HORNET FIXATION DEVICE
Master Thesis

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Abstract

Objective: Laparoscopic suturing can be very time consuming and frustrating for inexperienced surgeons. It is one of the hardest actions to perform in a laparoscopic fashion. There are alternative fixation methods such as automatic needle passers, knot-tying devices, staplers, tacking devices and adhesives but they all have their limitations. The aim of this graduation project was to design an alternative to suturing trough a $5mm$ trocar.

Methods: A device has been designed that places small cannulated tacks to achieve wound closure. This instrument is called the Hornet Fixation Device (HFD), it is aimed at closing the vaginal cuff after Total Laparoscopic Hysterectomy (TLH). The HFD was designed through an iterative design process. A list of requirements was created using the Tom Gilb method. The HFD was developed to fulfil these requirements. The design was further refined through the fabrication and evaluation of prototypes.

Results: The HFD can place cannulated tacks to connect two tissue layers. The placement device contains a cartridge in which these tacks can be stored. A tack can be loaded onto a needle, which is then deployed and punctured through the tissue, the tack stays in place and can resolve over time. The tacks were tested on synthetic tissue and achieved a holding strength of $5.2N \pm 1.6N$ opposed to the $18.4N \pm 1.4N$ that was set by suture thread as a benchmark. The device is much easier to use than making a laparoscopic suture and a fixation can be made faster.

Conclusions: A device has been developed which has the potential to replace laparoscopic suturing. The HFD can save valuable time during a surgery and reduce suturing errors. However, the holding strength of the tacks is much lower than that of suture thread and the tacks are too fragile. Further in depth research is required into the dimensioning and material of the tacks to investigate whether enough holding strength can be achieved using a $5mm$ applicator.

Contents

1 Introduction

1.1 Laparoscopy

Laparoscopic surgery (also known as minimally invasive surgery or keyhole surgery) is a surgical technique performed through small incisions in the body (figure 1.1). The Oxford dictionary states the definition of laparoscopy as: *"A surgical procedure in which a fiber-optic instrument is inserted through the abdominal wall to view the organs in the abdomen or permit surgery"* [1].

The abdomen is inflated with gas to create space, vision is provided by a video camera. Tissue manipulations are performed with surgical instruments with a long shaft. A laparoscopic approach generally minimizes patient trauma, reduces scarring, lowers infection risk and shortens recovery time [2].

Figure 1.1: A laparascopic surgery. The surgeon and his assistant perform surgery with long-shafted instruments while viewing their actions on the monitor.

1.2 Total Laparoscopic Hysterectomy

A Total Laparoscopic Hysterectomy (TLH) is the removal of the uterus without making a large incision in the abdomen. The diseased uterus is carefully dissected free of surrounding tissue and then extracted through the vagina or by morcellation. A TLH shows significantly speedier returns to normal activities than an abdominal surgery. The required hospital stay is shorter and the chance of infection is lower [2].

A TLH leaves a large gap at the top of the vagina which is an open connection to the abdomen, this needs to be closed. This vaginal cuff is circular in shape and is commonly closed through suturing (figure 1.2). Suturing according to the Oxford dictionary: *"A stitch or row of stitches holding together the edges of a wound or surgical incision"* [1]. The definition of a stitch is: *"A loop of thread used to join the edges of a wound or surgical incision"* [1]. The suture is secured by tying a knot in the thread. Knot tying can be done extracorporeal (outside of the body) or intracorporeal (inside of the body). There are several types of sutures, for example: 'running', 'interrupted' or a 'figure-8'. In the early days of laparoscopy, the vaginal cuff was sometimes left open, only the edges of the cuff were sutured to prevent bleeding [3].

1.3 Problem definition

Suturing takes a long time to master and can be very time consuming for inexperienced surgeons. It is one of the hardest actions to perform in a laparoscopic fashion [5–11]. The long shaft of a laparoscopic instrument make them difficult to handle and require a trained surgeon. There is no depth of field on the monitor, making it hard to estimate distances. In addition, the camera position is not in line with the instruments, causing instrument movements to be inverted. To reach some regions in the abdomen, the tools need to be moved to places which result in awkward hand positions for the surgeon. Tactile force feedback of the tissue is also less present in laparoscopic surgery than in abdominal surgery.

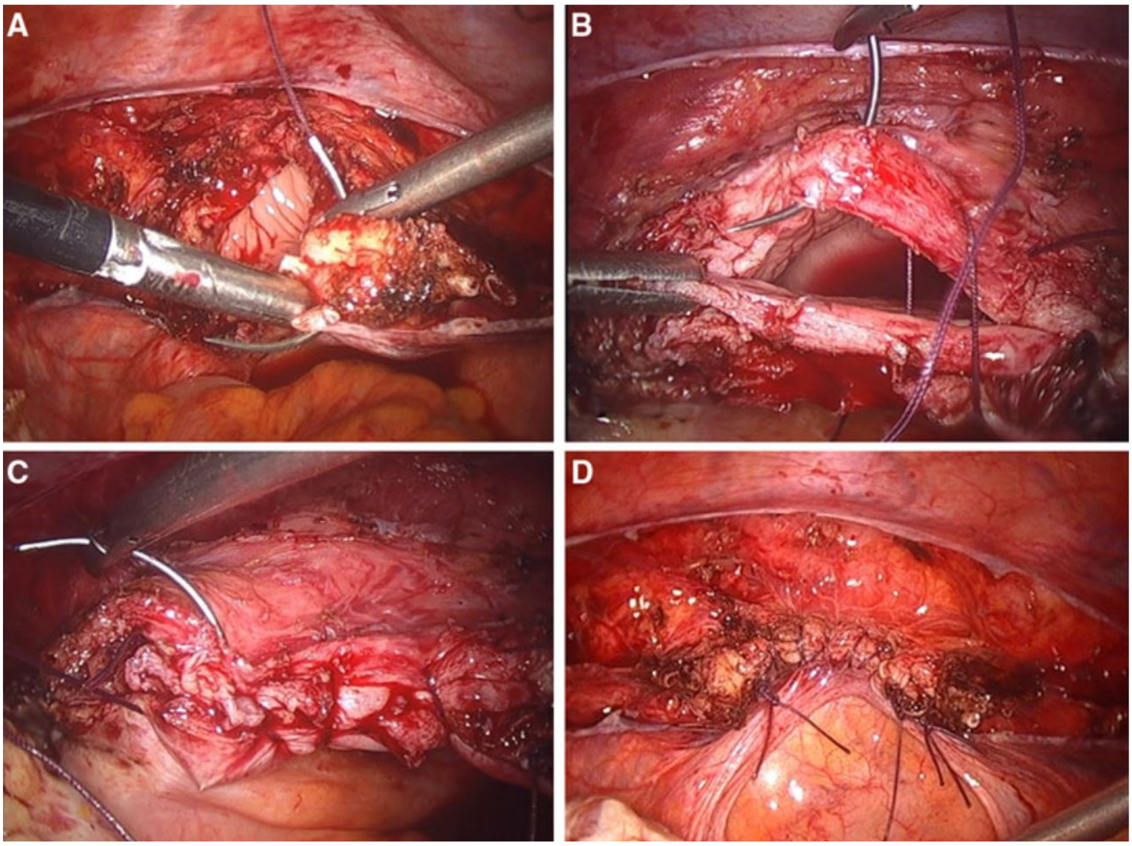

Figure 1.2: A method of cuff closure described by Jeung et al.: **a:** Two single-bite sutures are placed underneath the uterosacral ligament, incorporating the cardinal ligament at the corner and the lateral portion of the vaginal fornix. **b,c:** The rest of the vaginal cuff between the initial two sutures is closed with running sutures using 1-0 Polysorb, approximating the anterior and posterior vaginal epithelium with their underlying fascia. The two-layer running suture starts from the right, alternates left and right continuously, and is tied using an extracorporeal knot. **d:** The vaginal stump is shown with three completed suture knots [4].

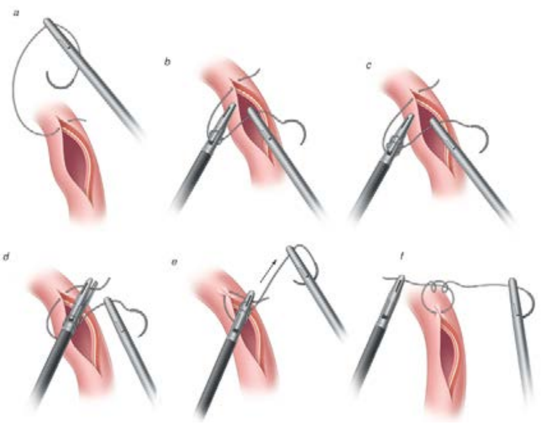

Figure 1.3: A schematic drawing of laparoscopic knot tying. [12]

Suturing requires a lot of instrument actions. The tissue needs to be grasped, while the needle needs to be properly secured in the laparoscopic needle holder. The needle is then passed through the tissue and then needs to be grasped again on the other side of the tissue to tighten the stitch. To make a row of stitches, lots of needle handling and tissue handling is required, making it a slow process (figure 1.3). There are alternative fixation methods such as automatic needle passers, knot-tying devices, staplers, tacking devices and glue but they all have their limitations. The goal of this thesis is to provide a new alternative for laparoscopic wound closure.

1.4 Context of this thesis

The problem of laparoscopic suturing was tackled during the final stage of my Master studies in Biomedial Engineering. The project started with a three month internship at DEAM. DEAM is the commissioning company of this project and specializes in steerable medical instruments. During these three months, a concept direction was chosen and a first set of prototypes were made. After a reflection, it was decided that the device showed enough promise to be further developed during a graduation project. Part of this process was conducting a literature study [13]. The literature study was used to gain insight into the world of laparoscopic suturing and to set the benchmark specifications for the instrument. Finding the exact required specifications was not possible, there is a wide variety of parameters that influence the quality of the suture. These parameters include: tissue type, thread type, thread thickness, tissue thickness, healing time, etc. As such it is not possible to provide exact values for 'the perfect suture', this has been analyzed in depth during the literature study [13]. During the graduation project, the design has been further finalized and tested to evaluate its effectiveness.

1.5 Research questions

The research questions that drive this graduation project are:

1. What are the current principles that are used in laparoscopic fixation?
   (a) What kind of mechanisms can be found in patent literature
   (b) How have these principles been applied in suturing products?
   (c) Is it possible to provide an overview of the current market?
2. What parameters determine the quality of a fixation?
   (a) Can the parameters be quantified?
3. What are the existing patents surrounding the HFD?
4. Is it possible to realize a working clinical prototype?
   (a) What is the technical feasibility?
   (b) What are the user desirabilities?
   (c) Is the device viable?
5. What is the efficiency of the device?
   (a) What is the suture quality?
   (b) How does it compare to other suturing methods?

Question 1-3 have been answered through literature research, this thesis attempts to answer the questions that stem from the newly developed suturing device.

1.6 General list of demands

A general list of demands has been set up to quantitatively assess the concept after completion. The demands were further specified during a later phase when they could be catered towards a specific concept. This list has been made using the Tom Gilb method. This method was chosen because it specifies each demand in a quantitative way. Values are assigned to the wish, plan and must a certain aspect of the device must fulfil. Each demand contains targets to which the design will strive. The values of these targets were set mostly by using estimates. The estimates were based on assumptions, user interviews and literature study [13]. The description of each demand also states how the value can be measured or determined.

1. **Force:** The instrument should be able to place a fixation with sufficient holding strength.
   (a) Scale: The force can be measured in Newtons (N).
   (b) How to determine: The holding strength can be measured by fixating a piece of tissue that is similar to a vaginal cuff in structure and geometry. The sample is then exposed to a tensile test until failure after which the required force can be determined.
   (c) Must do: Should be able to hold at least $15N$ over the entire length of the vaginal cuff.
   (d) Plan: The fixation should be on the higher end of the spectrum of suture strengths reaching a strength of approximately $45N$ over the entire length of the vaginal cuff.
   (e) Wish: Make the fixation stronger than surrounding tissue, where tearing occurs at circa $60N$.
   (f) Rationale: These forces are based on the strengths of existing tacks and sutures, the actual strength required to keep the vaginal cuff closed is unknown.
2. **Time:** The instrument should be able to close the vaginal cuff quickly
   (a) Scale: The time can be measured in seconds (s).
   (b) How to determine: The placement time can be measured by fixating a piece of tissue that is similar to a vaginal cuff in structure and geometry. The test should be performed in a setup that mimics the laparoscopic environment and its difficulties.
   (c) Must do: Should be able to close the vaginal cuff in under 10 minutes.
   (d) Plan: The instrument should be able to close the vaginal cuff in under 10 minutes with a low standard deviation time, even in the hands of less experienced surgeons.
   (e) Wish: Reliably close the vaginal cuff twice as fast as is possible with sutures, below 5 minutes.
   (f) Rationale: Reduced closure time is beneficial for every party involved in the OR. Times are based on current cuff closure times.
3. **Usability:** The instrument should be easy to use
   (a) Scale: Usability can be subjectively measured in a user test.
   (b) How to determine: The usability can be measured by fixating a piece of tissue that is similar to a vaginal cuff in structure and geometry. The test should be performed in a setup that mimics the laparoscopic environment and its difficulties. User satisfaction can be rated on a Likert scale through interviewing.
   (c) Must do: Should be easier in use than placing a normal laparoscopic suture.
   (d) Plan: The instrument should be able to make a good closure even when used by a less experienced surgeon. It should be less 'frustrating' than making a normal suture.
   (e) Wish: Close the vaginal cuff easily without any frustration and very little training in the device.
   (f) Rationale: Making a laparoscopic suture is one of the most difficult and frustrating surgical skills, which is part of the reason why the instrument is being developed.
4. **Dimensions:** The instrument should be able to function within the existing environment during a TLH
   (a) Scale: The dimensions can be measured in millimetres (mm).

(b) How to determine: During the design the size limitations of the device must be taken into consideration.

(c) Must do: The device must be able to operate in a laparoscopic fashion and fit through a $5mm$ trocar.

(d) Plan: Same as the 'Must do'.

(e) Wish: The instrument does not inflict any trauma to the patient.

(f) Rationale: A TLH is currently mostly performed through a $10mm$ scope trocar and 2-3 $5mm$ instrument trocars. If the instrument does not fit through a $5mm$ port it would require a larger lesion, greatly diminishing the attractiveness of the device.

5. **Residual material:** The instrument may not leave any material permanently in the body

   (a) Scale: The amount of material can be measured in volume (mm^3).

   (b) How to determine: The amount of non-resorbable material that is used in the fixation.

   (c) Must do: The instrument may not leave any material permanently in the body.

   (d) Plan: Same as the 'Must do'.

   (e) Wish: Same as the 'Must do'.

   (f) Rationale: Current laparoscopic sutures can be made with exclusively resorbable materials. After approximately half a year there is no trace of the suture, except the formation of scar tissue. Developing a new instrument that does leave materials in the body would be a step back in time and diminishes the business case.

6. **Cost:** The cost of the instrument should be justifiable

   (a) Scale: The price at which a hospital can buy the instrument can be measured in money (€).

   (b) How to determine: The selling price can be estimated from the estimated production cost of the instrument.

   (c) Must do: The instrument should cost less than €200.

   (d) Plan: The instrument should cost less than €100.

   (e) Wish: The instrument should be in the same price range as suture threads €3 - €20.

   (f) Rationale: The vaginal cuff is currently closed using suture threads, which are very cheap. The price of the instrument should be low in order for it to be considered a viable alternative.

2 | Instrument design

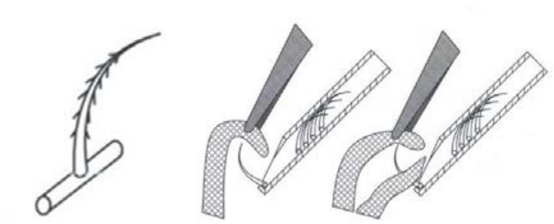

Figure 2.1: The closure of a wound using a barbed tack. Tacks are dispensed by a laparoscopic cartridge instrument while the surgeon uses his other hand to manipulate the tissue with a standard laparoscopic grasper.

2.1 Barbed tacks

The idea of developing a new instrument for laparoscopic suturing originated from an experienced gynaecologist. Through his clinical experience he noticed that he and his colleagues sometimes had difficulty making a good suture in a short time. His idea was to close the vaginal cuff using barbed tacks. The tacks were described as a resorbable T-shaped object. The sharp tip of the tack would be used to penetrate the tissue and held in place by a rod perpendicular to the tip. To avoid the tack sliding out again in the same direction the shaft would have been barbed. The tacks were to be dispensed from an instrument containing a cartridge of tacks (figure 2.1).

Laparoscopic suturing is still the golden standard in internal wound closure, a better alternative is not available. However, even though the gynaecologist suggested barbed tacks, it might not be the best solution for closing the vaginal cuff. There are already numerous types of wound closure solutions (glue, staplers, etc) available that do not make use of suture thread. This project is not exclusively focussed on developing a barbed tack, but rather developing a new method of closing the vaginal cuff. A broad approach was taken where different methods of wound closure were tested.

The development started of with the exploration of the T-shaped tacks that were suggest from field experience. Closing a wound using tacks is faster and easier than traditional suturing. However, the principle of a tack in this form has never been tried. There were several issues that had to be resolved before a tack could be used:

1. The tacks must be incorporated into a dispenser instrument to introduce them to the laparoscopic environment. How can the tacks be presented and released from this instrument?

2. How can the tacks be oriented in the right direction? During suturing a needle is clamped by a needle holder in an almost perpendicular fashion. The needle is also curved. If the tack has a curve, it will be difficult to fit in a $5mm$ shaft.

3. The tissue is penetrated with a sharp tip at the distal side of the tack. After placement, that tip still sticks out of the tissue and could cause damage to the surrounding tissue.

4. To ensure that the wound stays closed, the tack has to be sufficiently anchored into the tissue. If the barbs do not provide enough holding strength, a good suture cannot be guaranteed.

5. A tack that is made from a resorbable material requires greater dimensions than a steel suture needle to achieve the same stiffness. A stiff structure is required to penetrate the tissue.

The challenges in the design were addressed with several design ideas which can be viewed in the appendix (section 7.1). A test was also done to assess the holding strength of barbed thread

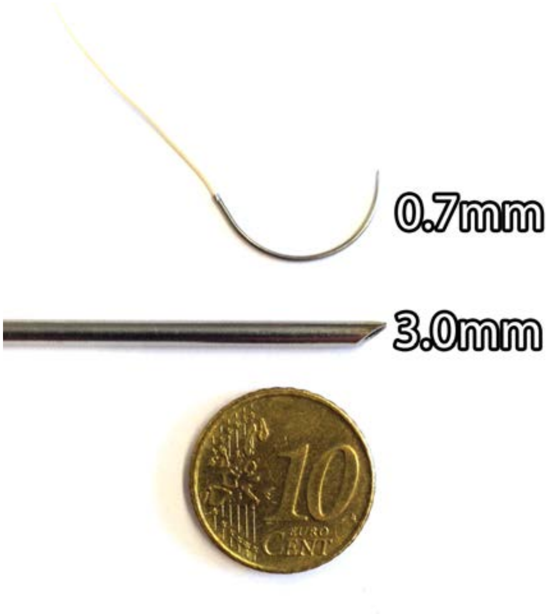

Figure 2.2: A tack made from PLA would require a diameter of 3mm to achieve the same stiffness as a common V-20 suture needle.

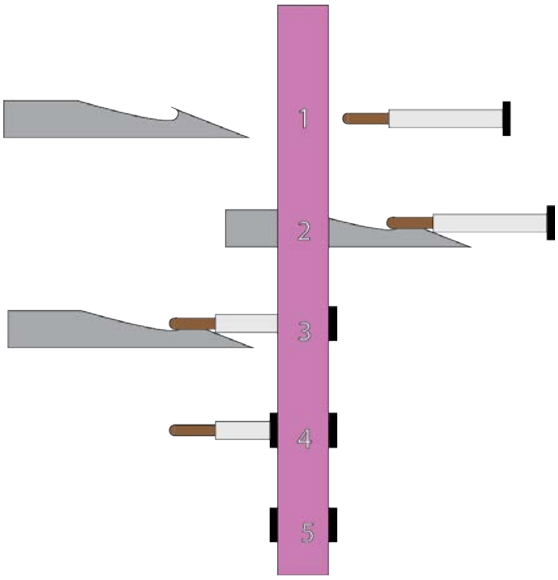

Figure 2.3: A hooked needle is used to pull a looped piece of thread through the tissue. This thread is then locked in place, securing the fixation.

(section 7.2), the most important conclusion was that small barbs over a short length hardly provide any traction, indicating that barbed tacks will probably not work as a solution. In the end, using rigid tacks for wound closure presented too many obstacles to be solved. Using a combination of the problem solutions would have resulted in a complex instrument of which the functionality could not be ensured. Using the resorbable tack itself for penetration would have been challenging considering the required stiffness (figure 2.2). A different direction was chosen to continue with the project.

2.2 EndoHook

The EndoHook describes a curved suture needle containing a notch at the tip (figure 2.3). The notch can be used to latch onto a looped thread which can then be retracted through the tissue. This approach is much closer to normal laparoscopic suturing than using tacks, but still offers a significant improvement. During standard suturing, the needle has to be constantly regrasped by the needle holder to pierce the next tissue layer. The thread is directly attached to the needle, this means that the entire path the thread makes has also been passed by the needle. The EndoHook allows the surgeon to penetrate the tissue layers and then retract the suture thread and the needle at the same time, drastically reducing the amount of required regrasping actions.

This principle was tested with a makeshift prototype and proved promising enough to be further developed (section 7.4). Several design drawings were made in which the EndoHook principle was incorporated into a laparoscopic instrument (section 7.3).

Two ideas were selected and further developed into a conceptual stage. Both concepts feature a looped piece of thread with an anchor at the proximal side. The anchor serves as a lock into the tissue, but is also used to load the next thread after placement. The concepts were called the TwinTube and the PushRod. These concepts both describe the dispenser instrument, which can be used to both dispense the threads and manipulate the tissue. The second instrument held by the surgeons other hand would be a needle grasper holding onto the notched needle.

The TwinTube (figure 2.4) is a $5mm$ instrument based on the EndoHook principle. The

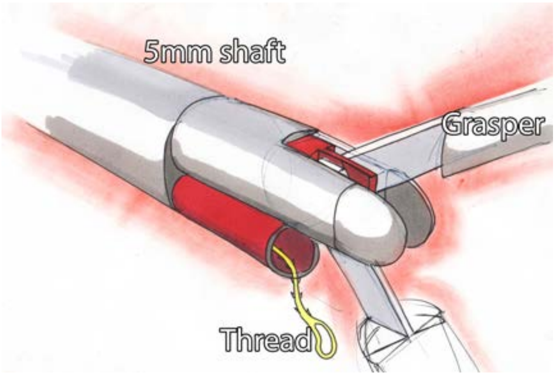

Figure 2.4: The Twintube contains two cannula. One to drive the graspers and another one to store the thread.

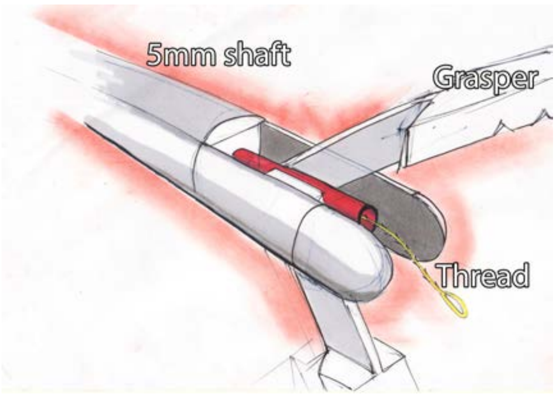

Figure 2.5: The Pushrod contains a central shaft that is used to both drive the graspers and dispense thread.

instrument consists of a shaft containing two smaller shafts. One of these shafts can be used to actuate the grasper at the tip, the other shaft contains the looped threads that are required to make the suture.

The PushRod (figure 2.5) contains a hollow central shaft to drive the graspers. The looped threads are stored within this central shaft.

After these designs were drawn, it was decided to prototype a simple laparoscopic version of the EndoHook (section 7.4). Using a small crochet needle and a piece of looped suture thread, an attempt was made to make several stitches in a tissue model. It was found to be nearly impossible to latch the hook onto the thread, an issue that was not detected in the first makeshift prototype ('open surgery'). The thread would fold from the tip, making the concept impractical. The notched needle also caused extra tissue damage during retraction, a significant risk during surgery. Yet another conceptual direction was required to tackle the challenge of closing the vaginal cuff.

2.3 Cannulated tacks

Using looped threads proved to be infeasible in a surgical environment. To get feedback on the progress made so far, a meeting was held with the involved surgeons. During this meeting, a brainstorm session lead to a different direction for the instrument. From previous designs and tests it was evident that a solid resorbable tack posed too many challenges to be overcome while respecting the general demands set at the start of the project (section 1.6). A suggestion was made to place a tack with a cannulated needle, or the other way round, using a cannulated tack. This way the stiffness of a steel needle could be used for puncturing tissue, allowing smaller dimensions. A hollow needle would make a hole that is larger than the tack that fits inside the needle, making a cannulated tack the better option. The tack could have wings on both ends similar to a hollow-wall-plug to lock itself into position.

The tacks are placed using a needle, but still require an instrument to introduce them to the surgical field in the right orientation (figure 2.6). Having a needle that can rotate at the tip of a laparoscopic instrument makes that possible. The needle is aligned with the shaft for reloading, making it possible to slide a tack onto the needle. The needle can then be deployed by a user action to present the tack for suturing (figure 2.7).

The instrument required for placing these cannulated tacks would consist of a shaft containing two cannula. The lower (smaller) cannula is used to actuate the needle located at the tip, the upper (larger) cannula is used to store the tacks. The upper cannula has a certain diameter in which there is space to store the tacks. The tack itself has hereby become a 'black box'. It can have any shape or working principle as long as it fits within the cannula and can be loaded onto the needle. At this point the assignment can be treated as two separate design assignments: the tack dispenser instrument (chapter 2 and 3) and the tack itself (chapter 4).

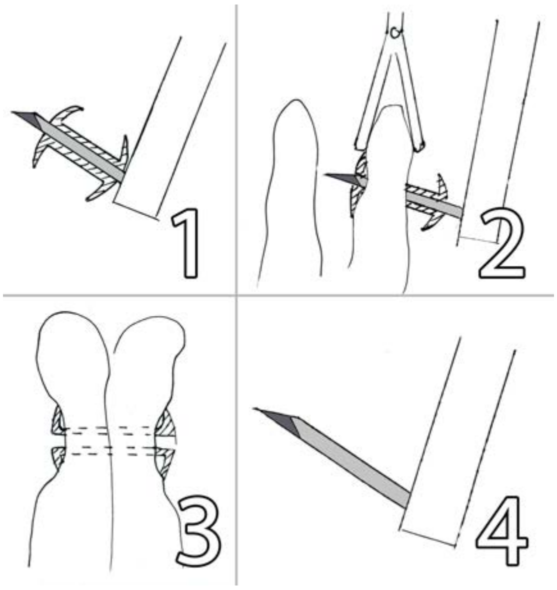

Figure 2.6: The tack is placed over the needle and then pushed through the tissue. After penetrating both tissue layers the needle can be retracted and the tissue is locked in place.

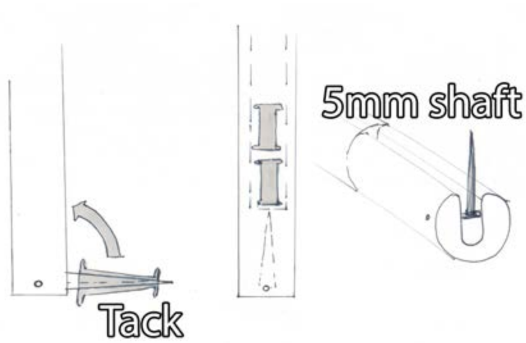

Figure 2.7: Although very simple, this sketch formed the basis for the further development of the HFD. It shows a $5mm$ instrument containing a needle that can be folded into the shaft. A tack can then be reloaded in the shaft. After deployment the needle can be used to place the tack.

Since the instrument contains a stinger that can be deployed through actuation, it was called the Hornet Fixation Device (HFD) from here on.

2.4 Needle mechanisms

Now that the basic principle of a cannulated tack had been laid out, the instrument to place them had to be further defined into a functional $5mm$ instrument. The needle is actuated by a pushrod that is housed inside the shaft of the instrument. This rod, driven by a handle, undergoes a translation along the axis of the instrument. This translation has to be converted into a rotation at the tip of the shaft to deploy the needle which places the wound fixation. Three mechanisms were designed to achieve this rotation, a longitudinal section view of the distal end of the shaft is shown in these drawings:

1. This mechanism (figure 2.8) contains a pushrod, the needle and a small pushlink to convert the linear motion into a rotation. Retracting the pushrod causes the needle to deploy. The downside of this design is that the instrument might not fit through a $5mm$ trocar when the needle is retracted, the pushlink could stick out making the outer diameter exceed $5mm$.
2. The second mechanism (figure 2.9) is similar to the previous one, except the pushlink has been placed in a more distal position. This design adaptation ensures that the instrument does not exceed $5mm$ in a retracted position. However, a compromise is made in the position of the needle. Instead of being located at the far distal end of the instrument, there is now some space between the needle and the outer tip, which could result in hindrance during the use of the instrument.
3. Instead of a pushlink, this design (figure 2.10) features a slotted needle and a pushrod with a slider axis at the distal end. This design is simpler and does not require an extra part to convert the translation into a rotation. By retracting the pushrod, the needle deploys. A high precision production method is required to make sure the slider fits tightly into the needle slot.

It was decided to further develop the instrument with the slotted needle mechanism (figure 2.10). This mechanism required the least amount of parts making it the most simple. A simple system is more robust and uses less of the limited space available in the shaft. The other mechanisms both require an extra part and an extra axle.

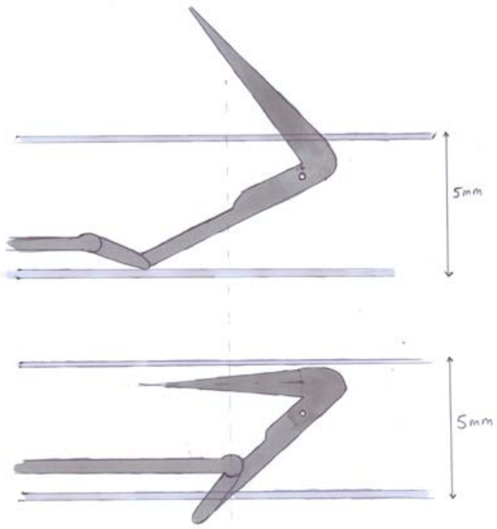

Figure 2.8: A mechanism where the needle is placed at the distal end of the pushlink. When the handle is compressed the pushrod retracts, deploying the needle.

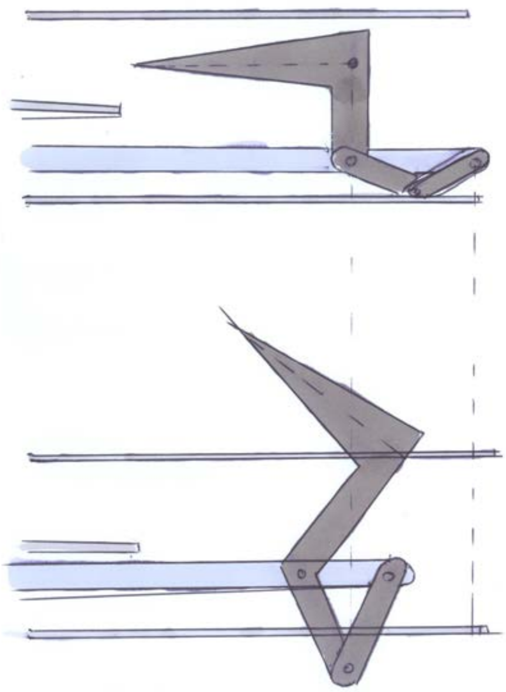

Figure 2.9: A mechanism where the pushlink is placed at the distal end of the needle. When the handle is compressed the pushrod retracts, deploying the needle.

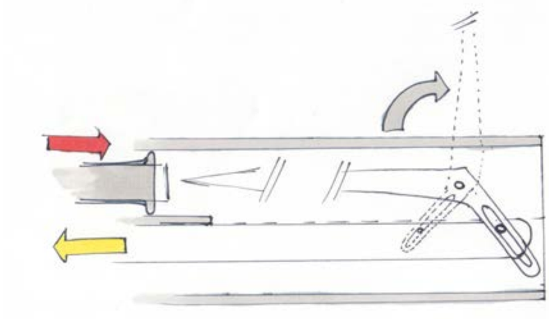

Figure 2.10: A mechanism where an axis in the head of the pushrod slides through a slot in the needle part. When the handle is compressed the pushrod retracts, deploying the needle.

2.5 Reloading mechanisms

To make the suture, the instrument would require a reloading mechanism to present the next tack. To select the most suitable reloading mechanism, a list of demands was made. Since this is only a step in the development of the design, this list was not as elaborate and objective as the general list of demands in section 1.6.

1. To reduce the amount of required user actions it is preferable to combine the needle rotation and tack reloading in a single action

2. The mechanism is fit for prototyping on a 1:1 scale ($5mm$). The prototype consists of a very small series (≤ 2), thereby excluding production methods that are suitable for large batch sizes

3. A low amount of custom parts is preferable to keep the design simple. Every extra prototyped part will come with added costs, assembly time and room for errors

4. The mechanism must be reliable and failproof. If the system is able to jam it could proof dangerous in laparoscopic environments

Several designs were created through brainstorming, using different types of spring/lever actuated objects as inspiration. The biggest challenge to overcome was finding a way to control when the next tack is loaded. The needle needs to be fully retracted and aligned with the shaft first, only then can the next tack be slid onto the needle. A longitudinal section view of the distal end of the shaft is shown in these drawings:

1. The instrument contains two cannula, the upper cannula contains the tacks which are loaded onto a rod place in the center. The lower cannula contains the shaft which drives the needle. (figure 2.11). The tacks (only one is drawn) are being pushed towards the distal end by a compressed spring the upper cannula, they are held in place by a small lever. Once the driveshaft reaches its final position (retracting the needle), the lever is rotated, this releases the next tack to be loaded onto the needle

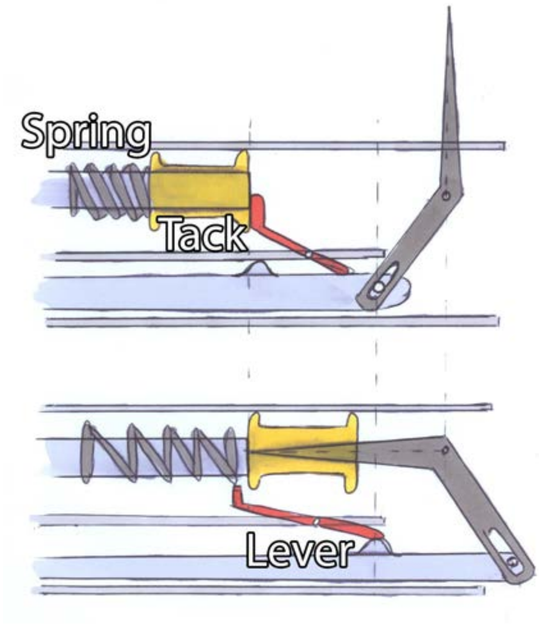

Figure 2.11: A reloading mechanism that operates with spring loaded tacks and a lever. The pushrod has a small bump which moves the lever on needle retraction. The spring pushes the next tack onto the needle.

2. This mechanism is similar to the previous one, but instead of a small lever there is a pawl connected to the needle itself (figure 2.12).

3. This system can reload a tack by a small leaf spring (figure 2.13). When the needle deploys, the leafspring curves and is set under tension. Retracting the needle causes the driveshaft to actuate the spring, releasing it and thereby load the next tack. This mechanism was inspired by the Ethicon EndoClip.

4. This 'humming-top' mechanism features a long thread rod on which the tacks are stored (figure 2.14). By rotating the rod at the proximal side, there is a small threaded block at the distal end which moves forward, propelling the next tack. The distance at which the tack displaces can be easily controlled by checking the amount of rotations the center rod makes.

5. The fifth mechanism shows a reloading action that is not coupled to the needle deployment (figure 2.15). The tacks are stored on a small rod, placed over this rod

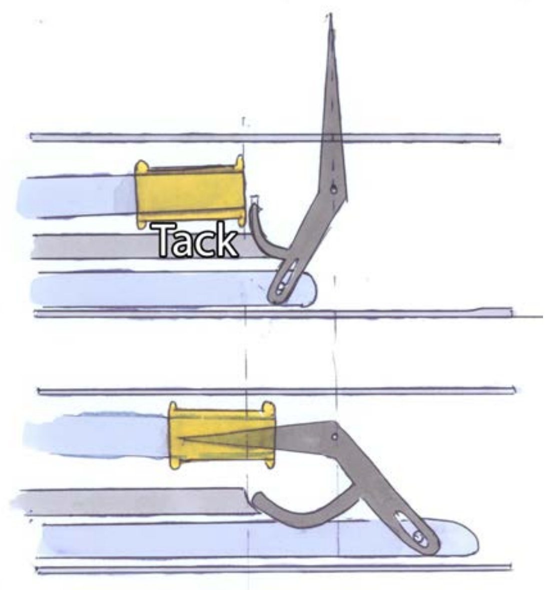

Figure 2.12: This mechanism reloads when the needle is fully retracted. The needle has a stop which block the tack until the needle is fully retracted. Spring not shown.

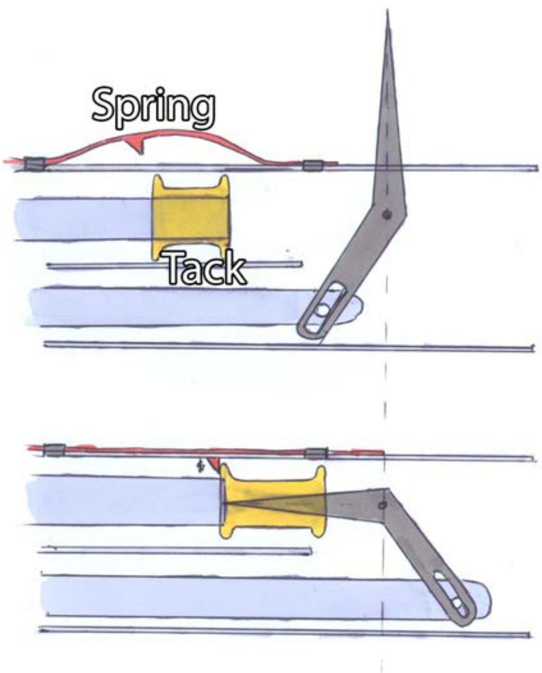

Figure 2.13: A leaf spring mechanism that loads the spring when the needle is deployed. The next tack reloads on needle retraction.

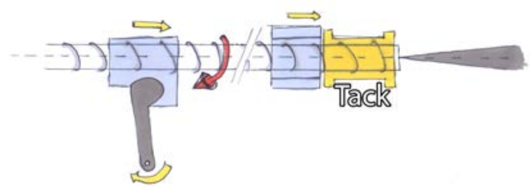

Figure 2.14: The 'humming-top' mechanism that works by rotation the center rod on which the tacks are loaded.

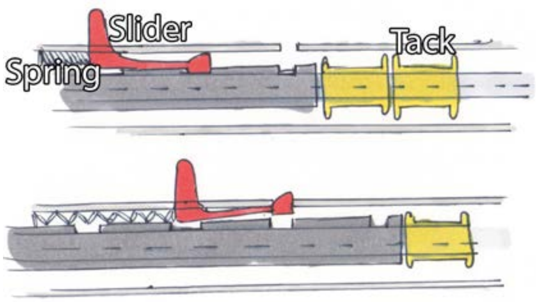

Figure 2.15: A decoupled mechanism where the user can reload the next tack by pushing a slider in the handle. This mechanism does not couple reloading and needle movement.

is a tube with several notches. At the handle side there is a small button that latches onto the tube to propel the tacks towards the distal end.

6. This mechanism reloads by having a small leaf spring pop from the lower cannula to the upper cannula (figure 2.16). When the pushrod moves forward, the first part of that movement is used to retract the needle. When the needle is retracted, there is an open space between the two cannula where the leaf spring can latch onto a notch reloading tube in the upper cannula, the leaf spring is attached to the pushrod. The pushrod can then be retracted again by opening the handle, thereby deploying the needle which is now loaded with a tack.

7. This last mechanism uses a decoupled version of the needle deployment and the tack reload (figure 2.17). This mechanism requires no extra part in the shaft of the instrument, reloading can be done by sliding the button on the proximal side. The

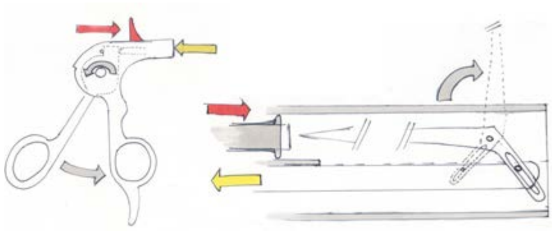

Figure 2.17: A leaf-spring mechanism that reloads when the needle is retracted.

tacks can be propelled forward by a notched shaft.

It was chosen to further develop the instrument using mechanism six (figure 2.16). This mechanism requires no extra axles and uses only one moving part. It is also possible to combine the reloading and needle deployment action.

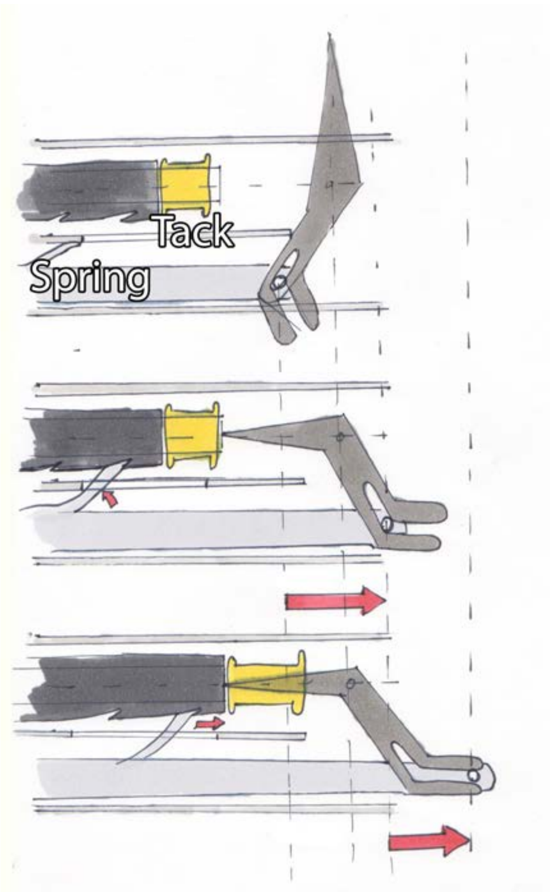

Figure 2.16: A leaf-spring mechanism that reloads when the needle is retracted. There is a gap between the shaft where the leaf spring can spring towards the upper shaft, hooking into a notched tube. This tube is then translated towards the needle together with the tacks.

3 Instrument prototyping

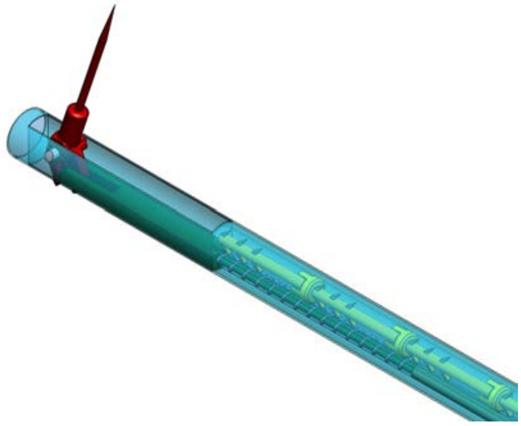

Figure 3.1: An isometric view of the tip of the instrument.

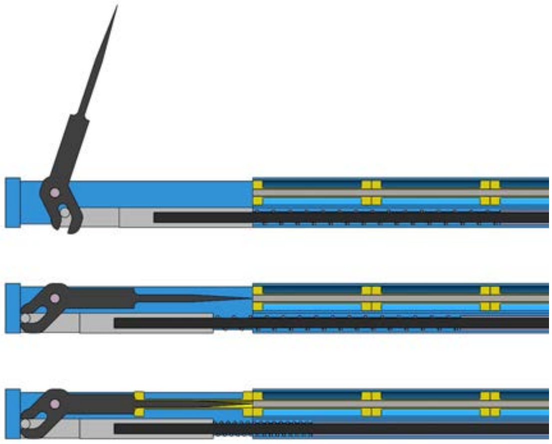

Figure 3.2: An animation of the reloading action in the Hornet. First the needle is retracted, the outer pushrod is then pushed further, compressing the spring and loading the next tack with a leaf spring in the shaft.

Now that the basic instrument principle and its subcomponents were determined, they could be further detailed and dimensioned in a CAD environment. This model would also serve as a basis to develop prototypes that were required for testing. The model was made using SolidWorks (figure 3.1). The model contained all the needle deployment and reloading functionalities (figure 3.2) of the final instrument and was used to tweak the dimensions of the parts.

3.1 Prototype I

After the design was laid out, a prototype had to be made to assess the instrument. This was done through an iterative process, lots of choices made in the design were made whilst regarding the prototyping step, not all geometries/materials are as easy to fabricate. Even if it works in a CAD environment, it might turn out very different after fabrication and all shortcomings that it brings. The cost of prototyping also plays an important role, and sometimes forces to choose a sub-optimal fabrication method. Having a part custom made through CNC machining might result in a stronger and more accurate part, but it is also more costly than (for instance) SLS printing.

The goal of this prototype was to test the needle deployment and the reloading system. A handle had not yet been designed and would also be excluded from this prototyping step, seeing as the handle was not a necessity to reach the goal. The prototype consisted of the tip parts and the shaft (figure 3.3). It was chosen to make the prototype from a combination of SLS printed parts and metal parts where possible.

This first prototype has been made on a 1:1 scale and a 3:1 scale (table 3.1, table 3.2, figure 3.4 and figure 3.5). The 3:1 parts have been made with a PA2200 SLS printer by 3D Worknet, whereas the more detailed 1:1 parts have been made from 'Envisiontec r05' with an Ultraviolet printer by VDM. A 3:1 model is easier to fabricate and will suffer less from inaccura-

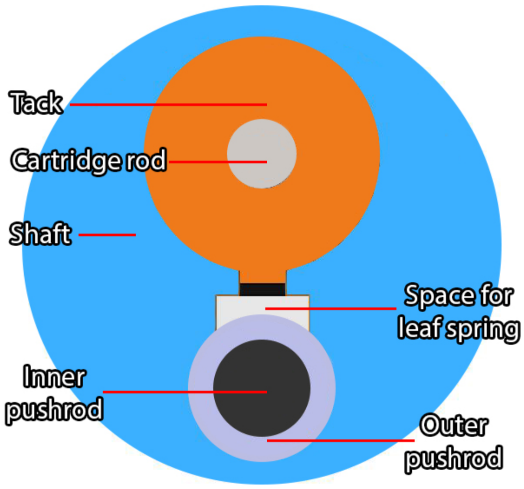

Figure 3.3: A cross section of the shaft of prototype I.

Figure 3.4: The 3:1 model and the 1:1 model from a top view with a Euro coin as comparison.

cies and structural weaknesses, making it easier to test the reloading system. The 1:1 model has been made from a resin based polymer since it required more detail, also making it more expensive. The prototype shaft lengths were shortened to $150mm$ (3:1) and $100mm$ (1:1) instead of the required $300mm$ to reduce the cost of the model. The parts and their chosen fabrication method are hereby specified:

1. **Shaft:** The shaft consists of a long rod with two cannula running through it over the entire length. Normally, this could be prototyped with a series of metal tubes, but the chosen reloading system required a non-circular shape of the cross section and a window in the center of the shaft, making 3D printing the preferred fabrication method. The risk of printing small cannula is that the filler material will fuse, clogging the hole, resulting in an inaccurate part

2. **Needle body:** The part that holds the needle, it contains a hole for an axis and a slot that is used to actuate the tip parts. In this prototyping step, the needle itself was printed onto the needle body. An earlier version of prototype I used a longer needle body to accommodate the tack reloading step (appendix 7.6)

3. **The Needle Axis:** A small metal rod rod around which the needle body pivots, can be press fitted into the shaft

4. **The slider:** The slider contains a $1mm$ axis that fits into the slot in the needle body. When the slider translates, the needle body rotates

5. **Inner pushrod:** A rod which drives the slider. This part was made from available metal tubing material

6. **Outer pushrod:** A tube that fits over the inner pushrod. When the outer pushrod is driven, it first transfers that motion to the needle body via the pushrod spring, retracting the needle. The outer pushrod is then driven to its final position, compressing the spring and reloading the next tack. The outer pushrod fits in the lower cannula of the shaft. This part was made from available metal tubing material

7. **Pushrod spring:** A spring that fits over the inner pushrod and in the shaft. The required spring were bought at Tevema

8. **Tack rod:** A rod in the upper cannula over which the tacks are stored. This part was made from available metal tubing material

9. **Tack slider:** A cannulated cylinder with small nooks to reload the next tack. This part was also printed

After receiving all parts from the suppliers, they were assembled in the workshop. 3D printing comes with geometric intolerances, sanding and trimming was required at certain places to ensure every part fits. The 3:1 model was the easiest to assemble and showed that the needle deployment mechanism works. It was even possible to load a dummy tack onto the needle with the reloading system, however this system did not work reliably and would often jam or slip. After deployment, the needle stayed firmly

Table 3.1: Specification of the parts used in prototype I, 1:1 scale.

Parts	**Material**	**Dimensions**	**Make/buy**
Shaft	Envisiontec R11	55mm length x5mm ⌀	Make (VDM solutions)
Needle body	Envisiontec R11	12mm length	Make (VDM solutions)
Needle axis	SS304 steel	4mm length	Buy
Pushrod head	Envisiontec R11	20mm length x 2.5mm x 2.5mm	Make (VDM solutions)
Inner pushrod	SS304 steel	0.8mm ⌀	Buy
Outer pushrod	SS304 steel	1.2 x 0.15mm ⌀	Buy
Pushrod spring	Springsteel	1.5mm x 0.15mm ⌀	Buy
Tack rod	SS304 steel	0.8mm ⌀	Buy
Tack slider	Envisiontec R11	2.5mm ⌀	Make (VDM solutions)

Table 3.2: Specification of the parts used in prototype I, 3:1 scale.

Parts	**Material**	**Dimensions**	**Make/buy**
Shaft	PA2200	165mm length x 15mm ⌀	Make (3D worknet)
Needle body	PA2200	36mm length	Make (3D worknet)
Needle axis	SS304 steel	12mm length	Buy
Slider	PA2200	60mm length x 7.5mm x 7.5mm	Make (3D worknet)
Inner pushrod	SS304 steel	3mm ⌀	Buy
Outer pushrod	SS304 steel	4mm x 0.25mm ⌀	Buy
Pushrod spring	Springsteel	5.5mm x 0.5mm ⌀	Buy
Tack rod	SS304 steel	2mm ⌀	Buy
Tack slider	PA2200	7.5mm ⌀	Make (3D worknet)

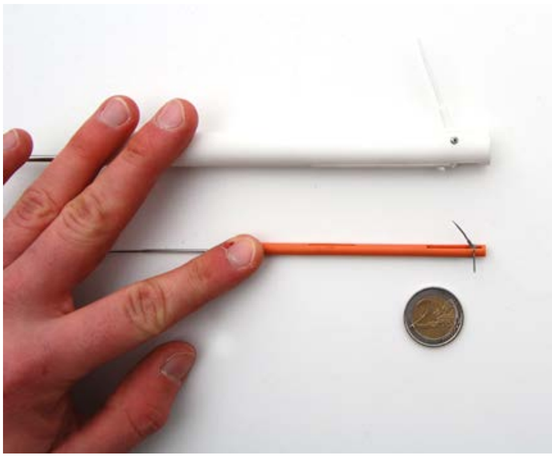

Figure 3.5: The 3:1 model and the 1:1 model from a front view with a Euro coin as comparison.

in position. The play in the needle body was mostly caused by the low elastic modulus of the PA2200 and the geometric inaccuracies. Unfortunately, the 1:1 model did not become fully functional. The needle did deploy but there was a lot of play in the tip parts. The cannula in the shaft got clogged and showed inconsistent wall thickness. The springs that were required for reloading often jammed in the small cannula.

Prototype I has shown that the needle deployment system works well. The combination of a slotted needle body and an actuated slider results in a reliable system that still works after many actuations. The reloading system did not work. There were too many issues in the 5mm instrument assembly and it was not possible to make it function. Reloading will require a different approach.

3.2 Prototype II

After evaluating the first prototype it was necessary to build a prototype that could be used for user tests, thus also requiring a handle. Prototype II uses the same mechanism to actuate the needle, the reloading action however was decoupled. Assembling the spring system in the prototype I shaft proved infeasible, a simplification was required. It was decided to relocate the reloading system to the newly design handle, where more space was available.

Besides a working mechanism the user tests would also require a prototype with sufficient strength and stiffness, thereby disqualifying the plastic shaft of the first prototype. By relocating the reloading system outside of the shaft, a configuration of metal tubes would suffice as shaft (figure 3.6). Various calculations were done to determine the right dimensions for the shaft configuration (section 7.7). Secondly, a deflection test was performed with an existing needle holder to check the stiffness of its shaft, and to compare it the calculated values (section 7.8. The outer shaft was set at a diameter of $5mm$ with a wall thickness of $0.5mm$, a standard tubing dimension. This would put it in the same stiffness range as the existing needle holder and would give it sufficient strength to undergo the extreme situation of a heavy load at the tip.

Now that the outer shaft dimensions were set, the dimensions of the cannula had to be determined. It was chosen to create these cannula by placing (smaller) metal tubes inside the outer shaft. The shaft contains a circle of $4mm$, it was chosen to place a tube of $2.5mm$ and a $1.5mm$ tube, resulting in a tight fit that would not buckle inside the outer shaft. The upper cannula serves as a cartridge for the tacks, the lower cannula is a guidance tube (to prevent buckling) for the rod that drives the needle.

The outer shaft contains a slot at the distal end and a hole through which the axis of the needle body can be fitted. At the proximal side of the shaft there are three holes to connect it to the handle using screws. These shapes were cut out of the shaft through laser CNC by Veld-Laser. The detailed drawings of every part can be found in appendix 7.10.

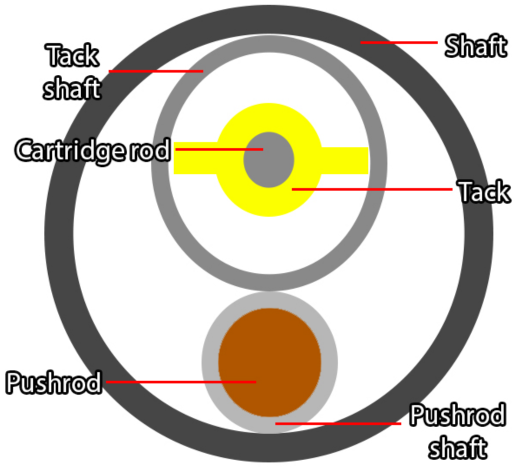

Figure 3.6: A cross section of the shaft of prototype II.

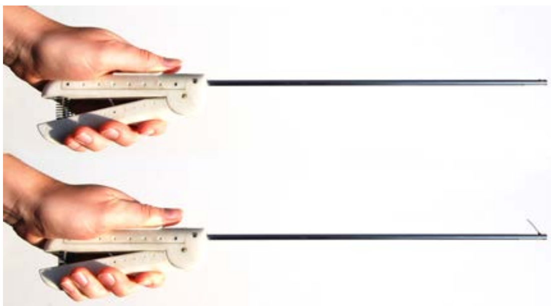

Figure 3.7: Hornet prototype II in an open and closed state. The needle can be deployed by squeezing the handle.

3.3 Prototype II adjustments

The main flaw of prototype II were the SLS printed tip parts that lacked in strength (figure 3.8). These parts are very small and are exposed to high forces. The needle body contains

Table 3.3: Specification of the parts used in prototype II.

Parts	Material	Dimensions	Make/buy
Outer shaft	SS304 steel	$300mm$ length x $5mm$ x $0.5mm$ ⌀	Make (VeldLaser)
Tack shaft	SS304 steel	$2.5mm$ x $0,15mm$ ⌀	Buy
Pushrod shaft	SS304 steel	$1.5mm$ ⌀x $0.25mm$ ⌀	Buy
Needle body	PA2200	$2.5mm$ x $2.5mm$ x $4mm$	Make (3D worknet)
Needle	SS304 steel	$12mm$ length x $0.7mm$ ⌀	Buy
Needle axis	SS304 steel	$4mm$ length x $1mm$ ⌀	Buy
Slider	PA2200	$20mm$ length x $2.5mm$ x $2.5mm$	Make (3D worknet)
Pushrod	SS304 steel	$1mm$ ⌀	Buy
Handle top	PA2200	$135mm$ x $20mm$ x $20mm$	Make (3D worknet)
Handle top cover	PA2200	$100mm$ x $20mm$ x $20mm$	Make (3D worknet)
Handle slider	PA2200	$40mm$ x $15mm$ $10mm$	Make (3D worknet)
Handle bottom	PA2200	$130mm$ x $20mm$ $20mm$	Make (3D worknet)
Handle axis	SS304 steel	$20mm$ length x $3mm$ ⌀	Buy
Handle spring	Springsteel	$10mm$ ⌀	Buy
Handle pushLink	SS304 steel	$27.5mm$ length x $2mm$ x $1mm$	Make (VeldLaser)

Figure 3.8: This image clearly shows the grainy structure of the poly-amide that is used for printing. The edges are not well defined and the structure easily deforms.

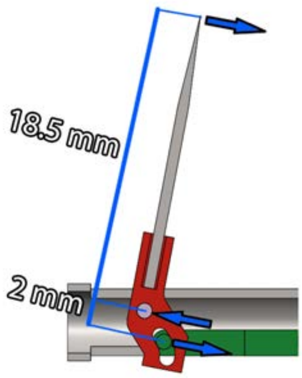

Figure 3.9: The extreme situation where a force is exerted on the needle in a perpendicular fashion. This results in a high stress situation on the body of the needle.

an axis around which it pivots and a slot for the slider. These axes are placed very close to each other at a distance of $2mm$. When a high force is exerted perpendicular to the needle, the needle acts as a lever, resulting in very high forces on the needle body (figure 3.9). The tip of the needle is located at $18.5mm$ from the axis, this results in a force amplification of $\frac{18.5}{2} = 9.25$. It was clear that more sturdier parts were required to use the device for puncturing tissue. The most obvious solution was to produce them from metal instead of poly-amide.

To ensure that metallic parts would bring sufficient strength, calculations were done

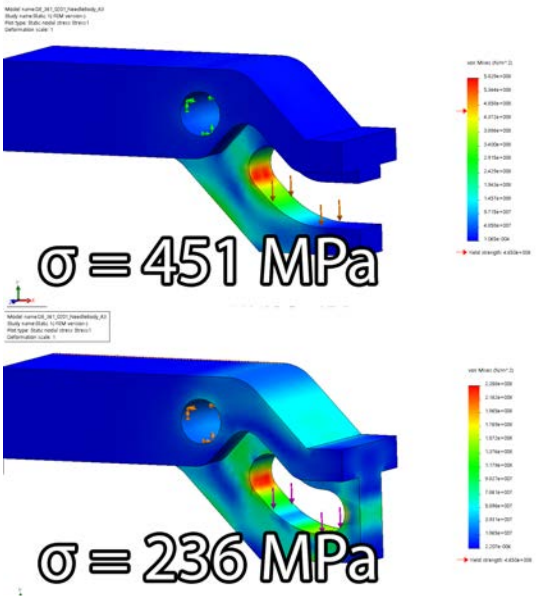

Figure 3.10: A FEM analysis of the needle body. It can be seen that peak stresses are much lower and more evenly distributed when the profile is closed.

specifically on the tip. The shape of the tip did not have a very regular cross section, making manual calculations difficult. It was chosen to assess the strength of the tip through FEM using SolidWorks Simulation. A force was applied directly to the surface of the needle body to which the slider connects. When a $5N$ force is placed upon the needle tip, this results in a $46.25N$ force on the needle body from the lever effect. This resulted in a peak stress of 451 MPa, a relatively high value which lies in the yield strength range of most steel types. To structurally improve the design, the profile was changed to a closed shape. This ensured a more even distribution of stresses throughout the part, resulting in a peak stress of 236 MPa, a much more favourable outcome (figure 3.10). The downside of this design change is that the needle-slider combination cannot be disassembled, they will need to be fabricated in an assembled state.

Having a closed profile in the needle body eliminates (metallic) 3D printing as a fabrication method. The needle body and the slider would fuse together during laser sintering making them unable to move in relation to each other. It was chosen to fabricate these tip parts

Figure 3.11: A photo of the Hornet tip assembly which is placed in the shaft. The straight suture needle that is used to penetrate the tissue is glued in at a later stage in the assembly.

through micro-machining. Instead of a solid piece, the tip parts were split up into three layers. These layers were laser-cut from sheet metal and then stacked and welded to form the tip parts. This also made it possible to place the axis of the slider through the closed profile and then securing it by welding it in place (figure 3.11).The downside of this fabrication method is that the holes in the tip parts are square instead of circular, since the sheet metal layers are flat.

The part was made by VeldLaser according to specification of the tip drawings (appendix 7.10). The new tip parts were assembled in the HFD prototype II by removing the failed SLS tip parts. The pushrod that drives the needle body was then connected with epoxy glue. To puncture the tissue it was chosen to use a straight surgical needle. The required suture needles were provided by the surgeon, they were cut to length and glued in the needle body. The suture needle contain a very sharp diamond tip which can puncture tissue with only little force. Unfortunately, the suture needles were slightly larger in diameter then what was specified, the tacks that were being designed and fabricated alongside this instrument (chapter 4) would not fit over this needle.

4 | Tack prototyping

It was decided to continue the development of the Hornet using cannulated tacks. This effectively resulted in two separate design assignments: The instrument, and the tack itself. This chapter describes the development and prototyping of the tack required for suturing.

4.1 Tack design

The instrument required for placing the tacks houses two cannula inside a $5mm$ outer shaft. The tacks are stored in the larger cannula of the two, the outer dimensions of this tube are $2.5mmx0.15mm$. This is a boundary condition, the tack itself can have any shape as long as it does not exceed the restraints. The tack should also be hollow to allow it to be loaded onto a needle and then placed into tissue.

A first test was conducted to test the viability of using a hollow tack as a suturing object (figure 4.1). A tack was made from a piece of PTFE tubing, both ends were cut and folded to create an 'anchor shape'. The tack was placed in a piece of tissue using a common V-20 suture needle. Several of these tacks where placed in a row to close a gap in the tissue. The tissue was then lifted and lightly pulled by hand. Although not as strong as suture thread, the tacks kept the gap closed, showing enough promise for further development. A small test was also done to check how well the tacks can be reloaded in the instrument (section 7.9).

Closing the vaginal cuff after a TLH is performed using resorbable thread, which dissolves after a period of 90 to 180 days. After the thread is dissolved, there is no trace of the suture except for scar tissue. Using a non-resorbable object to close the wound (such as a metallic staple) would be a step backwards. A permanent foreign object in the body is an added risk and would reduce the viability of the Hornet. It was decided to design a tack made from PLGA, a resorbable plastic with a high Young's modulus.

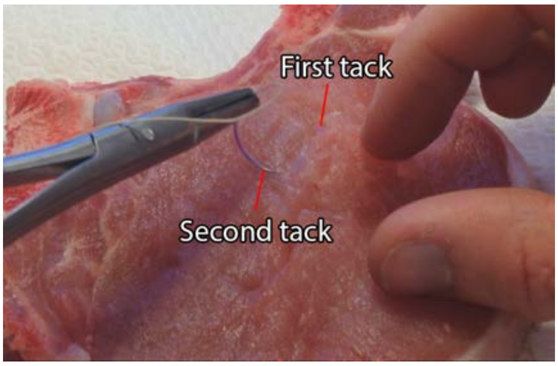

Figure 4.1: A screenshot of a test where PTFE tubing was used to create a tack.

Since the tacks are very small, they are not easy to prototype and test. A different iterative approach was required to find the desired shape and to test their functionality. It was chosen to prototype and test the tacks in a digital environment using a dynamic FEA in SolidWorks Simulation. The maximum outer diameter of the tacks is $2.2mm$, with a cannula in the center of $0.7mm$ to fit the V-20 needle. The tack was initially given a $0.2mm$ wall thickness for the first FEA analysis. The tack was given a length of $12mm$, a length that is sufficient to bridge two layers of tissue to make a suture. The goal of the analysis was to determine the holding power of the tack after it was placed in a piece of tissue. The holding power stems from the size and shape of the wings that are fitted on the tack.

In the analysis, the shaft of the tack was made to be rigid, after which a circular piece of tissue with a hole in the center would be translated against the anchors. Since the stiffness of the tissue is several orders of magnitude lower than the tack, the tissue deforms more than the tack (figure 4.2). An increase in Von-Mises stress was observed as the tissue moved further along the tack. Unfortunately, the simulation software could not cope with the extremely large tissue deformations and another experimental setup had to be made. To avoid large deformations, the tissue was simulated as a rigid part (figure 4.3). The only object deforming in the FEA now is the tack itself. This would still provide the force required to deform the tack, but less accurate since the interaction with the tissue is not taken into account.

A dynamic analysis requires a lot computing power and calculation time. To optimize the calculation time and the accuracy of the results, several parameters were taken into account and modified through trial and error (table 4.1):

1. Material of the tack. A high Young's modulus of the tack results in a higher holding power of the suture. It also causes more stress in the tack leading to failure.
2. Tissue material. Having a deformable tissue severely increases calculation time but does result in a more accurate tack to tissue interaction.
3. Displacement. The tissue was given a predescribed displacement, increasing the displacement also results in a larger deformation of the tack. The more the tack deforms, the more force is required. However, excessive deformations will cause the simulation to fail and end prematurely.
4. Symmetry. Since the tack is symmetrical over two planes, symmetry can be enabled to reduce calculation time.
5. Mesh size. The tack and the tissue were both given a certain mesh size. Increasing the mesh size decreases calculation time, but also reduces accuracy.
6. Detail mesh size. The wings on the tack were given an ultra fine detail since they are the critical components in the tack which need to be tested for holding power. The higher detail increases calculation time and accuracy.
7. Step size. The size of the time step that is done on each iteration throughout the displacement of the tissue. Using a smaller step size results in more data point in the end results, but also demand for more iterations to be calculated. Decreasing the step size also reduces the deformation opposed to the previous step, reducing the amount of errors caused by excessive deformation.

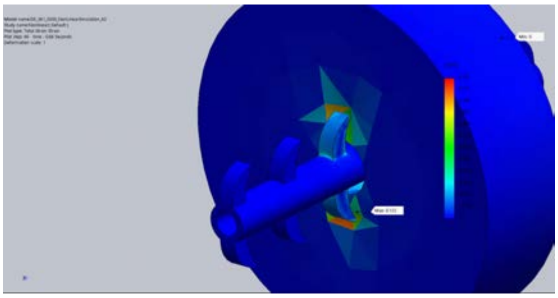

Figure 4.2: A plot of the deformation in both the tack and tissue.

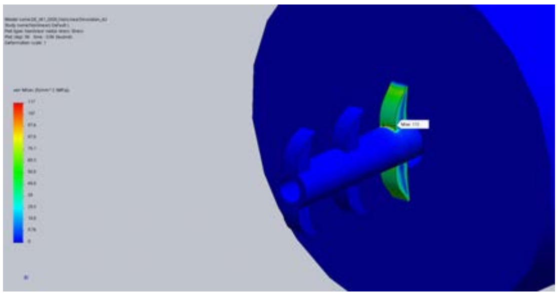

Figure 4.3: A plot of the Von mises stress in the tack using a rigid tissue part.

8. The solver. FFEplus was used for all calculations. Defending on the mesh size that was used, the degrees of freedom would be in the 100.000 range, making FFEplus the most suitable solver.

After the correct settings for the simulation were determined, it was computed for the full duration. By the end of the simulation (last time step) the tack would be stressed beyond its yield strength. It was necessary to determine the holding power of the tack at the time step were the PLGA yield strength was surpassed. This time step (t=0.65s) was then intersected with the plot of the reaction force of the anchors (figure 4.4). The simulation shows that the two anchors on a single tack can hold 1.9N. This is much lower than the strength of a suture thread, but when several tacks are placed in a row the force is more evenly distributed. Even though the forces are lower than suture thread, they should be sufficient to close the vaginal cuff, the internal suture is not exposed to high mechanical loads during the healing process.

Table 4.1: An overview of the materials that were used for the simulation and prototyping

Name	Completion	Duration	Stress	Force	Δ s	Mesh size	Δ t	Solver
Run1	Failed 60%	40 min	47.2 MPa	0.57 N	0.3mm	0.3mm	0.05s	FFEplus
Run2	Stopped 6%	55 min	-	-	0.4 mm	0.3mm	0.01s	FFEplus
Run3	Failed 5%	30 min	-	-	0.4 mm	0.3mm	0.01s	FFEplus
Run4	Failed 7%	30 min	-	-	0.4 mm	0.3mm	0,02s	FFEplus
Run5	Failed 40%	30 min	7.34 Mpa	-	0.3mm	0.3mm	0,03s	FFEplus
Run6	Failed 40%	30 min	-	-	0.3mm	0.3mm	0.025s	FFEplus
Run7	Failed 25%	5 min	-	-	0.3mm	0.3mm	0.025s	FFEplus
Run8	Failed 20%	5 min	-	-	0.3mm	0.3mm	0.05s	FFEplus
Run9	Failed 30%	20 min	21.3 Mpa	-	0.3mm	0.2mm	0.05s	FFEplus
Run10	Failed 20%	10 min	-	-	0.3mm	0.15mm	0.05s	FFEplus
Run11	Failed 17%	20 min	-	-	0.3mm	0.1mm	0,01s	FFEplus
Run12	100%	10 min	55.7 Mpa	-	0.3mm	0.1mm	0,01s	FFEplus
Run 13	100%	45 min	117 MPa	2.71 N	0.3mm	0.1mm	0.01s	FFEplus
Run 14	100%	40 min	184 MPa	2.13 N	0.4 mm	0.1mm	0.01s	FFEplus

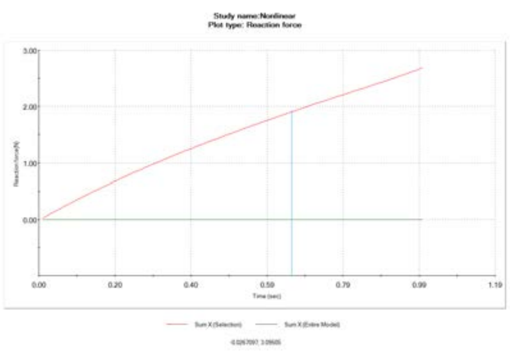

Figure 4.4: A plot of the reaction force of the tack.

4.2 Tack prototyping

Prototyping the tacks was difficult since they are very small and contain a hollow core. The design is too small to be 3D printed accurately and having several of them custom made through CNC production would be too expensive. It was decided to prototype a mould that could be used to produce the tacks manually, that way several casting materials could also be tried to see how that influences the properties of the tack.

The mould was dimensioned to accommodate four tacks being cast at the same time. It is beneficial to use a mould with multiple cavities since the hardening of casting materials usually takes up several hours, making it a slow production process. On top of the mould there is an opening design for a syringe with a luer-lock. The casting material can be forced into the mould under high pressure with a syringe. The mould would not completely fill without added pressure since the viscosity of the casting material resembles that of maple syrup (circa 30.000 cP).

The mould contains four slightly different tack shapes to test the effect of different types of anchors. For detailed drawings of the tacks please refer to appendix 7.10.

1. **Tack 1:** This tack has an outer diameter of $2mm$ and can therefore fit in the cartridge shaft of the Hornet without any deformation. It has one set of anchors as a stop pointing towards the tissue. On the distal side there are three sets of wings which can be pushed further into the tissue depending on the thickness of the tissue that needs to be sutured.

2. **Tack 2:** This tack contains a set of anchors on each end with an outer diameter of $3mm$. Being slightly larger than the cartridge shaft, the wings will have to slight deform and 'snap back' upon exiting the cartridge.

3. **Tack 3:** This has the same layout as tack one, except the wings are $3mm$ instead of $2mm$. The wings contain a small notch which makes it easier for them to fold back when being pressed through the tissue. If they are however stressed in the other direction (when trying to pull them out) the shape of the anchors locks in place against the center shaft.

4. **Tack 4:** Is the same as tack 2, but the wings are thicker than the rest of the tacks. This take has wings of $1mm$ thick instead of $0.5mm$.

The cavities in the mould, especially the wings, are very small and therefore difficult to prototype accurately. The mould also needs to be strong enough to retain the small details after several castings, in addition the casting material should not bond with the mould. Several manufacturers now offer high detail stainless steel 3D printing, but after an inquiry at iMaterialize it turned out that their level of detail was not sufficient. Instead it was chosen to prototype the mould using CNC machining combined with laser manufacturing. The mould was constructed in such a way that a minimum amount of machining time would be necessary, using blind holes and dimensions that can be made with a standard drill. The teeth are too small for the milling machine, since the radius of the drill would make it impossible to produce sharp anchors. A short-pulse-length laser was used to laser up to a depth of $1mm$ with a neglectable radius. A solid block of polycarbonate was used as a basis, all the required holes were machined into the material (Firstmodel, Groningen). The semi finished mould was then send to Veldlaser where the anchors were added to the cavities. The added benefit of polycarbonate is its transparency, making it much easier to produce a good casting since the flow of the material can be inspected.

The tacks contain a hollow core, so the center of the casting cavity would have to consist of a rod. The tacks can be moulded around these rods and can then be removed once the casting has solidified. The core consists of a metal rod with polycarbonate cylinders on both ends. So the final mould is made up of two mould halves, four metal rods, eight accompanying cylinders and four $5mm$ dowel pins to align the mould halves (figure4.5, figure 4.6).

A resorbable material is too difficult to acquire and process for prototyping, prototyping possibilities were limited to materials that are suitable for DIY casting. These materials can be roughly divided into silicones, polyurethanes and epoxies. Unfortunately these materials are pretty different from PGLA considering their strength and strain, but a material that is more similar to PGLA was not found (4.2).

As a first test, the mould was filled with sili-

Figure 4.5: A photo of the mould that was used to cast the tacks.

Figure 4.6: A disassembled view of the mould.

Table 4.2: An overview of the materials that were used for the simulation and prototyping.

	Yield strength	**Young's modulus**	**Strain**
PLGA	42 – 55 Mpa	1.25 - 2.86 Gpa	2.3% - 9.5%
Tissue	0.53 - 1.2 Mpa	1 - 4 Mpa	70% - 112%
Epoxacast 655	86 Mpa	14.1 Gpa	0.5%
Smooth-sil 945	4.82 Mpa	1.8 Mpa	320%

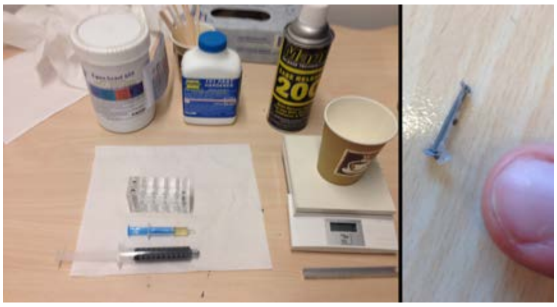

Figure 4.7: **Left:** The setup and materials that were used for casting. **Right:** One of the tacks that comes out of the mould.

cone. Silicone binds with barely any surface so it was a safe test which could not damage the mould. The low Young's modulus and strength result in a tack that is too weak to be pushed into the tissue. These first tests have shown that the material finely flows into the detailed engravings in the mould, the next batch of castings was done with a high strength epoxy. The mould was coated with ease-release 200 to prevent the epoxy from binding with the mould. Epoxacast 630 is made by mixing the epoxy with hardener in a 10:1 ratio. This was done by sucking up a precise amount of volume with medical syringes and injecting them into a container. The epoxy and hardener were then thoroughly mixed and sucked back into the syringe. The syringe was then fitted with a (shortened) needle which was used to fill the mould by applying pressure. The mould was then placed in an oven at 50 degrees Celsius for several hours. After 24 hours the epoxy would be hard enough to be extracted from the mould and then slid of the center rod. After a successful casting, this resulted in four tacks per casting which could be used for the evaluation.

5 | Evaluation

The Hornet consists of a placement instrument and a cartridge of tacks to close a wound. Now that both parts of the design have been prototyped, an evaluation was necessary to answer the research questions that were set at the start of the project (section 1.5). Design, prototyping and assembling the various versions of the Hornet so far has provided insight into questions: 4a, 4b, 4c. The testing therefore consists of two parts:

1. **Holding power:** Three tacks are placed into the tissue using either the Hornet or a manual placement method. The tissue is then pulled apart and the tensile forces are measured. A similar setup to what was found in literature was used to make it possible to compare the results. The same tissue patch will also be sutured conventionally as a control group. This test answers research questions: 5a, 6a, 6b

2. **Usability:** The user will handle the device and place several tacks into a piece of tissue. The tissue will be circular in shape to resemble a vaginal cuff. The test will be used to provoke discussion and gain insight into new demands and wishes from the user. The orientation of the needle in is device is not one that has been used in other instruments before and the effectiveness and manoeuvrability is therefore unknown. This test answers research question: 4b, 6b

To make a fair comparison between conventional suturing and the tacks it was chosen to use artificial tissue instead of animal tissue, since the product is more homogeneous. A multi-layered foam that mimics human skin was used. The pads measure $125mm x 72mm$ and were obtained from `Limbandthings.com` with part number 90065. The pads are intended to practice minor procedures such as suturing, stapling and cutting. Although it was slightly tougher than uterus tissue, it was suitable for this test.

To ensure that good sutures were made for the control measurements, the tests were executed by the gynaecological surgeon that was involved with the project. The available tissue foam was cut into rectangular pieces measuring circa $50mm x 50mm$. Two patches were stitched together using three interrupted sutures, the same thing was done with the tacks. Since it takes about 24 hours to produce 4 tack prototypes, there were a limited amount of tacks available. Two sets of tissue were connected with sutures and two sets of tissue were connected using tacks. Even though this is a small amount, it still provides insight into the suture times and holding power.

To mimic the laparoscopic environment the test were conducted in an Endotrainer, a device that is used by surgeons to train their laparoscopic surgery skills. The tissue patches were placed in a clamp which was positioned in front of the camera. Unfortunately, the circumstances were not suitable to make the sutures in the Endotrainer. Because of the size of the clamp the tissue could not be placed in a desired position, the foam tissue was also different compared to the tissue the surgeon was used to. In addition, the suture thread kept breaking when a knot was tied or when it was clamped with the needle holder. After changing the position of the camera and the clamp several times it was decided to make the sutures in an open environment, using medical tweezers. All suture times both laparoscopic and open were recorded (table 5.1).

There were also issues in the laparoscopic environment when the Hornet was used to place the tacks (figure 5.2), this was caused by the size of the needle. The Hornet is fitted with a straight medical suturing needle which was supplied by the hospital. A medical needle has a very sharp tip designed for penetrating tissue, however these needles were not available in the desired dimensions. The straight suture

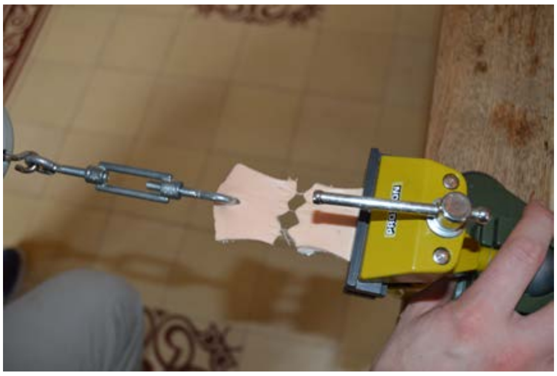

Figure 5.1: The setup that was used to measure the holding strength of the sutures and the tacks. Pictured is a test with three interrupted sutures.

Figure 5.2: The Hornet is used in the Endotrainer to test the usability and its ability to puncture the tissue

needle has a diameter of $0.9mm$ whereas the cannula in the tack is only $0.7mm$. The tacks were therefore applied in an open environment using a non-medical needle. The Hornet applicator itself worked well. The user was satisfied with the ability to easily penetrate the tissue patches. Having a straight needle instead of a semi-circular needle did not pose unforeseen problems and was easy to manoeuvre.

After the tissue patches were stitched together with either tack or suture thread, they were forcefully pulled apart (figure 5.1). One of the patches was mounted in a clamp while the other was pulled with a force gauge (KERN CH-15K20). The forces were recorded for each sample (table 5.2).

The holding strength of the tacks was much lower than the holding strength of interrupted sutures, which was expected. Suture threads can withstand a high force before breaking and are mechanically locked in place through knots. However, placing the tacks was much harder than expected. The tacks were weak and could easily be fractured upon placement, they had to be carefully placed manually with a needle. This can be largely explained by the casting material that was used (Epoxacast). The maximum allowable strain is much lower, making the material more brittle. However, its high stiffness is still required to puncture the tissue in the first place. It was not possible to make a tack with the desired strength and ductility within the dimension constraints that the Hornet applicator allows.

Table 5.1: Suture times.

Suture	**Time**
Laparoscopic 1	Broken thread 5:40
Laparoscopic 2	Failed after 2:40
Laparoscopic 3	Broken thread 2:10
Laparoscopic 4	Broken thread 3:07
Open 1	Completed 2:49
Open 2	Completed 3:02

Table 5.2: Suture and tack holding strengths.

	Suture thread	**Hornet tack**
Test 1	$19.8N$	$6.8N$
Test 2	$17.0N$	$3.5N$
Average	$18.4N \pm 1.4N$	$5.2N \pm 1.6N$

6 Discussion

The goal of this thesis was to develop a new method for closing the vaginal cuff after TLH. It had to be simple and fast since suturing can be difficult and time consuming, especially for inexperienced surgeons. An instrument was developed to accommodate this wish of the user. Gradually, the design started consisting of two parts: The Hornet instrument itself, and the tack that is used to make the suture.

6.1 The Hornet instrument

The Hornet is the result of an iterative design process. The initial idea was to use tacks instead of suture thread to decrease closure times and difficulty. Several designs were tried on a conceptual level before selecting an instrument that uses cannulated tacks to close the wound: 'The Hornet fixation device'. The first prototype validated the needle deployment mechanism but also revealed the flaws in the reloading system, which did not function properly on a $5mm$ scale. The reloading mechanism was therefore simplified to that the shaft of the device could be made from metal tubing, which served as the basis for the second prototype. After reinforcing the tip parts of the Hornet it could easily penetrate tissue in a very intuitive manner, far more quickly than with a suture needle. The reloading system however did still not function as desired, the tacks were too brittle and would not properly fit inside their cartridge.

6.2 The Hornet tack

The evaluation of the tack showed that the fixation is weaker than suture thread, it is also a long way ($5.2N$) from the $15N$ that was specified in the demands. However, the suture thread also performed mediocrely with a holding power of circa $18.4N$, which can be explained by the type of tissue that was used amongst other parameters. The foam might have been more susceptible to a 'cheese-wire' effect, making a tear out happen quickly. There are of course many other parameters that determine the strength of a suture, but a comparison shows that the tacks do not perform very well (figure 6.1). The epoxy also splintered upon placement, violating another demand. The wings on the tack do not work as was intended and simulated in the finite element analysis. These failures can partially be explained due to the casting material that was used, epoxy can only be strained circa 1% before failure.

6.3 Conclusions

- An instrument has been developed to place cannulated tacks in the abdomen to close the vaginal cuff. The device is called 'Hornet fixation device' and has two cannula running through the entire shaft.
- The Hornet is very intuitive and can be used to quickly penetrate the vaginal cuff tissue without much training.
- The tacks were prototyped using a CNC milled mould, and epoxy as a casting material. It was not possible to prototype a resorbable casting material so the tack was not made with the desired material properties. The tacks do not function well in their current dimensions, larger anchors are needed to properly secure the tissue. The tacks lack in strength and are too brittle. The tacks need to be made from a more ductile material such as PGLA for further testing. It would also be possible to use a separate instrument (through the 3rd trocar) as a cartridge to deliver the tacks, allowing larger tack dimensions.
- The fixation that was made during the test was about two and a half times weaker

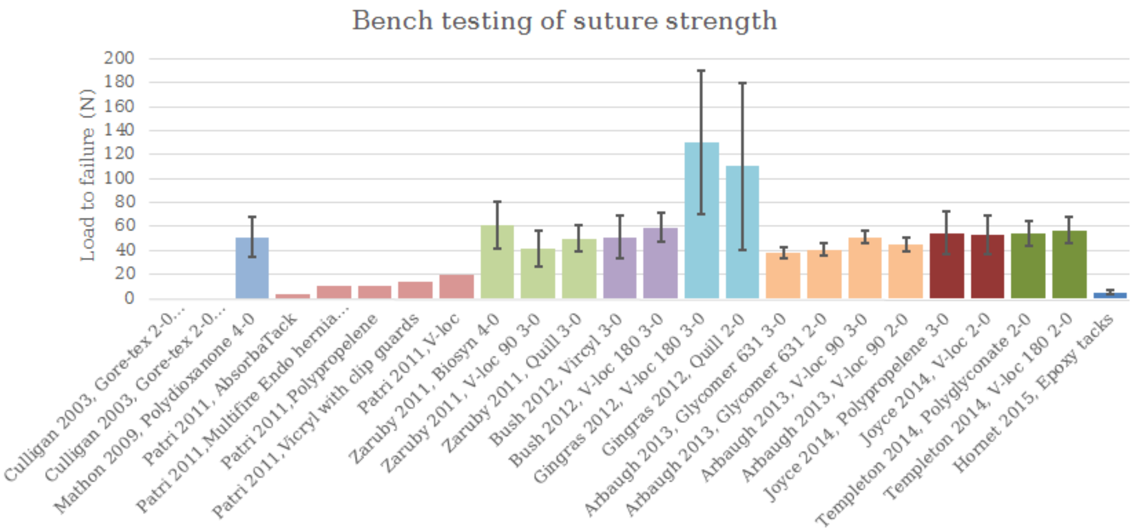

Figure 6.1: A comparison of the values that were found in the literature study with the evaluation of the Hornet tacks.

than suture thread. Making a fixation with thread allows the user to adjust the slack of the knot, resulting in a tighter or looser suture. This proved harder to do with the tack since the tack has a fixed length.

The Hornet is not yet a finished product. Further research needs to be done in order to make it a viable alternative to laparoscopic suturing:

- The tack needs to be further researched. The suture force that was currently achieved was done under one set of experimental conditions. The influence of each tack parameter needs to be mapped, these parameters include: geometry, material, tissue etc. Several tack designs will have to made in various material to research their influence on the suture force.

- After further tack development more testing is required with regards to the resolvability of the material. Currently suture thread and mesh tacks are some of the few products that are made from PGLA. The Hornet tack is a completely different shape of which the exact resorbtion times are uknown.

- The HFD can be further optimized, especially the space in the shaft. The tube configuration could be altered so that the tack shaft is as large as possible, allowing larger tacks and higher suture forces.

7 | Appendix

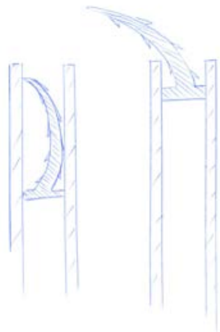

Figure 7.1: The tack is elastic and regains its curvature after exiting the shaft, maintaining a good shape for suturing.

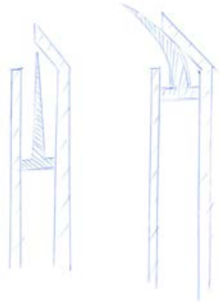

Figure 7.2: The tack is forcefully pushed out of the shaft, giving it curvature through plastic deformation.

7.1 Barbed tack design ideas

The initial project described the idea of using a tack with barbs to fixate two layers of tissue. This assignment was split up into 5 separate challenges. For all these partial challenges, ideas have been generated. This section shows the first (very rough) idea sketches that were made regarding each separate challenge.

1. How are the tacks presented and released from the dispenser instrument? (figure 7.1, 7.2, 7.3)

2. How can the tacks be oriented in the right direction? In normal suturing a needle is clamped by a needle holder in an almost perpendicular fashion. (figure 7.4)

3. The tissue is penetrated with a sharp tip at the distal side of the tack. After placement, that tip could cause damage to the surrounding tissue. (figure 7.5, 7.6, 7.7)

4. The ensure that the wound stays closed, the tack has to be sufficiently anchored into the tissue. If the barbs do not provide enough holding strength, a good suture cannot be assured. (figure 7.8, 7.9)

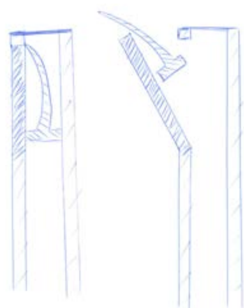

Figure 7.3: An articulating dispenser system at the distal end of the shaft allows for a more curved shape than a rigid shaft would.

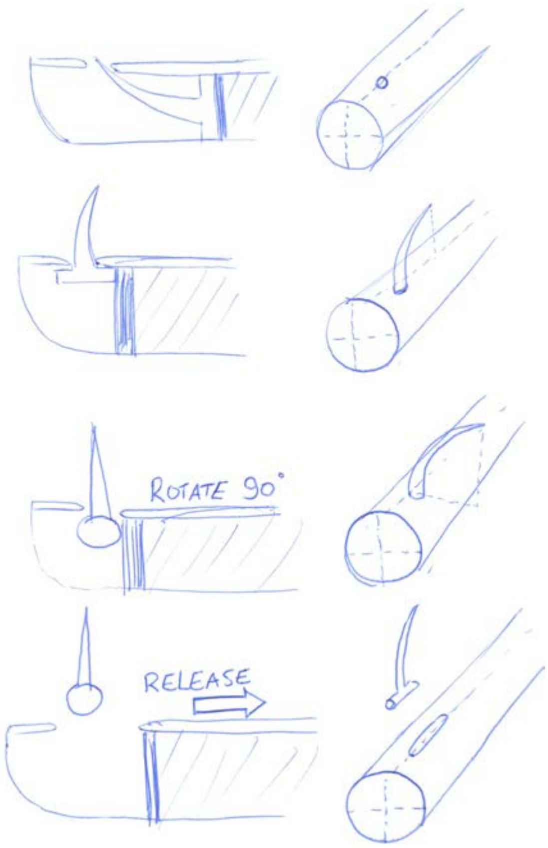

Figure 7.4: A system of two separate tubes which can be rotated in relation to each other. This system can be used to present the tack and orient it in the correct direction.

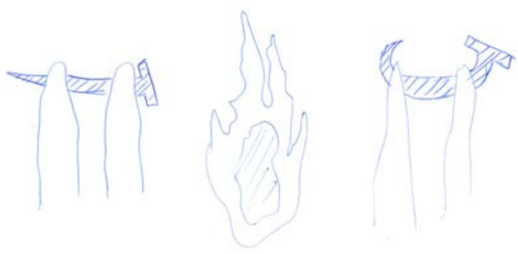

Figure 7.5: The tack is made from a shape memory material, the tip can be curled inwards after placement.

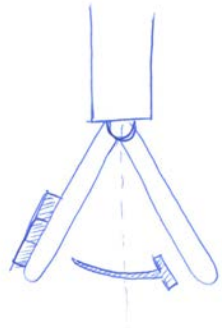

Figure 7.6: The sharp tip of the tack can be blunted by placing a cap on the tip afterwards.

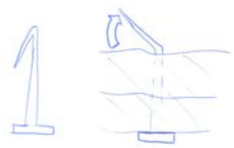

Figure 7.7: The tip of the tack is flexible and folds away into a blunted state after penetration.

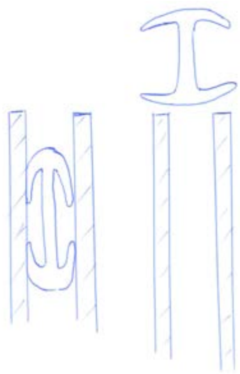

Figure 7.8: Similar to a hollow-anchor plug, the tack locks itself in place after penetration.

Figure 7.9: The tack contains barbs which prevent retraction.

Figure 7.10: The experimental setup of the suture thread test.

5. A tack that is made from a resorbable material requires greater dimensions than a steel suture needle to achieve the same stiffness.

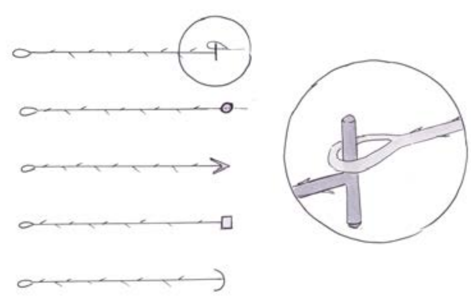

Figure 7.11: Each thread is capped with a small object that hooks into the loop of the next thread. When a thread is dispensed, the next one is loaded automatically.

7.2 Suture thread test

To investigate the holding strength of (barbed) sutures, several tests were done using existing suturing materials and a tension gage (7.10). The test was performed using beef tissue to somewhat simulate the vaginal cuff.

The following conclusions were drawn from this simple experiment:

1. A suture thread that is passed through the tissue only once (no loops) does not provide any holding strength. They can be pulled out with hardly any resistance

2. When a thread is looped two times or more, much force is required to pull it out of the tissue ($> 10N$). The suture thread will break before it slides.

3. A QUILL thread (barbed) that is passed through the tissue once without loops does **not** provide any holding strength. Barbs over such a short length do not show any difference between barbed thread and smooth thread

4. A QUILL thread that is looped twice or more provides an even firmer fixation than smooth thread, making knot-tying obsolete. Barbed suture thread will also break before it slides

5. A (barbed) suture thread generally works very well for closing wounds and fixating tissue. Loops are required to achieve this strength, the placement of thread however is often time consuming and difficult.

7.3 Endohook concept drawings

Several concept drawings were made to illustrate how the threads could be dispensed in the Endohook instrument (figure 7.11, figure 7.12). The Endohook consists of a grasper in one hand of the surgeon, while the other hand holds the hooked needle. This means that the thread will have to be dispersed from the grasper.

7.4 Endohook concept test

The working principle of the Endohook was tested on a makeshift foam model (figure 7.13). The foam was penetrated with a $2mm$ crochet needle. The looped thread was made from a tie-wrap with a piece of metal wire at the distal end. In this crude large-scale setting it was easy to place the thread and close the gap.

At a later stage this concept was tested in an Endotrainer, a device that is used to train surgeons in laparoscopic surgery. A $1mm$ crochet needle was used to make the suture. The suture thread consisted of $3-0$ Vicryl thread with a loop tied in one end. The crochet needle was held by a grasper while the other grasper held a piece of looped thread. Latching the loop onto the crochet needle proved hardly possible, the

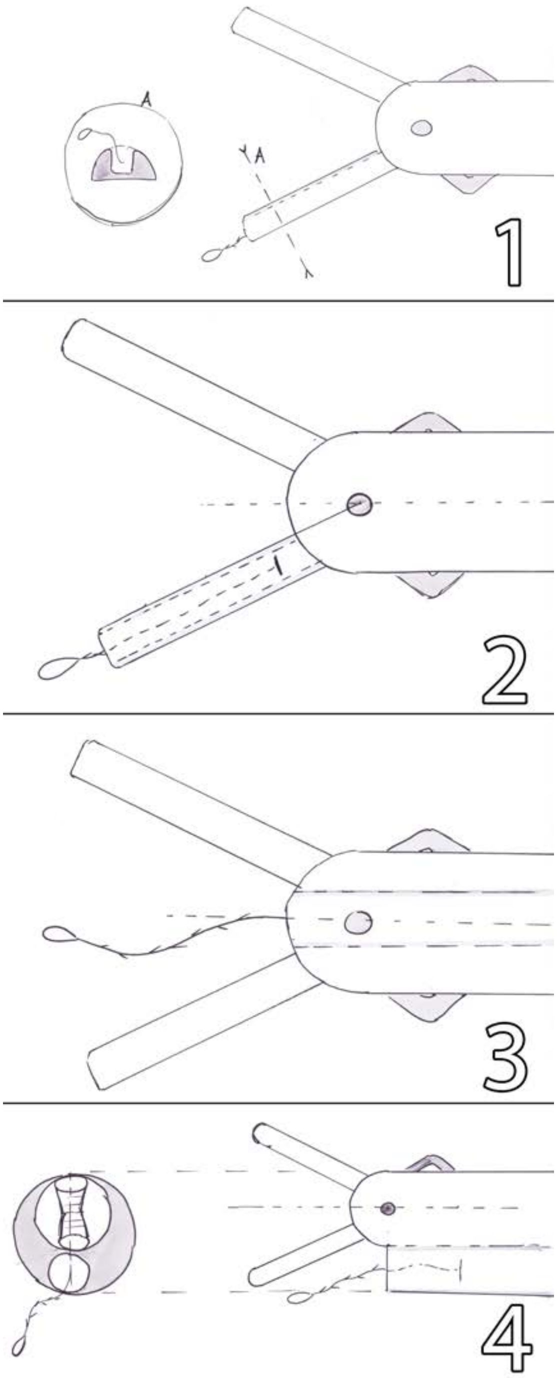

Figure 7.12: The Endohook threads can be stored in the instrument in various ways. This image shows 4 design drawings that illustrate how the threads could be stored.

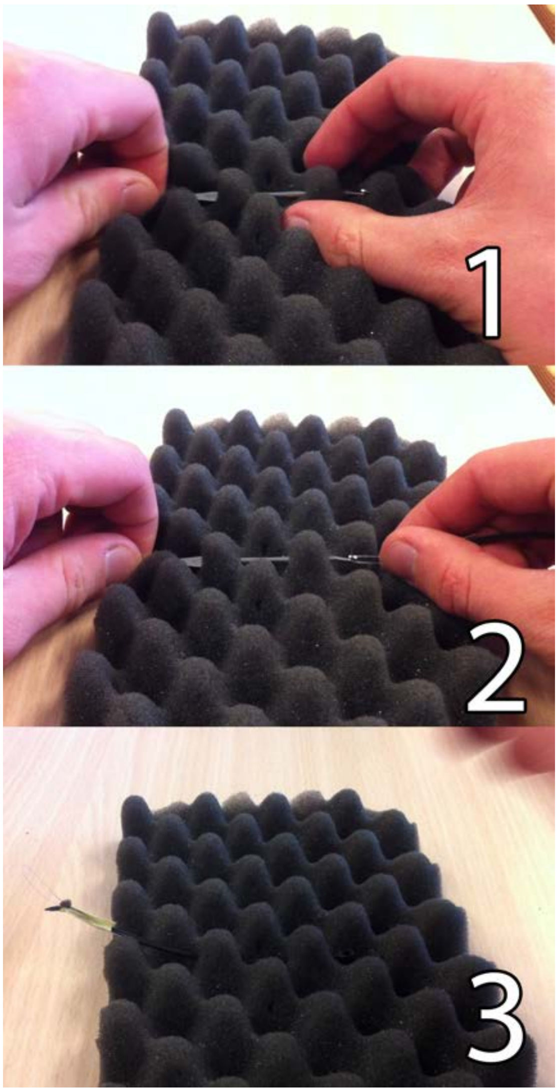

Figure 7.13: A conceptual test of the Endohook. step 1: The needle is pushed through the 'tissue'. Step 2: The looped thread is hooked onto the needle. Step 3: The needle is retracted, making the suture.

Figure 7.14: The Endohook is tested in an Endotrainer.

thread kept unhooking or folding away from the needle.

7.5 Pushrod Kinematics

The kinematics of the Endohook pushrod concept were demonstrated in a 20:1 kinematic model (figure 7.15). The center rod is used to drive the jaws of the instrument. The center rod which was $2.5mm$ real size could have been used to store the looped threads.

7.6 Prototype I earlier design

Prototype I of the Hornet uses a spring in the tip to first retract the needle and then load the next tack. An earlier version of this design shows a more crude and simple mechanism with viewer parts (figure 7.16). Instead of a spring, this design has needle body with a long slot. The slot allows the pushrod to overextend when the needle is retracted, providing the linear movement space to load the next tack. It was later chosen to dismiss this design since it requires much more space to deploy and retract the needle, which is not always available.

7.7 Prototype II strength calculations

Before prototyping the first version of the Hornet, calculations were done on various parts of the design. A maximum load of $5N$ was assumed. This is based on a user situation where

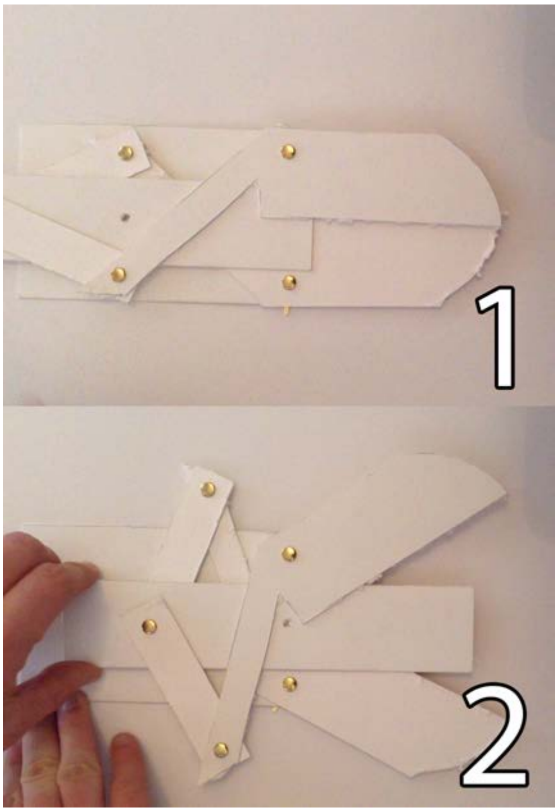

Figure 7.15: A 20:1 kinematic model of the Endohook pushrod.

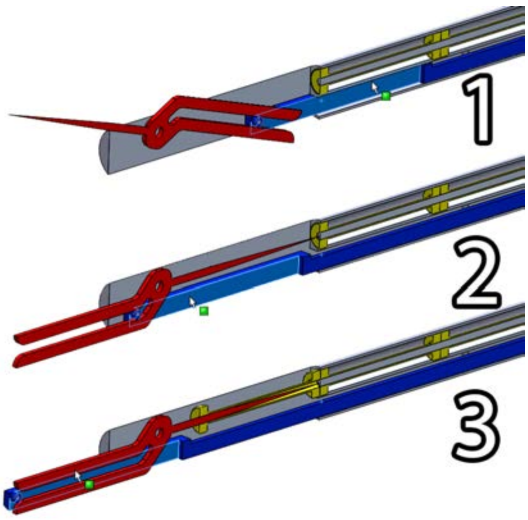

Figure 7.16: An earlier version of the Hornet prototype I.

the tip of the instrument is used to lift a piece of tissue that weighs $500g$. Applying this load at the tip will result in the most extreme case. The variables used in the calculations have been based on the dimensions of the model (table 7.1). All calculations were done assuming homogeneous and linear material properties. The shaft is assumed to consist of a hollow tube. The following calculations were performed to assess the structural integrity of the design:

1. The maximum bending stress in the shaft caused by applying a load at the tip (figure 7.17, equation 7.1). The value was calculated by determing the maximum bending moment and the area moment of inertia of the cross section. This resulted in a stress of 138.02 MPa, well below the yield strength of steel

2. The maximum torsion stress in the shaft caused by applying a load at the tip (figure 7.18, equation 7.2). The value was calculated by determing the maximum bending moment and the polar moment of inertia of the cross section. This resulted in a stress of 69.01 MPa, well below the yield strength of steel.

3. The maximum shear stress in the axis of the needle caused by applying a load at the tip (figure 7.19, equation 7.3). The value was calculated by determing the maximum shear force and the area of the cross section. This resulted in a stress of 9.02 MPa, well below the yield strength of steel.

4. The maximum bending stress at the base of the needle caused by applying a load at the tip (figure 7.20, equation 7.4). The value was calculated by determing the maximum bending moment and the area moment of inertia of the cross section. The result is given as a function of the needle diameter, this makes it possible to research the effect of the needle diameter on the maximum stress in the needle (figure 7.21). A steel needle of $1.05mm$ would be able to withstand a $5N$ load. However, using a needle bigger than $0.7mm$ causing too many lesions during suturing. This formula has been inverted to see the effect of the maximum load the needle is able to withstand a function of its diameter (figure 7.22, equation 7.5)

Table 7.1: A list of the variables and their values used in the calculation.

Parameter	Symbol	Value
Force at the tip	F	$5N$
Length of the shaft	l_{shaft}	$300mm$
Depth of the trocar	d_{trocar}	$100mm$
Outer shaft diameter	$\oslash_o$	$5mm$
Inner shaft diameter	$\oslash_i$	$4mm$
Length of the needle	l_{needle}	$15mm$
Axis to axis distance of the needle	l_{AtoA}	$2.5mm$
Yield strength of steel	σ_{steel}	656 MPa
Emodulus of steel	E	$200 \cdot 10^9$

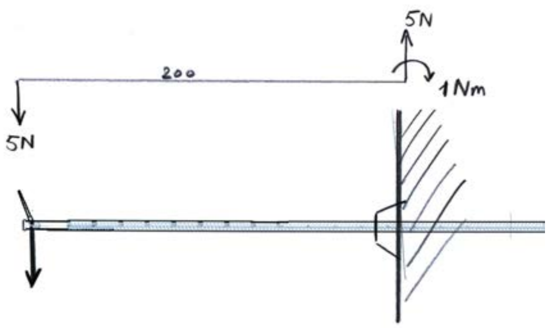

Figure 7.17: A free-body-diagram of the shaft. A perpendicular load is applied to find the maximum stress in the shaft.

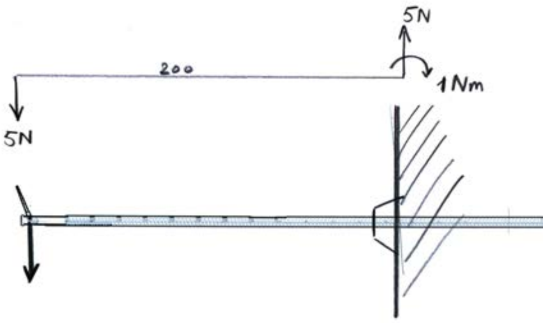

Figure 7.18: A free-body-diagram of the shaft. A load is applied perpendicular to the needle at the tip to find the maximum torsion stress in the shaft.

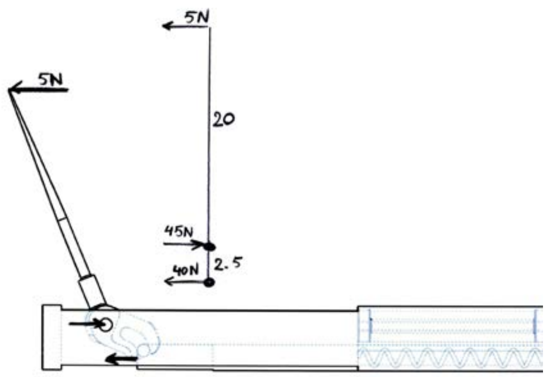

Figure 7.19: A free-body-diagram of the needle. A load is applied at the tip of the needle to find the maximum shear stress in the axis.

$$\begin{aligned} M &= (l_{shaft} - d_{trocar})F \\ I &= \frac{1}{4}((\frac{1}{2}\oslash_o^4) - (\frac{1}{2}\oslash_i^4))\pi \\ \sigma &= \frac{M(\frac{1}{2}\oslash_o)}{I} = 138.02MPa \end{aligned} \tag{7.1}$$

$$\begin{aligned} T &= F \cdot l_{needle} \\ J &= \frac{1}{2}((\frac{1}{2}\oslash_o^4) - (\frac{1}{2}\oslash_i^4))\pi \\ \sigma &= \frac{M(\frac{1}{2}\oslash_o)}{J} = 69.01MPa \end{aligned} \tag{7.2}$$

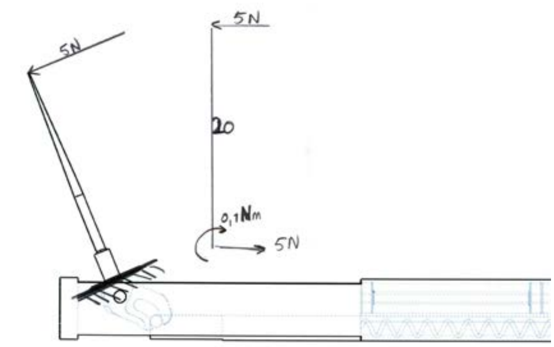

Figure 7.20: A free-body-diagram of the needle. A load is applied at the tip of the needle to find the maximum bending stress in the needle.

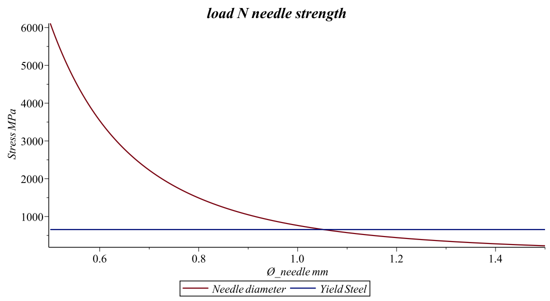

Figure 7.21: The maximum stress the needle is able to withstand as a function of its diameter. The straight line shows the yield strength of steel.

$$\begin{aligned} F_{pushrod} &= \frac{F \cdot l_{needle}}{l_{AtoA}} \\ F_{axis} &= F + F_{pushrod} \\ A &= ((\frac{1}{2}\oslash_o)^2 - (\frac{1}{2}\oslash_i)^2)\pi \\ \sigma &= \frac{3F_{axis}}{2A} = 9.02MPa \end{aligned} \tag{7.3}$$

$$\begin{aligned} M &= l_{needle} \cdot F \\ I &= \frac{1}{4}(\frac{1}{2}\oslash_{needle}^4)\pi \\ \sigma &= \frac{\frac{1}{2}\oslash_{needle} \cdot M}{I} = \frac{763.94}{\oslash_{needle}} \end{aligned} \tag{7.4}$$

$$\begin{aligned} M &= l_{needle} \cdot F \\ I &= \frac{1}{4}(\frac{1}{2}\oslash_{needle}^4)\pi \\ F_{max} &= \frac{\frac{\sigma_{steel}}{F}}{\frac{\frac{1}{2}\oslash_{needle}M}{I}} \end{aligned} \tag{7.5}$$

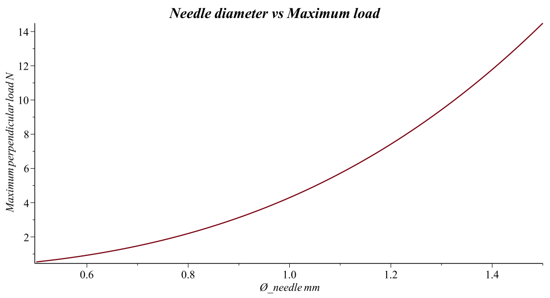

Figure 7.22: The maximum load the needle is able to withstand at the tip as a function of its diameter.

7.8 Prototype II shaft deflection

Besides having a shaft with sufficient strength, the stiffness is also important. A high stiffness is required for accurate laparoscopic handling. Equation 7.6) was used to calculate the deflection at the tip.

$$\delta = \frac{F \cdot l_{needle}^3}{3 \cdot E \cdot I} \tag{7.6}$$

To verify the amount of deflection that was given as output from the deflection model, a number of measurements were done on three different existing tubes (figure 7.24). The deflection of an existing needle holder was also measured to compare the amount of deflection to the proposed prototype dimensions. The test specimen was clamped in place in a horizontal position, a weight was then hung at the tip of tube. The deflection was measured by checking the millimetre scale paper that was positioned behind the tube.

These tests and calculations have shown that it is necessary to incorporate a metal outer tube in the shaft design. The first prototype relied on a printed shaft, which deflects more than $100mm$ according to the equation. This is caused by the Young's modulus of plastic, which is far lower than metal. A design with supporting rods has also been evaluated. Since the outer diameter is far smaller than an outer tube they barely had any effect on the stiffness (figure 7.23).

The comparison of the calculations with the deflections measurements show that the mathematical model is reasonably accurate, the real deflection is always higher than the calculated deflection by circa 15% (table 7.2). This difference could be caused by the materials being less stiff, measurement inaccuracies or other assumptions. It can also be seen that the deflection of the needle holder is even lower than the tubes that were tested. The needle holder deflects very little since there is less shaft space required for moving parts, the cross section will show a very thick outer tube. The deflection of the tested tubes is deemed acceptable. The $5mm$ x $0.5mm$ tube deflects by $14mm$ when a $5N$ weight is applied at the tip. This value lies close to other laparoscopic instruments, this tube dimension was also used in the Hornet prototype.

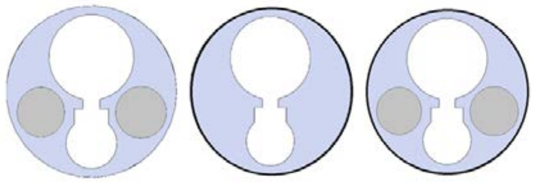

Figure 7.23: Various Hornet prototype I cross-sections. Calculations show that a solid shaft is not enough, only a metal outer tube provides sufficient stiffness.

Figure 7.24: The test setup that was used to determine deflection.

7.9 Tack test

The tacks are loaded onto a center rod, the most proximal tack is pushed forward, thereby driving the other tacks. To test this principle a

Table 7.2: The deflection of various tubes and a needle holder compared to the model values given in mm.

	F (model)		**F (real)**		**Difference**	
	$5N$	$10N$	$5N$	$10N$	$5N$	$10N$
Needle holder			6	14		
Tube (4 x 0.75)	13,9	27,9	15	31	7,9%	11,1%
Tube (5 x 0.5)	12,4	24,8	14	28	12,9%	12,9%
Tube (6 x 0.75)	5,2	10,3	6	12	15,4%	16,5%

Figure 7.25: A still image of the video that was taken during the sliding test of the tack.

simple test was conducted using high stiffness tubing with a wall thickness of $0.1mm$ (figure 7.25). The tacks could easily slide back and forth along the center rod with little resistance. The tacks would splinter if the first tack was blocked while force was still applied at the proximal end. This test shows that its important that the device should not jam during reloading, because it could damage the tacks.

7.10 Hornet Prototype II CAD model

The CAD model was created using SolidWorks® and has been embedded into this report (figure 7.26).

Figure 7.26: An interactive 3D model of the Hornet prototype II. If this file is not displayed correctly, please download the latest version of Adobe Acrobat Reader.

REVISIONS

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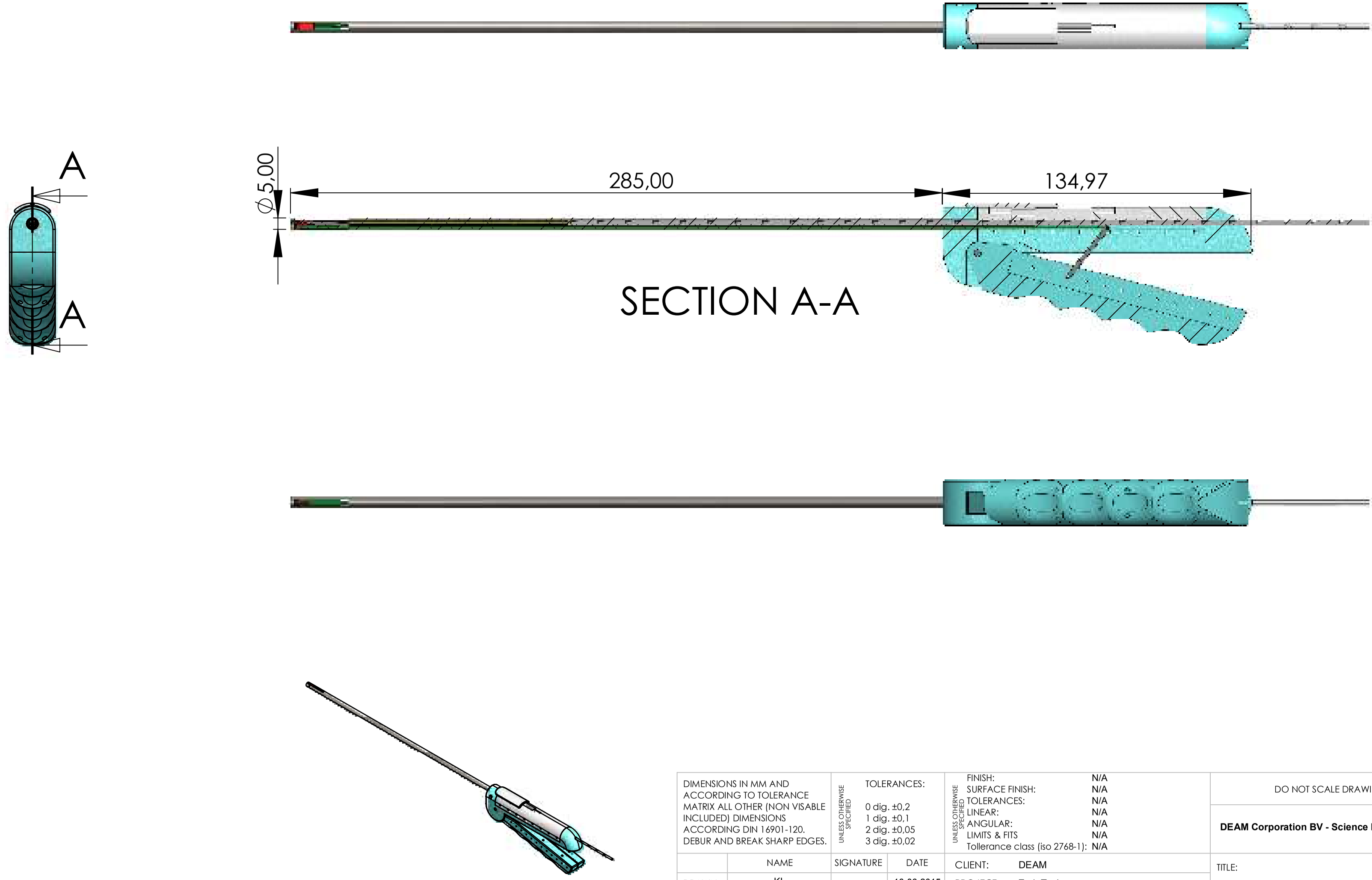

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES: 0 dig. ±0,2; 1 dig. ±0,1; 2 dig. ±0,05; 3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED

FINISH:	N/A
SURFACE FINISH:	N/A
TOLERANCES:	N/A
LINEAR:	N/A
ANGULAR:	N/A
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	N/A

	NAME	SIGNATURE	DATE
DRAWN	KL		16-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	Material <not specified>
WEIGHT:	109.56109.56

SUPPLIER:

DRAWING IS ACCORDING 3D FILE: DE_361_0000_Hornet_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.

DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING

REVISION -

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TITLE:

DWG NO. DE_361_0000_Hornet_A3

A3

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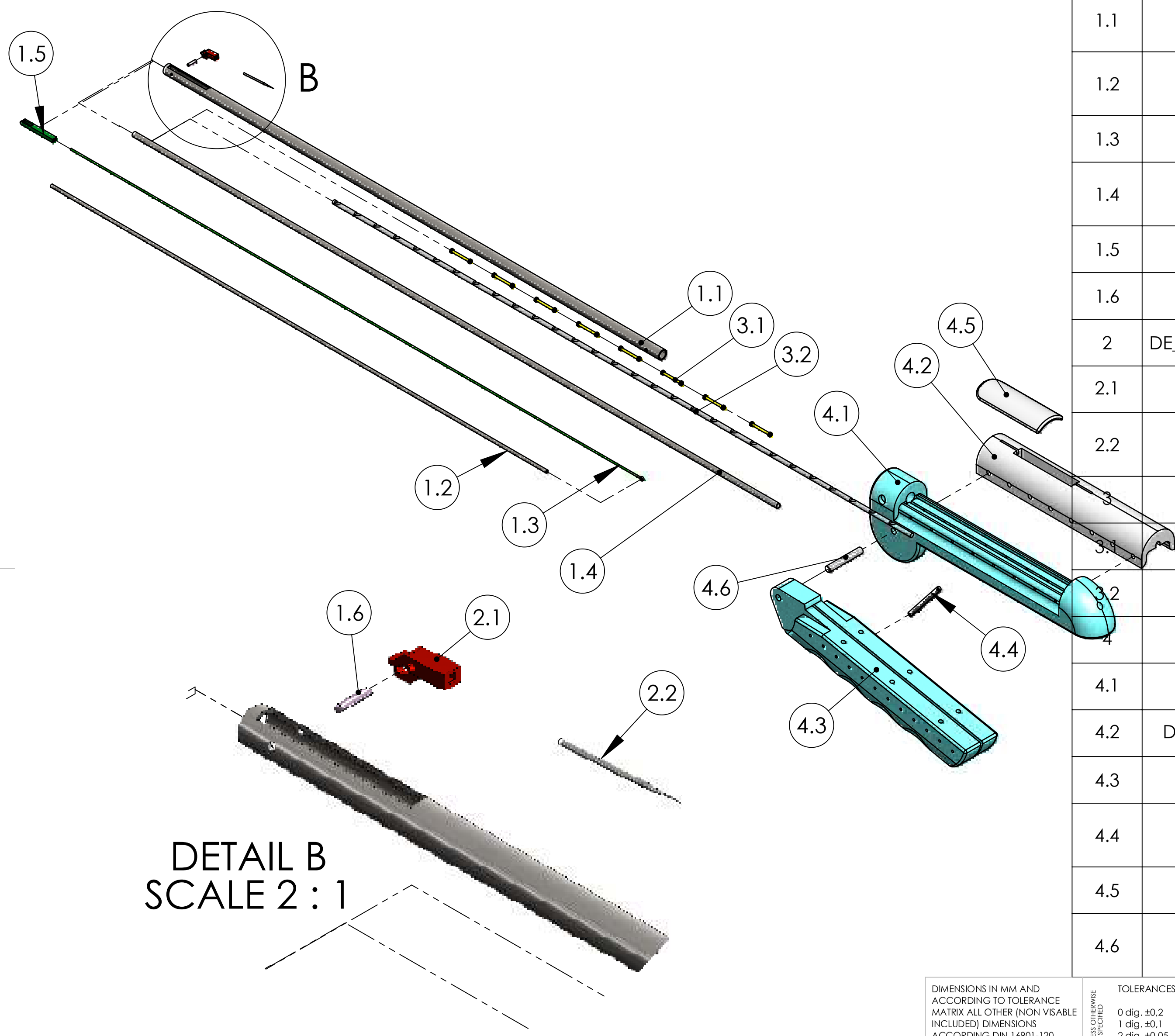
SHEET 1 OF 2



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1.2	DE_361_0102_PushRodShaft_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)	2.30	-	1
1.3	DE_361_0103_Pushrod_A3			-	1
1.4	DE_361_0104_TackShaft_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)	3.37	-	1
1.5	DE_361_0105_PushrodHead_A3	AISI 304		-	1
1.6	DE_361_0106_Axis_A3			-	1
2	DE_361_0200_NeedleMechanism_A3			-	1
2.1	DE_361_0201_NeedleBody_A3	AISI 304		-	1
2.2	DE_361_0202_Needle_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)	0.04	-	1
3	DE_361_0300_Cartridge_A3			-	1
3.1	DE_361_0301_Tack_A3			-	8
3.2	DE_361_0302_TackSlider_A3			-	1
4	DE_361_0400_Handle_A3	Material <not specified>	84.18	-	1
4.1	DE_361_0401_HandleTop_A3	PA2200	31.49	-	1
4.2	DE_361_0402_HandleTopCover_A3	PA2200	13.86	-	1
4.3	DE_361_0403_HandleBottom_A3	PA2200	36.07	-	1
4.4	DE_361_0404_PushLink_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)	0.44	-	1
4.5	DE_361_0405_TackControl_A3	PA2200	1.21	-	1
4.6	DE_361_0406_HandleAxis_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)	1.10	-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED
FINISH: N/A
SURFACE FINISH: N/A
TOLERANCES: N/A
LINEAR: N/A
ANGULAR: N/A
LIMITS & FITS N/A
Tollerance class (iso 2768-1): N/A

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APPV'D			
QA			
MFG			
QA MFG			

SUPPLIER:
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CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL: Material <not specified>
WEIGHT: 109.56109.56

American projection

SOC MEANS: SUBJECT OF CHANGE.
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DO NOT SCALE DRAWING
REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:

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A3
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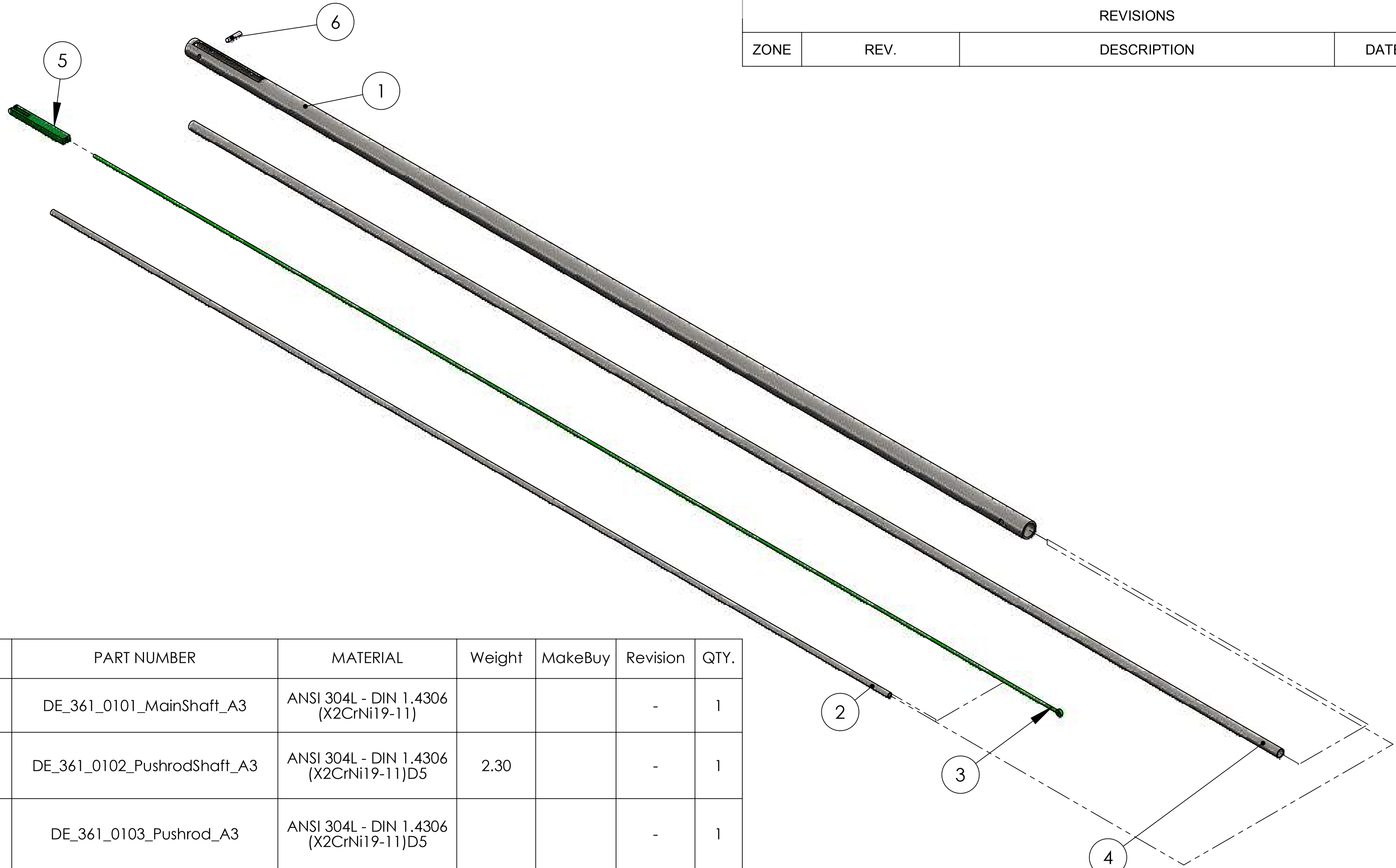
SHEET 2 OF 2



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2	DE_361_0102_PushrodShaft_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)D5	2.30		-	1
3	DE_361_0103_Pushrod_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)D5			-	1
4	DE_361_0104_TackShaft_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)	3.37		-	1
5	DE_361_0105_PushrodHead_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)			-	1
6	DE_361_0106_Axis_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)			-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED — TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED:
FINISH: Ra 0,8
SURFACE FINISH: Ra 0,8
TOLERANCES:
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS N/A
Tollerance class (iso 2768-1):

DO NOT SCALE DRAWING

REVISION -

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DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL:
WEIGHT:

TITLE: Shaft

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0100_Shaft_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.
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DWG NO. DE_361_0100_Shaft_A3

A3

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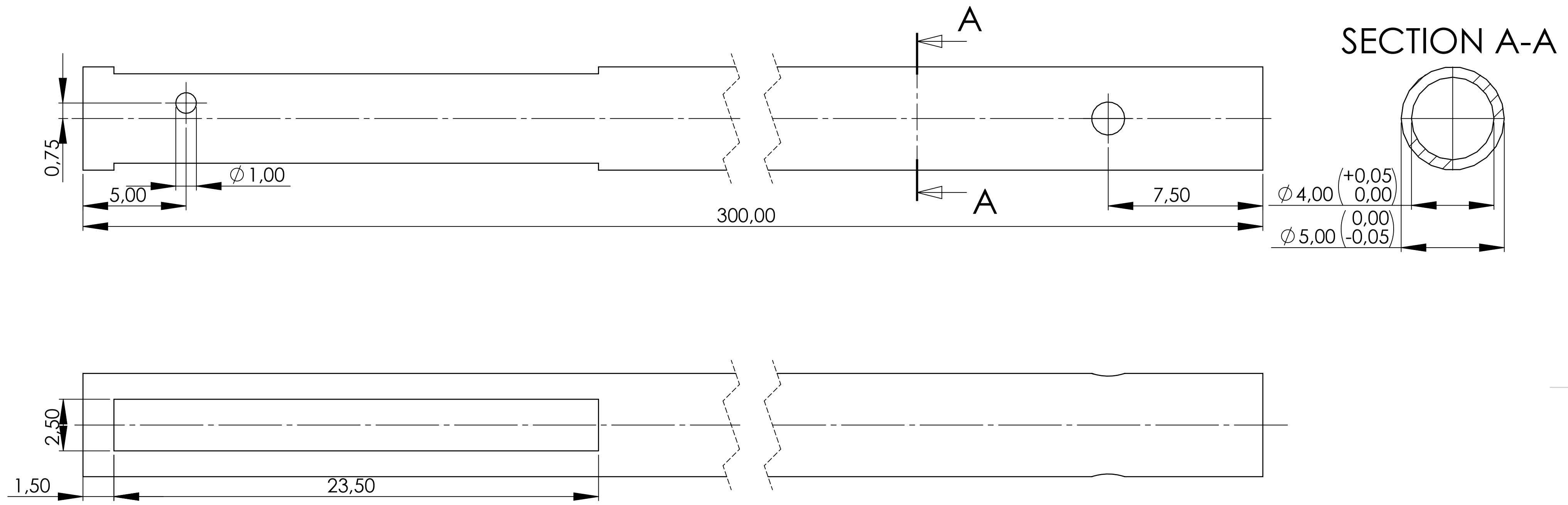

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DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120 DRAWING ACCORDING 3D FILE.

UNLESS OTHERWISE SPECIFIED — TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED
SURFACE FINISH CAVITY: Ra 1,2
SURFACE FINISH CORE: Ra 1,2
SURFACE FINISH OTHER: Ra 0,8
RADII: 0,2 (mm)
ANGULAR: +/- 0,15°
DEBUR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING | REVISION -

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CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS Concept
MATERIAL ANSI 304L - DIN 1.4306 (X2CrNi19-11)
WEIGHT:

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0101_MainShaft_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

TITLE:
Main shaft

DWG NO.
DE_361_0101_MainShaft_A3

A3

SCALE: 5:1 | SHEET 1 OF 1

REVISIONS

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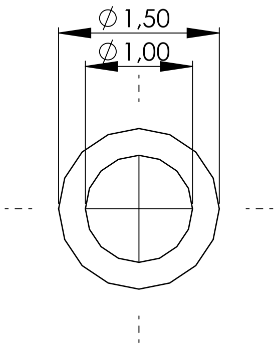

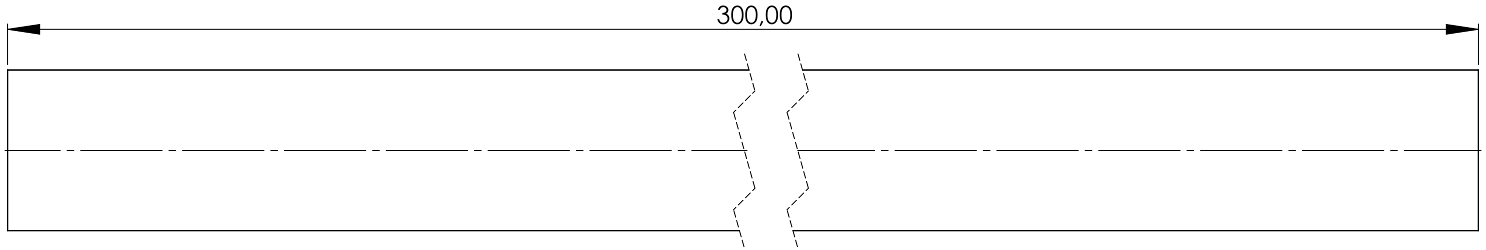

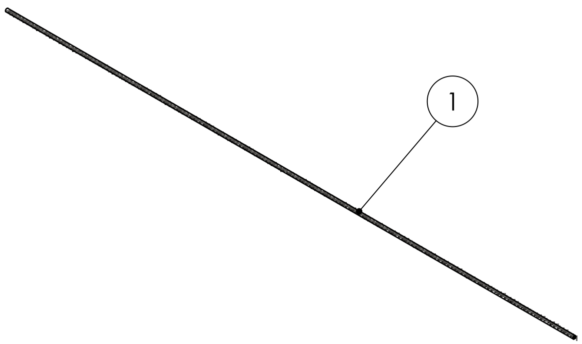

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DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120.
DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED

FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	3

DO NOT SCALE DRAWING

REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

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DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	ANSI 304L - DIN 1.4306 (X2CrNi19-11)
WEIGHT:	2.302.30

TITLE:

Pushrod Shaft

SUPPLIER:

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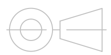

SOC MEANS: SUBJECT OF CHANGE.

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DWG NO. DE_361_0102_PushrodShaft_A3

A3

SCALE: 20:1

SHEET 1 OF 1

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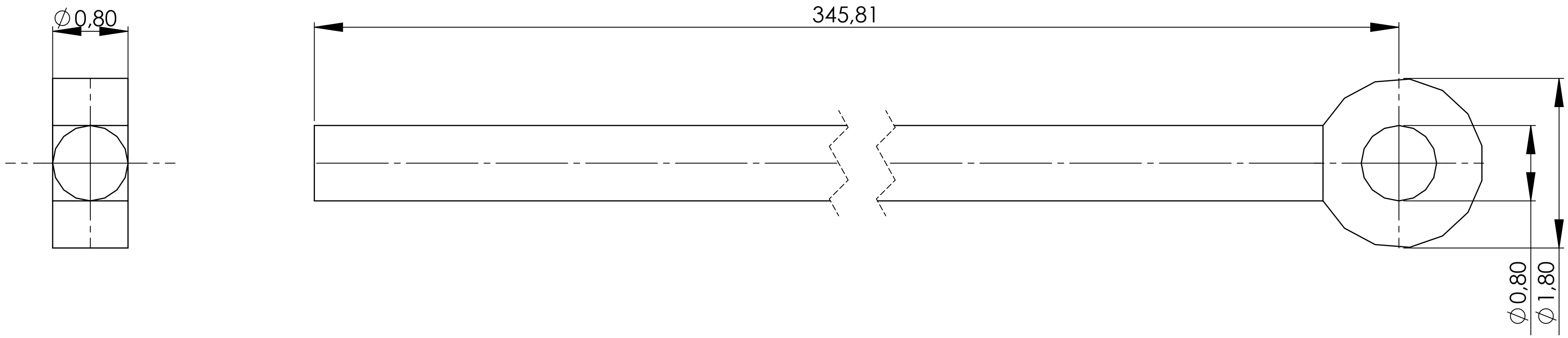

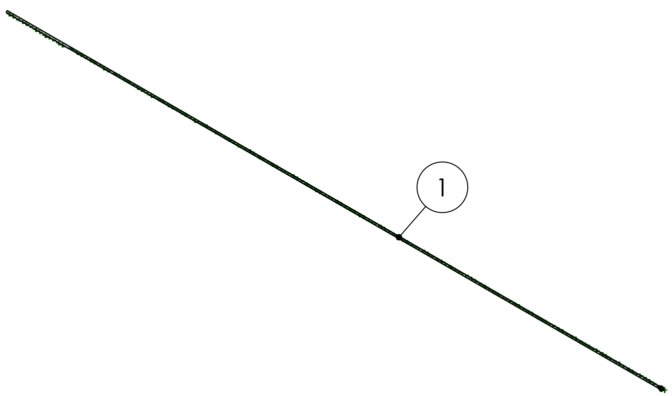

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DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED
FINISH: Ra 0,8
SURFACE FINISH: Ra 0,8
TOLERANCES:
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS N/A
Tollerance class (iso 2768-1):

DO NOT SCALE DRAWING

REVISION -

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL:
WEIGHT:

TITLE:

Pushrod

American projection

SOC MEANS: SUBJECT OF CHANGE.

DRAWING IS ACCORDING TO 3D FILE.

DWG NO. DE_361_0103_Pushrod_A3

A3

SUPPLIER:

DRAWING IS ACCORDING 3D FILE: DE_361_0103_Pushrod_A3

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SHEET 1 OF 1

REVISIONS

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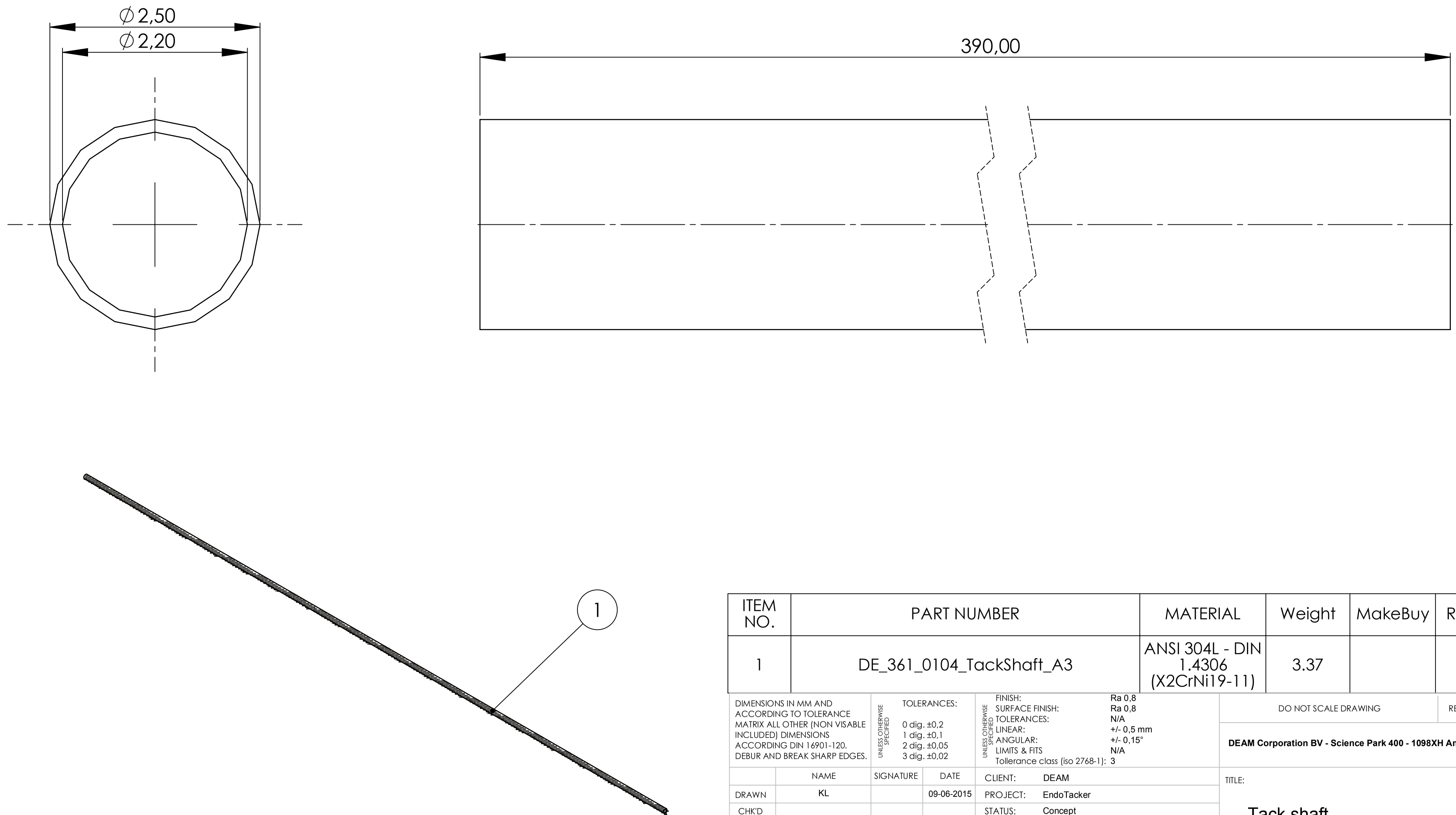

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DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED

FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	3

DO NOT SCALE DRAWING

REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	ANSI 304L - DIN 1.4306 (X2CrNi19-11)
WEIGHT:	3.373.37

TITLE:

Tack shaft

American projection

SOC MEANS: SUBJECT OF CHANGE.

DRAWING IS ACCORDING TO 3D FILE.

SUPPLIER:

DRAWING IS ACCORDING 3D FILE: DE_361_0104_TackShaft_A3

DWG NO. DE_361_0104_TackShaft_A3

A3

SCALE: 20:1

SHEET 1 OF 1

REVISIONS				
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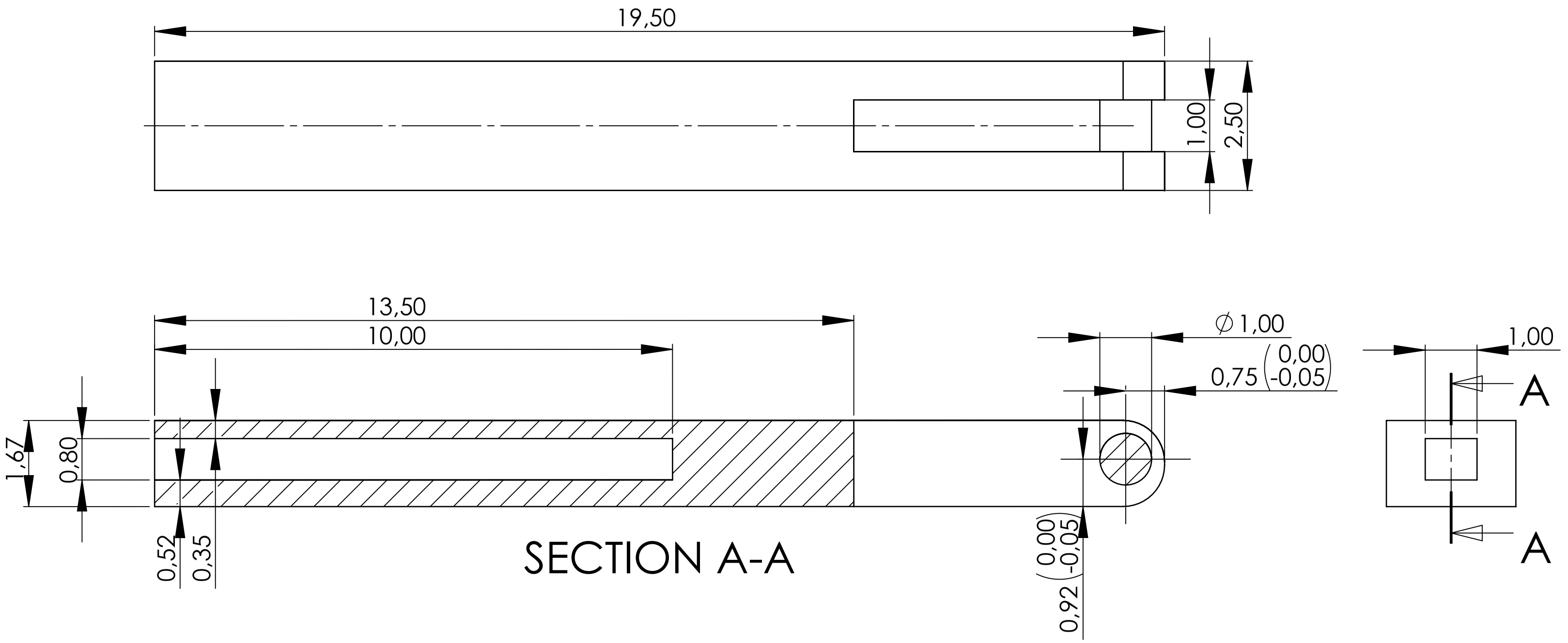
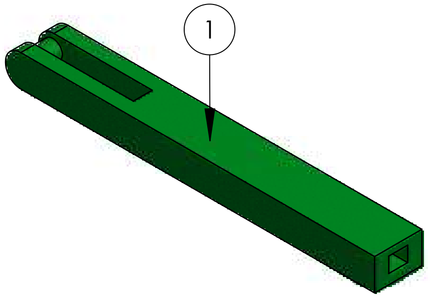


Note 1:
The part consists of a center layer (1mm thick) and another layer on each side of the center (0.75mm thick). The side layers contain a 1mm hole which need to be filled with a 1mm axel over the entire width of the part.

Profiles are defined by the supplied DXF files



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DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES: 0 dig. ±0,2; 1 dig. ±0,1; 2 dig. ±0,05; 3 dig. ±0,02

FINISH: Ra 0,8
SURFACE FINISH: Ra 0,8
UNLESS OTHERWISE SPECIFIED TOLERANCES:
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS: N/A
Tollerance class (iso 2768-1):

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DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL: AISI 304
WEIGHT:

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0105_PushrodHead_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING

REVISION -

TITLE: Pushrod head

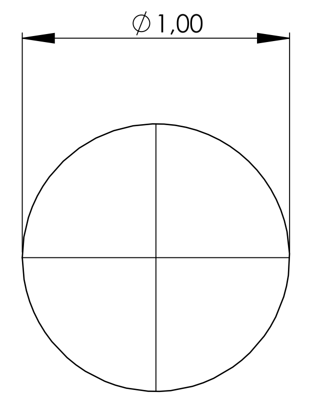
DWG NO. DE_361_0105_PushrodHead_A3

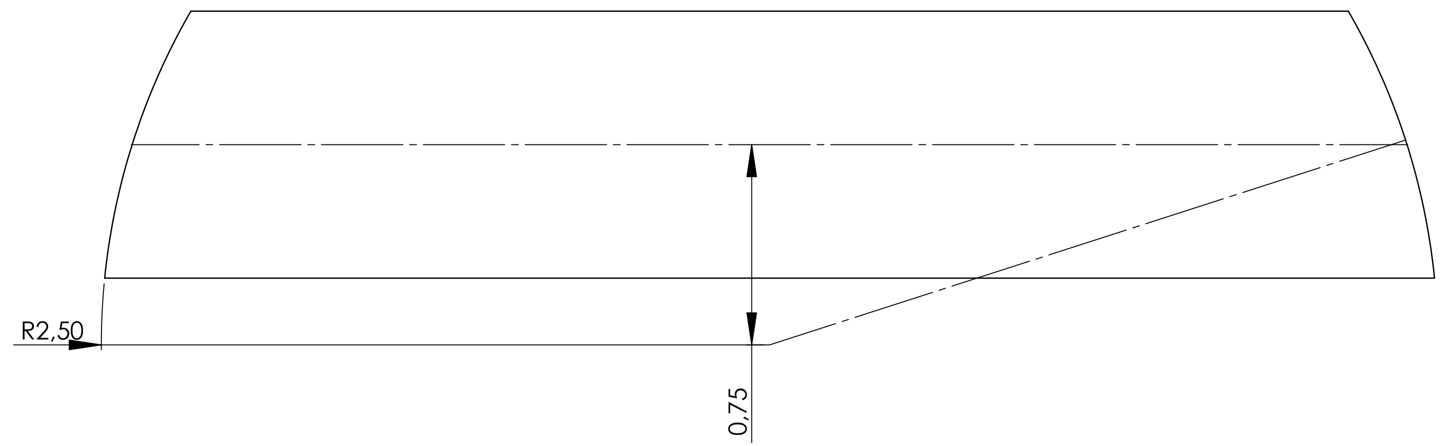
A3

SCALE: 10:1

SHEET 1 OF 2

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED





ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0106_Axis_A3				-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

FINISH: Ra 0,8
UNLESS OTHERWISE SPECIFIED
SURFACE FINISH: Ra 0,8
TOLERANCES:
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS N/A
Tollerance class (iso 2768-1):

DO NOT SCALE DRAWING — REVISION -

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL:
WEIGHT:

TITLE: Axis

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0106_Axis_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.

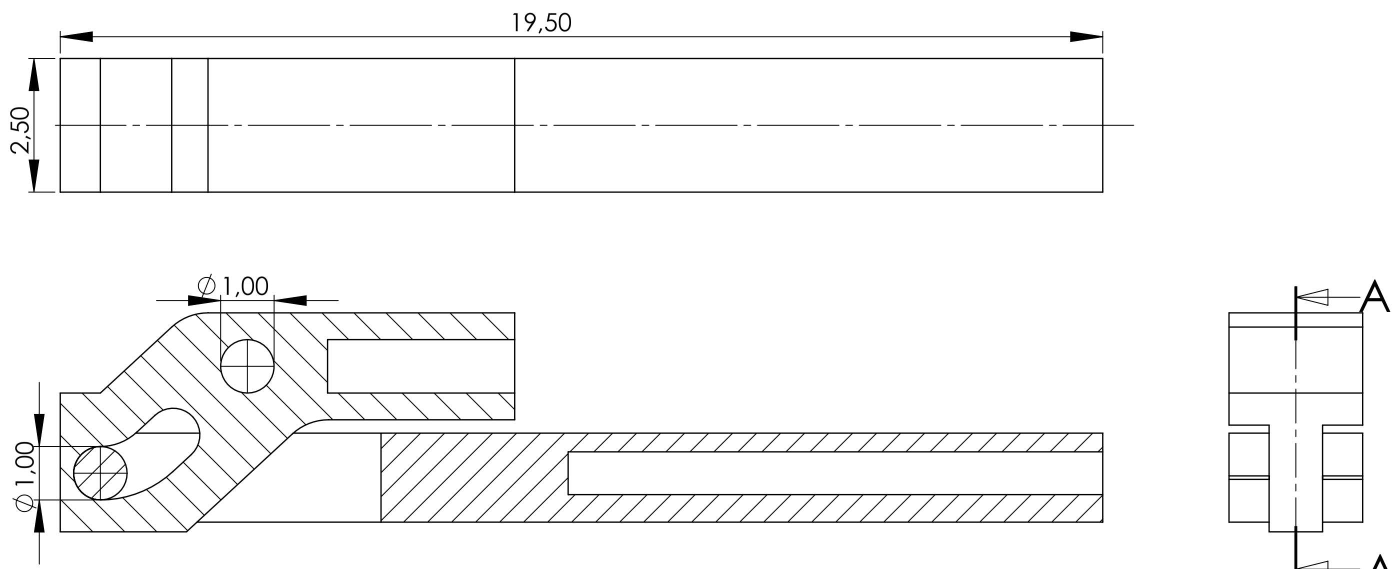
DRAWING IS ACCORDING TO 3D FILE.

DWG NO. DE_361_0106_Axis_A3 — A3

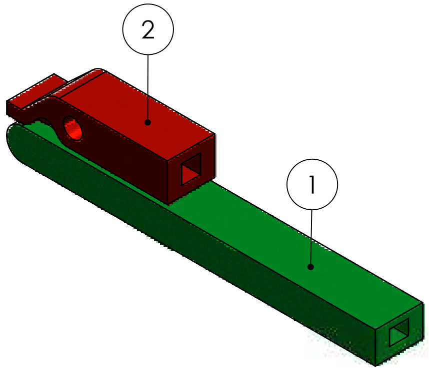
SCALE: 50:1 — SHEET 1 OF 1

REVISIONS

ZONE	REV.	DESCRIPTION	DATE	APPROVED



SECTION A-A



Note 1:
The parts in this drawing are assembled during production. The PushrodHead contains an axel of 1mm. This axel should be welded into place AFTER it has been assembled through the slot in the needle body. The axel in the PushrodHead should glide smoothly through the slot in the NeedleBody.

ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0105_PushrodHead_A3	AISI 304			-	4
2	DE_361_0201_NeedleBody_A3	AISI 304			-	4

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120.
DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED — TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED
FINISH: N/A
SURFACE FINISH: N/A
TOLERANCES: N/A
LINEAR: N/A
ANGULAR: N/A
LIMITS & FITS N/A
Tollerance class (iso 2768-1): N/A

	NAME	SIGNATURE	DATE
DRAWN	KL		13-08-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL: Material <not specified>
WEIGHT: 0.780.78

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0000_NeedlePushrod_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

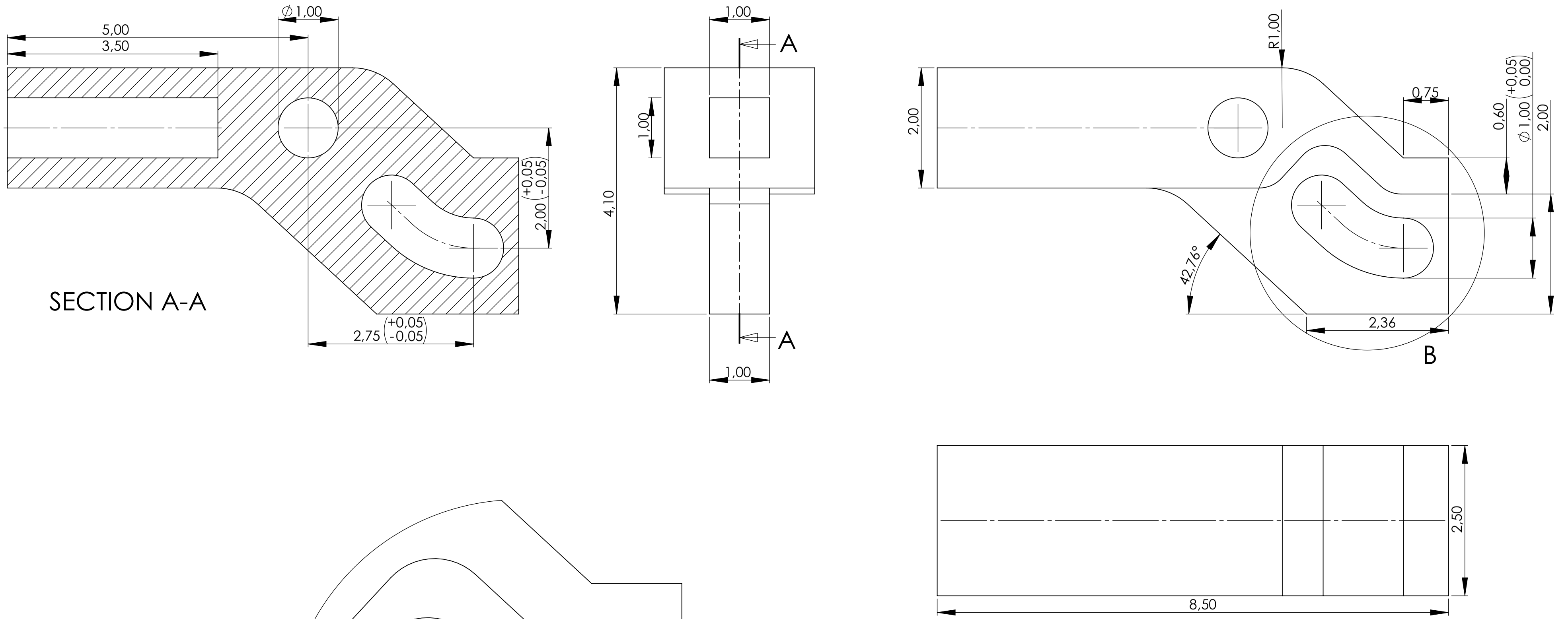
DO NOT SCALE DRAWING
REVISION -

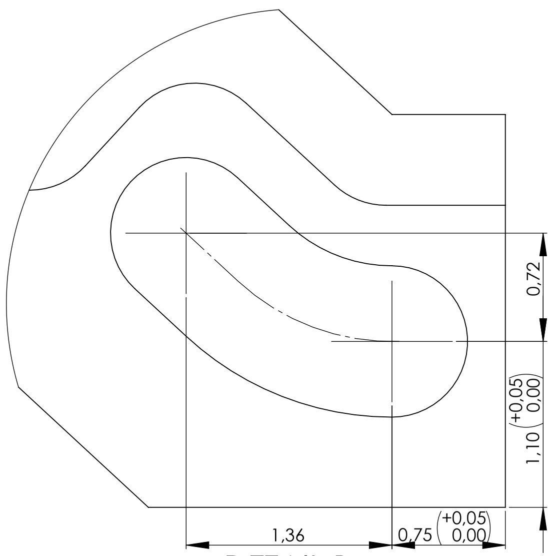
DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:

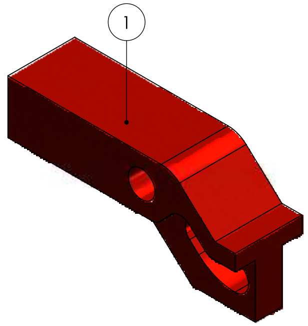
DWG NO. DE_361_0000_NeedlePushrod
A3
SCALE: 10:1
SHEET 1 OF 1

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED





DETAIL B
SCALE 40 : 1



Note 1:
The part consists of a center layer (1mm thick) and another layer on each side of the center (0.75mm thick).

Profiles are defined by the supplied DXF files

ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
	DE_361_0201_NeedleBody_A3	AISI 304			-	4

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES

UNLESS OTHERWISE SPECIFIED
TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED
FINISH: Ra 0,8
SURFACE FINISH: Ra 0,8
TOLERANCES:
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS N/A
Tollerance class (iso 2768-1):

DO NOT SCALE DRAWING
REVISION -

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			
SUPPLIER:			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL: AISI 304
WEIGHT:

TITLE:
Needle body

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

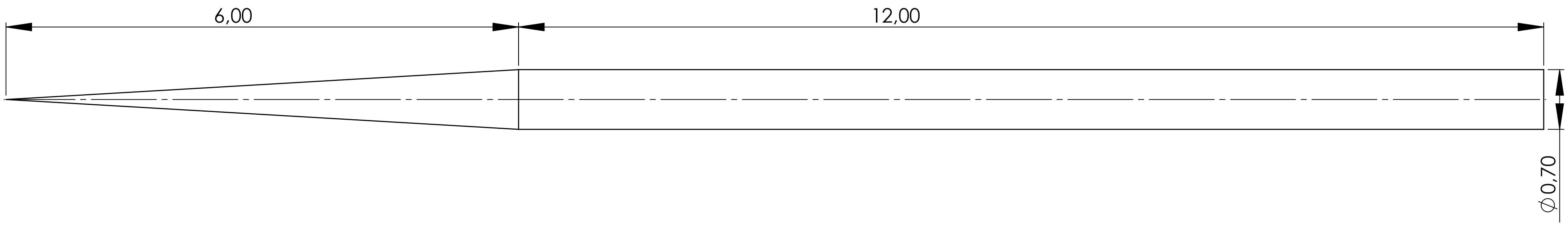
DWG NO.
DE_361_0201_NeedleBody_A3

A2

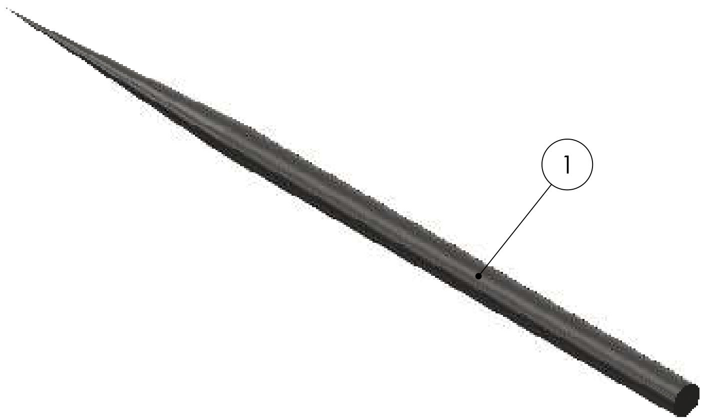
Drawing is according to 3D file: DE_361_0201_NeedleBody_A3

SCALE: 20:1
SHEET 1 OF 2

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED



Note: V-20 suture needle



ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0202_Needle_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)	0.04		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED
FINISH: Ra 0,8
SURFACE FINISH: Ra 0,8
TOLERANCES: N/A
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS N/A
Tollerance class (iso 2768-1): 3

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0202_Needle_A3

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL: ANSI 304L - DIN 1.4306 (X2CrNi19-11)
WEIGHT: 0.040.04

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING
REVISION -

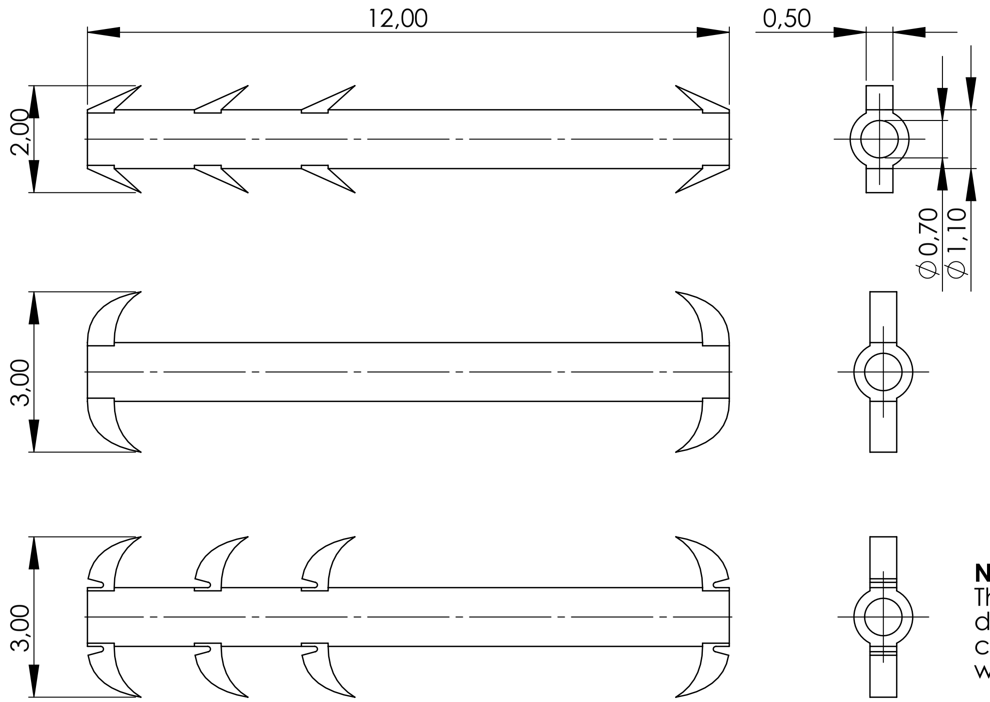
DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:

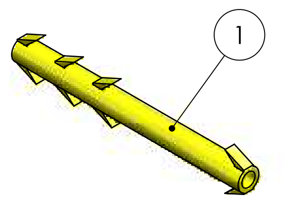
DWG NO.
DE_361_0202_Needle_A3
A3

SCALE: 20:1
SHEET 1 OF 1

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED



Note:
There are 4 tack configurations, each with different types of anchors. The fourth configuration is the same as configuration 3 but with a teeth with of 1mm instead of 0.5mm



ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0301_Tack_A3				-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED
FINISH: Ra 0,8
SURFACE FINISH: Ra 0,8
TOLERANCES:
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS N/A
Tollerance class (iso 2768-1):

DO NOT SCALE DRAWING

REVISION -

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL:
WEIGHT:

TITLE:
Tack

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

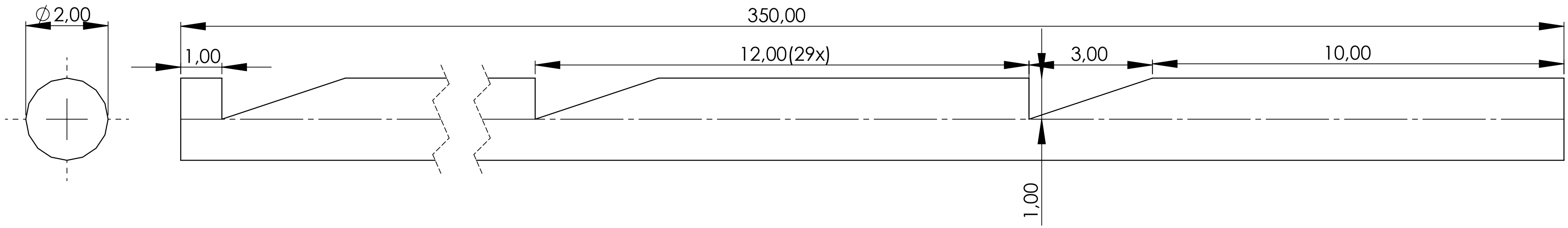
SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0301_Tack_A3

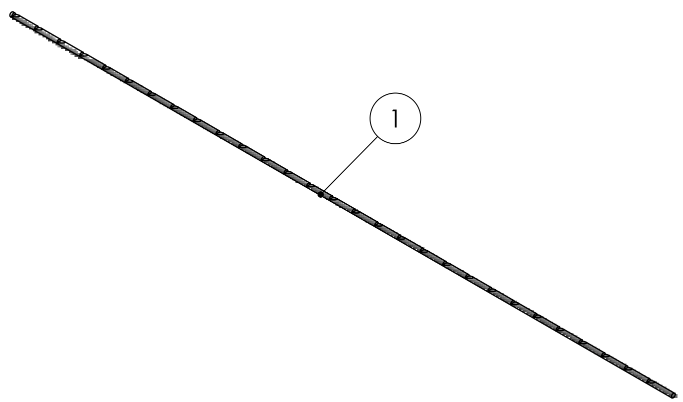
DWG NO.
DE_361_0301_Tack_A3

A3

SCALE: 10:1
SHEET 1 OF 1

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED





ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0302_TackSlider_A3				-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

FINISH: Ra 0,8
SURFACE FINISH: Ra 0,8
UNLESS OTHERWISE SPECIFIED TOLERANCES:
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS N/A
Tollerance class (iso 2768-1):

DO NOT SCALE DRAWING
REVISION -

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL:
WEIGHT:

TITLE:
Tack slider

SUPPLIER:
DRAWING IS ACCORDING 3D FILE:
DE_361_0302_TackSlider_A3

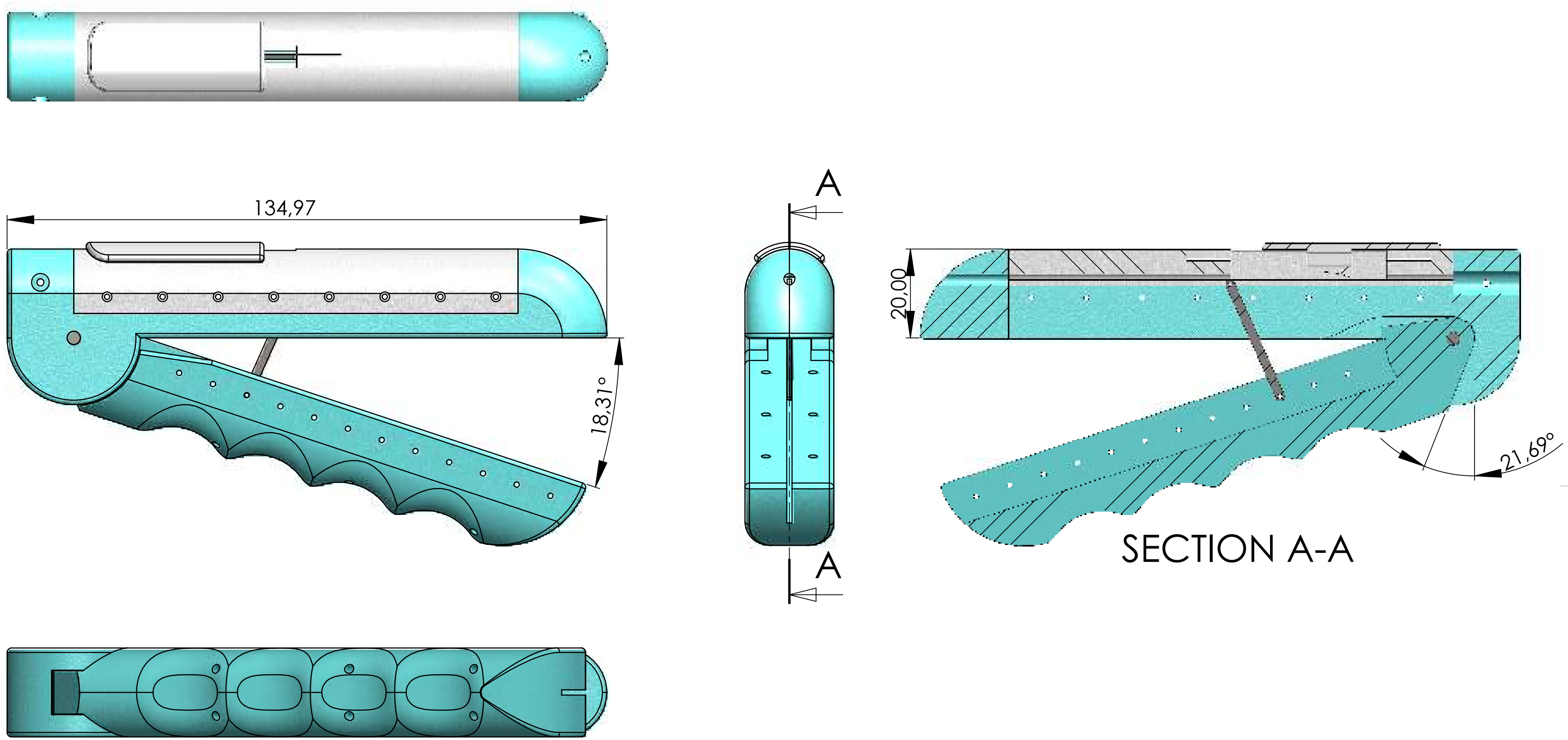
American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

DWG NO.
DE_361_0302_TackSlider_A3
A3

SCALE: 10:1
SHEET 1 OF 1

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED



DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED	
FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	N/A

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	Material <not specified>
WEIGHT:	84.1884.18

SUPPLIER:
DRAWING IS ACCORDING 3D FILE:
DE_361_0400_Handle_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING
REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

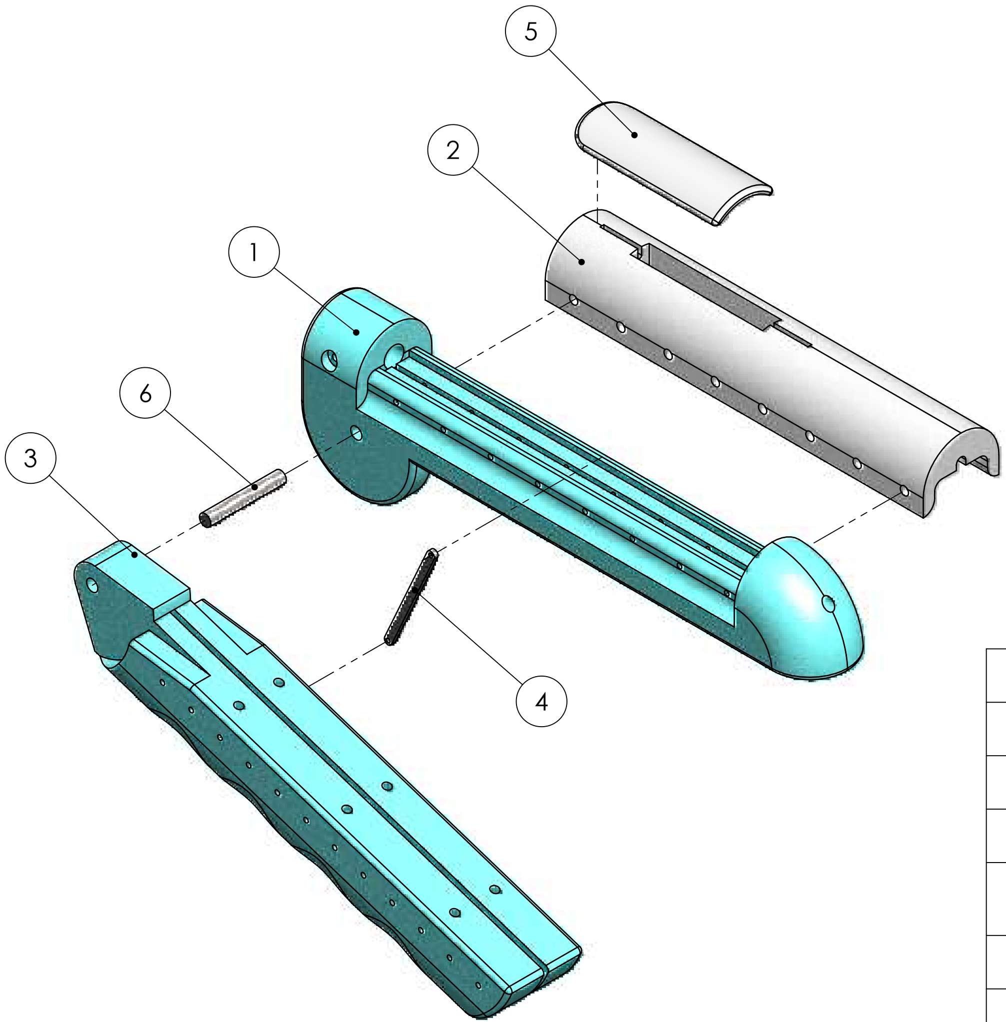
TITLE:
Handle

DWG NO.
DE_361_0400_Handle_A3
A3

SCALE: 1:1
SHEET 1 OF 2

REVISIONS

ZONE	REV.	DESCRIPTION	DATE	APPROVED
-	-	See SAM	-	-



ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0401_HandleTop_A3	PA2200	31.49		-	1
2	DE_361_0402_HandleTopCover_A3	PA2200	13.86		-	1
3	DE_361_0403_HandleBottom_A3	PA2200	36.07		-	1
4	DE_361_0404_PushLink_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)	0.44		-	1
5	DE_361_0405_TackControl_A3	PA2200	1.21		-	1
6	DE_361_0406_HandleAxis_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)	1.10		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES: 0 dig. ±0,2; 1 dig. ±0,1; 2 dig. ±0,05; 3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED
FINISH: Ra 0,8
SURFACE FINISH: Ra 0,8
TOLERANCES: N/A
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS: N/A
Tollerance class (iso 2768-1): N/A

DO NOT SCALE DRAWING — REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL: Material <not specified>
WEIGHT: 84.1884.18

TITLE: Handle

SUPPLIER:

DRAWING IS ACCORDING 3D FILE: DE_361_0400_Handle_A3

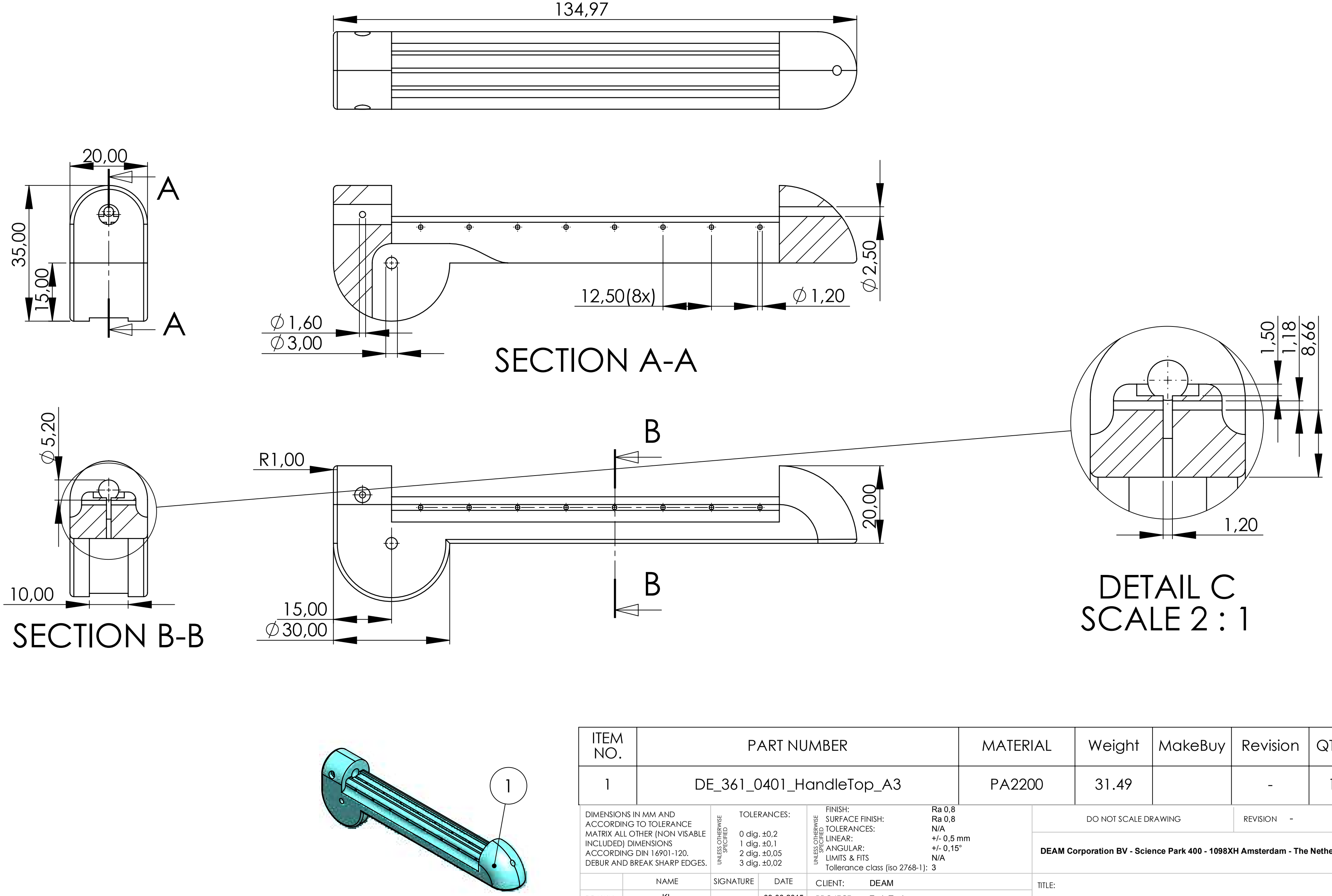
American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

DWG NO. DE_361_0400_Handle_A3 — A3

SCALE: 1:1 — SHEET 2 OF 2

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED



ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0401_HandleTop_A3	PA2200	31.49		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED

FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	3

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	PA2200
WEIGHT:	31.4931.49

SUPPLIER:

DRAWING IS ACCORDING 3D FILE: DE_361_0401_HandleTop_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.

DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING

REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:

Handle Top

DWG NO.

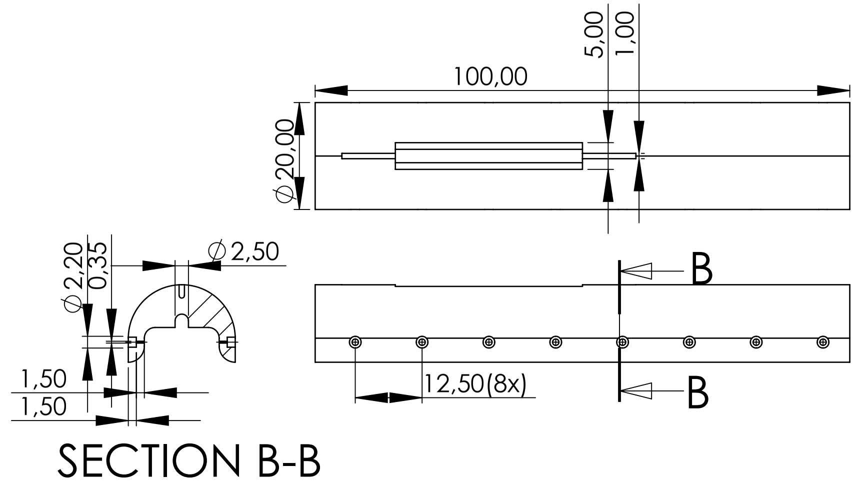
DE_361_0401_HandleTop_A3

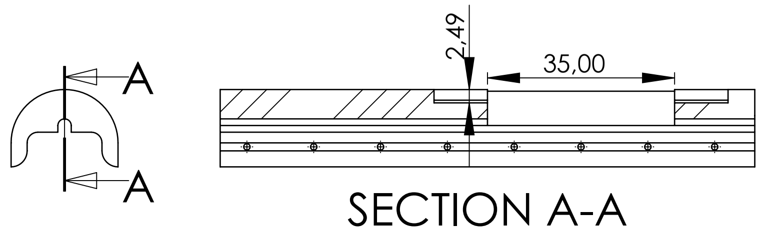
A3

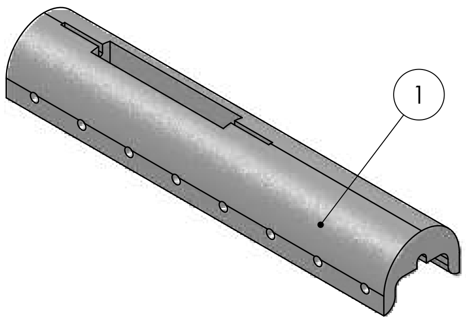
SCALE: 1:1

SHEET 1 OF 1

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED







ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0402_HandleTopCover_A3	PA2200	13.86		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES: 0 dig. ±0,2; 1 dig. ±0,1; 2 dig. ±0,05; 3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED
FINISH: Ra 0,8
SURFACE FINISH: Ra 0,8
TOLERANCES: N/A
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS N/A
Tollerance class (iso 2768-1): 3

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL: PA2200
WEIGHT: 15.8531.49

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0402_HandleTopCover_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING
REVISION -

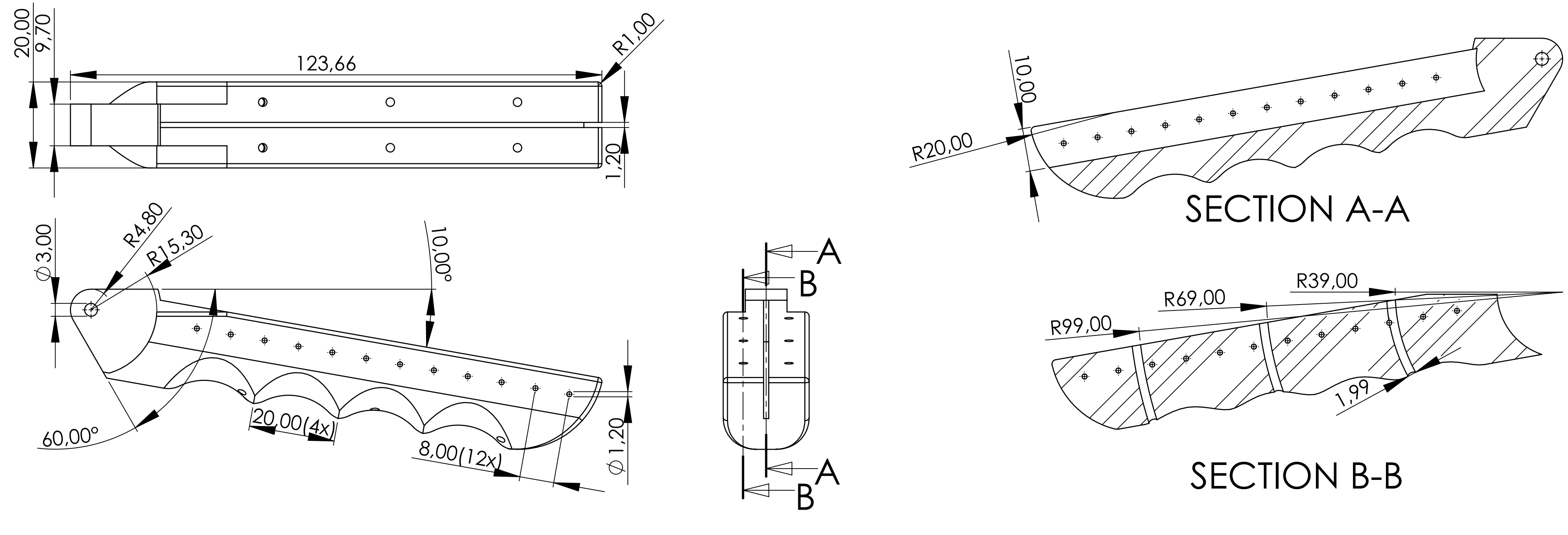
DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

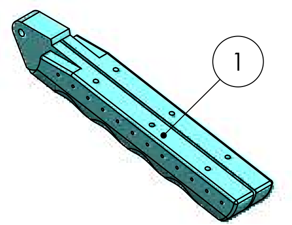
TITLE:
Handle top cover

DWG NO.
DE_361_0402_HandleTopCover_A3
A3

SCALE: 1:1
SHEET 1 OF 1

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED





ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0403_HandleBottom_A3	PA2200	36.07		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
UNLESS OTHERWISE SPECIFIED TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	3

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	PA2200
WEIGHT:	36.0736.07

SUPPLIER:

DRAWING IS ACCORDING 3D FILE: DE_361_0403_HandleBottom_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.

DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING

REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:

Handle Bottom

DWG NO.

DE_361_0403_HandleBottom_A3

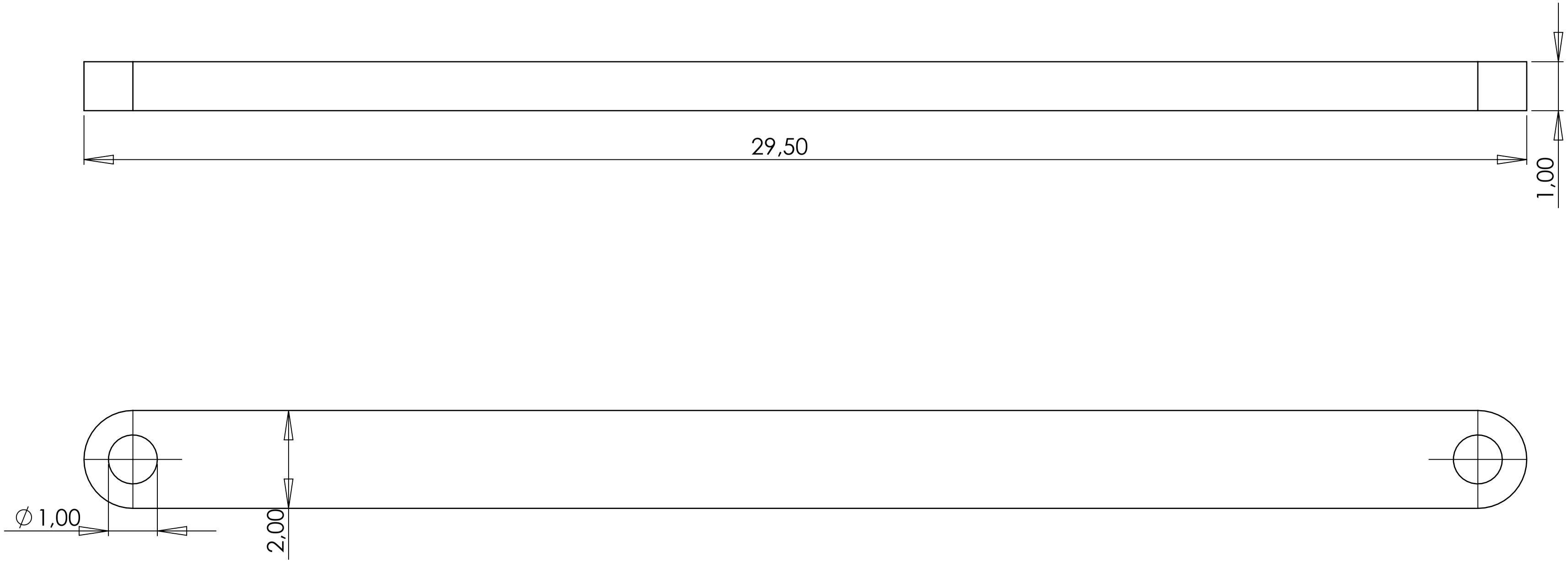
A3

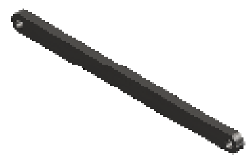
SCALE: 1:1

SHEET 1 OF 1

REVISIONS

ZONE	REV.	DESCRIPTION	DATE	APPROVED





ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0404_PushLink_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)	0.44		-	2

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED — TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED

FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	3

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

SUPPLIER:

DRAWING IS ACCORDING 3D FILE: DE_361_0404_PushLink_A3

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	ANSI 304L - DIN 1.4306 (X2CrNi19-11)
WEIGHT:	0.440.44

American projection

SOC MEANS: SUBJECT OF CHANGE.

DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING

REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:

Push link

DWG NO.

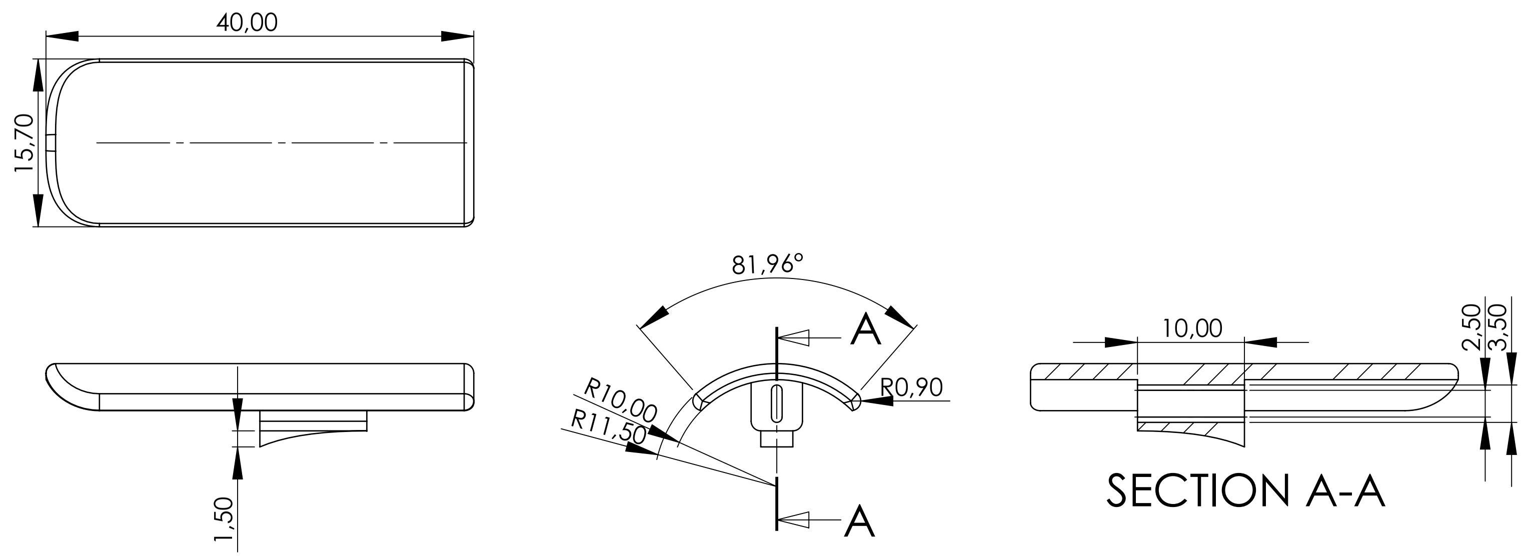
DE_361_0404_PushLink_A3

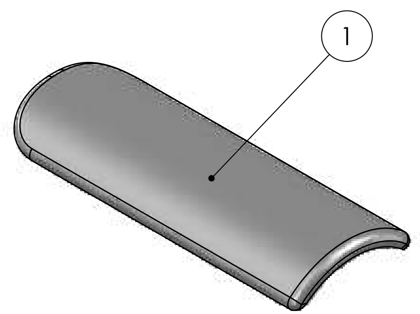
A3

SCALE: 10:1

SHEET 1 OF 1

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED





ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0405_TackControl_A3	PA2200	1.21		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

FINISH: Ra 0,8
UNLESS OTHERWISE SPECIFIED
SURFACE FINISH: Ra 0,8
TOLERANCES: N/A
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS N/A
Tollerance class (iso 2768-1): 3

	NAME	SIGNATURE	DATE
DRAWN	KL		09-06-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0405_TackControl_A3

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	PA2200
WEIGHT:	1.211.21

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

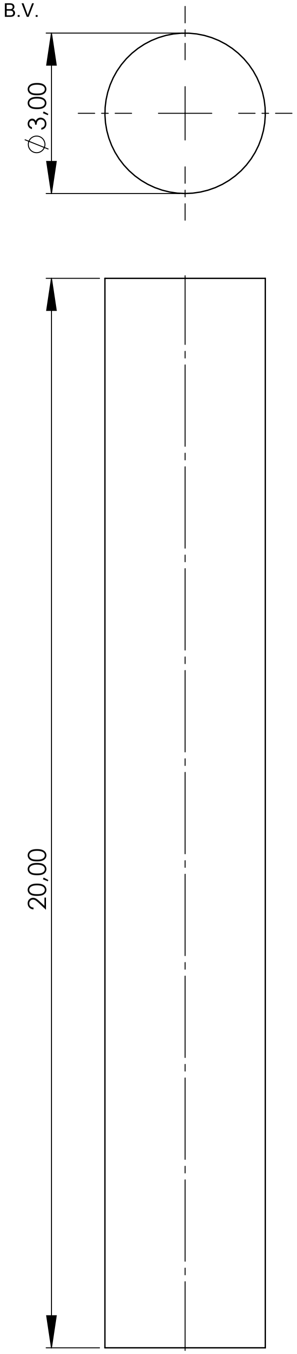
DO NOT SCALE DRAWING
REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:
Tack control

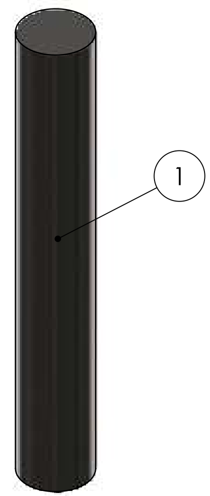
DWG NO.
DE_361_0405_TackControl_A3
A3

SCALE: 2:1
SHEET 1 OF 1



REVISIONS

ZONE	REV.	DESCRIPTION	DATE	APPROVED



ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0406_HandleAxis_A3	ANSI 304L - DIN 1.4306 (X2CrNi19-11)	1.10		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED

FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	3

DO NOT SCALE DRAWING — REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

	NAME	SIGNATURE	DATE
DRAWN	KL		12-10-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	ANSI 304L - DIN 1.4306 (X2CrNi19-11)
WEIGHT:	1.101.10

TITLE:

SUPPLIER:

DRAWING IS ACCORDING 3D FILE: DE_361_0406_HandleAxis_A3

American projection

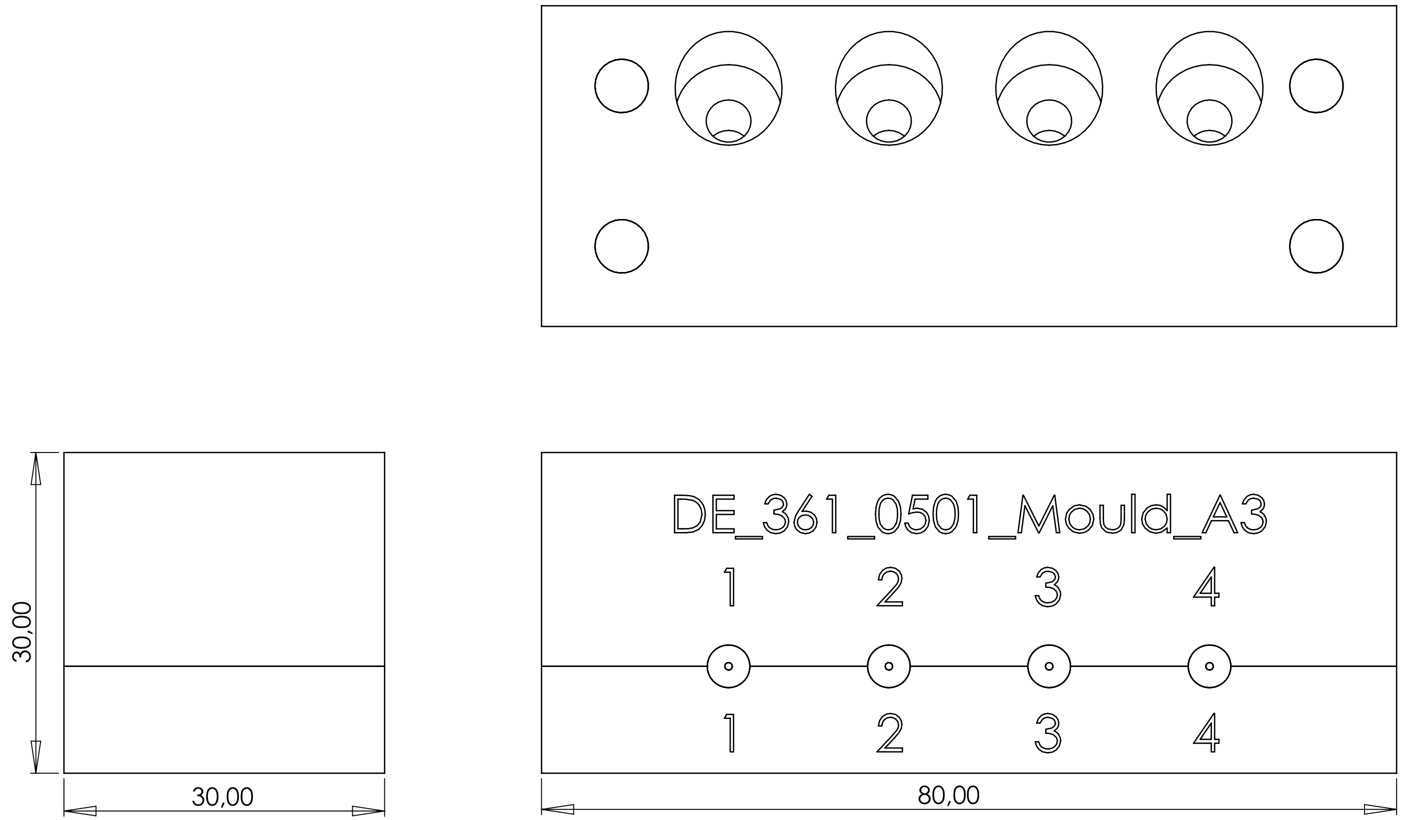
SOC MEANS: SUBJECT OF CHANGE.

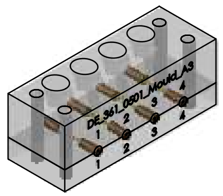
DRAWING IS ACCORDING TO 3D FILE.

DWG NO. DE_361_0406_HandleAxis_A3 — A3

SCALE: 10:1 — SHEET 1 OF 1

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED





DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES: 0 dig. ±0,2; 1 dig. ±0,1; 2 dig. ±0,05; 3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED
FINISH: N/A
SURFACE FINISH: N/A
TOLERANCES: N/A
LINEAR: N/A
ANGULAR: N/A
LIMITS & FITS N/A
Tollerance class (iso 2768-1): N/A

	NAME	SIGNATURE	DATE
DRAWN	KL		09-09-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	Material <not specified>
WEIGHT:	104.69104.69

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0500_Mould_CNC_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING
REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:

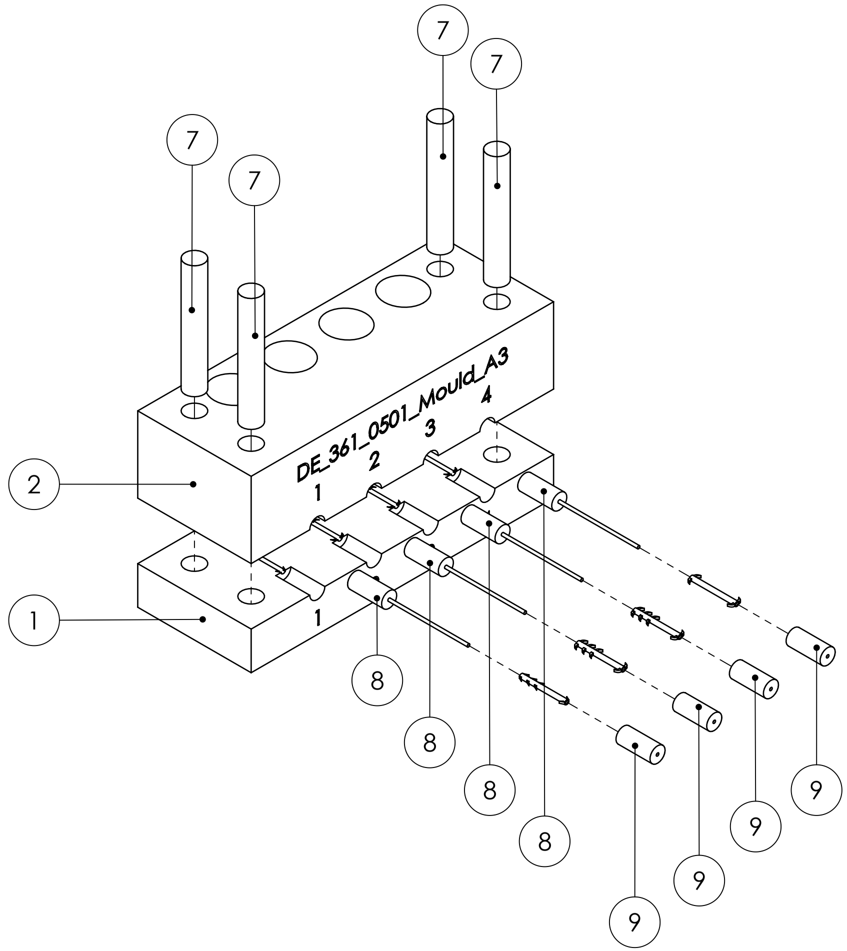
DWG NO. DE_361_0500_Mould_CNC_A3

A3

SCALE: 2:1
SHEET 1 OF 2

REVISIONS

ZONE	REV.	DESCRIPTION	DATE	APPROVED
-	-	See Sheet1	-	-



ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0501_Mould_A3	TECANAT PC	27.04		-	1
2	DE_361_0501_Mould_A3	TECANAT PC	50.92		-	1
3	DE_361_0301_Tack_A3				-	1
4	DE_361_0301_Tack_A3				-	1
5	DE_361_0301_Tack_A3				-	1
6	DE_361_0301_Tack_A3				-	1
7	DE_361_0502_MouldRod_A3	DEAM Steel SS 304	4.71		-	4
8	DE_361_0504_TackCore_A3	Brass	1.03		-	4
9	DE_361_0505_TackCoreCap_A3	Brass	0.93		-	4

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED
FINISH: N/A
SURFACE FINISH: N/A
TOLERANCES: N/A
LINEAR: N/A
ANGULAR: N/A
LIMITS & FITS N/A
Tollerance class (iso 2768-1): N/A

DO NOT SCALE DRAWING
REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

	NAME	SIGNATURE	DATE
DRAWN	KL		09-09-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL: Material <not specified>
WEIGHT: 104.69104.69

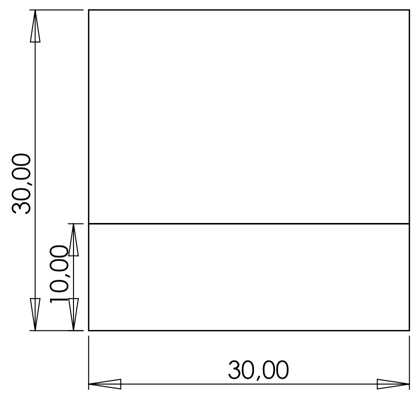
TITLE:

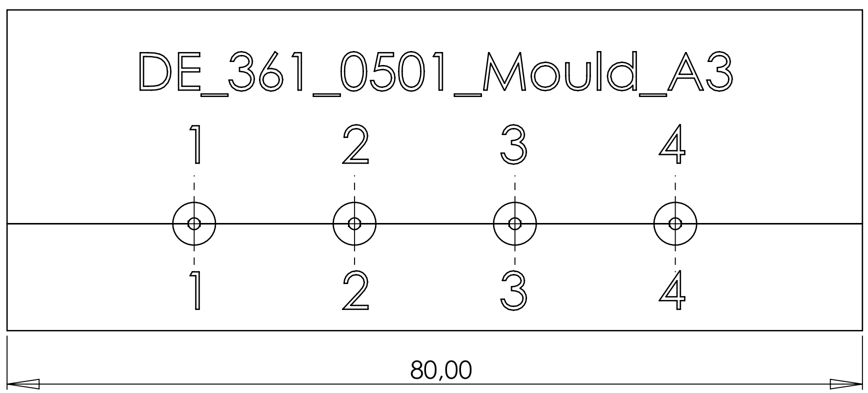
SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0500_Mould_CNC_A3

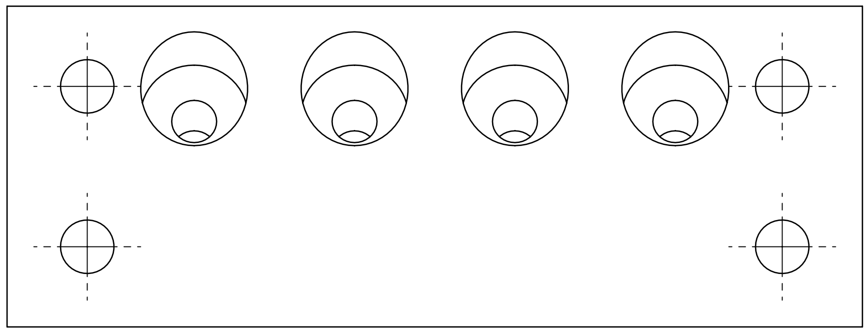
American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

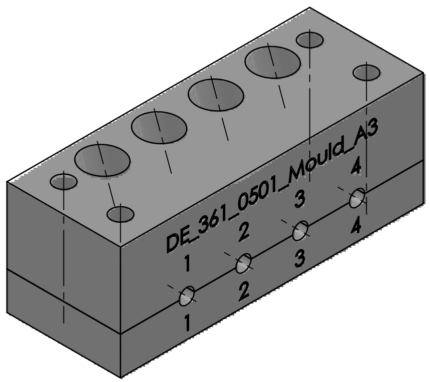
DWG NO. DE_361_0500_Mould_CNC_A3
A3
SCALE: 2:1
SHEET 2 OF 2







Note for prototyping
The mould base with the required holes will be produced through CNC machining. The teeth will be added through laser micro-machining. The T-shape in both sides of the mould is a marker to allign the laser



ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0501_Mould_A3	TECANAT PC	77.95		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	3

	NAME	SIGNATURE	DATE
DRAWN	KL		09-09-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	TECANAT PC
WEIGHT:	50.9250.92

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0501_Mould_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING
REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:

DWG NO. DE_361_0501_Mould_A3

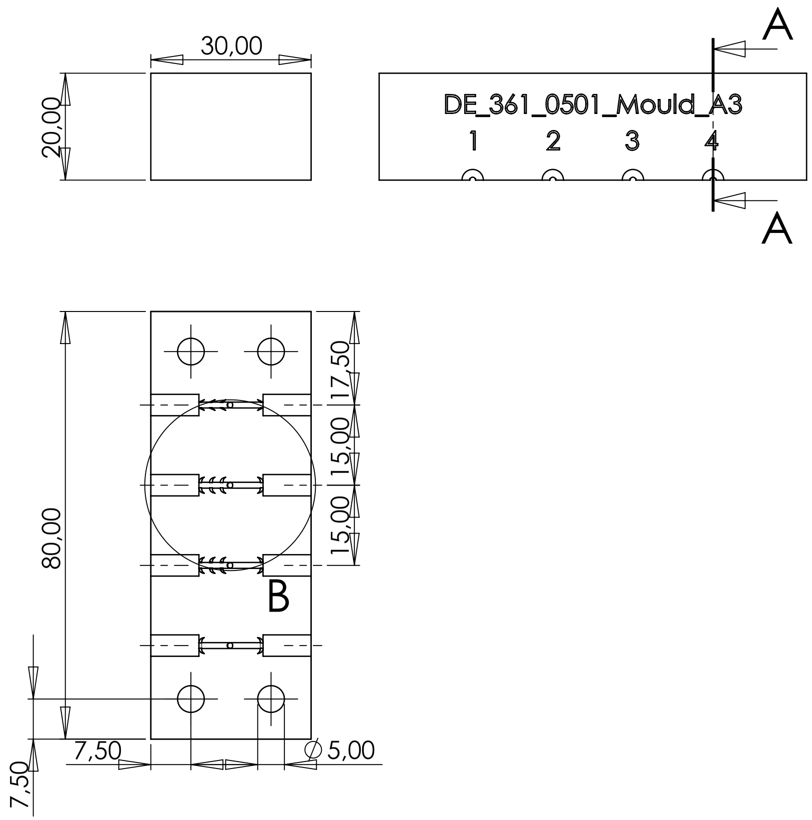
A3

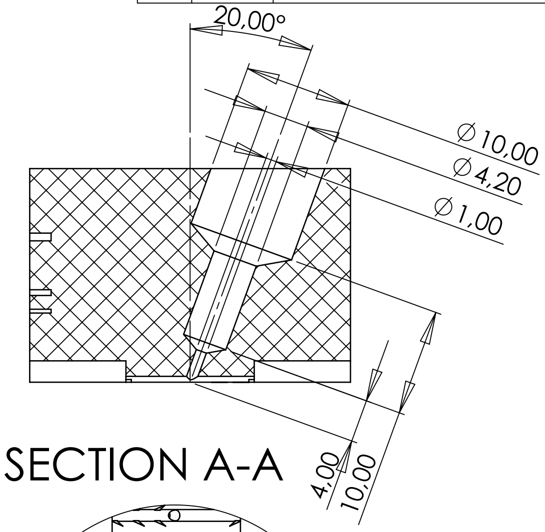
SCALE: 2:1

SHEET 1 OF 4

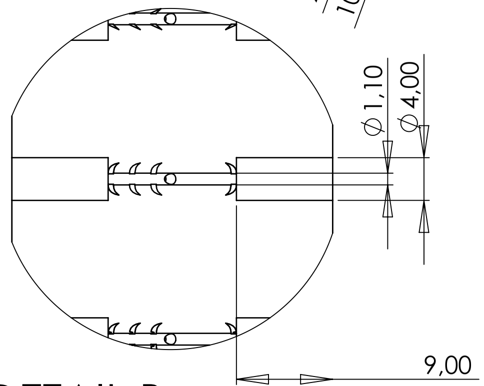
REVISIONS

ZONE	REV.	DESCRIPTION	DATE	APPROVED
-	-	See Full mould	-	-

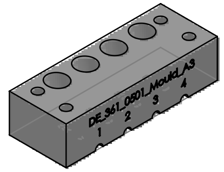




SECTION A-A



DETAIL B



Note for prototyping
The mould base with the required holes will be produced through CNC machining. The teeth will be added through laser micro-machining. The T-shape in both sides of the mould is a marker to allign the laser

ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0501_Mould_A3	TECANAT PC	50.92		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES: 0 dig. ±0,2; 1 dig. ±0,1; 2 dig. ±0,05; 3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED

FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	3

	NAME	SIGNATURE	DATE
DRAWN	KL		09-09-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	TECANAT PC
WEIGHT:	50.9250.92

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0501_Mould_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING
REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:

DWG NO. DE_361_0501_Mould_A3
A3

SCALE: 2:1
SHEET 2 OF 4

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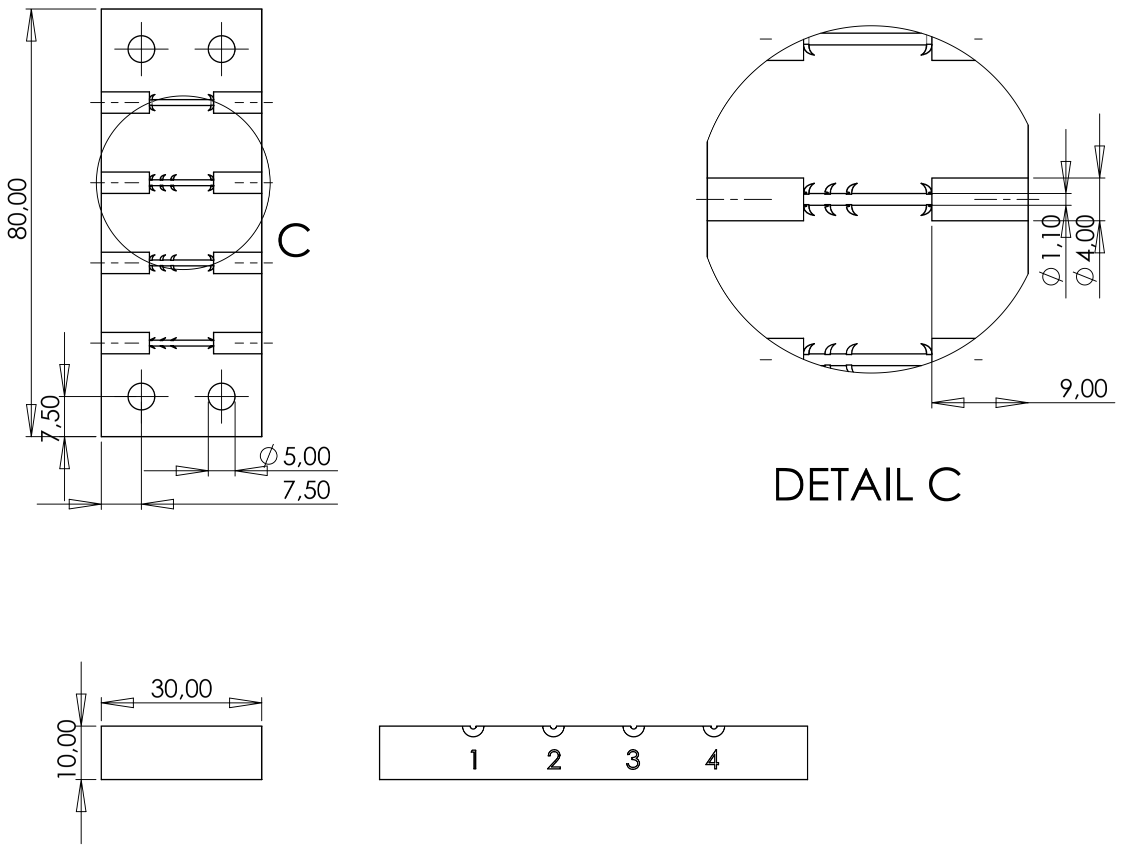
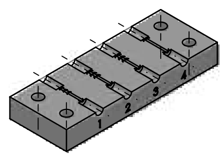
REVISIONS

ZONE	REV.	DESCRIPTION	DATE	APPROVED
-	-	See Full mould	-	-





ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0501_Mould_A3	TECANAT PC	27.04		-	1

Note for prototyping
The mould base with the required holes will be produced through CNC machining. The teeth will be added through laser micro-machining. The T-shape in both sides of the mould is a marker to allign the laser

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DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

FINISH: Ra 0,8
UNLESS OTHERWISE SPECIFIED SURFACE FINISH: Ra 0,8
TOLERANCES: N/A
LINEAR: +/- 0,5 mm
ANGULAR: +/- 0,15°
LIMITS & FITS N/A
Tollerance class (iso 2768-1): 3

	NAME	SIGNATURE	DATE
DRAWN	KL		09-09-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT: DEAM
PROJECT: EndoTacker
STATUS: Concept
MATERIAL: TECANAT PC
WEIGHT: 50.9250.92

SUPPLIER:
DRAWING IS ACCORDING 3D FILE: DE_361_0501_Mould_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.
DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING

REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:

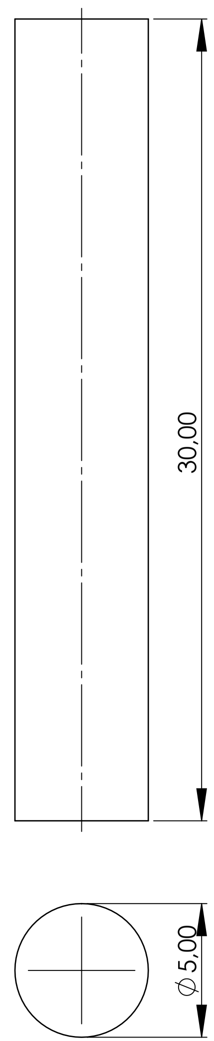
DWG NO. DE_361_0501_Mould_A3

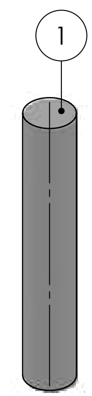
A3

SCALE: 2:1

SHEET 3 OF 4

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED





ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0502_MouldRod_A3	DEAM Steel SS 304	4.71		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED

FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	3

DO NOT SCALE DRAWING

REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

	NAME	SIGNATURE	DATE
DRAWN	KL		04-09-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	DEAM Steel SS 304
WEIGHT:	4.714.71

TITLE:

American projection

SOC MEANS: SUBJECT OF CHANGE.

DRAWING IS ACCORDING TO 3D FILE.

SUPPLIER:

DRAWING IS ACCORDING 3D FILE: DE_361_0502_MouldRod_A3

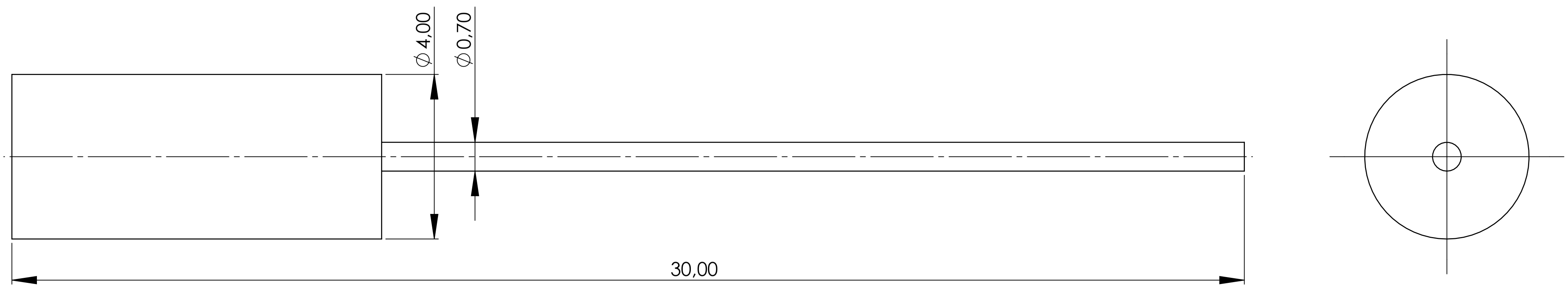
DWG NO. DE_361_0502_MouldRod_A3

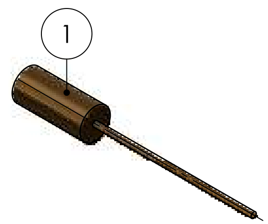
A3

SCALE: 5:1

SHEET 1 OF 1

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED





ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0504_TackCore_A3	Brass	1.03		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED

FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	3

	NAME	SIGNATURE	DATE
DRAWN	KL		09-09-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	Brass
WEIGHT:	1.031.03

SUPPLIER:

DRAWING IS ACCORDING 3D FILE: DE_361_0504_TackCore_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.

DRAWING IS ACCORDING TO 3D FILE.

DO NOT SCALE DRAWING

REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

TITLE:

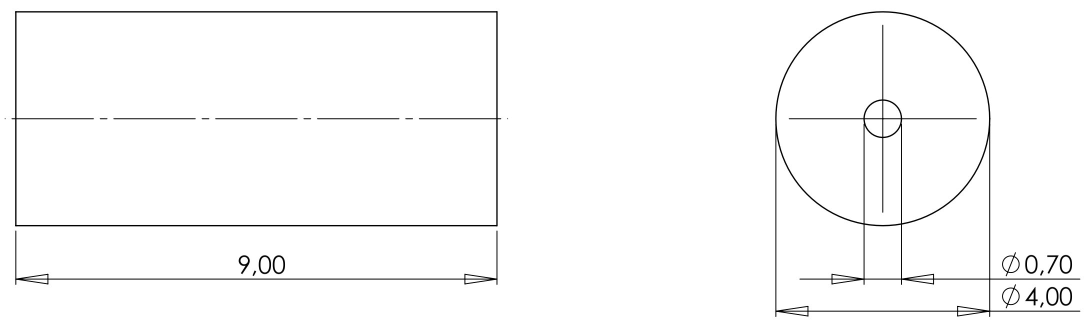
DWG NO. DE_361_0504_TackCore_A3

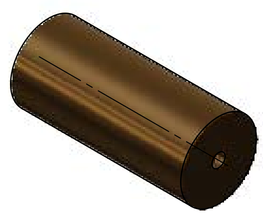
A3

SCALE: 10:1

SHEET 1 OF 1

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED





ITEM NO.	PART NUMBER	MATERIAL	Weight	MakeBuy	Revision	QTY.
1	DE_361_0505_TackCoreCap_A3	Brass	0.93		-	1

DIMENSIONS IN MM AND ACCORDING TO TOLERANCE MATRIX ALL OTHER (NON VISABLE INCLUDED) DIMENSIONS ACCORDING DIN 16901-120. DEBUR AND BREAK SHARP EDGES.

UNLESS OTHERWISE SPECIFIED TOLERANCES:
0 dig. ±0,2
1 dig. ±0,1
2 dig. ±0,05
3 dig. ±0,02

UNLESS OTHERWISE SPECIFIED

FINISH:	Ra 0,8
SURFACE FINISH:	Ra 0,8
TOLERANCES:	N/A
LINEAR:	+/- 0,5 mm
ANGULAR:	+/- 0,15°
LIMITS & FITS	N/A
Tollerance class (iso 2768-1):	3

DO NOT SCALE DRAWING — REVISION -

DEAM Corporation BV - Science Park 400 - 1098XH Amsterdam - The Netherlands

	NAME	SIGNATURE	DATE
DRAWN	KL		14-09-2015
CHK'D			
APPV'D			
QA			
MFG			
QA MFG			

CLIENT:	DEAM
PROJECT:	EndoTacker
STATUS:	Concept
MATERIAL:	Brass
WEIGHT:	0.930.93

TITLE:

SUPPLIER:

DRAWING IS ACCORDING 3D FILE: DE_361_0505_TackCoreCap_A3

American projection

SOC MEANS: SUBJECT OF CHANGE.

DRAWING IS ACCORDING TO 3D FILE.

DWG NO. DE_361_0505_TackCoreCap_A3

A3

SCALE: 10:1

SHEET 1 OF 1

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