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heartstitch
the art of cardiac intervention

Bachelor of Engineering Thesis

Biomedical Engineering Course at the University of Applied Sciences in Zwickau

# Development of a suture-based device for mitral valve repair


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## Abstract

This bachelor thesis is about the development and design of the suture-based HeartStitch MR device for functional restoration of the mitral valve when a mitral regurgitation is present. The mitral valve is one of the four existing heart valves and due to their load, the mitral valve is most commonly affected by valve defects. In principle two different malfunctions can be distinguished; on the one hand the valve stenosis, in which the leaflets of the valve do not open sufficiently to pump the blood forward. On the other hand, the valve insufficiency, in which the leaflets are no longer completely closing. That causes that the blood of the chamber flows back into the atrium. In case of a mitral regurgitation, the leaflets of the mitral valve are not closing tight enough, which causes a reflux of the oxygenated blood from the left ventricle into the left atrium. As consequence, the human body won´t be sufficiently supplied with oxygen anymore, which results in a disproportionate cardiac output. Untreated, this can lead to respiratory distress, cardiac arrhythmias and stroke or even to death. In this case, a heart surgery is essential to improve the patient's life. The operation method for this device, based on the surgical technique of Dr. Alfieri, implies that the two leaflets of the mitral valve are sutured together and the suture material is tight together by using a knot below the mitral valve.

The significant development of the device was concerned to take into account the physiological and anatomical characteristics of the user and to find methodical solutions for the present task. However, the main task was to design a mechanism to replace the lever of the original design with a button. First prototypes were produced with use of common household objects to implement the considered mechanisms. Later designs were created with the help of the 3D program SolidWorks and implemented into practical prototypes with the 3D printer. The individual prototypes were tested and developed to produce a working prototype of the mechanism. Not only the individual tests of the prototypes, also prepared failure modes an effects analysis had an impact of the development. As result, the mechanism will be integrated into the original device and surgeons will use it in the future. In addition to the successfully development, the company has registered an U.S. patent.

## Autorenreferat

Die vorliegende Bachelorarbeit beschreibt die Weiterentwicklung und das Design des nahtbasierten HeartStitch MR Instruments zur Funktionswiederherstellung der Mitralklappe bei einer vorliegenden Mitralklappeninsuffizienz. Die Mitralklappe ist einer der vier vorhandenen Herzklappen und ist Aufgrund ihrer Belastung von den Klappendefekten am häufigsten betroffen. Prinzipiell können zwischen zwei verschiedenen Defekten unterschieden werden; zum einen die Klappenstenose, bei der sich die Segel der Klappe nicht mehr weit genug öffnen um das Blut voranzutreiben oder die Klappeninsuffizienz, bei der sich die Segel der nicht mehr vollständig schließen und das Blut somit von der Kammer zurück in den Vorhof fließt. Im Falle einer Mitralklappeninsuffizienz, schließen die Segel der Mitralklappe nicht mehr vollständig, was zum Rückfluss des sauerstoffreichen Blutes von der linken Herzkammer in den linken Vorhof führt. Der menschliche Körper wird daher nicht mehr ausreichend mit Sauerstoff versorgt, was eine überproportionale Herzleistung nach sich zieht. Unbehandelt kann dies zu Atemnot, Herzrhythmusstörungen, Schlafanfall oder auch bis zum Tod führen. Eine Herzoperation ist notwendig um das Lebens des Patienten wieder zu verbessern. Die Operationsmethode des vorliegenden Instrumentes wird auf die Operationstechnik von Dr. Alfieri gestützt, welche beinhaltet, dass die beiden Segel der Mitralklappe zusammengenäht und das Nahtmaterial unterhalb der Mitralklappe mittels eines Knotens befestigt wird.

Die wesentliche Weiterentwicklung des Instrumentes befasste sich sowohl damit, die physiologischen und anatomischen Gegebenheiten des Anwenders zu berücksichtigen, als auch methodisch Lösungen für die vorliegende Aufgabenstellung zu finden. Jedoch bestand die Hauptaufgabe darin, einen Mechanismus zu konstruieren, der den Hebel des Originalgeräts mit einem Knopf ersetzt. Für die Umsetzung der verschiedenen überlegten Mechanismen wurden zunächst haushaltsübliche Gegenstände verwendet, um erste Prototypen herzustellen. Später wurden Zeichnungen mittels des 3D-Programms SolidWorks erstellt und mit dem 3D-Drucker in praktische Prototypen umgesetzt. Die einzelnen Prototypen wurden getestet und ebenfalls weiterentwickelt um einen funktionierenden Prototypen des Mechanismus herzustellen. Einfluss auf die Weiterentwicklung hatte nicht allein nur die einzelnen Tests der Prototypen, sondern ebenfalls durch die angefertigte Fehlermöglichkeits- und Einfluss Analyse. Resultierend soll der Mechanismus künftig in das Originalinstrument integriert und von Chirurgen angewendet werden. Neben der erfolgreichen Weiterentwicklung konnte ebenfalls ein U.S. Patent durch die Firma angemeldet werden.

## Note of thanks – Danksagung

Because this thesis has emerged in cooperation with the Zwickau University and the companies HeartStitch Inc., I want to thank first and foremost to my supervisors. The Thanks is due to my university side supervisor Prof. Dr.-Ing. Leonore Heiland who supported me with constructive criticism and questions from and in Germany during the processing of my Bachelor project in America. The gratitude is also addressed to Prof. Anthony Nobles, who helped a lot with the development of the project during the 12-week internship and the subsequent time to deepen the Bachelor thread with critical questioning. I thank my two supervisors for the support, the time and the invested effort they have invested in my work.

I also would like to thank Michael Heidel, who has invested much time in correcting my bachelor thesis with its strong language skills. Numerous set positions, forgotten commas and spelling mistakes has been mended and corrected with his help.

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## List of used symbols and abbreviations

| | |
|---|---|
| FMEA | Failure Mode- Effects Analysis |
| FTA | Failure Tree Analysis |
| RPN | Risk priority number |
| TTE | transthoracic echocardiography |
| TEE | transoesophageal echocardiography |
| IFU | Instructions for use |
| PQ | Production Qualification |
| PPQ | Process Performance Qualification |

# 1. Introduction

With the progress of demographic change and the associated increase in life expectancy of the population also increases the likelihood of a lethal disease to cancer. In Germany, the life expectancy for women is now about 86 years, at around 82.5 years for men. Factors affecting current life expectancy are by rising health consciousness and conscious lifestyle. Especially in the progress of today's technology and the ever ongoing research in the field of medicine and preventive measures an increase of the age of the patient is recorded.

Due to the frequently occurring in age-related diseases such as diabetes, arthritis, cancer and diseases of the lungs and bronchi, a large proportion of aged patients occupies the heart disease. At the age thus increases the risk of heart attack and many older and younger patients suffer from one or more heart disease such as cardiac arrhythmia, coronary artery disease and heart failure. Those heart diseases can be caused by a defect of the heart valves, it suffers the patient has a loss of the heart performance, which can be turn into limits in daily life. Therefore, therapeutic and surgical interventions are unmissable depending on the severity of the valve defect.

Until a few years', difficult operations on valvular apparatus were made in an open heart surgery. With the current state of technology, however, attempts to perform such surgical procedures minimally invasive in order to minimize the risk of infection as well as the healing process and minimize engagement in the cardiovascular system. Therefore, the focus is set in research and development on such minimally invasive devices. Since most minimally invasive instruments have a rather complicated structure and operation, many users of such instruments with the large number of buttons and simultaneous functions are distracted. Therefore, users need to change the grip during the procedure several times to use the instrument effective and safe. Therefore, the development of instruments such as the HeartStitch MR, which is used for operation of the mitral valve and the KwiKnot, which is used to place a knot on a suture after an operation, especially to meet the needs and the ease of operations and the ergonomics of the users The user should be able to use the instrument easy, secure and use efficiency so that greater complications in minimally invasive area can be avoided. In the development the surrounding area, entertainment and the anatomical circumstances of individual users are taken into consideration and tried to improved and implement**.**

# 2. Theoretical principles

## 2.1 Anatomy and physiology of the heart

The heart, which pumps nearly 5,6l blood per minute, is the most important muscle in the human body. The size totals around one and a half of a fist. The weight of a woman´s heart is about 280g and the weight of a man´s heart is approximately 330g and may vary on the gender, age and condition of the carrier [1, p. 216]. It is inclined to the right side and is in between the two lungs directly below the sternum. On the 5$^{th}$ level of the intercostal space the heart apex touches the chest wall [1, p. 214]. The function of the heart is to keep running the systemic circulation of the blood. The left heart pumps oxygenated blood from the pulmonary system to the organs. The right heart pumps deoxygenated blood from the organs back to the pulmonary circulation. The heart circulatory system is essential to support the organs with blood. In case of failure of this circulatory system the organs are not adequately supplied with blood and transport substances such as oxygen, in this case the organs are unable to perform their functions efficiently. In general, the heart consists of four chambers and is divided by the septum into the left and right side. Each side consists of two chambers; an atrium and a ventricle. As described above, the left ventricle takes the oxygen-rich arterial blood from the pulmonary circulation and the right ventricle, takes the oxygen-depleted, venous blood from the systemic circulation. Besides the four chambers there are four valves that ensure the direction of the blood flow. In the middle of the right atrium and ventricle is the tricuspid valve and in the middle of the left atrium and ventricle is the mitral valve. Besides those both valves is the pulmonary valve which is between the right ventricle and the pulmonary artery and the aortic valve which is in between the left ventricle and the aorta. In addition to the heart interiors the heart also has the heart muscle, fibre tracts ranging from the cardiac skeleton to the apex surrounds it. Because of the various forces that are effecting the heart interiors, the left heart wall has a greater thickness than the right heart wall. Thus, it comes to the efficient cardiac cycle and the circulation of the blood. Particular important is the systole and diastole. The systole describes the contraction of the heart wall and the diastole describes the respective relaxation of this. A cardiac action begins with the atrial systole and a simultaneous diastole of the ventricles. This is followed by the systole of the ventricles and concurrent diastole of the atria. [1, p. 220] The systole in the chambers is differentiated into two different phases. The exertion phase, where the heart muscle contracts and closes the atrioventricular valves it comes to an isovolumetric contraction. Isovolumetric means that the contained blood in the heart is incompressible and the volume remains constant. Due to the increasing pressure during the expulsion, the semilunar valves opens and the blood is flows out. Towards the end of the systole, the arterial pressure is higher than the ventricular blood pressure, while it comes to the closing of the semilunar valves.

### 2.1.1 Arrangement and function of the heart valves

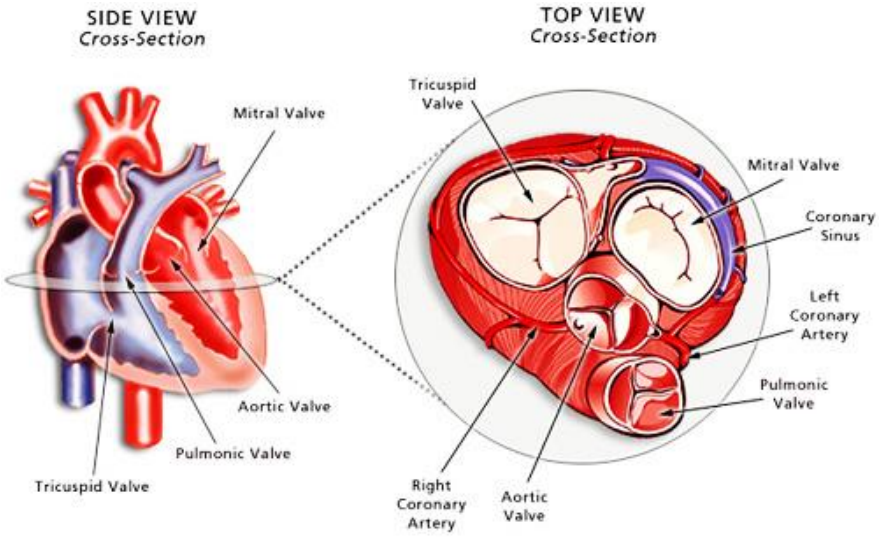


***Figure 2-1-1**: Arrangement and illustration of the four heart valves [2]*

“The valves of the heart are located within the chambers of the heart and are critical to the proper flow of blood through the heart.” [2] As described in the previous chapter, the heart valves are essential for the correct course of blood through the heart and the human organism. In general, the heart has four heart valves. There are two atrioventricular valves, the tricuspid valve which, has three leaflets and the mitral valve, which has two leaflets. Both valves are located between an atrium and a ventricle. Besides the atrioventricular valves, the heart has also two semilunar valves. The pulmonary valve and the aortic valve. These described valves have the function to ensure no backflow or regurgitation in the heart. All valves have flexible leaflets that will open and close to ensure the correct flow of the blood. The cardiac skeleton representing the connective tissue that manifests itself in connective tissue rings at each valve, surrounds the heart valves. [1, p. 218] At the transition of the Rings to the respective valves, this tissue distributed in triangular fibreboard. As shown in the top view of the cross-section figure 2-1, all four valves are approximately on one level in the cardiac skeleton. Thist level is also referred as a valve level.

The function of each valve is to open wide enough that blood is able to flow into the circulation and close tight enough to avoid a regurgitation. The opening and closing of the heart valves are caused by the systole, the blood-efflux phase and by the diastole, the blood-inflow phase of the heart muscle. When the ventricles are filled with the blood at the zero incidence of the atria, they begin to contract, while there is a growing pressure in the chambers. [3] The resulting pressure ensures the closing of the mitral- and tricuspid valve, that avoids a backflow of blood into the atria. The further pressure development causes to the opening of the pulmonary and aortic valve. During the completion of the systole, the ventricles get empty because of the outflow of blood through the pulmonary and aortic valves. The semilunar valves will close, that

avoids the backflow of the blood from the aorta and the pulmonary artery. During this process the two atrioventricular valves reopen almost simultaneously. This will cause that the two chambers can fill with blood again. The different processes in the cardiac cycle are illustrated in table 2-1.

***Table 2-1:*** *Cardiac cycle and internal processes [4]*

| Cardiac Cycle Phase | Atrial state | Ventricular state | State of Atrioventricular valves | State of Aortic and pulmonary valves |
|---|---|---|---|---|
| Passive filling | relaxed | relaxed: filling | open | closed |
| Atrial contraction | contracting | relaxed: filling | open | closed |
| Ventricular isovolumetric contraction | relaxed | isovolumetric contraction | closed<br>*1st sound heart | closed |
| Ejection | relaxed | contraction: ejection | closed | open |
| Ventricular isovolumetric relaxation | relaxed | isovolumetric relaxation | closed | closed<br>*2nd sound heart |

The table shows that both valves in the ventricular isovolumetric contraction and relaxation are closed. In these phases, the first and second heart-sound is audible. In all other phases, the atrioventricular and pulmonary valves are located in the respective opposite state.

### 2.1.2 Valve defects and their causes

If a malfunction of the heart valves in the cardiac cycle occurs, it can lead to harmful chain of events. In general, it can be distinguished in a valvular stenosis and a valvular insufficiency. A combination of both defects is also predictable.

A valve stenosis of an affected valve manifests itself in an inadequate opening of the leaflets and thereby leads to restricted cardiac output. Contrary to the valvular valve, the leaflets of the affected valve close no longer sufficient to prevent the backflow of the blood. This defect is called valvular insufficiency. Depending on the present valve defect and affected valve the malfunction is further defined as aortic stenosis or aortic regurgitation, pulmonary stenosis or pulmonary insufficiency and tricuspid stenosis or tricuspid regurgitation. Due to the forces of a high pressure, the mitral valve is the most affected valve in the heart. The acquisition and the causes of those malfunctions can be caused by calcification and changes of the valve components, inflammation and infections such as myocarditis or endocarditis. Approximately 10% of all defects are innate. [5]

### 2.1.3 Mitral regurgitation

With approximately 70% of valves defects the mitral valve is most affected. [1, p. 218] The mitral regurgitation manifests itself with the leak of the closing leaflets of the mitral valve. Because of this, the heartbeat is a reflux of the inflowing oxygen-rich blood of the left pulmonary vein from the left ventricle back to the left atrium. The congesting and oscillating blood volume causes together with the re-incoming blood in the advancing course to dilatation of the atrium. [6] In high-grade forms a development of an elongation of the left ventricle is also possible. The pendulum volume causes a performance limitation over the course of this malfunction. This is also referred as left heart insufficiency. The further course of the mitral regurgitation may result in a fatal heart failure.

When a mild mitral regurgitation occurs, the affected patient usually remains symptom free. General performance degradation, rapid fatigue, dyspnoea, arrhythmia, tachycardia until atrial fibrillation may occur as symptoms of a severe mitral regurgitation. [6] An insufficiency caused by anomalies of the heart valves apparatus, is referred as primary mitral regurgitation. A secondary mitral regurgitation is given, in case of pre-existing conditions and defects of the heart.

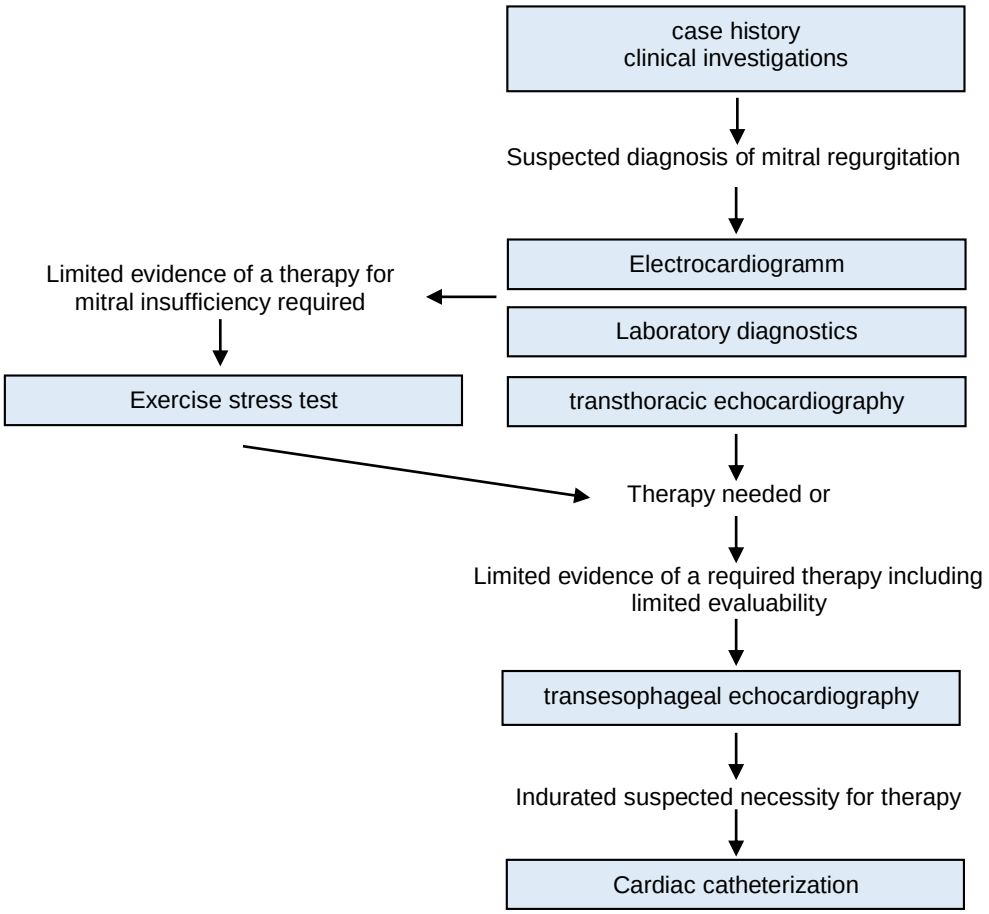


**Figure 2-1-2:** Simplified Schematic of clinical diagnostic procedure of mitral regurgitation. translated and simplified from its original [7]

The diagnostic methods are directly related to the classification of the severity degree of mitral insufficiency. The figure 2-1-2 is an illustration of the sequence of diagnosis. At the beginning is the case history, where clinical examination like auscultation is performed and the recording of clinical symptoms suggestive deduce possible mitral insufficiencies are performed. Such symptoms manifest themselves, for example, in dyspnoea, dizziness or shortness of breath. Auscultation is for detecting body sounds like the characteristic heart sounds and cardiac murmurs. In the course of a comprehensive diagnostic an electrocardiogram is taken and analyzed. Here, the focus will be especially laid on heart rhythm and conduction system of the heart. If the analysis is able to infer suspicions of a therapy needy insufficiency, but the suspect is not confirmed, a stress test needs to be performed. In addition to the stress test a transthoracic echocardiography is also possible to performed. At the transthoracic echocardiography – short TTE, the heart is analyzed by ultrasound. In this case a sound head is placed in various positions on the outside on the chest wall. With this non-invasive method of examination morphological classification of the severity of mitral regurgitation can be carried out. In principle, the chronic malfunction is divided into three different levels of severity.

According to the heart surgeon Alain Carpentier, the mitral regurgitation can be morphologically divided into three levels of severity: In case of a dilation of the valve, it is called grade 1 of the malfunction. In grade 2, is the mitral valve prolapse, in which the systole causes the curvature of the leaflets, described. If deformed leaflets do not return back into the original position, a malfunction of grade 3 occurred. [8] In order to enable an optimization of the surgical and interventional therapy plan, a transoesophageal echocardiography – short TEE can be performed. [7] Here, the derivation is improved by the oesophagus via an endoscope by means of the transducer in the near the heart.

In the final invasive cardiac catheterization, the filling performance of the left atrium is investigated. The contrast agent is introduced into the left ventricle to examine the severity of mitral regurgitation and its extent. The levels of severity are divided into four stages. In grade I, the atrium is not completely in contrast, therefore this level is on a minimal mitral regurgitation. In case of a completely opacification in the left atrium, the contrast of the left ventricle still differs in its intensity. This is called grade II with a regurgitation fractionation of 20-40 percent. Grade III describes the malfunction of 40-60 percent. In this case, the contrast intensity of the left atrium and left ventricle is on the same level. Once immediately contrasted with injection of the contrast agent the left atrium is contrasted in the first action of the heart and the pulmonary veins are also contrasting. This level is referred as grade IV of up to 80 percent. [8,]

A present heart failure is restricted by the pump performance of the heart. Based on the NYHA classes different heart failures can be divided. The NYHA classes, published by the New York

Heart Association, are related to the performance of the patient in the following classes: NYHA I describes the heart disease without any physical limitations. Class NYHA II describes the limited to patients only a small extent, the patient suffers no specific complaints in the resting phase. With stronger limitations of performance in the usual physical stress without restrictions in the resting phase is referred as NYHA III. NYHA IV is determined when it comes to complains of physical activity as well as in non - activity rest. [9]

To improve the living conditions and symptoms like dyspnoea, nocturnal coughing attacks and general underperformance of the patient, various therapeutic interventions such as medication or operation are used. These interventions are depending on the level of severity; the mitral regurgitation is distinguished between primary or secondary mitral regurgitation.

### 2.1.4 Therapeutic and operative interventions for mitral regurgitation

As explained in the previous chapter, the treatment depends on analysis of severity of symptoms and the level of performance of the affected patient. In general, the treatment options can be divided into three different categories, the medical, surgical or nonsurgical interventions.

The symptoms caused by the mitral regurgitation, can be alleviated with a drug therapy. Drugs that are able to reduce side effects like high blood pressure or fluid retention in the lower limbs, are for example ACE angiotensin 2 blockers, beta-blockers or diuretics. The applied drugs alleviate the symptoms, but they cannot cure the mitral regurgitation.

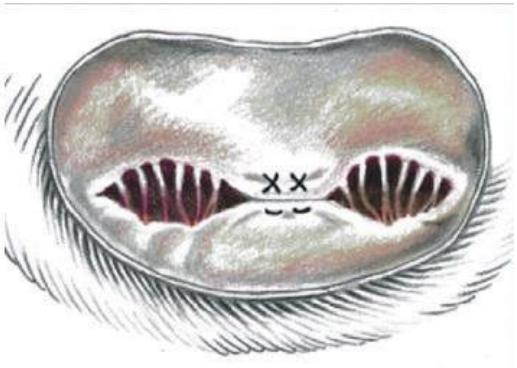

**Figure 2-1-3**: Schematic representation of the double opening of the mitral valve after a surgical "Alfieri stitch" which presents itself the same through the MitraClip®. [10]

In the surgical intervention, where a surgery on the heart takes place, is used when a severe symptomatic of the mitral regurgitation is present. Two techniques are possible, the valve repair and the valve replacement. When a valve repair takes place, the leaflets of the valve, will be stitched together as shown in figure 2-1-3. The function of the valve can be reconstructed. In this way, with the difference that the blood flows through two small holes. However, this is

only applicable for patients whose own valve indicates no serious damage and can be accordingly obtained. The operation method, also called Alfieri stitch, was established by the Italian cardiac surgeon Alexander Alfieri in the early 1990s. [11, p.1.]

If a valve replacement is necessary to correct the malfunction, the damaged valve will be replaced by a bio-prosthetic or mechanical valve. [9] The operation is performed on an open-heart, while the patient is connected to the heart-lung machine. This machine takes over the function of the lungs and heart during the procedure. The advantage of mechanical prostheses is their long durability. Patients with such a prosthesis are long life depending on drugs which reduce blood clotting and preventing the formation of a blood clot on the prosthesis and ensures their function. The durability of biological prosthesis´ are lower, because they are made out of porcine heart valves or pericardial tissue of cattle. The advantage is that medications used at mechanical prosthesis are not necessary, because of the low durability. It can happen that the heart valve has to be operatively treated or replaced again. Not every patient with a high degree of mitral regurgitation can be surgically treated, because their age or their accompanying symptoms.

The non-surgical method is used for patients who cannot be treated operative and suffer from moderate to severe mitral regurgitation. Here, the minimally invasive MitraClip procedure is used, which has the same effect as the Alfieri stitch. The MitraClip is guided by a catheter through a vein in the groin to the heart and is attached to the leaflets of the valve. This procedure can be performed on the beating heart under general anaesthesia while a heart-lung machine is not required. The clip allows the heart to work efficiently again, thus improving the quality of life and reduces the symptoms of the previously NYHA classified mitral regurgitation. [9] Advantage of this intervention is that patients with primary mitral regurgitation, high risk for operations or with a high age can be treated. Another advantage is the short operation time of up to one hour. Long-term effects cannot be estimated for patients so far, because of the novelty of this surgery method. As with other treatment methods, the patient is further examined by TTE or in special suspicion with TEE. Another minimally invasive surgical method also provides the HeartStitch MR product of HeartStitch Inc., which is described in the next chapter.

About the innovations in the field of valve replacement, as recorded in figure 2-1-4 reconstructing is an important part occupies in contrast to spare. The chart shows the operated mitral valve by reconstruction or valve replacement at the German heart centre in Munich from 1991 to 2008, while the numbers of the mitral valve replacement are falling over the years. Generally, it can be inferred that the possible preservation is primarily aimed to the patient's heart valve.

**Figure 2-1-4:** Proportion of patients with mitral valve replacement and reconstruction, Deutsches Herzzentrum, Munich 1991 – 2008. [12]

### 2.1.5 Illustration, function and surgical method of the HeartStitch MR device.

The HeartStitch MR product is a surgical instrument and serves the function of restoring the mitral valve by using a minimally invasive surgery. Like the MitraClip the surgical procedure with the HeartStitch MR device can also be performed under general anaesthesia on a beating heart.

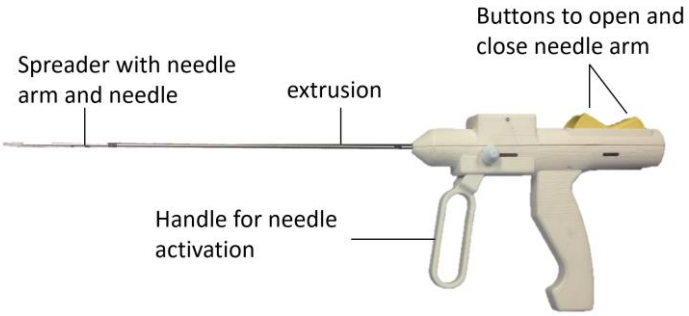


**Figure 2-1-5:** HeartStitch MR device [13]

The device, shown in figure 2-1-5, has a proximal handle with two buttons for opening and closing of the needle arm and a lever for activating the needle. Between the handle and the distal end is an extrusion of sterile and biocompatible nitinol. At the distal end is the needle arm with the needle placed, which are used to suture the leaflets. On the top is a flexible tip to avoid damaging of the surrounding tissue. This device is used in case of a mitral regurgitation of grade III or grade IV occurs. The package for the surgical intervention, with the HeartStitch MR, includes the Instruction for Use and two HeartStitch MR devices and one KwiKnot device to set a node on the resulting stitches.

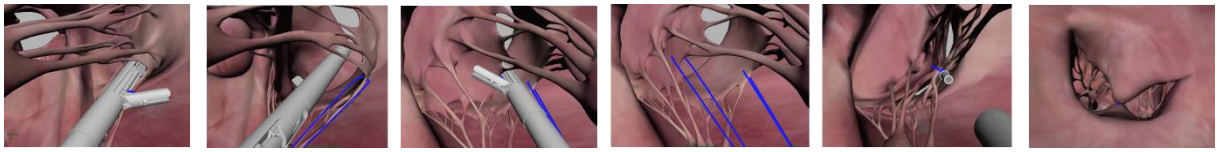

**Figure 2-1-6:** Methodical illustration of the operation using the HeartStitch MR. [13]

The surgical method of the device is based on the Alfieri Stitch. This technique is also called edge-to-edge technique because the ends of the leaflets are stitched together. The access to the mitral valve is set by a catheter placed transapical through the 5$^{th}$ intercostal space. The patient is operated under general anaesthesia and need not be artificially ventilated. First, the instrument is in the closed position and is guided through the catheter into the heart. To catch the moving leaflets of the mitral valve, a guidewire is used which is first steered in one direction of the pulmonary vein. As shown in the first picture of figure 2-1-6, the device after the insertion into the heart. The needle arm will be opened by pushing the first yellow button. The moving leaftlet will be catched by using the in the pulmonary vein bended guidewire. With the activation of the lever, the needle will be deployed and stitches through the tissue of the leaflet to catch the suture donut. The needle continues holding the suture and will be retracted into the spreader. As shown in the second picture of figure 2-1-6 the device will be withdrawn to release the catched leaflet. The needle arm is retracted by pushing the second yellow button. The whole device will be withdrawn out of the heart, which results the first stitch in the first leaflet. For the stitch in the second leaflet a new device is inserted through the catheter another guide-wire is used which is bent into the other direction of the pulmonary vein to catch the second leaflet. Here, shown in the third and fourth picture the described steps will be repeated which, results in a second stitch in the other leaflet. To complete the operation on the mitral valve, a tight node is added to the two existing sutures by using the KwiKnot device. In that way, the function of the mitral valve is reconstructed, thereby the mitral valve can close again with the difference that the blood is flowing through two smaller openings, as shown in the last picture of figure 2-1-6. At the end of the surgical procedure the created whole in the apex of the heart and in the intercostal space will be closed.

The described minimal-invasive intervention with the HeartStitch MR unless further complica-tions needs about 15 minutes. The whole intervention from the beginning to introduce the cath-eter and close the whole in the end needs about one hour. If there are no complications, the patient can live a long life with this reconstruction without having to be re-operated. Like the other intervention the patient has to be investigated with the use of the TTE or TEE. Long-term effects, as well as further need for treatment, cannot be assessed due to the novelty of the method of operation.

## 2.2 Basics of mechanics

### 2.2.1 Gears and their functions

A gear refers to a machine element which has evenly distributed teeth over a circumference. By means of the located teeth gears rotary motion can be transferred from one shaft to a second. Of the positive connection of the adapted teeth, high forces can be transmitted. Depending on the size and arrangement of the gears either a high force impact or quickness can be transmitted. The combination of two or more gears is called Transmission. A pair of wheels is always composed of a driving gear and a driven gear. [14, p. 557] Here, different wheel elementary forms also play an important role. In summary, a distinction is made between spur gears, bevel gears helical gears and racks. Spur gears are also referred as cylindrical gears. If spur or helical gears are interacting in case of external gearing, the wheel axles are parallel as shown in figure 2-2-1 a). In case of internal spur gears, the internal toothed wheel is also called ring gear. Here, only rotary motions are transmitted. In order to transfer rotary motion to the rectilinear motion a rack in combination with an external gear are used. This is illustrated in figure 2-2-1 d). If the rotary motion is transferred from horizontal to vertical, bevel gears like in figure 2-2-1 e) are used, which overlap the wheel axles. Here, both straight teeth and helical gears may occur. In the last basic shape are various combinations, such as the worm gear or helical-screw-wheel-pair for the helical gears are possible. This is shown in figure 2-2-1-i)

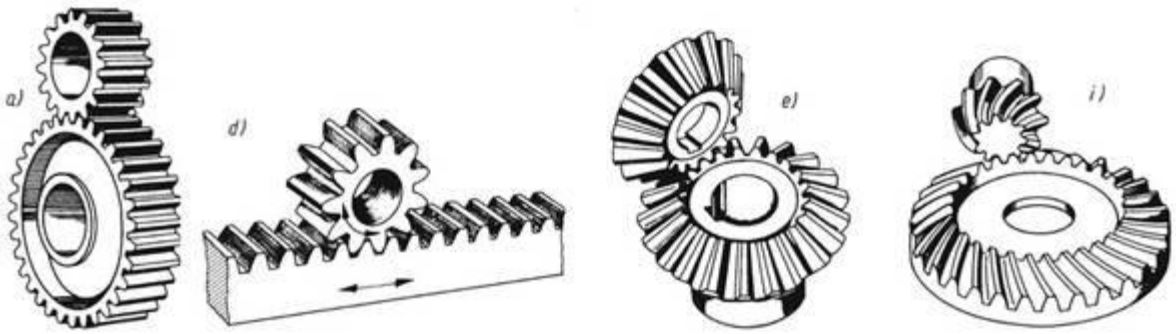


**Figure 2-2-1:** Basic types of gears depending on the position of the wheel axles mutual relatedness: a) cylindrical gear, straight teeth, d) rack with an external gear, e) bevel gear with straight teeth, i) cone screw-wheel-pair [16]

In addition to the various gear types, the application of these different types of toothing is important. Here, the general law of gearing is applied, which describes how a tooth has to be shaped to ensure an interference for a free rotary motion between interlocking gears. [15] That means that on the tooth flanks, should have a slip-free motion at their contact points. This ensures that, the contact points always pass the pitch point. At a correct gearing the flank points have to touch and the vectors of velocity are perpendicular to the pitch points. The teeth

will not lift off if the speed of ratio of input and output need to be the same transmission as well as the both interlocking gears.

Generally, there are two different gearing types. The so called cycloidal and the involute. Involute is the most important gearing type in a machine construction. This results in the tooth flank geometry. Required for that is the law of gearing. The requirements are fulfilled by the geometry of an involute of a circle, which has the aim to minimize the wear and heat development at the sliding surfaces: This helps to transmit smooth rotation with a constant ratio. The specific case of the involute lies in the fact that the line of action is even.

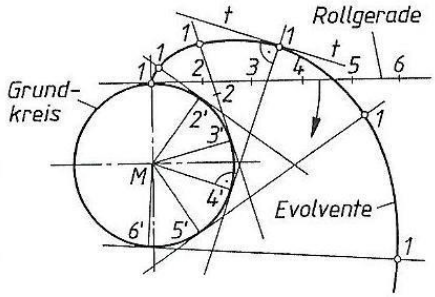


**Figure 2-2-2:** Construction of the involute (german: Evolente) between the steps 1-6 by using the rolling line (german: Rollgerade) on the base circle (german: Grundkreis) [17]

The design of the involute is effected by the means of the base circle and the rolling line. However, the basic circuit is unrolled with the tangential rolling straight and binds with the constructed path of the involute.

When the engagement line consists of two circular arcs, this type is referred as cycloidal. Here, is a pitch used instead of a rolling line that forms other cycloids on different rolling underlays.

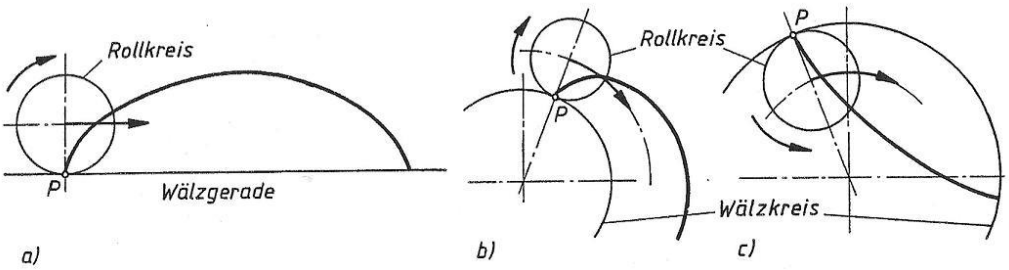


**Figure 2-2-3:** Construction of the cycloidal by using a pitch (german: Rollkreis) on a) straight under layer b) circular under layer on the outer surface and c) circular under layer at the inner surface. [17]

When the pitch is rolling on a straight under layer, it forms the orthocycloide as shown in figure 2-2-3. If the pitch is following on the outside of the circular under layer it forms the epicycloide. On the inside of the circular under layer, it forms the hypocycloide. The toothing is engaged with a convex concave and a curved edge profile. Through the conform of the tooth flanks, the tooth wear is low and thus the carrying capacity of gears increases. The production of a cycloid

is costly and time consuming. That is why this gearing is only used in special areas such as precision engineering. The advantage of the tooting is, to produce the gears with small numbers of teeth. [17] A special form of cycloidal is the lantern gear. It is attemted to minimize the wear and tear with the increasing diameter in which the bolt is adapted to the pinion of the gear. Applications of this form are in areas where a large translation is required, such as at carousels or rotary crane works.

### 2.2.2 Basis of calculation of the zero external gearing

Zero external gearing means, that the teeth of a gear have no profile shift. That is why a spur gear is present. It specifically corresponds to the pitch circle of the gear wheel, whereby no difference between the two parameters is given. For the transfer of an undisturbed rotation motion it is necessary to calculate important parameters such as the pitch diameter *d*, the module *m* and the number of teethes *z* are necessary. Another important parameter is the circular pitch *p*, that corresponds with the length of the partial arc between two successive and identical flanks. This is shown in figure 2-2-4. When the circular pitch *p* is multiplied with the number of teethes *z*, the pitch circumference *U* results. [14, p. 571]

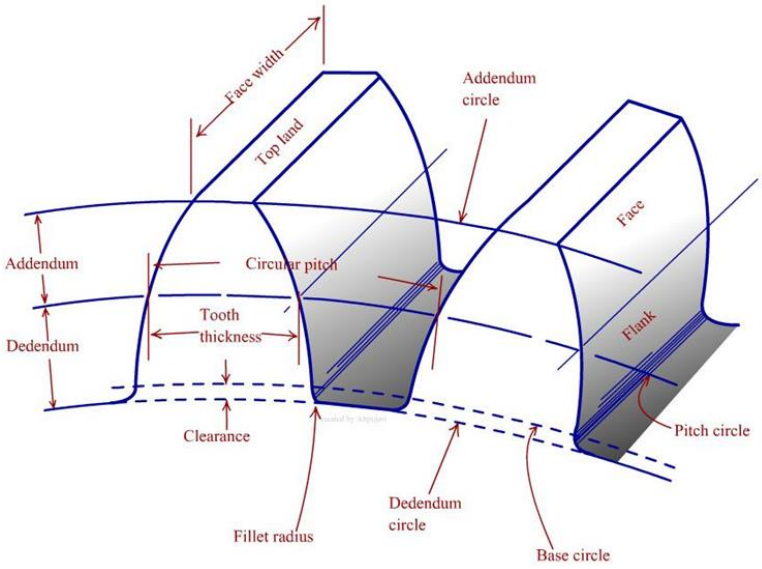


**Figure 2-2-4:** Terminology of spur gears [18]

The pitch circumference corresponds to calculating circles $d \cdot \pi$, that's is equate $z \cdot p$. When thits equation is formed to $d/z = p/\pi$ the module *m* will result that serves as a standard reference measurement and is regarded as a pitch circle diameter. As showmn in figure 2.2.4 on the left side, spur gears have an addendum *a,* which is assimilated to the module *m*. It was considered that the dedendum of the teeth is greater than the addendum, because the bottom

clearance c, a prevention of contact of the addendum circle and dedendum circle of two interacting wheels, is given. The fillet radius $\varrho_t$ is provided, to prevent yourself bump at corners at the engagement of the teeth. Accordingly applies to ISO 53 for $c = 0.25 \cdot m$ with $\varrho_t = 0{,}38 \cdot m$. According to DIN 867, the pressure angle $a = 20°$ is standardized for spur gears. [14, p. 571]

Therefore, every gear consists of four different constructed circuits. The outer diameter referred as an addendum circle and the root diameter is referred as dedendum circle. Between the two circles is the pitch circle, which is considered as a general diameter of gears. Here, the circuit goes through the flanks points. The results for the calculation of the zero straight-toothed outer wheel,is shown in the following formulas taken from the source [19]:

| | | |
|---|---|---|
| Addendum: | $h_a = m = 0{,}3183 \cdot \rho$ | (1) |
| Base Circle diameter: | $D_b = d \cdot \cos\alpha$ | (2) |
| Circular pitch: | $p = m \cdot \pi$ | (3) |
| Circular tooth thickness: | $ctt = p/2$ | (4) |
| Dedendum: | $h_f = h - h_a$ | (5) |
| Module: | $m = d/z$ | (6) |
| Number of teeth: | $z = d/m$ | (7) |
| Pitch circle diameter: | $d = z \cdot m$ | (8) |
| Whole depth: | $h = 2{,}25 \cdot m$ | (9) |

The centre distance of two interacting spur gears, with the same pressure ankle, modul, pitch and height of the teeth is:

| | | |
|---|---|---|
| Centre distance: | $a = r_1 + r_2 = \frac{m}{2}(z_1 + z_2)$ | (10) [14, p.572] |

The small and large wheel transmission *u* are composed with the parameters of the peripheral speed of the pitch circles *v*, the pitch circle diameters $d_w$ and speeds *n*:

| | | |
|---|---|---|
| Tranmission: | $u = \frac{n_1}{n_2} = \frac{d_{w2}}{d_{w1}} = \frac{z_2}{z_1}$ | (11) [14, p.560] |

Here the drive wheel has the index 1 and the wear side has the index 2. Depending on the amount of translation either power or speed can be transmitted by using two gears. If *u >1,* then speed reducing will be transferred, whereby a greater force transmission is possible. If the translation is *u <1*, a larger gear will be translated to a smaller gear, with a higher speed, but a lower power transmission is achieved.

### 2.2.3 Force transmission with combination of two spur gears

The opposing forces of $F_1$ and $F_2$, the contact points of the interacting teeth, are generated by the flanks. The force acting on the driven gear has the index 1 and the force that results on a driving wheel, has the index 2. The driving gear mechanically generates the first force $F_1$. This will push the driven gear with the touching teeth as shown in the first picture of figure 2-2-5. The counterforce $F_2$, also referred as inertia, is a resisting force, which is a factor that stops objects that have been moved or to stop objects, which are in motion. That's why the force vectors of $F_1$ and $F_2$ are equal. The driving gear can be understood as a motor which has to overcome the inertia of $F_2$. In this case, $F_1$ needs to have a bigger amount than $F_2$ to get the driven gear into motion. [14, p. 600]

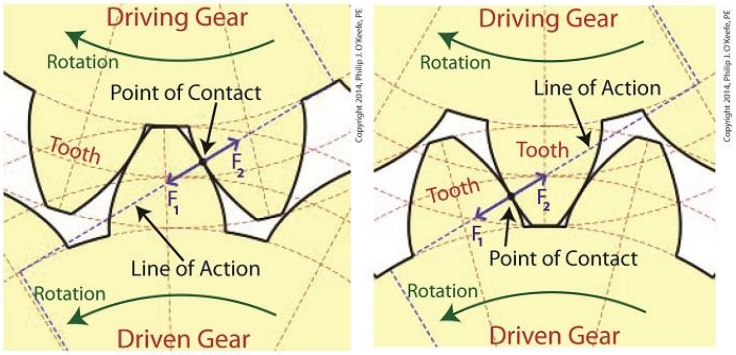


**Figure 2-2-5:** Force interaction between spur gears and its line of interaction [20]

The forces slide along the touching points of the teeth and goes always through the pitch points. This forms the line of action. In addition to the action and reaction there is located the tangential force $F_t$ on both sides and horizontally from the force point and the radial force $F_r$ is perpendicular thereto of the respective vectors. The tangential force acts on embossed wheel into the direction of rotation. The tangential force on the driving wheel, acts into opposite direction and the radial forces are directed into the centre point of the gear. This is shown in figure 2-2-6. [14, p. 599]

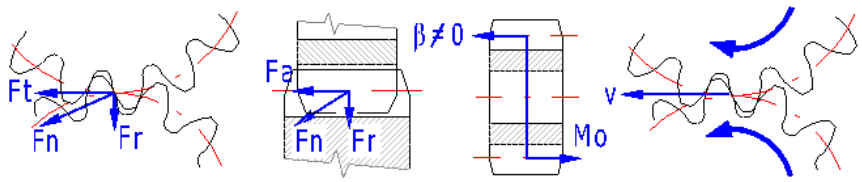


**Figure 2-2-6:** tangential, radial and axial forces at helical spur gears [21]

The figure 2-2-6 shows the forces acting on the helical gears with $\beta \neq 0°$, where in addition the axial force $F_a$ is added. In spur gears is $\beta = 0°$ and to the axial forces are eliminated. In the reverse direction of rotation of the gears the resulting forces $F_1$, $F_2$ and the radial forces $F_r$ are constant, whereby the tangential force is changing its direction due to the reverse.

## 2.3 Failure Mode and Effects Analysis – FMEA for product improvement

### 2.3.1 Content, aim and implementation

Failure Modes and Effects Analysis is a standardized quality assurance method of analysis, for the detection and prevention of the risks of errors. The risk analysis is carried out, depending on the object, to be examine on products, a system or processes. It function is to prevent and detect potential failures or consequent risks. There are three different types of a FMEA analysis; the System FMEA, in which the subsystems are examined the overall system and the construction and design FMEA, with the aim, to ensure and optimization of subassemblies and to avoid failures of the development. The essential method for the medical technology area is the product and process FMEA, where the product and its components will be examined in order to minimize errors and risks and to optimize the functional reliability. The FMEA is a reliability Inductive method in which is deduced from the possible effect to the cause. It is used to avoid a failure mode. [22]

The implementation of the FMEA is done in several steps. A Team, consisting of different departments, discusses and processes the FMEA. The analysis is carried out with a structure analysis, a functional analysis, a failure analysis, a mitigation analysis and the final optimization. This error analysis is important to spot possible malfunctions. This will help to draw conclusions on the cause. The mitigation analysis of the system, the product or process evaluates and describes the possibilities to avoid failures and to reduce or eliminate risks. The occurrence probability and the probability to spot the described risks are particularly important to discover the cause of a failure. This analysis step is performed to determine the risk priority number – RPN. The RPN and the derivation of further activities are necessary to prevent, to reduce or eliminate risks. In the final step of the optimization the discussed activities will be implemented. The optimization describes changes of the describes changes of the design, processes and products. This helps to avoid discovered failures for a longer period and to test the products and processes. After that a new RPN number will be calculated. [23]

The FMEA is finally summarized in a large table that shows the potential failure, probable effects and causes, severity, likelihood, the initial risk, mitigation and to these related documents. An example of an FMEA is attached in the appendix page 2. The structure may varies depending on the company. In medical technology, the FMEA and their tests are necessary for each instrument. The process and product FMEA, is especially used to analyse failures caused by humans, materials, methods, mediums and machines. A complementary analysis method for this analysis is the fault tree analysis – called FTA. Unlike the FMEA, the FTA is deductive, while causes of the effects are examined. [23]

### 2.3.2 Determination of the risk priority number and classification of risk classes

The risk assessment is carried out by the determined RPN for each type of failure. The RPN is calculated by multiplying the occurrence probability *A*, the significance of the severity of the risk *B* and the likelihood of detection *E*. In this case, the determination of the individual evaluations is carried out according to standardized specifications in the table according DIN EN ISO 12100. [23]

Risk priority number: $RPN = A \cdot B \cdot E$ (12) [23]

The following table 2-3-1 shows the different determinations of the individual parameters with a scale from 1 to 10 points. They are needed to calculate the RPN.

**Table 2-3-1**: rating scale for occurrence probability, severity and likelihood of failure modes. Translated from: [22]

| *Occurrence probability (A)* | *Severity (B)* | *Likelihood I* |
|---|---|---|
| 1<br>• virtually be ruled out<br>• Probability approximately 1: 20,000 | 1<br>• no effect on the process<br>• Customer does not notice | 1-2<br>• inevitable discovery in the following process stages |
| 2<br>• unlikely<br>• Probability approximately 1: 5,000 | 2-3<br>• insignificant<br>• Customer is only slightly disturbed | 3-4<br>• high probability of detection in the following process stages |
| 3<br>• low<br>• Probability approximately 1: 1,000 | 4-6<br>• Process faults<br>• Problems with some customers | 5-6<br>• Discovery only of targeted testing |
| 4-6<br>• random occurrence<br>• Probability of approximately 1: 500 – 1: 100 | 7-8<br>• limited service<br>• Customers are upset | 7-8<br>• No discovery of receipt by the customer<br>• Customer will likely discover errors |
| 7-8<br>• frequent occurrence<br>• Probability approximately 1:50 to 1:20 | 9-10<br>• Violation of regulations<br>• financial damages in the organization or the customer | 9<br>• expert customer will discover errors |
| 9-10<br>• ongoing occurrence<br>• Probability about 1:10 – 1:5 | | 10<br>• Discovery is not immediately possible, in the course of time |

Depending on the values shown in the table above, the result for the RPN can vary. This results in other risk assessments. If the value of the RPN is between 1 <RPN <100, this means a tolerable residual risk. In this case are no further action are necessary to reduce the risk. A small residual risk is in the range of 100 <RPN <125. Then here an additional warning is required. Additional precautions are required, if the residual risk value of 125 <RPN> 250. An intolerable residual risk value requires constructive mitigations to reduce or avoid the residual risk. This residual risk assessment is necessary, if the risk value is between 250 <RPN <1000. [23]

Another additional possible assessment of the risk, especially for medical products, are divided into risk classes which are carried out in a risk matrix. This is shown in Figure 2-3, where the likelihood and severity are compared. The several risk level depends on the multiplication of the severity and the likelihood as classified in table 2-3-1 of the previous page.

| | | Likelihood | | | | |
|---|---|---|---|---|---|---|
| | | Rare | Unlikely | Possible | Likely | Almost Certain |
| Severity | Severe | MEDIUM | MEDIUM | HIGH | EXTREME | EXTREME |
| | Major | LOW | MEDIUM | MEDIUM | HIGH | EXTREME |
| | Moderate | LOW | LOW | MEDIUM | MEDIUM | HIGH |
| | Minor | LOW | LOW | LOW | MEDIUM | MEDIUM |
| | Minimal | LOW | LOW | LOW | LOW | LOW |

**Figure 2-3:** Risk matrix to evaluate the four risk-classes. Green: class I, yellow: class IIa, orange: class IIb, red: class III. Adapted from its original [24]

The Classification in the European Union is defined by Annex IX of EU Directive 93/42 /EEC – Anhang IX der EU-Richtlinie 93/42/EWG. The classification is carried out into risk class I, risk class IIa, risk class IIb and risk class III. The risk class I, shown in green in figure 2-3 has a low risk potential, an action is not necessary. The risk class marked yellow IIa has an average risk potential, several actions are necessary to keep the risk under control. Class IIb, in figure 2-3 marked in orange, also has an average increased several actions are essential. An extremely high danger potential is in the red marked Class III. Those are extremely high risk potentials which implement binding measures before a product is released on the market. [25]

### 2.3.3 Benefit of the analysis

In summary, the FMEA is used for an early possible detection. classification of the failure and appropriate action regulation. Advantages are mainly the momentary failure reduction what helps to reduce the customer complaints to increase the quality and to be competitive with other companies. The Product-FMEA especially helps to improve products and to avoid possible failure modes. However, disadvantages of this analysis are reflected in the high temporal and personnel expenses and in the subjective risk assessment. [26]

## 2.4 Patent and Utility Model Registration in Germany and in the U.S.

In the 19th century run sit Chemical Society and the Association of German Engineers to obtain together a patent legislation in the Industrial Development of Germany. The first patent law was on 1 July 1877 as rich patent enacted that 1891 was a comprehensive redesign. The patent protection is the assignee of the patent granted, which, however, did not necessarily have to be the inventor, therefore, called this patenting principle “applicant” principle which still exists today in most industrial countries. As an exception, however, is one of the USA in the “inventor” principle has been established. The inventor´s principle applies who has the invention the first invented, therefore, the applicant is primarily the inventor. The registration of the patent on the company’s common these days, but the designation and signature of the inventor in the United States is always necessary. In 1891 it came to the additional passage of the Utility Model Law in Germany. [27, p. 19]

### 2.4.1 Patent

A patent is a right which entitles the holder to use the invention. It is issued by the State Patent Office. The patent thus has the capability, to avoid the use or manufacture the invention by other companies. Unless there is an improvement of an invention with a pre-existing patent, the unlimited use is possible only through cross-licensing. Patent protection applies in most countries from filing date of 20 years and serves to the invention is exclusively used by the patentee. In patent application, the invention must be described detailed so third parties will be able they are to follow. Other companies use this description in order to circumvent the patent protection or to be used commercially after expiry of the patent itself. [27, p. 29]

The documents related to the invention must include a patent application a description and drawings of the object, as well as the patent claims and marking the desired scope. The drawings and descriptions should be as detailed that a third could reconstruct it faithfully. In patent application all data and embodiments should be left uncapped as a later add additional data is not possible in an already filed invention. In the register, which is kept by the Patent Office, all patent application and the issued patents are listed. A granted patent contains in addition to the descriptions and drawings, the term of the patent both destination and name of the patentee and the term of the patent. After application of the patent, the Patent Office shall examine whether the patent meets the requirements, novelty and inventive step. The publication of a patent application is carried out in Germany and Austria after 18 months and has also established itself in the industrial world such as USA, Japan or Canada. The publications include the scope of granted patents by patents and content of patents registered. Thus, everyone is free to see this and to learn about the state of development of a certain sector. [27, p.30]

Granted patents are classified in different fields of engineering. It was developed by the World Intellectual Property Organization into international classification – short ICP, that develops eight different areas and further subsections. The eight sections are*:*

*"[…] Section A »Daily Value«, Section B »work process«, section C »Chemistry and Metallurgy«, Section D »textiles and papers«, section E »Building, drill ground, mining«, Section F »Mechanical Engineering, lighting, heating, weapons«, section G »Physics« section H »Electricity«."* Translated quotation. [27, p.34-35]

Using this classification, patent signatures are better to sort and therefore better to find for researches. In general, the term is from filing a patent granted by the TRIPs agreement 20 years. In order to maintain the patent renewal fee is necessary. Patentable are products, processes such as manufacturing processes, mechanical and operational devices and applications, the scope and the claim category are to be formulated in detail. [27, p.35] According to current information from the patent office, the cost of a patent application in the national scope with 10 patent claims is 60€, each further claim is made with 30€. In addition to the registration fee, the cost of the search request from 300€ and its circumference coming nationally additionally 350€ on at international level added 150€. Thus, the cost of the patent application at a maximum of 10 claims and research amount to the national level to approximately 710€ and in international research to 560€ in the application area of Germany. In patent application on an international scope, the cost of a patent amount to about 3000€. [28] A patent in America costs for the basic fee $ 310, search fee $ 510 and examination fee $ 210. The cost of registration of the patent amounts a total of $ 1030. If the patent is granted, the fees of issuing §1440 and publication §300 will be added to give a total cost for granted patent of $2779. [29]

### 2.4.2 Utility Model

When utility model is going to be filed, minor inventions can be protected, with the difference that already published writings does not prohibit the registration on the utility model of up to 6 months in advance. The examination of the utility model is less extensive than that in the patent, because is only checked in a formal way and not through objectivity. The maturity from registration date is at maximum maturity of 10 years. Like the patent renewal fees are to be paid, but the amount will be lower. The granting of the utility model is faster, so the possibility of an intellectual property right of the utility model also next to an ongoing patent application to obtain. As with the patent, the utility model is coded in order to achieve a specific International Classification. [27, p. 39] The cost of the Utility Model Registration Application in Germany amount to 290 €, thereof If the registration charge 40€ and research fee 250€. A utility model is not announceable in America.

# 3. Development of the HeartStitch MR

## 3.1 Task statement and Motivation

The general task of the bachelor projects was the development of the already existing on the market HeartStitch MR Instruments for mitral repair. In addition to the comprehensive understanding of the equipment and the operational methodology primarily the interests of the user should be considered. Here, in addition to the use of the device, the physiological position of the user to the operating table and the movement and the anatomical differences in size of individual users should be considered and improved. Also taken into account should be a simple operation of the appliance and ensuring safe working with this.

In the current application the device is held like a gun in one of the surgeon´s preferred hand. In order to activate the buttons and close the needle arm, the user is therefore forced either shifting hand or to use the other hand to press the buttons. Subsequently, the user had to rearrange again to pull the lever that activates the needle. One-handed operation of the instrument was therefore currently not possible. The motivation for the further development therefore was to design the device in that way that the user can operate with one hand in order to have the second hand free for eventualities or to stabilize the device with the other hand. The primary design consideration, was to replace the lever by a button to construct a one-handed operation mode. In this case the attitude of the device in the user's hand was included in the considerations, because the user needs to lift up the elbow to the level of the shoulder in order to use the device. With the new design this unfavourable position should be prevented in order to allow the user a cramp-free and comfortable working. Also the anatomical differences of various users were taken into account, because of the different sizes if the hands of the users. Another consideration was that the developed mechanism for the lever replacement needed to suit with its parameters into the existing device.

The motivation of the project was in the design to improve the user to enable a simplified application of the device, without the need of cramp and to use the HeartStitch MR with one hand. Therefore, the button has to be developed in that way that the user can press it easily and securely, without having to apply too much force. The surgical procedure itself is not changed, so that the safe operation of the equipment is still guaranteed.

## 3.2 Development process of the HeartStitch MR

### 3.2.1 Basic parameters and conditions for the further development

#### *3.2.1.1 Parameters*

First, the given parameters were taken for the construction. The distance that the needle needs to move out of the spreader requires 0.5 inch (1,29 cm). Therefore, the travel distance of the needle wire, which is linear translated by the lever, is 0.6in (1,524cm). To ensure that the needle is extended and catches the suture safely by the mechanism, a higher range is initially assumed. That can be adjusted at the end of construction. Here, a parameter of 0.9in ≅ 2.23cm was assumed. The total length of the whole device is approximately 17.5 in ≅ 44.45 cm. The case amounts 6.9 in ≅ 17.5 cm, the nitinol extrusion 7.8 in ≅ 20 cm and the spreader with the extrusion amounts 2.75 in ≅ 7 cm together. A drawing with all needed and explained assemblies is shown in figure 3-2-1.

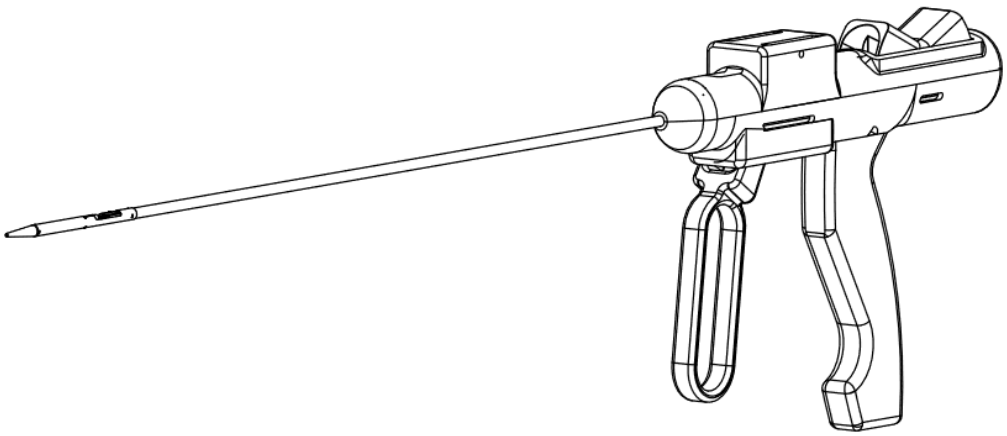

**Figure 3-2-1:** 3D-Drawing of the HeartStitch MR.

#### *3.2.1.2 Rapid Prototyping by using 3D-Printers*

Rapid prototyping is used, when fast manufacturing of constructions is needed. The implementation of ideas took place for the most parts by means of SolidWorks. The subsequent expression, previously-made 3D drawings, with the help of 3D printers. 3D printers are very precisely. They can create simple several layers of plastic components. After the assembling of the items they were tested. The duration of a print job depends on the selected quality of the print and the size of the component. In most cases, rework needs to be done on the components, because some components need to be printed with support material to implement notches in the desired dimensions. It takes several hours to assembly a prototype, because a 3D printer is not able to construct all components. Some components are also used in in household printers like pens, toy cars or pins.

### 3.2.2 Presentation and procedure of the development process

#### *3.2.2.1 Development of mechanical fundamental principle*

On the basis of predetermined parameters, a mechanism had to be found, in which a button from a height of 1.0 -1.5 cm. the route of 2.23 cm = 0.9  is used to extend the needle at the distal end., Spur gears, in combination with one or several racks as basis, are used To translate the movement from vertical to horizontal. Therefore, the mechanism has to be removable to get the needle back into the spreader. Two different mechanisms, which have approximately the same function, have been developed:

*Idea I:*

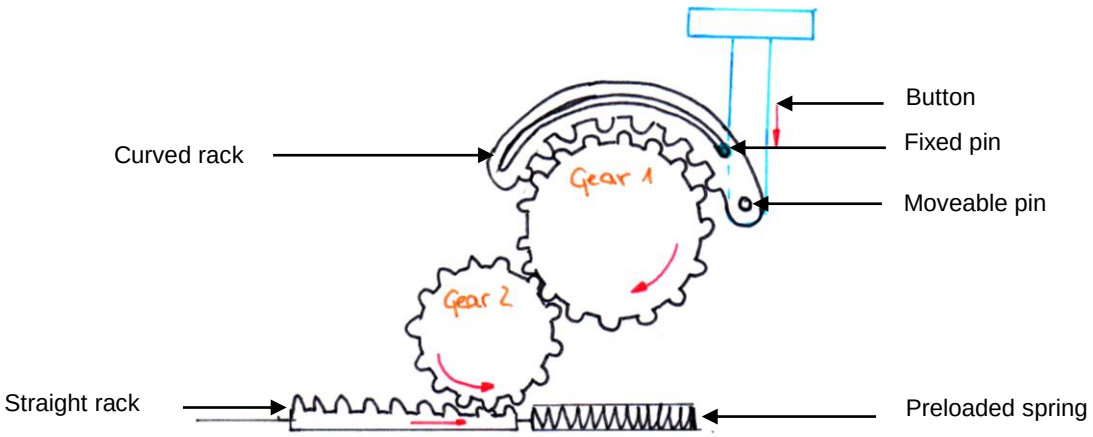


**Figure 3-2-2-1a:** Schematic drawing of the first mechanism.

The first mechanism works in the way that the button is pushed down 0.63in, whereby the curved rack is simultaneously moved. The curved rack  has a slot with a length of 0.9in, in which a fixed pin ensures that the distance between the rack and the first gear stays constant. During the movement, the curved rack slides behind the button, because the connection of the rack and the button is movable. Thus, the first gear rotates with a distance of 0.9 in. That transmits the movement, via the second gear, to the straight rack. The straight rack must have a minimum length of 0.9 in. The rack pushes back and presses on a pre-loaded spring, which pushes the process back into the original state. The red arrows in the figure 3-2-2-1a show the movement history of the individual components, when the button is pressed down. The implementation, shown in Figure 2-3-3-1b on page 24, of the mechanism is difficult to implement. The production of a curved rack is connected with difficulties.  In addition, the button is connected by the arrangement and the non-ideal curved rack has a high effort. On the other hand, the rack jumps with this construction quickly from its envisaged path. The first prototypes, as shown in figure 3-2-2-1b, of the first mechanism consisted of parts from play toys, parts from office tools and parts from 3D-printers. The prototypes illustrate, that the mechanism works, but still not efficiently enough.

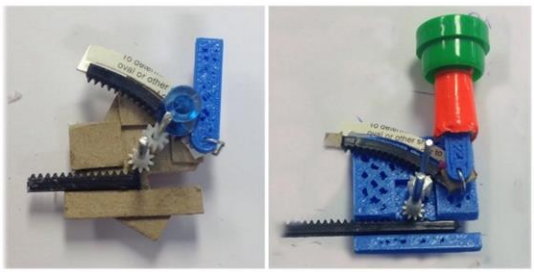

**Figure 3-2-2-1b:** Implementation and first prototypes for the first mechanism.

The mechanism reaches the desired travel distance of motion and saves the desired place for the button, but it is ruled out by the difficult implementation as a mechanism.

*Idea II:*

The second mechanism works like the first mechanism. The first gear is, instead of a rack, directly driven by the button.

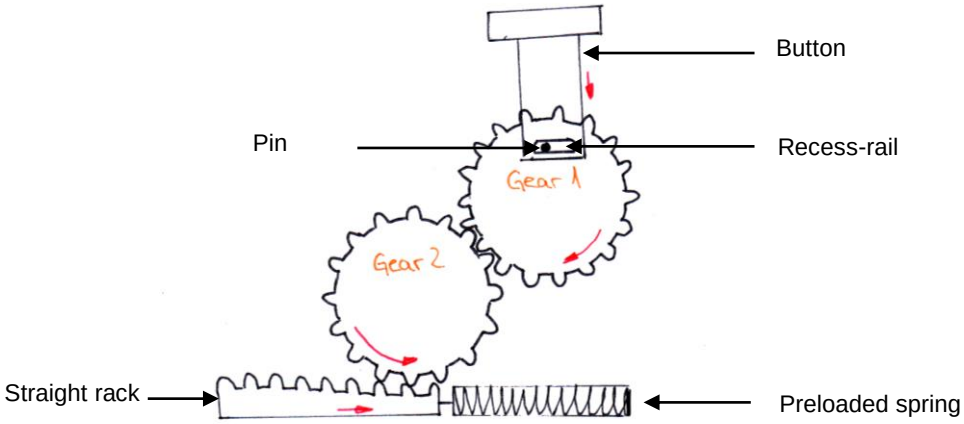


**Figure 3-2-2-1c**: Schematic drawing of the second mechanism.

At the bottom of the button, a recess is located as shown in Figure 3-2-2-1c. A pin can slide along, which is fastened in the gear at a certain distance from the centre of the gear. By pushing the button, the pin slides along the recess of the button. The first gear will be driven and rotates 180° to the right. The second gear drives with the same distance, and transmits the force as in the first mechanism to the rack. Again, the process can be reversed by using of a preloaded spring. In this mechanism the half circumference of the first gear fulfils the targeted travel of the straight rack and the needle will expand. The distance, depending on the way the button will be pushed, corresponds to the doubled length of the distance of the fixed pin and the centre of the gear. That means, if the pin is placed 5mm away from the centre, the distance to push the button down will be 10mm. The implementation of this mechanism shows that the

desired travel distance is achieved and the implementation is easy to translate as shown in figure 3-2-2-1d.

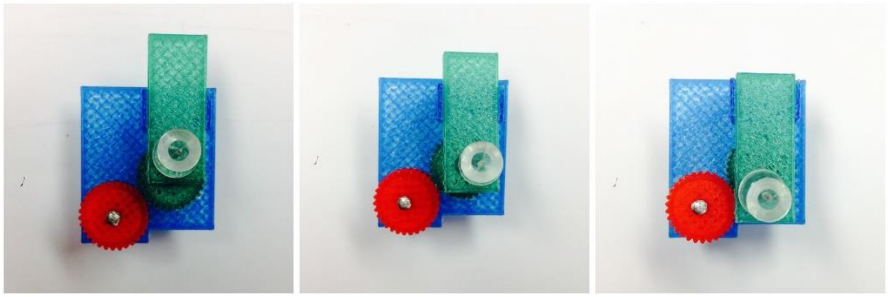

**Figure 3-2-2-1d:** Implementation and movement of the first prototype for the second idea of the mechanism.

The way and the simple implementation of the second mechanism, as a basic principle, established a further development of the mechanism.

### *3.2.2.2 Calculations to the fundamental principle*

By defining the basic principle, the calculations of gears, things, module size, number of teeth have a great importance. According to the second idea, as described on page 24, the condition assumes that the first gear needs to rotate 180 degrees to translate the 0.9in. The result is that the circumference of the first gear corresponds to the double of the travel distance:

$$U = 2 \cdot 0.9 = 1.8in \cong 46\,mm$$

This results in a gear diameter:

$$d = \frac{U}{\pi} = 0{,}573in \cong 14{,}5\,mm$$

In order to ensure that the preferred travel distance is guaranteed by the arrangement of the gears and of the button, a larger gear has been selected with a diameter of *d=16mm*. The parameters listed in Table 3-2-2 serve for the calculation to ensure a trouble-free and smooth movement between the two gears and the rack.

**Table 3-2-2:** Overview of the parameters for the first gear

| *Parameter* | *Formula* | *Result in [mm]* | *Result in [in]* |
|---|---|---|---|
| Module m | $m = d/z$ | 0.5 | 0.01968 |
| Pitch circle d | $d = z \cdot m$ | 16 | 0.62992 |
| Number of teeth z | $z = d/m$ | 32 piece | 32 piece |
| Addendum $h_a$ | $h_a = m$ | 0.5 | 0.01968 |
| Whole depth h | $h = 2{,}25 \cdot m$ | 1.125 | 0.04429 |
| Dedendum $h_f$ | $h_f = h - h_a$ | 0.625 | 0,02460 |
| Circular pitch p | $p = m \cdot \pi$ | 1.571 | 0,06185 |
| Circumference U | $U = 16 \cdot \pi$ | 50.265 | 1,97893 |

The first gear has to be as large as possible, so that the force can be transmitted from the button to the gear. The ideal translation for the second gear is 1/1, but according to the place in the device it is not possible to place a gear in the same size. Therefore, the second gear must be as large as possible to transmit the force, but also small enough to fit into the existing device. The second gear needs to have the same module *m* and circular pitch *p* to ensure a smooth translation. Therefore, a determination of the diameter of *d= 10 mm* for the second gear was held, with a number of teeth *z = 20*. With gear one d=16mm and z=32 and a second gear of d=10 mm and z=20mm a translation of u<1 is achieved:

$$u = \frac{z_2}{z_1} = \frac{20}{32} = \frac{5}{8} = 0.625$$

For the distance of the two gears is obtains a value of:

$$a = \frac{m}{2}(z_1 + z_2) = \frac{0{,}5}{2}(32 + 20) = 13mm$$

The corresponding rack, to transmit the force for the extension of the needle, must have a minimum length of the half circumference of the first gear with $U_{1/2}$*=25,13mm* and needs to have the same module of 0,5mm like the gears. After the determination of the gears, which are used to carry the pin on the gear, the gear needs to be defined as shown in Figure 3-2-2-2a. The pin, which slides in the recess of the button, is mounted at a distance of 5 mm from the centre of the gear. The therefore achieved pressing length of the button is only 10mm, which corresponds to the distance, travelled by the pin at a 1/2 rotation, of the gear through the recess in the button.

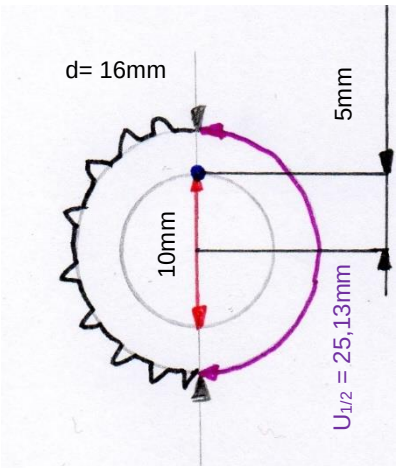


**Figure 3-2-2-2a:** Illustration and dimensions of the pin attached on the gear.

The calculations for the gears above, the final calculating for the arrangement and space expenditure were made for the mechanism as shown in figure 3-2-2-2b. In the drawing above, the gears are mutually arranged at 45 °, so that the force can be transmitted optimally and are arranged to safe space. The top lid drawing is used to illustrate the head of the housing and is removed about 3mm from the first gear. With a rack of a height of 6mm, the mechanism results in a total height of about 31mm. The width of the mechanism has not yet clearly defined. The wide flat case depends on the length and type of spring employed. a minimum width of 50.26mm must be given by the movement of the rack from the starting point to the end point.

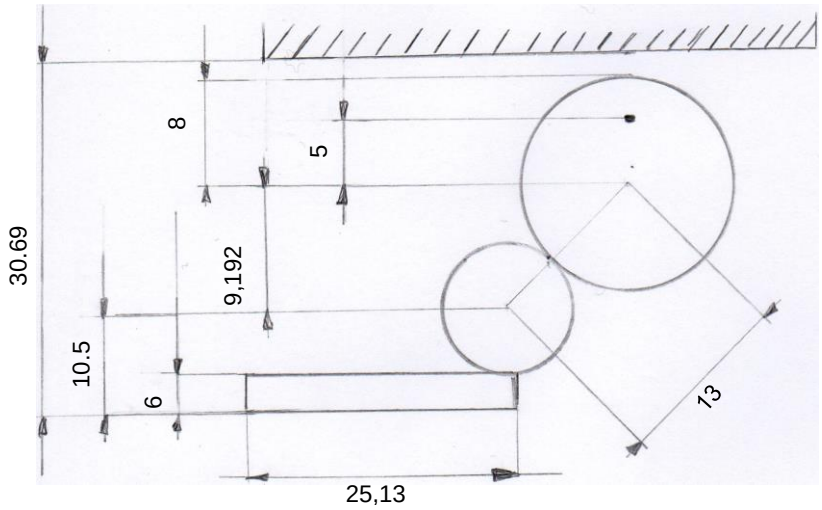


**Figure 3-2-2-2b:** Arragement and dimensions for the second idea of the mechanism. All dimensions are in [mm]

### *3.2.2.3 Development stages and individual prototypes*

By lockup and the specific calculations for mechanism the individual development steps, their prototypes, the implementation and improvements are carried out in this chapter by lockup the specific calculations of the mechanism. The first prototype, shown in Figure 3-2-2-1d on page 25, shows the movement and the implementation of the specified mechanism. The design consideration according to this prototype shows, that the desired travel distance has been achieved The implementation was easy to transfer, but the button, that is pushing directly on top of the death centre is not working. That means, that the first gear is not moving, because the force in the pin is too high to slide in the recess. Therefore, a further consideration needs to be found for the recess-shape.

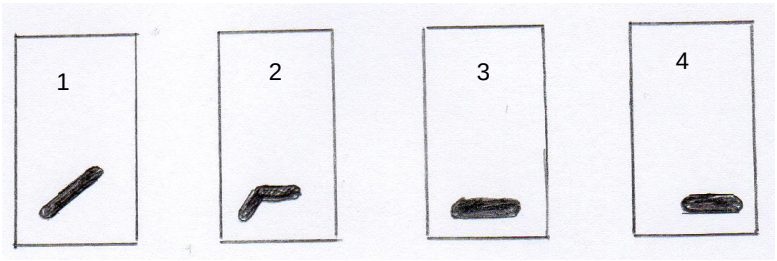


**Figure 3-2-2-3a:** Different recess-shapes to get the first gear 180° turn.

Figure 3-2-2-3a shows four different types rot the recess shape. The first shape 1 shows an ankled 45° as a straight recess. It bypasses the first top death centre but can´t turn the first gear 180°. A turning back of the first gear is not possible with this shape. The second shape 2 consists out of two parts The first part consists of an 45° ankle und at the half of the recess is a horizontal part with the same distance like the ankled part. The consideration to this shape was that it will turn the gear 180° and bypasses the first top death centre but the pin isn´t moving smoothly in the recess. It also cannot get back to the starting point, because at the end

point is pushing on top death centre, when the process needs to return. The recess shape number 3 is the shape, which is shown in figure 3-2-2-1c on page 24. The consideration to this shape is that it also pushes on top death centre and therefore it is hard to push but it the desired distance. the recess shape number 4 is designed to overcome the top death centre.,. By using the recess shape 4 the starting point of the pin will not be in the vertical line of the gear centre. The consideration was to move the starting point that the button will not push on the top death centre, but with this design the whole 180° are not able to promote. According to the consideration in chapter 3.2.2.2 the desired travel distance of 23mm is still promoted.

It followed the implementation of a second prototype for the mechanism:

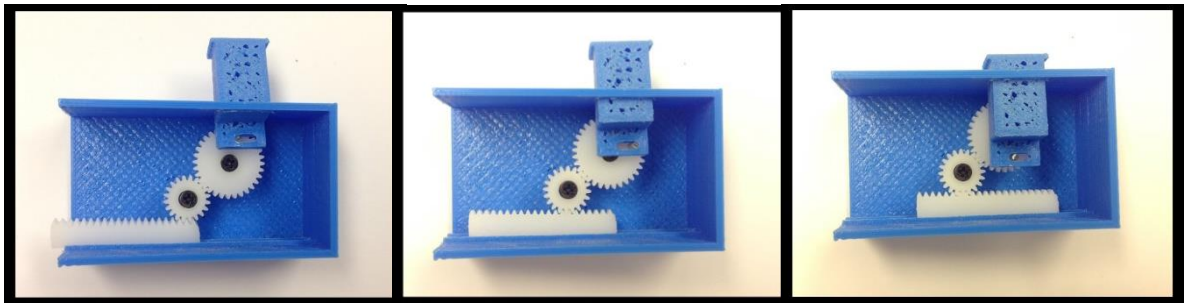

**Figure 3-2-2-3b**: Movement and Implementation of the second prototype.

As shown in Figure 3-2-2-3b, the mechanism, on the basis of calculations and arrangement of figure 3-2-2-2b on page 27, with the recess shape 4 of figure 3-2-2-3a of the previous page was implemented in the second prototype. In this prototype the starting point is shifted, therefore the entire length of the rack is not exhausted. Regardless, the top death centre is bypassed by the shifted starting point. At the beginning the pin is on the left side of the recess and starts moving to the right side when the button is pushed. At the horizontal line of the recess with the gear centre, the pin is at the maximum of the right side in the recess and turns further left after overcoming the horizontal line. At the end point of the rotation the pin is again on the left side of the recess. The travel distance of the button is smaller than the at first expected 10mm. The gears of this mechanism were normed manufactured gears. All blue parts have been produced by printing. For simplification the gears had been fixed by screws. The testing of the prototype revealed that the gears in combination with the rack are working smoothly and the mechanism works like expected. Nonetheless the button sticks in the recess which is on the top of the case, hence the button is hard to push and the recess jumps out of the pin because of the high force of the pushed button. The design consideration according to this prototype therefore show up in a rail for the button, that it cannot slip out anymore or to remove the straight button to a curved button. The force on the pin could be decreased by the ankled and curved button because the incoming force is not pushing on top death centre in the vertical-line anymore. The considerations for the improvement were implemented in the next prototype.

According to the third prototype, the main consideration was to have a recess that is shaped like the travel-way of the pin on the gear. The drawing for the size and dimension of the button is attached in *appendix page 3*. The implementation, illustrated in figure 3-2-2-3c, shows the movement of the mechanism with an ankled button with the round recess shape. The considered travel distance of the pin was thought to stay the same.

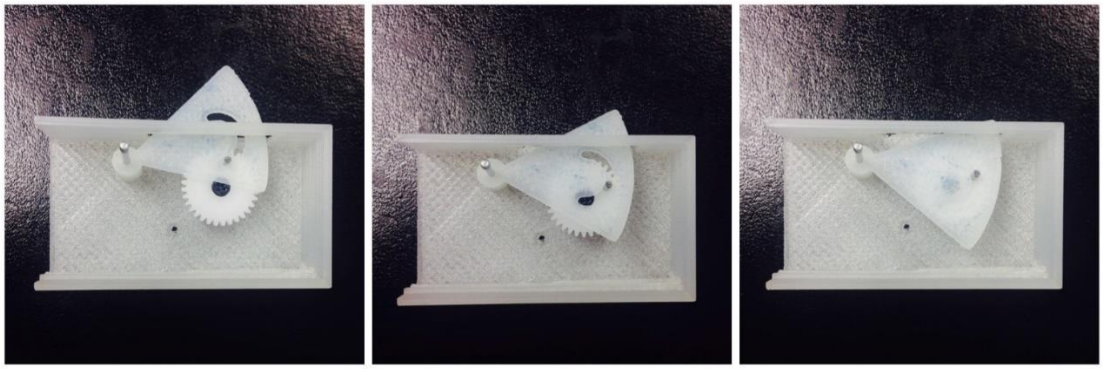

**Figure 3-2-2-3c:** Prototype 3 with a half round recess and it´s movement.

The testing of the third prototype showed, that the design idea with an ankled button and a half round recess stops moving after the gear has turned 90°. The further design consideration was to use the straight recess again. In this case, the correct placement of the button needed to be considered.

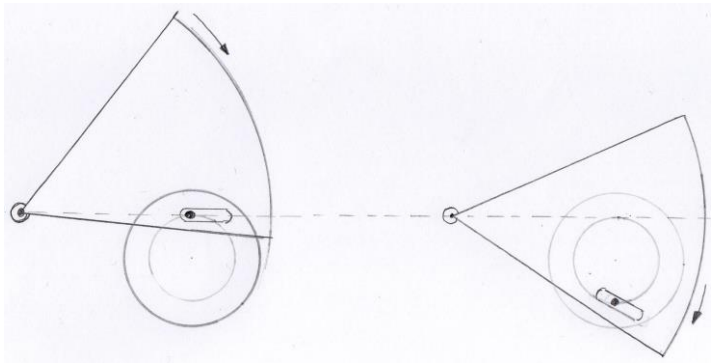

**Figure 3-2-2-3c:** Movement of an ankled button which is placed horizontal to the pin.

As drawn in figure 3-2-2-3c, the button is placed on the horizontal line of the pin, which is placed on the button. At the starting point, shown left in the drawing, the pin is in the left position of the recess. When the gear starts moving and will turn 180°, the pin will not be at the left position of the recess again. This is caused by the different distances from the starting point in comparison to the end point. That means, that the gear would turn furthermore, then it has to. This would cause that the gear would turn more than 180° and the pin would slip to the left side if the recess. In that way, the button is not able to be pushed back again, because of the position of the pin in the recess. The design consideration needed to take into account, that the distances of the pin in the recess needs to be equal at the starting position of the button

and in the end position. In the reconsideration of the button placement, the distances of the anklepoint of the button and the starting and end position of the pin in the recess needs to be the same. Therefore, the anklepoint of the button needs to be on the horizontal line of the gear centre. The illustration of the dimensions and the arrangement of the consideration are drawn in figure 3-2-2-3d.

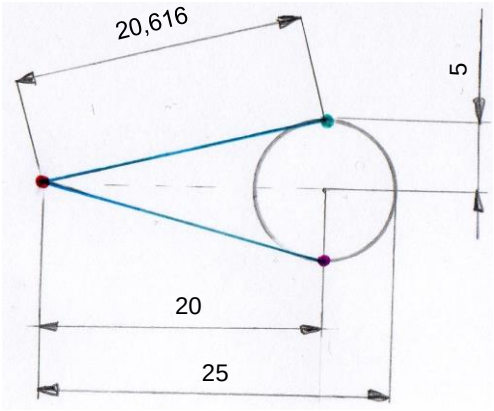


**Figure 3-2-2-3d:** Dimension in [mm] of the distances from the anklepoint (red) to the starting point (green) and end point (violet) of the pin on the gear.

The circle, shown in the figure above, illustrates the travel way of the pin on the gear. The blue lines show the distance of the anklepoint of the button, to the starting point and the end point of the pin on the gear. Those two distances are equal and amounts 20.616mm when the button is fixed 20mm away from the centre of the gear. With the dimensions, the length of the recess can be calculated. The shortest distance of the recess amounts 20.616mm, when the pin is either in the starting position or in the end position. The largest distance is reached when the pin is in the horizontal line of the anklepoint of the button and of the gear centre. This distance amounts 25mm. In that way, the rage of the recess on the button needs to be from 20.616 - 25mm which amounts a recess length of 4.384mm. The length of the recess needs to be bigger, because the pin itself will have a diameter in minimum of 1mm. In this case, the length of the recess will be 4.5mm. Figure 3-2-2-3e shows, that the consideration according to the arrangement and the recess are correct.

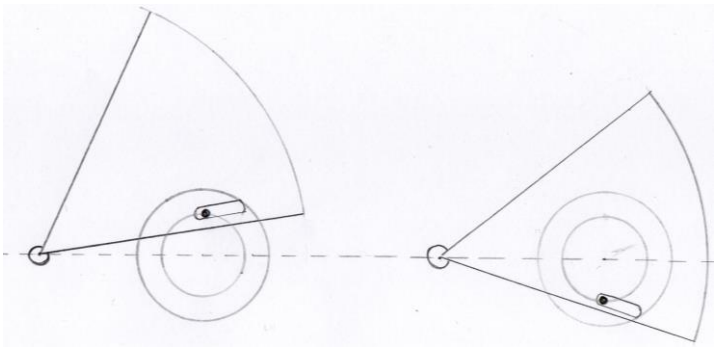

**Figure 3-2-2-3e:** Movement of the ankled button which is placed on the horizontal line of the gear centre.

The implementation of the previous consideration showed, that the calculations and the mechanism is implemented correct. In figure 3-2-2-3f, the function and implementation of the considerations are shown in the fourth prototype.

The function of the mechanism is ensured with the use of the fourth prototype. As considered, the first gear turns 180° when the button is pushed down and promotes the desired travel distance. According to the test of the prototype, new considerations arose. The test showed, that the button is fully in the case after it´s movement. This consideration is shown in the third picture of figure 3-2-2-3f. This could cause, that a user could squeeze or scratch his finger at the corners of the case. The test showed that the rack is still loose. The connections of the button with the case and connection of the gears with the case needs to be improved. Another consideration showed, that the button is colliding with the rack. This cause that the rack is not able to move further and the desired travel distance is not achieved. The function of the mechanism is ensured but the pressure to push the button is still too high for a user to push. This is caused by the floppy connections of the button, the gears and the rack.

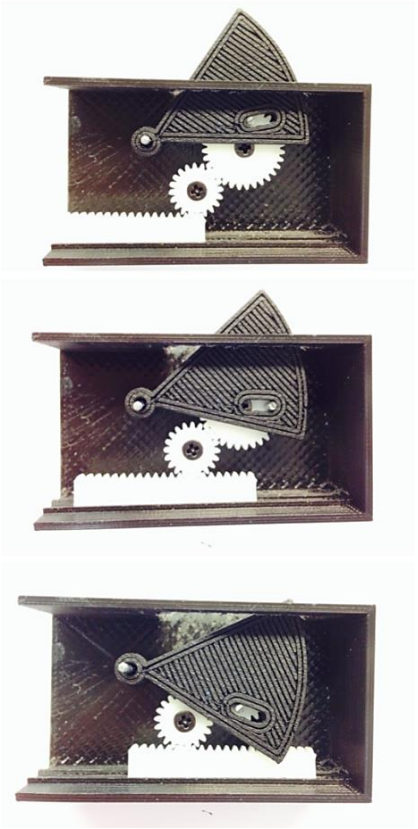

**Figure 3-2-2-3f:** Prototype 4

A possible solution for the consideration is that the case can be constructed lower in its height. In that way, the button is not able to get fully in the case. The button also needs to be modified to not collide with the rack below. This is achieved by adding a recess on the back of the button. In this way, a further movement of the rack is ensured. A connection of the button on both sides ensures, that the button is fixed safely. To get the gears fixed, bolts instead of screws should be used. It should be noted, that the bolts should not stick out of the surface of the gear. In that way, the pin on the gear is still able to be attached. To improve the fixture of the rack, a possible solution could be, that a notch is attached on the rack and the rail in the case. Several considerations could also be implemented and improved, when an instrument-like case is used.

A few improvements of the design consideration described above, have been implemented in the fifth prototype. The button of the fifth prototype, illustrated in figure 3-2-2-3g, has been modified by adding a recess on the back. In this case a collision with the rack and the button is avoided. The case has

**Figure 3-2-2-3g:** Prototype 5

been scaled down in the height, in order to avoid that the button is fully in the case after pushing it down. The function of the prototype is as good as the function of prototype 4. The floppy connections still need to be designed to avoid a sticky dysfunction of the mechanism. The described prototype was the final prototype of 12-week internship. This prototype was part of the defence by the poster presentation at the University of Applied Sciences Zwickau on the 11th of February 2016.

Further developments include mainly the improvement of movement and disturbance influences of the mechanism. In the last step of the development a linkage, instead of a recess in the button, is used. In that way, the movement of the mechanism and the interaction of the assemblies was tried to improved. The fundamental principle, that the first gear hast to turn 180° and moves the is still the same. By using the linkage, the force surface caused by the recess on the pin, is decreased and an improvement of the movement of the assemblies is considered. The dimensions and sizes of the gears and the rack stay the same.

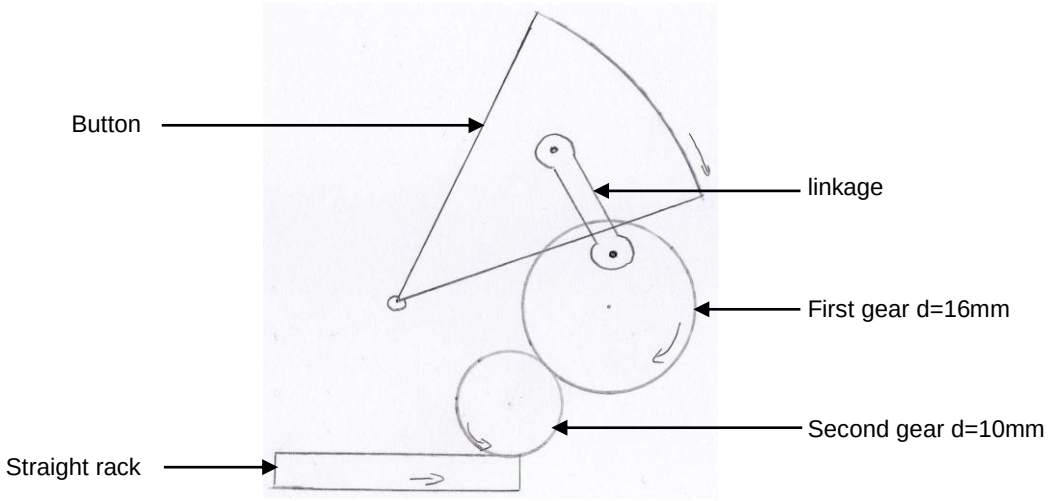


**Figure 3-2-2-3h**: Arrangement of the consideration with a linkage

As shown in figure 3-2-2-3h, the main fundamental principle is the same. The linkage is taking over the function of the recess of the previous prototypes. For the implementation, an analysis of the correct position, arrangement and dimension of the linkage is necessary to ensure the function of the considered mechanism. The movement of this mechanism is generated by pushing the button down, in that way, the applied force is transmitted to the linkage which is pressing against the fortified pin on the first gear. Because of the force of the pin, the first gear starts moving and transfers the travel distance through the second gear to the rack. The distance of pushing the button is still 10mm, if the pin on the gear is still placed 5mm away from the centre, with the difference that the button is pushed like an ankle. By using a linkage instead of a recess in the button, the top death centre is bypassed and the force is decreased. To overcome and ensure that the linkage will overcome the top death centre and stops after 180°

turning of the first gear, the calculation of the correct linkage size and the arrangement linkage is the most important part of this consideration.

The minimal length of the linkage can be calculated by taking into account the dimensions of the first gear. The travel distance, the linkage has to transfer is 10mm. The gear has a diameter of 8mm and the distance between the pin and the outer surface of the gear amounts 3mm. That means that the minimum length of the linkage needs to be 13mm, to avoid that the fixture of the linkage at the button is not colliding with the gear. An addition of 2mm is recommendable. In this case, the length of the linkage amounts 15mm. To ensure a smooth movement, the correct arrangement of the linkage has to be analysed.

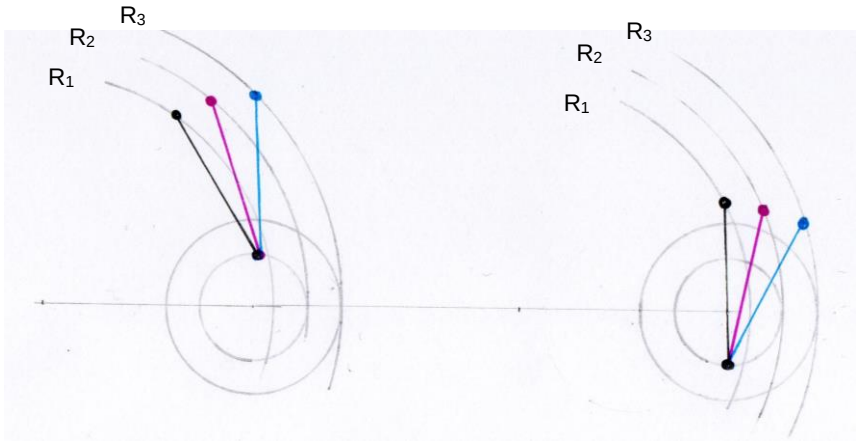


**Figure 3-2-2-3i:** Illustration of different linkage positions at the starting point (left) and at the end point (right)

Figure 3-2-2-3i illustrates different linkage positions at the starting point and the end point. The button is still placed on the horizontal-line of the gear centre with a distance of 20mm. Therefore, the linkage is fixed on the button, which is illustrated by the curves in figure 3-2-2-3i, in which the linkage is placed on different radii. The different radii illustrate the different positions of the linkage on the button. By virtue of the fixture of the linkage on the button, the fixture will stay on the same radius in the movement. In this way, a reconstruction of the positions is implementable. The consideration takes into account, that the linkage needs to be with an angle to the pin at the beginning and also needs to be with an angle in the other direction to the pin. This is necessary, to overcome the top death centre and to move the gear 180°. The black coloured linkage in figure 3-2-2-3i, is fixed on a radius of $R_1$=22,5mm on the button. As shown in the end position of the linkage, the end position it is not with an angle to the pin. This would cause, that the process is not removable, because the linkage would push on the top death centre of the bottom. The violet linkage is fixed on a radius of $R_2$=25mm, which is equal of the distance between the anklepoint of the button and the distance when the pin is also on the horizontal-line. As shown, the linkage promotes an angle at the beginning and at the end position. In this way, this position and placement of the linkage with the length of 15mm pro-

motes the desired function and movement of the gear. The linkage, which is placed on a radius of $R_3$=27,5mm, is shown in blue in the figure above. A placement on this radius would cause, that the linkage is pushing on top death centre and the gear wouldn´t move. Summarized, a linkage with a length of 15mm can only be fixed on the button at a radius of $R_2$=25mm, to ensure the desired movement of the gear. To place the linkage in the correct distance to the pin and the button, several calculations are necessary. Those calculations are attached in *Appendix page 5.*

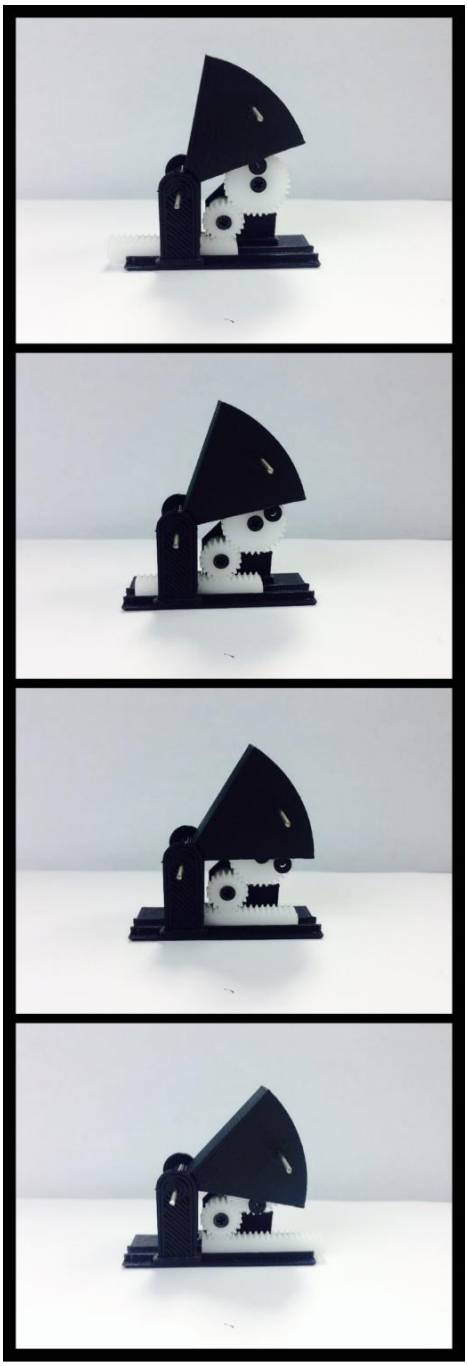

**Figure 3-2-2-3h**: final prototype

According to the calculations and the considerations of the previous pages, a new prototype has been implemented. The implementation of the final protoype is transposed to a spatial arrangement, which is more like the arrangement in a case. The button is fixed on both sides by two uprights with a rod through the button. In this way, the button is fixed in a better way than in the previous prototypes. The linkage is fixed by a rod on the inside of the button. The protoype promotes a smooth movement with a small amount of force. It promotes the desired length with the whole 180°-degree movement of the first gear. The considerations according to this final prototype are, that a spring needs to be attached to remove the process. Besides the button, the pin on the gear needs to be attached on both sides to decrease the forces on the pin. The pin needs to have a head. In that way the linkage is not able to jump out of the pin. Another improvement would be to decrease the angle of the button. As shown in the first picture of figure 3-2-2-3h, the button is too high to be pushed comfortable by the user. In that way, a user with small fingers could have problems to push the button. To improve the movement of the mechanism, several springs such as a torsion spring on the gear centre or the anklepoint of the button need be attached. Another improvement could be implemented for the fixture of the gears, button and the rack. For further improvements an analysis of the forces for this has been made. In this way, possible improvements of the shape and movement of the mechanism can be considered. The final prototype for the button, which will be added into the HeartStitch MR is shown in figure 3-2-2-3h.

*3.2.2.4 Analysis of the forces*

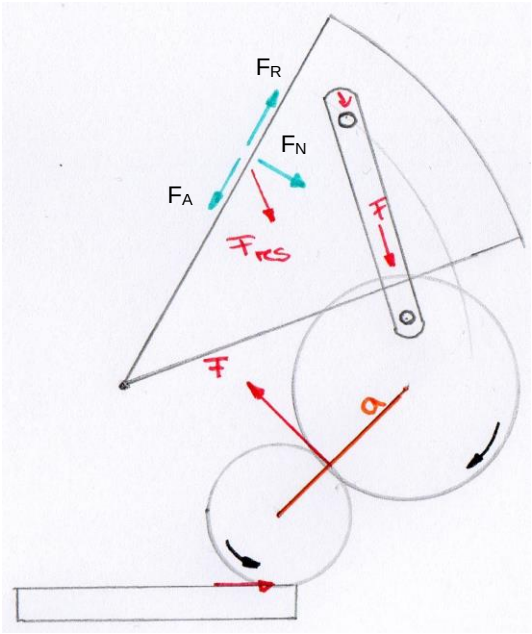


**Figure 3-2-2-4a**: Analysis of the forces in the mechanism with the linkage

The analysis of the forces, as shown in figure 3-2-2-4a, resulted that different forces are existing in the mechanism. The force on the surface of the button is comparable with the force, which is on the inclined plane. $F_A$ corresponds to the pull-down force and $F_R$ on the friction force. $F_N$ is referred as normal force. The resulting force $F_{res}$ is due from the pull-down force and the normal force. The red arrows illustrate the forces, which are expected, when the button is pushed. The present forces at the gears are already increased by the use of the law of gearing. A smooth movement of the gears with the rack is already achieved by the use of the law of gearing. The expectation is, that the highest force is on the rod, where the linkage is fixed with the button. This could cause, that the linkage could bent if the linkage or the fixture is not stable. A consideration to decrease the forces in the mechanism could be achieved, if a bigger diameter of the rod for the fixture of the linkage with the button is used. This would cause, that the force is divided up on the bigger surface of the pin. Therefore, the linkage needs to get a design update. The implementation ensues, that the rod for the fixture is bigger which cause, that the head of the linkage will be bigger in its wide. The side of the connection with the pin stays the same. A decrease of the forces could also be achieved, if the mechanism would have two linkages, placed on each side of the gear. In that way, the force which is applied by pushing the button, is divided on both linkages. The approximated shape of the linkage will be like a V. An improvement could be achieved if several springs such as a torsion spring is used to support the movement of the mechanism. The process is reversible, when the springs to the support for the pushing-process is the same like the springs to reverse the process.

### 3.2.3 Evaluation of the result

The further development of the HeartStitch MR was to find a mechanism of a button, which is pressed only 1cm-1.5cm in order to pull a stable wire with a travel distance of 2.23cm. With this mechanism, the needle is extended and the mitral valve can be sutured. Various users, with different anatomical characteristics are able to use the button instead of the lever. The current result amounts, that the desired mechanism was achieved. In this case, gears were used to translate the movements in connection with a rack. Out of the considerations and development steps with a large amount of time, a well-functioning mechanism has been developed. The mechanism and the prototype, still needs further development.

A multiple actuation and test of the button showed that the mechanism works reliably to move the needle for their operation at the heart. The general evaluation can be summarized in that way, that mechanism from the first prototype to the final prototype has been steadily improved. Based on the available materials, software and 3-D printers an improvement of the individual sub-components and the entire mechanism has been achieved with the increasing knowledge for implementation. Difficulties have been shown in all prototypes in the implementation of the fixture of the components such as the gears, the rack or the button itself.

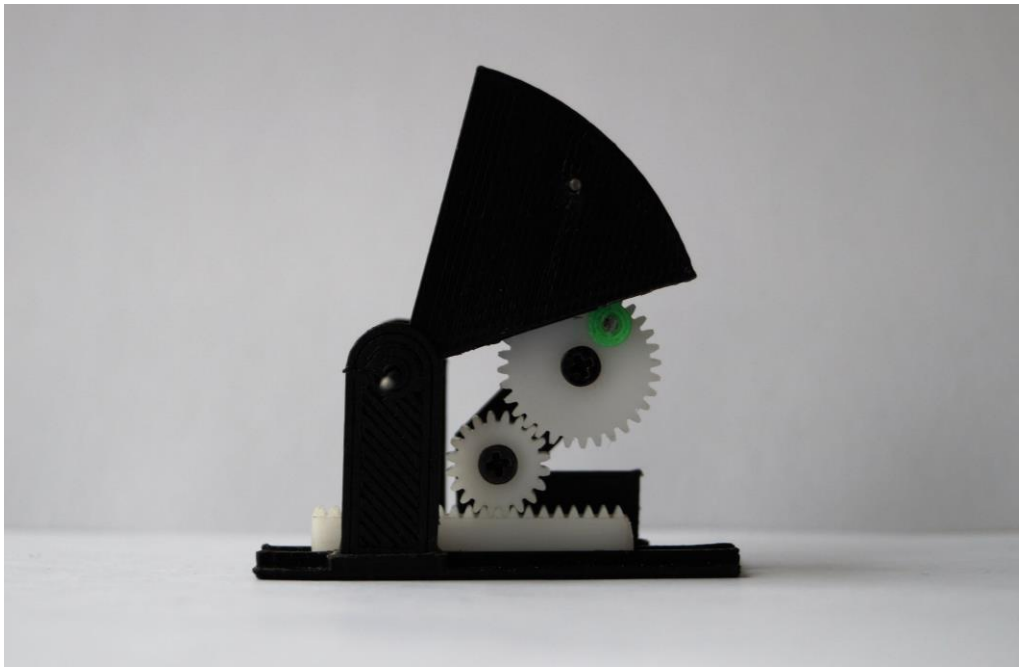

**Figure 3-2-3:** Enlarged image of the final prototype

Besides many extensive development steps of the mechanism, further steps need to take place to install and place the mechanism into the future HeartStitch MR II instrument. Furthermore, the device must go through several tests in the production and animal experiments-laboratory need to be carried out before the device is established on the market.

## 3.3 Failure Mode and Effects Analysis of the HeeartStitch MR

### 3.3.1 Summary of the FMEA for the HeartStitch MR

A FMEA for the HeartStitch MR was made by using the prepared FMEA of a similar product. The complete table of the FMEA is attached in the Appendix on Page 5 It consists, beside the top sheet, 15 more pages and is a kind of a product-design FMEA. The FMEA of the Heart-Stitch Inc. company consists out of four main categories. Those four sectors are the Biological Facts, Environmental Hazards, User and Design and the Sector of Fabrication/Function. The classification of risk is carried out similar to the risk categories described in chapter 2.3.2. Here, the risk factor is calculated by the values of the probability of likelihood and severity. The respective multiply risk can be divided into three different categories: If the result of the risk factor has a value of 1 to4, a minimal risk in which no further action is required. At a result of 5 to9 an acceptable risk occurs in which further efforts needs to be taken to control and detect the risk possibility. An unacceptable risk factor occurs at a value equal or more than 10. This risk needs to be reduced until the production is over to avoid hazards in the use of the device. An accurate indication of the recent exact values of the likelihood and severity of the attached FMEA was not possible until now, because the production of HeartStitch MR II has not started yet. Therefore, there is a need of further steps for the completion of the FMEA of the Heart-Stitch MR II until it will be released on the market. However, possible errors are listed, analysed and adjusted by the template of the FMEA of another suture based-device.

The table in the attachment shows that different failure modes can have other causes. In section 1 is described, which biological factors such as allergic effects, infections and inflammatory response can be caused by the potential failure modes and their causes. An example for the same potential failure modes are shown under line 1.1 and 1.2 Non-sterile device. This failure mode can be caused by inadequate sterilization or packaging failure. Mitigations for the inadequate sterilization can be made by the validation of the sterilization and different steps of sterilization procedures. In case of packaging failures mitigations can be made by special inspections of received materials and the validation of the packaging procedure. Both failure modes with the different causes got the same risk factor and is therefore an acceptable risk where many inspections of the materials and the associated validation of the procedures takes place to reduce the risk factor. The table also shows that the likelihood is able to be decreased by several mitigation steps. Because these errors and their risks also apply for use of the HeartStitch MR, the first section of the biological effects can be taken over.

Section 2 describes the environmental hazards especially when electrical components are used in the device. An example for this hazard could be described as electric discharge, which not applies to the HeartStitch MR, because the device is not connected to any power supplies.

Failure modes and their causes and effects of users and the design is described in section 3 of the FMEA. An example for the adaption of the FMEA for the HeartStitch MR can be found in row 3.2, which describes that the arm is not going to deploy. Probable causes are a misuse of the device such as an incorrect insertion of the device into the heart or that the user is bending the extrusion. A cause in the design could be that a failure of the internal components in the handle are preventing the components for the arm to get deployed. A detailed Instructions for Use –IFU for the correct use could be attached into the package to avoid such errors, as well as doing a design verification and production qualification PQ can be accomplished. Another failure mode is described in line 3.10, page 7 of 16 of the FMEA, where the needle does not engage the suture end, which has the effect that the procedure cannot be completed and an alternative method or another device needs to be used to complete the stitch. The user can find probable causes in a misuse of the device. Especially for the development of the button, for the activation of the needle a cause could be that the user is not pushing the button down enough. This causes that the travel distance will not fully achieved. The design verification as well as the IFU and instructions how to press the button fully could be a mitigation to minimize this risk. Another mitigation could be to add a sign or a snapping of the button to convey the user that the button has been fully pushed.

In the last section the fabrication and function and their failure modes are described at the beginning of page 10 of 16 of the FMEA. In this section the causes of the fabrication such as the function of the device itself are described. Causes in the fabrication especially in the production and the procedures and the resulting failures are for example when the needle is jamming out of its guide and is unable to catch the suture end. Causes in the fabrication can be found in a failure or dispositioning of the needle guide in the fabrication during the assembly of the components or in the function of the components as well as an insufficient clearance of the needle in the needle guide. Mitigations can be made in testing of the process performance qualification- PPQ, process validation and in design verifications. Final inspections of the function and collection of the assemblies can also reduce the likelihood of the failure mode.

### 3.3.2 Effect of the Analysis on the Prototype

The effect on the prototype and the development on the device are to add a feedback or sign for the user, that the button is pushed fully to show that the needle is retracted and the suture is catched safely. Another effect is made in the IFU with exact drawings and explanations for the correct use of the device. Also test such as PPQ, process validation and design verifications need to take place to reduce the likelihood of the development specific possible failure modes.

## 3.4 Patenting

A patent about the developed mechanism was handed in November 2015 at the patent office. According to current knowledge, the patent status is in the examination state. Accordingly, the claims and the investigation of existing patents are reviewed. The patent was applied with the help of a patent attorney, who previously examined and discussed further development steps., The claims were similarly discussed and understood in a team. All needed requirements for the registration of the patent like important considerations, drawings and prototypes have been described and collected.

# 4. Summary and Outlook

In summary, the task statement was to develop a button, which is able to push 1.0 cm down to move a travel distance of 2.23 cm, has been achieved and implemented. A mechanism, a doctor is able to push to activate the needle has been found by using the theoretical principles of interacting gears. The implementation of several ideas and considerations have been realized by using 3D-printers to produce individual prototypes. Besides the use of the theoretical principles for gearing, a FMEA has been prepared to reduce the risk of several failure modes. This FMEA still has to develop until the development of the HeartStitch MR is completed and is ready to be released on the market. Besides the successful development of the mechanism a U.S. patent has been registered. Assumed that the research of the patent office is successful without any qualifications the patent according to the mechanism will be accomplished. In conclusion the mechanism still needs to be developed. In further development the fixture of the gears, racks and the button needs to be improved. Furthermore, the movement of mechanism has to be able to be returned with several springs like torsion springs or compression springs. Extensive drawings, calculations and arrangements have to be made to include the mechanism into the original device. Therefore, several test like the process performance qualification – PPQ needs to be proceed to ensure that the production is equal to avoid fatal failure modes. The FMEA needs to develop too. This is necessary to avoid other failure modes according the fabrication, design or in the use of the device. In outlook on the HeartStitch MR device, the mechanism will be installed into the device. In that way, users like surgeons and physicians are able to use the device easily with one hand. The comfort and the ergonomic for the user will be improved. In the course of the development and the continuous development of the device a surgery using of only one instrument instead of two is possible. This is possible when the function is build doubled into the device. Here, it should be taken into consideration that the needle needs to be activated sequent. With this improvement, the operation time and the risk of infection can be minimized during the procedure.

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# Appendix

Page 1

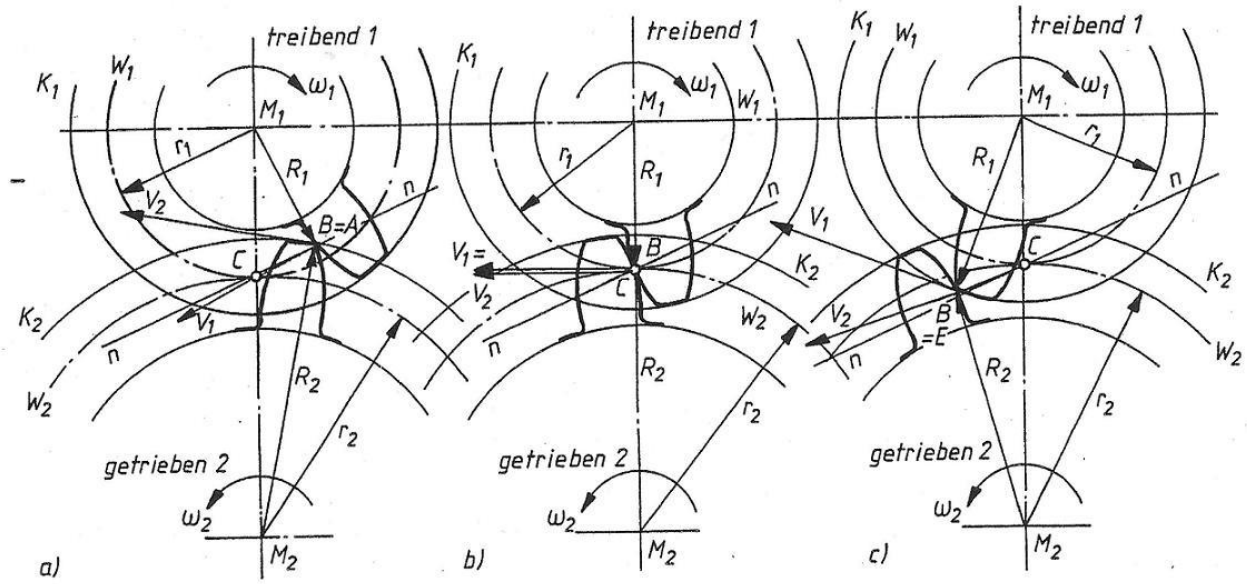



**Figure A1:** law of gearing and movement of the teeth of the gears. [30]

The figure above shows the movement of two touching teeth of two interacting gears. The figure shows the first touching point, the movement and the line of interaction n until those two teeth stop touching. With the calculations in chapter 2.2.2 the smooth movement of the law of gearing is ensured.

| Process Function/ Requirements | Potential Failure Mode | Potential Effect(s) of Failure | Sev | Potential Cause(s)/ Mechanism(s) of Failure | Occur | Current Process Controls | Detec | RPN | Recommended Actions | Responsibility & Target Date | Actions Taken | Action Results | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | Sev | Occ | Det | R.P.N |
| Joining of similar metals via solder process | Incomplete braze joint | Intermittent Function | 8 | Improper Set-Up (i.e. Power setting, Coil Size, Time Setting, etc.) | 8 | Documented Work Instruction | 8 | 512 | Develop Point of Use (POU Work Instructions with Set-Up Matrix & "Flip Chart" | John Doe 11/10/2006 | POU's deployed. | 8 | 5 | 7 | 280 |
| | | | 8 | | 8 | Leak sampling test based on part-specific requirements | 4 | 256 | | | | | | | |
| | | | 8 | | 8 | Visual inspection | 6 | 384 | | | | | | | |
| | | | 8 | Improper Coil condition | 8 | Clean & Wire Brush | 7 | 448 | Develop Preventive Maintenance Program | John Doe 11/10/2006 | PM's developed and activated. | 8 | 5 | 7 | 280 |
| | | | 8 | Improper Flux application | 8 | Visual | 5 | 320 | | | | | | | |
| | | Inoperable function | 9 | Improper Set-Up (i.e. Power setting, Coil Size, Time Setting, etc.) | 6 | Documented Work Instruction | 8 | 432 | Develop Point of Use Work Instructions with Set-Up Matrix & "Flip Chart" | John Doe 11/10/2006 | POU's deployed. | 8 | 5 | 7 | 280 |
| | | | 9 | | 6 | Leak sampling test based on part-specific requirements | 4 | 216 | | | | | | | |
| | | | 9 | | 6 | Visual inspection | 5 | 270 | | | | | | | |
| | | | 9 | Improper Coil condition | 6 | Clean & Wire Brush | 7 | 378 | Develop Preventitive Maintenance Program | John Doe 11/10/2006 | PM's developed and activated | 8 | 5 | 7 | 280 |
| | | | 8 | Improper Flux application | 6 | Visual | 5 | 240 | | | | | | | |

**Figure A2:** Example of a FMEA- Analysis. [31]

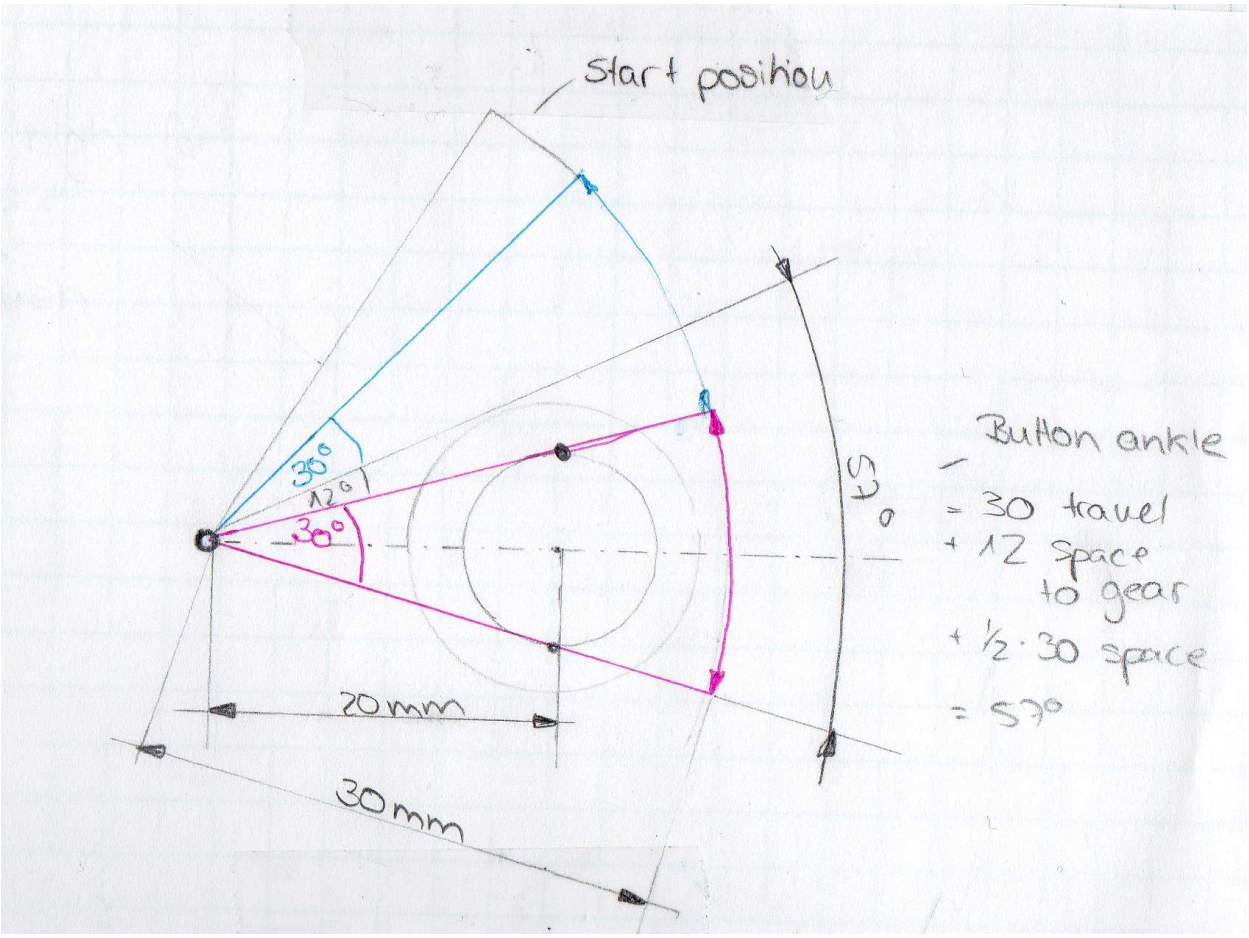



**Figure A3:** Position and angle of the button at the horizontal placement of the button to the gear centre.

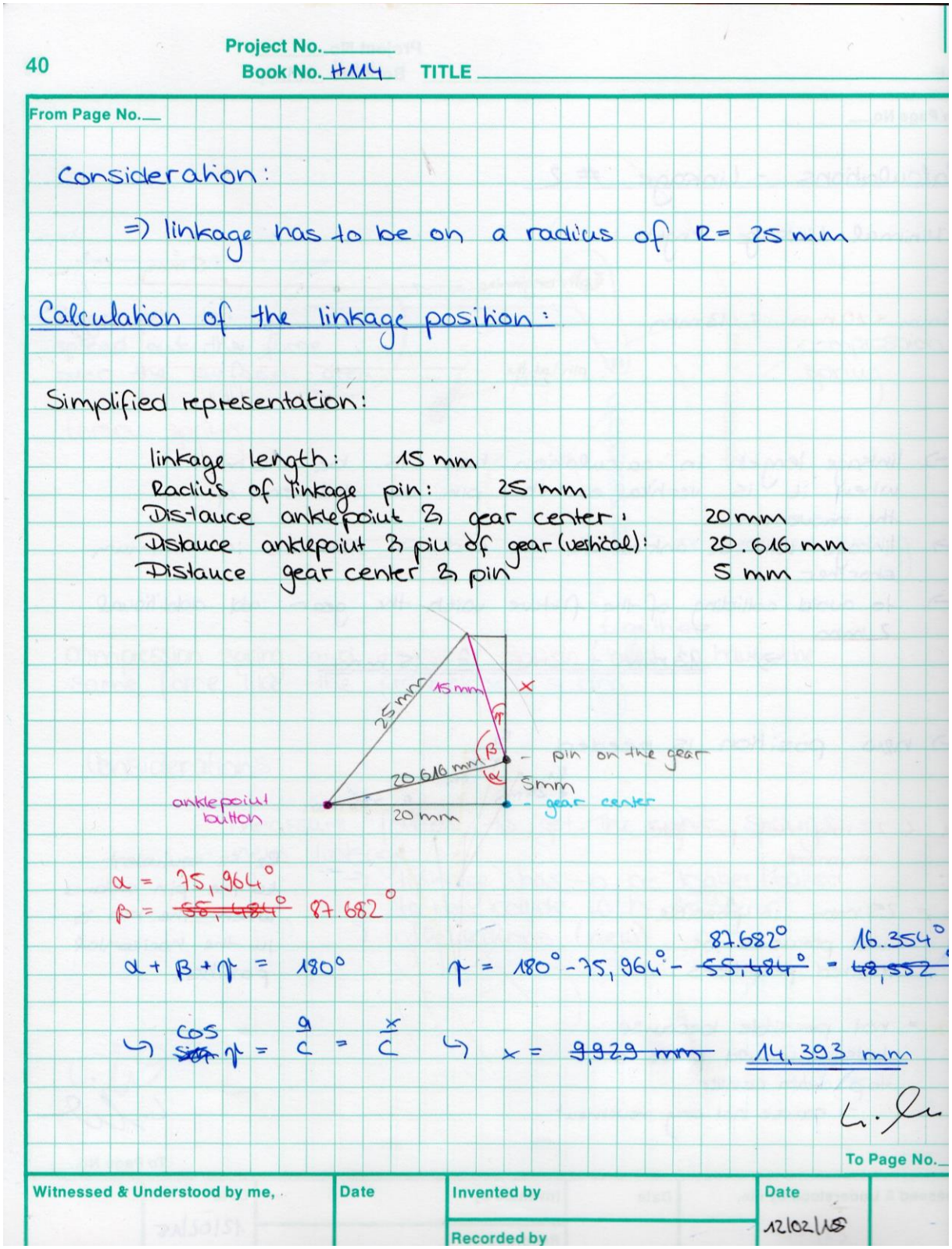



**Figure A4_1:** Calculations for linkage 1.

TITLE

Project No.

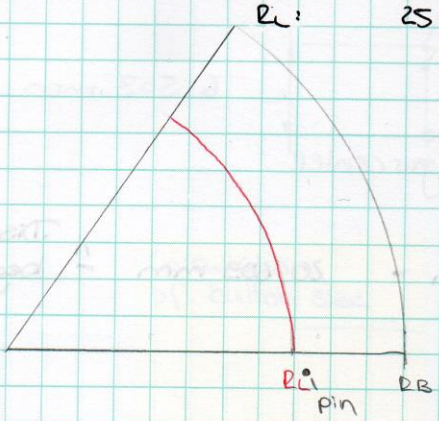
Book No. H114

From Page No.

Button:

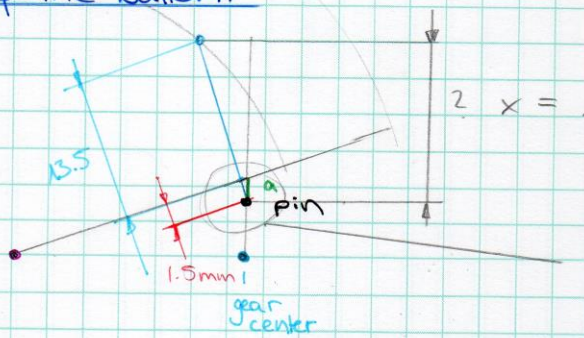
outher radius of the button $R_B$: 35 mm

Radius linkage $R_L$: 25 mm




→ let linkage overlook at the end to attache it better in the production process → 1,5 mm

Startankle of the button:




2 x = 14,393 mm

b = 0.44 mm

c = 1.563

15

16.354°

→ 1.5 mm above pin

→ linkage in button → 15 mm − 1.5 mm = 13.5 mm

→ distance on button needed

To Page No.

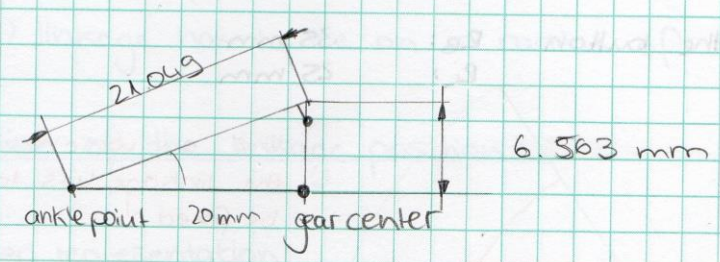
| Witnessed & Understood by me, | Date | Invented by | Date |
|---|---|---|---|
| | | Recorded by Linda Weichenhain | 12/07/15 |

**Figure A4_2:** Calculations for linkage 2.

42 Project No._____
Book No._____ TITLE _____

From Page No.___

Position on the button




21.049 − 0.44 mm = 20.609 mm ≙ Distance vertical beginning of linkage

To Page No.____

| Witnessed & Understood by me, | Date | Invented by | Date |
|---|---|---|---|
| | | Recorded by | 12/09/15 |

**Figure A4_3:** Calculations for linkage 3.

HEARTSTITCH®

Title: **HeartStitch MR, Suture-Based Closure Devices** **FMEA** Rev.: A

| Section 1, Biological Factors | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Potential Failure Mode | Probable Effect | Probable Cause | Severity (A) | Likelihood (B) | Initial Risk (A) x (B) | Mitigation | Final Likelihood (C) | Final Risk (A) x (C) | Reference Document |
| 1.1 | Non-sterile device | Infection | Inadequate sterilization cycle | 4 | 2 | 8 | Sterilization validation conducted. Finished product release includes cycle review. | 1 | 4 | Sterilization Validation Report<br>Sterilization Procedures |
| 1.2 | Non-sterile device | Infection | Packaging failure | 4 | 2 | 8 | Incoming materials inspection is performed for all components. In-process inspection. Packaging validation completed including integrity, environmental and shipping studies on aged, sterile devices. Packaging process validation. | 1 | 4 | Receiving / Inspection Procedure<br>Packaging PQ<br>Product PPQ |
| 1.3 | Not biocompatible | Allergic or inflammatory, response. | Materials not biocompatible | 4 | 2 | 8 | Material and finished device biocompatibility studies successfully completed. Receiving inspection ensures correct materials are ordered. Certificate of conformance verified. | 1 | 4 | Biocompatibility Test Report |
| 1.4 | Not biocompatible (suture) | Allergic or inflammatory response. | Incorrect material used | 4 | 1 | 4 | Suture is a currently marketed and proven device supplied by a qualified vendor. Certificate of conformance verified. | 1 | 4 | Receiving / Inspection Procedure<br>Biocompatibility Test Report |
| 1.5 | Breach of user's sterile barrier in operating room. | Potential infection / disease via body fluid contact. | Perforation of surgical gloves by device due to sharp edge, burr, or needle. | 4 | 2 | 8 | Design utilizes rounded edges and retracted needles. In-process inspection, finished device inspection. IFU states user should avoid needle path. | 1 | 4 | Recieving inspection of handles. In-process inspection & final inspection of device. |

| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | LEGEND |
|---|---|---|---|
| 1 – No injury | 1 – Very Low | 1-4 Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | |

| Section 2, Environmental Hazards | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Potential Failure Mode | Probable Effect | Probable Cause | Severity (A) | Likelihood (B) | Initial Risk (A) x (B) | Mitigation | Final Likelihood (C) | Final Risk (A) x (C) | Reference Document |
| 2.1 | Electric discharge | N/A | N/A | N/A | N/A | N/A | Does not contain or connect to power sources. | N/A | N/A | N/A |

| Section 3, ~~Product Use~~ User and Design | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Potential Failure Mode | Probable Effect | Probable Cause | Severity (A) | Likelihood (B) | Initial Risk (A) x (B) | Mitigation | Final Likelihood (C) | Final Risk (A) x (C) | Reference Document |
| 3.1 | Bullet tip is separated from the bullet. | Bullet tip becomes embolized or may require surgical intervention. | Bullet tip catches on the access device. | 4 | 2 | 8 | Design Verification conducted Production Qualification of bullet tip insert molding process conducted. | 1 | 4 | Bullet Molding PQ |
| 3.2 | Arms do not deploy. | Inconvenience to user. | User does not insert device sufficiently to allow device bullet past end of cannula. Variation in length of introducers. | 1 | 2 | 2 | IFU contains instructions for proper use. Design incorporates markings for positioning of device. | 1 | 1 | IFU<br>Assembly Drawings |
| | | | User twists or bends extrusion while attempting to open arms. | 1 | 2 | 2 | IFU contains instructions for proper use. | 1 | 1 | |
| | | | Failure of internal components of the handle. | 1 | 1 | 1 | Design Verification conducted Production Qualification of handle components (Functional testing). | 1 | 1 | |
| 3.3 | Arms do not close. | Surgical intervention required to remove the device. | User does not follow proper procedure when using device. | 3 | 2 | 6 | IFU contains instructions for proper use. User instructed to cycle arms open/close prior to use. | 1 | 3 | IFU |
| | | | Failure of internal components of handle. | 3 | 2 | 6 | Design Validation conducted Design Verification conducted (Functional Testing). | 1 | 3 | PPQ |
| | | | Needles catch on arms due to improper use of the device. | 3 | 2 | 6 | Final inspection on 100% of finished product verifies needle clearance through arms. | 1 | 3 | Work Orders |
| | | | | | | | Relief added to arm design. | | | Product Drawings |

| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | LEGEND |
|---|---|---|---|
| 1 – No injury | 1 – Very Low | 1-4 Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 3.4 | User unable to retract device due to tissue captured in arms after closing. | Inconvenience to user.<br>Surgical intervention may be required if tissue is unable to be dislodged. | User does not relax tension on the device prior to closing the arms. | 3 | 2 | 6 | IFU contains instructions to open / close arms if difficulty in retraction experienced. This should free trapped tissue. | 1 | 3 | IFU |
| | | | Loose tissue around suturing site or chordea catches on arms. | 3 | 1 | 3 | Design Verification conducted (Functional Testing in bovine artery). Animal studies.<br>Design Validation conducted. IFU contains instructions for proper use. | 1 | 3 | PPQ |

| Section 3, ~~Product Use~~–User and Design | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Potential Failure Mode** | **Probable Effect** | **Probable Cause** | **Severity (A)** | **Likelihood (B)** | **Initial Risk (A) x (B)** | **Mitigation** | **Final Likelihood (C)** | **Final Risk (A) x (C)** | **Reference Document** |
| 3.5 | User unable to retract device due to tissue capture after needle retraction. | Inconvenience to user.<br>Surgical intervention may be required if tissue is unable to be dislodged. | Loose tissue around suturing site catches in distal end. | 1 | 3 | 3 | IFU contains instructions for proper use, User training. | 2 | 2 | IFU |
| | | | | 3 | 2 | 6 | Design Validation completed | 1 | 3 | PPQ |
| 3.6 | Needles do not deploy. | Unable to complete the procedure with the device. Alternative method used to close site. | Inadequate withdrawal of access device to allow deployment. | 1 | 2 | 2 | IFU contains instructions for proper use of device.<br>IFU contains instructions for user to compare length of device and it's indexing features against the length of the access device.<br>Design Validation conducted. | 1 | 1 | IFU<br>PPQ |

| | | | |
|---|---|---|---|
| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | LEGEND |
| 1 – No injury | 1 – Very Low | 1-4 Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 3.7 | Needles are deployed into the wall of the access device. | Needles not likely to both engage and deliver suture. Alternative method may be used to achieve closure.<br><br>Surgical intervention may be required if introducer is stitched to cardiac tissue. | Improper positioning of access device to allow deployment. | 1<br><br>3 | 2<br><br>2 | 2<br><br>6 | IFU contains instructions for proper use.<br><br>Design incorporates features for device positioning. | 1<br><br>1 | 1<br><br>3 | IFU<br><br>Product Drawings |

**Section 3, ~~Product Use~~ User and Design**

| | Potential Failure Mode | Probable Effect | Probable Cause | Severity (A) | Likelihood (B) | Initial Risk (A) x (B) | Mitigation | Final Likelihood (C) | Final Risk (A) x (C) | Reference Document |
|---|---|---|---|---|---|---|---|---|---|---|
| 3.8 | Needle path altered. | Suture ends missed | Sheath not properly retracted. | 1 | 2 | 2 | IFU contains instructions for proper use. | 1 | 1 | IFU |
| | | Needle Prolapse | Patient anatomy. | 2 | 1 | 2 | Design incorporates features for device positioning. | 1 | 2 | Product Drawings |
| | | Needle break | | 3 | 1 | 3 | Design Validation.<br>Receiving inspection of the material. | 1 | 3 | PPQ report XXXX |
| 3.9 | Needle engage both suture ends, but not through tissue wall. | Inconvenience to user, unable to achieve closure. Alternative method may be used. | Improper positioning of device prior to needle deployment | 1 | 2 | 2 | IFU contains instructions for proper use.<br><br>Design incorporates features for device positioning.<br>User training. IFU contains instructions for proper use. | 1 | 1 | IFU<br><br>Product Drawings |

| | | | |
|---|---|---|---|
| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | LEGEND |
| 1 – No injury | 1 – Very Low | 1-4 Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 3.10 | Needle, does not engage suture end. | Unable to complete the procedure with the device. Alternative method used to achieve closure. | User does not activate control to the required position to effect proper needle travel. | 1 | 3 | 3 | IFU contains instructions for proper use. Instructions state to minimize lateral movement. | 1 | 1 | IFU |
| | | | User bends device in lateral direction affecting travel of needle. | 1 | 3 | 3 | IFU describes proper use. | 1 | 1 | Product Drawings |
| | | | User applies inadequate tension on device when deploying needles. | 1 | 3 | 3 | In-service training as to feel of adequate force. (e.g. leg training model). | 1 | 1 | |
| | | | Suture ends become dislodged from the suture delivery arm during insertion through access device. | 1 | 3 | 3 | Design Verification ~~conducted~~. | 1 | 1 | PPQ |
| | | | User doesn´t push the button down enough. | 2 | 2 | 4 | Design Verification. IFU contains instructions for proper use. Instructions state to press fully. | 1 | 2 | PPQ |

| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | LEGEND |
|---|---|---|---|
| 1 – No injury | 1 – Very Low | 1-4 Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | |

| Section 3, ~~Product Use~~ User and Design | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Potential Failure Mode** | **Probable Effect** | **Probable Cause** | **Severity (A)** | **Likelihood (B)** | **Initial Risk (A) x (B)** | **Mitigation** | **Final Likelihood (C)** | **Final Risk (A) x (C)** | **Reference Document** |
| 3.11 | Device perforates ~~vessel wall.~~ Aortic valve, septum, myocardium or chordea. | Unable to complete the procedure with the device. Surgical Intervention may be required to repair damaged vessel to achieve hemostasis. | Guidewire in tip pushes tissue. | 3 | 1 | 3 | Device tip designed with flexible tip.<br><br>Design Validation conducted.<br><br>User training<br><br>IFU contains instructions for proper use. | 1 | 3 | Product Drawings<br><br>PPQ<br><br>IFU |
| 3.12 | Device damages tissue wall. | Intervention may be required to repair damage to tissue. Alternative method may be required to achieve closure. | Sharp edges of arms cause damage during positioning.<br><br>Needles tear through tissue due to improper needle retraction. (Needles deployed arms open). | 2<br><br>3 | 2<br><br>2 | 4<br><br>6 | Device arms are designed with blunt ends to minimize damage.<br><br>Histopathology performed on animal studies.<br><br>IFU containes instructions for proper use.<br><br>User training. | 1<br><br>1 | 2<br><br>3 | Product Drawings<br><br>Test Reports 900156, 900158, 900162.<br><br>IFU |
| 3.13 | Suture tears through tissue. | Suture not able to be tied. Unable to complete the procedure with the device. Alternative method may be required for closure. | Excessive force applied to suture or weak tissue.<br><br>Tissue capture inadequate, or weak tissue. | 2<br><br>2 | 2<br><br>3 | 4<br><br>6 | IFU contains instructions for proper use.<br><br>User training<br><br>Design Validation conducted | 1<br><br>2 | 2<br><br>4 | IFU<br><br>PPQ |

| | | | |
|---|---|---|---|
| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | LEGEND |
| 1 – No injury | 1 – Very Low | 1-4 Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | |

| Section 3, ~~Product Use~~ User and Design | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Potential Failure Mode** | **Probable Effect** | **Probable Cause** | **Severity (A)** | **Likelihood (B)** | **Initial Risk (A) x (B)** | **Mitigation** | **Final Likelihood (C)** | **Final Risk (A) x (C)** | **Reference Document** |
| 3.14 | Device incompatible with access device. | Device cannot be inserted into access device | Incorrect closure device selection relative to access device. | 1 | 2 | 2 | IFU specifies that user needs to gauge device against introducer. Introducer Compatibility Tested. | 1 | 1 | IFU |
| | | Device unable to close site because access device is too large. | | 1 | 2 | 2 | Product labeling specifically defines intended access device size. | 1 | 1 | Device packaging |
| 3.15 | Suture ends become untied while advancing knot through and out of tissue. | Unable to complete closure | Hand knot tied incorrectly by physician | 1 | 2 | 2 | IFU contains instructions for proper use.<br><br>User training<br>Using KwiKnot 2 | 1 | 1 | IFU |
| 3.16 | Only one of the sutures is captured (secondary or primary) | Unable to complete the procedure with the device. Alternative method used to achieve closure or additional single side device deployed. | User does not activate control to the required position to effect proper needle travel. | ~~1~~ | ~~3~~ | ~~3~~ | IFU contains instructions for proper use. Instructions state to minimize lateral movement. | ~~1~~ | ~~1~~ | ~~IFU~~ |
| | | | User bends device in lateral direction affecting travel of needle. | ~~1~~ | ~~3~~ | ~~3~~ | IFU describes proper use. | ~~1~~ | ~~1~~ | ~~Product Drawings~~ |
| | | | User applies inadequate tension on device when deploying needles. | ~~1~~ | ~~3~~ | ~~3~~ | In-service training as to feel of adequate force. (e.g. leg training model). | ~~1~~ | ~~1~~ | |
| | | | Suture ends become dislodged from the suture delivery arm during insertion through access device. | ~~1~~ | ~~3~~ | ~~3~~ | Design Verification conducted. | ~~1~~ | ~~1~~ | ~~PPQ~~ |
| | | | Anatomy restricts the placement in the exact opposing location | ~~1~~ | ~~3~~ | ~~3~~ | Repositioning of device (in service traing) | ~~1~~ | ~~1~~ | |

S = SEVERITY SCALE
1 – No injury
2 – Minor Injury
3 – Moderate Injury
4 – Severe Injury
5 – Likely Death

L = LIKELIHOOD
1 – Very Low
2 – Low
3 – Medium
4 – High
5– Very High

RF = RISK FACTOR (SEVERITY x LIKELIHOOD)
1-4 Minimal Risk – No action required.
5-9 Acceptable Risk – Reasonable effort must be take to control or detect.
10 or > Unacceptable Risk – Must be reduced before production turn over.

LEGEND
S = SEVERITY
L = LIKELIHOOD
RF = RISK FACTOR
FL = FINAL LIKELIHOOD

| Section 4, Fabrication / Function | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Potential Failure Mode | Probable Effect | Probable Cause | Severity (A) | Likelihood (B) | Initial Risk (A) x (B) | Mitigation | Final Likelihood (C) | Final Risk (A) x (C) | Reference Document |
| 4.1 | Tapered tip is separated from the bullet. | Tapered tip becomes embolized. | Molding process inadequate.<br><br>Drive wire travel extends too far, bullet tip pushed out the end of device. | 3<br><br>3 | 2<br><br>2 | 6<br><br>6 | In-process inspection/testing conducted for each lot of components produced.<br><br>Process validation<br><br>Production Qualification of Tapered tip insert molding process conducted.<br>Design modification. | 1<br><br>1 | 3<br><br>3 | Work Order<br><br>IQ/OQ/PQ XXXX<br><br>PQ |
| 4.2 | Bullet is separated from the extrusion. | Arms fail to close. Surgical intervention may be required to remove the device.<br><br>Possibility of bullet becoming embolized. | Drivewire or pin connecting arm breaks and the bullet to extrusion bond fails. | 4 | 1 | 4 | Verification Testing conducted on drivewire subassembly.<br><br>Production Qualification conducted on bullet to extrusion bonding process and drivewire subassembly .<br><br>In-process and finished device inspection. | 1 | 4 | PQ<br><br>PQ<br><br>Work Orders |
| 4.3 | Arms separate from the device and become embolized . | Surgical intervention may be require to remove components. Alternative method used to achieve closure. | Arm drivewire pin does not have adequate strength. | 4 | 1 | 4 | Process Validation and Design verification conducted. | 1 | 4 | PQ<br><br>PPQ |

| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | | LEGEND |
|---|---|---|---|---|
| 1 – No injury | 1 – Very Low | 1-4 | Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 | Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > | Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | | |

| Section 4, Fabrication / Function | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Potential Failure Mode** | **Probable Effect** | **Probable Cause** | **Severity (A)** | **Likelihood (B)** | **Initial Risk (A) x (B)** | **Mitigation** | **Final Likelihood (C)** | **Final Risk (A) x (C)** | **Reference Document** |
| 4.4 | Spreader to bullet weld failure resulting in device not working properly. Orientation and location do not allow for suture engagement. | Unable to complete the procedure with the device. Alternative method used to achieve closure. | Weld between the spreader and bullet has inadequate strength. | 2 | 1 | 2 | Design Verification conducted.<br>Production Qualification conducted on welding process<br>In-Process inspection conducted. | 1 | 2 | PQ<br>Work Orders |
| 4.5 | Needle deploys, do not engage suture end. | Unable to complete the procedure with the device. Alternative method used to achieve closure. | Needles not manufactured to specification (too long, too short, dull, poor suture hook, etc). | 2 | 3 | 6 | Final Inspection conducted on 100% of finished product includes needle penetration through arms.<br>Design Verification conducted. | 1 | 2 | Work Orders<br>Product Drawings<br>PPQ |
| | | | Needle hook tears through suture end "drops" suture end. | 1 | 2 | 2 | Inspection criteria | 1 | 1 | Work Orders |
| | | Potential foreign object embolization. Surgical intervention may be required. | Suture ends become dislodged from the suture delivery arm due to improper loading. | 2 | 3 | 6 | IFU instructs user to inspect suture in arms prior to use. | 1 | 2 | IFU |
| | | | Needle tip breaks off at a weak point (fabrication flaw) when deployed against spreader. | 3 | 2 | 6 | Design Validation conducted. | 1 | 3 | PPQ |

| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | LEGEND |
|---|---|---|---|
| 1 – No injury | 1 – Very Low | 1-4 Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | |

| Section 4, Fabrication / Function | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Potential Failure Mode | Probable Effect | Probable Cause | Severity (A) | Likelihood (B) | Initial Risk (A) x (B) | Mitigation | Final Likelihood (C) | Final Risk (A) x (C) | Reference Document |
| 4.6 | Suture fails prior to completion of procedure. | Unable to complete procedure with device. Alternative method to closure may be used. | Inadequate suture material strength.<br><br>Cut or fray caused during fabrication of donut. | 1<br><br>1 | 2<br><br>2 | 2<br><br>2 | Design Verification Testing.<br><br>In-process inspection and Quality Control inspection of suture and suture loading | 1<br><br>1 | 1<br><br>1 | Suture 510(k) K994087<br><br>PPQ |
| 4.7 | Latent suture or knot failure after completion of procedure. | Potential failure of suturing site. Medical attention may be required. | Suture strength inadequate. Knot slippage. Suture breaks, is cut or fray caused during handling or loading by our firm. | 3 | 2 | 6 | IFU recommends knot tying methods<br><br>Design validation conducted. | 1 | 3 | IFU<br><br>Test Reports 900156, 900158 and 900162 (Animal Studies).<br><br>PPQ |
| 4.8 | Extrusion clamp to extrusion bond failure prevents proper device function. Arms and needles do not operate properly. | Unable to complete the procedure with the device. Alternative method used to achieve closure. | Inadequate bond strength between extrusion clamp and extrusion. | 1 | 2 | 2 | Design verification conducted.<br><br>Production Qualification conducted on bonding process | 1 | 1 | PPQ<br><br>PQ |
| 4.9 | Drive wire to Puller attachment fails preventing proper device function. Arms do not open / close properly. | Unable to complete the procedure with the device. Alternative method used to achieve closure. | Inadequate weld strength between drive wire/shaft and tab.<br><br>Inadequate strength of dowel pins and/or improper assembly. | 1<br><br>1 | 2<br><br>2 | 2<br><br>2 | Design verification conducted (drivewire/shaft to tab functional testing).<br><br>Production Qualification conducted on welding process | 1<br><br>1 | 1<br><br>1 | PQ<br><br>PPQ |

| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | LEGEND |
|---|---|---|---|
| 1 – No injury | 1 – Very Low | 1-4 Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | |

| Section 4, Fabrication / Function | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Potential Failure Mode | Probable Effect | Probable Cause | Severity (A) | Likelihood (B) | Initial Risk (A) x (B) | Mitigation | Final Likelihood (C) | Final Risk (A) x (C) | Reference Document |
| 4.10 | Needles experience interference with needle guide. Jamming of needles prevents suture engagement. | Unable to complete the procedure with the device. Alternative method used to achieve closure. | Needle guide positioned improperly during fabrication.<br><br>Insufficient needle clearance in needle guide. | 1<br><br>1 | 2<br><br>2 | 2<br><br>2 | Design verification conducted.<br>Process Validation<br><br>Final inspection on 100% of finished product for proper needle function. | 1<br><br>1 | 1<br><br>1 | Product Drawings<br>PQ/IQ/OQ<br><br>Work Orders |
| 4.11 | Handles break apart causing device failure. Distal end of device potentially trapped in patient. | Unable to complete the procedure with the device. Surgical intervention may be required to remove the device. | Inadequate holding strength between handle halves. | 3 | 2 | 6 | Design verification conducted.<br>Process Validation<br><br>Final inspection on 100% of finished product. IFU warning to cycle arms open / closed prior to use. | 1 | 3 | PQ<br>PPQ<br>Work Orders |
| 4.12 | Guidewire port (if present) is obstructed or does not allow for proper guidewire use. | Inconvenience to user. Alternative method to achieve closure may be selected by user if desired. | Improper assembly of guidewire port and / or components affecting guidewire use.<br>Failure in extrusion | 1 | 2 | 2 | Design verification conducted.<br>Process Validation<br><br>Final inspection on 100% of finished product for guidewire clearance if guidewire port is present. | 1 | 1 | PQ<br>Work Orders |
| 4.13 | Needle experiences difficulty deploying or retracting. | Inconvenience to user. Alternate method to achieve closure may be required. | Device components improperly aligned or fit. Improper part | 1 | 2 | 2 | Design validation conducted<br>Design verification conducted.<br>Process Validation<br><br>Manufacturing Process Instructions<br>Quality Control, Inspection | 1 | 1 | PQ<br><br>W/O |

S = SEVERITY SCALE
1 – No injury
2 – Minor Injury
3 – Moderate Injury
4 – Severe Injury
5 – Likely Death

L = LIKELIHOOD
1 – Very Low
2 – Low
3 – Medium
4 – High
5– Very High

RF = RISK FACTOR (SEVERITY x LIKELIHOOD)
1-4 Minimal Risk – No action required.
5-9 Acceptable Risk – Reasonable effort must be take to control or detect.
10 or > Unacceptable Risk – Must be reduced before production turn over.

LEGEND
S = SEVERITY
L = LIKELIHOOD
RF = RISK FACTOR
FL = FINAL LIKELIHOOD



XXX

| Section 4, Fabrication / Function | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Potential Failure Mode | Probable Effect | Probable Cause | Severity (A) | Likelihood (B) | Initial Risk (A) x (B) | Mitigation | Final Likelihood (C) | Final Risk (A) x (C) | Reference Document |
| 4.14 | Spring pin dislodges, comes out of needle holder. | Unable to deploy needles properly. | Contaminated pins during molding.<br>Improper mold setup.<br>Mold misfire. | 1 | 1 | 1 | Design verification and process validation conducted | 1 | 1 | PPQ<br>PQ |
| 4.15 | Arm Lockout, comes out of Needle Holder. | Unable to close arms.<br>Surgical intervention may be required to remove the device. | Contaminated wire during molding.<br>Improper mold setup.<br>Mold misfire. | 1<br>3 | 1<br>1 | 1<br>3 | Design verification and process validation conducted<br>Design verification and process validation conducted | 1<br>1 | 1<br>3 | PPQ<br>PQ |
| 4.16 | Needle Holder Spring breaks. | Failure to retract needles. | Defective spring | 1 | 1 | 1 | Use emergency bail out Feature. | 1 | 1 | Product Drawings<br>Receiving / Inspection Procedure |
| 4.17 | Needle Button stud breaks off. | Needles may partially deploy. | Molding defect.<br>Excessive force with arms closed. | 1 | 1 | 1 | Device ineffectice; replace device | 1 | 1 | Product Drawings<br>Receiving / Inspection Procedure |
| 4.18 | Needle Button pivot breaks. | Needles will not deploy. | Molding defect. | 1 | 1 | 1 | Device ineffectice; replace device | 1 | 1 | Product Drawings<br>Receiving / Inspection Procedure |

| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | LEGEND |
|---|---|---|---|
| 1 – No injury | 1 – Very Low | 1-4 Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 4.19 | Needle Button lock-out feature breaks off. | Needles will deploy without arm being opened. | User did not follow proper operating instructions. | 1 | 1 | 1 | IFU states proper use of device | 1 | 1 | IFU<br>Product Drawings |

| Section 4, Fabrication / Function | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Potential Failure Mode** | **Probable Effect** | **Probable Cause** | **Severity (A)** | **Likelihood (B)** | **Initial Risk (A) x (B)** | **Mitigation** | **Final Likelihood (C)** | **Final Risk (A) x (C)** | **Reference Document** |
| 4.20 | Arm Button pivot point breaks. | Arms will not open. | Molding defect | 1 | 1 | 1 | Device ineffectice; replace device | 1 | 1 | Product Drawings<br>Receiving / Inspection Procedure |
| 4.21 | Arm Button pops out after use. | none | Molding defect or improper assembly. | 1 | 1 | 1 | None, procedure complete | 1 | 1 | Product Drawings<br>Work Orders<br>Receiving / Inspection Procedure |
| 4.22 | Arm retraction spring breaks. | Failure to close Arms. | Defective spring | 1 | 1 | 1 | Use emergency bail out feature. | 1 | 1 | Product Drawings<br>Receiving / Inspection Procedure |
| 4.23 | Needles come out of Needle Holder. | Unable to complete the procedure with device. Surgical intervention may be required to remove device. | Assembly error | 3 | 1 | 3 | Design verification and process validation conducted | 1 | 3 | PPQ<br>PQ |
| 4.24 | Arm Retraction Button Breaks | Failure to close arms | Molding defect | 1 | 1 | 1 | Manually pull up button #1 | 1 | 1 | Product Drawings<br>Receiving / Inspection Procedure |

| | | | |
|---|---|---|---|
| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | LEGEND |
| 1 – No injury | 1 – Very Low | 1-4 Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 4.25 | Guidewire perforates ~~vessel wall~~ Myocardium, surrounding tissue. | Unable to complete the procedure with the device. Surgical intervention may be required to repair damaged vessel to achieve hemostasis | User applies excess force to kink flexible tip | 3 | 1 | 3 | Tip is designed with blunt, flexible tip.<br>Manufacturer design validation performed. | 1 | 3 | Manufacturer FMEA Appendix 1 |

| | | | |
|---|---|---|---|
| S = SEVERITY SCALE | L = LIKELIHOOD | RF = RISK FACTOR (SEVERITY x LIKELIHOOD) | LEGEND |
| 1 – No injury | 1 – Very Low | 1-4 Minimal Risk – No action required. | S = SEVERITY |
| 2 – Minor Injury | 2 – Low | 5-9 Acceptable Risk – Reasonable effort must be take to control or detect. | L = LIKELIHOOD |
| 3 – Moderate Injury | 3 – Medium | 10 or > Unacceptable Risk – Must be reduced before production turn over. | RF = RISK FACTOR |
| 4 – Severe Injury | 4 – High | | FL = FINAL LIKELIHOOD |
| 5 – Likely Death | 5– Very High | | |

## Declaration of Originality

I hereby declare that the present thesis and the work reported herein was composed by and originated entirely from me without any help. All sources used from published or unpublished work of others are reported in the list of references. All parts of my work that are based on others work are cited as such.

This paper has not been submitted for any degree or other purposes, neither at the University of Applied Sciences Zwickau not at any other university or college.

14th of March 2016

Linda Weichenhain