3 in figure 11).

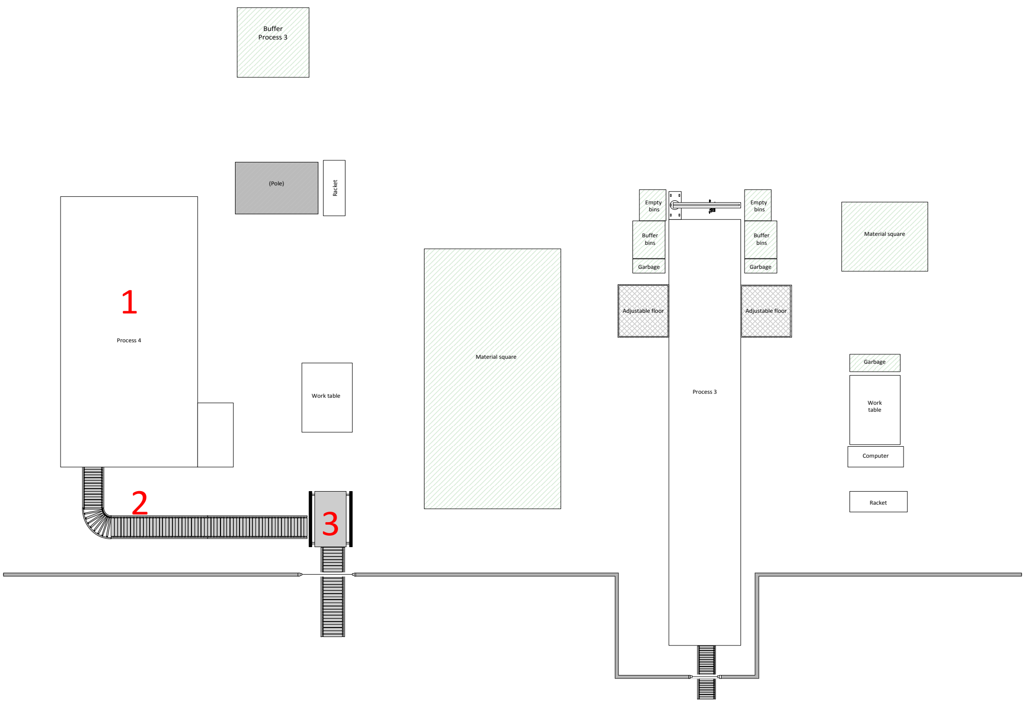

Figure 11 Principal sketch of the production area at Process 4, current state flow 3

The bins are placed in a buffer in the packaging area (1 in figure 12), waiting for the entire order to be finished before moving all bins at once outside the cleanroom (2 in figure 12) and placing them on a pallet.

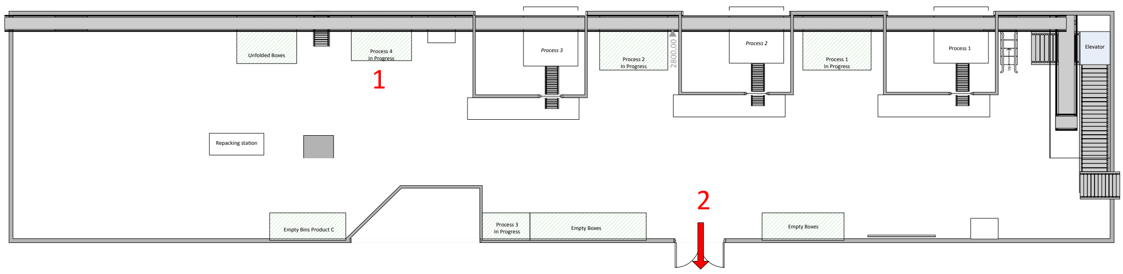

Figure 12 Principal sketch of the packaging area, current state flow 3

Outside the cleanroom the dispatch personnel collects the pallet (1 in figure 13) and places it in a storage area (2 in figure 13), awaiting a truck which will ship it to the co-working company. Trucks arrive in the morning on Mondays, Wednesdays and Fridays at which time the pallet has been wrapped in plastic (3 in figure 13) and placed closer (4 in figure 13) to the loading dock (5 in figure 13) to facilitate loading. The products spend three days at the co-working company before returning to Astra Tech. The co-working company only perform one task, which have been performed in-house earlier but was moved due to lack of space in the plant. In the afternoons on the same days, trucks deliver punched products from back to Astra Tech. When they do, the pallets are unloaded (5 in figure 13) and placed in a buffer close to the loading dock (4 in figure 13), in the same area as before they were sent away. When every pallet is unloaded they are transported into an airlock where they are unwrapped and ready to enter the production area once again (6 in figure 13).

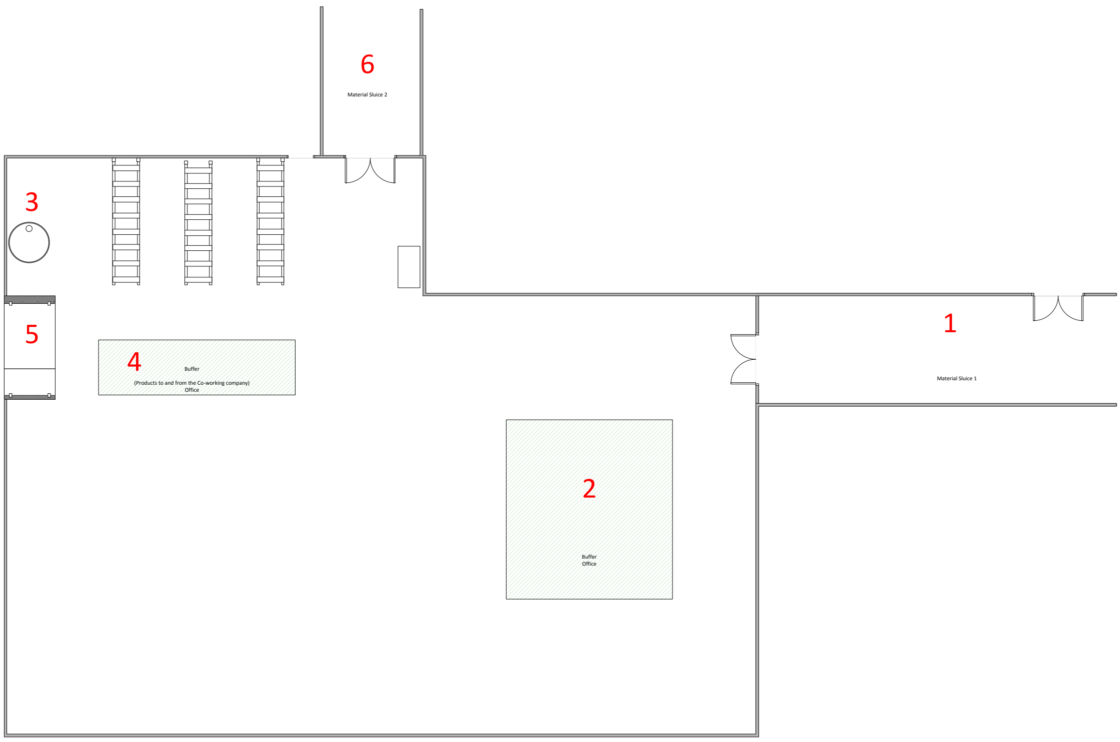

Figure 13 Principal sketch of the dispatch area, current state flow 3

The entire order is transported into a buffer inside the clean production area (1 in figure 14). When it is time to package the order into plastic packages, all bins are moved to buffers by the Process 3 (2 in figure 14), which is a manual version of Process 1 and 2. Two operators manually place the catheters into individual plastic packages from each side of the machine (3 in figure 14). After they are placed in the packages the procedure is the same as for the first flow, passing through Process 1 and 2, and handled in the packaging area.

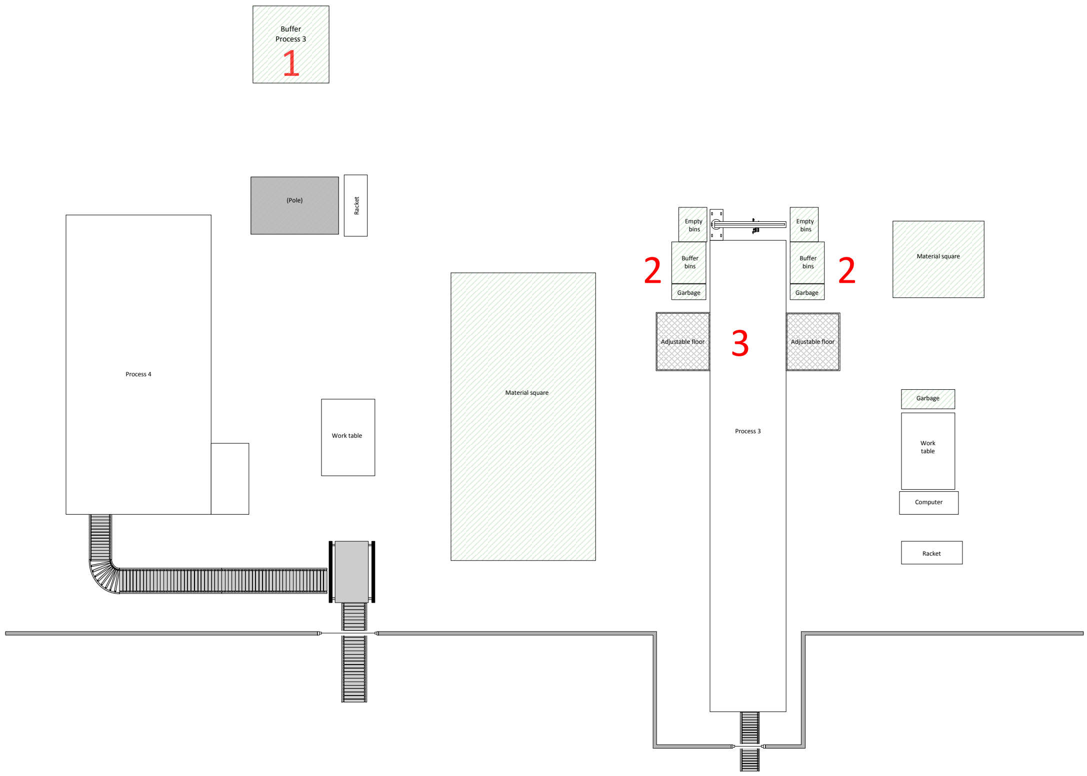

Figure 14 Principal sketch of the production area at the Process 3, current state flow 3

5.4 Overall Equipment Efficiency

In order to measure the efficiency Astra Tech works with OEE values. There is an overall goal of OEE, which is a common number for the whole company. This is further broken down into the different plants, departments and machines, where the goal vary. The reason to why they use OEE measures is to be aware of how efficient the equipment is, with the intention to be able to base decisions on facts and to improve the process.

The specific product family includes OEE values for Process 1, Process 2 and Process 3, where goals exist for Process 1 and Process 2, the goals for the year 2012 is presented in table 4. The actual OEE values are measured continuously, but the decision whether the goals are reached is if the last quarter of the year is on or over the target value.

Table 4 The goals of OEE 2012, for the machines Process 1, Process 2 and Process 3

	OEE Goal, 2012
Process 1	65 %
Process 2	60 %
Process 3	NO GOAL

In the area of the production flow for this product family, the measurements of OEE values have been rough calculations, see formulae 9.

$$OEE = \frac{Produced\ Products\ [no.]}{Planned\ Operating\ Time\ [s] * Takt\ Time\ [no./\ s]} \qquad (9)$$

Lately the OEE measurements have been put more in focus and more precise calculation have been made, this by calculations in the same way as described in theory chapter of OEE (see chapter 2.4.3).

Numbers given from the company, show the OEE values for the period January to April 2012 see figure 15 for total OEE per month in comparison to the goal.

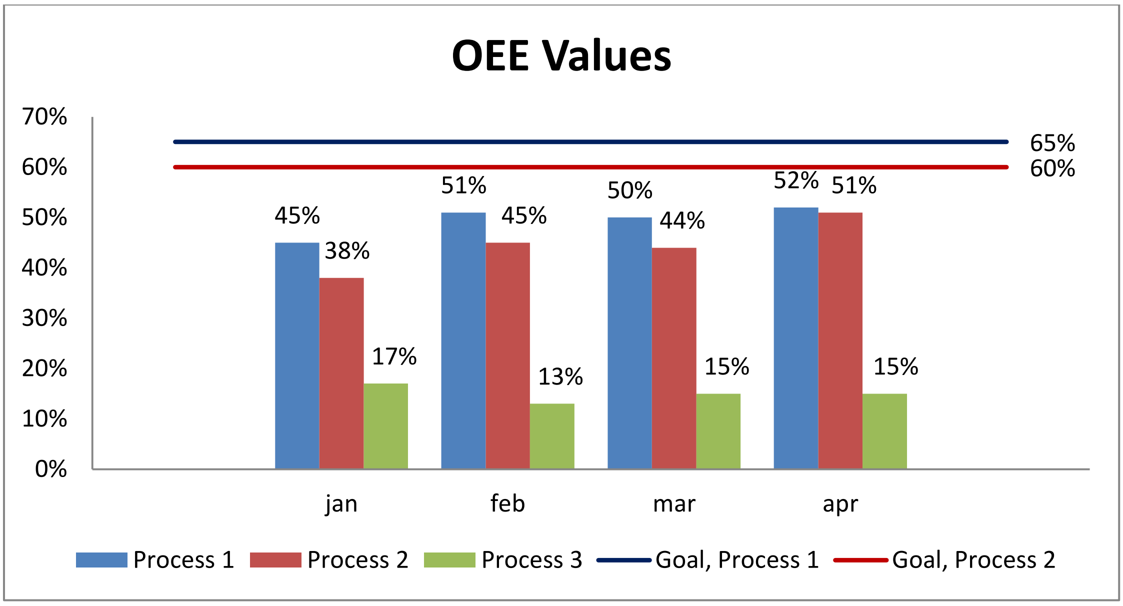

Figure 15 Chart of the total OEE value per month in 2012, for Process 1, Process 2 and Process 3. Compared to the goal for Process 1 and Process 2

The data provided by the company and observations and interviews indicates that performance is the main cause of low OEE values, followed by availability and quality.

Performance

Only stop times over five minutes are documented, first by hand on a sheet of paper and later, at the end of every shift, the stop times are transferred onto a computer. The reason for the stop is noted as well as the duration. Reduced speed occurs since the production does not reach the planned production.

Availability

The setup times at Astra Tech varies depending on which products the machines are going to produce. All activities that are performed during setup are divided into internal and external activities to make it as efficient as possible. When the setup is done it is often required to adjust the settings of the equipment so that it performs as planned. Stops caused by equipment failure are commonly occurring and does therefore affect the outcome of the availability. A common reason to this is poor design of the machines at the feeder.

Quality

At Astra Tech, materials and products are scrapped, however, the reason for it can vary. The more common reasons include; scratches on the product, the weld on the package is insufficient which is often caused by products not being placed properly into the packages, products that are dropped on the floor, and that there are not enough products produced to fill the last box while repacking products. Material that is used during the production process is not registered, except for catheters, which are reported in PING. From there the scrap rate is calculated by comparing the used catheters to the number of catheters needed to finish the order. The scrap rate at the external company is counted into the values for Process 3. Inspection of catheters is done manually by the operators before packaging. If there is a problem with the packages, the catheters are removed and repackaged, while the package itself is scrapped.

5.5 Other Lean Methods and Tools Used

This section presents general observations that are connected to Lean production, and also have an effect on the production flow. These methods and tools are included to provide a holistic view of the production flow.

5.5.1 Kanban

There are no kanban systems used to manage the production flow. There are, however, kanban systems used for replenishing material to the production area. They use both kanban cards and two bin systems to alert operators that they need to collect new material. When operators discover that material needs to be refilled they either go get it themselves when they have the time, or they tell the operator in charge of material to get it, if there are enough operators working to spare one person for managing material.

5.5.2 Standardized Work

There are instructions describing how work should be performed, detailed descriptions with principal pictures of the performing. The instructions are used when training new employees, which are to be learned the procedure by heart. At each work station, there are maps with the printed instructions which can be used if an operator needs a reminder. Further, the instructions are also available in electronic format at the computers. The instructions are usually updated when larger changes occur and whenever a change is made to the instructions, new once are printed out. The production manager is responsible for updating the instructions and replacing outdated once, but there are no standardized routines for how to do this.

Each shift is allowed to plan and put up their own work sequences, thereby there are five different overall standards. However, there is a standard of work rotation every 30 minutes which all shifts have to follow.

5.5.3 Kaizen

Astra Tech actively works with continuous improvements throughout the organization. There are goals for how many improvement suggestions each employee should turn in every year. If an improvement suggestion is implemented the person who handed in the idea is awarded a small bonus, if it is a group of people who have collaborated the bonus is divided among them. There is no time devoted to development of improvement ideas and instead employees have to hand in their suggestions when they can find the time in-between tasks or during breaks. Suggestions are handed in by computer to the suggestion support, where a group is responsible for evaluation of the ideas. When a suggestion has passed, the operators who handed in the suggestion are not included in the implementation of the solution.

Astra Tech offers their employees personal development through training, which is mandatory for all employees to participate in. Even though every employee receives the same training when managers notice a gap in their skill set, some employees feel that it is required to actively contact the managers themselves to request what training they want in order to get it. When an employee has developed new skills it is marked in competence matrices on a board visible to all employees in the production area. When an employee has been on leave for more than six months it is required that they retake the training, otherwise there is no follow-up to see that they actually remember what they have learned and use it properly.

5.5.4 Andon

When there is a problem with the process, the operators stop it and try to solve the problem by themselves if possible. If the problem proves too difficult, a technician is contacted by phone. The time it takes to get help from the technicians depends on how available they are at the moment. All downtime longer than five minutes and the reason for it is registered manually on a paper by the operators, at the end of each shift the downtime is reported in the computer.

5.5.5 Visualization

Astra Tech use visual aids in the form of monitors that are located over machines to show how the current rate of production compares to the production goals. However, the monitors do not show correct updated values.

There are visualization boards of general information of the employees in the form of competence matrices. Shift handover are done in front of another visualization board with information of e.g. achieved shift production, current problems and shift schedule.

5.5.6 5S

One visualization method is 5S, which is used to straighten up the workplace so that everything can be easily found when needed and to discover if something is missing. In order to accomplish this, both shadow boards and inventory footprints are used. Every week during maintenance the operators perform 5S-rounds where they go through the production area to make sure that 5S is followed and everything is up to standards.

5.5.7 Ergonomics

At Astra Tech there are many repetitive work tasks that can put strain on the body, therefore they have worked a lot to ensure that the work place is ergonomically safe. They have aids available in the production area that are meant to facilitate the work tasks and help avoid repetitive strain injuries and over burden of the operators. On each side of the Process 3 the operator stands on a, adjustable floor which can be elevated to assure that they can work in the most natural position possible. There are also lifts to help transport and handle heavy material in many places in the production area, and every half hour operators rotate between the tasks to avoid injuries from monotone work. By the packaging stations there are adjustable tables on wheels that can be tilted to make it easier to access when filling the cardboard boxes with products.

6 Analysis

This chapter will handle the analysis of the empirical data, this with the comparison to the theoretical framework. It is out of respect to the three research questions that this analysis will be presented, and thereby the following methods; VSM, Seven plus one wastes, and OEE. In the end of each method section there will be a section with a general analysis of the related research question.

6. 1 Value Stream Mapping

This section will handle the analysis of the current state and future state VSMs, first general comments, followed by some specific comments on each of the three flows.

6.1.1 General for All Flows in the Current State

Bicheno J. et al. (1993) argues that in order to create a efficient production flow the throughput time need to be short, where the essence is to minimize non value adding activities. The results of the current state VSMs (see Appendix C, D and E) shows that the proportion of non value adding time is remarkably high compared to the value adding time per product, which only deals with a number of seconds. This gives an insight of the fact that most of the time is considered non value adding time for all the three different flows. The main reason for this is the time spent in buffers.

An overall fact that complicates the situation is that Astra Tech has a lot of different types of catheters, since they vary in length, thickness, material and function. This is a challenge because it creates a large variety with different flows, which thereby creates a challenge in the production planning and how to level out production. In order to achieve an efficient production flow, it is vital to minimize the number of products in the flow and have a low variety of products (Bicheno, J. et al, 1993).

A general comment to the three flows is that they are all push flows, which do not coincide with Lean where the aim is to use pull flow (Liker, J.K., 2004). The customer in the VSMs, which is the dispatch, delivers to bulk storage. The demand in the bulk storage is not considered in the flows, instead the production is triggered by a production plan which is based on a MPS. This shows that the production is not based on the direct customer demand, and products are produced to an inventory. According to Modig N. and Åhlström P. (2011) is the most vital goal of Lean to meet the customers' demand and thereby shall the production be based on this.

The information flow in the production is based on the information system, PING, inside the production area. However, outside the production area, in the dispatch, they use MOVEX. The two information systems are not connected, which creates a gap and a risk of misunderstandings. Thereby, there are areas where there do not exist any information flow, this is when the products leave the production area and go in to the dispatch. In these cases, the operators note "finished" in PING and just leave the products in the airlocks, where the dispatch personnel pick it up when they walk by and see the products and then enter the information into MOVEX.

6.1.2 General for All Flows in the Future State

There are some solutions that apply to all of the flows. According to Lean, the ideal state is to create a one-piece flow to minimize non value adding activities (Liker, J.K., 2004). The first general solution to the flows is thereby to decrease the batch sizes, which would minimize WIP. However, one-piece flow of catheters would not be practical at Astra Tech due to the nature of the products, which are demanded in large volumes and sold in bundles. Also Astra Tech already has a transport systems and machines suited to handle the currently used load carriers. Therefore, instead of single products, each load carrier can be viewed as one flow unit. The large batch sizes cause problems in the production flow, because it leads to large buffers and prevent the production to flow smoothly. Decreasing the batch size would be better for the flows since the risk of waiting for an order from the warehouse is lower if all flows only require less every time. It would also decrease buffers throughout the flow and therefore decrease throughput time. In this ideal state the batch sizes are set to two load carriers, to make calculations for future states.

Introducing an electronic kanban signal for ordering from the warehouse would prevent buffers from occurring at the next process, which is a risk if using a push system based on a predetermined schedule. Currently an order has to be released by the process before a new order can be sent. If a new order was automatically sent as soon as the previous has entered the process, waiting can be decreased.

A general observation was that the information system has its flaws, this concerning the gap between the production and the dispatch. It would be optimal to use a common information system, in order to minimize the risk of misunderstandings as well as enabling a smoother flow with good communication. Liker J.K. (2004) argues that it is important to use visualization in order to ease the work for the operators. Thereby, an additional recommendation would be to introduce some kind of signal system that could act as a direct communication, which would visualize the status. This signal system could also be of use in the material flow between the production and the dispatch, which could indicate that there is a need for material as well as that material need to be picked up.

6.1.3 Current State of Flow 1

The main reason for the high amount of non value adding time for flow 1 is the two buffers, which contributes to prolonging waiting and increasing WIP. The size of the batches determines the size of the buffers and since batches can not be split it also determines how long time the products need to wait in the buffers. See Appendix C for the VSM of flow 1.

A summary for the results of the VSM for this flow (see Appendix C) is presented below in table 5.

Table 5 Summary of value adding time vs. non value adding time for flow 1

Total time	Value adding time	Non value adding time
3 h, 44 min	1.1 s	3 h, 44 min

The value adding time is in general the total operating time summarized. The reasons for the non value adding activities are summarized with total time in table 6.

Table 6 Non value adding activities for flow 1

Number of buffers	Time in buffers	Number of transportations	Transportation time
2	3 h, 43 min	4	1 min, 40 s

6.1.4 Ideal Future State of Flow 1

The first flow is quite simple as it is at the moment, and does therefore not require a lot of improvements without investing in new expensive equipment. However, according to Lean, the workstation shall be designed to eliminate or reduce the risk of making mistakes (Liker, J.K., 2004).

Therefore, mistake-proofing the packaging process by installing scales that calculate the number of products based on weight would be suitable and speed up the packaging process. It would also make work easier for the operators (Liker, J.K., 2004). Another solution that is being tested at the moment is a vision system, which will hopefully be able to detect defects automatically, thereby decreasing the need for the manual inspection. Thus only one operator would have to handle the packaging process.

Process 1 only produces the most commonly ordered products while Process 2 is used for all types of products that are packaged automatically. Because of this, Process 1 has higher output since it requires fewer changeovers. If the tasks for Process 1 and 2 are reversed it would mean that the process with the highest output is located closest to the exit, thereby decreasing their travelling distance.

Based on these changes the VSM of the future state is presented in Appendix F. The future state VSM of the first flow presents no larger changes. The changes are connected to the decreased batch sizes which decreased the buffer sizes.

Table 7 presents a summary of the result of the VSMs for the future state in comparison to the current state. It shows that by making these changes the non value adding time can be significantly reduced, and thereby the total time with 89%.

Table 7 Summary of value adding time vs. non value adding time for the future state in comparison to the current state, for flow 1

	Future State	Current State
Total time	24 min, 36 s	3 h, 44 min
Value adding time	1.1 s	1.1 s
Non value adding time	24 min, 35 s	3 h, 44 min

The Value Adding time is in general the total operating time summarized. While the different reasons to the non value adding activities are summarized with total time for the future state in comparison to the current state in table 8.

Table 8 Non value adding activities for the future state in comparison to the current state, for flow 1

	Future State	Current State
Number of buffers	2	2
Time in buffers	23 min	3 h, 43 min
Number of transportations	4	4
Transportation time	1 min, 40 s	1 min, 40 s

6.1.5 Current State of Flow 2

According to Lean, the ideal is to place the equipment in the same direction as the flow of material (Liker, J.K., 2004). Concerning flow 2, the reason behind the high non value adding time is three large buffers and unnecessary movement due to illogical layout for the last packaging station. The products are first packed once and then repacked at a station close by, this is an extra step that takes time and requires transportation, which could be avoided by rearranging the layout. See Appendix D for the VSM of flow 2.

A summary for the results of the VSM for this flow (see Appendix D) is presented below in table 9.

Table 9 Summary of value adding time vs. non value adding time for flow 2

Total time	Value adding time	Non value adding time
2 h, 23 min	1.8 s	2 h, 23 min

The value adding time is in general the total operating time summarized. The reasons for the non value adding activities are summarized with total time in table 10.

Table 10 Non value adding activities for flow 2

Number of buffers	Time in buffers	Number of transportations	Transportation time
3	2 h, 21 min	6	2 min

6.1.6 Ideal Future State of Flow 2

The second flow would also benefit from mistake-proofing the packaging process which would save time. This would reduce the risk of making mistakes and ease the work for the operators (Liker, J.K., 2004). The same goes for changing tasks between Process 1 and 2. In the current state of flow two, all products are handled by Process 2, even though loading the boxes onto the conveyor is done adjacent to Process 1, which causes unnecessary movement. Unnecessary movement are defined as movements that that the workers do that is not necessary to perform the work task (Lewis, J., 2005). Liker, J.K. (2004) defines overprocessing as performing unnecessary steps in production. Therefore, in an ideal state the flow would only contain one packaging station instead of two. By packaging catheters directly into smaller boxes and placing them on the conveyor right away, overprocessing could be avoided. It would also decrease transportation and eliminate buffers, thereby decreasing the throughput time.

The problem with waiting during the loading of boxes onto the upper conveyor belt can be solved by calibrating the sensors that detect when the upper conveyor belt is free. This way, operators could simply put all boxes on the lower conveyor belt, which would act as a queue, and the upper conveyor belt can automatically collect a new box when there is room for it. It would avoid occupying the operators and allow them to begin with a new order. Because the elevator causes unnecessary waiting and needs to be synchronized with the sensors, it would be better to use a tilted conveyor belt connecting the upper and lower conveyor belts. See figure 16 for principal sketch of the layout.

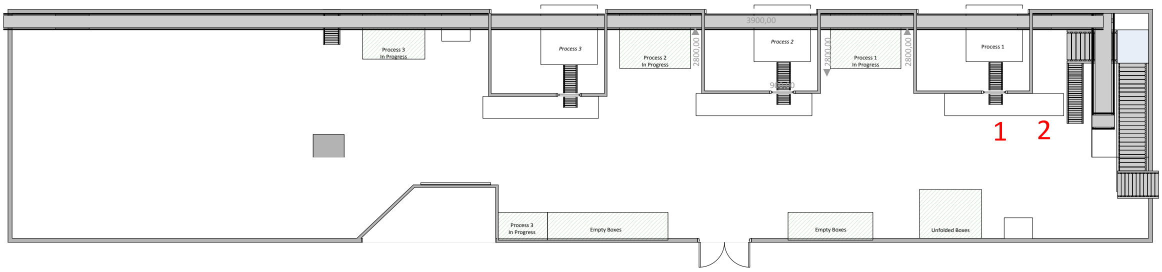

Figure 16 Principal sketch of the ideal future state layout of the production area, flow 2

Based on these changes the VSM of the future state is presented in Appendix G. The future state VSM of the second flow is changed due to the removal of the first packaging station, and the merging of the packaging and the loading station. This in combination with the decreased batch sizes which decreased the buffer sizes.

Table 11 presents a summary of the result of the VSMs for the future state in comparison to the current state. It shows that by making these changes the non value adding time can be significantly reduced, and thereby the total time with 90%.

Table 11 Summary of value adding time vs. non value adding time for the future state in comparison to the current state, for flow 2

	Future State	Current State
Total time	13 min, 35 s	2 h, 23 min
Value adding time	1.6 s	1.8 s
Non value adding time	13 min, 33 s	2 h, 23 min

The value adding time is in general the total operating time summarized. While the different reasons for the non value adding activities are summarized with total time for the future state in comparison to the current state in table 12.

Table 12 Non value adding activities for the future state in comparison to the current state, for flow 2

	Future State	Current State
Number of buffers	2	3
Time in buffers	12 min	2 h, 21 min
Number of transportations	3	6
Transportation time	1 min	2 min

6.1.7 Current State of Flow 3

The third flow is a bit more complex due to the fact that there is an external source that handles a part of the production. According to Liker J.K. (2004) is the path of Lean is always that the company shall make everything for itself, with the attitude "let's do it our self" instead of trust an outside partner with the assignment. Due to the external company, transports and long lead times are created. This do not only contribute to non value adding time in form of long transports and the buffer at the external co-working company, but also a need of building up an inventory before the transport and an inventory after the delivery. Further it also leads to the need of taking the products outside the cleanroom environment, which not only creates buffers before, in, and after the airlocks, but also additional work in form of plastic binding. See Appendix E for the VSM of flow 3.

A summary for the results of the VSM for this flow (see Appendix E) is presented below in table 13.

Table 13 Summary of value adding time vs. non value adding time for flow 3

Total time	Value adding time	Non value adding time
5 days, 6 h	7.1 s	5 days, 6 h

The value adding time is in general the total operating time summarized. The reasons for the non value adding activities are summarized with total time in table 14. Here, the external co-working company is considered as a buffer.

Table 14 Non value adding activities for flow 3

Number of buffers	Time in buffers	Number of transportations	Transportation time
12	5 days, 4 h	18	1 h, 47 min

6.1.8 Ideal Future State of Flow 3

Using a mistake-proof aid, e.g. a scale, to count the catheters in the packaging process would speed up the process and would make work easier for the operators (Liker, J.K., 2004). In order to create a more continuous and flexible flow of the third production flow, it is out of a Lean perspective most optimal to totally remove the external production part. This would mean that the punching need to be done in-house instead, and should then be placed in the middle of Process 4 and Process 3 (in the same direction as the natural production flow). By removing the external production, the need of building up buffers before and after transports will be eliminated, as well as several other buffers which are connected to this action. Further, the unnecessary transportations in themselves will be eliminated.

The fact that there is limited space in the production area will be handled by the means of the reduction of buffers (the combination of no need of building up buffers before and after the external production, and the reduction in batch sizes). Which will mean cleared space by elimination of inventory squares, which thereby will clear space for the punching machines. See figure 17 for principal sketch of the layout.

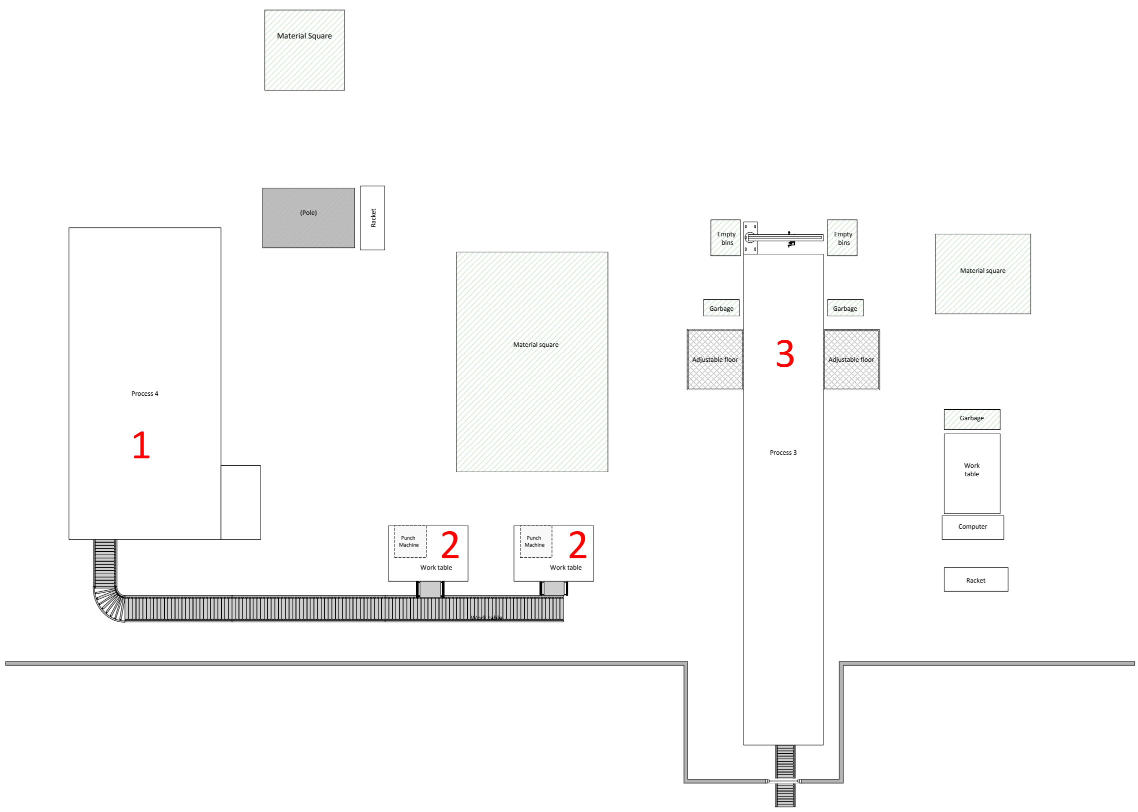

Figure 17 Principal sketch of the Future State layout, flow 3

There are further benefits of removing the external production, the products no longer will have to leave the cleanroom before it is totally done. This will reduce the risk and increase the quality assurance of the products. Based on this the VSM of the future state is presented in Appendix H. The future state VSM of the third flow is changed in several ways, mostly due to the removal of the external production. This in combination with the decreased batch sizes which decreased the buffer sizes.

Table 15 presents a summary of the result of the VSMs for the future state in comparison to the current state. It shows that by making these changes the non value adding time can be significantly reduced, and thereby the total time with 99.4%.

Table 15 Summary of value adding time vs. non value adding time for the future state in comparison to the current state, for flow 3

	Future State	Current State
Total time	46 min, 28 s	5 days, 6 h
Value adding time	2.7 s	7.1 s
Non value adding time	46 min, 25 s	5 days, 6 h

The value adding time is in general the total operating time summarized. While the different reasons to the non value adding activities are summarized with total time for the future state in comparison to the current state in table 16. The external co-working company is considered as a buffer.

Table 16 Non value adding activities for the future state in comparison to the current state, for flow 3

	Future State	Current State
Number of buffers	2	12
Time in buffers	44 min	5 days, 4 h
Number of transportations	6	18
Transportation time	2 min, 20 s	1 h, 47 min

6.1.9 Usability of Value Stream Mapping in the Medical Device Sector

This section will handle the general analysis of the first research question:

> *"How can the use of Value Stream Mapping ease the understanding of how to improve a production flow with the special requirements of the Medical Device Sector?"*

VSM is a method often to use to visualize the production flow, and providing a common overview of the entire production flow (Rother, M. and Shook, J., 2003). Which coincide with this case, where VSM gave a holistic view of the production flow. Further, by the use of VSM it was possible to locate waste in the production flow, which helped identify where actions of improvements were needed.

VSM can be used to visualize and analyze the current and the future state of the production flow (Jones, D. and Womack, J., 2003), which were possible to perform in this case as well. Therefore, despite the specific requirements of the Medical Device Sector, VSM was a usable method to use in this case in order to understand how to improve a production flow.

6.2 Seven Plus One Wastes

The current state of the production flows will in this section be analyzed out of respect to the seven plus one waste (see chapter 2.4.2).

6.2.1 Overproduction

According to Lean, overproduction refers to producing more than what is necessary to meet the customer demand, thereby shall the production be based on the customers' order (Lewis, J., 2005). The general production in this case is planned out of respect to a MPS, thereby are the production is not planned after what is actually ordered. The fact that the customer demand is rather levelled contributes to a situation where the MPS is relatively suitable since it is easier to predict what is required. The MPS generates a prediction of the need at the production plant which thereby is planned every third or fourth day, which generates orders at each process. Then if raw material is available the order is started without respect to if the products actually is needed further down in the flow, and products are thereby produced to inventory.

To compensate for the summer production stop, the production planned to overproduce. However, this is a necessary form of overproduction in this case since it should suit the company's situation.

Specific for the second flow of Product C, where there is a need of a complimentary step of packaging, is that finished products are scraped. This due to the fact that the boxes at the second packaging do not get filled and perfectly fine and finished products has to be scraped. The reason to this is that the lot number can not be mixed with another lot number according to regulations.

6.2.2 Waiting

Waiting is defined as available time that is wasted, e.g. waiting because there is stop somewhere else in the flow (Lewis, J., 2005). Due to problems earlier in the production plant in combination with the fact that this product family has a low priority, it has been observed that it is common that both Process 1 and Process 2 get standing still and out of work. Then it is only Process 3 which can run and thereby most of the work teams are out of work and can do nothing else than wait for material. However, the root of this problem lies outside of the scope of this Master's Thesis. Thereby this is an area which the company is recommended to put further focus on, since it contributes to waste in form of e.g. waiting. Still the current situation could be improved by using the waiting time to something useful, e.g. work with 5S or continuous improvements.

A similar problem occurs when there are no available load carriers in the warehouse. Before an order can be activated at either one of the machines (Process 1, Process 2 or Process 4), the operator has to check if there are enough load carriers for the whole order in the warehouse. If that is the case, all the load carriers are ordered to the waiting buffer before the machine. If there is not enough load carriers the operator has to wait for available load carriers.

Waiting can also be caused by standing around and waiting for the next processing step (Lewis, J., 2005). The setup times are many in this case, due to the fact of broad variety in article numbers which are not optimal according to Lean since an efficient flow shall have a low variety of products (Bicheno, J. et al, 1993). The setup time for Process 1, Process 2 and Process 3 tends to get relatively long due to the need of start-up times. A common problem which occurs is that the setups are malfunctioning and machines need to run empty for several turns, which causes not only waste in waiting but also waste in material. This is combined with the fact that the machine settings are not standardized, the values need to be tested from time to time in order to reach the right level. Then for every setting, the machine needs to run empty for a couple of turns to see the test result. This also complicates the machine settings. This does not coincide with Lean, Liker J.K. (2004) argues that the work shall be standardized in order to work in the best way, ease the work, to assure quality and enable continuous improvements.

Unexpected stop times are common in Process 1, Process 2 and Process 3, where stops less than five minutes are ignored and almost accepted as a part of the work while stops over five minutes are notated. According to Liker J.K. (2004) it is suitable to use andon system to handle stops. However, when a stop occurs in this case, the operator at the machine try to fix the problem as fast as possible, meanwhile the two operators in the packaging have to just wait. It is common that the problem needs to be fixed by a technician, who is called after a period of trying after which all the three operators have to wait for the technician to arrive. This can take up an hour, since the technicians have too much to do. There exists an andon system, but it is not used, only in the way of different light signals visualizing the status of the process. The operators would need more responsibility and education in maintenance of the machines in the common problem areas, but since the technicians have too much to do they do not prioritize to educate the operators. Which results in a vicious circle, since if operators are educated and can fix problems themselves this would result in more time for the technicians. Who might even get time to actually get to the root of the problems and find solutions to them.

Specific for flow two is waiting during the loading of boxes on to the conveyor belt (the last operation of flow three), which refers to waiting for the next processing step (Lewis, J., 2005). The elevator at the conveyor belt is not working as it should which contributes to that boxes do not always get lifted to the upper conveyor belt, and are passed on to a waiting area to await one of the operators to pick it up and redo the operation. This do not only contributes to waiting at the operation itself and the operators at this station, but also waiting for the whole process. This due to the fact that a new order can not be started before the on-going order is checked out and totally finished. The cause to the problems with the elevator is the fact that the upper conveyor belt connects to another product family's conveyor belt and thereby can not the elevator lift when another product is already at the upper conveyor belt. A contributing problem to this is that at the lower conveyor belt can only be loaded with one box at a time, then the operator have to stand and wait for the box to be transported along the conveyor belt and until the elevator is lifted. In order to co-operate more smoothly with the other product family at the upper conveyor belt, it would be suitable with a small waiting buffer on the lower conveyor belt. However, the best way of solving the problems at this station would be to change the layout of the entire process and connect the station before to this station and combine the two operations and create a flow where the boxes can be placed at the conveyor belt direct after the packaging.

Waiting can also be caused works having to watch an automated machine (Lewis, J., 2005). Specific for flow three and Process 4 is that the machine is almost fully automated. The first thing that the operator has to do is to activate the order and wait for the load carriers to arrive. This is complemented with assuring that the machine is loaded with enough paper and the right paper, otherwise the machine needs to be refilled. The same applies to the empty bins. From that moment on the machine is automated, and just needs to be refilled if it run out of paper or bins. Thereby, the operator only needs to observe the machine and wait for a whole bin to be filled, which take approximately 13 minutes, and then move the filled bin along a manual conveyor belt to a plastic binding station and wrap the bin, which takes approximately 40 seconds. This causes waiting time of just watching the machine and stand around waiting for the next operation step.

6.2.3 Unnecessary Transport

Unnecessary transportation refers to transportation that is not needed to produce the product, or unnecessary long transportations (Liker, J.K., 2004). The ideal state is to have minimal or no transportation of material between process steps (Lewis, J., 2005). Unnecessary transport is most obvious in the third flow, where the products need to be moved a long distance to an external co-working company and back. This to perform one single operation which can be done in-house, with the obstacles; lack of space in the cleanroom environment and resistance from operators which do not like this manual work. The operation means manual punching of one catheter at a time, with precision of the tip angle. The fact that the products are transported to another city creates long transports both in the truck transportation in itself, but also in-house where transportations is needed in and out from the dispatch and inside the dispatch as well.

Illogic layout can cause unnecessary transportation in the production (Liker, J.K., 2004). Additional to the previous statement regarding unnecessary transportation in relation to the co-working company, is the placement of the machine for plastic binding of pallet in the dispatch. The products are moved from one buffer to the plastic binding and on to another buffer. Where the second buffer is placed between the first buffer and the plastic binding (see figure 13), thereby the products are transported back and forward. Instead should the products be moved along in the same direction as the production flow.

Unnecessary transports also occur in the second flow, where the most critical area is the one in relation to the second packaging station. The layout of this packaging area is causing longer transportations than necessary, since the location of the workstation is in the opposite direction to the following workstation (see figure 10). This leads to transportations back and forward, but also extra transportations to additional buffers. Therefore, this would be improved by changing the layout into placing the workstations in the same direction as the production flow.

6.2.4 Overprocessing

To perform unnecessary steps in production is to overprocess the products (Liker, J.K., 2004). A general observation which affects all the three flows is that during packaging into boxes or bins (after Process 1, Process 2 or Process 3) the catheters are counted manually as they inspect and verify the products. This increases the risk of mistakes, and do also slow down the production flow. The manual counting is referred to as an unnecessary step since the work method could be improved or eliminated by minor changes. This step should be mistake-proof, where the counting is automatically e.g. by using a scale or a sensor.

Overprocessing is often caused by poor tool, fixture, and equipment design (Lewis, J., 2005). Specific for the machines Process 1 and Process 2, which are involved in flow 1 and 2, is that poor design causes unnecessary work steps. This since it has been common that the machines take out more test samples than they should, which lead to extra work for the operator. The operator then needs to go and pick up the test samples, cut the packaging up, and reload the catheters manually into the machine. During this step, the operator also has to stop the automated loading of catheters and thereby is the process slowed down even more.

Due to poor machine design in Process 1 and Process 2 there is a common problem of products lying skewed. The reason to the problems lay in the feeder, since it has difficulties in e.g. grabbing the connectors of the catheters. The feeder is extra sensitive when it comes to Product C, due to the fact that it has a special connector which is larger and stiffer. The problem with skewed products leads to the need of the operator to constantly observe the line and to move skewed products into their right position. Thereby do the operator need to delay other work tasks which usually are done parallel while the machine run. However, since the operators find their own ways of dealing with the problem, the problems remain unnoticed by the managers since it is covered by overprocessing (Lewis, J., 2005).

Specific for the second flow, and the fact that it has two packaging stations, leads to the need for operators to count the products twice. This with the notation that the first packaging is not necessary, except for storing the products in a bin in order to transport them to a buffer, where they wait, and then transporting them to the next packaging station. Furthermore, at the first station the product arcs are put in layers of ten and ten, while they are put in layers of seven and seven at the second station. Thereby are the counting at the second station more complicated than needed, since if the layers at the first station would have been of seven arcs directly this would have eased the second packaging because then the operator only have to grab one layer at a time.

Overprocessing can also be caused by the fact that the used material is not standardized, which also increases the risk of mistakes (Liker, J.K., 2004). In the third flow, specifically regarding Process 4, when the machine shall put a paper in between each layer in the bins the machine need to turn the bin 90 degrees. It is considered as poor machine design since the paper holder is not adapted to the bins, if the paper would lay in the same direction as the bin then the turning could be removed.

6.2.5 Excess Inventory

Because orders can not be split, much material needs to be dedicated for a process long before it is actually needed. Smaller batch sizes would therefore mean that the buffers between the warehouse and the following processes in all of the three flows could be smaller (Liker, J.K., 2004). Thus, there would not be as much material devoted for each process and the inventory could be decreased and thereby reduce WIP.

From a Lean perspective there are an excessive number of buffers in the production area, since the optimal flow is to build to order (Modig, N. and Åhlström, P., 2011). However, some of them are necessary to enable the use of a cleanroom area. Especially flow number three has many buffers and a lot of WIP where the round trip to the co-working company is a contributing factor.

The products that are manually placed into plastic packages in Process 3 are usually not of high priority, therefore each shift only do enough to fill their expected quota for the day. This causes space in the production area to be claimed for longer time than necessary, even though the production area is already limited as it is.

Using one piece flow would not be possible at Astra Tech since the setup of machines would take too long compared to the time it takes to manufacture the products. Because Astra Tech shuts down production a few weeks every summer for maintenance they need to carry extra stock to be able to meet demand during that period. Nonetheless, WIP could be decreased through minimizing the need for buffers by keeping batch sizes small and eliminating buffers where they are not needed (Liker, J.K., 2004).

Sheets of paper are used to separate the layers when catheters are placed in bins in Process 4. However, there are two different thicknesses of paper used, which require more storage space. It would be preferred to standardize the choice of material and components to minimize inventory (Lewis, J., 2005).

6.2.6 Unnecessary Movement

Even though every tool has its designated place in the production area they are often misplaced, which means that operators have to spend time looking for them and it is mainly a problem during setup. A straightened workplace means that items shall be placed in a way that ease the work, e.g. close to where they are used (Liker, J.K., 2004). The disinfectant is located in a rack shared by more than one process and the operators have to move away from their station to apply it before handling the products. This have to be done every time something other than the products has been touched to assure that the products are safe for the customers to use.

There are clear instructions describing how work should be performed, which are frequently used when educating new employees. However, the instructions are seldom updated, even though they should be updated for all improvements (Whitmore, T., 2008). Even though it is not possible to deviate too much from the instructions due to the nature of the tasks, operators sometimes tend to find their own ways of doing them. For example, operators sometimes change the order in which tasks are performed. This can mean that unnecessary movements are made by the operators.

6.2.7 Defects

There are large volumes of materials and products that are disposed of, and the reason for it can vary. Often the problems occur in the Process 1 and Process 2 and the more common reasons for scrap or rework include; scratches on the product making it unsafe to use, the weld on the package is insufficient which is often caused by products not being placed properly into the packages, and products that are dropped on the floor. The scrap rate of catheters is registered in PING. However, there are no records kept on the causes for disposal of products. This leads to a risk that problems goes unnoticed and can therefore happen again (Lewis, J., 2005). Scrap rate of material that is used in the production process is not registered at all.

Catheters are inspected manually, which makes it is a subjective task and the assessment can differ from one operator to the next. Since it can be difficult to determine the quality of the products, operators tend to be willing to dispose of them rather than, when in doubt, approve products. An indicator that this is true is that the co-working company often has a higher scrap rate than anticipated when compared to Astra Tech. Educating the employees on how to determine when to approve, rework and scrap products should help even out the scrap rates between the two companies. Also education on how to use machines properly can have an effect on the scrap rate.

Because instructions are available, but rarely used once a task is mastered by an operator it happens that steps are overlooked, which leads to problems later on. It causes delays when settings are discovered to be wrong and it generates defected products that need to be disposed of. Ensuring that instructions are up to date and followed (Whitmore, T., 2008), and work is standardized is a means to achieve high quality (Liker, J.K., 2004).

6.2.8 Unused Employee Creativity

Astra Tech actively works with continuous improvements throughout the organization. There are goals for how many improvement suggestions each employee should turn in every year. This however does not motivate employees to come up with more good ideas (Freifeld, L., 2011), but rather to simply hand in any suggestion just for the sake of filling their quota. If an improvement suggestion is implemented the person who handed in the idea is awarded a small bonus as an incentive, if it is a group of people who have collaborated the bonus is divided amongst them. Incentives can be useful in the beginning when introducing continuous improvement in order to get people interested and involved (Freifeld, L., 2011). Though when it has become a part the company’s culture, the improved work situation and satisfaction of contributing and being heard should be enough motivation (Freifeld, L., 2011). Individual incentives can lead to a competitive nature where everyone keeps ideas to themselves to avoid sharing the bonus, instead of working together and discussing ideas which would benefit the company most (Cameron, K.S., Quinn, R.E., 2011).

Because there is no time devoted to development of improvement ideas it happens that operators do not hand in suggestions since they do not feel that they have enough time. Handing in suggestions by computer can be a good way to make sure that it is delivered to the decision makers, but sometimes it is easier to use pen and paper, e.g. if the operator wants to draw a sketch to help explain the idea. Not including the operators in the implementation process can result in a lack of interest or understanding of why the new solution has been put into effect (Liker, J.K., 2004). If they feel they have participated in developing an improvement it is more likely that they want to make sure that it will be successful (Liker, J.K., 2004).

Marking a board to show what areas each employee is trained in makes it easy for others to see who they can ask if they need help. It is more likely that they will get to use their skills when others are aware of their knowledge. It will also benefit both the operator possessing the knowledge who gains repetition when explaining and helping others, and the operator who asked for help will hopefully gain new knowledge. However, not having any follow-up when some time has passed after the training means that there is no way of telling if the operators actually remember what they have learned and use it properly.

6.2.9 Usability of Seven plus One Wastes in the Medical Device Sector

This section will handle the general analysis of the second research question:

> *"How can an analysis with the Seven plus One Wastes ease the understanding and identification of problem areas in a production flow within the Medical Device Sector?"*

In Lean production, seven plus one wastes have been identified which are actions that do not add any value to the product (Liker, J.K., 2004). By using the definition of these seven plus one wastes, an analysis of the production flow was possible by comparing these with the case. Thereby, activities that disturb the production flow, which refer to as problem areas, could be identified. Identification and elimination of waste in a production flow is a key factor towards a more efficient production flow (Modig, N. and Åhlström, P., 2011).

In the Medical Device Sector, there are specific requirements such as e.g. cleanroom regulations that affect the production flow and can make some activities necessary even though they are defined as waste according to Lean. An example of this is additional inventory before, in and after an airlock when moving the products in and out of the production area. When taking the specific regulations into consideration, the seven plus one wastes eased the identification of problem areas in the production flow.

6.3 Overall Equipment Efficiency

The OEE values for the processes in the studied flows are considered to be too low by the company, and their goal is to increase them in the future. The reason why the company wants to increase their OEE values is that they want their processes to be as efficient as possible when they run. Increasing OEE would enable them to turn off the machines, and e.g. change the shift structure by reducing the number of shifts. However, from a Lean perspective it is of priority to level out the production rather than force the most efficiency out of the machines in the shortest period of time (Modig, N. and Åhlström P., 2011). The company's goals can be questioned, due to the fact that the optimal OEE value might vary over a period of time with respect the customer demand (Dal, B. et al., 2000).

6.3.1 Performance

The performance is affected by idling and minor stoppages, and reduced speed (Dal, B. et al., 2000). The low OEE values are mainly due to the low performance rate, with the main effect that the machines do not produce enough products in relationship to the takt time. Stop times frequently occur, which contributes to obstacles of reaching the expected number of produced products and takt time. Specific for stop times, the reported stop times are only stops longer than five minutes. Thereby, there is a risk of misleading numbers in this category since the number should actually be higher. This because observations has shown that shorter stops than five minutes are common.

From a Lean perspective it is vital to eliminate or reduce unexpected stop times, even stop times less than five minutes, in order to get a stable process (Modig, N. and Åhlström P., 2011). To enable this, the first step is to identify why the stop times occur, and identify the reason that causes the problem. Therefore, it is vital to document stop times including reason, which also enlightening that the problem do exist (Lewis, J., 2005).

6.3.2 Availability

Availability is influenced by setup time, adjustment of equipment, and breakdowns due to equipment failure (Dal, B. et al., 2000). After a setup, the machines often requires additional adjustments of the settings, which often differ from the instructions and are thereby not standardized. This leads to the fact that the operators need to test different settings in order to identify the right one. Thereby, the availability rate is influenced, which would be minimized by optimizing the machine settings and standardize the instructions (Liker, J.K., 2004), this in order to ease the work for the operators and create a more mistake-proof process.

Poor equipment design causes breakdowns and long stop times (Nakajima, S., 1989). The most common reason is that the feeder put the products in a skewed position, which lead to breakdown of the welding plate. If this happens, the operators have to change the welding plate and replace it with a new (which need to be warmed up, and thereby extra setup time). This reduces the availability rate as well, and since it is a common problem it is vital to get to the root of this problem and fix it.

6.3.3 Quality

Quality is affected by defects in process and rework, and reduced yield between machine startup and stable production (Dal, B. et al., 2000). When studying the quality rate it appears to be high. However, the reported scrap rates are above the targeted goal, for Process 3 the scrap rate is remarkably high. The reason for this is that the scrap at the external company is added to this process. This fact contributes to misleading, and affects the quality rate of this process negatively. Further, since it has been observed that the scrap rate is higher at the external company the effect is increased. Therefore, it is vital to cooperate with the external company and educate them in how to inspect the products (Liker, J.K., 2004).

Since these machines produces large volumes of products, every percent amounts to a great amount of products in the end. The reason for the scrap is not notated in the current state. To be able to reduce the scrap rate it is vital to identify the problem which causes it. Thereby, it is vital to start with documenting the scrap rate with related reason, to enable to fix the actual problem.

6.3.4 Effects of the Overall Equipment Efficiency on the Production Flow

This section will handle the general analysis of the third research question:

“How does the OEE value affect the production flow?”

It is important to keep in mind that the first priority is to focus on creating an efficient flow, by reducing non value adding activities. Only then shall the focus be put on making the resources more efficient (Modig, N. and Åhlström P., 2011). As long as the machines can deliver what is expected by meeting the customer demand, it is of interest to level out the production. However, unexpected stop times and scrap rates contribute to non value adding time, and are thereby of interest to eliminate (Modig, N. and Åhlström P., 2011). Further, the problem with the scrap rate and stop times result in additional problems, due to the fact that the machine can not produce products in the meantime.

The company's intentions with reaching higher OEE values in order to have efficient machines, is positive in the aspect of having machines work as they should. Which minimize the risk of operators having to deal with non value adding activities, and get the benefits of having reliable machines and processes. However, it should be combined with the intention to be able to create an efficient flow.

Depending on which factors the company are focused on, a work towards a high OEE can have both positive and negative effects on the production flow. If the focus is on e.g. reducing scrap and stop time it is good for both the OEE value and the production flow. However, if the focus is on just reaching a high utilization of resources the risk is that it contradicts the efficiency of the production flow.

7 Recommendations to the Company

This chapter will handle the areas of improvements, which is a result of the previous analysis of the current state in combination with the theory. The first subchapter will present the recommended changes, and mainly handle the alternative solutions to two of the production flows, which are smaller changes that can be implemented in a shorter time perspective. This is a complement to the suggested ideal states that are presented in the analysis chapter. The second subchapter will present the general solutions of changes, which refers to problem areas that concern the common work situation of all the three flows.

7.1 Solutions to improve the Production Flows

This section will handle the recommended solutions to the company which refers to the different production flows. First recommended solutions for an ideal state (which were thoroughly described in the analysis chapter), followed by alternative solutions to the second and the third production flow will be described.

7.1.1 Ideal states

The suggested changes of the ideal changes for production flow 1, 2 and 3 were introduced and described in the analysis chapter. These will be briefly summarized in this section.

General for All Production Flows

- Decrease the batch sizes, in order to minimize the WIP.
- Introduce an electronic kanban signal between the warehouse and the processes.
- Introduce a common information system for the Production and the Dispatch.
- Introduce a signal system between the Production and the Dispatch.

Flow 1

- Introduce a mistake-proof calculating system for the packaging station.
- Change the production set-up/structure between Process 1 and Process 2.

Flow 2

- Introduce a mistake-proof calculating system for the packaging station.
- Change the production set-up/structure between Process 1 and Process 2.
- Remove the second packaging station by performing this packaging directly at the first station. Connect that packaging station to the conveyor belt, and allow a small waiting buffer at the conveyor belt (when the upper conveyor belt is full).
- Introduce a tilted conveyor belt between the upper and lower conveyor belt, and calibrate sensors.

Flow 3

- Remove the external part of the production, and do the manual punching in-house. Place the punching machines between Process 3 and Process 4, and connect them to Process 4 with a conveyor belt.

7.1.2 Alternative Suggestions

This section will present and explain the alternative suggestions which were developed to production flow 2 and 3. These are smaller changes which could be implemented in a nearby future.

Flow 2
An alternative solution to removing one of the packaging stations is to move the second station closer to the loading process. By placing the second packaging station behind Process 1 and adjacent to the loading process instead of at the opposite end of the packaging area, unnecessary transportation would be avoided and space would be freed. At the time for this study there is a planning board placed on the wall behind Process 1, however, it could be moved to a wall where the second packaging station used to be instead. See figure 18 for principal sketch of the layout.

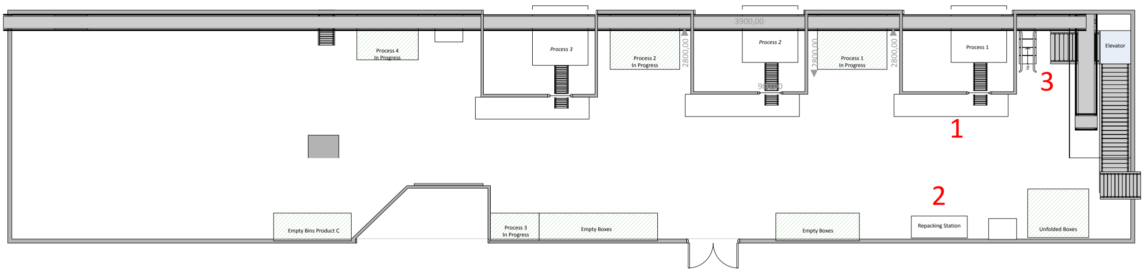

Figure 18 Principal sketch of the alternative future state layout of the production area, flow 2

If the flow continuous to use two stations instead of one, the packaging pattern at the first station should be changed. Placing products seven at a time instead of ten in the bins would facilitate work at the second station, thereby decreasing the cycle time.

At the second packaging station there are two helping devices for the folding of boxes, one for each product length. If it was possible to switch between the two lengths on the devices it would either be enough to have one device or it would be possible for two operators work simultaneously with the same task.

Flow 3
An alternative solution would be to move the Process 3 machine to the external co working company as well. Thereby the need of reintroducing the products into the in-house production area will be eliminated, and then also minimize the need of buffers which bind work in process. Instead, with the Process 3 at the external production, the products will be finished and the lead time to the customer will decrease. Additional benefits of this are the elimination of one in and out passage to the clean room and that more space will be available in the plant.

Alternative, smaller, solutions which would improve the third production flow in a short-term perspective is to standardize the number of different paper types at the BP to one. It would lead to quality assurance and reduce the risk of problems with papers being dropped outside the bin, which happens with the thinner papers and leads to stops. Another result is that material in buffers would decrease and thereby clear space in the material warehouse and the production area. A second alternative solution is to move the placement of the plastic binding in the dispatch in order to place it in the natural direction of the production flows. To a location in-between the two buffers (see figure 19 for principal sketch of the layout), this would reduce the unnecessary transportations.

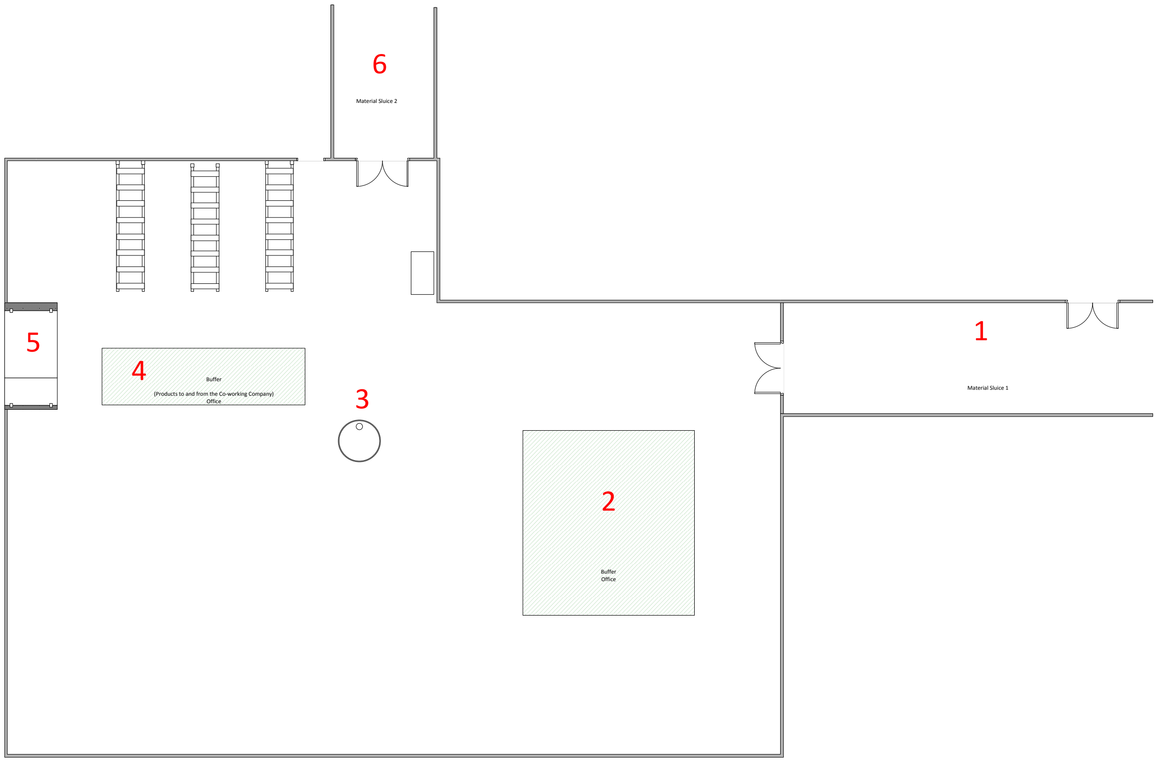

Figure 19 Principal sketch of the Alternative Future State layout, flow 3

7.2 General Solutions

This part will present the general recommendations, which are solutions that are applicable for the whole production area of this product family. The chapter is basically a follow up on the results from the observations and interviews, where specific problem areas where defined. The suggested solutions are generated out of respect to a Lean production perspective which is handled in the theory chapter.

7.2.1 Standardized Work

Instructions are not updated often enough, which need to be changed. Unless instructions are updated, the best way of performing a work task might not be communicated to everyone. Thereby, it is most likely that employees perform tasks differently, which means that standardization does not succeed. Therefore it is vital to introduce a standardized way to work with establishments of standardized work. Having one person responsible for updating the instructions and changing them is good, but when the changes have been made it can sometimes go unnoticed by employees. Every employee should be informed when new instructions are available, e.g. at the shift meetings, when a change is done.

It is vital to spread the fundamental meaning of why standardized work is used and reason to importance of following the standard. This in combination with the encouragement of suggesting improvements of the standard, even small changes which can have a greater effect then one can imagine.

7.2.2 Kaizen

There exists a work with continuous improvements and a vision of evolving the employees in this process. However, this could be improved further. It can be stated that the motivation of the employees is not what it could be. The company puts up goals on how many suggestions of improvements that each employee should submit. This on the other hand do not motivate the employees to develop good suggestions, instead they leave anything just to achieve the target number. Since the goals are set for each individual employee they keep their suggestions to themselves. An alternative solution to this would be to set up common goals for each team in order to encourage teamwork, this in combination with a common reward for motivation and which at the same time could increases the team communion. There should also be set dedicated time for improvement work, since the employees do not experience that they have enough time to develop suggestions of improvements.

Due to different personalities of the employees, some operators do not want to ask for training even though they want to learn more. Instead they want to be offered the opportunity from their manager. Therefore, it could be suitable to check this e.g. every month, and also encourage employees to perform personal development as much as possible.

Employee training needs to be followed up, since it has been notated that not all employees remember what they have learned after a period of time, even though it seems as they have the knowledge according to the knowledge board. Thereby it is vital to follow up the information on the knowledge board, in order to visualize the real situation instead of give an illusion of a close to perfect state where the majority got full knowledge. This can be done through a standardized procedure where the work manager asks the operator questions from a protocol covering the essentials of the task. It is important to communicate that the reason for the procedure is not to control them, but rather to improve their work environment, which is beneficial for everyone involved.

7.2.3 Andon

To decrease scrap rate and avoid problems with quality, andon systems should be used in the production flow. If machines automatically stop at the first sign of trouble instead of waiting for operators to detect it, fewer faulty products would get through the process before it is stopped. By stopping the process, it becomes more obvious that there is an actual problem which forces a change. It is rather common with stops and when a problem occurs it is fixed as fast as possible without trying to find the root cause of the problem. To reach a long-term solution to the problem, it is vital to prioritise the need of finding the root cause of the problem and fix it. This would save time and trouble in the long run. A first step towards this is to follow up the notated downtimes in order to identify the root cause of the problem. Using the five why method is a good approach to assure that the underlying reason that cause the problem are actually found.

7.2.4 Visualization

Since the monitors portraying the current production rate show false information, they need to be corrected. PING contains the correct and updated values and therefore it is a problem with the software providing the screens with information. If the problem is not fixed the monitors should be removed completely, otherwise they can be misleading and creates a distraction rather than facilitate the daily work.

7.2.5 5S

The work with 5S is in the right direction. However, it is a fact that 5S is not completely followed, since tools are not always at their place, which obstruct the operators' work. Thereby, more information needs to be communicated to the operators regarding the reason to 5S and why it is important.

7.2.6 Ergonomics

It is good that Astra Tech puts interest in ensuring the work stations are safe and ergonomically designed. Due to the fact that some work tasks are repetitive, it is vital that the work rotations every half hour is kept.

The loading of boxes on to the conveyor belt (in flow 2) is not working as it should, are operators forced to load the boxes manually to the upper conveyor belt. This leads to unsafe work postures, where the operators stand on the lower conveyor belt and reach above their head to place boxes on the upper conveyor belt. Due to the fact that this problem only occurs because of an earlier problem with the conveyor belt, this is a problem which should not exist and solutions should be found to the root problem. Therefore, the loading station should be redesigned, which was presented in section 6.1.6.

7.2.7 Scrap Rate

At the current state, it is common with scraped products and material. However, this is not directly notated with the reason of the scrapping. Thereby are waste hidden in a category of just scrap, since the reasons are not notated is it not possible to see what the actual problem is. A first step towards an improvement of this is to document the reasons to the scrap and follow it up, which thereafter can ease the localisation of the actual problem. Even though the notation will take extra time from the operators in the short-term thinking, the goal is to eliminate the problem and thereby also the scrapping, which will eliminate the extra work task of notation.

Since the product verification is made manually (which makes it a subjective judgement) it is vital to regularly keep education of the employees as well as for the co working company. Recommended is also to visualize with samples, at the work stations, of borderline products which symbolize what correspond approved and not approved products. This could act as a guideline in cases when operators are uncertain.

The ongoing tests which are made on Process 2, regarding the vision system, would mean a remarkable improvement. If it would work, this means a higher quality assurance and a more mistake-proof design of the work task, as it remove the subjective judgment of an operator.

7.2.8 Stop Times

In the current state, the stop times longer than five minutes are notated. However, it has been observed that stops occurs frequently and disturbs the production flow, where smaller stops are common and almost accepted. Therefore, should all stops be notated and documented with the reason. This in order to visualize the problems and clarifying the need of improvements, which also enables the possibility to follow up and identify if there has been changes.

By enabling the opportunity to improve and eliminate unexpected stops, the OEE values will be affected positively and the machines will be more reliable.

8 Discussion and Conclusions

This chapter will handle the discussion regarding the contribution of this Master's Thesis, with respect to the fulfillment of the purpose, the research questions, and a general discussion of observation and the generalizability of the study. It is combined with the reliability of the results and the weaknesses of the research approach. The subchapters include discussion on the topic and what conclusions that have been made.

8.1 Using Lean Methods in the Medical Device Sector

The result of this Master's Thesis can be regarded as a complement to the existing literature of the possibility to implement Lean production in other sectors than the automotive sector. This with the requirement of the need for adaption to the specific company.

The purpose of this Master's Thesis was to get an understanding of how to improve a production flow, using Lean methods, within the Medical Device Sector. This subject was handled during the execution of the case study at Astra Tech. The three different Lean methods; VSM, Seven plus one wastes and OEE, was used to get an insight in the subject. This provided a thorough research of the applicability of these methods within this sector. However, it was found that it is not possible to just transfer Lean production into the Medical Device Sector, it needs to be adapted to meet the sector's requirements.

The requirement of cleanroom conditions for the production area sets demands on the formation of the production flow. The handling of both material and products are affected by this, as well as the employees. It requires operation steps that would be considered as non value adding in other sectors, which are mandatory in this sector. This contributes to the need of extra inventory, in the airlocks, when entering and exiting the production area. There is also a need for extra work tasks, which do not directly add any value to the product, e.g. putting plastic binding on products and material when passing the airlocks.

The conclusions that are made from this are that this study shows Lean tools can be used to improve a production flow within the Medical Device Sector. It also indicates that the methods that have been covered in the study should be usable in other companies within the same sector.

8.1.1 Value Stream Mapping

The first research question was regarding whether VSM is an applicable method to use for understanding how to improve a production flow within the Medical Device Sector. Looking at the results from this Master's Thesis it is apparent that it is in fact so. Using VSM to map the production flow it was possible to identify many problem areas in need of improvements. It was also useful for this study because it provided an overview and assured that all people involved perceived the flow in the same way. In addition to that it played a big role in developing future states, where it acted as a method to assure that the intended improvements would in fact lead to a more efficient production flow. However, because none of the suggestions have yet been implemented at the time for this thesis it is impossible to be certain that the improvements identified by the VSMs in actuality makes the flow more efficient.

An issue that occurred while using this method, is the need for cleanroom facilities. As a result the production flow requires more buffers than might seem necessary, in order to enable transferring products to and from the cleanroom. Therefore, this is something that needs to be considered when using VSM in these types of production conditions. Another issue is that it can be difficult to decide on what quantities of products to work with in the calculations. Most processes handle more than one product at a time, but usually not the same amount from one process to another. Because production is highly automated and since orders can not be split, one order has to be finished before a new one is ordered, therefore kanban systems are difficult to implement in most parts of the production flow. In the VSMs that were developed for the future state it shows that adaptations have to be made that are typical for this sector.

VSM was a useful tool in many ways as it helped visualize the entire flow instead of only the single process, which gave more of an overview of where problems occur. Not only did it help with locating waste, it also helped in locating the source of that waste, so that action could be taken where it is truly needed. The conclusion that can be made from this is that VSM can be used to understand how to improve a production flow within the Medical Device Sector.

8.1.2 Seven plus One Wastes

The second research question was about the Seven Plus One Wastes and it has proven to be a useful method for understanding and identifying problem areas in the production flow within the Medical Device Sector. It makes it easy to determine what parts of the organisation that disturbs the flow, and thereby what parts that needs to be improved. However, there are some issues that are specific for this sector that somewhat complicates the use of this method. In some aspects activities that are defined as waste in Lean literature is a vital part of the production process in this sector, e.g. inventory in order to cover for entering and exciting products through airlocks. Other times it is not possible to remove wastes due to government regulations, for instance that traceability is required, which means that orders can not be split and therefore some waiting is unavoidable. However, if these things are kept in mind when analysing a production process using this method, it is a clear indication on what to focus on in order to improve the flow.

At Astra Tech the space in the production area is limited, and therefore some transportation is necessary at the moment when certain processes are outsourced to another company. From a purely Lean perspective this is clearly a huge waste, and it could be possible to perform these tasks in-house instead. However, it all depends on what happens in the rest of the plant and the observed line of products if this is something worth pursuing.

The conclusion regarding this research question is that it is a useful method for identifying problem areas within the production flow in the Medical Device Sector. Still, it is important to take into consideration regulations that can make activities that are defined as waste necessary.

8.1.3 Overall Equipment Efficiency

Striving to increase the Overall Equipment Efficiency does have effect on the production flow, which is what the third research question was about. Reducing scrap rate and stop time is important, both to increase the OEE value by having high resource utilization and to make the production flow more efficient. However, to reduce stop time in the long run, Lean production promotes stopping the flow when problems occur to find the root cause of the problem. Focusing on high OEE values, on the other hand, can lead to a culture of using quick-fixes to get the process up and running again as fast as possible without actually solving the problem. A high utilization of the resources requires a lot of buffers between processes in case there is a problem somewhere else in the flow. Having many buffers hides problems which is contradictory to having an efficient production flow where the idea is to bring problems to the surface and thereby forcing them to be solved.

At Astra Tech, the factor that affects the OEE value the most is the number of produced products during uptime. By increasing the number of produced products during uptime, there is a risk for either over production or that the production flow becomes uneven, unless it is done to meet an increasing demand. A reason for increasing the number of produced products during uptime is to be able to schedule planned stops for maintenance or improvements work on the resources. Since Astra Tech uses five shift and work around the clock, which can tear on some people in the long run, increasing the number of produced products during uptime can be a means towards changing the shift structure.

An issue during the case study is that it is based on secondary data from the company, which somewhat compromises the reliability of the study. Because Astra Tech does not report stop times shorter than five minutes there is a lot of data missing, which can be misleading and focus can be put on improving the wrong areas. As the data is not documented back far enough, it is difficult to make any certain assumptions regarding trends in production compared to the measured OEE values, which makes it hard to see what effects an increased OEE value actually has in the production flow.

Based on the study the conclusion is that working towards a high OEE can have both positive and negative effects on the flow, depending on which factors are focused on. If the focus is on e.g. reducing scrap and stop time it is good for the production flow as well, if the focus on the other hand is on high utilization of resources the risk is that it contradicts the efficiency of the production flow.

8.2 Contribution to the Company

This Master's Thesis contributes to the studied company with a thorough mapping of the current state of the specific production flow. Followed by an analysis of the current state and identification of problem areas, with the result of improvement suggestions.

The authors have been gathering information in a systematic way, by several observations at different times, as well as several interviews with different key persons. This in order to get different points of view, however due to the human factor the outcome might be subjective when it was interpreted by the authors. This effect, on the other hand, was minimized since there were always two observers or interviewers present and thereby two different perspectives.

The analysis and suggestions of improvements has been out of a Lean perspective, which the authors has strengthen by a thorough literature study as well as a foundation of prerequisites of the subject which where gained from earlier studies and courses at Chalmers University of Technology. However, the suggestions are made out of respect to the scope and the limitations of this Master's Thesis. Thereby, the changes might affect other areas within the extended production flow and also the production flow of other products. An investigation of this is therefore recommended as further research to the company, this in order to understand the whole picture.

A general comment to the reliability of the suggested changes is that the optimal batch sizes need to be investigated further, and it is not possible to assure that the changes will mean an improvement. This can only be stated when they have been implemented and used for a period of time, and then analyzed. However, the improvements have been suggested based on the theoretical framework in combination with influences from the company and its employees. The indication is that the suggestions would improve the production flows and the work environment.

8.3 General Discussion

This part will present a general discussion regarding the results from the case study. It will address observations that were made that can affect the flow but are not within the scope of the study and the generalizability of the findings. The last part will be general reflections about the case study.

8.3.1 General Observations

Some findings that were outside the scope of this thesis, but still have affects the production flow, have been observed during the study. Overall Astra Tech is well on their way in their work with Lean production. They do however need to continue working with implementing a culture of thinking Lean throughout the company, otherwise some problems that were discovered with the tools and methods they use will not be improved. In an organization with a strong Lean culture everyone will understand the importance of standardized work and thereby avoid straying from the predetermined instructions. For the same reason, tools will be placed in their rightful place after usage and the possibility to improve and facilitate the daily work will be incentive enough to get involved in the continuous improvement process. For this to work, however, it is vital to communicate the purpose for doing things a certain way. Reporting the causes of scrap is one example of where communication is important because people will consider it a waste of time. If it is explained that the purpose is to find out what causes the scrap to be able to avoid it, and that the goal is to reduce scrap rate so that it will hardly be any scrap to report in the future, people may be more positive towards the idea.

At times it has been observed that the information given from managers does not coincide with what actually happens in the production area. If this is caused by managers being provided with false information, that they describe what their vision is although it is not being followed, or that they try to uphold a front to appear better is difficult to say. However, no matter what the reason is it is important that managers know the actual situation and that problems are not hidden, otherwise they will never come to terms with them. In the same way, visualization boards and monitors that does not provide correct information does more harm than good, the purpose of them is that anyone should be able to walk through the production area and see for themselves how things are going. Incorrect visualization tools should be removed since they are misleading, either by feeding false information to someone that is unaware of the problem, or by making people that are aware of the problem distrust other visualization tools as well, because if one is incorrect others might be too.

8.3.2 Generalizability

The research approach was a case study, where only one company within the Medical Device Sector was investigated. This lead to the fact that it is not possible to draw final conclusions of whether it is possible to generalize the results for the whole sector or not. However, a major benefit of this research approach is that it opened the opportunity of a focused study where a deeper investigation could be made.

In order to strengthen and confirm the results of this Master's Thesis, further research in the given field is recommended. The further research should include other companies within the Medical Device Sector, to cover eventual deviations. This with allowance of different types of product groups, since the product specifications can have large variations. On the other hand, it is vital to keep in mind that Lean production is a business strategy, which no matter what need to be adapted to the specific company. Thereby, can it be hard to draw a general conclusion for an entire sector anyhow.

This Master's Thesis mainly focused on three Lean methods. Even though these methods indicate to be suitable to use in this sector, there might be other Lean methods which are not. Thereby, it is recommended to investigate the suitability of other Lean methods in the Medical Device Sector. Since the analysis in this Master's Thesis has focused mainly on Muda (or the Seven plus one wastes), it is recommended to do an extensive analysis where all the three M's are considered (Muda, Mura and Muri).

8.4 Sustainable Development

This section will briefly handle the connection that this Master's Thesis has to the concept of sustainable development. It is a vital subject to keep in mind since the society industrializes increasingly, which contributes to a need of ventures in sustainable development for the sake of the future.

There are three main dimensions of sustainable development; economic, social and ecologic. The purpose of this Master's Thesis was to improve a production flow using Lean methods, which aims at creating a more efficient flow by eliminating wastes. There is therefore a connection to the economic dimension since a more efficient production flow leads to a financial gain by minimizing the activities that do not add any value to the products and still cost money. Further, the fundamental value of Lean production is that the employees are the most valuable resource. The employees' wellbeing is considered important, the improvements of the production flow aims at improving the work environment and help the employees to work smarter and not harder. It is out of that aspect that the purpose of Master's Thesis contributes to the social dimension. Finally, regarding the contribution to the ecological dimension, one of the wastes which are to be eliminated is unnecessary transportations, this leads to the aim of minimizing emissions. Another waste is excess inventory, by eliminating this it reduces the risk of hidden material and products that gets too old and has to be disposed, which contributes to a sustainable material usage.

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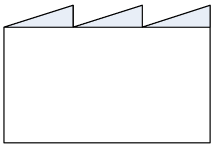
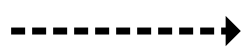
Appendix A – VSM Symbols

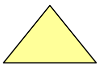


Customer/Supplier

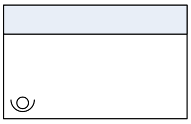


Electronic Pull System

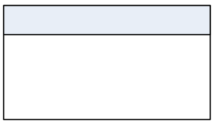
Electronic Information



Inventory

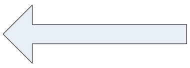


Process



Production Control

Push Flow



Shipment Arrow

Shipment Truck

Appendix B – Interview Questions

Intervjuformulär

Fråga om det är okej att spela in samtalet, endast för att vi skall kunna sammanfatta bra senare. Endast vi som kommer att lyssna på det och vi kommer isf. att radera filen så fort vi har gått igenom den.

Vi kommer att återkoppla med en sammanfattning för att verifiera att vi har uppfattat det hela rätt.

OBS! Börja med att berätta om examensarbetet, syftet med intervjun och hur informationen kommer att användas.

- *Examensarbete gällande produktionsflödet för Classic torra, med avsikt att effektivisera själva flödet och minimera slöserier. Samt att övergripande utvärdera hur Lean (och TIA) fungerar. Kollar i huvudsak på tre flöden, visa dessa!*
- *Syftet med intervjun är att få en djupare inblick i hur arbetet fungerar. Se hur det faktiskt går till istället för hur det "ska" gå till, samt att få höra åsikter och tankar från de som faktiskt arbetar med detta dagligen.Ta tillvara på den kunskap som redan finns och få inspiration, med förhoppning att kunna förbättra arbetssituationen med hjälp utav er.*
- *Informationen kommer att sammanfattas och svaren kommer att vara anonyma (kommer ev. bara refereras till som "operatör" eller dyl.). Slutresultatet kommer att bli en skriftlig rapport och muntliga presentationer, samt att vi hoppas kunna införa vissa förändringar om detta är möjligt.*

Allmänt

Namn: ....

Skift: ....

Övergripande frågor

1. Hur tycker du rent allmänt att de tre olika flödena fungerar?
    a. Flöde 1: ....

    ....

    ....

    ....

    b. Flöde 2: ....

    ....

    ....

    ....

c. Flöde 3: ....

....

....

....

2. Upplever du att det är mycket problem med de tre olika flödena?
   a. Flöde 1: ....

   ....

   ....

   ....

   b. Flöde 2: ....

   ....

   ....

   ....

   c. Flöde 3: ....

   ....

   ....

   ....

3. Vad anser du är det största problemet?

   ....

   ....

4. Finns det några småproblem som ofta dyker upp?

   ....

   ....

5. Har du några tankar på hur dessa problem skulle kunna motverkas eller förbättras?

   ....

   ....

6. Har du några idéer rent allmänt på hur flödena skulle kunna förbättras?

   ....

   ....

Stopp i produktion

1. Är det ofta stopp i produktion? Ungefär hur ofta?

....

....

2. Är det ofta samma orsak till stoppen?

....

....

3. Vad är den vanligaste orsaken?

....

....

4. Rapporteras stopp in? Isf. hur?

....

....

5. Hur hanteras stoppen? (Fixar ni de själva, eller tillkallas någon annan?)

....

....

6. Sker det uppföljning på problem som orsakar stoppen?

....

....

7. Har du några idéer på hur stopp-hanteringen skulle kunna hanteras bättre?

....

....

Förbättringsarbete

1. Om ni kommer på förslag till förbättringar hur hanteras det då?

....

....

2. Sker det kontinuerligt förbättringsarbete?

....

....

3. Genomförs förbättringsförslag?

....

....

4. Vem besultar om förbättringar skall genomföras? (Får ni vara delaktiga?)

....

....

5. Känner du att du har möjlighet att vara med och påverka?

………

………

6. Känner du att du har möjlighet att delge din kunskap?

   ………

   ………

7. Har du några idéer på hur arbetet med förbättringsförlag skulle kunna hanteras bättre?

   ………

   ………

Visualisering av arbetsplatsen

1. Hur hanteras arbetet med 5S?

   ………

   ………

2. Efterföljs 5S?

   ………

   ………

3. Känner du att 5S är en del av de vardagliga rutinera?

   ………

   ………

4. Tycker du att placering av t.ex. verktygstavlor är rätt?

   ………

   ………

5. Tycker du att 5S underlättar arbetet?

   ………

   ………

6. Tycker du att skärmarna med info om mål etc. är användbara?

   ………

   ………

7. Är det tillräckligt med information på dessa?

   ………

   ………

8. Bör de utformas annorlunda?

   ………

   ………

9. Har du några idéer på hur arbetsplatserna skulle kunna utformas mer tydligt?

....

....

Standardiserat arbetssätt

1. Är själva arbetssätten standardiserat?

   ....

   ....

2. Finns det tydliga instruktioner?

   ....

   ....

3. Finns isf dessa instruktioner nära tillhands?

   ....

   ....

4. Följs dessa instruktioner?

   ....

   ....

5. Hur lägger ert skift upp arbetet?

   ....

   ....

Kassationer

1. Är det mycket kassationer?

   ....

   ....

2. Vilken är den vanligaste orsaken?

   ....

   ....

3. Hur följs dessa upp?

   ....

   ....

Felsäkring

1. Är det lätt att göra fel eller finns det någon form av felsäkring?

   ....

   ....

2. Tycker du att det finns områden där felsäkring skulle behövas?

………

………

3. Har du några idéer på hur detta skulle kunna införas?

………

………

Övrigt

1. Hur pass delaktiga är ”cheferna” i produktionen?

………

………

2. Är arbetsbördan varierad?

………

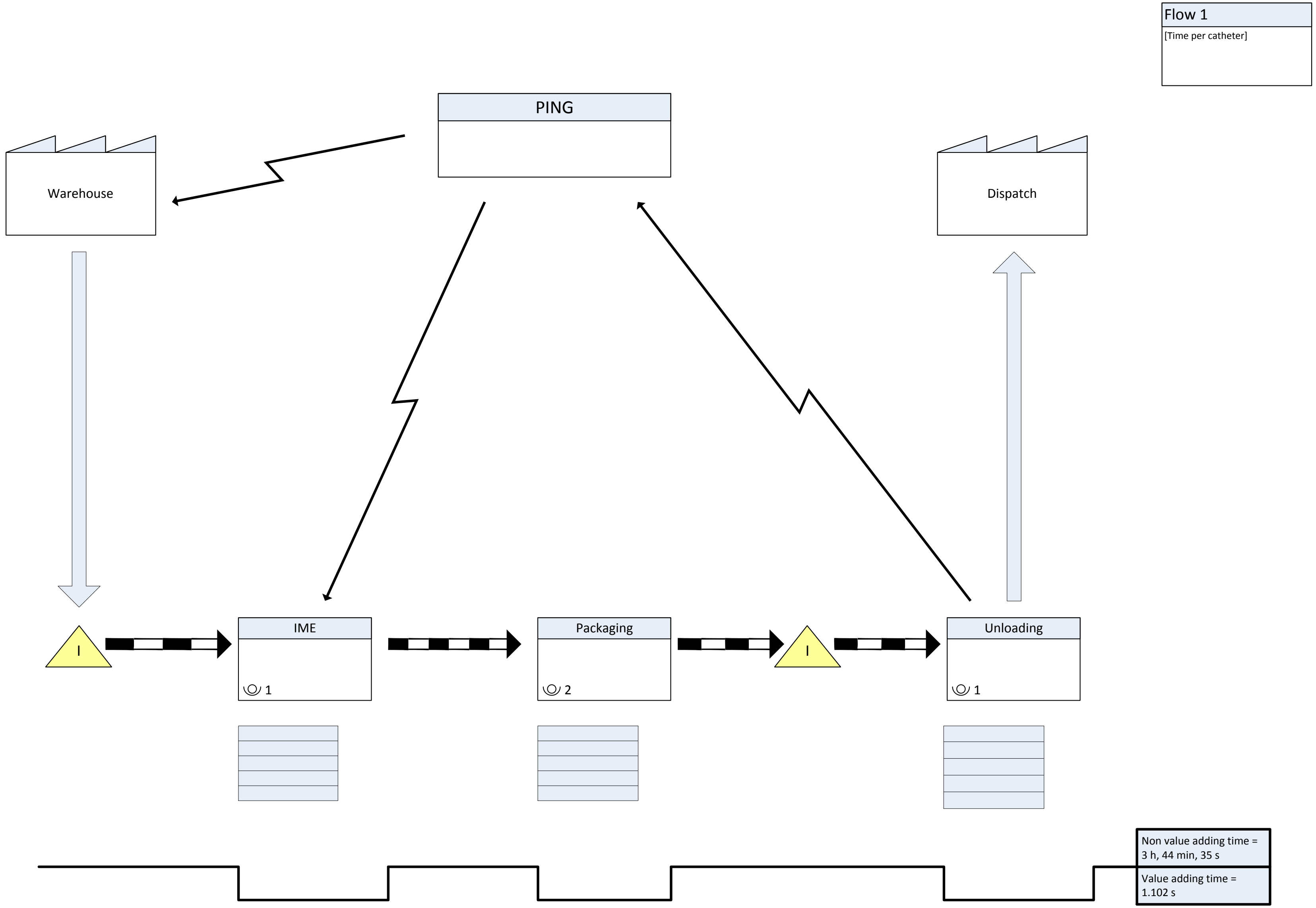
………

3. Finns det möjlighet till utbildning/utveckling?

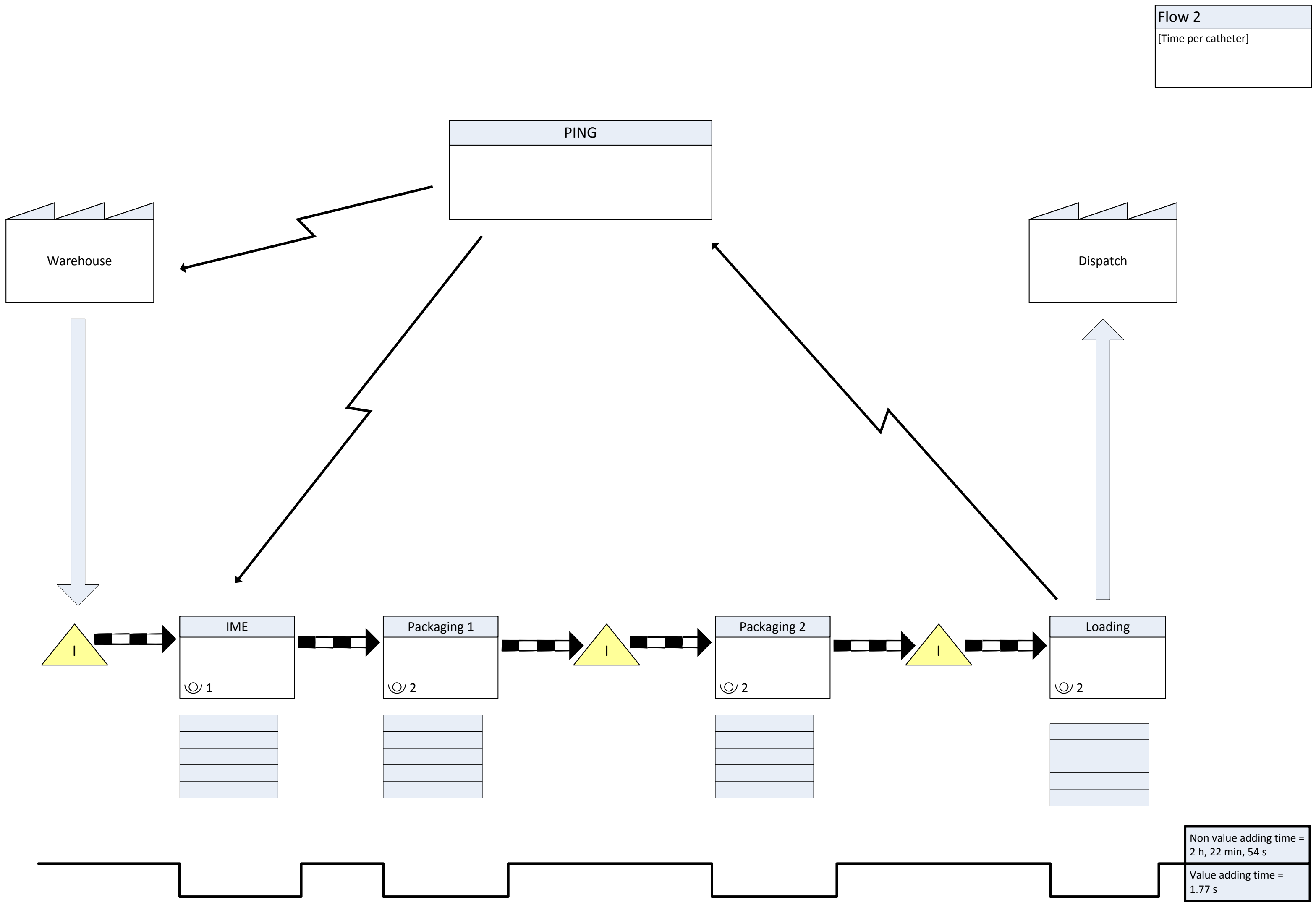
………

………

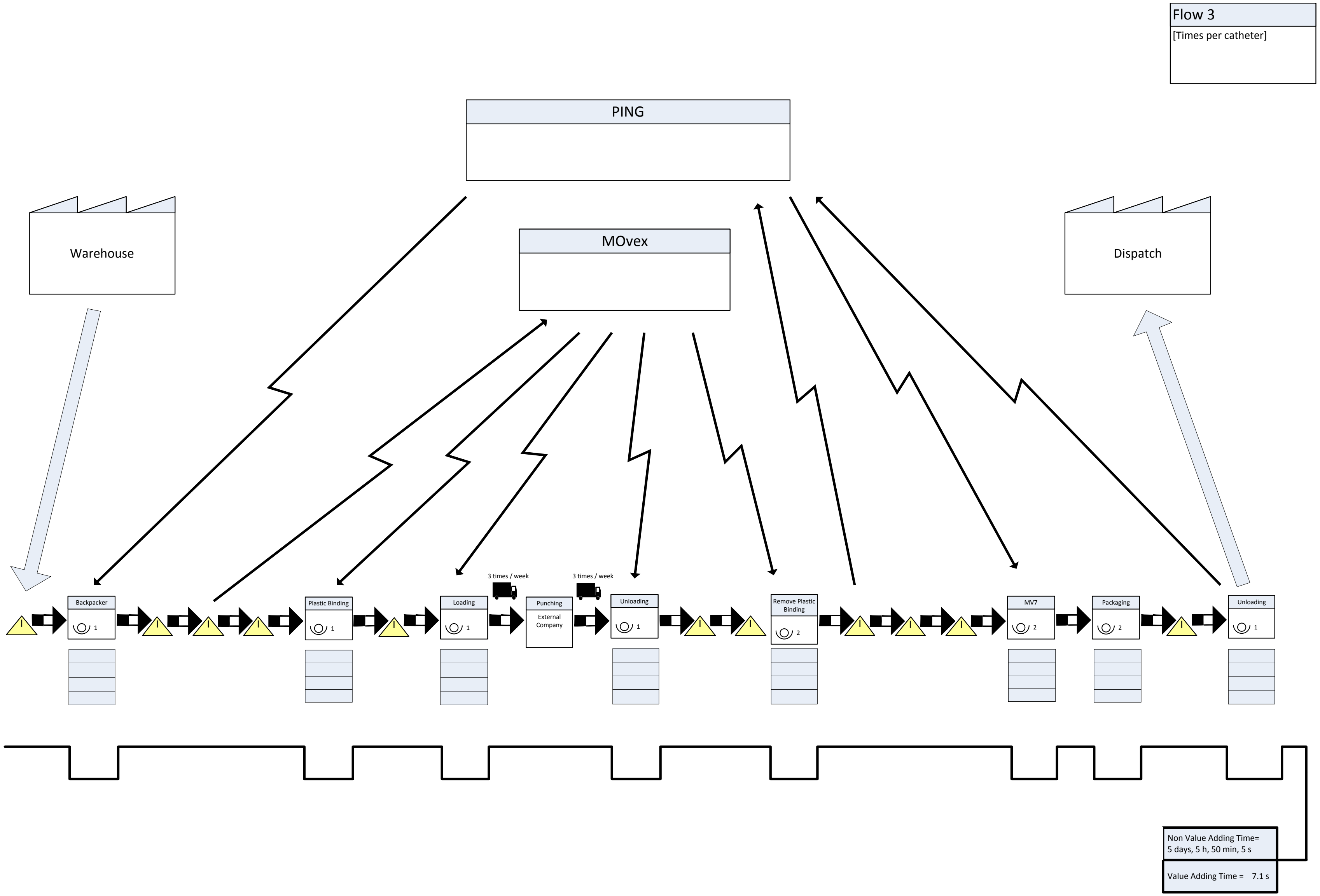
Appendix C – VSM Flow 1



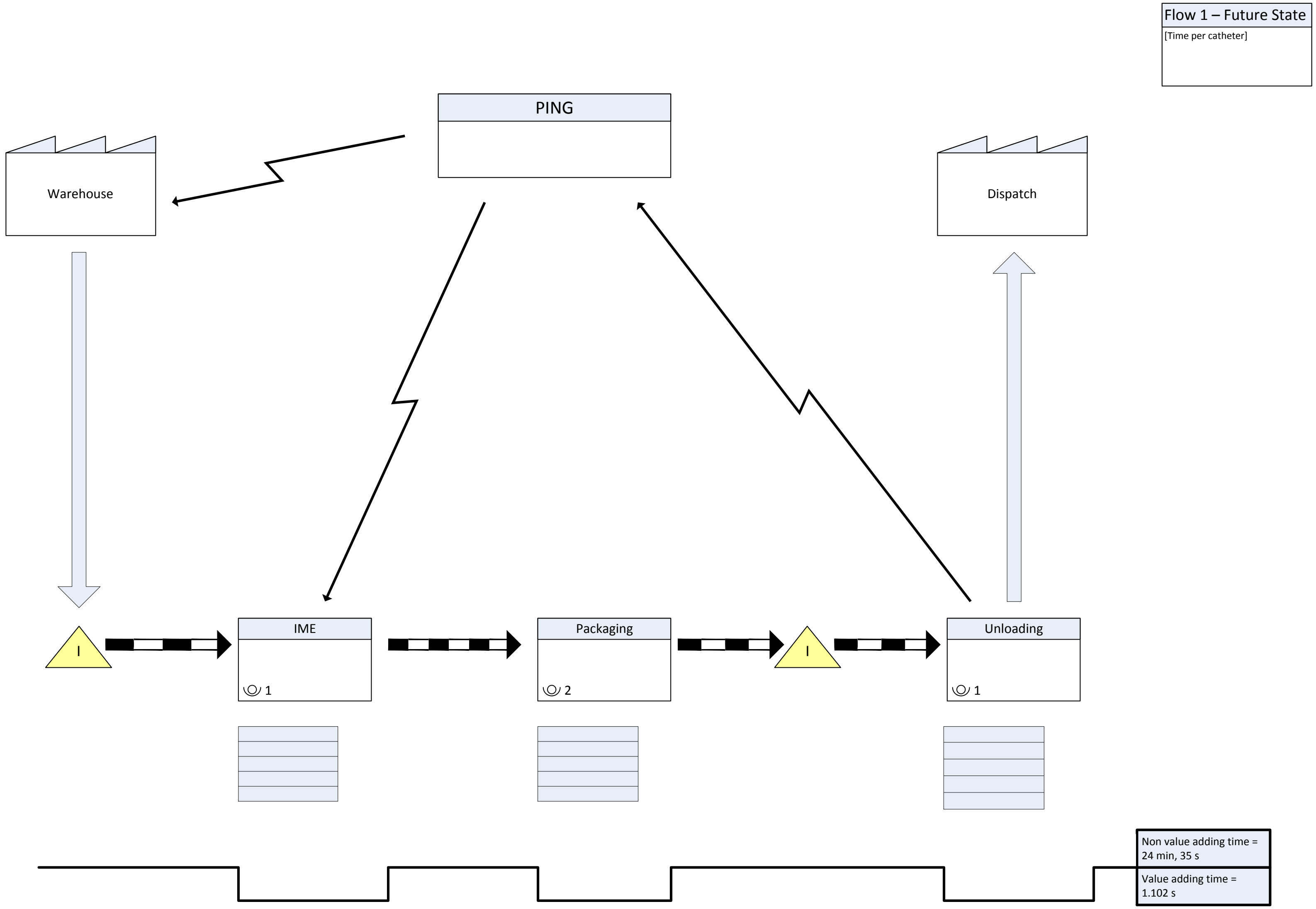
Appendix D - VSM Flow 2



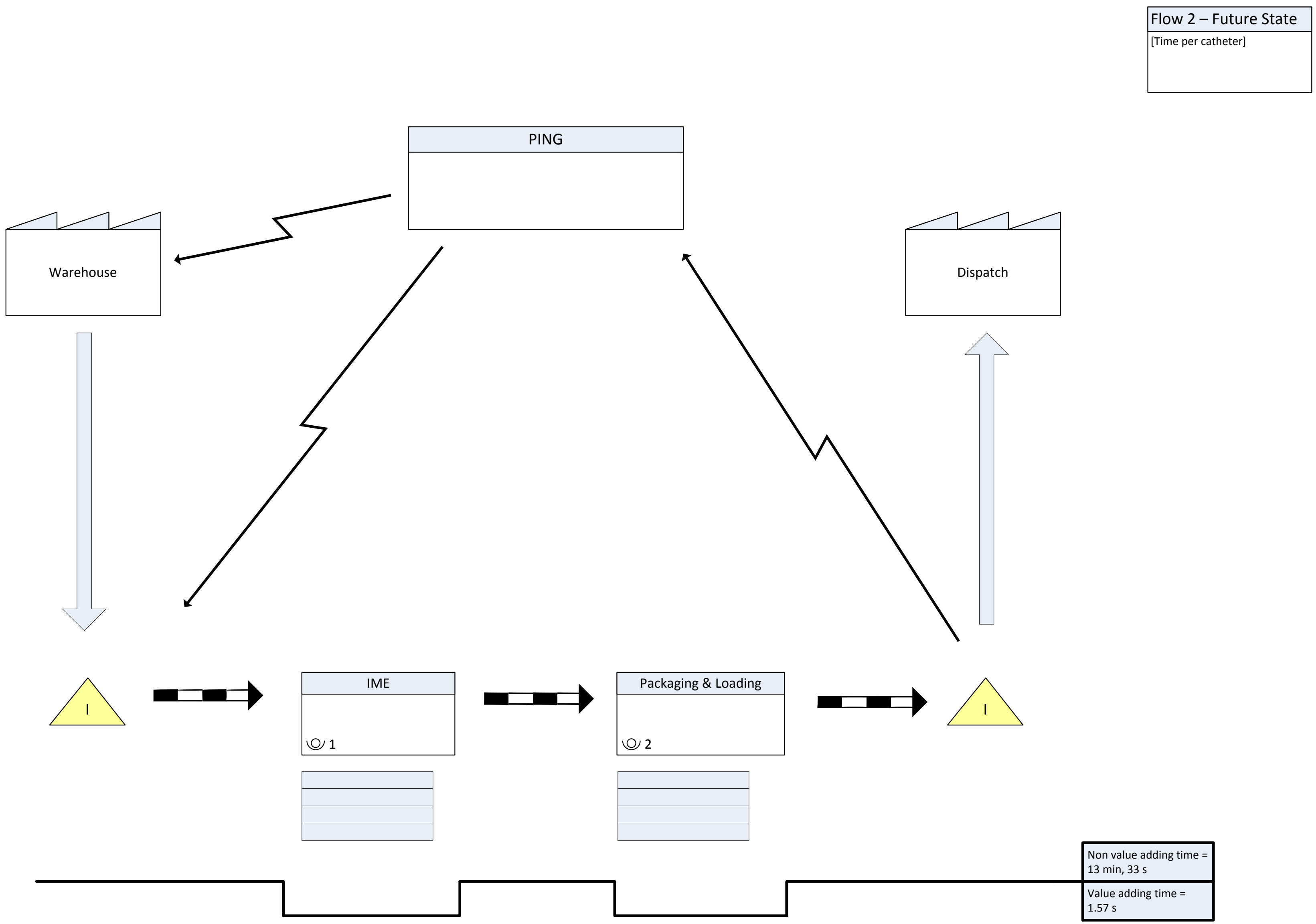
Appendix E - VSM Flow 3



Appendix F – Future State VSM Flow 1



Appendix G – Future State VSM Flow 2



Appendix H – Future State VSM Flow 3