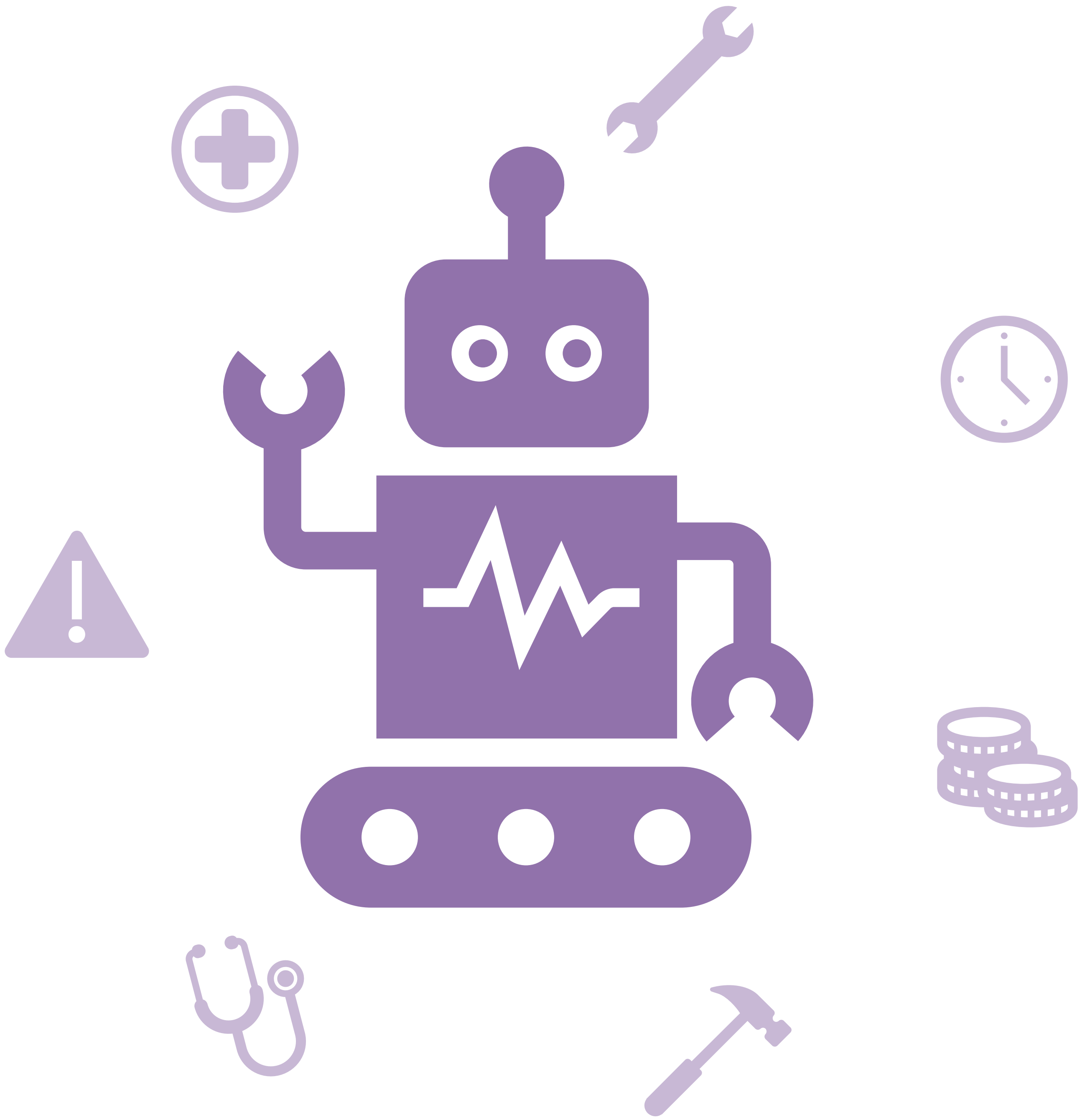
How many defects?!



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Industrial Engineering and Management
Bachelor thesis – 4 July 2019

St. Antonius-Hospital Gronau GmbH

UNIVERSITY OF TWENTE.

This report is intended for the St. Antonius-Hospital Gronau GmbH and for my supervisor from the University of Twente. This version is the public report in which some parts are left out and marked as (*Restricted*).

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HOW MANY DEFECTS?!

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Preface

Before you lies my bachelor thesis 'How many defects?!', which is about the study that I performed at the St. Antonius-Hospital Gronau GmbH. With this study, I finish my Bachelor's programme in Industrial Engineering and Management at the University of Twente. It was nice to apply the knowledge that I gained in the last three years to this project. I learned a lot about robotic surgery and it was a privilege that I got the opportunity to attend and observe several surgeries.

I would like to thank Prof. Matthias Oelke for supervising my project. Thank you for giving feedback on the parts of the report which I sent you over the course of the weeks. I would also like to thank Dr. Christian Wagner. Thank you for sharing your knowledge about the Da Vinci® robotic system and for being interested in the progress and results of my study. I also want to thank you for reading my final report and for the useful feedback that you gave. Additionally, I would like to thank Esther Grävemäter and Jens Breer. Thank you for welcoming me in the hospital and for always making sure that I was doing fine and that I had everything I needed.

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Finally, I want to thank my housemates, friends and family. Thank you for your interest and support.

Nynke Meijer
Enschede, July 2019

Management summary

Problem definition

The St. Antonius-Hospital Gronau GmbH uses the Da Vinci® robotic system of the company Intuitive Surgical to perform Minimally Invasive Surgery. This robotic system contains a robot to which multiple surgery instruments are connected. These instruments have a lifespan of ten uses. However, sometimes they break down earlier. The supplier does not always refund the remaining, unused lives.

Each time an instrument is defect, the instrument is returned to the supplier and the failure description and the amount credited are stored in a database. However, the hospital does not use this information. As a result, the hospital does not know how to decrease the number of defects or how to defend itself at the supplier to get a refund. So, the core problem is the following:

The hospital does not have a supporting system to analyse the failures of the Da Vinci® instruments to evaluate which defect types occur most frequently or cause the greatest financial loss.

Method

To solve this problem, we used the database to investigate which instruments caused the biggest financial loss during 2015 to 2018. This turned out to be the Curved Bipolar Dissector and the Hot Shears™ (Monopolar Curved Scissors). Therefore, we focussed on these instruments. Additionally, we investigated the instruments with similar functions because they might have similar failure types. These instruments are the instruments that can be categorised as EndoWrist™ Bipolar Cauterisation Instruments or as EndoWrist™ Monopolar Cauterisation Instruments.

We developed a data analysis tool in Excel to analyse the failure data and to categorise the defects per failure type. We used Failure Mode Effect and Criticality Analysis to perform this categorisation. Additionally, we searched for possible failure causes. We did this by carrying out a systematic literature review and by observing staff and by having conversations with them.

Results

This resulted in a data analysis tool which the hospital can use to analyse future failure data. We already used the tool to analyse the data from 2015 to 2018. It turned out that the average financial loss per year is €27,669. There is no clear increase or decrease of the loss per surgery. The failure types that happened most often were bent tips, bent shaft extensions and scratched blades.

Conclusion and discussion

For these failure types, possible causes are found. *(Restricted)* The lack of haptic feedback might cause surgeons to apply too much force on the instruments.

The hospital should investigate if preventing these causes decreases the financial loss which the defects cause. If this is not the case, the hospital should look for other causes that occur during surgeries or the hospital should talk with the supplier to find possible causes.

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Glossary

Criticality	Average financial loss per year per failure type
FMECA	Failure Mode Effect and Criticality Analysis
Hospital's report	The report which the hospital makes and sends to the supplier when an instrument malfunctions
MIS	Minimally Invasive Surgery
OR	Operation room
Result of supplier's investigation	The report in which the supplier tells the hospital which defects they found after investigation of the instrument
Severity	Average financial loss per defect per failure type

1. The context

In this chapter, we are introducing the context of this study.

1.1. Da Vinci® robot

This study is about the Da Vinci® robotic system of the company Intuitive Surgical. This is a surgery robot which can be steered by the surgeon to perform Minimally Invasive Surgery (MIS), which is surgery via a few little holes in the body. The St. Antonius-Hospital Gronau, Germany, which we will call 'the hospital' from now on, uses five of these robotic systems (including one for training). It uses them primarily for urologic surgeries (e.g., robot-assisted radical prostatectomy, partial nephrectomy or cystectomy).

The system consists of three components: the *surgeon console*, the *patient cart*, and the *vision cart* (Intuitive Surgical, 2019). These are shown from left to right in **Figure 1**. During the surgery, the surgeon sits at the *surgeon console*. He watches a screen with a 3D image of the abdomen and uses his hands and feet to control the robotic arms. The system enlarges the image up to ten times; therefore, the surgeon is able to visualise the operative field enlarged and in greater detail compared to conventional MIS. The *patient cart* is the component of the system which consists of four robotic arms to which the instruments the surgeon uses during the operation are attached. Finally, the *vision cart* contains several screens that show the video to the other staff in the operation room (OR), especially to the assistants who sit next to the patient to operate extra instruments. In addition, the vision cart connects the instruments to the power source and hosts the insufflator, which supplies CO_2 gas to maintain pressure in the patient's abdominal cavity.

Figure 1: The da Vinci surgical system. (Reprinted from *QNS* website, by Flushing Hospital, 2015, retrieved from https://qns.com/story/2015/03/27/flushing-hospital-marks-milestone-use-of-surgical-robot/)

After the patient is anesthetised and operation site is disinfected, the OR assistants insert small metal tubes in the abdominal wall to get access to the patient's belly. An assistant then moves the patient cart to the patient and attaches the instruments to the four robotic arms. One of these instruments is the endoscope (i.e., the internal camera). The other three instruments are for example scissors, graspers and needle drivers. Some of these instruments can use an electrical current to cauterise tissues and vessels to prevent them from bleeding.

Figure 2: Variety of Da Vinci® EndoWrist™ Instruments (e.g., different scissors, graspers and needle drivers) (Reprinted from Maxon motor website, by Intuitive Surgical Inc., 2010, retrieved from https://www.maxonmotorusa.com/maxon/view/application/Surgical-Robots-for-Minimally-Invasive-Procedures)

Figure 3: Front part of the Hot Shears™ (Monopolar Curved Scissors) (Reprinted from Instrument & Accessory Catalog, by Intuitive Surgical Inc., 2015, retrieved from https://www.intuitivesurgical.com/images/on-site-banners/1008471rB-EU_Xi_IA_Catalog.pdf)

Amongst others, some of the advantages of the robotic system are minimising trembling of the surgeon's hands, and holding the endoscope in a stable position during the operation. Moreover, the robotic instruments have more degrees of freedom than conventional instruments (five degrees in conventional laparoscopic vs seven degrees in robot-assisted surgery) thanks to the EndoWrist™ technology in the shaft extension (i.e., the component between the tip and the shaft). Hence, the Da Vinci® robot can replicate all hand movements of the surgeon even beyond the natural limits. The instruments can be used for a defined number of operations, for most of the instruments ten times. Between the uses, the instruments are cleaned and sterilised in the hospital. The re-use cycles are programmed in the instrument (i.e., when the maximum life cycle is reached, the robot will no longer accept the use of the instrument). Therefore, the hospital cannot use the instruments more often than the pre-defined number of lives.

1.2. Defect handling process of instruments

When one of the instruments of the robot breaks before the end of the life cycle, the OR staff marks the instruments and claims and describes the defects. The purchasing department of the hospital then returns the instrument to the supplier. The supplier then investigates which component of the instrument caused the defect and sends the results of the investigation back to the hospital. If the defect is caused by a product-related error (e.g., a material or production error) and is still under warranty, the supplier will refund the instrument. The amount of the refund is then based on the remaining lives of the instrument. However, if the defect is caused by a mistake of the hospital (e.g., wrong usage etc.), the supplier will not refund the instrument, so the hospital must pay for a new instrument.

Both the failure description which the hospital sends to the supplier and the failure description which the supplier returns to the hospital after having investigated the problem are stored in an Excel sheet. Before this study, the hospital did not use this information.

2. The problem

In this chapter, we are describing the research aim and methodology.

2.1. Problem identification

The problem the hospital faces is that instruments of the robot occasionally break and the supplier does not always refund the costs or provide new instruments. If we go back in the causal chain, we find that one of the reasons for this is that the supplier generally attributes the defect to a failure in the hospital rather than to a product-related error. This can be seen in **Figure 4**. Therefore, the hospital must frequently pay for new instruments. Although the supplier provides the hospital with short descriptions of the failures, the hospital has not investigated these data so far. Therefore, the hospital is unaware of how many instruments break down exactly or how much instrument failure costs. Consequently, the hospital does not know how to lower the costs for replacing instruments. This is a cause that we can influence. Therefore, the core problem is:

The hospital does not have a supporting system to analyse the failures of the Da Vinci® instruments to evaluate which defect types occur most frequently or cause the greatest financial loss.

The hospital is not able to investigate the cause(s) of these defects. The purpose of this study is to develop a data analysis tool for the hospital to categorise the defects per component and per failure type (e.g., bent tip or broken wire) in order to show which instruments and defect types cause high costs and what possible causes of these defects can be. By using this procedure, the hospital will know which defects it needs to identify and correct. This can be achieved by either preventing the cause of the failure (e.g., wrong usage) in the hospital or by approaching the supplier to get a refund.

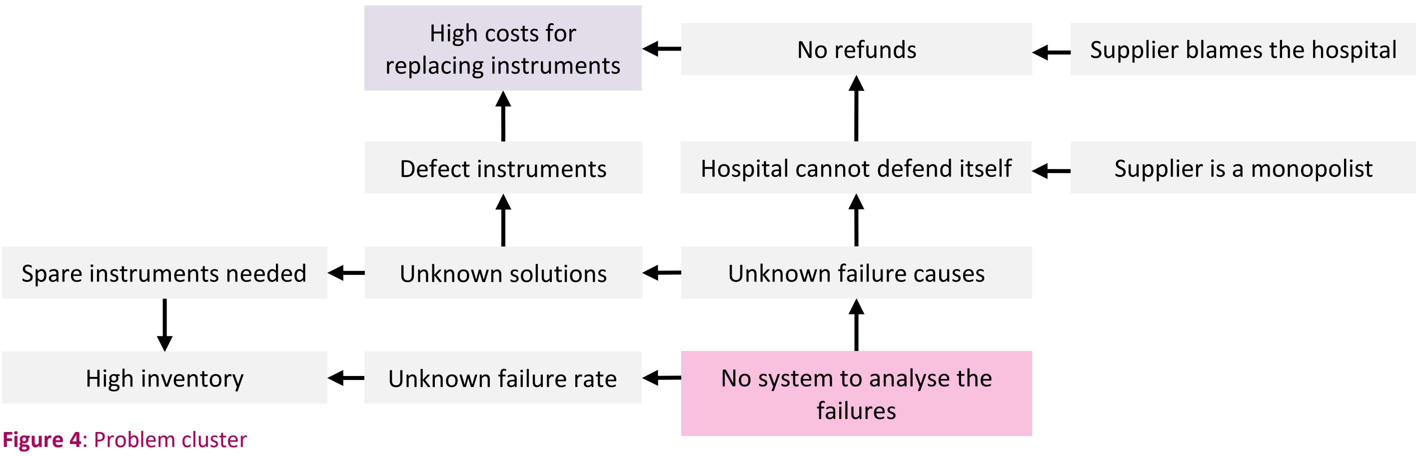

Figure 4: Problem cluster

Once the problem has been identified, we can define the norm and reality. We will measure the norm and reality in two ways. Firstly, by the percentage of defects that are *categorised* and secondly, by the percentage of the defects of which the cause is *suggested correctly*. The reality is that currently no defects are categorised. The norm for the first measure is that hundred percent of the defects are classified as a specific failure type. The norm for the second measure is that hundred percent of these classifications is correct. We will not be able to measure the latter, because that will need to be assessed after using the tool for a while. However, we will implement the measure in the system so that the hospital can measure it later.

2.2. Intended deliverables

The goal of this study is to deliver a spreadsheet tool that structurally analyses failure data by categorising defects. Hereby, it should show which instruments and which failure types cause the biggest financial loss. In addition, on the dashboard, possible failure causes should be suggested. These causes are suggestions and no proofs, so they should always be checked by the staff. Another feature of the tool is that it should learn from user feedback to provide better suggestions. This tool can be used by the purchasing department to reduce the financial loss that the defects cause. This can be done by improving the acts of the staff or by talking to the supplier about the failures.

2.3. Scope

In this study, we focus on two versions of the Da Vinci® system, namely the Da Vinci® Xi and the Da Vinci® X. These are the two models which the hospital currently uses. We will look at the instrument failure data of these models of the years 2015 to 2018. The reason for this time frame is that the first Xi system was put into use at the end of 2014. So, 2015 was the first year in which the instruments were used from the start of the year. Most failures from then on are about the X and Xi instruments. So, they are relevant for this study.

2.4. Research questions

To solve the problem, several things needed to be done. Therefore, we defined research questions:

1. *Which instruments caused the biggest financial loss from 2015 to 2018?*

First, we investigated which instruments caused the biggest financial loss from 2015 to 2018. These instruments are the instruments which we would investigate.

2. *What causes the defects of these instruments?*

For the instruments that caused the biggest financial loss, we investigated which components caused the defects and what could be potential causes for the breakdowns of these components. We did this by examining the failure descriptions which the supplier provides. Additionally, we looked for other possible causes in the literature. Further, we made a process map of the flow of the instruments through the hospital, from being delivered to being sterilised and being used. This way, we could point out in which stage mistakes are most likely to be made. Also, we investigated if the staff correctly handles the instruments and we asked them what they thought could cause the defects.

3. *Which information should be in the dashboard?*

Using this information, we were able to develop the dashboard. This dashboard should be useful for the hospital, so we first investigated which information was important to show on the dashboard. When this was implemented, the commercial manager, who will be the user, tested the tool, to see if it was user friendly and if all necessary information was included.

4. *How can the hospital use the dashboard to prevent high replacement costs in the future?*

At the end, the hospital should understand how to use the dashboard, so we made a user manual.

We will answer question 1 to 3 in chapter 4 to 6 respectively, and we will answer question 4 in appendix A.

3. Research design

Now that the problem and research questions are described, we will explain more about the design of the research.

3.1. Research type

This study is a case study in which we designed a tool for the St. Antonius-Hospital Gronau to analyse data and to indicate which failure types need attention and what possible causes are. We gathered the needed data mainly through asking for the data that the hospital received from the supplier and by observing how the staff handles the instruments. The purpose of this research is mainly descriptive and slightly reporting, because we wanted to show how big the financial loss is that is caused by the defects, and which instruments contribute the most to this. In addition, the study is causal-explanatory, because the tool which we design suggests possible causes.

3.2. Research subjects

In this study, there are several research subjects. The main research subjects are the defect instruments, because that is what this study is about. Other research subjects are the employees of the hospital, because they use the instruments. We observed them while doing that to find possible failure causes. Further, the user of the tool is a research subject, because the tool should be user friendly.

3.3. Key variables

The variables that we used in this research and in the tool that we developed are the following:

- Size of the problem, which is measured by the cost of the defects since 2015 and within the last six months.
- Most urgent failure type, which is measured by the cost per failure type since 2015 and within the last six months.
- Categorisation completeness of the dashboard, which is measured by the percentage of the defects that the tool could categorise by using the results of the supplier's investigation.
- Categorisation consistency of Intuitive Surgical, which is measured by the percentage of the defects for which the results of the supplier's investigation are consistent with the results of similar defects in the past.
- Cause suggestion reliability of the dashboard, which is measured by the percentage of the failure causes which the tool suggested right according to the hospital's staff.

The reason that the time frame for the first two variables is the last six months is that that is enough to see if the failure is just an accident or if it becomes a trend, while you are still in time to intervene. Additionally, from the data we observed that of quite some instruments defects are occurring during more than half a year.

3.4. Theoretical perspective

The theoretical perspective that we will use in this study is based on the Failure Mode Effect and Criticality Analysis (FMECA). This is a systematic way of identifying possible failure causes in a bottom-up way (Tinga, 2012). It starts by identifying possible failures of, in this case, components of the instruments and then shows the consequences of the failures. In addition to this, a criticality analysis is performed. The results of the FMECA are then presented in an FMECA form, which is a table that shows the name and function of the component, the failure mode and the frequency, effects, symptoms, severity and criticality of the failure mode (Topan, 2019). More information about the FMECA can be found in paragraph 6.1, where we will explain how we derived the needed information from the database.

The reason that we used this analysis method is that is a structured approach. This makes it harder to forget a failure. In addition, the fact that the FMECA form is a standardised way of displaying the results makes it more suitable for implementation in a spreadsheet tool. Namely, a spreadsheet tool cannot easily analyse graphical data, but it can analyse textual data, in particular when it is in a standardised form. Therefore, the FMECA is useful to categorise the failures of the hospital automatically.

3.5. Framework

The framework that we used for this study is shown in **Figure 5**. In this framework the research questions and theoretical perspective are combined.

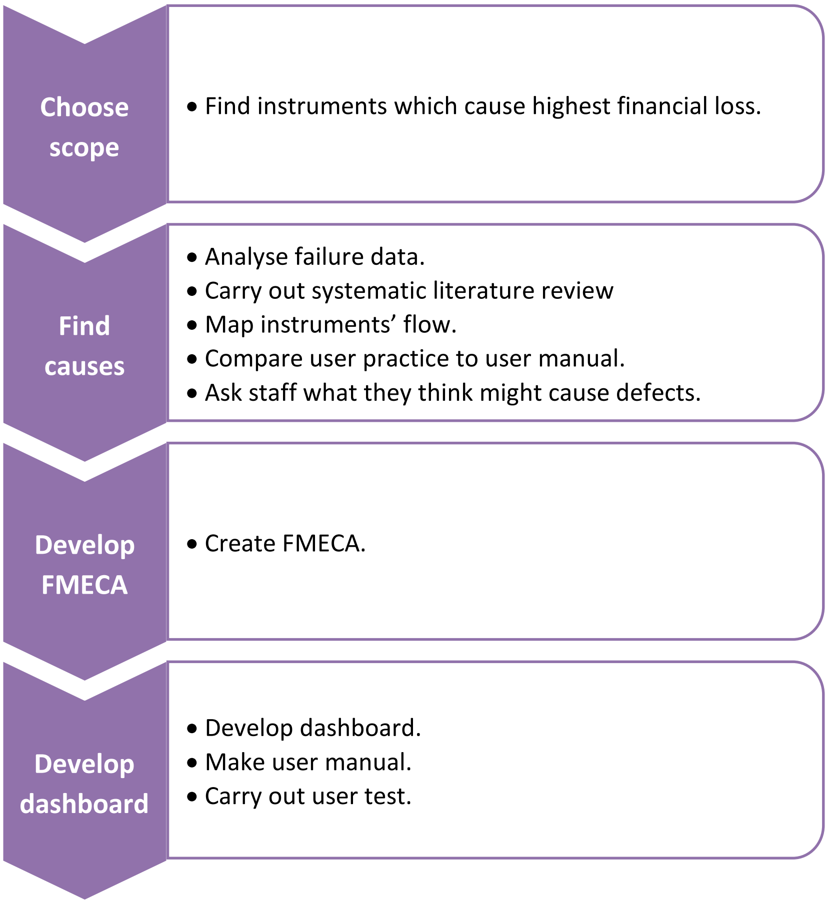

Figure 5: Research framework

4. Instruments causing greatest loss

In this chapter, we are showing which instruments caused the greatest financial loss from 1 January 2015 until 31 December 2018. The purpose of this is to decide on the scope of this study.

4.1. Comparison of defect instruments

The instruments can be divided into several categories (e.g., EndoWrist cauterisation instruments, graspers and needle drivers). In **Figure 6**, the categories in which defects have happened during the last four years are illustrated. It can be concluded that the instruments which caused the greatest financial loss are both the bipolar and monopolar EndoWrist cauterisation instruments. The two instruments which caused the greatest part of the loss are the *Curved Bipolar Dissector* (purple) and the *Hot Shears™ (Monopolar Curved Scissors;* green).

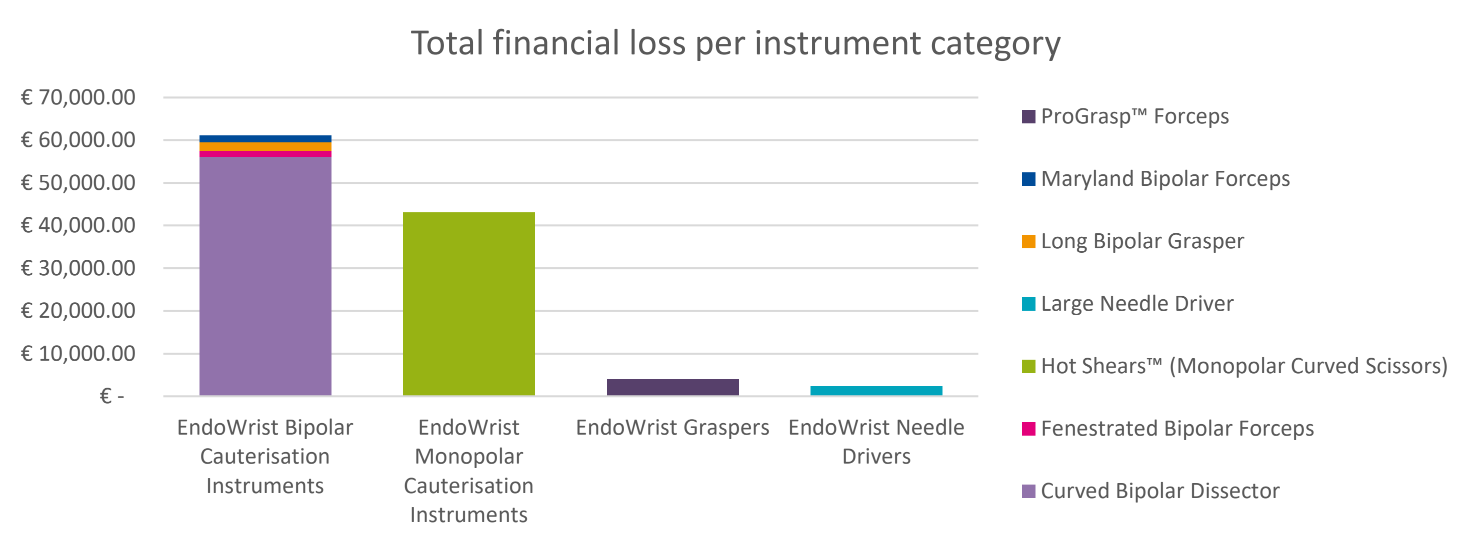

Figure 6: Total financial loss per instrument category from 2015 to 2018

In **Figure 7**, it can be seen that the *Curved Bipolar Dissector* and the *Hot Shears™ (Monopolar Curved Scissors*) already cause the highest loss for a long time. So, this is a long-lasting problem.

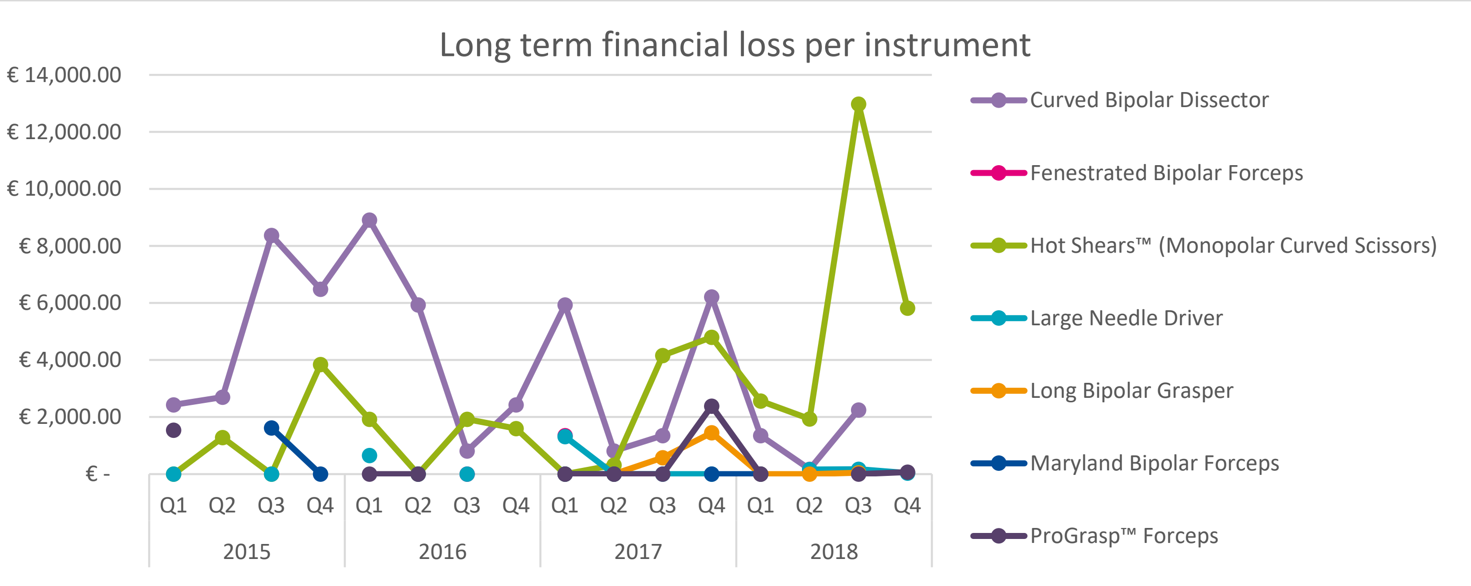

Figure 7: Long term financial loss per instrument (Q = quarter year)

Some instruments are used more often and for longer times than others. So, it is logical if these instruments break more often. To take this into account, we look at the number of defects in comparison to the number of purchases and at the financial loss in comparison to the purchase price. We did this by using percentages. For the instruments that broke, these percentages are shown in **Figure 8**. Additionally, the number of purchases is shown. The reason why we compared the number of defects to the number of purchases instead of to the number of instruments that last their entire life cycle is that there is no data about the latter.

From the figure, it can be seen that the *Small Graptor™ (Grasping Retractor)*, *Hot Shears™ (Monopolar Curved Scissors)*, *Long Bipolar Grasper* and the *Curved Bipolar Dissector* had the highest defect rate in comparison to their number of purchases. However, the *Small Graptor™ (Grasping Retractor)* did not cause a financial loss, because the single time that it broke, it was refunded. So, we can conclude that the fact that the *Curved Bipolar Dissector* and *Hot Shears™ (Monopolar Curved Scissors)* caused the highest loss for a long time is not solely caused by the fact that they are used frequently. The number of defects as a percentage of the number of purchases is also relatively high. Additionally, the *Long Bipolar Grasper* had a high percentage of defects and should therefore also be investigated.

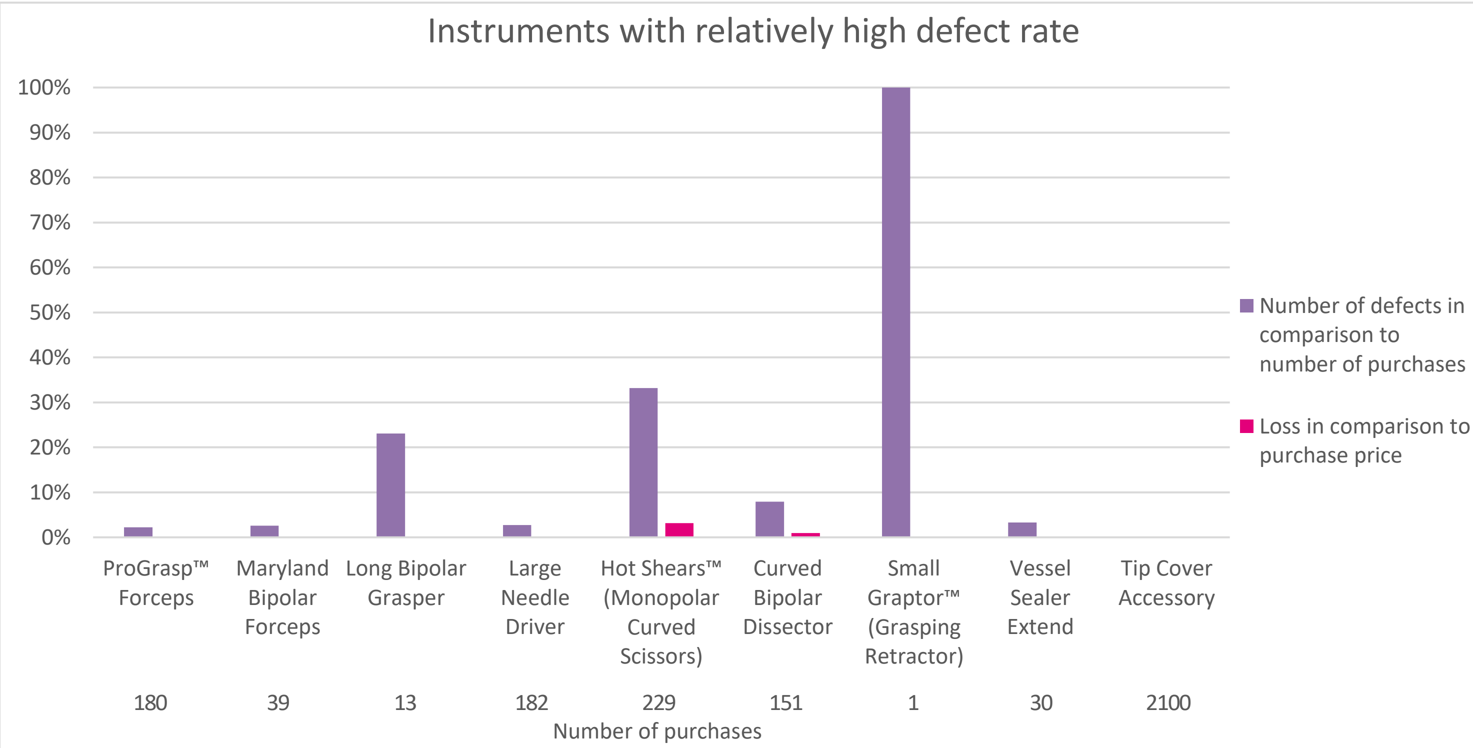

Figure 8: Instruments with relatively high defect rate

4.2. Conclusion

The instruments on which we will focus in this study will be the instruments that have caused the greatest financial loss and the instruments which broke relatively frequently in comparison to their number of purchases. In addition, we will include instruments which broke less frequently but are part of an instrument category that caused a big financial loss, namely the *Long Bipolar Grasper*, *Fenestrated Bipolar Forceps* and the *Maryland Bipolar Forceps*, because the causes of the defects of these instruments might also have caused defects of other instruments in the same category. The instruments on which we will focus are shown in **Table 1**.

Table 1: Instruments on which this study will focus

Instrument number	Description	Reason
470344	Curved Bipolar Dissector	• High financial loss • Relatively high defect frequency
470179	Hot Shears™ (Monopolar Curved Scissors)	• High financial loss • Relatively high defect frequency
470400	Long Bipolar Grasper	• Relatively high defect frequency • Part of category 'EndoWrist Bipolar Cauterisation Instruments' which causes high financial loss
470205	Fenestrated Bipolar Forceps	• Part of category 'EndoWrist Bipolar Cauterisation Instruments' which causes high financial loss
470172	Maryland Bipolar Forceps	• Part of category 'EndoWrist Bipolar Cauterisation Instruments' which causes high financial loss

5. Defect causes

In this chapter, we are showing which defect types happen most often and which causes are known of these defects. We found these causes by investigating the data of the hospital, by carrying out a systematic literature review (of which the protocol can be found in appendix D) and by observing the flow of the instruments through the hospital. We included these causes in the data analysis tool to combine them with the FMECA, which can be found in appendix B.

5.1. According to the data of the hospital

Using the database with all failure data of the Da Vinci® X and Xi robotic systems of the hospital, we investigated which components of the instruments got damaged and which type of damage it was.

5.1.1. Components

In **Figure 9**, the components that broke most frequently are shown. We can conclude that the instrument tips broke most often. In addition, the blades and the shaft extensions broke often.

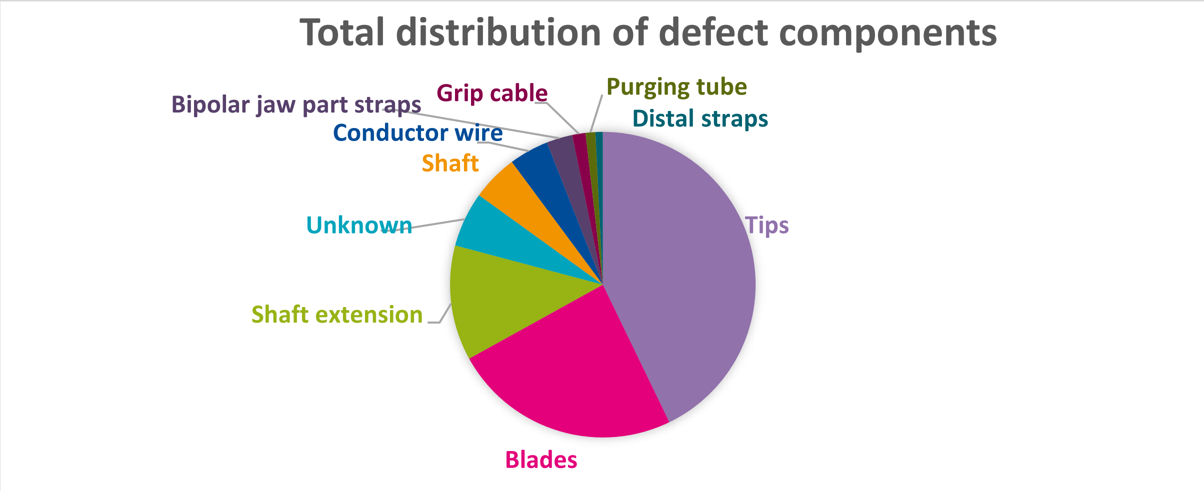

Figure 9: Total distribution of defect components

In **Figure 10** and **Figure 11**, the failing components of the two instruments that caused the greatest loss are shown. These figures show that in case of the Curved Bipolar Dissector mainly the tips fail and that with the Monopolar Curved Scissors, the blades and the shaft extension fail most often.

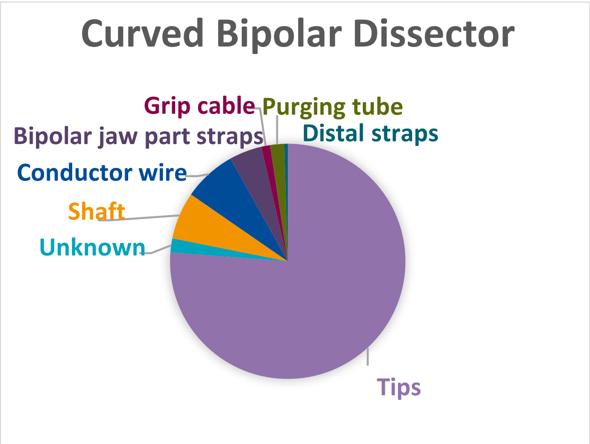

Figure 10: Distribution of the defect components of the Curved Bipolar Dissector

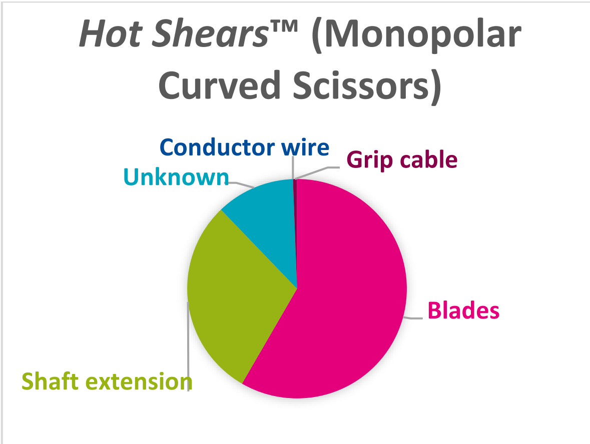

Figure 11: Distribution of the defect components of the Monopolar Curved Scissors

5.1.2. Failure types

From the data, we can conclude, that the problem with the tips most of the time is the fact that they are bent (**Figure 13**). The problem that Intuitive Surgical reports about the shaft extensions is 'miscellaneous'. However, from the hospital's reports we can conclude that it has the same symptoms as the failure type of the tips, which was 'bent'. So, the shaft extensions are also bent (**Figure 12**). Further, the blades always have mechanical notches or scratch marks (**Figure 14**). According to the reports of Intuitive Surgical, most of the failures of the tips and blades might be caused by misuse.

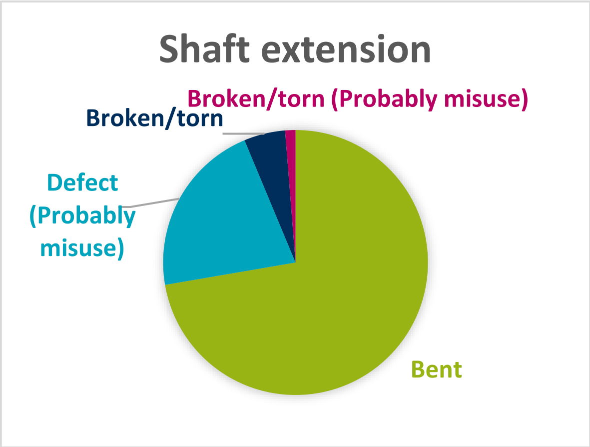

Figure 12: Distribution of the failure types of the shaft extension.

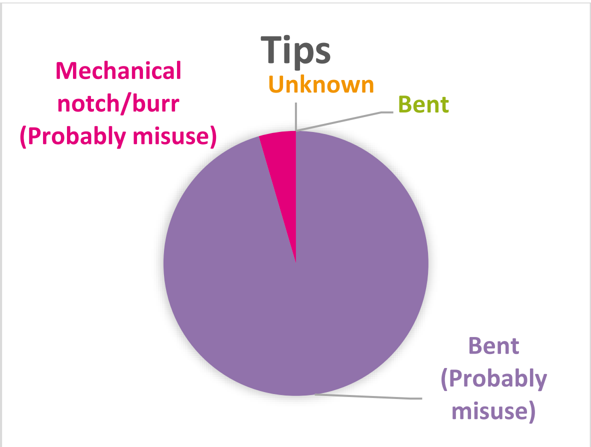

Figure 13: Distribution of the failure types of the tips.

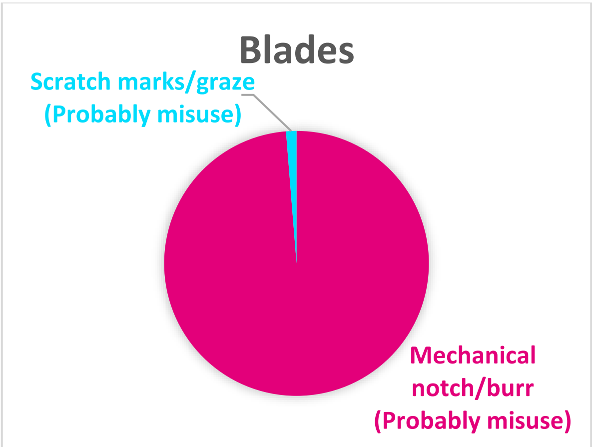

Figure 14: Distribution of the failure types of the blades.

5.1.3. Conclusion

In **Table 2**, the most frequently failing components are shown, as well as the corresponding failure types and the possible causes according to the supplier's reports.

Table 2: Frequent defects and possible defect causes according to the supplier's reports.

Component	Failure type	Cause
Tips	Bent	Misuse
Shaft extension	Bent	
Blades	Mechanical notches or scratch marks	Misuse

5.2. According to the literature

Using systematic literature review, we investigated which failure causes are known by the literature. The systematic literature review protocol can be found in appendix D. Sometimes these causes resulted in failures that could be solved during the surgery, for example by restarting the system. Other causes resulted in permanent defects. In the latter case, the defect components needed to be replaced. We focussed on the last type of defects, because that is about instrument failure. However, we also included failure causes of non-permanent failures of the robotic arms, because these could influence instrument failure.

5.2.1. Robotic arms

Components that fail relatively frequently, without causing permanent defects, are the robotic arms. The arms can collide if they are mispositioned (Buchs, Pugin, Volonté, & Morel, 2014) or make large movements (Corcione et al., 2005). To solve this problem, 8 mm instruments can be used instead of 5 mm instruments: Although some studies suggest that 8 mm instruments are less effective (Corcione et al., 2005), Ballouhey et al. showed that 8 mm instruments cause less instrument collisions and less damage to the patient (Ballouhey et al., 2018). The St. Antonius-Hospital Gronau mainly uses 8 mm instruments. In 2018, the hospital bought 30 times as many 8 mm instruments as 5 mm instruments. None of the 5 mm instruments broke, but they are also barely used, so it cannot be concluded that the 5 mm instruments are of better quality than the 8 mm instruments. However, from the failure data of the hospital it can neither be concluded that the 8 mm instruments are qualitatively better.

5.2.2. Instruments

Although failure of the robotic arms does not automatically result in defects, failure of the instruments does. So, it is important to know the causes for these failures. Friedman, Lendvay and Hannaford (2013) divide instrument failures in five categories, which are, in order of reported frequency: wrist or tool-tip, cautery, shaft, cable and control housing. They do not mention many failure causes, but for shaft defects they mention that shafts can be scratched by scraping against the cannula through which the instrument enters the body or by instrument collision or misusage. According to Nayyar and Gupta (2010), defects which involve broken wires, can be caused by user-related mistakes (e.g., moving the instruments beyond their range).

Instruments that fail often are the scissors. These failures are primarily broken tool tips/blades (Buchs et al., 2014; Friedman et al., 2013). Additionally, the tool tip covers are fragile and hard to install (Friedman et al., 2013). So, the fact that a great force is needed to install the tool tips could probably be a cause of the frequent defects of the scissors.

Another effect of the fragile tool tips is energy leakage (“arcing”), which can cause damage to the patient (Fuller, Vilos, & Pautler, 2012; Lorenzo et al., 2011). According to a study of Mendez-Probst et al. (2011), energy leakage occurs relatively frequently. In that study, all instruments that were at the end of their life cycle showed energy leakage. This can be caused by fragile tool tips, but also by stray currents burning away insulation. Additionally, it can be caused by operating small instruments through big cannulas, cleaning instruments insufficiently or by re-using disposable instruments (Fuller et al., 2012; Mendez-Probst et al., 2011).

5.2.3. Conclusion

From this literature review, we extracted several possible failure causes (**Table 3**). However, many articles solely describe the failures and the failure frequencies. Not much research has been done on failure causes.

Table 3: Defect causes according to literature

Component	Failure type	Causes	Sources
Shaft	Scratch marks	• Instrument scrapes against the cannula. • Instruments collide. • Instruments are misused.	(Friedman et al., 2013)
Wires	Broken	• Moving instruments beyond their range.	(Nayyar & Gupta, 2010)
Tool tip and tool tip cover	Broken	• Great force needed to install tip cover.	(Friedman et al., 2013)
No specific component	Energy leakage	• Fragile tool tips • Stray currents • Operating small instruments through great cannulas. • Cleaning instruments insufficiently. • Re-using disposable instruments.	(Fuller et al., 2012; Lorenzo et al., 2011; Mendez-Probst et al., 2011)

5.3. According to observations in the hospital

After having investigated what could cause the defects according to the literature, we observed the usage of the instruments in the hospital. We observed this both during surgeries and during the cleaning and sterilisation processes. In this paragraph, we will show the flow of the instruments and indicate in which phase the cause of the defects could probably be found.

5.3.1. The flow

We are using a flow chart to show the flow of the instruments through the hospital. This flow chart is shown in **Figure 15**.

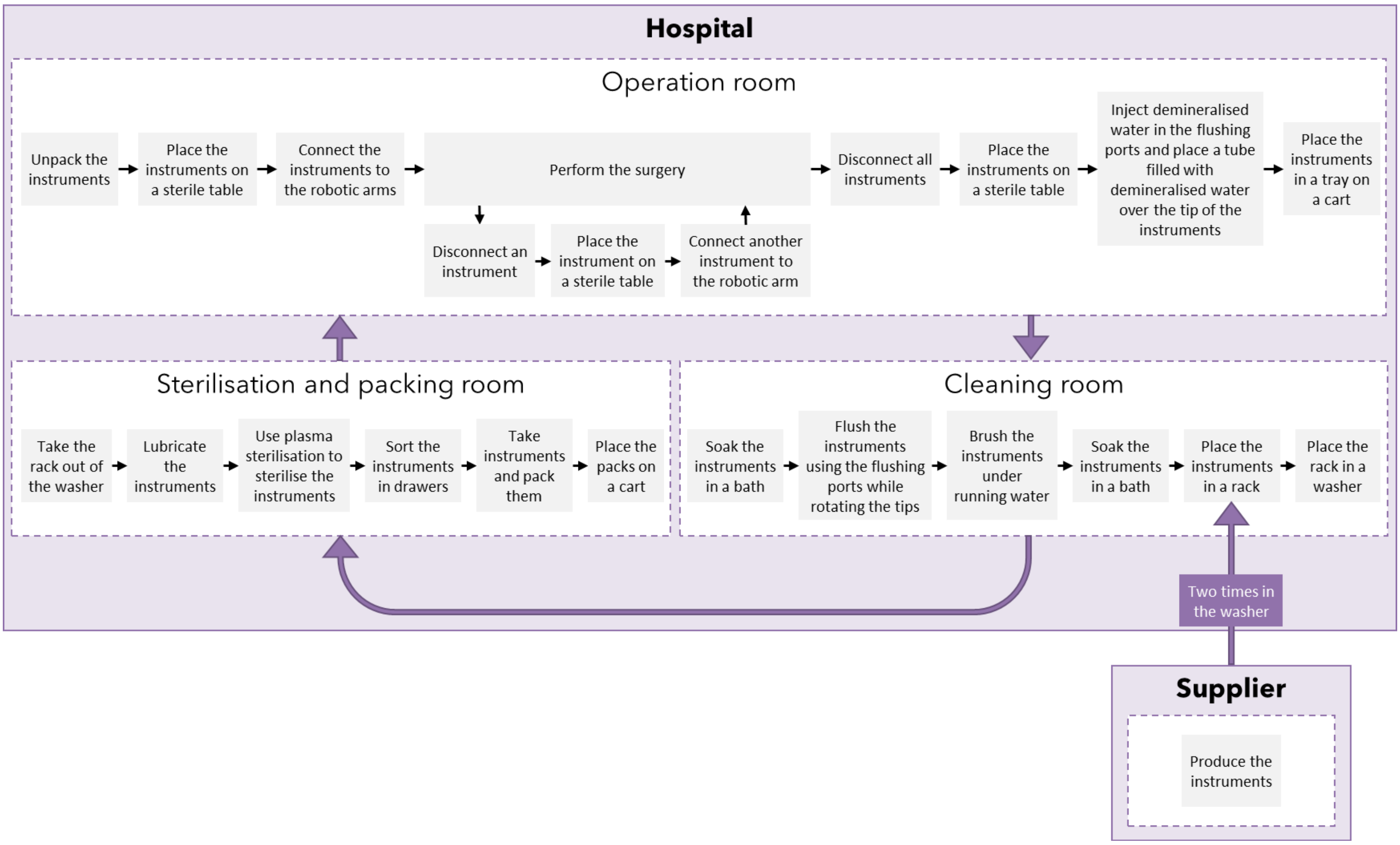

Figure 15: Flow chart of the instruments' flow through the hospital

If mistakes were made in the cleaning and packing rooms, problems would occur with multiple instruments, because in these rooms, all instruments are treated in the same way. Therefore, it is most likely that defects are caused by a product-related error (e.g., a material or production error) or during a process in the operation room. During surgery some instruments are used more frequently than others and the different instruments are used for different purposes and in different ways. So, if a specific instrument breaks relatively often it may be caused by a product-related error at the supplier or by wrong usage during the surgery.

5.3.2. Usage of the instruments

During the surgery, we noticed a few possible causes of defects. (*Restricted*)

Another flaw during the surgery was that second and third arm interfered close to collision. These were the arms to which the endoscope and the Curved Bipolar Dissector were attached. From the literature, no cases appeared in which interference of arms caused damage to the instruments. However, this interference can be solved by moving the back end one of the arms towards the other arm. Hereby, the front ends can work in parallel (Intuitive Surgical Inc., 2018a).

In a conversation with the surgeon, two other possible failure causes came forward. Firstly, the lack of haptic feedback can cause surgeons to use too much pressure, which can bend the instrument tip. (*Restricted*)

Additionally, we observed that much pressure was needed to install the tip cover, as the literature stated. The reason for this is that the tooltip must be tight.

(*Restricted*)

5.3.3. Conclusion

In summary, by observing the flow of the instruments and by having conversations with staff members, we found several possible failure causes. These are shown in **Table 4**.

Table 4: Possible defect causes according to our observations and conversations.

Instrument	Component	Failure type	Cause
Instruments which break relatively frequently	-	-	• Product-related error at the supplier • Wrong usage during the surgery
(*Restricted*)	(*Restricted*)	(*Restricted*)	(*Restricted*)
-	Blades	• Bent	• Tip covers are hard to install.
(*Restricted*)	(*Restricted*)	(*Restricted*)	(*Restricted*)
-	Tips, blades or shaft extension	• Mechanical notches • Bent	• Lack of haptic feedback
(*Restricted*)	(*Restricted*)	(*Restricted*)	(*Restricted*)
(*Restricted*)	(*Restricted*)	(*Restricted*)	(*Restricted*)

6. Information in the tool

Now that we defined the scope and found causes for the defects of the instruments which are part of this scope, we could build a data analysis tool. This tool should support the hospital in analysing the failure data of the Da Vinci® instruments and it should show which instruments, components and failure types cause the highest financial loss and what could possibly cause these defects. To make this tool, we included several types of data. Firstly, we included the FMECA to analyse which failure types need attention. Secondly, we included the failure causes which are shown in the previous chapter. Thirdly, we added three reliability measures to show the reliability of the tool and the consistency of the supplier's investigations. Finally, we made two dashboards that give an overview of this data. In this chapter, we are explaining more about these data and dashboards of the data analysis tool. The user manual of the tool can be found in appendix A.

6.1. FMECA

The tool is built on the Failure Mode Effect and Criticality Analysis (FMECA). This analysis results in a table which contains several aspects. These aspects will be explained now.

6.1.1. Component descriptions and failure modes

The failure types (also called 'failure modes') of the defects are determined by splitting the results of the supplier into smaller parts containing the failing component and the failure type (e.g., bent or scratch marks). In some cases, we needed to modify the components or failure types. We will now explain why we did that.

In some cases, the results were not clear enough to categorise the defects. In these cases, we marked the components or failure types concerned as 'Unknown'. In appendix C, we show which components and failure types this includes.

The failure type 'Defect' also sounds too general to show what type of failure occurred. However, this type of failure often happens to wires. It turns out that this means that the wires are broken (defect). So the failure type 'Defect' is clear enough and did not need to be marked as 'Unknown'.

For components that were bent, there were two failure types: 'Bent' and 'Strongly bent'. However, these failure types had equal effects and also in the hospital's reports there were no differences. Therefore, these failure types were combined in the failure type 'Bent'.

6.1.2. Functions and effects

In the FMECA, the functions of the components and the effects of the failure types are included. The reason for this is that the function of the component indicates why it is a problem if the component malfunctions. The effect of the failure type is based on the lack of this function and on additional effects that appeared from the hospital's report. The effect can show how harmful the failure is.

6.1.3. Symptoms

We obtained the symptoms by analysing which failure descriptions the hospital's reports contained per failure type. The symptoms are used to analyse the consistency of the results of the supplier's investigations. For example, if the supplier's report 'bent tips' always occurred together with the hospital's report 'dull scissors', 'dull scissors' is the symptom of the defect 'bent tips'. If in some case, the symptom is 'dull scissors', but the supplier indicates that the problem is a broken cable instead of bent tips, the categorisation consistency of the supplier becomes less. This consistency measure is shown in the data analysis tool.

6.1.4. Failure mode frequency

The failure mode frequency shows which percentage of the failures of a specific component are caused by a given failure type. For example, if the failure mode 'Worn distally' of the component 'Grip cable' has a failure mode frequency of 32%, it means that in 32 out of 100 grip cable defects the grip cable wore distally.

6.1.5. Failure rate

The failure rate shows per component or per instrument how often a failure happens on average per year.

6.1.6. Severity and criticality

We calculated the severity and criticality using the failure mode frequency, failure rate and the financial loss. The financial loss is calculated using the following formula: *purchasing price / total lives * remaining lives – amount credited.* So, the financial loss is the part of the costs of the unused lives which is not refunded. The severity is the average financial loss per defect per failure type and the criticality is the average financial loss per year per failure type.

6.2. Reliability measures

On the homepage, three reliability measures are shown. These measures give an indication of the reliability of the conclusions and advices which the dashboard shows. The measures are based on the variables which I introduced in paragraph 3.3.

The categorisation completeness of the dashboard shows the percentage of the defects which are categorised by using the results of the supplier's investigation. These categorised defects are all the defects of which the failure type is not 'Unknown'.

The categorisation consistency of Intuitive Surgical shows the consistency of the results of the supplier's investigation (i.e., the component and failure type according to the supplier) when compared to the symptoms. More information about this measure can be found in paragraph 6.1.3.

The cause suggestion reliability of the dashboard shows the percentage of the failure types for which the cause is suggested right. There is not yet data for this measure. But when the data analysis tool is being used, the users can indicate if a suggestion is right. Based on that feedback, the measure will be updated.

6.3. Dashboard

There are two dashboards. On the first one, conclusions are drawn based on the data from 2015 to 2018. On the second one, conclusions are drawn based on the data from the last six months of 2018. When data of 2019 is added, the conclusions on this sheet will be about the past six months. The reason that data from the past is interesting is that it shows long-term problems. The reason that data from the last six months is interesting is that it can indicate emerging problems.

On both dashboards the instruments, components and failure types that caused the highest financial loss over the time frame of the dashboard are shown, both in text and in figures. Further, the size of the problem is indicated by the total financial loss over the time frame. Additionally, the possible causes can be looked up via the dashboards.

7. Results from the tool

In this chapter, we are showing the results that are obtained from the tool, based on the data from 2015 to 2018.

7.1.1. Size of the problem 2015 to 2018

The loss that the defects cause is on average €27,669 per year. To compare this to the total amount of money spend on Da Vinci® instruments: In 2018, the loss caused by the defects was €27,552. This is about 1.2% of the €2.3 million that was spent on purchasing Da Vinci® instruments in that year. When looking at the number of defect instruments, instead of at the loss that is caused by the defects, a higher percentage is found: Of the instruments that were purchased in 2018, 11.9% broke.

The losses per surgery case in 2015 to 2018 are respectively €24, €19, €21 and €16. So, there is no clear increase or decrease of the loss per surgery. The same conclusion holds for the number of defects per surgery, which are respectively 0.05, 0.06, 0.07 and 0.06.

7.1.2. Defects which need attention

Looking at the defects from the last six months of 2018, we see that the defects that happen most frequently are bent shaft extensions and scratched blades. We also see this when we look at the long-term data from 2015 to 2018. In the long-term data we also see another frequent defect, namely bent tips. This will probably be related to the bent shaft extension, because these are connected. The instrument that breaks most often in both the long-term and the short-term is the Hot-Shears™ (Monopolar Curved Scissors).

7.1.3. Reliability

As we described in the previous chapter, the tool also contains some reliability measures. The *cause suggestion reliability* cannot yet be measured, because it can only be measured when the tool is used for a while. However, the *categorisation completeness of the dashboard* and the *categorisation consistency of Intuitive Surgical* can be measured already. It turns out that the categorisation completeness is 88%, which means that 88% of the defects can be categorised by using the results of the supplier's investigation. The categorisation consistency is 43%, which means that in 43% of the cases, the report of Intuitive Surgical was in line with the symptoms of the defect.

Conclusion

In this conclusion, we will first show the conclusions of the study. Thereafter, we will show the limitations of this study and give recommendations for further research.

Conclusion

The core problem which this study is about, is: ‘The hospital does not have a supporting system to analyse the failures of the Da Vinci® instruments to evaluate which defect types occur most frequently or cause the greatest financial loss.’

Data analysis tool for the future

To support the hospital, we developed a data analysis tool. The hospital can use the tool to analyse the new failure data. Our advice is to use the tool every three to six months, because per six months on average seventeen defects that cause loss occur. So, if the time frame is shorter than a quarter, too few new defects will have occurred to see new trends. A time frame of six months gives the opportunity to notice common causes, while still being in time to solve the problems at an early stage.

Advice based on the data from 2015 to 2018

Based on the data from 2015 to 2018 we have investigated which failure types caused the highest financial loss. These were bent tips of the Curved Bipolar Dissector and bent shaft extensions and scratched blades of the Hot Shears™. (*Restricted*) A possible cause is the lack of haptic feedback. Because of this lack, the surgeons might apply too much force, causing bent tips or bent shaft extensions. (*Restricted*)

To prevent these common defects from happening, the hospital should investigate if the financial loss decreases when (*Restricted*). If this does not lower the defects, the hospital should talk with the supplier to find a cause of the high loss which the Hot-Shears™ caused or to find a solution for the lack of haptic feedback.

Discussion

We will now show the limitations of this study and the assumptions that we made.

Firstly, the FMECA is based on the data from 2015 to 2018. It is possible that new failure types will occur in the future. These are not yet included in the FMECA. However, the hospital can do this later.

Secondly, we solely investigated the data, literature and instruments’ flows. We have not investigated the instruments at a more mechanical level, because that is outside of our discipline. Therefore, we were not able to find all the functions of components and effects of defects. Additionally, more causes could be found when inspecting the instruments at a more mechanical level.

Thirdly, we did not have our study checked by the supplier, because we should first determine which defects happened frequently and look for causes in the hospital itself. So, the hospital should investigate whether solving the suggested causes really decreases the number of defects. To find more causes, they can turn to the supplier.

In this study, we made two assumptions about the failure modes. Firstly, when a defect consisted of multiple failure modes, we assumed that the failure modes were equally responsible for the financial loss. In reality, this might not be the case. For instance, scratched distal straps almost always occur together with other, bigger issues concerning the tips. So, probably the scratch marks are just a side issue.

The second assumption is that, when a defect consisted of multiple failure modes, the failure modes are independent of each other. In reality, this might not be the case. For example, damaged bipolar jaw part straps almost always occur together with a defect conductor wire. So, there might be a correlation between these defects.

Recommendations

To improve the reliability of the data analysis tool and to find more failure causes, further research can be done. We would like to suggest a few topics to investigate.

Firstly, the two assumptions that we made concerning defects with multiple failure modes can be checked. This can for instance be done by further investigating the hospital's reports to see how big the effect of a specific failure mode is. The correlation of the defects can probably be investigated by talking to the supplier Intuitive Surgical, because more technical information might be needed for that.

Secondly, we only observed urological surgeries. This department is the main user of the Da Vinci® system in Gronau. However, also the other specialties (e.g., gynaecology) could be investigated into to find out if there are more, less or different defects and what could be learned from that.

Thirdly, the hospital could look at the data analysis tool to investigate which failure types are not categorised consistently and what could cause this inconsistency.

Additionally, from the literature, energy leakage (for example because of damaged insulation) seemed to be a common problem. However, damaged insulation rarely appeared in the database of the hospital and it was never the reason for returning the instrument to the supplier. Therefore, we have not investigated it further. However, when it turns out to be a problem later, the literature can be used to find possible causes and solutions.

Furthermore, in some cases the hospital's failure report contains the number of remaining lives. However, this does not always correspond to the number of remaining lives in the separate column of the database which always shows the number of remaining lives. It might be interesting to investigate what causes this discrepancy and if it is a problem.

Finally, it would be useful to ask the IT department to carry out maintenance on the code of the tool every year to make sure that the code stays updated and to prevent errors.

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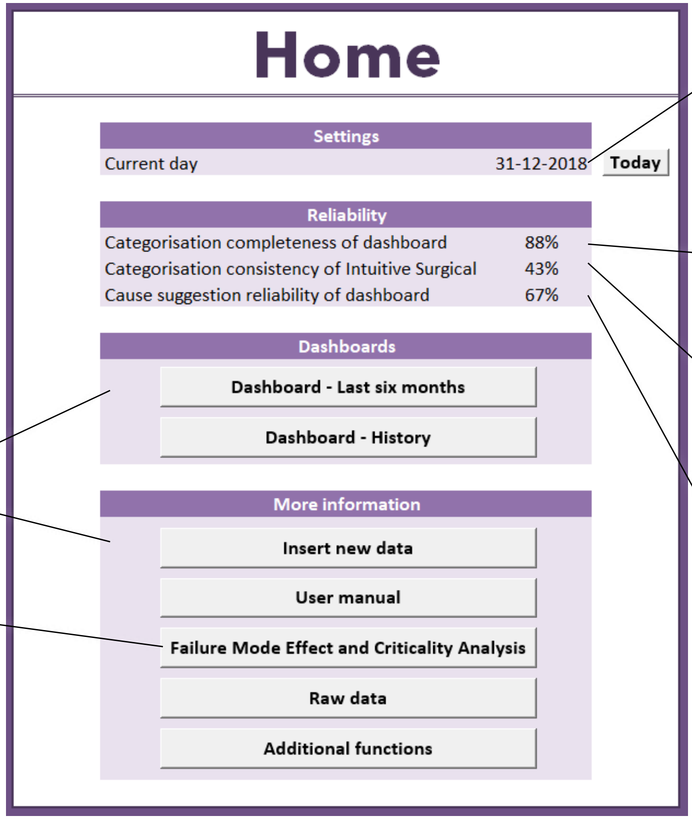
A. User manual

This is the user manual for the Excel tool 'Data analysis tool for failing Da Vinci instruments'. It consists of a manual for using the tool and of a manual for periodic maintenance. The name of the file should not be changed and macros should be enabled.

A.1. Using the tool

The tool consists of several pages. First, it will be explained what the pages show. After that, a flow chart will be given for using the pages. The advice is to use the tool every three to six months.

A.1.1. Home



Current day: This is used to determine which defects occurred most recently. You can change it to a date in the past. To reset it to the current date, press the 'Today' button.

Categorisation completeness: The percentage of the defects which the tool could categorise by using the results of the supplier's investigation.

Categorisation consistency: The percentage of the defects for which the results of the supplier's investigation are consistent with the results of similar defects in the past.

Cause suggestion reliability: The percentage of the failure causes which are suggested right.

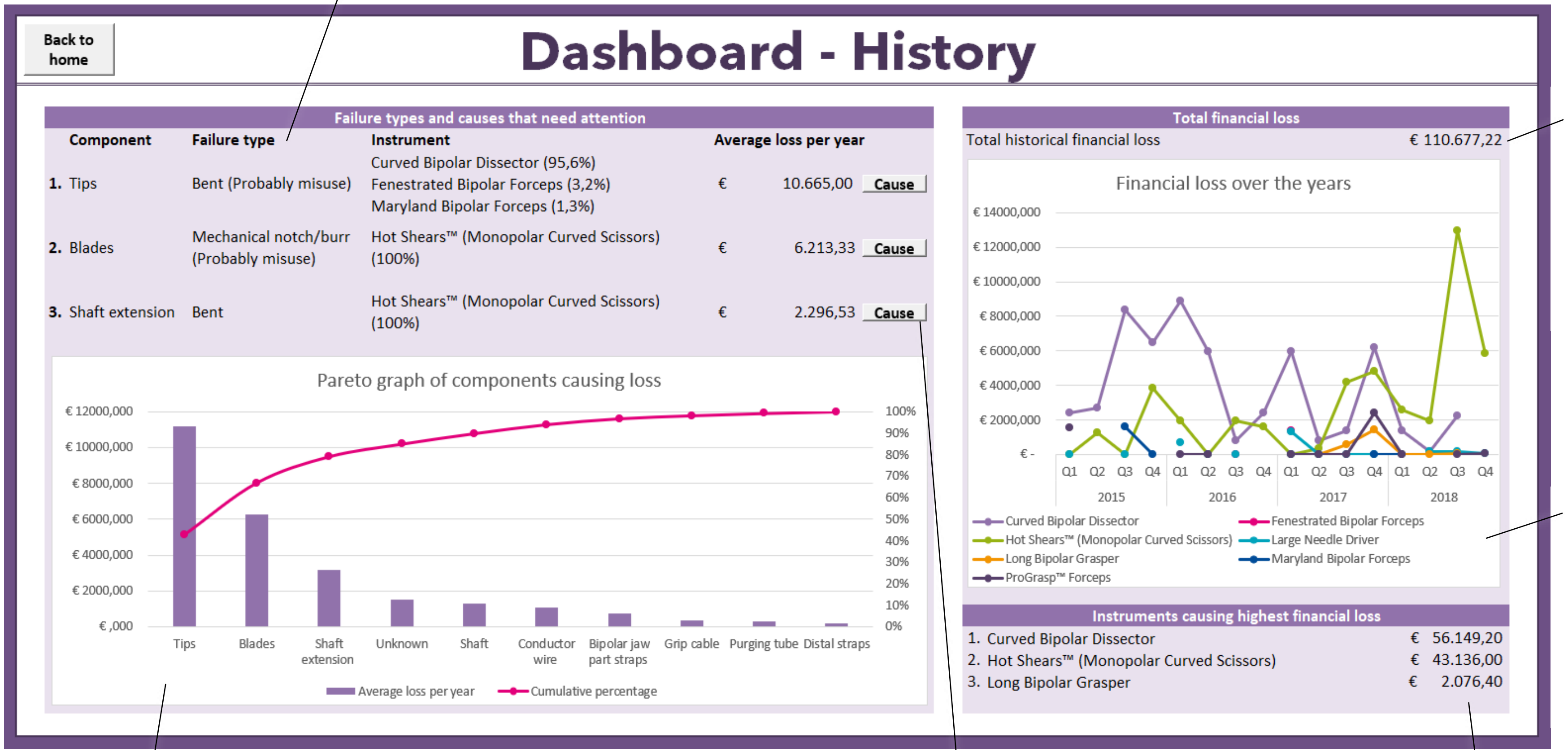
Buttons: Use these buttons to go to other pages.

More details: This brings you to the page with the FMECA, which shows the different failure types per instrument as well as their frequencies, symptoms and criticality.

A.1.2. Dashboards

There are two dashboards: one about the last six months and one about the defects from 2015 until today. Both dashboards look the same.

Component, failure type, instrument and average loss: The failure types and corresponding components that caused the highest average loss are shown. Additionally, the instruments to which these failure types happened are shown, including the percentage that these instruments contributed to the loss caused by this failure type.



Total historical financial loss: This is the total loss that is caused by failing instruments, taking into account the remaining lives.

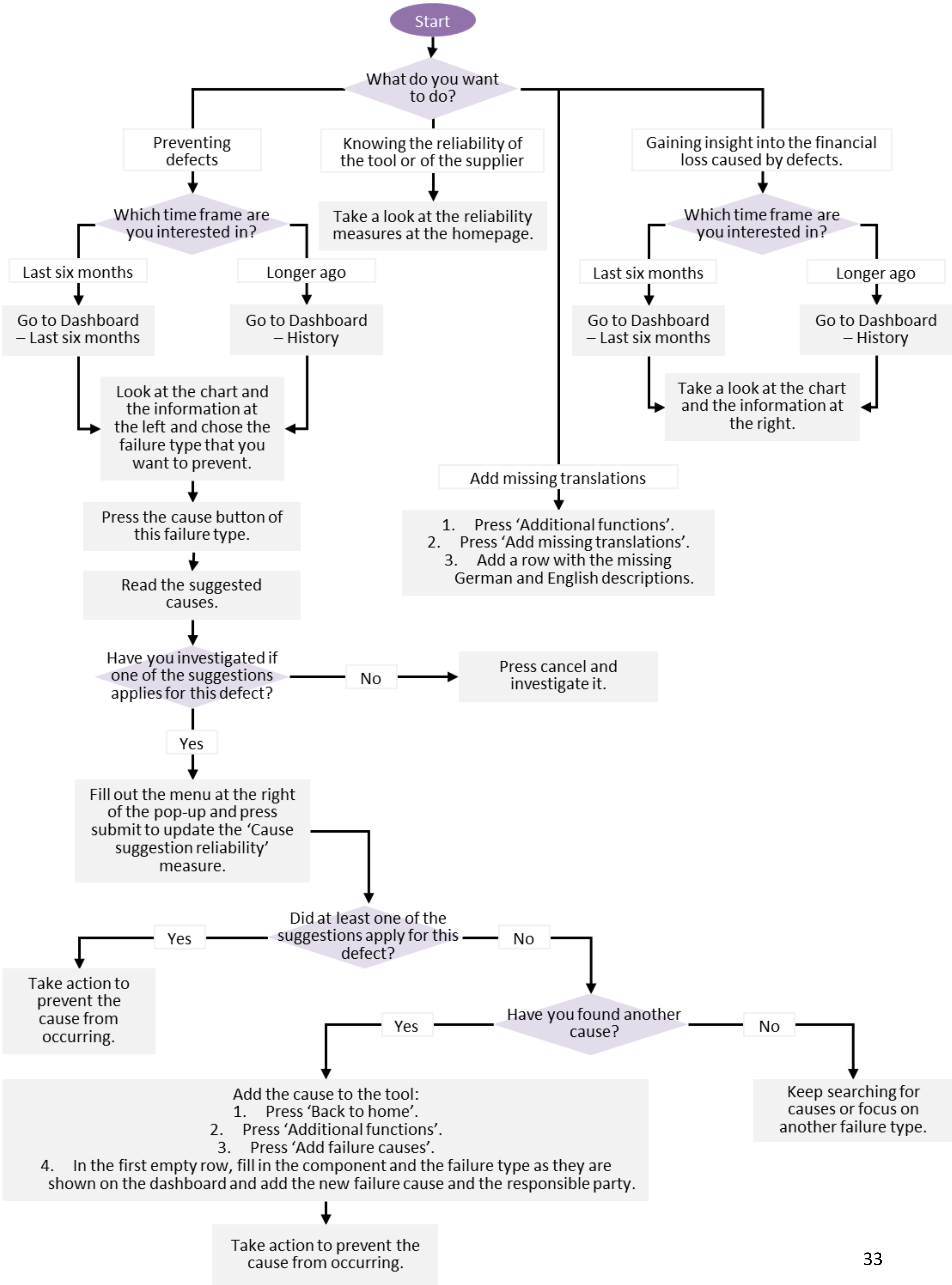
Financial loss over the years: This chart shows which instruments caused loss in the past and how these losses developed.

Pareto graph: This chart shows the loss per component and the cumulative percentage. Often 20% of the components cause 80% of the failures. Therefore, you should focus on the small group of components to solve the mayor part of the problem.

Cause buttons: Press these buttons to view suggested causes of the failure types and to give feedback to update the cause suggestion reliability.

Instruments causing highest financial loss: These are the instruments which caused the highest loss in the past. These losses are also shown.

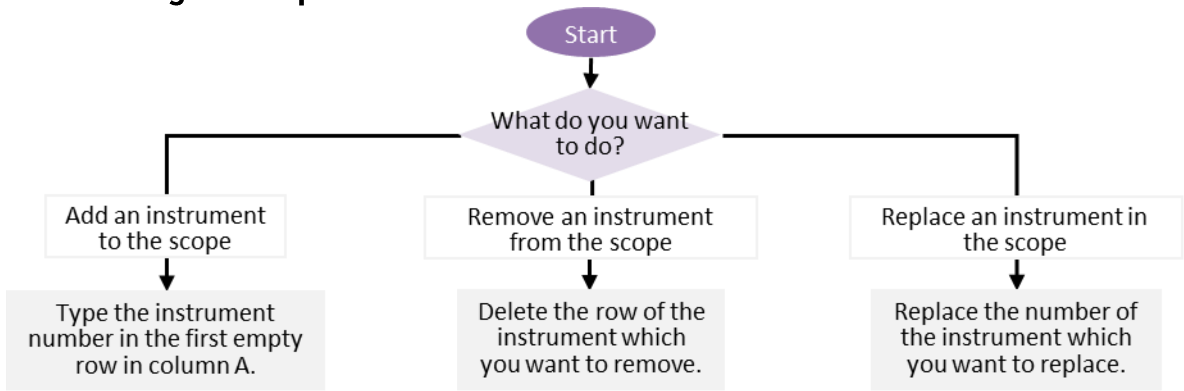
A.1.3. How to use the tool?



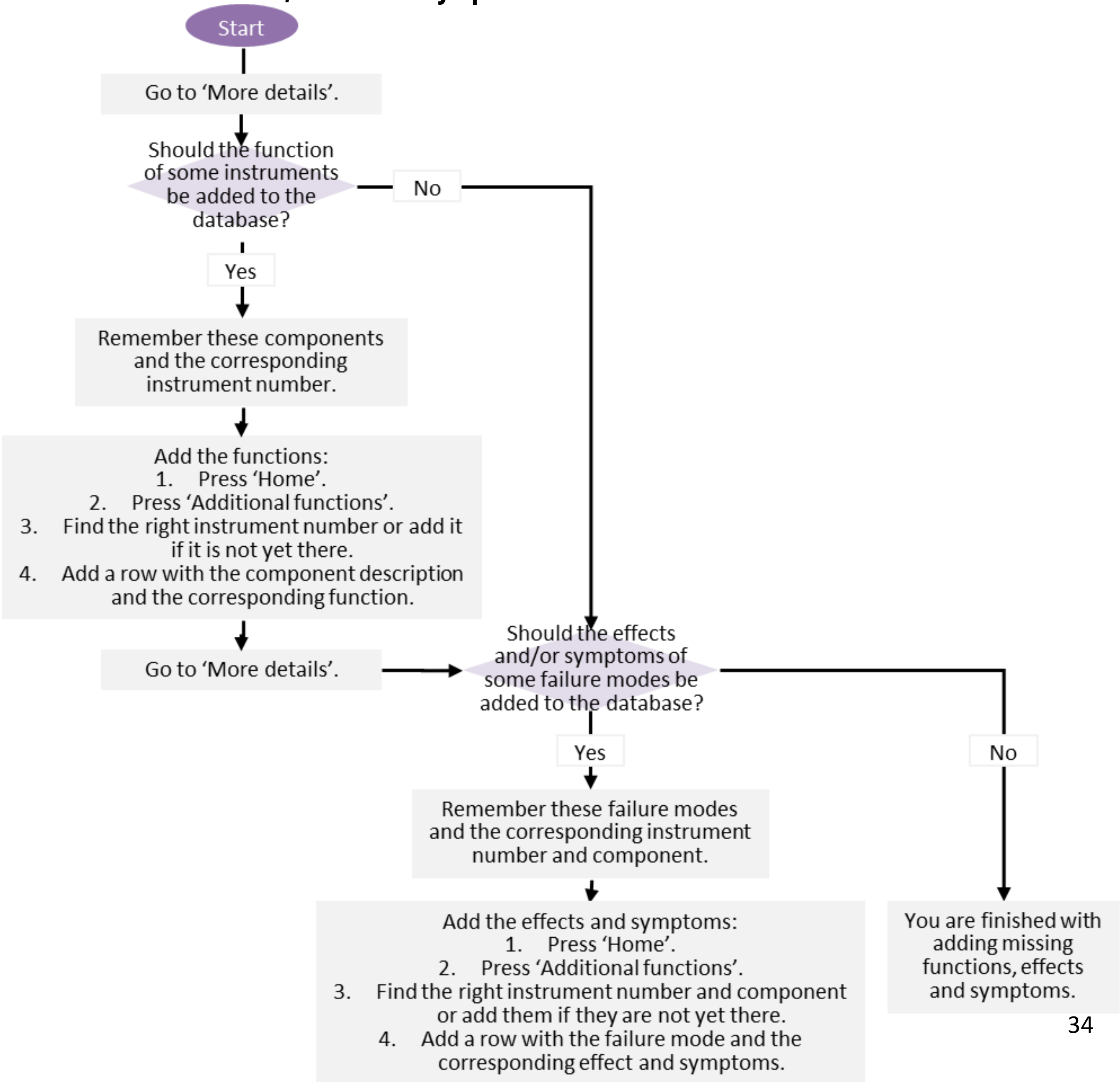
A.2. Maintenance on the tool

There are several pages that need periodic maintenance. All pages can be reached via the homepage when pressing the button 'Additional functions'. Per type of maintenance, we will show a flow chart for using it. The changes which you make will be automatically processed when you add new failure data.

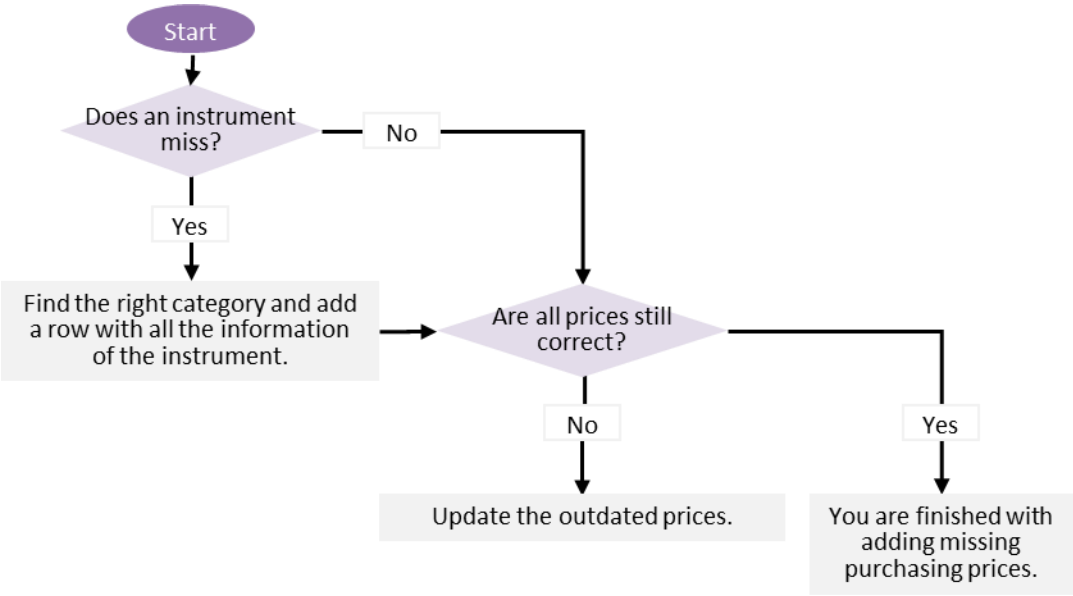
A.2.1. Change the scope



A.2.2. Add functions, effects and symptoms



A.2.3. Add purchasing prices



B. FMECA

Table 5: FMECA

Instrument description	Component description	Function	Failure mode (i)	Failure mode frequency (α_i)	Failure rate component (λ; per year)	Failure rate instrument (per year)	Failure effect	Symptoms	Severity (Si)	Criticality (Ci = αi*λ*Si)
Curved Bipolar Dissector						32.5				
	Grip cable	Controlling the jaws			6.25					
			Worn distally	32%			Unable to grap tissue	Cable at the tip of the instrument broke / Seilzug an der Spitze gerissen	€ 33.75	€ 67.50
			Run of the roll	8%			Unable to grap tissue	Cable / Wire at the tip of the instrument broke	€ 202.50	€ 101.25
			Broken distally	60%			Unable to grap tissue	Cable at the tip of the instrument broke / Seilzug an der Spitze gerissen / Wire broken / torn	€ -	€ -
	Conductor wire	Conducting electricity			9.75					
			Damaged insulation (Probably misuse)	3%			Risk of energy leakage/No cauterisation	?	€ 405.00	€ 101.25
			Damaged insulation	3%			Risk of energy leakage/No cauterisation	?	€ 630.00	€ 157.50
			Dislocated	54%			Risk of energy leakage/No cauterisation?	The black power cable at the tip is no longer tight / sticking out more than usual / loose / Das Schwarze Kabel / Seilzug / Stromkabel / an der Spitze liegt nicht mehr eng an /guckt ungewöhnlich weit aus / locker / hevorschauendes Kabel	€ 63.77	€ 334.80

			Defect	41%			Risk of energy leakage/No cauterisation	Cable / wire / Yaw-Pulley / Seilzug at the tip of the instrument broke / torn / broken / defective / gerissen ; Missing fragment / plastic part / Plastikstück / Stück Plastikof the yaw pulley ; No energydispensed / No current at tip / Does not coagulate / Strom kan nicht mehr abgegeben werden / Kein Strom an der Spitze / Koaguliert nicht	€ 106.88	€ 427.50
	Tips	Grabbing and cauterising tissue			18.75					
			Unknown	3%			Unknown	-	€ -	€ -
			Mechanical notch/burr (Probably misuse)	5%			Unknown	-	€ 506.25	€ 506.25
			Bent	44%			Loss of grip	Instrument has bent jaws / yaws / tip / brances / grips / Jaws are not aligned / misaligned / Spitze ist verbogen / Branchen verschoben	€ -	€ -
			Bent (Probably misuse)	48%			Loss of grip	Instrument has bent jaws / yaws / tip / brances / grips / Jaws are not aligned / misaligned / Spitze ist verbogen / Branchen verschoben	€ 1,132.50	€ 10,192.50
	Distal straps	Securing the grip cable?			0.5					
			Scratch marks/graze	50%			Loss of control of the jaws?	Cable at the tip of the instrument broke	€ 270.00	€ 67.50
			Mechanical notch/burr (Probably misuse)	50%			Loss of control of the jaws?	Cable at the tip of the instrument broke	€ -	€ -
	Shaft	Bridging distance between robot and patient			7.75					
			Scratch marks/graze	100%			Not cleanable?	?	€ 117.58	€ 911.25

	Bipolar jaw part straps	Securing the conductor wire?			4.25					
			Unknown	6%			Missing part?/No cauterisation	-	€ -	€ -
			Defect	18%			Missing part/No cauterisation	Cable / wire / Yaw-Pulley / Pulley / Seilzug at the tip of the instrument broken /defective / gerissen ; Missing fragment / plastic part / Plastikstück / Stück Plastik of the yaw pulley	€ -	€ -
			Defect (Probably misuse)	76%			Missing part/No cauterisation	Cable / wire / Yaw-Pulley / Pulley / Seilzug at the tip of the instrument broken /defective / gerissen ; Missing fragment / plastic part / Plastikstück / Stück Plastik of the yaw pulley	€ 193.85	€ 630.00
	Unknown	Unknown			2					
			Unknown	100%			Unknown	-	€ 135.00	€ 270.00
	Purging tube	Enabling cleaning			0.25					
			Dislocated (Probably insufficient cleaning)	100%			Not cleanable	?	€ 1,080.00	€ 270.00
Hot Shears™ (Monopolar Curved Scissors)						31.5				
	Unknown	Unknown			13.75					
			Unknown	58%			Unknown	-	€ 114.60	€ 916.80
			Intuitive movement	5%			Unable to cut tissue	-	€ 106.67	€ 80.00
			Improper fit	5%			Unable to cut tissue	-	€ 258.84	€ 194.13
			Cutting test failed - no blade damage	31%			Unable to cut tissue	-	€ 13.93	€ 59.20
	Blades	Cutting and cauterising tissue			6					
			Scratch marks/graze (Probably misuse)	4%			Unable to cut tissue	Blunt / dull scissors / do not cut / Schere schneidet nicht mehr / Stumpf Schere	€ 320.00	€ 80.00
			Mechanical notch/burr (Probably misuse)	96%			Unable to cut tissue	Blunt / dull scissors / do not cut / Schere schneidet nicht mehr / Stumpf Schere	€ 1,080.58	€ 6,213.33
	Shaft extension	Moving the tip			13					
			Broken/torn (Probably misuse)	2%			Unable to cut tissue	?	€ 160.00	€ 40.00
			Broken/torn	10%			Unable to cut tissue	?	€ 128.00	€ 160.00
			Bent	85%			Unable to cut tissue	Distales Ende / Spitze / Schere ist verbogen / stumpf / krumm	€ 208.78	€ 2,296.53
			Defect (Probably misuse)	4%			Unable to cut tissue	?	€ 1,360.00	€ 680.00

	Grip cable	Controlling the jaws			3.25					
			Worn distally	8%			Unable to cut tissue	Cable at the tip of the instrument broke (Seilzug an der Spitze gerissen)	€ -	€ -
			Broken distally	92%			Unable to cut tissue	Cable at the tip of the instrument broke / Seilzug an der Spitze gerissen / Wire broken / torn ; Scissors do not cut / Schere lässt sich kein Gewebe mehr schneiden / nicht öffnen und schließen / schliessen / öffnet die Branchen nicht	€ 21.33	€ 64.00
	Conductor wire	Conducting electricity			0.25					
			Dislocated	100%			Risk of energy leakage/No cauterisation?	The black power cable at the tip is no longer tight / sticking out more than usual / loose / Das Schwarze Kabel / Seilzug / Stromkabel / an der Spitze liegt nicht mehr eng an /guckt ungewöhnlich weit aus / locker / hevorschauendes Kabel	€ -	€ -
Maryland Bipolar Forceps						2				
	Tips	Grabbing and cauterising tissue			0.25					
			Bent (Probably misuse)	100%			Loss of grip	Instrument has bent jaws / yaws / tip / brances / grips / Jaws are not aligned / misaligned / Spitze ist verbogen / Branchen verschoben	€ 540.00	€ 135.00
	Grip cable	Controlling the jaws			1.5					
			Worn distally	33%			Unable to grap tissue	Cable at the tip of the instrument broke (Seilzug an der Spitze gerissen)	€ -	€ -
			Broken distally	67%			Unable to grap tissue	Cable at the tip of the instrument broke / Seilzug an der Spitze gerissen / Wire broken / torn	€ 135.00	€ 135.00
	Distal straps	Securing the grip cable?			0.25					
			Scratch marks/graze	100%			Loss of control of the jaws?	Cable at the tip of the instrument broke	€ 540.00	€ 135.00

	Conductor wire	Conducting electricity			0.25					
			Dislocated	100%			Risk of energy leakage/No cauterisation?	The black power cable at the tip is no longer tight / sticking out more than usual / loose / Das Schwarze Kabel / Seilzug / Stromkabel / an der Spitze liegt nicht mehr eng an /guckt ungewöhnlich weit aus / locker / hevorschauendes Kabel	€ -	€ -
	Unknown	Unknown			0.25					
			Unknown	100%			Unknown	-	€ -	€ -
Fenestrated Bipolar Forceps						0.75				
	Unknown	Unknown			0.25					
			Unknown	100%			Unknown	-	€ -	€ -
	Grip cable	Controlling the jaws			0.5					
			Worn distally	50%			Unable to grap tissue	Cable at the tip of the instrument broke (Seilzug an der Spitze gerissen)	€ -	€ -
			Run of the roll	50%			Unable to grap tissue	Cable / Wire at the tip of the instrument broke	€ -	€ -
	Shaft	Bridging distance between robot and patient			0.25					
			Scratch marks/graze	100%			Not cleanable?	?	€ -	€ -
	Tips	Grabbing and cauterising tissue			0.25					
			Bent (Probably misuse)	100%					€ 1,350.00	€ 337.50
Long Bipolar Grasper						2.5				
	Tips	Grabbing and cauterising tissue			0.25					
			Bent	100%			Loss of grip	Instrument has bent jaws / yaws / tip / brances / grips / Jaws are not aligned / misaligned / Spitze ist verbogen / Branchen verschoben	€ -	€ -

	Bipolar jaw part straps	Securing the conductor wire?			1.75				
			Defect	86%			Missing part/No cauterisation	Cable / wire / Yaw-Pulley / Pulley / Seilzug at the tip of the instrument broken /defective / gerissen ; Missing fragment / plastic part / Plastikstück / Stück Plastik of the yaw pulley	€ 7.73	€ 11.60
			Defect (Probably misuse)	14%			Missing part/No cauterisation	Cable / wire / Yaw-Pulley / Pulley / Seilzug at the tip of the instrument broken /defective / gerissen ; Missing fragment / plastic part / Plastikstück / Stück Plastik of the yaw pulley	€ 290.00	€ 72.50
	Conductor wire	Conducting electricity			1.25				
			Dislocated	20%			Risk of energy leakage/No cauterisation?	The black power cable at the tip is no longer tight / sticking out more than usual / loose / Das Schwarze Kabel / Seilzug / Stromkabel / an der Spitze liegt nicht mehr eng an /guckt ungewöhnlich weit aus / locker / hevorschauendes Kabel	€ -	€ -
			Defect	80%			Risk of energy leakage/No cauterisation	Cable / wire / Yaw-Pulley / Seilzug at the tip of the instrument broke / torn / broken / defective / gerissen ; Missing fragment / plastic part / Plastikstück / Stück Plastikof the yaw pulley ; No energydispensed / No current at tip / Does not coagulate / Strom kan nicht mehr abgegeben werden / Kein Strom an der Spitze / Koaguliert nicht	€ 72.50	€ 72.50
	Shaft	Bridging distance between robot and patient			0.25				
			Defect (Probably misuse)	100%			Unable to reach patient	Shaft broken / Schaft gebrochen	€ 1,450.00	€ 362.50
	Unknown	Unknown			0.25				
			Unknown	100%			Unknown	-	€ -	€ -

C. Data modifications

In this appendix, we are showing which components and failure types we marked as ‘Unknown’.

C.1.1. Components marked as ‘Unknown’

- ‘No failure found’
- ‘Failure could not be reproduced’
- ‘Could not be reproduced’

C.1.2. Failure types marked as ‘Unknown’

- ‘Does not correspond to reported failure’
- ‘Expected condition’
- ‘External event not confirmed’
- ‘No problem reported’
- ‘No refund – No parts replaced’
- ‘Miscellaneous’

D. Systematic literature review protocol

In this appendix, we are describing the systematic literature review protocol that we used to answer the question what can cause the instrument defects according to the literature.

D.1. Key concepts

The question that we wanted to answer using systematic literature research was: ‘What can cause the defects of the Da Vinci® instruments according to the literature?’ This translates in the following key concepts:

- Cause
- Defect
- Da Vinci®
- Instrument

D.2. Inclusion and exclusion criteria

To make sure finding the most relevant sources, we defined inclusion and exclusion criteria.

D.2.1. Inclusion criteria

- *English, Dutch and German sources*
  These are the languages which we are able to understand.

D.2.2. Exclusion criteria

- *Sources which are not about Da Vinci® surgical systems*
  The focus of this study is on the Da Vinci® X and Xi systems. Nevertheless, we did not exclude sources about their predecessors (e.g., Da Vinci® S and Si systems), because their failure causes can be similar. However, we excluded other robotic systems, because they would differ too much.
- *Sources that do not mention technical defects in the summary*
  If no information regarding technical defects was mentioned in the summary, too little attention will be paid to that in the rest of the article.
- *Paid sources*
  We only included sources that we could get for free, either because they are open source or because we can access them via the University of Twente. It turned out that we could get almost any source for free.
- *Sources originated before 1995*
  In 1995 Intuitive Surgical was founded and there had not been any major robotic surgical systems before that time.

D.3. Databases

The databases that we used are PubMed, Scopus and Web of Science. The reason that we used Scopus and Web of Science, is that they contain many sources. The reason that we also used PubMed is that it contains sources which are related to health care. So, that is relevant for this topic about surgery robots.

D.4. Search terms and strategy

To find relevant sources, we needed to define search terms. We will now explain which terms we used.

D.4.1. Search matrix

In **Table 6**, a search matrix is shown in which the strategy and constructs that we used are shown. The strategy is used is PICo, for that is useful for qualitative, exploratory studies. Based on the search matrix, we defined the following search strings:

- (defect* OR fail* OR damaged OR malfunction*) AND cause* AND “Da Vinci$” AND robot* AND instrument*
- (defect* OR fail* OR damaged OR malfunction* OR error) AND (cause* OR effect* OR contribute* OR “due to” OR “because of”) AND “Da Vinci$” AND robot AND instrument*
- (defect* OR fail* OR damaged OR malfunction* OR error) AND (cause* OR effect* OR contribute* OR “due to” OR “because of”) AND “Da Vinci$” AND ("Bipolar Dissector" OR "Hot Shears" OR "Curved Scissors" OR "Bipolar Forceps" OR "Bipolar Grasper")

The reason that we did not include the related terms “broken” and “break*” is that these words have many different meanings. Further, the reason that we used “damaged” instead of “damage*”, is that “damage” is often used to describe an illness-related issue rather than a mechanical failure.

Table 6: Search matrix

PICo	Constructs	Related terms	Broader terms	Narrower terms
Population	Defect*	Break* Fail* Broken Damage* Malfunction*	Error Weak*	
Interest	Cause*		Effect* Contribut* “Due to” “Because of”	

Context	"Da Vinci$" AND "instrument*"	"Intuitive Surgical"	"Surgery robot*" "Robot-assisted" "Robot-assisted surgery" "Robot* instrument" "Minimally invasive surgery" MIS	"Curved Bipolar Dissector" "Hot Shears" "Monopolar Curved Scissors" "Bipolar Forceps" "Bipolar Grasper"

D.4.2. Search report

In **Table 7**, the results of our search for literature are shown. After reading the entire articles, we removed four articles. In **Table 8** the motivation for these removals is shown.

Table 7: Search report

Search string	Scope	Date of search	Date range	Number of entries
Search protocol for PubMed				
(defect* OR fail* OR damaged OR malfunction*) AND cause* AND "Da Vinci$" AND robot* AND instrument*	Text word	16 April 2019	1995-present	8
(defect* OR fail* OR damaged OR malfunction* OR error) AND (cause* OR effect* OR contribute* OR "due to" OR "because of") AND "Da Vinci$" AND robot AND instrument*	Text word	16 April 2019	1995-present	24
(defect* OR fail* OR damaged OR malfunction* OR error) AND (cause* OR	Text word	27 May 2019	1995-present	0

effect* OR contribute* OR “due to” OR “because of”) AND “Da Vinci$” AND ("Bipolar Dissector" OR "Hot Shears" OR "Curved Scissors" OR "Bipolar Forceps" OR "Bipolar Grasper")				
Search protocol for Scopus				
(defect* OR fail* OR damaged OR malfunction*) AND cause* AND “Da Vinci$” AND robot* AND instrument*	Article title, abstract, key words	16 April 2019	1995-present	9
(defect* OR fail* OR damaged OR malfunction* OR error) AND (cause* OR effect* OR contribute* OR “due to” OR “because of”) AND “Da Vinci$” AND robot AND instrument*	Article title, abstract, key words	16 April 2019	1995-present	48
(defect* OR fail* OR damaged OR malfunction* OR error) AND (cause* OR effect* OR contribute* OR “due to” OR “because of”) AND “Da Vinci$” AND ("Bipolar Dissector" OR "Hot Shears" OR "Curved Scissors" OR "Bipolar Forceps" OR "Bipolar Grasper")	Article title, abstract, key words	27 May 2019	1995-present	1

Search protocol for Web of Science				
(defect* OR fail* OR damaged OR malfunction*) AND cause* AND “Da Vinci$” AND robot* AND instrument*	Topic	16 April 2019	1995-2019	7
(defect* OR fail* OR damaged OR malfunction* OR error) AND (cause* OR effect* OR contribute* OR “due to” OR “because of”) AND “Da Vinci$” AND robot AND instrument*	Topic	16 April 2019	1995-2019	28
(defect* OR fail* OR damaged OR malfunction* OR error) AND (cause* OR effect* OR contribute* OR “due to” OR “because of”) AND “Da Vinci$” AND ("Bipolar Dissector" OR "Hot Shears" OR "Curved Scissors" OR "Bipolar Forceps" OR "Bipolar Grasper")	Topic	27 May 2019	1995-2019	1
Total				**126**
Removing duplicates				-59
Removing sources that do not mention defects in the summary				-49
Removing paid sources				-2
Removed after complete reading				-4
Total selected for review				**12**

Table 8: Removed articles after complete reading

Journal	Authors (Year)	Reason for exclusion
Swiss Medical Weekly	(Bodner et al., 2005)	The article mentions some failures, but it focusses on investigating the feasibility and safety of robot-assisted surgery rather than on investigating failure causes.
Journal of Endourology	(Gupta et al., 2017)	The article does not mention failure causes, for its purpose is to show a system to classify the severity of the effects of defects.
Best practice & research. Clinical obstetrics & gynaecology	(Tse, Ngan, & Lim, 2017)	The article investigates health-related complications instead of technical failure.
Spine	(Yang et al., 2011)	The main purpose of the article is describing a test of robot-assisted surgery. It does not focus on defect causes.

D.5. Results

Once we found the right sources, we read them, and categorised and synthesised the information in a concept matrix (**Table 9**).

Table 9: Concept matrix

Journal	Authors (Year)	Object	Key findings regarding causes of defects
Journal of the Society of Laparoendoscopic Surgeons	(Akbulut et al., 2011)	Da Vinci® S: Hand piece spring	A spring in the hand piece of the surgeon console disassembled, but since its only function was to push the fingers apart, the surgeon could continue the surgery by moving his fingers apart himself. Another failure of which the cause was not known was solved by restarting the system.
Surgical Endoscopy	(Ballouhey et al., 2018)	Da Vinci® Si: 5 mm and 8 mm instruments	8 mm instruments cause less instrument collisions and less parietal damage. So, also in pediatric surgery 8 mm instruments are preferred over 5 mm instruments.
Minimally Invasive Therapy & Allied Technologies	(Boggi, Moretto, Vistoli, D'Imporzano, & Mosca, 2009)	Da Vinci®: Endo-GIA stapler	Endo-GIA staplers can malfunction when a row of staples lacks or when ligation fails. From the article it cannot be concluded if this is about temporary or permanent malfunction.

American journal of surgery	(Buchs et al., 2014)	Da Vinci® S and Si: Harmonic scalpel, robotic arms, optical system	• The instrument that failed multiple times was the harmonic scalpel. This failure was caused by the tip of the instrument and the instrument needed to be replaced. • The arms of the robot malfunctioned multiple times, because the arms were not positioned well. • The optical system failed once due to a light source failure. • When the system stopped working, it could be restarted.
Surgical Endoscopy	(Corcione et al., 2005)	Da Vinci®	The arms of the robot can collide because of their large movements and their arm elevations when the patient is in an extreme position. Additionally, the article states that the large diameter (8 mm) of the instruments and the fact that the robot has only three arms can cause problems. However, it does not proof this.
Surgical Endoscopy	(Friedman et al., 2013)	Da Vinci®: Instruments	• This study categorises failures in five categories, which are, in order of frequency of reporting: wrist or tool-tip, cautery, shaft, cable and control housing. The failures types of the wrists, tool-tips and cables were primarily broken parts. The cautery failures included arcing and damaged conductor wires. The shafts broke or were scratched by scraping against the cannula or by instrument collision or misusage. The housing failures varied a lot. • Moreover, the instruments that break down most frequently are the Monopolar Curved Scissors. • Additionally, the disposable tool tip covers are fragile and require a great force to be installed.
Proceedings of SPIE	(Fuller et al., 2012)	Da Vinci®: Electrosurgical instruments	Many of the defects of electrosurgical instruments were caused by installing the tool tip cover incorrectly to the monopolar instruments. Additionally, insulation defects occurred, which can be caused by stray currents that burn away the insulation. Other causes can be using 5 mm instruments through 10 mm cannulas, re-using disposable instruments and cleaning the instruments insufficiently.
Surgical Endoscopy	(Joseph et al., 2010)	Da Vinci® S: Robotic arms	In single-incision laparoscopic surgery, the robotic arms often collide, which can cause instrument defects. This can be prevented by arranging the instruments in a ‘chopstick configuration’, which means that they cross inside the body.

Yonsei Medical Journal	(Lorenzo et al., 2011)	Da Vinci® S: Hot Shears™	The tip cover of the Hot Shears™ showed two holes, which caused a current leakage.
Journal of Endourology	(Mendez-Probst et al., 2011)	Da Vinci®: Instruments	In this study, all instruments, which were at the end of their life cycle, showed energy leakage. The causes are unknown, but causes can be using 5 mm instruments through 10 mm cannulas and re-using disposable instruments.
BJU International	(Nayyar & Gupta, 2010)	Da Vinci® S	According to this study, breakage or disconnection of wires can be caused by user-related mistakes (e.g., moving the instruments beyond their range).
Canadian Urological Association Journal	(Rajih et al., 2017)	Da Vinci® Si	Failed encoder errors and robotic arm output/power limit exceeded errors were caused by collisions of the arms or by rough handling of the instruments.

E. Instrument list

Table 10: Instrument list

Instrument number		Number of uses	Price excl. VAT
***EndoWrist®*-Instruments, 8 mm**			
***EndoWrist* Monopolar Cauterisation Instruments**			
470179	*Hot Shears™* (Monopolar Curved Scissors)	10	(*Restricted*)
470183	Permanent Cautery Hook (Monopolar)	10	(*Restricted*)
470184	Permanent Cautery Spatula (Monopolar)	10	(*Restricted*)
***EndoWrist* Bipolar Cauterisation Instruments**			
470172	Maryland Bipolar Forceps	10	(*Restricted*)
470205	Fenestrated Bipolar Forceps	10	(*Restricted*)
470344	Curved Bipolar Dissector	10	(*Restricted*)
470171	Micro Bipolar Forceps	10	(*Restricted*)
470400	Long Bipolar Grasper	10	(*Restricted*)
***EndoWrist* Clip Appliers**			
470327	Medium-Large Clip Applier	100 closures	(*Restricted*)
470230	Large Clip Applier	100 closures	(*Restricted*)
470401	Small Clip Applier	100 closures	(*Restricted*)
***EndoWrist* Needle Drivers**			
470006	Large Needle Driver	10	(*Restricted*)
470309	*Mega SutureCut™* Needle Driver	10	(*Restricted*)
470194	*Mega™* Needle Driver	10	(*Restricted*)
470296	Large *SutureCut* Needle Driver	10	(*Restricted*)
***EndoWrist* Graspers**			
470093	*ProGrasp™* Forceps	10	(*Restricted*)
470207	Tenaculum Forceps	10	(*Restricted*)
470048	Long Tip Forceps	10	(*Restricted*)
470347	Tip-Up Fenestrated Grasper	10	(*Restricted*)
470318	*Small Graptor™* (Grasping Retractor)	10	(*Restricted*)
470049	Cadiere Forceps	10	(*Restricted*)
470190	Cobra Grasper	10	(*Restricted*)
***EndoWrist* Scissors**			
470001	Potts Scissors	10	(*Restricted*)
470007	Round Tip Scissors	10	(*Restricted*)

Special Instruments			
470181	Resano Forceps	10	(*Restricted*)
470246	Atrial Retractor Short Right	10	(*Restricted*)
470249	Dual Blade Retractor	10	(*Restricted*)
470033	Black Diamond Micro Forceps	15	(*Restricted*)
470215	Cardiac Probe Grasper	10	(*Restricted*)
470036	Debakey Forceps	10	(*Restricted*)
Ultrasonic Energy Instruments			
480275	*Harmonic Ace*® Curved Shears	1	(*Restricted*)
Suction Flushing System			
480299	Suction Irrigator	1	(*Restricted*)
***EndoWrist* Bipolar Cauterisation Instruments**			
480322	Vessel Sealer	1	(*Restricted*)
480422	Vessel Sealer Extend	1	(*Restricted*)
***EndoWrist* Stapler Components**			
***EndoWrist* Stapler Starter Kits 45**			
381251	*EndoWrist* Stapler System Starter Kit - 45mm - 2x *EndoWrist* Stapler 45 Instrument, reposable - 470298 - 1x Stapler Sheath (box of 10), disposable procedural item - 410370 - 2x Stapler Cannula Kit, reusable - 470443 - 1x 12mm & Stapler Cannula Seal (box of 10), disposable procedural item - 470380 - 2x 12-8mm Cannula Reducer (box of 6), disposable procedural item - 470381 - 1x Stapler In-Service Kit - 381250-T	Not specified	(*Restricted*)
381252	*EndoWrist* Stapler System Starter Kit without Cannula - 45mm - 2x *EndoWrist* Stapler 45 Instrument, reposable - 470298 - 1x Stapler Sheath (box of 10), disposable procedural item - 410370 - 1x 12mm & Stapler Cannula Seal (box of 10), disposable procedural item - 470380 - 2x 12-8mm Cannula Reducer (box of 6), disposable procedural item - 470381 - 1x Stapler In-Service Kit - 381250-T	Not specified	(*Restricted*)

***EndoWrist* Stapler 45 Reload**			
48645W	Stapler 45 White Reload	1 Schuss	(*Restricted*)
48645B	Stapler 45 Blue Reload	1 Schuss	(*Restricted*)
48445G	Stapler 45 Green Reload	1 Schuss	(*Restricted*)
***EndoWrist* Stapler 30 Reload**			
48630M	Stapler 30 Gray Reload	1 Schuss	(*Restricted*)
48630W	Stapler 30 White Reload	1 Schuss	(*Restricted*)
48630B	Stapler 30 Blue Reload	1 Schuss	(*Restricted*)
48630G	Stapler 30 Green Reload	1 Schuss	(*Restricted*)
Instruments and und accessories for the *EndoWrist* Stapler 30/45			
470298	*EndoWrist* Stapler 45 Instrument	50 shots	(*Restricted*)
470545	*EndoWrist* Stapler 45 Curved-Tip Instrument	50 shots	(*Restricted*)
470430	*EndoWrist* Stapler 30 Instrument	50 shots	(*Restricted*)
470530	*EndoWrist* Stapler 30 Curved-Tip Instrument	50 shots	(*Restricted*)
410370	Stapler Sheath	1	(*Restricted*)
381386	Stapler Release Kit	Not specified	(*Restricted*)
Access system for the *Endowrist* Stapler, 12 mm			
470443	Stapler Cannula Kit - 1x 12mm & Stapler Cannula (100mm) - 470375 - 1x 12mm & Stapler Blunt Obturator - 470376	Not specified	(*Restricted*)
470375	12 mm & Stapler Cannula	Not specified	(*Restricted*)
470376	12 mm & Stapler Blunt Obturator	Not specified	(*Restricted*)
470389	12 mm & Stapler Cannula, Long	Not specified	(*Restricted*)
470390	12 mm & Stapler Blunt Obturator, Long	Not specified	(*Restricted*)
470380	12 mm & Stapler Cannula Seal	1 Operation	(*Restricted*)
470381	12 - 8 mm Cannula Reducer	1 Operation	(*Restricted*)
470395	12 mm & Stapler Bladeless Obturator	Not specified	(*Restricted*)
470396	12 mm & Stapler Bladeless Obturator, Long	Not specified	(*Restricted*)
Accessories			
***da Vinci X* Drapes**			

470015	Arm Drape	1	(*Restricted*)
470473	Arm-4 Extension Drape	1	(*Restricted*)
***da Vinci Xi* Drapes**			
470015	Arm Drape	1	(*Restricted*)
470341	Column Drape	1	(*Restricted*)
Reusable Accessories			
381312	Instrument Release Kit (IRK)	Not specified	(*Restricted*)
470397	Gage Pin	Not specified	(*Restricted*)
380989	Blue Fiber Cable Kit	Not specified	(*Restricted*)
342562	Instrument Introducer	Not specified	(*Restricted*)
Hasson Cone			
470398	8 mm Hasson Cone	Not specified	(*Restricted*)
470399	12 mm Hasson Cone	Not specified	(*Restricted*)
8 mm Cannulas, Obturators und Seals			
470361	5 mm - 8 mm Cannula Seal	1	(*Restricted*)
470002	8 mm Cannula	Not specified	(*Restricted*)
470004	8 mm Cannula, Long	Not specified	(*Restricted*)
470319	8 mm Flared / Grounded Cannula	Not specified	(*Restricted*)
470008	8 mm Blunt Obturator	Not specified	(*Restricted*)
470009	8 mm Blunt Obturator, Long	Not specified	(*Restricted*)
470359	8 mm Bladeless Obturator (Optical)	1	(*Restricted*)
470360	8 mm Bladeless Obturator, Long (Optical)	1	(*Restricted*)
8mm Disposable Instrument Accessories			
400180	Tip Cover Accessory	1	(*Restricted*)
Vision Equipment			
8 mm Endoscopes			
470026	Endoscope with Camera, 8 mm, 0°	Not specified	(*Restricted*)

470027	Endoscope with Camera, 8 mm, 30°	Not specified	(*Restricted*)
Sterilization Trays			
400490	Endoscope Sterilization Tray	Not specified	(*Restricted*)
Energy Equipment			
Energy Activation Cables			
371716	Energy Activation Cable, Covidien Force Triad ESU	Not specified	(*Restricted*)
371870	Energy Activation Cable, Ethicon Gen11 ESU	Not specified	(*Restricted*)
Energy Instrument Cords			
470383	Monopolar Energy Instrument Cord (13 ft. / 4 m.)	Not specified	(*Restricted*)
470384	Bipolar Energy Instrument Cord (17 ft. / 5 m.)	Not specified	(*Restricted*)
Skills Simulator™			
373373	*Skills Simulator*	Not specified	(*Restricted*)
381129	Blue Fiber Cable, Simulator	Not specified	(*Restricted*)
372363	Simulator Skills Drills	Not specified	(*Restricted*)
600092	Simulator Procedures by 3DS (annual subscription)	Not specified	(*Restricted*)
***da Vinci Xi* Integrated Table Motion**			
600062	Integrated Table Motion Upgrade	Not specified	(*Restricted*)
Training Instruments			
Training Instruments			
470001-T	Potts Scissors	30	(*Restricted*)
470006-T	Large Needle Driver	30	(*Restricted*)
470033-T	Black Diamond Micro Forceps	30	(*Restricted*)
470048-T	Long Tip Forceps	30	(*Restricted*)
470093-T	*ProGrasp* Forceps	30	(*Restricted*)
470347-T	Tip-Up Fenestrated Grasper	30	(*Restricted*)
470171-T	Micro Bipolar Forceps	30	(*Restricted*)
470172-T	Maryland Bipolar Forceps	30	(*Restricted*)
470179-T	*Hot Shears* (Monopolar Curved Scissors)	30	(*Restricted*)

470181-T	Resano Forceps	30	(*Restricted*)
470183-T	Permanent Monopolar Cautery Hook	30	(*Restricted*)
470184-T	Permanent Monopolar Cautery Spatula	30	(*Restricted*)
470205-T	Fenestrated Bipolar Forceps	30	(*Restricted*)
470207-T	Tenaculum Forceps	30	(*Restricted*)
470309-T	*Mega SutureCut* Needle Driver	30	(*Restricted*)
470215-T	Cardiac Probe Grasper	30	(*Restricted*)
470230-T	Large Clip Applier	200 closures	(*Restricted*)
470249-T	Dual Blade Retractor	30	(*Restricted*)
470318-T	*Small Graptor* (Grasping Retractor)	30	(*Restricted*)
470246-T	Atrial Retractor Short Right	30	(*Restricted*)
470344-T	Curved Bipolar Dissector	30	(*Restricted*)
470327-T	Medium-Large Clip Applier	200 closures	(*Restricted*)
470007-T	Round Tip Scissors	30	(*Restricted*)
470049-T	Cadiere Forceps	30	(*Restricted*)
470296-T	Large *SutureCut* Needle Driver	30	(*Restricted*)
470194-T	*Mega* Needle Driver	30	(*Restricted*)
470190-T	Cobra Grasper	30	(*Restricted*)
470401-T	Small Clip Applier	200 closures	(*Restricted*)
470036-T	Debakey Forceps	30	(*Restricted*)
470400-T	Long Bipolar Grasper	30	(*Restricted*)
470430-T	*EndoWrist* Stapler 30 Instrument	125 shots	(*Restricted*)
470530-T	*EndoWrist* Stapler 30 Curved-Tip Instrument	125 shots	(*Restricted*)
470298-T	*EndoWrist* Stapler 45 Instrument	125 shots	(*Restricted*)
470545-T	*EndoWrist* Stapler 45 Curved-Tip Instrument	125 shots	(*Restricted*)
382048-01T	Stapler 45 Demo Reload	Not specified	(*Restricted*)
382051-01T	Stapler 30 Demo Reload	Not specified	(*Restricted*)
Documentation and System Support Accessories			
381230	*da Vinci X - da Vinci Xi* Documentation Kit	Not specified	(*Restricted*)
554023	*da Vinci X* User Manual	Not specified	(*Restricted*)
551413	*da Vinci Xi* User Manual	Not specified	(*Restricted*)
551470	*da Vinci X / da Vinci Xi* Instruments & Accessories Manual	Not specified	(*Restricted*)
470611	Cleaning & Sterilization Kit	Not specified	(*Restricted*)

Single-Site®-Instruments, 5 mm			
478050	5 mm Maryland Dissector	10	(*Restricted*)
478053*	5 mm Medium-Large Clip Applier	80 closures	(*Restricted*)
478054	5 mm Suction Irrigator	20	(*Restricted*)
478055	5 mm Cadiere Forceps/Grasper	10	(*Restricted*)
478057	5 mm Curved Scissors	7	(*Restricted*)
478058	5 mm Fundus Grasper	10	(*Restricted*)
478059	5 mm Crocodile Grasper	10	(*Restricted*)
478080	5 mm Maryland Bipolar Forceps	1	(*Restricted*)
478088	5 mm Curved Needle Driver	10	(*Restricted*)
478090	5 mm Permanent Cautery Hook	10	(*Restricted*)
478093	5 mm Fenestrated Bipolar Forceps	1	(*Restricted*)
478115	5 mm Wristed Needle Driver	10	(*Restricted*)
Reusable Accessories			
***Single-Site* Cannulas und Obturators**			
478263	8 mm Camera Cannula	Not specified	(*Restricted*)
478008	8 mm Blunt Obturator	Not specified	(*Restricted*)
478013	5 mm Blunt Obturator	Not specified	(*Restricted*)
478060	5 mm Accessory Cannula	Not specified	(*Restricted*)
478061	5 x 300 mm Curved Cannula, Camera Right	Not specified	(*Restricted*)
478062	5 x 300 mm Curved Cannula, Camera Left	Not specified	(*Restricted*)
428064	5 x 300 mm Flexible Blunt Obturator	Not specified	(*Restricted*)
478071	5 x 250 mm Curved Cannula, Camera Right	Not specified	(*Restricted*)
478072	5 x 250 mm Curved Cannula, Camera Left	Not specified	(*Restricted*)
428074	5 x 250 mm Flexible Blunt Obturator	Not specified	(*Restricted*)
428076	10 mm Accessory Cannula	Not specified	(*Restricted*)
428084	10 mm Blunt Obturator	Not specified	(*Restricted*)
***Single-Site* Disposable Accessories**			
***Single-Site* Seal und Port**			
478161	*Single-Site* Seal (Instruments + Camera)	1	(*Restricted*)

478065	*Single-Site* Port (for 8 mm Endoscope)	1	(*Restricted*)
***Single-Site* 5 mm-Training Instruments**			
478050-T	5 mm Maryland Dissector	30	(*Restricted*)
478053-T	5 mm Medium-Large Clip Applier	100	(*Restricted*)
478054-T	5 mm Suction Irrigator	50	(*Restricted*)
478055-T	5 mm Cadiere Forceps	30	(*Restricted*)
478057-T	5 mm Curved Scissors	15	(*Restricted*)
478058-T	5 mm Fundus Grasper	20	(*Restricted*)
478059-T	5 mm Crocodile Grasper	20	(*Restricted*)
478088-T	5 mm Curved Needle Driver	20	(*Restricted*)
478090-T	5 mm Permanent Cautery Hook	20	(*Restricted*)
478115-T	5 mm Wristed Needle Driver	20	(*Restricted*)