REDESIGNING OF LAPAROSCOPIC MONOPOLAR HOOK

THESIS IN PRODUCT DESIGN 2018

Submitted by: DHRUV MISHRA AU140020304001P/SSD/B.Des.(Product Design)

Guide: Surabhi Khanna





SUSHANT SCHOOL OF DESIGN ANSAL UNIVERSITY, GURGAON, INDIA







SUSHANT SCHOOL OF DESIGN ANSAL UNIVERSITY, SECTOR 55, GURGAON – 122003, HARYANA

BONAFIDE CERTIFICATE

This Thesis is submitted by <u>DHRUV MISHRA</u>, student of Fourth Year B. Des. Session 2014-2018, at Sushant School of Design, Gurgaon, as partial requirement for the Four Year B. Des. Degree course of Ansal University, Gurgaon.

Originality of the information and opinion expressed in the Thesis are of the author and do not reflect those of the guide, the mentor, the coordinator or the institution.

Signature of the Student: Roll No.: AU140020304001P Name: DHRUV MISHRA Signature of Guide Name: SURABHI KHANNA Date:

Signature of Coordinator Name: SURABHI KHANNA Date:

Institution Stamp & Signature of Coordinator Date:



Thesis Document submitted in partial fulfillment of the Product Design Department at Sushant School of Design, Ansal University Student name: Dhruv Mishra Faculty guide: Ms. Surabhi Khanna Designation: Head of Department – Product Design

Copyright © 2018 Product Design Department, Sushant School of Design, Ansal University All rights reserved. No part of this publication may be reproduced, distributed, or transmitted in any form or by any means, including photocopying, recording, or other electronic or mechanical methods, without the prior written permission of the publisher, except in the case of brief quotations embodied in critical reviews and certain other noncommercial uses permitted by copyright law. For permission requests, write to the publisher. Design and Edit: Dhruv Mishra Printed in New Delhi, Delhi

Acknowledgement

I'd like to acknowledge the efforts and support I've received throughout this eventful journey of learning.

Sushant School of Design, for all the education, experience and learning I've received through them and for providing me with the knowledge and skills essential to make this document and more ahead.

Director Mike Knowles for his relentless push and belief in me.

Ms. Surabhi Khanna, for her unbroken mentorship and kindness which helped to rise whenever I faltered. All my teachers and staff at SSD, for always supporting, believing in me and helping bring out the best in me.

To my batch mates, Henna Khanna and Bhanu Adhikari, without whom I would have no one to beat.

To Suhail Gandhi, Pulkit Rajendran, Adit Handa, Alinda Sharma and especially Ayushi Raj Dua for making college the best experience of my life.

To IIT-Mumbai's BETiC Cell for introducing me to this problem and my teammates, Ninad Watwe, Dr.Nitish Sancheti and Yash Gupte. Thank you for providing your insights and letting me take this project forward.

Mr. Pankaj Kumar Rai at the World Laparoscopic Hospital, Cyber City, Gurugram, 122002 And above all, to my parents who supported my decisions and stood by me throughout my life. I am nothing without them.



About Ansal University

The legacy of the Chiranjiv Charitable Trust in the realm of higher education goes back to 1989, when the foundation of the Sushant School of Art and Architecture was laid by Mr. Sushil Ansal, to address the gap in Indian architectural education. The School was conceived with the objective of combining traditional Indian aesthetics and modes of urban planning with the needs of a modern cityscape. As the School made a mark in the field of architectural education under the guiding force of late Fellow of the Frank Lloyd Wright Foundation, Padma Shri MM Rana, the Trust further expanded to establish the Ansal Institute of Technology in the year 2000 that received international recognition in the field of research, extension and global collaborations. The Sushant School of Design was instituted a decade later and in 2012 the 'Sushant Group of Institutions' came under the Ansal University, established through the legislation of the State of Haryana under Haryana Private Universities Act 2006.

http://ansaluniversity.edu.in/about-us/about





About Sushant School of Design



SSD was established in 2011. "We work towards nurturing our students who shall further go on to lead the communities and organizations of the future, where they can apply their talent &knowledge and conduct their work with the rigor and steadfast purpose that is common to all great institutions.

In keeping with the University's vision for the future, the Sushant School of Design is constantly reinventing itself to adapt to and work upon the challenges facing society today. We hope to create not just Designers but Design Thinkers who could go on to use the medium as a way of developing society.

Sushant School of Design solutions are essentially centered around the end user. Thus, design education and training at Sushant School of Design (SSD) are centered on the trainee learning all the skills needed to cater to the end user various aspects of the Design Industry. At Sushant School of Design, the curriculum is planned and progressed upon, keeping in mind the student's individual potentials and the abilities that one has to learn to benefit maximum from the facilities provided. Combination of research and practical studies gives students a holistic approach. It also gives the ability to think and develop designs in such a way that they create an individual style, which will stand out when they start working on professional projects. Placement Support: Entire Corporate Relations Team Working for you, in addition to an existing mandatory semester-long internship program in the final year of study along with many shorter opportunities."

http://ansaluniversity.edu.in/sushant-school-of-design

Product Design Course

Product Design course, which started in 2015, is a four-year degree program. It has to do with one's creative skills, methodological process and aesthetic alertness to design a vast range of products. As a product designer one is to address the plausibility of a variety of 3 dimensional design solutions addressing both problems and needs. In this course an in-depth understanding of materials, anthropometrics, behavioral psychology and production processes is inculcated in order to help the students find sustainable solutions that answer industry and consumer needs. Ansal University provides you one of the best custom designed product designing course of the industry. Product Design at SSD has academic collaboration with School of Architecture and Design, King Mongkut's University of Technology Thonburi Thailand. This encourages student exchange program, the first one at the school of design, Ansal University

http://ansaluniversity.edu.in/sushant-school-of-design/programmes/undergraduate/product-design





Contents

1.	Introduction	. 11
2.	Synopsis	. 11
3.	Aims and Objectives	. 11
4.	Research Methodology	.12
5.	Research	13
5.1	Cautery	. 13
5.2	Electrocauterization	. 13
5.3	Basic Principles	. 14
5.3.1	Joules Law	. 14
5.3.2	Work	. 14
5.3.3	Ohms Law	. 14
5.3.4	Current	. 14
5.3.5	Voltage	. 14
5.3.6	Resistance	. 14
5.4	Principles of Electrosurgery	. 14
5.4.1	Current Density	. 16
5.4.2	Time	. 16
5.4.3	Electrode Size	. 16
5.4.4	Tissue Conductivity	. 16
5.4.5	Current Waveforms	. 17
5.4.6	Electrosurgical Units	. 17
5.4.7	Electrosurgical Modalities	. 18
5.4.8	Dispersive Plate and Neutral Electrode	. 18
5.4.9	Causes of Burns	. 19
5.4.10	Guidelines for the usage of Electrosurgical Unit	. 20
6.	Monopolar Hook	. 22
6.1	What is it	. 22
6.2	Where is it used	. 22
6.3	How does it function	. 23
7.	Visit to World Laparoscopy Hospital	. 23
8.	Case studies	. 24



8.1	Case Study 1	24
8.2	Case Study 2	25
8.3	Case Study 3	25
8.4	Case Study 4	26
8.5	Discussion	27
9.	Issues and Risks	30
9.1	Unwanted Cautery	30
9.2	Wound Dehiscence	30
9.3	Hematoma	30
9.4	Strictures	31
10.	SWOT Analysis	32
10.1	Strengths	32
10.2	Weaknesses	32
10.3	Opportunities	33
10.4	Threats	33
11.	Design Process	34
11.1	Ergonomic Study	34
11.2	Sketches for form of Handle	37
11.3	Model Making and Prototyping	38
11.4	Final Outcome	39
11.5	Solutions and Recommendations	41
11.5.1	Move lever not shoulder	42
11.5.2	Auto cut-off with spring	42
11.5.3	Hole for venting smoke	43
11.5.4	Ergonomic handle	43
11.6	Materials used for the product	43
11.6.1	Handle	43
11.6.2	Rod	44
11.7	Production	44
11.8	Dimensions and Working Drawings	44
12.	Product Image Analysis	45
12.1.1	Ergonomic Handle	45
12.1.2	Index Finger Trigger	46
12.1.3	Auto Cut off	46



12.1.4	Smoke Vent	47
13.	Limitations	48
14.	Feedback	48
15.	Conclusion	49
16.	Webliogpraphy	50
17.	Annexures	51
1.	Sterilization Tests	51



1. Introduction

The last year of four year Product Design course at Sushant School of Design is a Thesis Document. Thesis gives students exposure to work in a professional environment where they get to work on real life industry projects where they are required to perform creatively under given constraints and come up with viable and practical solutions. It helps to develop a comprehensive ability to understand market, technology, production, construction, finishes, design principles. This amalgamation of the knowledge with the practical understanding forms the last key steps towards ending the degree course successfully. Final phase of this learning period is 20 weeks Graduation Project with a company which aims at testing a student's design knowledge and management gained in four years.

It also entitles a student to develop traits like team work, patience, sincerity, time management, work efficiency and the willingness to learn constantly in a corporate environment.

2. Synopsis

The project brief was to redesign the laparoscopic monopolar hook. The concept was to reduce the harm brought to the patient via this essential device.

This was based on the concern that a wide variety of surgical traumas are associated with this device and its usage. Also patients with specific ailments (like usage of pacemaker) could not take advantage of this surgery.

The product developed is an entirely hand controlled tool, which runs with electricity and can be operated by one surgeon. The unique selling point of this product is that it

- Provides surgeon with easier and more precise grip
- Removes need of patient contact plate
- Reduces unwanted cautery
- Reduces post-surgery trauma
- Gives surgeon more control over abdominal space and reduces irregular movement of the laparoscopic monopolar hook

It has been consulted upon with surgeons and doctors from eminent hospitals and their inputs and advice has led to creation of this new and improved laparoscopic monopolar hook.

3. Aims and Objectives

The aim of this document is to provide with a viable solution via design intervention to an existing problem in the bio-medical field of surgery. Along with this, the designer also wants the reader to have an in-depth knowledge of the field to understand why and how the product/ change/s are made.

Objectives

- 1. To gather information on said topic
- 2. Make reader understand the workings of the said product
- 3. Analysis of Information
- 4. To evaluate where existing product lacks



- 5. Deduction of problem/s
- 6. Solving problem/s with design intervention
- 7. Proposing change/s to said product or creating a new product
- 8. Proposing materials and methods for alteration/ creation of said product
- 9. Providing study and said product

4. Research Methodology

As the designer had little to no knowledge about the bio-medical field, experts were consulted for the same. After meeting some surgeons and general physicians, and past experience at IIT-Mumbai's BeTiC Cell's competitions the topic was chosen.

Two methods of research were employed in this thesis.

- The first being one-to-one interactions with medical practitioners such as surgeons and surgery aspirants, as well as general physicians. A plethora of concerns, inputs and data was collected via word-of-mouth and first-hand experience.
- The rest of the research was done via hospital visits, surgical institutions and the Internet. As a lot of red tape is involved due to patient-doctor confidentiality, the case studies provided were only on paper, when shown; and using them in one's thesis was not allowed. Hence, similar case studies were extracted from the Internet to allow the designer and this document's readers a better understanding of the issue at hand. Thus, the other research method is secondary research via notable and trustworthy medical websites.
- Secondary research through online studies from medical journals
 - 1. World Journal of Laparoscopic Surgery: http://www.wjols.com/
 - 2. Journal of Minimal Access Surgery: http://www.journalofmas.com/
 - 3. Laparoscopic Surgery: http://ls.amegroups.com/
 - 4. Free Medical Journals: http://www.freemedicaljournals.com/

5. Research

5.1 Cautery

The medical practice or technique of cauterization is a medical term describing the burning of part of a body to remove or close off a part of it in a process called cautery, which destroys some tissue, in an attempt to mitigate damage, remove an undesired growth, or minimize other potential medical harmful possibilities such as infections, when antibiotics are not available. Cauterization was used to stop heavy bleeding, especially during amputations. The procedure was simple: a piece of metal was heated over fire and applied to the wound. This would cause tissues and blood to heat rapidly to extreme temperatures (*Fig 1*) in turn causing coagulation of the blood thus controlling the bleeding, at the cost of extensive tissue damage.



Fig 1: Cautery done using a hot pike to seal open wounds, in medieval times

5.2 Electrocauterization

Electrocautery, also known as thermal cautery, refers to a process in which a direct or alternating current is passed through a resistant metal wire electrode, generating heat. The heated electrode is then applied to living tissue (*Fig 2*) to achieve hemostasis or varying degrees of tissue destruction. Electrocautery can be used in various minor surgical procedures in dermatology, ophthalmology, otolaryngology, plastic surgery, and urology.



Fig 2: Cautery being done via electricity



5.3 Basic Principles

Below is the basic knowledge required to know and understand in order to understand the workings to the laparoscopic monopolar hook. It is essential to understand how the existing device works in order to grasp how the design student has made changes and how they help the surgeon and patient together.

5.3.1 Joules Law

Joule's first law shows the relation between heat generated by an electric current flowing through a conductor, $Q = i^2 Rt$

5.3.2 Work

Energy in wattage (power) is the product of current and voltage. Power is the amount of current times the voltage level at a given point measured in wattage or watts (W). It corresponds to the rate of work being performed, W=V×I.

5.3.3 Ohms Law

Ohm's law, I=V/R, shows the relationship between the properties of electrosurgical energy.

5.3.4 Current

Current (I) is what flows on a wire or conductor like water flowing down a river. Current flows from negative to positive on the surface of a conductor. Current is measured in amperes (A) or amps.

5.3.5 Voltage

Voltage (V) is the difference in electrical potential between 2 points in a circuit. It is the push or pressure behind current flow through a circuit and is measured in volts (V).

5.3.6 Resistance

Resistance determines how much current will flow through a component. Resistors are used to control voltage and current levels. A very high resistance allows a small amount of current to flow. A very low resistance allows a large amount of current to flow. Resistance is measured in Ω ohms.

5.4 Principles of Electrosurgery

A basic knowledge of electricity is required to use electrosurgical technology in operating rooms for patient care. Atoms are composed of protons, neutrons, and electrons. Electric current flows as electrons move from one atom to another through an adjacent circuit. Voltage is the force that drives the movement of electrons; it is the current driving force against the circuit resistance. When electrons encounter this resistance, there is heat. And for current to flow, a continuous circuit is needed. Electricity has three basic principles:

(1) It always follows the path of least resistance;

- (2) It always tries to return to a reservoir of electrons, such as ground; and
- (3) There should always be a complete circuit.

Much of the understanding of how electrosurgery works, as well as the complications related, is based on these principles. In the operating room, the circuit is composed of the electrosurgical unit and the patient and the active and return electrodes. The principle of electrosurgery is based on the passage of high frequency electrical current through target tissues to achieve a desired clinical effect. Voltage is supplied by the generator, which from the common alternating current of low frequency (60 Hz) generates electric currents of very high frequencies (0.4–3 MHz) and high voltage (400–500 V). The current released through an active electrode goes through the patient's body, whose tissues determine the resistance (impedance) to the current flow. At the end of the circuit, the current flows out of a neutral electrode, which is the dispersing pad or neutral electrode, and returns to the electrosurgical unit, forms a single circuit, without need for grounding. (*Fig 3*)



Fig 3: Isolated circuit: the power released through the active electrode travels through the patient's body, exits through the neutral electrode, and returns to the electrosurgical unit.

Heat generation is described by Joule's Law, which is expressed by the equation:

$$Q = i^2 R t$$

In which the heat produced (Q) increases proportionally with the square of the current intensity (I), with the duration of exposure to the current (t) and tissue resistance (R).

Thus, by the exposed formula, the effects determined by the electrosurgical unit, as well as the causes of complications related to its use, are understood. Heat promotes coagulation, cutting or fulguration depends on the current intensity (I), exposed surface, tissue resistance (conductivity), and exposure time. On the side of the electrode (cautery tip), the rate at which tissues are heated plays a crucial role in determining the clinical effect. When an oscillating current is applied to the tissue, the rapid movement of electrons through cell cytoplasm increases intracellular temperature.

The amount of released thermal energy and the time fraction in which this occurs will determine the effects on tissues. Thus, cell damage is reversible when temperatures are lower than 45 °C,

but when temperatures reach over 45 °C, cell proteins start to denature and there is loss of cell integrity. Tissue fluid evaporates and dries at temperatures above 90 °C and other tissue solid components are reduced to carbon when the tissue temperature reaches 200 °C. Temperature can increase markedly, exceeding 1000 °C. Besides the heating effect, living tissues are affected in other ways, particularly the depolarization of cells from cell membrane due to disruption of cellular function. This can lead to neuromuscular stimulation, abnormal conduction, myocardial fibrillation, and death.

5.4.1 Current Density

Current intensity (I)—defined as the amount of electricity flowing through a tissue area—is the most important concept to understand electrosurgery, as the tissue exposed to the highest intensity undergoes greater thermal effects. The dispersion plate placement site is directly related to the current intensity. For example, if the plate is placed near the surgical site, less energy is lost in the circuit and thus lower current densities are necessary to achieve the desired tissue effects. On the other hand, if the plate is placed further away from the surgical site, a greater amount of energy is lost due to the body's resistance, which requires higher density, and there is the possibility of exposing the patient to increased risk of injury.

5.4.2 Time

The time of exposure (t) to the electric current plays an obvious role in the extension of the effects of its passage through the human body. The duration of exposure to current is directly related to the heat produced in the tissue. The longer the exposure time, the greater the effect and the risk of injury due to the greater potential for heat propagation to adjacent tissues. A prolonged activation will produce broader and deeper tissue damage. Other relevant factor is the target tissue resistance (R), as the greater the resistance to the electric current, the greater the amount of heat produced.

5.4.3 Electrode Size

The effect of electrosurgery also depends on the type of electrode. Smaller electrodes promote a higher current intensity and concentrate the heat effect on the contact site. For example, a needle tip electrode provides a greater heat effect compared to a ball tip electrode. This same concept applies to the return electrode.

5.4.4 Tissue Conductivity

The higher this inherent resistance, then higher will be the voltage required for the current passage. Also, the more superficial tissues are cauterized, the less they become electrically conductive, which increases its strength and requires a greater amount of voltage for current to penetrate into deeper tissue layers. Conductive materials, such as metal, soil, ionic solutions, and the human body are those that offer least resistance. The tissue specific resistance depends on the type of tissue concerned, humidity and thickness of the skin, presence of bony protuberances, and vascularization. Various tissue types have different electrical resistances that affect the rate of heat. The resistance of fat and bone tissue is greater than the skin, muscle tissue, and well vascularized areas. This is important in selecting a location to place the dispersive

plate; areas with more vascularized tissues and muscles should be preferred, avoid fat regions, bony prominences, and thick skin such as the plantar region.

Understanding it is also important to explain to the patient the mandatory removal of all conductive (low resistance) materials, such as jewelry, ear rings, piercings, clasps, buttons, and other metal adornments.

5.4.5 Current Waveforms

The final determinant of how tissue responds to electrosurgery is the current type. Electrosurgical units produce 3 different waveforms: cut, blend, and coagulation



Fig 4: Wave forms of electrosurgical units with different tissue effects.

A pure cutting (vaporization) waveform is continuous, unmodulated, and undamped. A coagulation waveform is interrupted, modulated, and damped current. A blend waveform is a modification of the cutting waveform and is used when hemostasis is needed while cutting. This waveform type consists of a combination of both cutting and coagulation waveforms. Higher blend settings translate into more time between bursts of current and greater coagulation, as seen in the following examples: Blend 1 (80% cut, 20% coagulation); Blend 2 (60% cut, 40% coagulation); and Blend 3 (50% cut, 50% coagulation). *(Fig 4)*

A cutting current power setting must be between 50W and 80W to be effective. Ideally, the electrode is held slightly away from the tissue to create a spark gap or steam envelope through which the current arcs to the tissue. This spark gap results from heating up the atmosphere between the electrode and the tissue. The coagulation current is effective with the power settings in the range of 30W and 50W.

Fulguration (Spray) is a noncontact coagulation that also utilizes spark gap to mediate tissue effects, which results in heating and necrosis as well as greater thermal spread. Desiccation (Deep) is another form of coagulation in which direct contact is made with the tissue, resulting in electrical energy being converted into heat within the tissue. The end result is deeper necrosis and greater thermal spread.

5.4.6 Electrosurgical Units

Currently, electrocautery, thermo-cautery, diathermy, electric and electronic scalpels are terms used interchangeably in reference to electrosurgery. Most authors agree that the generic term

electrosurgical unit is the most appropriate regarding the current generator used for electrosurgery. There are two types of electrosurgical units: generators called "ground referenced", which were used until 1970, and the latest, which are isolated. In the first type, the electrical current goes through the patient and then earth ground completes the circuit through a dispersive plate attached to the patient. In the absence of a complete circuit, the current will seek the earth (grounding). In this situation, any contact of the patient with a possible grounding, the current will choose the path of least resistance, may pass through the operating table, ECG electrodes or metal of a venous catheter in contact with the patient. If the current intensity is high enough at the contact point, there is the possibility of burning. This potential danger has been eliminated with the introduction of generators isolated from ground, in which the current passes through the patient and returns to the generator through the dispersive plate. The optional paths are avoided because there is no connection of the return electrode with the ground. The current flow is limited between the patient's active electrode and return electrode, which provides a low resistance path for the current coming from patient to return to the generator (Fig. 3). The electrosurgical unit activation is mediated by the hands or feet. This isolated generator system has reduced significantly the cases of burns, but did not eliminate entirely the possibility of this complication.

5.4.7 Electrosurgical Modalities

Generators can apply monopolar or bipolar energy. In monopolar mode, the current released passes from the generator to the active electrode, in which its effect is produced, passes through the patient and exits through the dispersive electrode (or neutral plate), returns to the generator and forms a complete circuit. Because the neutral electrode surface is much larger than that of the active electrode (on which the cutting, coagulation or ablation takes place), the current is spread over a large area, which minimizes the heating of tissue in contact with the dispersive plate. It is most often used due to its greater versatility. However, it offers more risk because larger amounts of tissue are exposed to electricity. In the bipolar mode, the instruments resemble surgical tweezers and there is no need for a dispersive return electrode, as both the active and return electrodes are integrated in order to release energy and promote its return. The energy does not travel through the patient because it is confined to the tissue between the forceps. Because of this configuration, the bipolar mode offers little chance of an unintended dispersal of current. The power generated by bipolar scalpel is smaller compared to the monopolar. It is indicated for delicate surgeries such as neurosurgery.

5.4.8 Dispersive Plate and Neutral Electrode

Various types of dispersive plate or neutral electrode are available, such as the single-use disposable and reusable adhesives. Such plates should be of sufficient size to maintain a wide area of electricity dispersion, in order not to cause tissue damage. The surface varies from 60 cm2 for children to 170–180 cm2 for adults, depending upon the supplier. The output power is limited to 150 and 400 W for children and adults, respectively. Moreover, gels or pastes should be used to increase contact between plate and skin and reduce its resistance. If the plate is not completely attached, or any kind of fluid is accumulate between the plate and the skin, the total area of dispersion becomes smaller, providing more risks. It is also necessary to select the location, as well as the plate correct placement. It should not be placed in scar tissue, bony



prominences, metal implants, and fat regions of the body. Skin preparation for dispersive plate placement includes a gentle cleaning of the area to remove any trace of fat (without using alcohol, as this may cause increased skin resistance) and hair removal. It is necessary to wait until any combustible cleaning agent used evaporates. When an adhesive grounding plate is fully adhered to the patient's skin, there is adequate area sufficient for current intensity dispersal, which subsequently returns to the generator.

5.4.9 Causes of Burns

Especially for monopolar mode, there are four basic causes of burns. The first refers to burn on surgical site itself as a result of inadvertent activation or inappropriate use. Exposure to electric current for long periods without interruption has direct association with the intensity of its effects and risk of injury. The second relates to the heating of solutions that results in thermal injury. Such injuries can be attributed to heated solutions by both the active and neutral electrodes. The third relates to thermal trauma in the dispersive plate region, also called return tissue damage. It happens when there is inappropriate contact between the plate and the skin of the patient, or when the plate size and positioning site are inadequate, scatter energy in a smaller area, increasing the heat at the points of contact with the plate and causes burn (injury mechanism of the first reported case). A condition often relegated to the background is tissue hypoperfusion. Typically, there is no injury at the dispersive plate site because the contact area is large and skin blood circulation dissipates the heat generated at the site. However, in situations where tissue perfusion at the plaque site becomes inadequate (shock, hypotension, hypothermia, tissue compression at the plate area), the lack of adequate heat dissipation can cause injury. In an effort to reduce burns, since 1981 the devices have a safety system to ensure that the generator operates only if the dispersion plate is attached. Finally, the fourth cause relates to burns that can also occur when the current takes a path through the patient's body other than the dispersive electrode. The partial or total interruption of the dispersive plate contact with the electrosurgical unit allows the flow of electric current through optional routes, including all the contact points of the patient's body to the ground potential. Among the most common optional routes, there are:

- Body surface in direct contact with the grounded operating table (Fig 3)
- Electrodes attached to the patient which enable contact with the ground potential (i.e., monitoring electrodes) (*Fig 3*)
- Patient contact with conductive materials, plastic or rubber (tubes or mattresses), for static dissipation. If the contact surface at these sites is small (high electrical resistance), there will be a large concentration of current, increased temperature, and tissue damage, often severe.
- Monitoring electrodes may cause injury even with the proper functioning of the neutral plate. When the dispersive plate is positioned at a point too distant from the active electrode action site, the electric current from it can be divided into two parts. One returns to the dispersive plate and the other returns through the monitoring electrode. Due to the reduced area of this electrode, burns occur in the skin of the patient.
- Several studies in the literature report the occurrence of burns related to ECG, EEG, rectal temperature probes or skin electrodes and internal monitoring devices using

needles. The electric current circulation through optional routes other than the diathermy circuit may also involve:

- Electrocution (electric shock): passage of electrical current through the body. Its consequences include shock-like sensation, burn, nerve injury, asphyxia (paralysis of respiratory muscles and respiratory centers), and others. Low frequency currents (60 Hz) can cause serious problems in excitable tissues, such as contraction of large muscle groups, which can be misinterpreted as intraoperative awakening of the patient and serious cardiac arrhythmias
- Electromagnetic interferences: the alternating electrical current, particularly of high frequency, generates a magnetic field that can produce interference in the functioning of other equipment (artifacts or noise in the pulse oximeter and cardioscope, for example). The best way to prevent this event is the use of proper grounding and electromagnetic isolation devices;
- Fires and explosions: the production of an electric spark in a rich environment of flammable gases and vapors can produce catastrophic accidents. Flammable materials (gauze or dry swabs, alcohol solutions for antisepsis, PVC endotracheal tube), in the presence of rich atmospheres with combustible gases, such as oxygen, may enter into rapid combustion with a single electric spark.
- Burn injury related to capacitance and magnetic induction phenomena are rare events. Both the first and the second are able to induce currents in conductive means (monitor cables connected to a patient, which function as "antennas") and may occur during use of an electrosurgical unit, which generates an extremely high-frequency alternating current, thus representing a further risk to a patient integrity. To avoid this type of accident, the unit should be placed as far as possible from monitors and wiring must be positioned perpendicular to each other.

5.4.10 Guidelines for the usage of Electrosurgical Unit

Some recommendations regarding the use of electrosurgery are established to reduce the risks related to this technology application, serving as preventive measures to be taken by all professionals working in the operating room:

- (1) The key point in preventing accidents with the use of electrosurgery is the correct positioning of the patient on the operating table. The contact with metal parts of the patient or the table and monitoring electrodes can concentrate the electric current or cause its leakage and result in injury. Insulating devices in the table and in the arm/leg rests must be used to prevent current leakage through the metal areas, in addition to dry swabs placed between the arms, torso or legs to avoid current concentration in areas with fluid accumulation.
- (2) Removal of metallic ornaments is mandatory, and electrodes should be placed as far as possible from the surgical site.
- (3) When using the monopolar scalpel in patients with prosthetic conductive joints, every effort to place the prosthesis out of the direct path of the circuit should be made. If the



patient has a right hip prosthesis, for example, the return plate should be placed on the left side of the patient.

- (4) The warning systems should always be working. The device sound indicator volume should be kept in audible level to signal immediately when the electrosurgical unit is inadvertently activated or when it is not working properly.
- (5) One should also avoid placing the dispersive electrode on tattoos, many of which contain metallic dyes. The active electrode should be placed away from the site when not in use; it avoids unintended activation and injuries.
- (6) Active electrodes should not be used in the presence of anesthetic gases and flammable agents, such as antiseptics for skin antisepsis. This is particularly important in ENT and head and neck surgeries, due to proximity to anesthetic gases.
- (7) The electrosurgical unit power should be confirmed prior to activation, which should be the lower and most effective possible, in order to achieve the desired effect for cutting or coagulation. If the surgeon requests continuous increase of power, or if there is unusual response from the patient, or if there is interference with the monitoring signal during its use, it is necessary to investigate the entire circuit for failures.
- (8) The dispersive plate location is generally dictated by the surgical site, it should be positioned as close as possible to the operative field, preferably in a clean, dry skin, placed in a well vascularized area and with greater muscle mass.
- (9) Patients with pacemaker should be continuously monitored because, although modern devices are designed to be protected from the current flow, they are still subject to interference and may be damaged beyond repair or have its function altered. Having a defibrillator on hand to immediate use in case of emergencies, keeping all the electrosurgical unit cables and wires away from the pacemaker and its connections and the generator power setting as low as possible.

It is also recommended that bipolar electrosurgery should be used whenever possible, but, if necessary, the use of monopolar electrosurgery must ensure that the distance between the active and dispersive electrodes is as short as possible.



6. Monopolar Hook

6.1 What is it

The Laparoscopic L Hook is intended for use in minimally invasive laparoscopic surgical procedures for coagulating, cauterizing and other manipulation of tissues and vessels during laparoscopic procedures.



Fig 5: The 'hook' end of the laparoscopic monopolar hook

6.2 Where is it used

Used in minimally invasive laparoscopic surgical procedures, i.e. abdominal surgeries which require less cuts and foreign body incursion.



Fig 6: Laparoscopic Surgery where the hook is being used



6.3 How does it function

The Laparoscopic L Hook is a versatile device. It can do multiple functions

- 1. Cautery: The main use is for this purpose of cutting and simultaneously sealing layers of tissue. This is done by passing current through the patient's body and the opposite node through the hook. When the circuit is complete, the hook heats and causes the tissue to tear due to burning and the tissue seals as well due to heat burning-off the sticking the tissue shut. *(Fig 2)*
- 2. Tugging: The hook when not heating, can be used to tug and pull at layers of tissue or organs to create a path for another device. The shape of the hook is like an 'L' and hence can be used to latch-onto and pull layers of tissue.
- 3. Sealing: The hook can also seal and shut-off small internal bleeds during surgery. This is done by the same principal of electricity exchange and heat production due to tissue resistance (as in Cautery)

7. Visit to World Laparoscopy Hospital

A visit was made to World Laparoscopy Hospital to further understand the nuances and workings of a typical laparoscopy hook. Short discussions with doctors were conducted and the design student was allowed to visit the instrument lab. There was hooks ranging from Rs. 1,500 up to Rs. 12,000 in their lab. Depending on the surgery and need for finesse, the surgeon suggests which hook to use.





Fig 7: Existing Monopolar Laparoscopic Hook (Cost-Rs 2,200)



The hook (*Fig 7*) is one of the basic ones. The handle is vulcanized rubber and so is the casing for the metal rod. The hook itself is Mild Steel as it's a great conductor of electricity and heats up at a steady pace. This type of device is for single use, as it can't be autoclaved/ sterilized post-surgery without its parts deteriorating.

8. Case studies

8.1 Case Study 1

A 21-yr-old lady presented to the OPD with a one-week history of haemorrhoidectomy under spinal anesthesia in lithotomy position. The operating time was 1 hour. The grounding pad had been applied over the distal thigh on posterolateral aspect. The grounding pad was found to have a deep burn after recovery from surgery *(Figs. 8 and 9)*. Our consultation was sought, and the patient was managed with excision and split thickness skin graft.



Fig 8: Deep burn post-surgery. The loose-lying grounding pad under the burn area resulted in deep burn injury.



Fig 9: Same patient, full-thickness skin loss.



8.2 Case Study 2

A 51-yr-old male who had triple vessel disease of the coronary arteries underwent successful coronary artery bypass grafting. His cardiac surgery proceeded uneventfully. The operating time was 3.5 hours. The grounding pad had been applied over the lower back, which was discovered to have a deep burn after recovery from surgery (*Fig. 10*). Consultation was sought and the patient was managed with hydrogel dressings. Once discharged from the cardiac surgery unit, he was followed as an out-patient. He was advised to have wound closure, but did not consent to another surgical operation continued with conservative management and healed by secondary intention after two months.



Fig. 10: This patient underwent successful coronary artery bypass but continued to suffer from cautery burn for two months.

8.3 Case Study 3

A 32-yr-old lady presented through the OPD with a two-week history related to a wound on her lower back. She had undergone orthopedic surgery for a fractured radius and ulna under general anesthesia. Her surgery had lasted for two hours and the grounding pad had been applied over the lower back. Consultation was sought, and the patient was managed with excision and split-thickness skin graft. (*Fig 11*)



Fig. 11: This patient had orthopedic surgery on the forearm under general anesthesia and sustained iatrogenic burns in the grounding pad site on her lower back.



8.4 Case Study 4



Figure 12: Third degree burn at the dispersive plate site.

Male patient, 30 years old, physical status ASA II due to smoking, reported a prior history of ureterolithiasis. Had undergone implantation of double-J catheter few months before and was scheduled for its withdrawal endoscopically. After standard monitoring, subarachnoid anesthesia was induced by a first year resident, with supervision. T10 sensory level was achieved, and the patient was placed in the lithotomy position.

However, due to the long-term catheterization, the catheter withdrawal was not possible as scheduled by the surgical team and there was the need for abdominal approach through suprapubic incision. The patient was then repositioned on the surgical table to a supine position. Monopolar electrosurgery was used, with a disposable dispersive pad placed on the back of the patient.

During the intraoperative period, the patient complained of pain in the left side of his back, which was not investigated by the anesthesiology resident. The patient was taken to the post-anesthesia recovery room and was discharged the next day—there were no complaints reported in the hospital records.

A month after the incident, he went to the Anesthesiology Clinic for a consultation on further urological procedure and, during the anamnesis, reported the occurrence of burn on his left flank during the procedure previously mentioned. Upon analyzing the injury shape, it was found a similarity with the contact metals of the operating table *(Fig. 12)*. Thus, it was concluded that the burn was caused by direct contact of the patient with the table metallic part. The patient was referred to the plastic surgery department of the institution for clinical management.



Figure 13: Burning in the flank region (left); and surgical table exposing the metal parts coincident with the burning formats (arrows).

8.5 Discussion

Use of monopolar cautery and improper placement of the grounding electrode constituted the cause of electrocautery burns in our cases. While modern electrodes have been designed to minimize this complication, such burn injuries still continue to inflict patients and are often deep. Ignorance or negligence regarding standard safety protocols often underlies such mishaps.

In a relatively recent attempt to abolish this complication, a noncontact electrosurgical grounding device has been developed, but its long-term safety benefits are yet not proven. In all our patients, the cause of burns was faulty application of the grounding pad, which failed to have good contact with the patients' skin. When the grounding pad is loose, this may cause heat generation and sparking at the contact site, without providing an appropriate exit for the current to pass safely through the circuit.

Several measures can be adopted to prevent these mishaps.

- The operating surgeon himself should have a proactive attitude and personally ensure that the grounding pad is adequately applied with firm contact to the skin over an adequate surface area.
- Preferably it should be secured to the skin with a crepe bandage. An area of at least 70 cm2 of firm skin pad contact should be ensured.
- Special care should be exercised to re-check the position of the pad if the patient's position is changed intra-operatively.
- One may employ the newer grounding pads with adhesive properties that firmly attach them to skin.
- The diathermy machine's active alarm system will also help to limit the extent of the resultant burn injury.
- If a bipolar cautery is employed the risk of grounding pad burns can be eliminated altogether.

All our patients had deep burns. One patient who had cardiac surgery was managed conservatively with dressings while two had resurfacing of their wounds with split thickness skin grafts. Sanders et al. reported a case of deep burns from the grounding pad in a patient undergoing shoulder arthroscopy. The literature has reported several other cases of cautery burns occurring during different various surgical procedures such as cardiac surgery, orthopedics, and neurosurgical procedures.

Most of these were deep burns and required plastic surgical interventions.

Mundinger et al reported a case of forehead burns in a patient with titanium plates in her skull bones previously implanted as part of treatment for her skull anomalies. The grounding pad was placed on the lateral thigh, however burns occurred at her forehead as she was positioned prone and circuit generated between the active electrode and an alternate grounding source (i.e. indwelling hardware). This case exemplified the alternate-site or capacitive coupling burns wherein an aberrant intra-operative circuit is generated by equipment contacting the body of the patient. This results in burns at sites of contact remote from the operative field and the normal grounding pad. Such injuries may occur on areas of un-insulated surgical table contacting the patient, electrocardiographic leads, temperature probe insertion sites, and sites of placement of various other monitoring devices.

Risk factors for burn injuries

- There is a recent growing recognition of the added danger posed by the combination of supplemental oxygen and electrocoagulation in facial surgery. Engel et al have reported three such patients sustaining burn injuries while undergoing facial plastic surgery under conscious sedation and supplemental oxygen. One prudent way is to avoid using supplemental oxygen without proper endotracheal intubation altogether as the oxygen-enriched atmosphere contributes to the fire as an oxidizer.
- The use of alcohol and spirit based skin preparation solutions is another risk factor for fires and burn injuries in the operating room. The solution, if not evaporated before employing the cautery, will lead to fire and burn injury. The electrosurgical diathermy



unit is the usual source of heat to ignite the flammable substance, although lasers and fiber optic lights can also be potent heat sources. The fuel is provided by alcohol-based prep solution, drapes, sponges, and endotracheal tubes. In the presence of a high oxygen environment, all of these substances can burst into flames and burn intensely. When alcohol-based prep is used and the patient is draped before the solution is completely dry, alcohol vapors can be trapped and channeled to the surgical site or the solution wick may get into the surrounding linen, where a heat source can ignite the vapors.

When using alcohol-based skin preparations a few precautions should be strictly adhered to.

- The surgeon must wait for at least 3 minutes for the solution to evaporate and the skin is wiped with a cotton swab before draping the surgical site; shaving the skin to prevent pooling of solution in the hair; effectively drape the patient with a clear plastic adhesive drape to prevent collection of flammable vapors beneath the drapes.
- The best policy is to avoid these flammable substances and use the much safer solutions of povidone iodine and chlorhexidine.

An electrocautery burn is a medical error which also has medico legal and ethical implications. There is a long list of such errors, from simple misdiagnosis to more serious harm that may culminate in the patient's death. Such errors may emanate from negligence or system failure. Unfortunately such errors continue to occur in every part of the world. Ideally the professional staff and hospital administration concerned should ensure patient safety by preventing such mishaps and compensate for the harm that ensues to the patients. Reporting such errors is imperative as this will ensure safer management of future patients by sensitizing the professionals involved, leading to the adoption of preventive strategies.

In Case I, besides the plate inadequacy, it was placed in a region with great resistance that allows the passage of electrical current, as the plantar area, which in addition to having a thicker skin it may facilitate contact with bony prominences. Resistance is also important to understand Case 2. The conductive materials (low resistance), such as the surgical table metal part, in addition to patient's metallic ornaments, can offer an optional route for the electrical current to exit from the patient's body.

In Case 2, the patient's body came in contact with the operating table metal part, which has become an optional route to the electric current exit, resulting in great heat and burning. This same mechanism explains the burning cases of patients with metal ornaments, with ECG and EEG electrodes, and other internal monitoring devices using needles.



9. Issues and Risks

The use of this surgery is prevalent and of great importance. It does the needful in terms of medical aid and solves its purpose as a medical instrument, but like all medical apparatuses it has room for improvement. The major risks and issues are as follows:

9.1 Unwanted Cautery

One of the most common risks is unwanted cautery, which happens due to human induced errors, the hook can touch and burn undesired regions in the abdominal area. This leads to stricture formation and surgical scars.

9.2 Wound Dehiscence

This is a surgical complication in which a wound ruptures along a surgical incision. Due to incorrect use or inadequate cautery, the tissues can rupture and re-open at surgery site. (Fig 14)



Fig 14: Wounds reopening at surgical site; post-surgery

9.3 Hematoma

This is generally defined as a collection of blood outside of blood vessels can result from surgeries of any sort, invasive medical. Because these procedures damage nearby tissues and blood vessels, often hematomas may form around the site of the procedure. Hence when cautery occurs, the surrounding areas get affected.



Fig 15: Hematoma on abdominal site post-surgery



9.4 Strictures

This is the narrowing of a path inside the body due to sealing of tissues. This constricts the space in the abdomen in the case of laparoscopic surgery, and leads to internal bleeding when the tissue expands.



Fig 16: Blood vessel; before and after cautery induced strictures



10.SWOT Analysis

10.1 Strengths

• The current device serves its purpose well. The device is simple, easy to manufacture and has low production costs ranging from Rs. 1500 to 7800 for the basic function model (trocar diameter and material differences are the reason for the price range gap).



Fig 17: Types of Monopolar hooks; separate price points according to use and functions

- Needs no technical know-how to operate it. The device is very simple to use (albeit it takes time to master)
- No need for re-sterilization as the production cost is negligible as compared to cost-tosterilize.
- The device is extremely old and there aren't many changes made to it, hence the learning curve for all surgeon aspirants is similar.

10.2 Weaknesses

- The hook is difficult to master and takes years to reach near perfection.
- The electricity flow is controlled by the doctor's foot as the leg-mind co-ordination is difficult to achieve.
- The opposite point plate/ nodes burn the patient whilst passing electricity through the patient's body
- Patients with pacemakers and metal body attachments (like skull plates and rods) are unable to have surgery using this device as these metallic parts will cause burns and ceases to work optimally once electricity passes through them.
- Needs direct line of sight to operate at highest efficiency.
- Surgical smoke hampers vision, which in turn leads to unwanted movement of the hook and thus ends up cauterizing undesired locations (if not handled with extreme precision)

10.3 Opportunities

- The device hasn't been re-designed for several years hence, scope of work is vast and of high importance as the post-surgery trauma has never been looked at/ solved
- The main function of the instrument is to burn, cut and seal tissues during surgery in a controlled manner and depends on the expertise of the surgeon. This is not a natural need of the body, but the surgery process requires it.
- An improvement can solve multiple issues related to surgical complications
- There needs to be work done in this area to elevate surgeon ease, in-surgery improvements and reduce post-surgery trauma many years down the line.

10.4 Threats

- If not controlled precisely can cause undesired outcomes like surrounding area burns
- Needs extreme precision and handling
- The handles are not ergonomically designed for best grip to provide exactness



Fig 18: Types of Handles for Basic Monopolar Hook

• The control of flow of electricity is done by the foot of the surgeon The surgeon is basically balancing his/her entire weight on one foot, whilst looking into a screen to perform intricate surgery using his entire concentration and fine motor skills



Fig 19: Foot Pedal for Monopolar Hook with amplitude modifier

• The surgical smoke hinders movement & vision, and increases surgery time as the surgeon needs for the smoke to clear out before making any further moves



Fig 20: Smoke produced at surgical site due to cautery



11.Design Process

The design was carried out from the bottom to the tip. Surgeons and doctors were consulted and grips (as per their references) were decided upon. Once the handle was in place, the mechanism was devised with engineers and placed within the constraints of the handle. In this process the foot pedal, need of contact plate and precision were addressed and successfully removed.

11.1 Ergonomic Study



Fig 21: Anthropometric dimensions of trigger grip



Fig 22: Anthropometric Dimensions of Hands and Cylindrical Grip





Fig 23: Surgeon Proposed Grip 1



Fig 24: Surgeon Proposed Grip 2



Fig 25: Various grips similar to surgeon suggested grip

After extensive research and ideation along with keeping in mind the inputs from the medical industry, the Dynamic Tripod and Quadrupod Grips were chosen *(Fig: 26)*. This is due to the fact that these grips provide the user with external precision, i.e. the user can exert fine pressure as and when required to move the end of the shaft in hand. Much like using a 'practo-knife' this grip can help achieve the desired results in such a small yet minute environment.



Fig 26: Various grips from selected grasp


11.2 Sketches for form of Handle



Fig 27: Concept generation for handles



Fig 28: Sketches for Grip, Venting and Slider



11.3 Model Making and Prototyping

The prototype was made via 3D printing in white PLA material (Polylactic Acid; biodegradable thermoplastic). The handle casing was made in 2 halves and the inner mechanism was attached from the inside of the device. Springs and guide rods were also attached to give the user a realistic experience. Below are images of the prototype.





11.4 Final Outcome



Fig 29: Proposed Device Render



Fig 30: Handle of Proposed Device





Fig 31: Close-up shot of Slider switch



Fig 32: Close up of Handle, Vent hole and Electric Input

a



Fig 33: Tip of the proposed device



Fig 34: Close-up of Smoke Venting Hole

11.5 Solutions and Recommendations

The solution given for the device is as follows. The improved laparoscopic hook has multiple parts to increase efficiency, ease and reduce unwanted results.



Figure 35: Sectional View of Handle Component of Proposed Device

11.5.1 Move lever not shoulder

During surgery, the surgeon is using the hook to cut, seal and tug at tissue. All these movements are done using certain muscles of the body. In earlier models, the lateral movement along the axis of the device is done using the posterior deltoid fibres, i.e. the shoulder muscles towards the back. This is a large muscle and is not used to making finer movements, hence this surgery takes a long time to master. In my design, I've replaced this movement with a simple lever, which drives a shaft (A, Fig 35) which can be used by the surgeon with his/her index finger. Since the surgical area itself is small and constricted, and the movement required to perform the 3 functions is not more than 3-5mm, my device provides play/ lateral motion for the same. This makes the surgery an easier process and decreases the learning curve for the surgeon him/herself and their muscle memory. The grip is formed in such a shape, that the movement is natural to the hands and provides a precision grip for finer moves which was earlier missing and required a great deal of practice.

11.5.2 Auto cut-off with spring

The existing monopolar hook is just a metallic hook which heats and cauterizes areas touched upon. The drawback of this is that tissues that are to be cauterized have tension in them. When the surgeon tugs at the tissue it cuts and seals at the same time but at the last fibre, once the tug is released, the force opposite to the tug is experienced by the surgeon. This leads to the heated metallic hook moving in the surgical area and touching undesired places inside the abdominal cavity. As the control of the electricity is controlled by the foot, the leg-mind-eye coordination along with the video delay leads to the heated hook burning tissues which do not require cautery. My solution to this problem is to make the mechanism such that the hook is spring loaded *(B, Fig 35)* and



only when it's in touch with the contact plate, does the circuit complete and the heat flows. In the middle position there is no contact, hence electricity doesn't flow. So the moment the tug is released, the contact is lost and the hook no longer heats. Therefore, unwanted cautery is avoided. Using this solution, the surgeon doesn't require the foot pedal and thus, there is one less thing for the surgeon to control and worry about. The element used to heat the hook is nichrome wire.

11.5.3 Hole for venting smoke

Laparoscopic surgery is usually done under a pressurized environment, in order to increase the area of surgery inside the abdomen. This helps the tools to move more freely as compared to a normal pressure environment. Cautery leads to burning and sealing of tissues. Any burn, leads to smoke production. This smoke hinders the vision and line-of-sight for the camera and hence, surgery needs to be paused. Any one tool is then removed and the smoke is sucked out. Post this, the area needs to be pressurized again for the surgery to continue. This is a task which requires time and stops procedural flow. The Operation Room efficiency is hindered. All doctors know and wish to reduce time wasted while the patient is under (anesthetized). This smoke production increases the very same. Hence I've introduced a small outlet hole in my device *(C, Fig 35)*. This hole carries from above the hook to the outside environment. Due to the pressure difference in the outside and inside environment the smoke takes the path of least resistance and ends up being sucked out automatically. This reduces the need for instrument removal to vent smoke, additional devices and increases OR efficiency.

11.5.4 Ergonomic handle

Current handles are made keeping production costs and ease of making in mind. But these handles aren't the best for the surgeon's grip as this level of dexterity requires a special grip. I have chosen the Chinese calligraphy grip for this purpose. Here, the thumb, middle finger and the ring fingertips are used to grip the device and the index finger is free to be used as the 'trigger finger' for the lateral movement of the hook. Hence, the surgeon is able to provide the precision he/she needs and the surgery is done in a better and more efficient manner. The diameter of the handle is 30mm (annexure 1) which provides ample grip space and hold for the surgeon's hand. As the handle is cylindrical, the device is compatible for any hand (left or right) which reduces the cost of production (to meet left and right hand requirements) and itself is an easy shape to mould. *(Fig 32)*

11.6 Materials used for the product

11.6.1 Handle

The proposed material is TPE. Thermoplastic elastomers (TPEs) are flexible, rubber-like materials that are highly stretchable and can be used for grip oriented instruments. They can be stretched to more than twice their original size and shape while still maintaining their structural integrity. TPEs are true thermoplastics and do not require vulcanization or curing. Thermoplastic elastomers are used in a variety of processes from injection molding to 2-shot molding, blow



molding and extrusion. On the hardness scale, they range from rigid and firm to soft and gel-like. TPE can be sterilized using all major methods: ethylene oxide (EtO), irradiation (both gamma and electron-beam), and steam autoclaving. TPE can also be disinfected with common clinical disinfectants, such as isopropyl alcohol (see annexure 1). Hence using it for the laparoscopic monopolar hook is logical.

11.6.2 Rod

Aluminum for shaft rod as it heats ups and cools down fast (see annexure 2). Hence the heat produced from the electrical charge can be quickly transferred to the hook as well as cooled down rapidly.

PC for casing as it doesn't let heat dissipate (see annexure 3). The tube which houses the aluminum rod can thus, be produced in this material. In the medical market, sterilization is a crucial factor in the development of devices that have direct contact with patients. A key attribute for polycarbonate is that it can be sterilized using all major methods: ethylene oxide (EtO), irradiation (both gamma and electron-beam), and steam autoclaving. Polycarbonate can also be disinfected with common clinical disinfectants, such as isopropyl alcohol. This range of techniques offers the device designer broad flexibility in determining the most cost-effective method for a particular product. Polycarbonate is not suitable for devices that will be autoclaved repeatedly. Thus the device has a limitation of deteriorating after a few uses.

11.7 Production

The handle will be injection moulded in 2 parts as the handle's inner parts are also to be included. The 2 parts can later be attached to each other once the required parts are set inside the moulded rubber.

The PC tube is extruded

The aluminium rod with the hook is casted

11.8 Dimensions and Working Drawings

Refer to Drawing 1

The mass, volume and surface area of the proposed device are in Fig 36

```
Mass properties of Assem1
Configuration: Default
Coordinate system: -- default --
Mass = 26.73 grams
Volume = 25366.03 cubic millimeters
Surface area = 26027.78 square millimeters
Center of mass: (millimeters )
X = 0.00
Y = -299.38
Z = -0.06
```

Fig 36: Product Mass, Volume and Surface Area



12.Product Image Analysis



Figure 37: Render of proposed device

12.1.1 Ergonomic Handle



Figure 38: Using the Quadropod grip the device can be used

Using the Chinese calligraphy grip the product ensures external precision. The diameter of the grip is 30mm (see *Fig 22*).

12.1.2 Index Finger Trigger



Figure 39: Slider Button moves using the 'free' index finger

As in the Chinese calligraphy grip the index finger is free, it can be used as a trigger finger to provide translatory motion to the slider.

12.1.3 Auto Cut off



Figure 40: See through model of handle; to understand working

The simple mechanism of electricity conduction via contact plate makes the device easy to operate and increases efficiency. The 'Trigger Slider' is a protected extension of the 'Contact Shaft'. When the surgeon requires, he/she can slide the trigger laterally to make minute cautery. The electricity doesn't flow until the slider makes contact with the 2 nodes placed above and below the 'Play' Area. The 'Trigger Slider' itself is suspended via springs, so the moment the pressure of a push or pull on it is lost, the contact breaks and so does the circuit. Hence, the tip quickly cools and unwanted cautery is avoided.

12.1.4 Smoke Vent



Figure 41: Outlet hole above the metal hook and out through the back end of the device

As laparoscopic surgery is held under high pressure than the outside atmosphere, the smoke and fumes produced follow the path of least resistance and are expelled. The fumes travel through the length of the device and are expelled from the back. Thus, removing the need for multiple devices, reduces OR time and increases surgery efficiency.



13.Limitations

The new improved laparoscopic device is still in its early stages. Medical devices take years to be developed and perfected to reach the stage of clinical trials. With the help of the thesis the design student has showcased that improvements are possible and moreover, easily attainable. Due to lack of time, funding and expertise in the field of bio-medicine, the designer has ended the development at this stage as per their aims and objectives.

14.Feedback

After making the device, showing the model and results of the study, the surgeons and doctors who were a part of the project were contacted again. They were surprised by the advancement of a simple device just through design intervention and thinking. A simple device, made easier and better just by problem solving. They asked the design student to further his studies to medical companies and to approach industry leaders with this new and improved monopolar laparoscopic hook.

They believe that this device could be a great use in the OT as it solves numerous complications. One surgeon was particularly pleased with the fact that the foot pedal was removed as hand-eye-foot coordination was a big task for him. Another was pleased by the resolution for instant smoke removal from the surgical site.

Overall the proposed device was well received and encouraged.



15.Conclusion

The Laparoscopic Monopolar Hook is a widely used device in the field of minimally invasive laparoscopy surgeries. As a designer, one is taught to keep the user in mind and his/her comfort. Hence, on the basis on this 'user-centric' ideology the device was well received by doctors and surgeons. Most were amazed by the possibilities that can be created via design intervention and how their surgical procedures can be done more safely and efficiently. The proficiency increase through this device is exponential.

The fact that this device can now be used by surgeons to have finer control on their movements and doesn't lead to undesirable burns, is a boon. Also, the removal of electricity flow through the patient's body leads to no burns from the contact plate and ones with pacemakers too can avail this type of surgery. Hence under the given circumstances, the designer has concluded the project of "Redesigning of the Laparoscopic Monopolar Hook."



16.Webliogpraphy

- 1. <u>http://www.scriberia.co.uk/journal/pen-grips</u>
- 2. <u>https://www.ncbi.nlm.nih.gov/pmc/?term=monopolar+hook</u>
- 3. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3664530/</u>
- 4. https://openi.nlm.nih.gov/detailedresult.php?img=PMC2988015 1749-799X-5-82-1&req=4
- 5. https://bmcresnotes.biomedcentral.com/articles/10.1186/1756-0500-6-18
- 6. http://stopiles.com/anal and rectal stenosis.html
- 7. <u>https://www.richard-</u> wolf.com/no_cache/products.html?tx_snetrwproducts_pi1%5Baction%5D=show&tx_snetrwproducts_pi 1%5Bcontroller%5D=Product&tx_snetrwproducts_pi1%5Bproduct%5D=65
- 8. <u>https://www.elitemedical.com.au/media/wysiwyg/Brochure Laparoscopic Consumables 2014 -</u> <u>Elite Medical V3.pdf</u>
- 9. https://www.molnlycke.co.uk/products-solutions/laparoscopic-surgical-instruments/
- 10. <u>https://healthmanagement.org/products/view/hook-electrode-laparoscopic-monopolar-coagulation-ackermann-instrumente</u>
- 11. <u>http://acemedicaldevices.com/medical-products/surgery/ace_monopolar_hook_l_shaped_-</u> <u>monopolar_alhm_l</u>
- 12. https://www.indiamart.com/proddetail/monopolar-double-pedal-footswitch-15001002188.html
- 13. <u>https://www.chdmedical.com/product/ethicon-gynecare-versapoint-bipolar-electrosurgery-system-w-foot-switch-00482/</u>
- 14. <u>https://www.youtube.com/watch?v=M-7Rme2Bj2E</u>



17.Annexures

1. Sterilization Tests



2. Thermal Conductivity Table



3. Medical Plastics

