Final Report:

# PART I – IMPLEMENT PHASE

## 1. Summary of SREENING PHASE And DESIGN(3 pages)

### Strategic focus and Selected Need statement (including evidence data/references that if solved the outcome would improve) (Half a page)

### TO DO

### Summary of full selected concept/solution.(2-3 pages) Include and justify detailed design specifications to meet needs specifications (recall need criteria, must haves and nice to have table). You may need to go back and search specific information related to your concept about disease fundamentals and epidemiological data.

### TO DO

## Prototype Design and Testing

### Proof of Concept prototype. Specify the question about your concept that you are answering with the prototype. Detail the design of the prototype and the parts that have been implemented.

In order to solve the needs posed by the problem associated with the use of the current models of laparoscopic trocars, the following questions have been asked and the answers will be answered and validated using the prototype.

The questions are as follows:

**Is it possible to prevent the generation of wounds and tears when performing abdominal laparoscopic surgery?**

Actually due to the technique used so far and the need to have to penetrate inside the abdominal tissue so far no new solution has been thought to avoid these wounds or tears, therefore it is not possible, so there will be Than to think in another way to solve this problem.

**Is it possible to treat these wounds and tears in ways that reduce their implications?**

Currently in certain medical interventions are used technologies that allow intervention on tissues of the human body avoiding the generation of wounds an interesting point would be the study of these techniques and transfer the technology and the method used to the intervention devices of operations of laparoscopic surgery.

**- Is it possible to use high frequency to cauterize wounds inside the abdominal cavity provoked by laparoscopic instruments?**

Traditionally, a classic scalpel is used to make incisions on the skin. From the 1970s a new way of cutting the skin has appeared electro surgery, which uses high frequency to make the incision. Studies have shown that these devices made the procedure more quickly, with less blood loss, less postoperative pain and less adverse effects on wound healing [1].

**-  Is it possible to generate a high frequency system in a cylindrical mould? Is it possible to insert it in a shape like a trocar?**

It was found in literature a patent of a trocar composed by an electrical component inside the trocar, so one can admit that this system will also be able to be composed by a high frequency system [17].

**-  Is it possible to generate high frequency, in the operating room? And handle with high frequency?**

The operating room included a laparoscopy system with instrumentation for general surgery. This system includes a high frequency generator which is commonly found in operating theatres. Once we are dealing with bipolar, the high frequency current will only flow between the two electrodes on the scalpel and not through the rest of the patient’s body. And there is no need of position a neutral electrode in the patient [2] [3] [13] [14].

**-   Is it possible to cauterize the tissues without harming the ones around it?**

The high frequency system will only cauterize the tissues that are in contact with. This means that the burning of tissues around will only depend on the surgeon's ability,

**-   Is it possible that the high frequencies burn the patient in unwanted areas?**

There are two types of potential complications related to the use of high frequency scalpel – mechanical trauma and electrothermal injury. The electrothermal injury can occur from an unrecognized energy transfer in the operational field or, less commonly, to unnoticed stray current outside the laparoscopic field of view. The current can dissipate due to insulation failure, direct coupling, or capacitive coupling. When applied in the appropriate way, is safe and effective but is very dependent on the surgeon’s technique and the patient’s anatomy.

In contrast to the monopolar method, in the bipolar method the energy flows between the isolated halves of special tweezers. No neutral electrodes are necessary and less energy is required owing to the essentially smaller high-frequency field between the two halves of the electrode-50 (W) as opposed to 400 (W) with the monopolar technique. This will diminish the risk of burns almost to none. [4]-[8] [15]

**-   Is it possible to isolate the system in a way that will not burn the surgeon?** [16]

Once the system will be composed by a bipolar scalpel, and as seen before the energy will only be transferred between the tweezers, and it will be surrounded by the trocar, composed by plastic – which has low electrical and thermal conductivity, the probability of burns and over heat is small.

With these ideas comes a first idea of ​​design:

Our design is lowered to modify the real model of the trocar to incorporate a system of high frequency that can be turned on and off when the surgeon wishes, thanks to the technology of the high frequency it is possible to cauterize the torn tissue avoiding complications and second Interventions due to these wounds.

On the other hand this new design has thought so that the device can be reused as many times as to allow the materials that makes it, leading to a great cost savings for our customers. To achieve this we have thought of dividing the trocar into two parts of a plastic that by means of a screw mechanism to assemble and disassemble easily allow inside it a second piece of conductive metal material that is the one that conducts the high frequency alternating current, It is thought of in this way because the metal is the most expensive component of this device has an almost unlimited use while the plastic is vulnerable to degradation by the use before, in this way when this happens only that the plastic housing is replaced and not the entire device.

In relation to the previous questions and trying to put a test the answers found and to solve the unanswered ones will make a schematic of the different design modules and the evidence that the rest of all things that appear in all the questions that in the end come that relate to the design have been grouped as follows:

* The prototype design will be based on three parts:

First, design of the prototype and second implementation plan of the prototype, and third testing plan of prototype.

Our design in order to cover all the aspects mentioned in the first point has been decided to separate in two blocks in order to evaluate the potential risks that suppose this idea:

* Design of the high frequency system.
* Detachable protective case design

Both parts of the design will be evaluated by the following aspects.

They meet the requirements of:

* Functionality
* Easy to Use
* Durability
* Security

|  |  |  |
| --- | --- | --- |
| Requirements: | High frequency System | Plastic Shell |
| Functionality | The system will be based on the technology that uses the electric knife to cauterize wounds therefore applying the same technology to this design our device would be able to cauterize the tissues affected by the tear of the blade solving the problem of the generation of ideas | System of support for the device that maintains a form similar to the original one that allows to use this device by way of trocar fulfilling the functions of the same while acting as insulation for the system of HF |
| Easy to use | Being an existing technique will not be an added complication for surgeons to apply, and our design will be equipped with a system that allows its implementation in the simplest and most intuitive way possible | This part of the device must have a very simple design that allows mounting and disassembling it in a very easy way to be able to introduce the HF device inside. |
| Durability | The metal used for the conduction of the high frequency current must be resistant to the passage of it avoiding loss of the properties of the metal.  Said metal must also withstand the thermoelectric effect generated by the current so it must also have adequate thermal resistance.  The metal must also withstand high pressures without losing its properties to adequately carry out the sterilization process in order to be reused, that it would be based on Steam Sterilization (AUTOCLAVE) | In this part of the device you have to take into account several points:  The dismantling system can withstand many uses without being damaged.  That in the contact of the HF system does not produce formations or alterations in the material.  Also be resistant to high pressures for sterilization in order to be reused. |
| Security | Such a system should be safe both for medical staff and for patients.  An insulation protector must be designed to avoid contact between the metal and the surgeon  The high frequency device should only act on the desired tissues avoiding causing damage on healthy tissues or unwanted areas. | That the system is safe in terms of structure to prevent its dismantling involuntarily or degradation during its use, in addition to being a biocompatible material that does not pose any problem against the health of the patient. |

**Detail plan for the prototype design (First Part):**

Design steps of the prototype:

* Search and choice materials.
* Design of the high frequency system
* Design of the shape of the structural part
* Assembly / Dismantling System Design

**Search and choice materials:**

For the housing it has been thought of XXXXXXX .., said material has insulating characteristics for the current, in addition to a sufficient thermoelectric voltage resistance to perform its function in a correct manner.

For the high frequency system, martensitic stainless steel has been chosen as material. This material can cut the tissues, and a cutting edge can be formed in the material for this purpose. This material presents ideal conductive properties, as well as resistance to degradation presented by very high thermoelectric voltages; the surgical steel family has little reactivity with the human body and minimizes allergies and adverse reactions. In addition, it does not corrode in environments in contact with biological fluids and can be sterilized by autoclaving which will allow reuse and sterilization without problems.

**Design of the high frequency system:**

The high Frequency system will be based on a source of current of low intensity but high Frequency, connected by two cables, (Vcc, Gnd) to the metallic material thus conducting the current and allowing generating the cauterized voltage.

This current will be activated or deactivated at the surgeon's discretion when it is considered opportune only to insert the hoses into the hole that allows the trocar to be connected to the source.

**Design of the shape of the structural part:**

For this section we will try to ensure that there is minimal dispersion of shape and dimensions with the current trocars, it is only necessary to take into account that inside this design will be inserted the sheet of conductive metal.

**Design assembly / dismantling System:**

This mechanism will serve to mount and disassemble the housing the initial idea is a threaded mechanism with double travel in such a way that halfway through the housing is unlocked, and at the end of the path is the metal part that is unlocked which allows a Easy access to assemble and disarm quickly and in a very simple way, "mechanism similar to that of a bottle cap".

**Prototype Implementation plan (Second Part):**

The design of the prototype will be carried out through stages or different phases:

- A first version of the prototype will serve to verify that the dimensions of our design remain consistent with those of the current trocars in order to be able to carry out laparoscopic interventions without incidences as they have been done up to now.

That is to say, to create a prototype that serves to validate the new removable design that will allow disassembling the device to be able to reuse the parts, while maintaining the proportions in such a way that it does not hamper the work of the surgeons and allow to enhance the intervention with normality.

- A second version of the prototype will be made with the materials chosen in the design phase of the piece that will serve as a high frequency cauterizer, and do so in a way that is compatible with the structure of the first prototype to be able to integrate it into the, ensuring that the product is functional and that complies with the mission for which it was designed without ceasing to guarantee the aspect of the first version of the prototype that is fundamental for the development of this idea.

- A third version of the prototype and this would be the last would be to replicate the two prototypes mentioned above but using this time high quality materials and a precise and high quality assembly (look for synonym), with a professional and industrial manufacturing equipment and specialized.

*Technical testing systems:*

* **Testing by modules:**

**Test of the high frequency system:**

1. Prove that it is possible to generate the desired current in fact that the amperage does not imply a problem and that the frequency is necessary to produce the cauterization.
2. Prove that the metallic material does not suffer loss of properties after supporting the electric current.
3. Prove that the metallic material does not suffer an abrupt increase in temperature that may lead to deformations in the plastic
4. Prove that the metallic material does not suffer degradation of its properties before the exposure of high pressures, because of Steam Sterilization (AUTOCLAVE).

**Testing of the plastic material module:**

1. Test at what temperatures the plastic material deforms
2. Test the physical resistance of the material to stress stresses
3. Test the resistance of the plastic to the contact of the high frequency metal material
4. Test the handling as well as the armature and disarm system of the plastic housing

**Testing of plastic + metal module:**

1. Prove that the interaction between the two modules does not produce degradation in the compound.
2. Prove that the system is isolated for use.
3. Prove that the system is comfortable manageable and easy to use.

**Plan of prototype:**

|  |  |  |
| --- | --- | --- |
| Work package | Milestone | Time expectation |
| Prototype design | Search and choice materials | 5 days |
| Prototype design | Design of the high frequency system | 5 days |
| Prototype design | Design of the shape of the structural part | 5 days |
| Prototype design | Assembly / Dismantling System Design | 5 days |
| Prototype Implementation | High Frequency System | 7 days |
| Prototype Implementation | Plastic Shell | 7 days |
| Testing Module | Test of the high frequency system | 7 days |
| Testing Module | Testing of the plastic material module | 7 days |
| Testing Module | Testing of plastic + metal module | 7 days |

### Prototype(s) construction. Several iterations would be desired. Specify phases in the development and steps taken to refine the prototype.

The construction of the different prototypes will be carried out sequentially but in an analogous way.

Fases de la construcción detalladas:

**First prototype model:**

* First we will take a dimensioned scheme of the current trocar models to try to replicate the dimensions and form to implement it in our design.

Following this we must take into account that the modifications that we are going to include are not incompatible with this.

* Second, after designing the size and format of our trocar, we will use a 3D design simulator to carry out a representative model of the trocar.

For this first prototype it has been thought to make use of the tool of 3d design of free software TinkerCad pertaining to the software of autodesk.

* Third, these designs will be printed in 3d to be able to corroborate the validation of the first prototype.

**Second prototype model:**

This second model is based on the creation of the "metallic" component that will allow conduction and cauterization based on high frequency. The dimensions of the previous prototype must be taken into account in order to adapt this new adhesion to it.

The phases for its development will be analogous.

* First, a sketch of the dimensioning of this part
* Second it will take this scheme dimensioned to design in 3d by means of software simulator.
* Third this new piece will be printed and it will be verified that the design is compatible with the dimensions of the first prototype.

**Third prototype model:**

As already mentioned this prototype will already require an industrial and professional equipment so we cannot carry it out, our work in the construction will be:

* First rigorous design with specialized software of all the pieces and dimensions of which the design conforms.
* Second selection of more specialized and suitable materials.
* Third, contact and commission a manufacturer to develop this prototype

### **Prototype testing.**

Las pruebas que se realizaran sobre los prototipos deben abarcar(cubrir) los siguientes aspectos:

Funcionalidad, seguridad, dimensionado……ç

Un inciso : la cosa es como dividir las pruebas en dos grandes grupos, las generales que son las d seguridad ergonmia diseño…. Y luego las especificas que se basaran en demostrar que cada modelo unciona y además cumple con los general.

Pruebas específicas sobre el primer prototipo.. ver que se desmonta y monta muy faculmente pero cuando keremos no que se desmonta de repent cuando le sale de la poya.

## 3. Clinical Validation

### 3.1. Motivate the clinical strategy within your product development (1 page)

### 3.2. Short term validation (1-2 pages) Define a preliminary clinical validation, cohort, population, testing, that could enable the clinical testing of a prototype as the one defined. Include here any preliminary results of the contrast of your prototype with the clinical environment.

### 3.3. Plan the outline of the clinical validation that would be needed to fulfill the regulatory requirements (1-2 pages) Go back to Regulatory basics and Clinical Strategy as well as inspiring similar products clinical validation.

## 4. References

## 5. Annex I- Details of Prototype design

## 6. Annex II- Details of experimental testing including interviews regarding the constructed prototype.

## 7. Author contributions