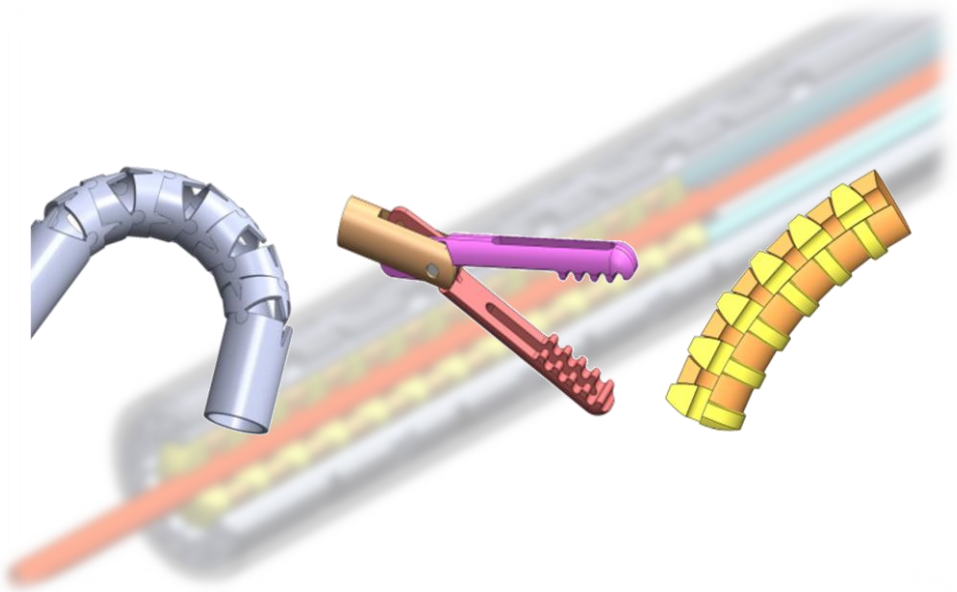
Design of a Steerable Laparoscopic Instrument for Cleaning and Sterilization



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RECOGNITIONS

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In the last thirty years, many new surgical methods and techniques such as laparoscopic surgery and natural orifice surgery have been introduced into hospitals worldwide. As these technologies have progressed, surgical instruments have become increasingly more complex and also much more difficult to clean and sterilize. In this paper, one such instrument, a steerable laparoscopic grasper which is currently too complex to clean and sterilize in a hospital, is examined in detail. The challenges which prevent this instrument from being properly cleaned are identified, and a new novel design concept to neutralize these challenges is suggested. In addition to this, cleaning and sterilization guidelines and strategies which can be applied to any surgical instrument are presented.

***Index Terms*— cleaning, design, sterilization, surgical instruments**

I. INTRODUCTION

A. *A rapidly changing world*

A lot has changed in the world of surgery in the last 30 years. In 1981, the very first reported laparoscopic organ resections were performed.[1] Four years later, the first reported laparoscopic cholecystectomies were performed.[2] Six years after that, the National Institute of Health (NIH) Consensus Development declared the laparoscopic cholecystectomy to be the method of choice for most patients.[3] Since then, laparoscopic surgery has continued to become more and more prevalent. Laparoscopic surgery is not alone either, in the last decades, at least two other new forms of surgery, Single Port Surgery (SPS) and Natural Orifice Translumenal Endoscopic Surgery (NOTES) have also begun to take root and further revolutionize the world of surgery.

These sweeping and rapid advances in surgery and treatment can almost universally be seen as a good thing. However, there is a downside. A large percentage of these devices are still designed to be reused. As these devices become more and more complex, they also become more and more difficult to clean and sterilize. In some cases, the increased difficulty in cleaning is an unavoidable consequence of the increased capabilities of the instrument; however, all too often, the increased difficulty in cleaning and sterilization can be directly attributed to the lack of knowledge and understanding of the cleaning and sterilization process by the designer.

Properly designing an instrument for cleaning and sterilization is not trivial, and takes knowledge and thorough understanding of the process, as well as the considerations which must be made during the design process. Using the redesign of a steerable laparoscopic instrument as a case study, this thesis endeavors to bring to light and clarify some of the issues which designers of surgical instrumentation must grapple with in this new day and age. However, before that is done, a brief introduction to laparoscopy, the instrument, and the characteristics which make it so difficult to clean must be given.

B. *Introduction to laparoscopy*

Unlike open surgery, which typically relies on one large incision which is big enough to allow for visualization as well as insertion of required surgical tools, laparoscopic surgery relies on usually three or more small incisions through which a camera for visualization and long surgical tools can be inserted (Figure 1).

When compared to open surgery, laparoscopic surgery has been associated with shorter hospitalization times, faster healing, and fewer wound related complications.[4] It is not without its drawbacks, however. Complications have been shown to occur, and some of these can be directly related to the lack of maneuverability in the instrumentation. [5] One reason for the lack of maneuverability is made clear upon examining the laparoscopic grasper in Figure 2 (top).

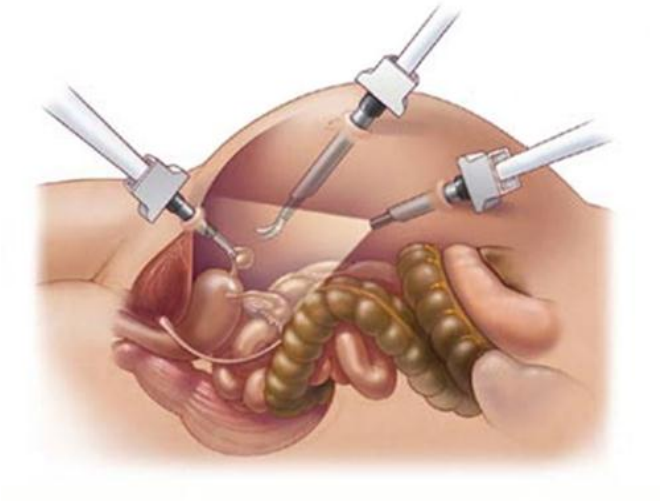

Figure 1: Diagram showing basic concept of laparoscopic surgery. [6]

Depending on the mechanism at the tip, laparoscopic graspers give the surgeon the ability to manipulate and/or cut tissue inside the body, among other things. One big drawback of these devices stems from the fact that they are rigid and can only pivot at the point where they enter the body. This means that many of them are limited to 4 Degrees of Freedom (DOF) (Figure 2, bottom). The cable ring grasper, which is the case study instrument used in this paper and is introduced next, is an attempt to address the problem of limited maneuverability by adding two additional degrees of freedom to the distal end of a laparoscopic instrument.[7]

C. ***Introduction to the cable ring grasper***

The principle technology behind the cable ring grasper is shown in Figure 3 (bottom). It adds two additional degrees of freedom (fore and aft, and side to side) to the distal end of the instrument. This is done through clever design which combines an array of cables arranged in a radial pattern. Those cables are held in a radial pattern by supporting structures on the inside and outside of the cables. The resulting instrument is shown in Figure 3 at the top.

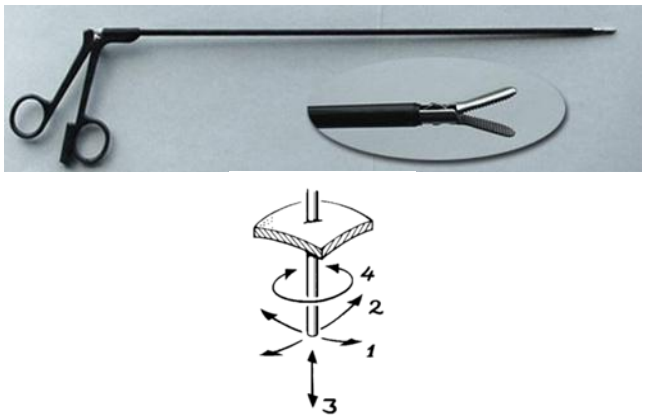

Figure 2: A typical laparoscopic grasper (top). Diagram showing a laparoscopic instrument can be limited to 4 degrees of freedom (bottom) [7,8]

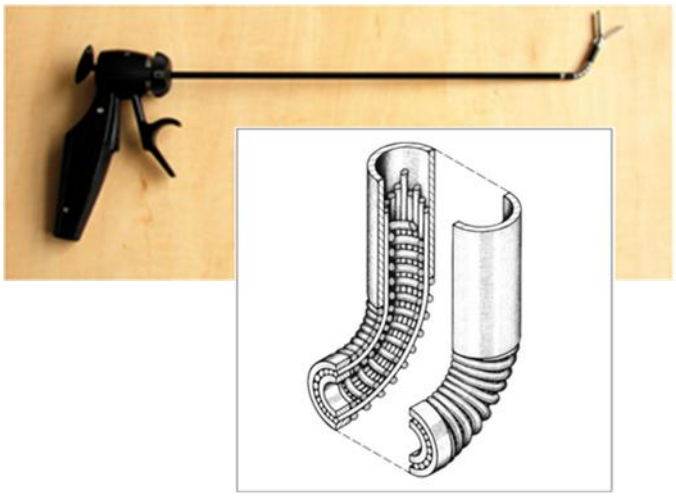

Figure 3: The steerable laparoscopic grasper using cable ring technology (top). A cutaway view of the basic concept behind the technology (bottom).

It is a simple yet robust design which is manufacturing friendly and has the ability to remain very small in diameter when needed. By introducing two additional degrees of freedom at the distal end of the device, this technology provides the surgeon much greater versatility in much the same way having a wrist at the end of a human arm increases the versatility of the arm.

D. ***Introduction to difficulties in cleaning the device***

Since the first cable ring grasper prototype was developed in 2005, much has been done to improve the overall design, including increasing axial, torsional, and bending stiffness and improving control of the technology.[7] Despite these improvements, there is still one aspect of the design which keeps it from reaching its full potential as a reusable surgical device. In its current form, the design is very complex and virtually impossible to properly clean and sterilize in a hospital Central Sterile Supply Department (CSSD).

There are numerous factors of the design of this instrument which makes cleaning and sterilization so difficult. Foremost, due to the complexity of the design and the many layers of components therein, it is nearly impossible to remove all the debris which becomes lodged in the instrument during normal use. This means that the instrument cannot be properly cleaned. If it cannot be properly cleaned, it cannot be disinfected. If it cannot be disinfected, it cannot be sterilized. If it cannot be rendered sterile, it cannot be reused on another patient.

Due to this limitation the design so far has been focused on making the complete shaft of the device disposable (a reposable device with a reusable handle and disposable shaft based on this technology will enter the market soon). While this may ultimately be successful, making a large part of this design disposable means the instrument will be much more costly to the hospital on a per use basis. This could ultimately hurt the potential for widespread adoption of this device. [9]

E. ***Aim of the research***

With this new field of complex devices, such as the cable ring grasper, it is now more difficult than ever to design for cleaning and sterilization. Despite that, there is very little information available to the design engineer to help to

navigate through this difficulty. The aim of this research is therefore twofold. First, it seeks to find a design solution which allows the cable ring grasper to be cleaned and sterilized in a standard hospital setting. Second, it seeks to put forth relevant recommendations and guidelines which can be used as a resource by any engineer when designing a medical device for cleaning and sterilization. These two aims are complementary, since the guidelines will help in the redesign of the cable ring mechanism, and the redesign will guide the research and help create more thorough guidelines.

1) Problem statement:

With steerable, 2 DOF, minimally invasive cable ring instruments, it has been shown that a completely disposable design is cost prohibitive.

2) Goal:

It is known that one way to reduce costs in a complex surgical instrument is to make part or all of the instrument reusable. The goal of this project is to determine a viable, clever reusable (or reposable design which has significantly less disposable pieces) instrument design concept for the cable ring grasper technology which is compatible with the cleaning and sterilization process.

3) Scope

The cable ring grasper is a very complex device with many aspects to the design. Therefore, this thesis will be limited to and focus only on the distal end of the laparoscopic instrument starting at the shaft.

F. ***Structure of this thesis***

The structure of this thesis is as follows: Section II deals with the redesign of the cable ring grasper. Section III tests select portions of the redesign concept for compatibility with cleaning and sterilization. Section IV first evaluates the redesign concept, and then builds upon the work and research done to offer a set of considerations, and guidelines and strategies that can be applied to the design of the surgical instruments. Section V then gives some concluding remarks.

In addition to these main sections, a complete and in depth review of the cleaning and sterilization process which has been tailored to the informational needs of the design engineer can be found in Appendix A. In this appendix, topics such as an overview of the process, device classifications, types and sources of contamination, design oversight, designer responsibilities, design verification, and the importance of a well written “Instructions for Use” (IFU) document are all addressed. Depending on the reader’s knowledge, it may be useful to review this first before continuing on to the next section.

II. REDESIGN OF THE CABLE RING GRASPER

A. ***Unique challenges for the cable ring grasper***

The bending section of the cable ring grasper is shown in Figure 4. There are three main characteristics of this current design which exclude it from reprocessing in a standard CSSD. The first is the multiple assembly layers which prevent any access to the difficult to clean components. The second is the several instances of tightly meshed components which can harbor infectious materials and cannot be cleaned. The third is

Figure 4: An up close view of the bending section of the cable ring grasper. [7].

the liberal use of cables, each of which can harbor infectious agents. The following subsections discuss some of these difficulties in detail.

1) Multiple layer assembly

The basic design concept for the cable ring grasper requires many layers of assembly; all with tightly meshed components (see Figure 5). Working from the outside in, these layers are the outer protective sheath, the outer supporting rings, the array of steering cables, the inner supporting structure, and the inner drive cable for the grasper at the distal end. In this multiple layer assembly, there is ample room for debris to become lodged inside the instrument, but not nearly enough to allow access to the inner parts to clean that debris away before sterilization.

Even the outer sheath shown in Figure 5 (which protects the patient from unwanted pinch wounds) is not enough to keep this from happening. The grasper and linkage at the distal end features too many moving parts that are impractical to seal. So debris can still enter in through there (especially when assisted by the pressure differential created from insufflation of the abdomen during laparoscopic surgery). Other laparoscopic graspers deal with this by incorporating provisions to allow for cleaning of the internal components, usually through flushing or disassembly, but this is not the case for this design. Furthermore, the material which the outer sheath is made of (Tecoflex) is a material that is not compatible with the autoclave process.)

2) Tight clearance between components

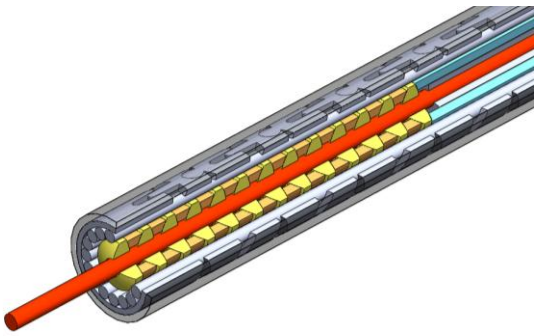

Figure 5: A cutaway view of the multiple assembly layers of the cable ring grasper laparoscopic instrument.

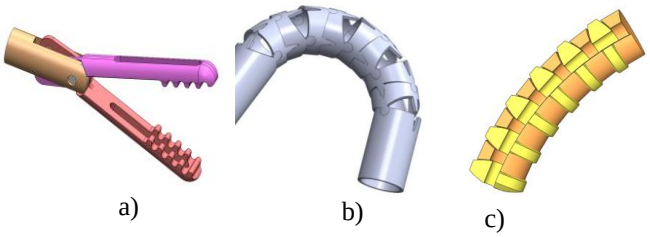

Figure 6: Three areas of the cable ring grasper which are difficult to clean due to tight clearances between components. (a) and (c) created from models provided by Deam Corporation.

There are three areas in this design which feature tightly meshed moving components (Figure 6). All of these areas can harbor contaminants, and cannot be adequately cleaned. The first area, the grasper (a), has the two moving mandibles. There are several crevices in the area where the mandibles come together where contaminant can be retained, but adequate flow and or brushing cannot dislodge them.

The second area, the outer interlocking rings (b), has a similar issue. In order to get good, controlled movement, the interlocking portions of each ring should fit as tightly together as possible. This ends up being too tight to get any cleaning tool or sufficient fluid flow, but not so tight that blood and other debris cannot be harbored inside. If these rings are exposed to contaminated soil, the spaces between them cannot be cleaned and reused. (Although there is no dimension to quantify what counts as too tight, three different CSSD inspectors in the Netherlands have inspected the design of these rings and ruled them out as being something which they would accept in their hospital.)

The final area is the inner support rings (c). Most of their surfaces fit tightly together. Unless they can be made to spread apart during the cleaning process, they cannot be properly cleaned.

3) Cables

The final main cleaning and sterilization challenge with the cable ring grasper is the predominant use of braided cables. Braided cables present a very real cleaning challenge because they can harbor debris between the windings that cannot be cleaned out. Also, as they move in and out of the shaft, these cables can be expected to shift debris further up inside the instrument; this is yet another location that would be difficult to clean.

B. ***Viable design strategies***

Once the challenging areas of the design have been identified, the next step is to evaluate all the design strategies and identify the ones which have the potential to address the issues with the current cable ring grasper design. Careful consideration of the problem revealed four main categories of options which should be considered (Figure 7). (In addition to the discussion here, a more in depth look at these categories can be found in Appendix B.)

The first category deals with the method of reprocessing. The options for this category are fully reusable, reposable (which refers to a device which is comprised of both reusable and disposable components) and disposable. Disposable can be immediately dismissed in this case, since the goal of this project is to design a reusable solution. This leaves reposable

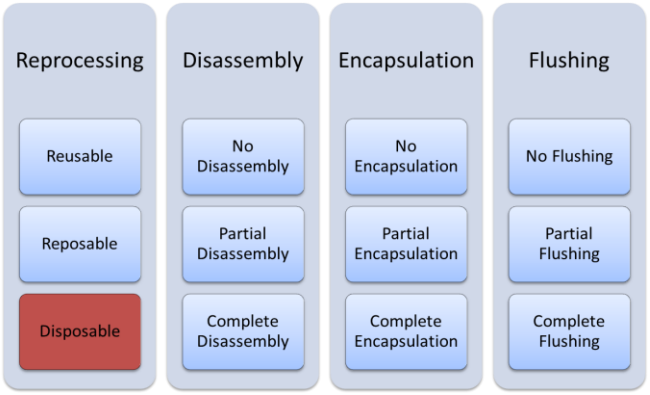

Figure 7: A diagram showing the breakdown of all the design strategies available when designing an instrument for cleaning and sterilization. (The option "disposable" is shown in red here because it is not a valid option for this project since it conflicts with the stated goal.)

and reusable. Another strategy, flushing the instrument, can also be quickly ruled out as a solution for this design, for the reasons described in Section A; the components are too tightly packed to allow for proper fluid flow.

After those, there are the two remaining strategies, disassembly and encapsulation. Disassembly refers to the idea of disassembling all or part of the instrument to expose the internal components so that they can be properly cleaned. Encapsulation refers to the idea of permanently enclosing all or part of the instrument in a sterilizable protective layer which is much easier to clean than the components themselves. Both have potential as solutions to the problem, and are explored in more detail in the following paragraphs.

1) Partial disassembly

A cable ring grasper which relies on partial disassembly would require significant disassembly of the shaft. In this scenario, the shaft would need to break into four different pieces in order to get access to all the necessary components (see Figure 8). Also, at the least, the outer supporting rings would have to be made disposable since they fit too tightly together to be cleaned, and would be prohibitively complex to completely disassemble.

One difficulty of this approach would be keeping the reprocessing complexity for the CSSD workers at an

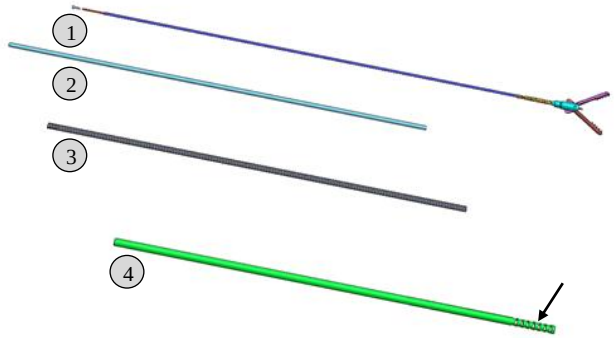

Figure 8: The four parts which must be separated in a design based on disassembly. From top to bottom, the components are: 1. the inner drive cable, grasper and inner support rings; 2. Inner cable support tube; 3. Array of cables; 4. Outer shaft tube and cable rings. This is a rough model of the outer shaft and cable rings. The groove pattern identified by the arrow is meant to represent the cable rings. (Image created from a model provided by Deam Corporation.)

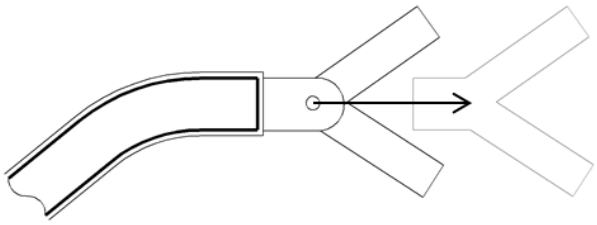

Figure 9: The basic concept behind the chosen design. The shaft internal components will be encapsulated, and the grasper will be removable so that it can be interchanged and cleaned, or disposed of separately.

acceptable level. Another would be managing the loose cables when the instrument is disassembled and during reassembly. Yet another would be making the array of cables cleanable, since braided cables can retain debris.

2) Partial encapsulation

In a design which relies on encapsulation, the main portion of the shaft, including the array of cables, the inner supporting rings, and the outer supporting rings would all be permanently encapsulated. The grasper, which is too complex to encapsulate would be made removable. It would either be disposable, or separately cleanable.

C. *Preferred approach*

1) Preferred method of sterilization

First, before choosing the preferred approach, the preferred method of sterilization must be chosen. Although gas plasma, EtO, and liquid Peracetic acid are all compatible with more materials than autoclave sterilization, steam sterilization is still by far the most prevalent, least expensive and least time consuming from the perspective of the CSSD, and therefore should be the preferred option if at all possible. The device will therefore be designed for autoclave sterilization.

2) Preferred design strategy

Even though disassembly and encapsulation both present viable options, a design based on encapsulation appears to have the highest chance of success and presents the least complications. Therefore, this is the preferred solution. The basic design concept for the preferred solution based on encapsulation is shown in Figure 9.

With the basic design strategy and approach being known, two major design challenges emerge. The first is how to encapsulate the bending section of the shaft. (The shaft will need to remain flexible, be as small in diameter as possible, and remain compatible with steam sterilization.) The second is to figure out how to drive the grasper from inside the encapsulated shaft in a way that debris cannot enter the encapsulated area. Both of these challenges will be explored in the following two subsections.

D. *Sealing the bending section*

1) Introduction

A design which relies on encapsulation is only as a strong as its weakest link. If any portion of the outer seal cannot keep complete integrity in all environments and all of the use cases it will be exposed to, then it cannot work in the final design. The seal which protects the bending section will be exposed to harsh chemicals during the cleaning process, high temperature and humidity during sterilization, possible impact and abrasion during use and also high elongation as the cable ring grasper bends from side to side. It must be able to withstand all of these things for the expected life of the instrument.

2) Problem description and requirements

Figure 10 shows a representative image of the bending section of the cable ring grasper design which must be protected. It is approximately 4.5 mm in diameter, and it has a non-moving straight section at either end of the bending section. In Figure 10, the bending section is shown at its maximum theoretical bending angle. Based on these measurements, at the extremities of motion the seal length can range from 14.5mm at the inner radius to 27.2 mm at the outer radius, which means it will be repeatedly subjected to elongations and contractions of up to 90%. The seal must be compatible with this.

The seal should also not add much to the overall thickness of the device. Ideally, it should add no more than about 0.5 mm to the diameter (which means it should be no more than 0.25 mm thick). Furthermore, it should also be able to withstand the abrasion which comes from the interlocking rings which move inside of it, and normal use inside the patient. The outside of the seal should also have low stiction with the trocar to allow for easier insertion and removal during surgery.

With regards to cleaning and sterilization, the seal must be able to withstand standard cleaning and autoclave sterilization. This means that it must have good chemical and pH resistance, be able to withstand humidity and temperatures of 134°C and above, have low water absorption, and must maintain sufficient material properties (including elasticity and biocompatibility) through hundreds of repeated sterilization cycles. It also must be able to withstand cleaning from tools such as brushes.

3) Solution space

Based on the requirements imposed on the seal, designing a seal for the bending section mostly becomes a problem of finding the correct material. The most ideal material would be one that is commonly used in medical applications, that has been shown to be completely compatible with the autoclave process, and that exhibits the qualities required.

Metals and rigid polymers do not have the required elasticity, and can be ruled out, leaving only flexible polymers. An exhaustive search was performed across

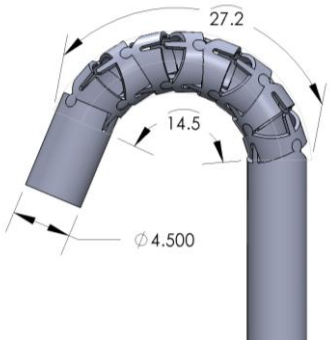

Figure 10: A model of the bending section showing the maximum theoretical bend. This is the worst case that the bending section seal will have to protect.

different resources, including material databases such is IDES the reference text Handbook of Biomaterial Properties, as well as individual manufacturer's websites.[10,11] Table 1 shows potential materials and their strengths and weaknesses as applied to this project. All of the materials are indicated as being suitable for medical use by the manufacturer. Also, since compatibility with the autoclave was determined to be a driving characteristic, only materials which seem to have potential to be autoclave compatible are listed in the table (with the exception of Tecoflex, which is included for comparison since it is used in the current version of the cable-ring grasper).

1) Chosen Solution

With the exception of Tecoflex, which his not compatible with the autoclave and HSMG-C and MT-3000, which are only rated for limited autoclave cycles, all the materials listed in the table have potential for use in the final solution, but many also have areas of which will require more investigation. A few materials which standout based on their intended use, potential compatibility with the autoclave process, and material characteristics include Santoprene, Versaflex, Iridium and Pebax.

Santoprene is a material which is widely used in the biotech and biomedical industries. It is compatible with steam sterilization. Some product examples including electrical wire insulation in a couple existing medical devices and use in a new laparoscopic instrument were found.[29–31] The biggest drawback of this material may be the wall thickness, which may only go down to 0.33mm, meaning that it would add an undesirable 0.66mm to the overall shaft diameter.[32]

Versaflex is another autoclaveable medical grade material. It is designed for medical tubing and overmolding, among other things. Minimum wall thickness capabilities are not listed. Depending on this, it may also work well in this application. [33]

Cobalt Iridium is a medical grade polyolefin based, heat shrinkable material which the manufacturer describes as highly flexible and tough. It is also available with very thin walls, getting down to 0.05mm if desired. One concern about the material, however, is that the manufacture does not declare the material to be autoclave compatible, but rather says that it must be tested for this.[15] Assuming this material shows itself to be compatible with autoclaving, it could be promising.

Finally there is the material Pebax which appears to most promising of all. It is autoclavable, comes in shrinkable tube form (if desired), is biocompatible, and can have low stiction qualities. It can also have wall thicknesses down to 0.05mm, and comes in a wide range of flexibilities.[34,35]

Table 1: Matrix with all the potential sealing flexible polymers that were found.

Trade name	Material type	Manufacturer	Specific model	Typical use	Heat shrink	Hardness, Shore A	Elongation at break	Tensile strength at break	Flexural modulus	Tensile at 100%	Tensile at 300%	Autoclaveable	Biocompatibility tests	Thin wall	Water absorption	Heat resistance temperature
Tecoflex[12]	thermoplastic polyurethanes	Lubrizol	EG-80A	-	no	72	660%	40 MPa	7 MPa	2.1 MPa	5.5 MPa	No[11]	-	-	-	-
AESNO[13]	nylon 12	Arkema	-	-	no	100	340%	50 MPa	360 MPa	-	-	yes	-	-	-	-
BESNO[14]	nylon 11	Arkema	-	-	no	100	405%	43 MPa	290 MPa	-	-	yes	-	-	-	-
Biospan[10]	polyurethane	DSM	-	cardiac assist devices	no	70	600%	38 MPa	12 MPa	-	-	yes [11]	yes	-	1.50%	-
Iridium[15,16]	Polyolefin	cobalt	-	-	yes	-	-	-	flexible	-	-	test	USP Class VI	-	-	-
MT 3000[17]	Fluoropolymer	Altera	-	-	yes	-	-	-	-	-	-	Limited cycles	USP Class VI	-	-	-
MT-LWA[18,19]	-	Altera	-	-	yes	-	-	-	-	-	-		-	-	-	135°C
MT-PBX[20]	Polyether Block Amide	Altera	MT-PBX26	-	yes	75	-	-	-	-	-	yes	USP Class VI	yes	-	-
Palladuim Pebax heat shrink[21]	-	cobalt	3533	-	yes	87	580%	39 MPa	19 MPa	-	-	test	USP Class VI	yes	1.20%	-
Palladuim Pebax heat shrink[21]	-	cobalt	4033	-	yes	91	390%	39 MPa	90 MPa	-	-	test	USP Class VI	yes	1.20%	-
Pebax[22]	thermoplastic elastomer	Arkema	2533 SA 01 ME	-	no	70	750%	32 MPa	12 MPa	-	-	Y	USP Class VI	-	1.20%	-
Pharmed BPT[23]	-	Saint Gobain		biotech tubing	no	64	375%	7 MPa	-	2.8 MPa	-	Y	USP Class VI, 10993 part 4	??	0.30%	150°C
Santoprene[24]	thermoplastic vulcanizate	Exxon	TPV 181-57W180	biotech tubing	no	61	330%	4.6 MPa	-	2 MPa	-	Y	USP Class VI, some ISO 10993 testing	.5 mm minimum	-	-
Santoprene[25]	thermoplastic vulcanizate	Exxon	TPV 8281-65MED	-	no	68	480%	5.9 MPa	-	2.4 MPa	-	yes	USP Class VI, some ISO 10993 testing	possibly down to .33 mm	-	-
Santoprene[26]	thermoplastic vulcanizate	Exxon	TPV 8281-75MED	-	no	79	470%	7.7 MPa	-	3.5 MPa	-	yes	USP Class VI, some ISO 10993 testing	possibly down to .33 mm	-	-
Versaflex[27]	thermoplastic elastomer	GLS	HC MT307	medical tubing	no	68	510%	6 MPa	-	2.69 MPa	4.55 MPa	yes	USP Class VI, 10993 parts 4 and 5	-	-	-
Versaflex[28]	thermoplastic elastomer	GLS	HC 2110 57B	gaskets, over molding, plugs	no	59	350%	3.7 MPa	-	2.54 MPa	3.85 MPa	yes	USP Class VI, 10993 parts 4 and 5	-	-	-

Each of these materials looks promising, and may provide all the needed characteristics for this design. Ultimately, the only way to determine which materials will work, and which material is best for this solution is to obtain representative samples of each, perform extensive testing on them, and then compare the results. For this report, only one of the four materials was available, Cobalt Iridium. As such, detailed testing to assess the suitability will be limited to this material.

E. ***Sealing the tip***

1) Introduction

The second challenge to encapsulating the cable ring grasper is sealing the tip. The biggest challenge with sealing the tip of the instrument is figuring out how to transfer the energy which is originally generated by the surgeon at the proximal end of the shaft through the shaft and then out the sealed distal end in order to control the removable grasper. The conceptual diagram in Figure 11 illustrates the challenge. There are really two problems in one: 1) a method of transferring energy down the shaft must be found, and 2) a compatible method of transferring energy across a hermetic seal must also be determined. In this section different options for doing this are explored.

2) Problem description and requirements

Requirements for the transfer of energy down the shaft are as follows: it must fit within the existing assembly design (which most likely means it must run the length of the shaft and be less than 0.5 mm in diameter). It must work in all bend configurations of the bending section. In the event of a seal breach, the solution must pose no risk to the patient (i.e. all components must be biocompatible, present no risk of dangerous electric shock, etc.). It also must utilize a method of energy transfer of which can be generated by the physical hand motion of the surgeon at the handle. Finally, it must be capable of generating sufficient force and motion in the grasper.

The actual tip seal which the energy is transferred across must have the following characteristics: it must be biocompatible and able to withstand the harsh environments introduced by repeated cleaning and autoclave sterilization. It must add only minimal thickness to the shaft (if at all) and should not add significant length. It must, of course, also be completely impervious to liquids and other bioburden. Finally, its outer surface must be easily cleaned and sterilized.

3) Solution space

With the requirements set forth, the next step is to determine the potential options. First, the method of transferring energy down the shaft should be determined, after which, the method of transferring that energy across a hermetic seal can be laid out.

a) Method of energy transfer

The viable methods of energy transfer which can potentially transfer across a seal can be determined by first listing all potential forms of energy transfer and then determining which ones could work for this application. The forms of energy transfer of which are considered here are: mechanical linkage, electrical, magnetic, hydraulic, pneumatic, heat, chemical, nuclear, and radio frequency. The last four can be quickly dismissed due to lack of efficiency and/or potential harm to the patient. The remaining five are explored below.

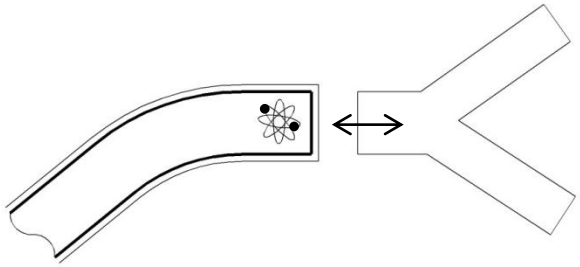

Figure 11: A basic diagram which illustrates the problem with having to transfer energy from the enclosed section of the shaft to the grasper.

Purely mechanical

This is the most obvious and perhaps simplest method of transferring energy down the length of the shaft. Considering the need to transverse the bending section, there are two main methods of implementing this. One is with a linear push/pull cable (or flexible rod), and the other is with a rotary cable. The linear push/pull cable is the method that is used in all of the cable ring grasper prototypes so far. Moving across a hermetic seal will present some challenges with this method, however. With both rotary and linear motion, the movement must transfer across the seal, and the displacement must be large enough to drive the grasper.

The biggest advantage of this method is that the mechanical energy created by the surgeon when operating the handgrip does not need to be converted into any other type of energy. This lowers complexity and will likely lead to a more robust design. Also, since this is the method that has been used in all previous cable ring grasper prototypes, there is an advantage in knowing that it can be implemented successfully. The biggest disadvantage is likely to be the difficulty which comes with designing a robust hermetic seal which is compatible with the cleaning and sterilization process.

Electrical

Unlike a mechanical linkage, electrical energy requires no moving parts to transfer energy across a hermetic seal. Hermetically sealed connectors exist for a lot of applications, and the same design philosophy can be applied here. Once the energy is passed across the seal, it would then need to be converted back into mechanical energy to drive the grasper. Three actuators types have been identified which could work in this application: rotary motors, solenoids (linear motors), and piezo actuators.

The biggest advantage with electricity is the ease in which the energy could be transferred down the length of the shaft and across the hermetic seal. Just two small wires (or possibly only one, if the body of the instrument is used as a return path) would need to be run down the length of the shaft. Disadvantages include potential difficulty in converting hand motion at the proximal end in to electrical energy, the potential need for an external energy source such as a battery, additional safety concerns which can arise from introducing

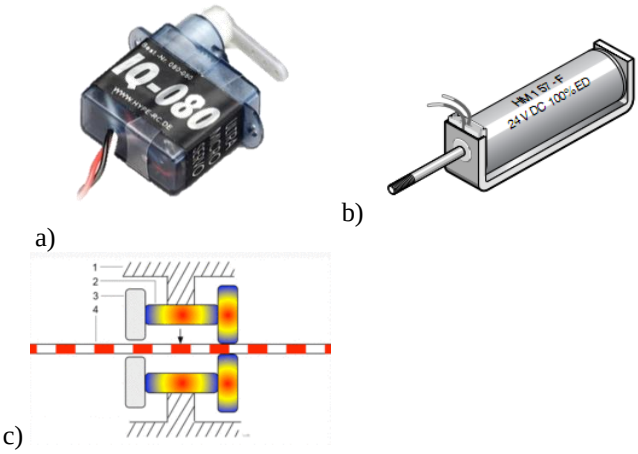

Figure 12: Different potential ways for incorporating an electrical actuator into the design. (a) is a miniature motor and gearbox, (b) is a miniature solenoid, (c) is a diagram showing the concept behind piezo actuators.[36,38,39]

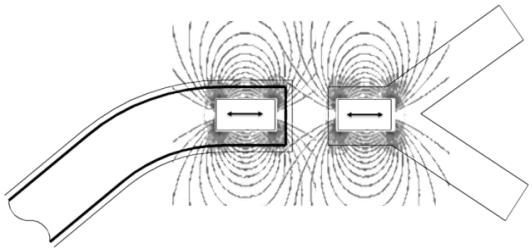

Figure 13: A basic diagram which illustrates the concept of magnetically coupling the grasper to the drive cable.

electricity into the body, the added complexity which comes from converting the electrical energy back into mechanical energy at the distal end, and potential loss of haptic feedback.

Regarding the actuators options, motors are known to exist which are small enough and could likely provide sufficient force when coupled to gearbox. Assemblies such as the one pictured in the Figure 12(a) which couple a small motor to a gearbox can be purchased for as little as €7.00.[36] It is therefore fair to assume that something similar could be designed as part of a motorized disposable grasper which is mounted outside the encapsulated area and stay within the required price constraints. Solenoids (b, a type of actuator which converts electrical energy into linear motion) provide another option, but in the size required, none exist which can provide the required force. The final option, piezo actuators (c), can be made to be very tiny and also are capable of providing relatively high forces. Regardless of their suitability, each of these technologies has one large shortcoming. Since they do not have built in force sensing capabilities, they greatly limit the ability to provide haptic feedback to the surgeon so that he/she can gauge how much force is being applied. This lack of feedback has been shown to be a significant limitation.[37] (It could be possible to estimate force using applied electrical power, however, that solution would require additional electronics and an additional actuator at the proximal end to generate the feedback force.) [37]

Magnetism

With this method, magnetic force would be used to couple the grasper to a magnet which moves within the hermetic seal (Figure 13). Like the electrical solution, a solution here would not require any moving parts to be incorporated into the hermetic seal, which would greatly simplify the design of the seal. Instead, a magnet would only move back and forth in the encapsulated area, and only the magnetic field would need to pass through the seal. Or as another option, a magnetic field could be created with electricity and coupled to another magnet attached to the grasper (essentially turning the combined shaft and grasper into a solenoid). Of course this would mean the seal would need to be made of a material which did not interrupt the magnetic field.

Based on the basic concept, the fact that the seal would not require any moving parts makes it a very appealing choice. Unfortunately, an investigation into magnet technologies has shown that even the strongest rare earth magnets do not even come close to providing the force required make this work.[40]

Pneumatics/hydraulics

No viable solution for the use of pneumatic or hydraulics was found which offered advantages over a purely mechanical solution. As is the case with the purely mechanical solution, this solution will require a hermetic seal to have moving parts in order to transfer the energy across it. Some novel ideas such as inflating the balloon at the distal end of the shaft were considered, but ultimately all ideas based on its approach were deemed unfeasible.

Preferred approach

Since the magnetic approach was deemed too weak, pneumatic/hydraulic unfeasible, and electric too complex and too compromising due to its lacking haptic feedback, the best solution appears to be the mechanical linkage approach. Both options, a linear push/pull rod (as has been implemented in previous cable ring prototypes) and a rotary cable are feasible. There is a small preference for the linear cable, since it is used in the current design, but ultimately the preference between these two will primarily come down to which one offers the best option for creating a hermetic seal at the tip of the shaft.

b) Method of sealing

With the method of energy transfer chosen as a mechanical linkage (either through a linear or rotary cable), the next task is to figure out how to design a seal which allows the motion to pass through. The grasper in the current design requires 3 mm linear motion; for now, the assumption will be the same for this design. If a rotary cable is used, the amount of rotary travel required is unknown, so for now, 360° will be assumed.

There are many types of linear and rotary seals which can be considered for this application. After distinguishing between rotary and linear seals, the options can be divided into two main categories: deforming seals, and sliding seals. Deforming seals are those which are permanently attached, and rely on deformation of the seal material itself to allow for transfer of motion. Sliding seals are those which are not

Linear Seals	Deforming Seals		Bellows (a) Condom type (b) Diaphragm (c) Rolling diaphragm (d)
	Sliding Seals	Contact	O-ring seal (e) Wiper seal (f)
		No Contact	Low Clearance (g)
Rotary Seals	Deforming Seals		Condom type (b)
	Sliding Seals	Contact	Ferro fluidic (h) Gland Seal (i) O-ring (e)
		No Contact	Labyrinth seal (j) Low clearance (g)

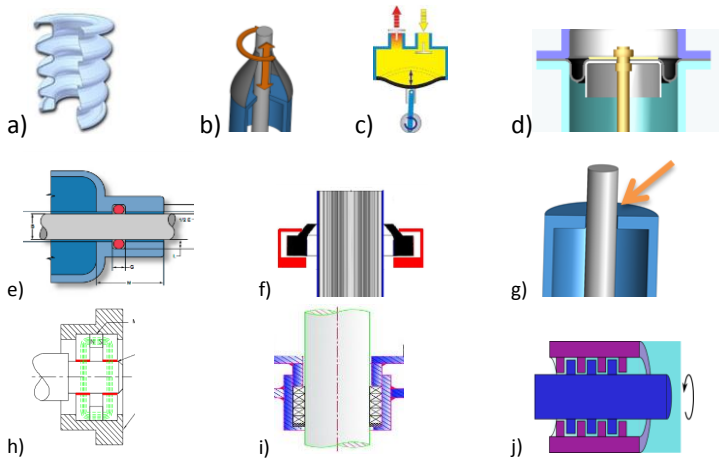

Figure 14: Tree showing all the potential seal types for consideration in use in the tip seal. Images a,c,d,e,f,h,i, and j from:[41–48]

permanently attached, and instead rely on a consistent relationship with the surface they seal against to transfer all of the motion. Sliding seals can further to be divided into those that rely on direct contact between the two moving parts, and those which do not rely on contact but rather extremely tight clearance. Examples of each of these types of seals are shown on the right in Figure 14, and a structured breakdown of the categories is shown on the left.

4) Chosen solution

Of all the seal types listed in Figure 14, none of the rotary seals provided a clear advantage in this application over the linear seals. They are either nearly identical in implementation (such as the condom and O-ring seal), or more complex (such as the ferrofluidic and gland seal). That, coupled with the fact that the current cable ring grasper is designed around the use of cables in a linear fashion, makes linear the preferred method. This leaves the six choices under the linear seals category in Figure 14.

The low clearance seal, O-ring seal, and wiper seal are all seals in which two contacting but not connected pieces move relative to each other. In the case of this design, this means that a portion of the drive linkage would alternate between being inside the sealed sterile area and being in contact with unsterile body tissues. Although it may be theoretically possible to guarantee a perfect seal that would last the lifetime of the instrument and prevent any contaminants from "piggybacking" from the unsterile area into the sterile area, this is a big risk to take. Among other things, a small scratch in the drive linkage could be all it would take to compromise the seal. This means that in this situation, these seal types can be ruled out.

This leaves the diaphragm, condom type, and bellows seals. A diaphragm seal will not work in this case, because given the diameter of the shaft and the required 3 mm of motion, the material that the seal is made out of a has to be far too thin and elastic. A condom type or rolling bellows seal could be suitable for this application, and would have the least potential impact on the shaft diameter and overall length (since they do not rely on the folds which the bellows relies on). However, these seal types require a much more elastic (and therefore thin) material than the bellows seal. This creates a big challenge for material selection (similar to the challenge in finding a seal for the bending section.) Based on the work done in choosing the sealing material for the bending section, it appears unlikely that a material exists that would suit this application. This makes a bellows seal the preferred approach for this challenge.

5) Design of chosen solution

One method of bellows manufacturing which would be suitable for this application is a thin-walled bellows which uses electro deposition technology. This type of bellows is formed in three steps (Figure 15, top): first, a mandrel is formed which matches the shape of the inner surface of the bellows (a). Then the chosen material (for instance, nickel, copper, gold or silver) is electroplated onto the mandrel (b). The thickness of this electroplating is determined by the time and current used in the electroplating process. Finally, the entire assembly is immersed in a caustic solution which dissolves away the mandrel, leaving only the thin bellows (c). This process allows bellows with walls as thin as 0.008 mm to be formed.[49]

There are at least several companies which manufacture small bellows using this process. One such company is Servometer out of Cedar Grove, New Jersey, US. Working with Servometer, and specifying an outside diameter of

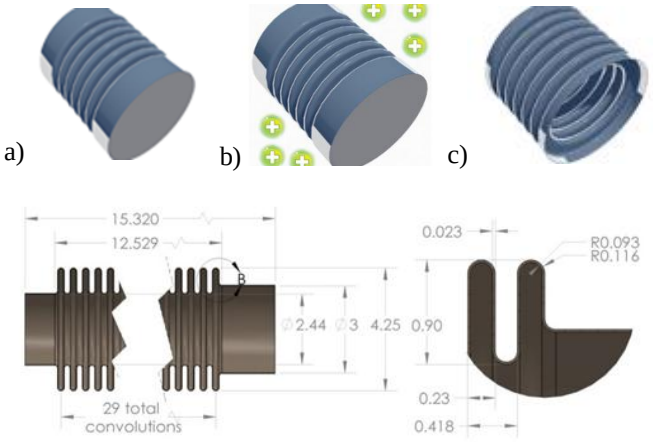

Figure 15: Top: The three steps in creating an electrodeposited bellows seal. Step 1 is creation of the inner mandrel. Step 2 is the electro deposition process. Step 3 is the dissolving of the inner mandrel. [49] Bottom: Detailed design of the bellows seal which will be tested for use in the redesign concept.

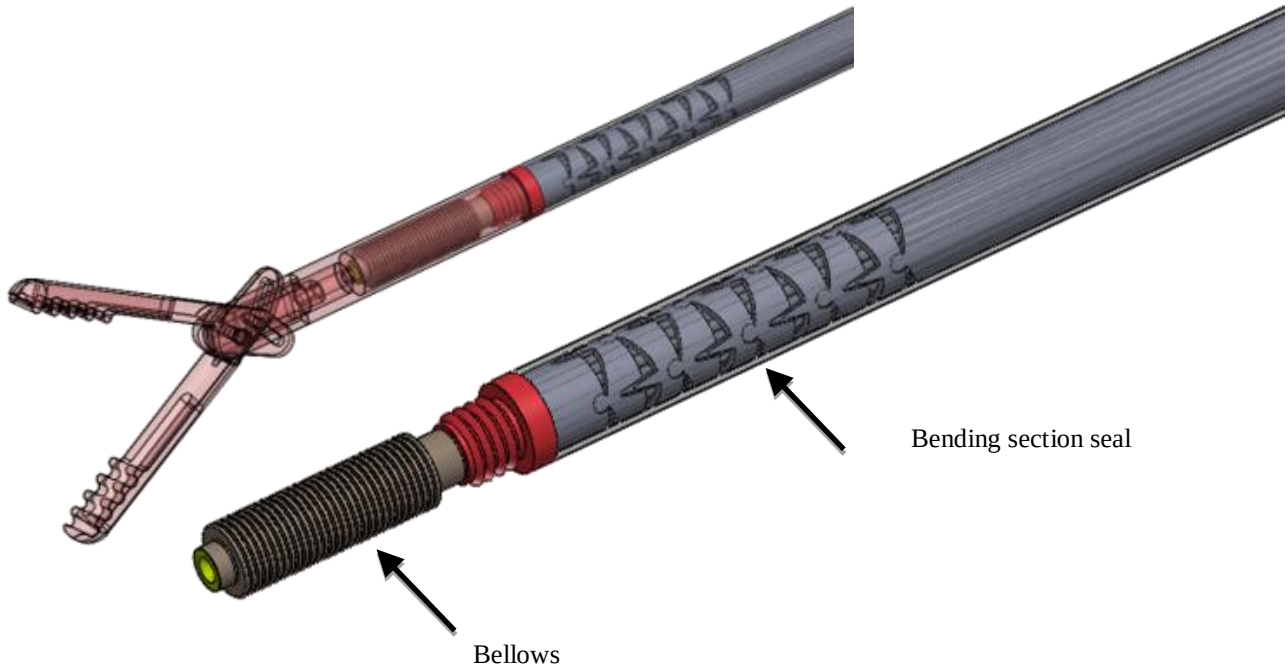

Figure 16: Solidworks model of the final design concept (All visible components are original work, with the exception of the grasper assembly which is modified from model provided by Deam Corporation.)

approximately 4 mm, it was determined that a commercially available bellows with 0.023 mm wall thickness, 29 folds, and 12.3 mm length would be required achieve the desired 3 mm of travel required for this application. The inside diameter will measure 2.44 mm and the material is to be a nickel and cobalt alloy. This material has purportedly been used in other medical instrument designs, and is believed to be biocompatible, however testing to verify this may still need to be performed.[50] The resulting design is shown on the bottom in Figure 15.

F. ***Final design***

Aside from the bellow and bending section seal, there are other design considerations which must be addressed for the encapsulation concept to work. These considerations are presented here.

1) Layout of final design

Figure 16 shows the final design concept of the cable ring grasper with and without the removable grasper attached. The portion shown without the laparoscopic grasper is the portion which would be subject to cleaning and sterilization. The grasper itself would either be cleaned seperately or could be made to be a disposable component. A cutaway view which exposes the internal components is shown on the left side in Figure 17. Finally, an exploded view which allows for identification of each individual component description of what the component does is shown on the right in Figure 17.

Some important features of the design include the following:

Leak testing port

As part of the reprocessing procedure for this instrument, it will need to have a port built into the handle which allows for leak testing with a separate test fixture. The fixture would introduce an overpressure into the encapsulated area, and verify that that pressure remains above a predetermined level for a specific amount of time. The purpose of this is to verify the integrity of the encapsulated shaft seal after the instrument has been clean and disinfected.

In the event that a breach in the seal is detected, the instrument will either need to be retired or returned for factory service. This will be similar to the testing which is currently done with endoscopes when they are reprocessed (see Appendix B, Section C, for more details). It is an important and necessary step because if a breach in the encapsulated seal were to occur without detection, it could allow debris inside the encapsulated area which would not be cleaned out during reprocessing, and could lead to cross contamination.

Termination the bending seal

Extra attention will need to be paid to how the bending seal and bellows seal are bonded to the assembly. Whether these things are bonded through gluing welding, or something else, no gaps can be left which might retain debris and infectious agents. The bonding method must also withstand cleaning and sterilization.

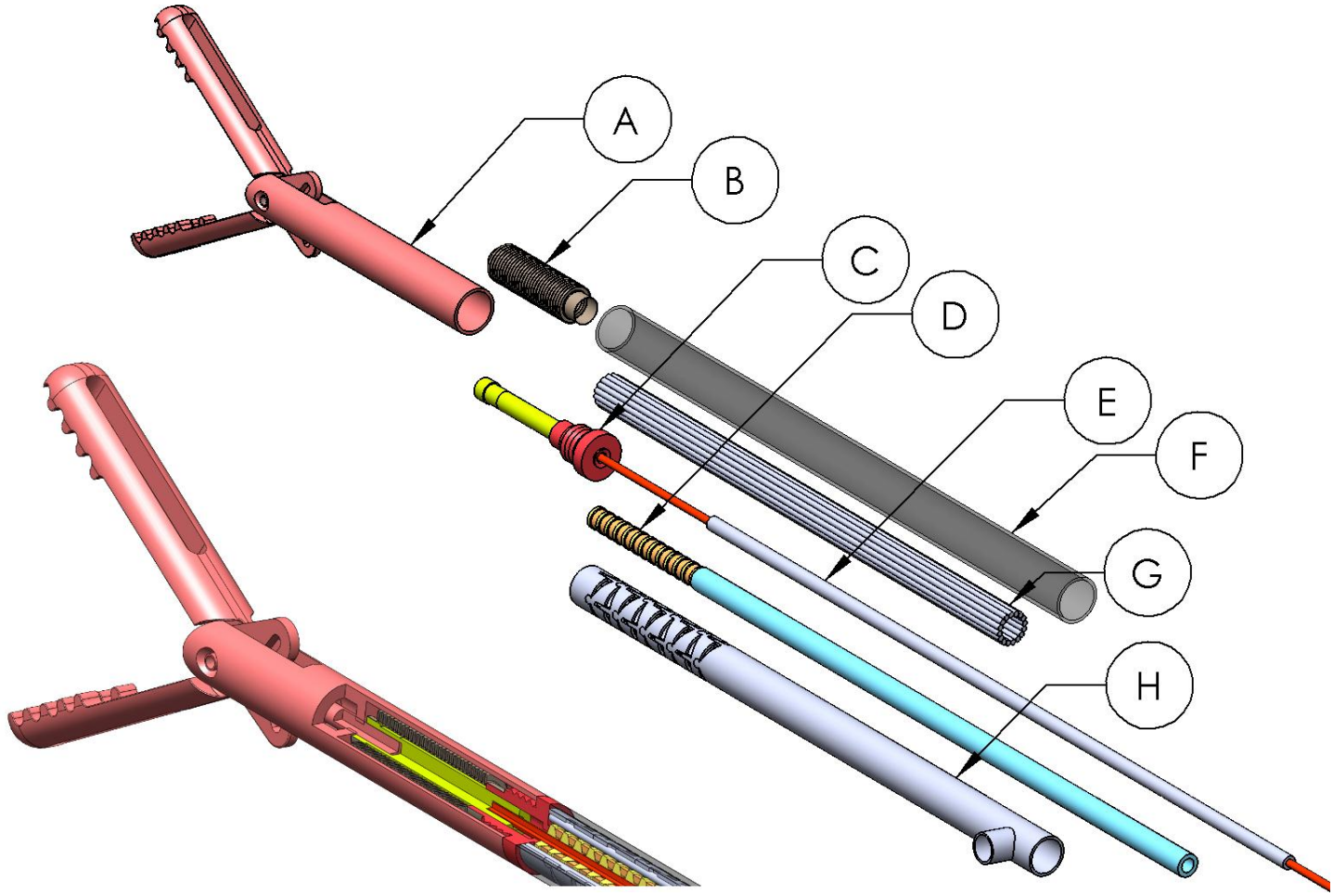

Figure 17: Breakdown of all the components in the final conceptual design. Descriptions of the components called out by the balloons are included below. (This model has been modified from an original model provided by Deam Corporation. Items D and E are unmodified from the original models which were provided. Item A has been modified to suit this design. Items B, C, F, G, and H are original models created for the design presented in this in this paper.)

Component	Description
A - Disposable grasper	This is a modified version of the interchangeable grasper design which is part of the original design. As in the previous design, the grasper would likely be connected by screwing into place. The biggest modification here is that the outer part of the grasper has been extended to encompass the bellows and protect it during use.
B - Bellows seal	This is the bellows seal that is discussed in detail in section II-E
C - Piston and support	This is an important component which will require much more detailed design work before can be implemented. (In a final design the subassembly will likely contain more components than shown here.) The support (shown in red) provides a support platform for the inner bending supports, and a mechanism for attaching the cables and the last cable ring. It will also support the piston's linear motion, and keeps the piston from twisting when the disposable grasper is threaded in place (as necessary, to keep from putting too much torsional force on the bellows). It also holds the proximal end of the bellows in place. The piston serves as the intermediary which attaches the grasper to the linkage cable and holds the distal end of the bellows in place.
D - Internal bending supports	The internal bending supports are unchanged from the original design. They hold the circular array of cables in place from inside.
E - Linkage cable with stiffener	The linkage cable and stiffener is also largely unchanged. The stiffener portion allows the linkage to work in both the push and pull directions, whereas the internal braided cable allows the linkage to bend with the rest of the bending section.
F - Bending section seal	This is the bending section seal that is discussed in detail in section II-D.
G - Cable array	This is the cable array that drives the bending of the steerable shaft.
H- Outer cable rings and main shaft	These cable rings and outer shaft remain unchanged. They provide strength and stiffness to the instrument in both straight and retroflexed positions.

III. Testing and Analysis of the Design

A. *Introduction*

When a prototype is completed, the entire cable ring grasper design will need to be tested. Since most of the design is still conceptual, this is currently not possible. However, the two components which were previously discussed in detail (the bending seal and the bellows seal) can be tested. When reviewing these for use in this design, there are two things to consider. First, are these solutions mechanically suitable for the task? Second, are these components compatible with the cleaning and sterilization process?

B. *Mechanical testing*

The mechanical suitability of both the bellows seal and the bending seal is certainly an important question. With regards to the mechanical suitability of the bending seal which uses the Iridium heat shrinkable material, the (0.1mm) wall thickness certainly fits the desire to have a low impact on the overall instrument diameter. Additionally, just by manually manipulating the material, it is clear that the material is indeed flexible enough, and that it does not create too much of a burden in the form of bending resistance.

For the bellows, an in depth finite element analysis simulation can be found in Appendix C to verify that the material stays within its elastic range throughout the 3mm of travel. This analysis also calculates the spring force which the bellows seal adds to the closing of the grasper. The findings are that the design is in fact sufficient with regards to travel distance, and that the spring force at full compression is expected to be approximately 1.4 Newton. The spring force will not have an effect on the structural design (the existing cable ring grasper design allows for up to 150N pulling force along the length of the cable), but could affect the feedback sensation which the surgeon feels. In both cases, the solutions appear to be mechanically suitable, although thorough mechanical testing and evaluation will need to be done in future research before a final conclusion can be reached.

C. *Cleaning and sterilization testing*

1) Test Objectives

To determine how compatible both the bellows seal and bending seal are with cleaning and sterilization, there are three main questions which must be answered. 1) Do the components maintain mechanical integrity when exposed to cleaning and sterilization? 2) Does the cleaning and sterilization process alter their ability to be considered biocompatible? and 3) Can they be adequately cleaned using standard processes and techniques? With the resources available to this project, it is not possible to answer all of these questions, but some can still be addressed.

For the Iridium bending seal, Questions 1) and 3) will be addressed. Resources to test for biocompatibility (Question 2) according to ISO 10993 are not available. Testing mechanical integrity of the material is very important here, since the manufacturer does not definitively specify whether the material can be autoclaved repeatedly. The material will therefore be tested for both seal retention ability, and flexibility before and after cleaning and sterilization. In the process of answering these questions, it will also be tested for cleanability (Question 3).

For the bellows, question 3) regarding cleanability will be the main focus of the testing. Question 2) about biocompatibility will again go untested. Testing for question 1), which relates to seal integrity, flexibility, thickness and surface characteristics of the nickel-cobalt material will be limited to visual inspection. (It is worth noting, however, that the manufacturer does claim that the material can tolerate common cleaning chemicals and autoclaving.) [50] The question of cleanability is still a very important one. The bellows design has many tightly packed folds, and it is important to make sure debris can be adequately cleaned out from between them.

2) Test setup and methods

To answer these questions, three different test fixtures were made. These can be seen in Figure 18, and are described in the following paragraphs.

Iridium bending test fixture

The test fixture in (a) shows some 0.1mm wall thickness Iridium tubing which has been shrunk around a chain which is properly sized for the material. Chain was chosen to approximate the bending section of the cable ring grasper because it could be found in the right size for the material, it provides rigid support to the material throughout its length, and it has individual links which bend only at the location they join with the other links, and therefor mimic the pivot points between rings in the cable ring grasper. The purpose of these fixtures was to provide a fixture in which the bending lifecycles of the material could be tested before and after the cleaning process. Four were made.

Iridium seal test fixture

The test fixture in Figure 18(b) was built to test the seal integrity of the Iridium shrink tubing before and after being subject to cleaning and sterilization. It uses the same chain and is sealed tight at the ends using Santoprene tubing and shrink wraps. On either end are Luer lock fittings to allow for attachment to the digital pressure meter. On the left side, there is a one way valve which allows for pressurization with a syringe, and then capping off during the test. A digital pressure gauge is attached on the opposite side. Due to the gaps in the chain, the pressure is able to equalize across the length of the chain. The seal integrity was first tested using 1.5 bar of pressure for four hours before cleaning and sterilization, and will be tested again afterwards.

Bellows cleanability test fixture

The test fixture in Figure 18 (c) shows a bellows mounted on a titanium rod. It was not possible to get a bellows which is identical to the one described in the final design, but this is very similar in dimensions. To differentiate between the two bellows, the one used in testing will hereafter be referred to as the "experiment bellows", and the one which is part of the final design will be the "final design bellows."

The "experiment bellows" is made from the same nickel cobalt alloy as the "final design bellows" and has the same wall thickness. It has a tighter distance between folds (0.33mm spacing, instead of 0.45mm) than the "final design bellows" and less depth to each fold (0.64mm instead of 0.90mm). It has only 15 grooves, compared to the 28 grooves in the "final design bellows". For testing, the "experiment bellows" is

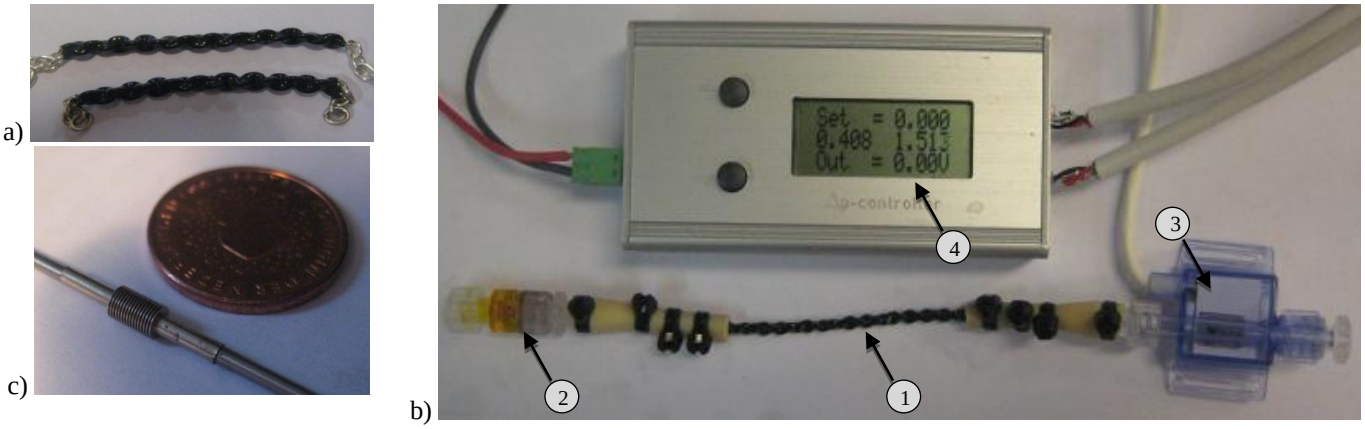

Figure 18: The test fixtures which were built for testing the Iridium seal and the "experiment bellows". (a) is the Iridium bending test fixture. It is comprised of the black Iridium heat shrinkable material shrunk around a chain carefully chosen for size. (b) is the Iridium seal test fixture. Balloon (1) shows the iridium material which has been shrunk around a chain and then sealed tightly at each end. (2) shows the one way valve which allows pressure to be added to the encapsulated section. (3) is the pressure transducer which monitors the pressure in the encapsulated section. (4) is the digital readout for the pressure transducer. (c) is the "experiment bellows" test fixture shown alongside a 5 Euro cent coin for scale. It comprises of an "experiment bellows" mounted to a titanium rod to allow for easier handling.

bonded in place to a titanium rod (to allow for ease of handling) using retaining compound. It is shown alongside a 5 cent Euro coin to give an idea of scale. Three of these were made.

3) Test preparation

Using the guidelines in ISO 15883 part 5 two artificial test soils were prepared. One biological soil was also prepared. The test soils, (egg soil and semolina pudding soil) were chosen mostly in response to the availability of the required ingredients. Additionally, a test soil using human blood was prepared under safe conditions at Leiden University Medical Center (LUMC). These soils were applied liberally to the outside of the test fixtures as indicated in Table 2.

The fixtures with egg and semolina were allowed to dry for 12 hours and then subjected to a 5 minute 110°C rapid drying. The human blood test soil was allowed to dry in open air for 60 hours. The soiled instruments (except the one with human blood) are all shown in Figure 19.

It is important to note that the 110°C rapid drying cycle is not part of the instructions laid out in the ISO instructions. [51] After going through this step, each of these soils become hardened and are believed to be more challenging to clean than any worst case use scenario for the cable ring grasper. As such, these soils will do well to demonstrate areas which are challenging to clean, however failure to completely eliminate these soils should not be seen as a failure in cleanability. The blood soil is a much more representative soil, however, and must be completely removed if the device is to be considered cleanable.

4) Test procedure

After the test soils were applied, each test fixture was subjected to a worst case scenario series of events as shown in Table 2. To represent worse case cleaning, the parts were all first exposed to the minimum cleaning which is expected to occur (one pass through the washer disinfector only), and then evaluated afterwards. To test worst case physical conditions, they were exposed to all available cleaning agents, and aggressively brushed. They were also put through the autoclave repeatedly. All testing was carried out at the CSSD at LUMC.

For the first cleaning in the washer disinfector, the parts were put in a basket and then placed in a location on the rack which gets cleaned the most poorly as judged by the CSSD inspector. This washer disinfector (a Getinge 86 series), subjects instruments to 90°C temperatures and a pH of 11. Neodischer FA Liquid alkaline cleaning solution and Neodischer Z, a liquid acid cleaning and neutralization solution is used in this washer disinfector. In the end, paraffin

Table 2: Matrix showing the different test scenarios each test fixture was subjected to.

	W/D	Enzyme soak	Aggressive brushing	Extended (60 hr.) Enzyme soak	Autoclave
Iridium seal test – egg soil	Y	Y	Y	N	5x
Iridium bending test - egg soil	Y	Y	Y	N	N
Iridium bending test – Semolina soil	Y	Y	Y	N	5x
Exp. bellows – Egg soil	Y	Y	Y	Y	N
Exp. bellows – Semolina soil	Y	Y	Y	N	5x
Exp. bellows – Human blood	Y	N	N	N	N

Figure 19: All the soiled test fixtures in a holding basket before being put through the washer disinfector.

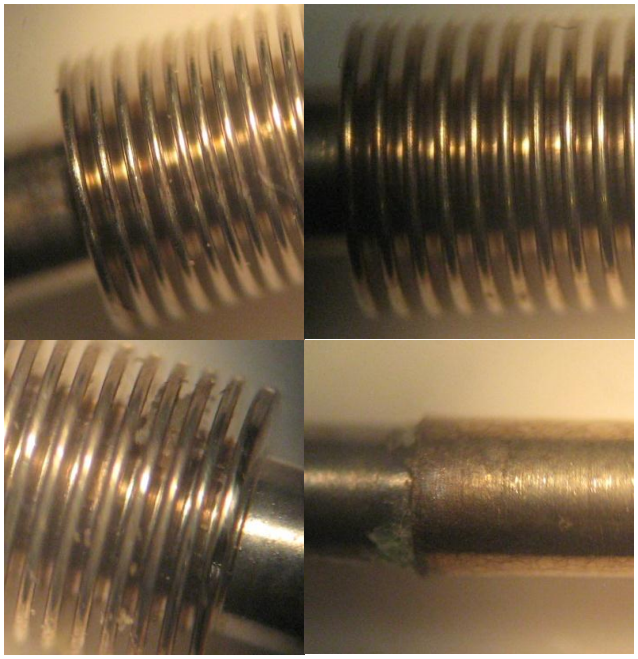

Figure 20: Magnified images of bellows seals after cleaning. Top left is human blood soil contaminated fixture. To the right is the semolina pudding soiled fixture. Bottom left is the cooked egg soil fixture. Bottom right is another view of the semolina fixture.

wax is also automatically applied to lubricate the instruments.

After going through the washer disinfector and evaluating the effectiveness, select fixtures were subjected to an enzyme soak as indicated in Table 2, as well as aggressive brushing. After that, select test fixtures were put through the autoclave process five times each.

5) Test results

Bending seal

The results from the bending test fixtures were very informative. Most fixtures returned clean from the washer disinfector. The exception to this was the fixture subjected to the cooked egg soil (which represents worse than worst case). It required additional aggressive brushing to get the soil out of the deep dips created by the chain. Based on a manual and visual evaluation, the material did not appear to be adversely affected by the cleaning and disinfection processes.

This, however, was not the case for the autoclave sterilization process. After five rounds of autoclaving, the Iridium test fixtures were noticeably less flexible than the unsterilized test fixtures. Even worse than this, though, are the results found after autoclaving the Iridium seal test fixture five times. At some point during autoclaving the fixture failed catastrophically. The expected reason for this is the degradation of the seal material combined with the vacuum stage which occurs at the beginning of the autoclave cycle. Before autoclaving, the material was shown to handle a differential pressure of 1.5 bar for four hours, so the fact that it failed under 1.0 bar differential pressure (atmospheric pressure inside, and vacuum pressure outside) must be attributed to degradation.

Bellows seal

The three "experiment bellows" fixtures were observed under a microscope after the first washer disinfector cycle, and again after aggressive cleaning. With regards to the mechanical characteristics, no visible physical damage could be seen. Most importantly, the aggressive brushing did not bend or damage any of the "experiment bellows'" folds. There were also no visually detectable negative surface effects or discoloration from the autoclave process.

As for cleanability, in the case of the semolina soil and blood soil, visual inspection under a microscope indicated that use of the washer disinfector alone is sufficient (Figure 21 top left and top right). No debris or staining could be found on either, despite the fact that the semolina soil had been subjected to 110°C extreme drying, and the blood had been allowed to air dry for 60 hours. This is a positive result for the cleanability of the bellows.

With the cooked egg soil, however, there were a couple areas which did not clean well. These are shown on the bottom of Figure 20**.** The egg, (bottom left), remained on the test fixture, even after all cleaning procedures, including a 60 hour enzyme soak. As previously mentioned, due to the aggressiveness of the soil this should not be seen as a failure, but does indicate that the folds are in fact substantially more difficult to clean than the flat surfaces of the bellows where no trace of the egg soil remains.

The other area (bottom right) had some semolina soil remaining. In that area, there is a gap between the titanium rod and the bellows which is less than 0.10mm. This is only present in the test fixture, and will not be in the final design. Regardless, it is still an interesting picture. It shows how troublesome areas with tight clearances that are not as easily accessed can be. It is clear to see that a lot of soil was retained by that gap, despite having gone through the washer disinfector, enzyme soak, and aggressive brushing. This is not a condemnation of the bellows, however. In the actual design, the method of bonding the bellows to the rod will need to be much better.

D. *Interpretation of test results*

The testing of the Iridium bending seal makes it clear that the Iridium shrink tube is not a sufficient material. It performed well in all tests before sterilization, but was degraded unacceptably after sterilization. This does not rule out the adequacy of the design concept, but does mean that further evaluation of other materials will need to be performed.

For the bellows, the testing and analysis results suggest that the selected bellows design has strong potential for use in the cable ring grasper redesign. It remained visually unharmed

Figure 21: Images of the seal testing fixture before and after five autoclave cycles.

after aggressive brushing and being subjected to many different cleaning solution, and can be adequately cleaned. The blood soil, which represented the most accurate worst case scenario, was completely cleaned from the "experiment bellows", and confirms the "experiment bellows'" cleanability. By extension of the fact that the "final design bellows" is similar in size and shape, has wider spaces between grooves, and uses the exact same material with the same thickness, it can be surmised that the "final design bellows" will be adequate as well.

Further testing must still be performed in future research, however, in order to evaluate biocompatibility of the material, to make sure the required flexibility and wall thickness is maintained, and to make sure the material does not go through any undesirable alterations from repeated cleaning and sterilization.

IV. Discussion

A. *Steps in the design process*

The path to get to the final conceptual design for the cable ring grasper presented here involved many steps. First, a complete understanding of the specific cleaning challenges was established. Then, a list of cleaning design strategies which can be applied to any reusable instrument was developed and applied to this challenge. Once that was complete, and the decision to pursue the encapsulation strategy was made, the key barriers to realizing this strategy were identified and analyzed.

In the case of this instrument, the key barriers were: determining how to seal the bending section and designing a method of transferring the energy inside the encapsulated section to the grasper. In order to find a way to seal the bending section, and extensive search of materials which are suitable for the task was performed, and some preferred materials were chosen. To find a way to transfer the energy, the problem was broken down into its most basic set of options, and then the best option, mechanical linkage combined with a metal bellows, was chosen.

Once the path forward on the two main barriers was determined, a conceptual design which incorporates those two elements into the existing cable ring grasper design was put forth. Representative models of those two elements were then tested in a CSSD to establish their potential as final solutions to the problem at hand, and a list of key design features for the concept as a whole was generated.

B. *Evaluation of the design*

1) Viability of the concept

Complete encapsulation of the internal components of the cable ring grasper is a novel approach that shows promise. The testing done in Section III and the analysis done in Appendix C indicates that inclusion of a bellows seal to allow for the transfer of energy across the enclosed section of the shaft is mechanically practical and also cleanable in a CSSD.

As for the bending seal, the testing performed there was a little less encouraging, but since there are still other potential materials which can be tested, the concept still has potential. The greatest hope lies with the Pebax material. Assuming the correct flexibility can be found, all the other characteristics, including wall thickness and biocompatibility look very promising. If that does not pan out, then Santoprene would almost certainly work in this application, although it comes with the penalty of being excessive in wall thickness.

With that said, there is still work which needs to be done before the design concept can be considered viable. A detailed design which addresses things such as how to bond materials, and how the removable grasper is attached still needs to be done. There also needs to be a complete design for the handle and steering mechanism which also follows the encapsulation concept. A determination also needs to be made regarding whether or not the bellows spring force

2) Incorporating the handle

With regards to the handle design, it is expected that a similar combination of bellows and elastic polymer can be used to encapsulate the steering mechanism and allow the motion generated by the handgrip to be transferred into the encapsulated shaft. If this is the chosen method, then the handle could be designed in a similar manner to the handle in the existing cable ring grasper design, and would not have to be entirely encapsulated as well.

3) Assessing the effect of the bellows

The additional spring force added by the bellows also needs to be addressed. It is not known if the 1.4N introduced at full travel is enough to adversely affect the force feedback felt by surgeon; however the expectation is that it will not be an issue. With the existing design, 2.5mm of motion in the cable is translated into roughly 23mm spread between the two grasper mandibles at the tip. This gives any force generated by the tissue on the grasper up to a 9x mechanical advantage over the force generated by the bellows spring.

The force from the bellows will also increase in a linear, predictable manner over the range of travel of the handle interface. Any force feedback from the tissue would almost certainly still cause a noticeable deviation in that, and should still be easily detectable. However, if the bellows spring force does still interfere with the force feedback too much, then a counterbalancing spring (such as one described in the work done by Dr. Herder at TU Delft) could still be included in the handle to neutralize the effect of the bellows spring force.[52]

4) Assessing the length increase impact

Finally, there is one other potential shortcoming from this design which may also need to be addressed. Figure 22 shows the total length of the instrument starting at the bending section. The addition of the bellows adds 13 mm to that length. This means that the length of the section which begins at the first cable ring and ends at the tip of the closed grasper will now be 83 mm long (using the current grasper design).

This is almost certainly too long, and will limit the functionality of the instrument. Among other things, this means that the instrument must be inserted no less than 83 mm past the end of the trocar to be able to get full use out of the bending section. This could be improved by lowering the travel required by the drive cable. Halving travel distance would decrease the bellows length by 6mm, but it would also double the force on the cable and could have undesired effects on the bending section. Redesigning the grasper, perhaps by shortening the length of the grasper mandibles, might also be

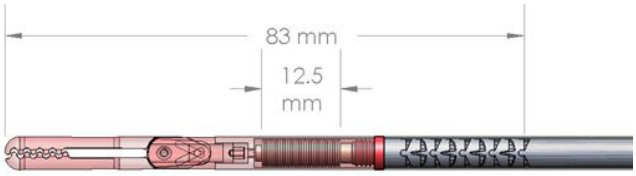

Figure 22: Drawing showing length of the bellows and the overall length of the final design concept starting with the first cable ring.

an option, but then the maximum spread between mandibles would also decrease. These things will need to be investigated further.

C. ***Lessons learned***

Presenting a new conceptual design which is expected to make the cable ring grasper compatible with cleaning and sterilization was not the only goal of this project. The other goal was to form a better understanding of the challenges of design for cleaning and sterilization for surgical instruments in general. In this regards, a lot was learned. Some of the more interesting and useful things are presented here.

1) Choosing a Strategy

Although it may seem trivial, understanding the available options with regards to cleaning and sterilization can be very useful. When trying to determine a path forward for the redesign of the cable ring grasper, applying the list of design strategies that was generated in Section II-B helped immensely. This list is believed to be all encompassing, and allows the designer to approach the problem in an organized manner, and to have confidence that all possibilities are being explored. A more in depth exploration of these topics can be found in Appendix B.

2) Choosing a sterilization process

There are four main methods of sterilization in a hospital: autoclave, gas plasma, ethylene oxide (EtO), and liquid Peracetic acid. Over the course of researching this topic, three different Dutch CSSDs were visited. At each of these locations, autoclaving is the core method of sterilization that they rely on. Gas plasma is also used, but not nearly as often. It is more costly to run, processes far fewer instruments at a time, and is less trusted by the people in the CSSD. Liquid Peracetic acid is rarely used, and EtO has been completely phased out of all Dutch hospitals.

These were the reasons that autoclave sterilization was chosen for the cable ring grasper redesign. Some things to remember when designing for autoclave sterilization are the extreme temperatures (up to 134°C), and the wide range of pressure (from full vacuum up to 2 bars). It is also important to remember that the steam can, among other things, lead to galvanic corrosion (for this reason, stainless steel should not be mixed with aluminum, brass, copper or chrome).[53] The designer should also be mindful that there are limitations on the overall length and length to width ratio for all lumens which are sterilized in an autoclave. (Further information about lumen limitations and some other relevant guidelines can be found in the "Assessment Criteria Checklist for New Reusable Medical Devices" which is used by many CSSD inspectors in the Netherlands and included in Appendix D.)

After autoclave sterilization, for the reasons previously stated, gas plasma is the next best alternative. This technology does allow for many more material options. However, there are several different systems based on this technology, and many hospitals have different versions. The list of compatible materials changes for each model, so it is important to verify that a chosen material is compatible with all models, not just one. Lumen dimensions are much more limited for gas plasma sterilization than they are for autoclave sterilization, information on this can be found in the individual model information sheets. [54]

3) Identifying challenging design features

Both the American Food and Drug Administration, and the American Society for Testing and Materials (FDA and ASTM) have put out lists of design features which they consider to be challenging for cleaning and sterilization. These two lists have been consolidated into the list in Table 3. During the research and execution of this project, a couple of these list items were explored in more depth, and are discussed in the following subsections.

4) Incorporating cables

There are two types of cables which can be problematic: braided cables, and Bowden cables. Braided cables (also known as wire rope) such as the one shown in Figure 23 (top left) are problematic because they are in essence an assembly composed of many tightly fitting components. These can therefore lead to the exact same cleaning and sterilization problems as any other tightly meshed components.

Table 3: List of features which make cleaning difficult. Combined from lists from the FDA and ASTM.[55,56]

- *Blind spots*
- *Mixed materials*
- *Sharp corners, fine features*
- *Omnidirectional cleaning vs. directional*
- *Long, narrow interior channels (lumens)*
- *Hinges*
- *Serrated edges*
- *Acute angles*
- *Coils*
- *Junctions between insulating sheaths*
- *Blind ends*
- *Threaded areas*
- *Sleeves surrounding rods, blades, activators, inserters, etc.*
- *Adjacent device surfaces between which debris can be forced or caught during use*
- *O-rings*
- *Valves that regulate the flow of fluid through a device (stopcocks)*
- *Devices with these or other design features that cannot be disassembled for reprocessing.*

Figure 23: Braided cable (also known as wire rope), top left. Debris can become intertwined in this. Bowden cable, bottom. Also retains debris. Nylon coated cable, top right. May be a solution for keeping debris from tangling intertwining and residing in cable.[57,58]

One way that was discovered during the cable ring grasper redesign that may reduce the risk of using such cables may be to use nylon coated cables (such as the nylon coated cable shown on the top right in Figure 23). However, there is no known literature or testing which has been undertaken to confirm this as an acceptable solution. Another option may be to use highly flexible Nitinol, or perhaps a rigid rod (if the design allows) instead of stranded cable in the design.

The other problematic type of cables is Bowden cables (Figure 23, bottom). Bowden cables typically combine a tightfitting sheath and a cable which runs through it. Together, they provide push/pull capability to the cable at the location that the cable exits the lumen. In addition to the fact that this type the cable is usually braided, a second problem comes from the cable pushing in and out of the lumen which houses it. With each actuation of the cable debris can be pulled from the surgical site further up the sheath. Once this has occurred, there is no way to clean it mechanically, and it is unlikely to be possible to get sufficient flow to clean it with fluidics.

5) Designing Lumens

Lumens are found in all types of devices, and can be particularly nasty to reprocess. Depending on the design, they are often too difficult to clean with a brush, and/or are impossible to inspect for cleanliness. For these reasons, things to avoid with lumens include: rough inner surfaces; lumens which are closed or restricted on one end; lumens with varying diameters; and curved lumens. When the design allows for it, it is worth considering to put an open groove in place of the lumen; but this is only the case if the groove can be made wide enough for easy cleaning, and the entire length of the lumen can be made into a groove (otherwise, it may become impossible to attach a flush line to the still portion which is still a lumen, make that section uncleanable). A very good example of the difficulties which come from lumens can be seen in Smith and Nephew case study in the section on flushing (Appendix B).

6) Including tight gaps and clearances

Tight gaps are a particularly interesting problem. This is partially because there are no clear guidelines about what is acceptable, and what is not. It is clear from the testing results that they can be a problem, though The testing done in this research suggests that the gaps distance present in the bellows (0.19mm) are acceptable, at least for materials with smooth surfaces that are easily accessed for cleaning like these.

That said, the aggressively hardened egg soil did show that grooves which are that tight can still present a challenge (Figure 20, bottom left). The slightly tighter groove (Figure 20, bottom right) which tapers ranges from 0.10mm down to 0mm, and is not as easily accessed was actually shown to be uncleanable. In fact it was the only surface on any of the test fixtures where the semolina test soil remained. Without doing further research, it is difficult to give concrete recommendations, but it is at least safe to say that gaps around 0.20mm and below do begin to present challenges, and that if they are not well exposed for cleaning, it is likely they will not be adequately reprocessed.

7) Choosing materials

The Association for the Advancement of Medical Instrumentation (AAMI) has identified some common failure modes for two typical types of medical materials, stainless steel and polymers. The three most common failure mechanisms for stainless steel "are pitting, crevice corrosion, and stress corrosion cracking (SCC) or hydrogen cracking." For polymers, incompatibility with cleaning and/or sterilization can show up as "crazing (thin silver streaks appear), cracking, swelling, dissolving, softening, or becoming brittle." [53].

Biocompatibility is very important when choosing a material. The world standard for testing for biocompatibility is ISO 10993 parts 4 and 5 from the International Organization for Standardization (ISO).[53] Another standard which is seen a lot is USP (US Pharmacopeia) Class IV. It is often possible to find materials which have already been tested to one or both of these standards. Some materials, such as Tecoflex which is used in the existing cable ring grasper design, can react adversely to autoclaving and become toxic, so it is important to establish biocompatibility both before and after sterilization.

The material surface properties are another thing which is important for compatibility with cleaning and sterilization. A good general rule for surface finish is: the smoother the better. Any roughness or texture on the surface can provide refuge for debris and infectious agents during the cleaning process. Figure 24 gives an example of a couple different surface finishes compared to the size of a typical bacterium.

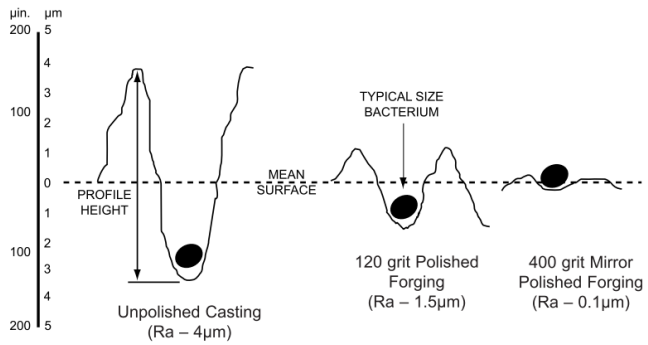

Figure 24: An image showing different surface finishes relative to the size of a bacteria.[59]

There are a number of resources which can help in choosing a material which is compatible with cleaning and sterilization. One such resource is a Handbook of Biocompatible Materials. [11] Another is the Ides database for polymers, which among other things allows one to search for a polymer based on the desired sterilization process.[10]

D. *Reflection*

The cable ring grasper is an interesting device, and it presented the perfect opportunity to study the challenges and methods to approaching a design which will need to be cleaned and sterilized. The end product of this research is both a unique solution for the redesign of the cable ring grasper, and a far better understanding of the process of designing for cleaning and sterilization. The presented concept is a novel solution for a very real problem. To the author's knowledge, there are no other laparoscopic instruments in existence today which have implemented such a solution. It is definitely worth pursuing further.

The work is not finished, however, and there are still a number of challenges and open questions which need to be addressed before it is known whether this solution will ultimately work. One big shortcoming of the presented design is the extra length which the solution adds. Also, there is still the open question about which, if any, material will work suitably for the bending section. Finally, it must be acknowledged that the solution presented here can only work if a successful solution can also be found for the proximal end. All of these things must be addressed before success can be confidently declared.

As for design for cleaning and sterilization, perhaps the biggest takeaway message from this project is that this topic has not traditionally gotten the kind of attention it deserves and requires. It can be easy for a design engineer to dismiss it as something which can be postponed to the end of the development project. However, as shown by the amount of thought and work it has taken to come up with a viable design concept for the cable ring grasper, it is clear that this is a mistake Such design considerations need to be made part of all surgical device design projects from the beginning. Doing so will prevent possible delays which may prevent a device from making it to market on time, and may also allow for tighter integration of the solution into the core technology of the device, making for a better solution overall.

E. *Future Research*

There are worthwhile topics of research which can be continued further for both of the subjects in this research. For the cable ring mechanism, pursuits such as furthering this design concept, positively identifying a suitable material for the bending section seal, and designing a hand grip to complete the instrument design still need undertaken.

For the topic of design for cleaning and sterilization, two important topics which still need to be taken further are investigating the inclusion of cables in designs (and determining if using nylon coated cables is really an alternative that will minimize the risks), and developing an even better understanding and clear guidelines for what types of gaps and close tolerances are acceptable in a design. Clear dimensions and thresholds for gaps and low clearances should be determined. These are both fundamental questions, and could go a long way towards helping many others as they design from cleaning and sterilization.

V. Conclusion

As stated in the aim and goal sections, this project set out to do two things: first, it set out to find a conceptual solution for how to redesign the cable ring grasper so that is reusable and compatible with hospital cleaning and sterilization; second, it aimed to offer up a better understanding of design for cleaning and sterilization in general.

On the first aim, this project can tentatively be labeled as a success. A conceptual design has been found for making the cable ring grasper compatible with cleaning and sterilization. However, there is still more work to be done before it is known whether a commercial device could be designed around this concept.

With the second aim, the success can be more confidently declared. Through research, discussion with experts in the field, and methodically working through the design process for the cable ring grasper, useful and relevant steps, information, and guidelines for designing for cleaning and sterilization have been determined and presented to the reader.

Designing for cleaning and sterilization is an extremely important topic which too often does not get the attention it deserves from design engineers. To a large extent, this may be due to the vagueness and obscurity of information which surrounds the topic. Hopefully this thesis helps to clear some of that up, and can serve as a small stepping stone on the way to better design of all surgical devices for cleaning and sterilization.

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VII. Appendix

Appendix A. Background Information

A. Introduction

This section provides an overview of the cleaning and sterilization process, and responsibilities of the design engineer. In section B, the typical life cycle of a reusable instrument is traced. In C, an introduction to the cleaning and sterilization process is given. In section D, classifications of medical devices are explained. Section E discusses the oversight process which governs the design and approval of medical devices. F then discusses the responsibilities which are imparted upon the designer and introduces the Instructions for Use (IFU) document. In the writing of this section (along with the rest of the report), three professional hospital instrument sterilization inspectors (Mariette Jungblut from Leiden University Medical Center, Judith Lambregste-Valdés from Combister, and Annelies Poth from Erasmus Medical Center) one CSSD department head (Jolanda Buijs from Erasmus Medical Center), and one expert consultant (Diana Bijl from Diana Bijl Consultancy) on cleaning and sterilization were consulted.

B. Lifecycle of a reusable instrument

There are three main types of sterile instruments which are used in the hospital: purchased disposable devices, purchased reusable devices, and borrowed reusable loaner instruments. Disposable instruments are outside the focus of this report. Loaner and purchase instruments should be considered to be roughly the same by the reader, with the only difference being that loaner instruments are returned to the distributor after use. The diagram in Figure 25 shows the lifecycle of these three types of instruments. Green arrows indicate the periods in which the instrument is sterile, and red arrows indicate an unsterile instrument. Each arrow also represents the transportation of a device from one area to another.

Each step in this process is crucial, and has implications which the designer must understand and take into consideration, as discussed below.

C. From fabrication to surgery

During the manufacturing process there are many things to consider, such as the quality system the manufacturing facility uses (most likely ISO 13485 and ISO 9001), the cleanliness of the manufacturing line, lubricants and chemicals used in manufacturing, training of the worker, packaging which the instrument will be delivered in, etc. This is itself a big topic, and is outside the focus of this report.

That said, perhaps the most prudent thing to say here is that the device should be delivered clean to the hospital, and free of any manufacturing residues which would prevent it from being properly cleaned, disinfected, and sterilized in a typical CSSD using the instructions provided in the IFU. It is not the manufacturer's responsibility to deliver a sterile reusable instrument that is ready to go directly to surgery (disposable instruments, of course, must be delivered sterile.). It is standard practice for the hospital CSSD to clean and sterilize instrument upon receipt and before putting it into use.

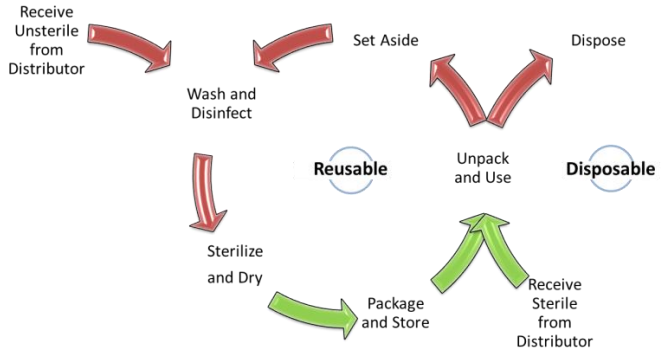

Figure 25: Diagram showing the lifecycle of a reusable instrument.

1) From surgery to surgery

Even the most innocuous seeming step in the lifecycle of reusable instrument can have big implications upon how the instrument should be designed. As such, each of the steps in a reusable device's life cycle s discussed below.

Set aside: This step accounts for the time which occurs between use of the instrument and when the cleaning process begins, and is not as harmless as it may first appear. The time between use and cleaning can be long. This often allows ample time for the blood and debris that the instrument has come in contact with to dry and harden on the instrument, making cleaning much more difficult. A designer has to assume debris drying and hardening occur with any device, and design accordingly.

Wash and disinfect: This is the step in which the instrument is rendered clean and free from most infectious agents. Although it may not be immediately obvious, an instrument subjected to this process is going to become dirtier before it becomes cleaner.

Throughout the cleaning process the instrument will be soaked and cleaned with cleaning solutions that may already be contaminated with the debris from other dirty instruments. Even if an instrument is cleaned with unused, sterile solution, it has to be assumed that the cleaning process will spread infectious agents from more contaminated areas of the instrument to the less contaminated areas. Even parts of the instrument which can be expected to remain relatively clean during use in surgery will become contaminated during this process.

The disinfection process comes after cleaning. It destroys all but the most challenging infectious agents. During this process, the device will likely be subjected to high temperatures, high velocity water flowing, and high levels of acidity.

Sterilize: In this step an instrument should already be free of all debris and many infectious agents. Here, it is rendered sterile for use in the next surgery. Before the instrument can undergo sterilization, the CSSD employee must visually inspect the instrument to make sure it is in fact free of all debris and contaminants. A properly designed device will make this step is as effortless as possible. Devices with areas that can become contaminated, and that cannot be visually inspected afterward make this step very difficult if not impossible, and may be rejected for use based on this. Also, depending on the chosen sterilization method, this is the step

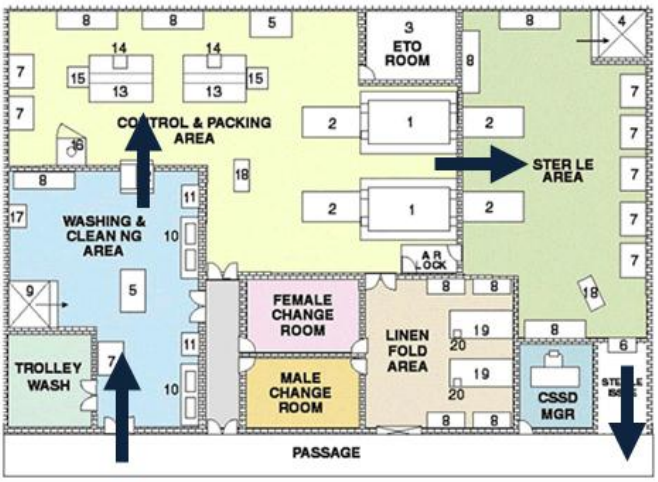

Figure 26: Example layout of a hospital CSSD.[60]. The numbered items are:

1.	Steam Sterilizer	11.	Ultrasonic Cleaner
2.	Carriage and Trolley	12.	Washer Disinfector
3.	ETO Sterilizer	13.	Control and Packing Table
4.	Dumb Waiter (Sterile Goods)	14.	Magnifying Lamp
5.	Work Table	15.	Sealing Machine
6.	Pass Box	16.	Drying Cabinet
7.	Free Standing Basket Rack	17.	Endoscope Washer
8.	Storage Rack	18.	Table Trolley
9.	Dumb Waiter (Dirty Goods)	19.	Linen Fold Table
10.	Work Table with Double Sink	20.	Gauze Cutting Machine

where the instrument will be subjected to some of the harshest conditions it will ever see.

Package and store: This step accounts for the time after sterilization and before the instrument is used again. This is a relatively benign step; however the designer does need to consider how the instrument will be packaged.

Unpack and use: This, of course, is the step in which the instrument carries out the function that the designer intended.

2) Typical layout and workflow of a CSSD

Figure 26 shows a fairly typical layout for hospital CSSD. As shown by the arrows, after surgery an instrument is first brought to the washing and cleaning area. Here it is prepared for cleaning, soaked and manually cleaned if necessary, and then cleaned and disinfected using the washer disinfector. In the next section, the control and packing area, the instrument is inspected for cleanliness, reassembled if necessary, documented, and then placed in its storage packaging and prepared for sterilization. Once these steps have been taken, the instrument is then processed using the specified method of sterilization, and passed through to the final area. In the sterile area, the instrument is removed from the sterilization device. At this point, it is already in its packaging (if it was sterilized in it), or is packaged here. In this place, it is allowed to dry, and then sorted and sent to its storage location until it is ready to be used again.

Depending on the hospital, the CSSD may see many thousands of instruments come through each day. Just one of the several CSSD's at John Hopkins Hospital, for instance, is estimated to see more than 37,000 instruments per day. [61]

D. Cleaning, disinfection and sterilization

1) Cleaning

This section on cleaning and disinfection, along with the next section on sterilization are only intended as basic introductions to the topics. There many resources which discuss the various technologies in detail. One excellent resource is the CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities.[62] Another is an overview document written by one of the foremost sterilization experts W.A. Rutula. [63]

Before a device can be sterilized, it must first be clean and disinfected. The purpose of this is to remove as much foreign material and contaminants as possible in order to allow sterilization technologies to work properly. Soil which remains on an improperly clean device can end up protecting the microorganisms harbored within it, and can damage instrumentation during sterilization processes (for example, rust proof instruments can become corroded by blood residue during the steam sterilization process).[62]

It has been shown by Spaulding that under identical processing conditions it took 30 min. to kill 10 Bacillus atrophaeus spores, and three hours to kill 100,000 of the same spores.[62] It has also been shown that cells in a clump formation are much more difficult to kill than individual cells.[64] It is therefore crucial that a device is completely cleaned and rid of as many contaminating agents as possible before sterilization can begin. This is even true for internal surfaces and surfaces which are not visible on an instrument, since they can also come in contact with blood and other body tissues and still transmit infection to the patient.

The main methods for cleaning a device include soaking, exposure to enzymatic and detergent solutions, manual cleaning, cleaning with ultrasonic equipment, and the use of automated equipment such as washer disinfectors.

2) Disinfection and sterilization

Sterilization and disinfection should not be confused with each other, even though there are many similarities. The main difference between the two can be found in the infectious agents that they eradicate. As shown Table 4, disinfection eliminates everything but bacterial spores and prions. (Bacterial spores are the highly resistant pods which are

Table 4:Infectious agents listed from most resistant to least resistant and alongside the process which is used to eliminate them.(Adapted from [62,65]

	Microorganism	Reprocessing method
Most resistant	Prions (Creutzfeldt-Jakob Disease)	Prion reprocessing
	Bacterial spores (Bacillus atrophaeus)	Sterilization
	Coccidia (Cryptosporidium) Mycobacteria (M. tuberculosis, M. terrae)	High level disinfection
	Nonlipid or small viruses (polio, coxsackie) | Fungi (Aspergillus, Candida)	Intermediate level disinfection
Least resistant	Vegetative bacteria (S. aureus, P. aeruginosa) Lipid or medium-sized viruses (HIV, herpes, hepatitis B)	Low level disinfection

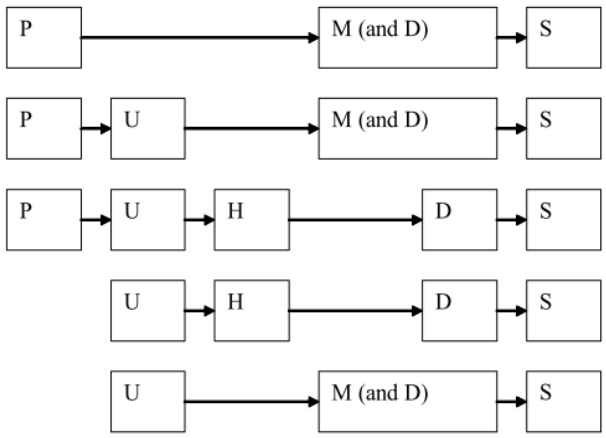

Figure 27: Various cleaning, disinfection, and sterilization steps an instrument can undergo during reprocessing. P = Pre-cleaning, e.g. wiping, cleaning out with a pipe cleaner or brushing under the tap, U = Ultrasonic cleaning, H = Cleaning by hand, M (and D) = Cleaning by machine and (if applicable) Disinfection, D = Disinfection (thermal or chemical or thermochemical), S = Sterilisation. [72]

dispersed by bacteria in order to survive unfavorable conditions for extended periods of time.[66] Prions are transmissible agents which can induce abnormal folding of normal cellular prion proteins in the brain, and lead to disease like Creutzfeldt - Jakob disease (CJD).[67]) Sterilization, on the other hand, eliminates all known infectious agents except for prions. (Since neither process is capable of dealing with prions, devices which are believed to come into contact with such things must typically be disposed of or reprocessed elsewhere. For instance, it is the policy of UCSF Medical Center to "Destroy by incineration" any instrument which has come into contact with a patient who is either confirmed or suspected of carrying CJD.) [68,69]

Sterilization is quantified using a probability called the Sterility Assurance Level (SAR). A medical device is considered sterile when it has less than one chance in 1 million of having viable microorganisms present on it.[70,71]

Disinfection is usually done with chemical agents such as hydrogen peroxide, glutaraldehyde, and Peracetic acid. Sterilization is usually performed using an autoclave, hydrogen peroxide gas plasma, Peracetic acid, and ethylene oxide (although, according to the Dutch CSSD inspectors consulted in the research for this report, ethylene oxide is being phased out due to its toxicity in many hospitals around the world, and has been completely eliminated as an option in the Netherlands.)

There are many paths that an instrument can take from being dirty through to becoming sterilized and ready for reuse. These paths are shown in Figure 27. In the Netherlands, guidelines give strong preference to automated cleaning and disinfection by machine.[73] One reason is because use of automated cleaning processes have also been shown to be as twice to fifty times more effective when compared to manual cleaning. .[74] So the third and fourth options in Figure 27are rarely used by Dutch hospitals. Reliance on these options such as manual cleaning without using the washer disinfector can be grounds for rejection of a device in a Dutch hospital.

E. Classification of devices

There are two classification schemes for medical devices which are universally used by designers, official oversight and hospitals: one which determines which certification and regulatory processes the device must undergo, and another one which establishes the requirements for cleaning and sterilization of the device.

In EU, the first classification scheme is divided into the following four classes: Class I, IIa, IIb, and III. Annex IX in the Medical Device Directive can be used to determine which of these classes a particular device falls into. [75] In the US, the classification scheme is similar, and is divided into the following three classes: Class I, II, and III. The FDA controlled document 21 CFR 860 is used to determine the class in this case.[76] In both regions, class I devices are considered to present the lowest risk, where is class III devices are considered sent the highest risk to the patient.

The second classification scheme, which is widely used to determine which method of reprocessing should be used on the device, is known as the Spaulding classification scheme. The scheme was developed in 1968 by EH Spaulding.[77] In this scheme, patient care equipment is divided into three categories: critical, semi-critical, and noncritical. A brief definition of each category as put forth by the Center for Disease Control (CDC) is below:

- Critical: Device enters normally sterile body tissues. This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities.
- Semicritical: Device contacts mucous membranes or non-intact skin. This category includes respiratory therapy and anaesthesia equipment, some endoscopes, laryngoscope blades, esophageal manometry probes, cystoscopes, anorectal manometry catheters, and diaphragm fitting rings.
- Noncritical: Contacts intact skin.

With very few exceptions, critical devices should be sterilized before reuse. Semi-critical devices need only be subjected to high-level disinfection, and noncritical devices to low-level disinfection.[62]

F. The design oversight process

There are, in essence, three levels of approval that a medical device must go through before it can come into contact with the patient in a commercial application. These are shown in Figure 28. The first level falls with the designers themselves. They know the design better than anyone, and therefore bear a lot of the responsibility in making sure the device is safe for patient use.

Next comes the official approval. In Europe, this comes from a notified body, which is tasked with verifying that the design and design process adhere to all the official regulations and has the ability to award CE marks. Well known examples of notified bodies include TÜV in Germany, and DEKRA in the Netherlands; there are 80 such accredited institutions in Europe.[78] In US, official approval comes from the Food and Drug Administration (FDA), which is a large governmental body tasked with protecting and promoting public health. They also verify that all standards and regulations have been followed.

Figure 28: The three level of oversight a design must go through with regards to cleaning and sterilization.

After that comes the approval of the hospital's cleaning and sterilization expert inspector (here forth referred to as the inspector) and/or head of the CSSD. According to the consulted inspectors, no hospital is obligated to accept and use a device just because it has received regulatory approval.

1) Designer oversight

No one is as intimate with the design of a medical device as the designer him/herself. Notified bodies which award CE marks, and the FDA all rely on the work and documentation done by the designer when approving a device. It is the responsibility of the designer to design for worst case cleaning and sterilization scenarios.[53] They also must be thorough in the risk analysis and testing performed on the device.

Incomplete documentation or failure to meet all the standards and regulations a designer must follow is likely to be detected by the official oversight bodies. However, a small design feature, such as a hidden crevice which retains infectious debris, or a bond between materials which degrades over time when subjected to the autoclave, can easily be overlooked by the inspectors and reviewers. The designer must respect the unique vantage point he/she has, and be thorough and meticulous in the design process.

2) . Governmental oversight

In Europe and the US, the type of oversight a device receives depends on how is classified. As described in section D, there are different classification schemes based on the device's intended use that each country refers to. The category in which the device is classified determines the level of involvement in oversight the notified by will have. Regardless of the level however, the notified body does not layout or perform tests itself. It merely reviews and scrutinizes the testing and documentation submitted by the designer.

3) Hospital oversight

After a reusable device has been validated for cleanability and sterilizeability by the designer, and has been awarded FDA or CE approval, there is still one safeguard remaining before it can be used on a patient. This is the hospital itself. However, depending on the country and even the individual hospital, the methods of assessment and approval can be inconsistent. The Netherlands has perhaps one of the strictest approval processes of all. The information which follows comes from the professionals who were consulted in the Netherlands.

Unlike many other countries, each hospital in the Netherlands has an independent expert whose main task is to assess the safety of new medical devices being considered for use in the hospital. According to the consulted inspectors, this allows the inspector to be more impartial and theoretically make better decisions about which devices to accept.

Even still, this process is not perfect, and this process should not be counted on to rule out faulty devices. In one example, an expensive device was approved for use at a Dutch CSSD and used for years based on the manufacturer's assurance that the device was safe and could be properly cleaned and sterilized. Only after the device was retired, and the inspector at the CSSD cut it open out of curiosity, was it discovered that the device had been retaining unsafe levels of debris between surgeries and should never have been approved.

Another imperfection is that even the best inspector at a hospital can fall prey to political pressure as well. Due to this political pressure, suboptimal designs are sometimes still approved for use. One high-profile example of this is a da Vinci Endowrist device. This is part of a cutting edge robotic surgical system. This device is notoriously difficult to clean and many Dutch inspectors would like to reject it based on this. However, there has been overwhelming political pressure generated by desire of surgical staff to have access to this cutting-edge technology. In turn, this has forced the CSSD to approve the device and develop specialized cleaning processes for it in order for it to be safely reprocessed.

Above all, a lot of the approval process at this level is based on the experience and instincts of the inspector. The inspectors at hospitals feel a very high level responsibility for patient safety; if they do not feel comfortable with the device, they will not allow it to be used.

G. Designer's responsibilities

There are number of standard practices in the design process which will help the designer to assure the product can be safely reprocessed. The most important practices are explained in this subsection.

1) Risk analysis

This step is crucial and defines how potential risks in the device design can be identified. One part of the risk analysis process must focus on the cleaning and sterilization of the device. ISO14971 gives guidelines on how to carry out a risk analysis for medical devices. These guidelines include instructions for performing risk analysis with regards to cleaning and sterilization process. [79]

2) Validating the cleaning and sterilization process

Once a design is completed and a prototype is built, the next task is to validate the design for cleaning and sterilization. This can be a daunting task. While validation is a required part of the design process, there are no universal, internationally recognized methods for how validation should be done, or even how clean the device should be.[56] In fact, the FDA specifically states that it has no intention to set acceptance specification, and instead prefers to rely on the manufacturer's knowledge.[80] This means a lot of the design of the validation testing is left up to the judgment of the designer him/herself.

There are two separate validations which need to be performed: one to validate the cleaning process, and one to validate the sterilization process.

Validating the cleaning process

Recently, an FDA review of manufacturer supplied validation data indicated "that many studies designed inadequate test conditions and used inappropriate measurement methods to validate that the tested device was clean." [55] They also found that manufacturers often did not

use a test soil which adequately reproduced real-world conditions, and also that manufacturers did not properly consider the inability to clean internal components of the device.[55] With this in mind. It is important to remember to be as thorough as possible and replicate a real-world (as opposed to a laboratory) scenario as accurately as possible. . [56]

To validate the cleaning process, instrument first needs to be contaminated. One way this can be done is through use of artificial test soils. ISO standard 15883 part 5 (which is actually part of a set of guidelines for validating washer-disinfectors, not instrument designs) can be helpful, since it lists a number of different tests or recipes which can be used, and even classifies them by country.[51] It is a good idea to use a test soil that most closely mimics the real world scenario. This test soil should be applied liberally to the instrument and in such a way that it mimics the worst-case use scenario. Mimicking worst-case means, among other things, allowing the test soil to dry and harden on the instrument. It also means making sure the soil is applied everywhere that could possibly become contaminated, even the internal components of the device. [81]

After the device has been contaminated under what is considered worst-case scenarios, it should then be cleaned as per the instructions in the IFU which will be supplied with the instrument. This should also be done under worst-case scenarios. This means using the shortest soak times described in the IFU, lowest temperatures, etc. [56]

Finally, measurement should be taken to verify the device is acceptably clean. Again, there is no international standard for this. Diana Bijl, (the president of the Dutch Association of Experts Sterile Medical Devices) an independent expert who consults in this field, recommends going with the German standard which states there should be less than 100µg/cm^2 soil remaining on the device after the cleaning process. She also stresses that this should be true for any given section of the device, not just the device as a whole. Also, it is certainly a good idea to disassemble (or cut apart, if necessary) the device so that inner surfaces and components can be inspected after cleaning as well. It goes without saying, but inspecting the outer surfaces alone is not sufficient. Methods for measuring the amount of soil remaining include "microorganism detection, chemical detection for organic contaminants, radionuclide tagging, and chemical detection for specific ions". [62]

To give an example of the validation process from a well-known manufacturer, Olympus (Japan) does the following when validating the cleaning process in their flexible new endoscope designs: they first simulate worst-case conditions for the Automatic Endoscope Re-Processor (AER) by decreasing supply voltage to a minimum, injecting the minimum amount of detergent, restricting the compressed air lines, and simulating a worn-out water pump. Then, to simulate the worst-case scenario for the endoscope, they fill every channel with the artificial soil and then let it sit for one hour. The soil they use has high levels of protein, hemoglobin, carbohydrate and bioburden. They then do a pre-cleaning with no detergent and at a reduced flush volume. They then eliminate the manual cleaning step altogether, before attaching the endoscope to the AER. When cleaning is complete they test the device to be sure that has less than 6.4 µg/cm^2 protein and less than 4LOG$_{10}$CFU/cm^2. (CFU: Colony-forming unit.) [81]

Validating the sterilization process

Unlike validating the cleaning process, validation of the sterilization process is a lot more standardized. ISO standard 11138 gives a lot of detail about how to set up the test and what measurements to take. In addition to the testing described in the standard, there is also the imaginary microorganism concept which may be worth considering.[82]

3) "Instructions for Use" (IFU)

The manufacturer's "Instructions for Use" (IFU) is a required to be supplied along with all reusable devices. It must contain the "information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging, and (where appropriate) the method of sterilization of the device to be resterilized, and any restriction on the number of reuses."[83] Thorough instructions for what to include in the IFU for Europe can be found in ISO 17664.[84] For the US, information can be found in 21 CFR 801 and FDA guidelines for labeling of medical devices for the US.[85,86]

The IFU will be one of the most important documents the designer generates with regards to the cleaning and sterilization process. As this is the designer's only line of communication with all the CSSDs, it must be well thought out and accurate. In addition to the regulatory requirements for an IFU, there a number of things the author should do to ensure the IFU is followed properly and the instrument is properly reprocessed every time. An improperly prepared IFU can create a lot of problems for the CSSD department. When citing some examples, an inspector from John Hopkins spoke about huge discrepancies in length and content between IFUs from different manufacturers. She also presented the information in Table 5 to illustrate the inconsistency in times and temperatures specified by manufacturers for steam sterilization. Of the nine manufactures shown in the table, eight specify different sterilization cycles.[87]

This lack of consistency creates a logistical nightmare for the CSSD. This can lead to mistakes which ultimately endanger to the patient. IFUs should therefore stick to accepted mainstreams as much as possible. A template for a basic IFU can be found in ISO 17664.[84]

Some other recommendations for writing a good, usable, and thorough IFU include:

- Make sure the IFU matches the cleaning procedure validated in the cleaning validation precisely.
- Whenever possible use minimum, maximum, or

Table 5: Inconsistency in autoclave sterilization parameters between 9 different instrument manufacturers.

Vendor	Autoclave temp	Autoclave exposure time	Drying time
Abbott	270°F/132°C	30 min	0 min
BrainLab	270-275°F	3 min	N/A
Depuy	132-135°C	4-6 min	30-60 min
ERBE	273°F/134°C	15 min	30 min
KLS Martin	273°F	5 min	N/A
Medtronic	270°F	4 min	30 min
Omni Guide	270°F	5 min	30 min
SBi	132°C	45 min	60 min
Stryker	270°F/132°C	4 min	30 min

ranges of values (i.e. 3 min. or more, 95-100°C, etc.) instead of exact times. This helps to avoid tying the CSSD's hands and allows them to adapt the IFU to the standard Times temperatures and practices more easily.

- Whenever deviation from accepted norm is necessary, explain the reasoning to help the CSSD understand, and make them more likely to follow the deviation is specified. (To accommodate all the devices that must be processed in a day, CSSD's often adapt instructions to match their processes.[88] If this would present a risk for reprocessing a specific device, the reasons for this should be made clear.
- Whenever possible, a device should be validated for use with an automatic washer disinfector. In the Netherlands a CSSD often will often reject a device if it cannot be processed in the washer disinfector. [73]
- Instruct the CSSD on how to dispose of the device when it is retired.
- Remember, sterilization cycles are validated. Special requirements are difficult to fulfil. If your device requires something special (i.e. extra time in the autoclave), it may be that the hospital will have to refuse to accept it. If they do accept it, the new sterilization parameter will likely have to be validated by the CSSD, at high cost.
- Specify any periodic maintenance or calibration that is required.

H. Design considerations

During the research for this report, which included numerous consultations with CSSD inspectors, and an expert in the field of design for cleaning and sterilization, there were some other considerations to keep in mind while designing for cleaning and sterilization which became apparent. These considerations are presented here.

1) Considering the inspector

In the design of the instrument, the designer should make as much of it inspect-able as possible for the inspector. Examples of how to do this include leaving ways to inspect the inner components of the device for cleanability, use translucent materials where feasible, and do things like keeping lumens straight whenever possible to allow the inspector to see down them. With regard to the IFU, whenever prudent, explain the reasons for any special or nonstandard requirements or procedures to help the inspector develop a cleaning plan and understand if the device is compatible with his/her equipment. Above all, for both the device design and the reprocessing instructions, it is best to be as transparent as possible.

2) Considering the skills, experience and working conditions of the worker

Working as a technician in the CSSD can be a dangerous job. As many as tens of thousands contaminated instruments can come through a CSSD each day.[87] As shown in the Figure 29, the worker is usually outfitted with one or two layers of gloves, a fluid resistant suit, a mask, head and foot covers and eye goggles or face shields. Furthermore, as is the case with the workers at the John Hopkins hospital, the worker

Figure 29: Example attire of the CSSD worker.[89] .

may only have a high school degree or equivalent and are often under tight time constraints and stress.[87]

A designer should keep all of these things in mind. The many protective layers that the worker is wearing make small parts (such as miniature springs) which must be disassembled very difficult to work with. Also, considering that the worker is probably not trained as a technician and is often under time pressure, overly complicated assembly and cleaning instructions can create difficulty. [87]

Appendix B. An in depth look at design strategies

As part of the figuring out how to approach the redesign of the cable ring grasper, it became necessary to organize and list the design strategy options with regards to the design of difficult to clean devices. In section IIsectio, four distinct categories were found which in combination can describe the cleaning procedure for any device. These categories are: reprocessing, disassembly, encapsulation, and flushing. Each of these are discussed in more detail here.

A. Reprocessing Method

The first category, reprocessing, deals with the choice between making an instrument reusable, partially reusable (reposable), or not at all reusable (disposable). This report is, of course, focused exclusively on reusable devices, but there are still some significant advantages to designing a device to be disposable which should be discussed.

The most obvious advantage is that a disposable part does not need to be compatible with any of the hospital cleaning and sterilization processes. Designing for single use can also allow for many more materials and design features (since there are fewer limitations regarding sterilization technologies). Another benefit of designing for single use is that wear, tear, and lifecycles of the device are of much less concern, since it will be used for only one surgery. Finally, since it is only used once, the risk of cross contamination between patients is greatly reduced.

There is one main disadvantage of designing disposable part, however, and this is that the cost of the device becomes much more crucial. To keep costs low, material options, and manufacturing cost must be limited. The existing design of the cable ring grasper has taken this approach, with the idea being to make all but the handgrip disposable. . To do this and remain commercially viable it was determined that manufacturing costs must be kept below 70€, which has proven to be a very challenging target to hit considering the complexity of the device. Disposable devices also represent a significantly higher cost to the hospital as well. They have been shown to be between 7-27 times more expensive per use. [90–92]

B. Disassembly

For a device with which it is too impractical to be made disposable, there are three additional design options which mitigate the difficulties in cleaning and sterilizing of a complex instrument. One option is making the device partially or completely disassemble-able. The predominant reason and advantage for doing this is to give the CSSD access to portions of the device which otherwise cannot be rendered clean and/or sterile. The main disadvantage, of course, is that this adds further complexity to an already complex device. One example of a disassemble-able device is shown in Figure 30. This laparoscopic instrument breaks into 4 separate pieces and allows the tightly packed shaft and connecting handle to be cleaned in a way that otherwise would not be possible.

Figure 30: Image of a disassemble-able instrument taking during one CSSD visit.

Whenever possible, it is best to design dissemble-able devices to be compatible with the sterilization process in their assembled form. This is because after sterilization, the device cannot be handled again until it is in the operating room, which leaves only the surgical staff to reassemble and inspect the device before surgery. Among other things, this takes time away from that staff, and is not the ideal situation to be in if any assembly problems arise. Some studies have been done on this topic, with results suggesting that most laparoscopic instruments can be reassembled before sterilization without increasing the risk.[93,94] However, a more recent review of the research suggests that more studies still need to be done before a conclusion is reached.[95]

Further design considerations when designing a disassemble-able instrument include not requiring extra tools to disassemble the device, and not using any small parts which can be easily misplaced or are difficult for the fully garbed worker to work with.

C. Flushing

When disassembly is not an option, another option may be flushing the device. All the Dutch CSSDs visited during the research for this report have ample means to hook a device to validated flushing equipment. Nowadays it is often even possible to find devices which combine flushing with ultrasonic cleaning.

One advantage of flushing compared to disassembly is that it may require far less effort to implement in a design. That said, the greatest disadvantage with this strategy is that after cleaning there is often no way for the CSSD to verify whether the internal components are adequately cleaned after flushing. It can also be a big challenge to design a device in which the flow through the entire fluid path is even and sufficient to clean all internal surfaces.

One very prevalent example in this shortcoming of this design strategy can be seen in one of the multiple use attachment for the DaVinci surgical robot. This device is flushable, but not disassemble-able. With no way to inspect, there is also no way to be sure it has been properly rendered clean. A study done in a German magazine found that only following the manufacturer's IFU for this device when reprocessing is insufficient. As can be seen in Figure 32, the flushing process described in the IFU left a lot of debris behind after many uses. [96]

Another example of the risks of relying on flushing to clean the internals of a device can be seen in an arthroscopic shaver which is distributed by Smith and Nephew. The top image in Figure 31 shows the assembled shaver, and the bottom one shows the path which the debris is sucked through and which must later be cleaned. Smith and Nephew performed an investigation in which they inspected 78 of these devices across 12 different medical facilities after they had been reprocessed and reused man times. Of the 78 devices inspected, they found that 95% still had unacceptable staining or residue remaining on the internal surfaces. The two biggest problem areas were the lumen step and drive fork.[97]

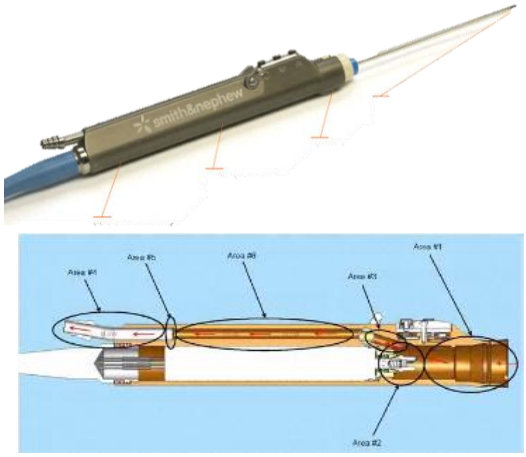

Figure 31: The Smith and Nephew arthroscopic shaver (top). A cutaway view of the device (bottom) which shows the flushing path.[97,98]

After the study, Smith and Nephew set out to improve the results of the C&S process. They tried using ultrasonic cleaners and exposing the devices to longer cleaning times. Neither approach worked. In the end, the only approach they found which gave satisfactory results was to provide custom cleaning brushes to all the CSSDs to aid in the cleaning process.

Flushing is a popular strategy, but it is also one which must be approached with extreme diligence. The designer should give careful thought the fluid path, and design the path so that the flow is adequate for cleaning all surfaces within the device. If there is concern that flushing alone may not be adequate, custom cleaning tools or simultaneous use of ultrasonic cleaners may also help.

D. Encapsulation

The final option for dealing with the cleaning of complex devices is encapsulation. If there is a portion of the design which cannot be cleaned under normal circumstances, or through disassembly or flushing, then the only option is to make sure it never gets dirty in the first place by encapsulating it. This is perhaps the easiest option with respect to reprocessing, but, as was seen with the cable ring grasper, it can also be the very challenging for the designer. When done

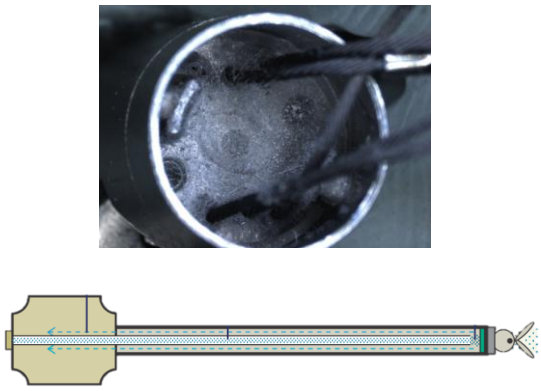

Figure 32: The DaVinci Endowrist device Top image shows the contaminants which remained in the device after cleaning per the manufacturer's instructions. The bottom image shows the flow path for flushing the instrument. [96]

Figure 33: Two device which rely on encapsulation to protect uncleanable portions. Top is a drill driver from ConMed. Bottom is an endoscope from Olympus.[99]

correctly, there should be only smooth, easy to clean and easily inspected surfaces remaining. As shown, it is also crucial to be able to guarantee the integrity of the seal over the life of the instrument, and also must often find a way for the encapsulated components to communicate with the outside world (either mechanically or electrically) in order to fulfill their purpose.

In addition to the proposed redesign of the cable ring grasper, some other examples of this design strategy can be found with surgical power tool and endoscopes. The surgical drill driver pictured in Figure 33 (top), for instance, is completely sealed to protect the electric motor during cleaning and sterilization. The endoscope shown below that also has all its steering component sealed from debris, which provides a single outside surface which is much easier to clean (it is worth noting, however, that endoscopes are usually only disinfected and rarely sterilized).

If there is a risk that the seal could fail, then this should also be considered. When this is the case, it must be safe for the internal components to come in contact with the patient's sterile tissue and fluids. This means that everything inside the device that is at risk of exposure must be made clean and sterile during manufacturing, and no toxic or otherwise dangerous parts should be used. Also, when failure is a risk, the integrity of the seal should be evaluated between uses. This is routinely done with endoscopes (see Figure 34), by attaching a pressure tester to a special port between uses. [100]

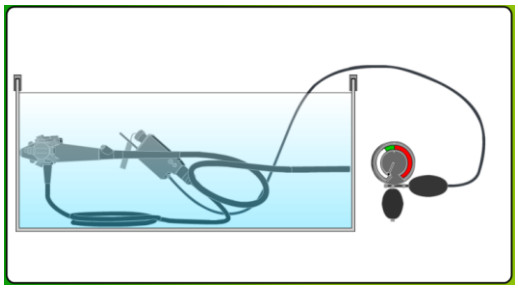

Figure 34: Image from Queensland Health interactive guide on endoscope leak testing. . [100]

Table 6: Material properties of the nickel cobalt alloy used in the bellows.

Yield strength	110,000 psi (758 MPa)
Tensile strength	125,000 psi (862 MPa)
Elongation	1.0%
Hardness	270 Vickers
Young's modulus	23,350,000 psi (161 GPa)
Metal hysteresis	Very low within stress limits
Density	0.321 lb./in^3

Appendix C. Analysis of the Final Design Bellows

In order to verify the bellows can withstand repeated cycling, an analysis is carried out here to verify that the bellows material never goes beyond its yield stress limit. This will be checked into ways. First the manufacture standard equation will be used. Second, Finite Element Analysis (FEA) simulation will be used to be sure.

As specified by the manufacture the nickel, cobalt alloy has the properties shown in Table 6.[101]

The manufacture does not give the Poisson's ratio for the nickel alloy, but since both nickel and cobalt have a Poisson's ratio of .31, it is assumed that the alloy combining both materials will be roughly the same.

Regarding the range of travel and lifecycles of the bellows, the manufacture provides a couple of equations which calculate this (all units are imperial). The equation for stroke rating with a given life expectancy of 100,000 cycles is:

$$S = \frac{.0010(O - I - t)^2 N}{t}$$

Where S is the maximum permissible stroke, O is the outside diameter of the bellows, I is the inside diameter, t is the wall thickness, and N is the number of folds.

The spring rate is given by the following question:

Table 7: Results of the two FEA simulations as compared to the results from calculating using the manufacturer's equations.

	Maximum stress	**Corresponding displacement**	**Corresponding force**	**Spring ratio**
Required values	<758 MPa (yield strength)	> 3 mm	Lower is better	Lower is better
ANSYS simulation	656 MPa	3.18 mm	1.36 N	0.43 N/mm
SolidWorks simulation	723 MPa	3.28 mm	1.45 N	0.44 N/mm
Manufacturers equations	Unknown	3.26 mm	6.62 N	2.03 N/mm

$$R = \frac{4.3E(O + 1)t^3}{(O - I - t)^3 N}$$

Where R is the spring rate in pounds per inch and E is Young's modulus.

Using the values above and the manufacturer's equations we get a maximum travel of 3.26 mm over 100,000 cycles with the force of 6.62 N at that maximum travel distance.

While these equations provide a good guideline, further checks should be done to be sure that this will work in the application as needed. Two Finite Element Analysis (FEA) simulations were performed, one using SolidWorks Simulation software, and another on the more powerful program called ANSYS. (Due to lack of computing power, only a section of the bellows could be modeled in the SolidWorks simulation; however, the displacements results for the two folds can easily be converted to results that represent 29 folds by multiplying by 14.5) In both simulations, the nonlinear option was enabled to account for the large relative displacement which occurs when compressing the bellows. The results from both simulations are shown in Table 7, ,and the stress distribution images (which show distribution of stress throughout the design) are shown in Figure 35.

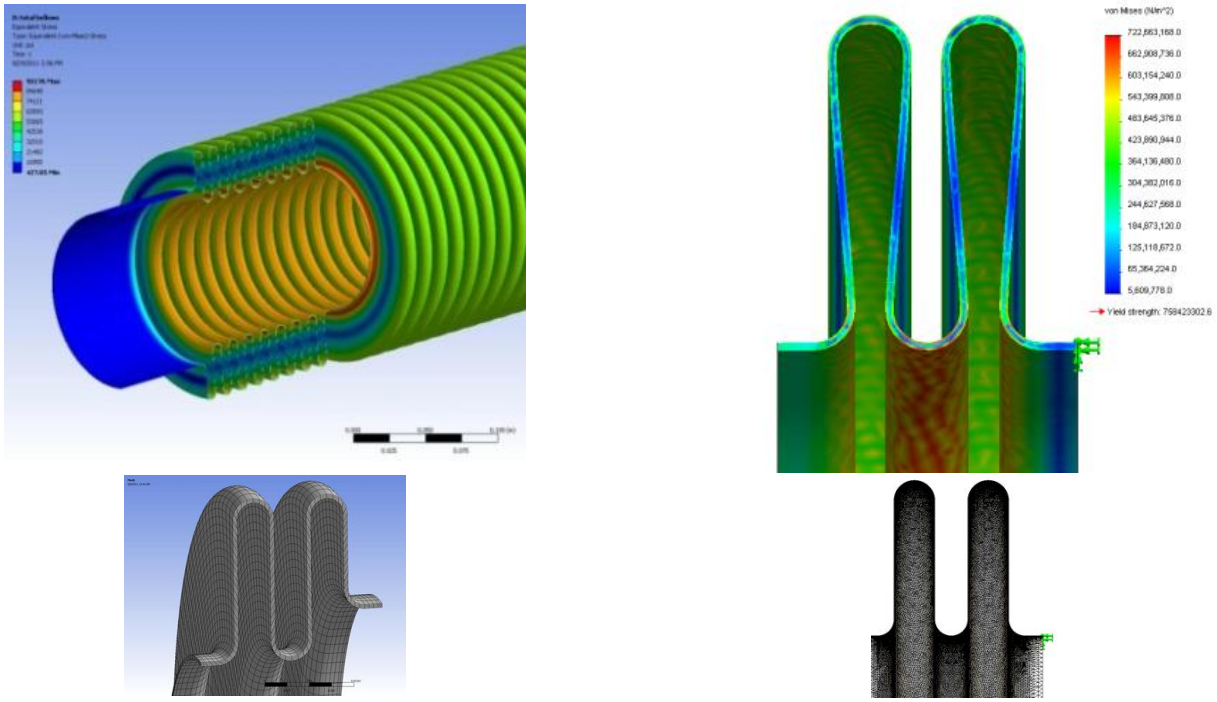

Figure 35: Stress distribution plots (top) along with the corresponding FEA meshes which were used to calculate them (bottom). The colors indicate the levels of stress, and have the values given in the legends. The left simulation was calculated using ANSYS. Blue is 427 psi (3 MPa) and red is the maximum value of 95176 psi (656 MPa). The Solidworks simulation is on the right. Blue is 6 MPa, and red is the maximum value of 723 MPa. All values are below the yield stress of the material, which is 758 MPa.

Table 8: Characteristics of three bellows which are similar to the design being analysed. The information is provided by the manufacturer in a brochure which accompanied the bellows shipment. (All units in newtons and millimeters)

	OD	ID	Conv Pitch	Wall thickness	Spring rate per Convolution	Spring rate for 29 convolutions
Typical #1	4.0	2.3	0.4	0.020	8.1	.28
Typical #2	4.0	2.3	0.4	0.025	15.8	.55
Typical #3	4.0	2.3	0.4	0.030	27.1	.93
As designed	4.25	2.44	0.42	0.023	??	??

Both simulation results returned similar maximum stress values, and nearly identical spring rates for the bellows. Both confirm what the manufacturer's equations suggested; the bellows remains within its elastic range during the required 3 mm of deflection. This, coupled with the manufacturer's assurance is a good endorsement for the use of this bellows in the final design. Ultimately, real world testing will need to be done to verify these numbers.

Verifying spring rate results

As can be seen in Table 7, there is a discrepancy between the calculated spring rate using the manufacturer's equation, and the results from the FEA analyses, so further analysis must be done to determine whether the error is in the FEA simulation results, or the manufacturer's equation. To do this, some additional information which is made available in a brochure provided by the manufacturer will be used. In addition to the equations for calculated spring rate, the manufacture provides a table with some typical design values. None of them precisely match the bellows that has been analyzed in this appendix, but three do get close. These three similar bellows are shown in Table 8.

By plotting the spring rate values for these three bellows, the spring rate of the bellows which is being analyzed in this appendix can be approximated. Applying the wall thickness of .023 mm to the chart Figure 36 gives a spring rate of approximately 11.5 N/mm. After dividing that by 29 to account for all the folds in the bellows, the approximate spring rate is given as 0.40N/mm. This gives a total force of 1.28 N at 3.2mm of travel, which matches the results from the FEA simulations quite nicely 1.36 N and 1.45N values calculated by the FEA simulations. This result suggests that the equation given by the manufacturer is inaccurate, and reinforces the results found by both simulations. An approximate force of 1.4 N at full travel is therefore assumed.

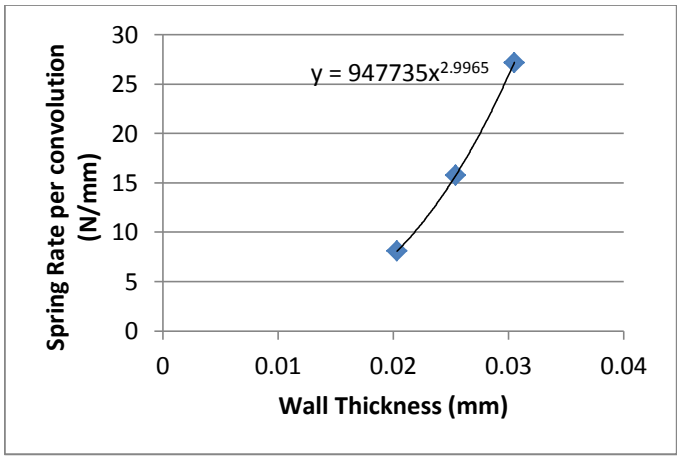

Figure 36: A plot which gives the spring rate of some example bellows. The chart can be used as a secondary check to estimate the spring rate of the bellows being analysed in this appendix reinforce previous findings.

Appendix D. vDSMH ASSESSMENT CRITERIA CHECKLIST

The checklist reproduced here is a useful reference. It was created by the Dutch Association for Experts Sterile medical Devices, and can be found in many CSSDs throughout the Netherlands. Its purpose is to help guide the inspector when reviewing a new reusable medical device for use in the hospital.

DSMH Vereniging van Deskundigen Steriele Medische Hulpmiddelen

ASSESSMENT CRITERIA
NEW REUSABLE MEDICAL DEVICES (RMD)

	Comply?	Standard	Points of interest
GENERAL			
Does it bear a CE mark?	Yes/No	(MDD)	- If no CE mark: is it a custom made RMD or a RMD for clinical investigation?
Does the manufacturer provide instructions for cleaning, disinfection and sterilization?	Yes/No	(MDD) (EN-ISO 17664:2004)	
Is the provided information sufficient?	Yes/No	- Conform the available processes in the Netherlands -In Dutch language	- Which detergent or disinfectant? - Which concentration? - Cleaning method (automated or manual) - At least one validated method - Which sterilization process can be used? (Steam, HPGP, EO, LTSF) - Are time and temperature in accordance with the processes in the Netherlands? (for steam: 3 min 134 °C or 15 min 121 °C?)
Does the manufacturer permit reuse?	Yes/No	- Permission is prerequisite (MDD art 12 paragraph 2 and Annex I) (NEN-EN-ISO 17664:2004)	- How many times can/may the medical device be reused? - When appropriate: is the required periodic maintenance or calibration feasible?
Are packaging requirements supplied?	Yes/No	(NEN-EN-ISO 17664:2004)	
TRAY/BASKET/CONTAINER:			
Is the tray made of stainless steel?	Yes/No		- No plastic trays/containers
Is the tray /basket/ container no obstruction to adequate cleaning, disinfection, drying and sterilization?	Yes/No	(B9210)	- Open mesh construction
Can the tray be packed adequately?	Yes/No	(NEN-EN-ISO 11607:2006) (R3210)	- No sharp rims or protrusions.
Is there enough space in the tray /basket /container for adequate cleaning and disinfection of the instruments?	Yes/No	- DIN/ISO measurements	- Not to many instruments in the tray - Good fixation - Fixation material doesn't obstruct cleaning
Is the size acceptable?	Yes/No	- Maximum size (l*w*h) 48*32*10 cm. (ISO)	
Are the instruments placed in multiple layers in the tray/basket/container?	Yes/No	- single layer	
Is the weight acceptable?	Yes/No	- < 8,5 kg (R3310)	- Including tray/basket/container
DESIGN			
Is the RMD submergible?	Yes/No	(NEN-EN-ISO 17664:2004)	
Can the RMD be disassembled?	Yes/No	(NEN-EN-ISO 17664:2004)	- If yes, are (dis)assembling requirements supplied?
Can the RMD be cleaned by ultrasound?	Yes/No	(NEN-EN-ISO 17664:2004)	
Does the RMD have holes or small lumens?	Yes/No	(R3120) (B9210)	
If yes, can the holes or lumens be visually inspected?	Yes/No	(R3120) (NEN-EN-ISO 17664:2004)	- Attention to instruments with a curved tip!
Can the holes and lumens be reached by flushing or brushing etc?	Yes/No	(NEN-EN-ISO 17664:2004)	
Is it possible to connect the lumens to the washer/ disinfector?	Yes/No	(R3120) (NEN-EN-ISO 17664:2004)	- Does the washer/ disinfector have the right flush connectors?
Does the RMD have a terminal lumen?	Yes/No		
Are length and diameter of the lumen within the sterilization standard?	Yes/No	- For a tube with one open end: the maximum length is 1500 mm with a diameter/length ratio of ≤ 1/750. - For a tube with two open ends: the maximum length	- How to clean? - It is possible to validate?

DSMH Vereniging van Deskundigen Steriele Medische Hulpmiddelen

ASSESSMENT CRITERIA
NEW REUSABLE MEDICAL DEVICES (RMD)

	Comply?	Standard	Points of interest
		is 3000 mm with a diameter/length ratio of ≤ 1/1500. (EN 13060)	
Are maintenance materials (e.g. lubricants) necessary?	Yes/No		- Specifications and requirements for the use of lubricants.
CHARACTERISTICS			
Can the RMD be processed in the cleaning-disinfection- and sterilization-processes of the hospital?	Yes/No	- Verify the supplied instructions to the local processes. - Resistance to the water temperature of 95°C. - Resistance to the drying temperature of >100°C. - Resistance to ultrasound cleaning. - Resistance to the steam sterilization temperature of 134°C or 121°C. - No restrictions on vacuum, pressure and or temperature changes.	- Materials other than: stainless steel, ceramic, PEEK, Titanium - What is the T_{max} of the materials used (°C)? - Are other sterilization methods possible? - Are special means or materials necessary for processing?
Are the chemical characteristics of the RMD compatible with the used cleaning, disinfection and sterilization processes?	Yes/No	(MDD)	- Specially coated instruments - Aluminium RMD will be damaged by the use of alkaline detergents (pH > 7)
Are there any known contraindications when using or processing according to the intended use?	Yes/No	(MDD)	- e.g.: silicon oil with silicon rubber, mineral oil with latex rubber

ABBREVIATIONS:

B9210	Dutch professional standard: Cleaning of instruments
CE	Conformité Européenne
DIN	Deutsches Institut für Normung (German Institute for Standardization)
DSMH	Expert Sterile Medical Devices (Dutch)
EN	European Standard
EO	Ethylene oxide Sterilization
HPGP	Hydrogen peroxide Gasplasma sterilization
ISO	International Organization for Standardization
LTSF	Low Temperature Steam Formaldehyde Sterilization
MDD	Medical Devices Directive
NEN	Standard of the Dutch Standardization Institute, the NEN
PEEK	PolyEtherEtherKeton
RMD	Reusable Medical Device
R3120	Dutch professional standard: Use of instrument (batch) washer disinfectors
R3210	Dutch professional standard: Packing of medical devices to be sterilized in health care facilities and sterilizing companies
R3310	Dutch professional standard: Loading and unloading of sterilizers
T_{max}	Maximum temperature