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The Making of an Instrument: From Concept to Market

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ABSTRACT

This is an account of the steps one goes through in the development of a new device or instrument. It starts with the conditions that generate the need and then the concept of a new instrument and goes through the process of designing it and protecting it with a patent; it then proceeds through the development of a working prototype and a final refined product. It provides an outline of the steps needed to get the device into the national or international market by selling or licensing it to a company willing to develop it.

To be able to demonstrate this process of invention and give real life to the steps involved in the making of an instrument as mentioned above, I describe the circumstances that generated the idea and the development of the Christoudias Tissue Approximator Grasper. The patent is published as issued to demonstrate its different components.

Key Words: Laparoscopy, Instrumentation.

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INTRODUCTION

The introduction of modern video equipment in laparoscopic surgery has led to a widespread acceptance of this modality as the dominant method for many procedures in all surgical specialties.[1-5] This revolution in the art of surgery, however, has in turn created a great need for new instrumentation.[6] Multifunctional instruments that decrease or eliminate the need for repeated instrument exchanges or decrease the number of ports needed for a certain procedure are areas of continuous research and development with hundreds, if not thousands, of engineers who are currently addressing the issue.[6]

As surgeons practicing minimally invasive surgery, we are generally the first to identify the need for a new instrument that could perform a certain function in a better way. The need in turn can generate the idea or concept which may then lead to the design and development of a new instrument. If that instrument provides features that facilitate or advance the art of surgery and, at the same time, provides an opportunity to the instrument companies to realize a financial gain, then it may gain the attention of the practicing surgeons and deserve the interest of the surgical companies.

THE STEP-BY-STEP ACCOUNT OF THE PROCESS

The Need

I started doing TAPP herniorrhaphies approximately six years ago. The frustration generated by the difficulty in approximating the peritoneum at the end of the TAPP herniorrhaphy forced the idea for the development of an instrument that could do the job safer, faster and more efficiently.

Bringing together, with one grasper, the opposing edges of the opened peritoneum at the end of the TAPP herniorrhaphy is at times an impossible task, more so for the inexperienced minimally invasive surgeon. Usually one edge of the peritoneum is grasped first and brought to the opposing edge; the jaws are then opened to accommodate the opposing edge in addition to the first edge. More often than not, the edge engaged first slides off the open jaws and forces repeated attempts until the engagement of

both edges by the same grasper succeeds, allowing stapling or suturing of the peritoneal edges.

One way of facilitating the approximation process is to use two graspers. The first one enters through the stapler's port, engages the more mobile inferior edge and brings it close to the superior edge, allowing the second grasper to engage both of the approximated edges with one move. The first grasper is then removed and the stapler inserted to fix the approximated edges together.

This, however, is time consuming and demands repeated instrument exchanges before closure of the peritoneal opening is accomplished, especially if leaving of the peritoneum occurred during the dissecting phase. Whenever I reached that point of the TAPP herniorrhaphy, I kept saying to myself over and over again, "There has to be a better way." The need for an approximating instrument had made its presence known to me in a very clear and convincing way.

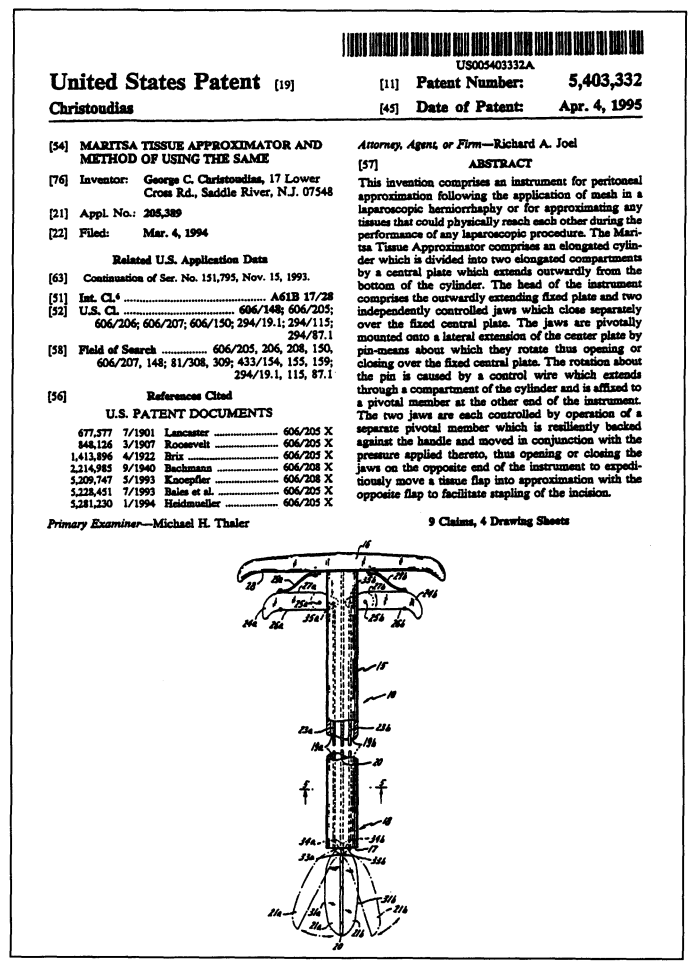
The Idea

A new instrument was generated in my mind which I called "The Approximator." This new instrument's principal property was the ability to grasp the tissue at a first point, advance it to a tissue at a second point and grasp that tissue without dropping the first one; this effectively approximates the tissues at the two desired points. The approximator would do just that if it had two independently operated jaws; the first jaw would grasp the more mobile edge of the peritoneum, advance it to the less mobile edge, which will then be engaged by the second jaw, approximating the edges in a very fast, safe and expeditious manner.[7] The development of the approximator was conceived by designing a central plate on the head of the instrument with a separate jaw functioning independently on each of its sides **(Figures 1, 1a, 1b, 1c, 1d)**.

Conceptually, the approximator appeared fine at the level of the independently operated jaws, although it was evident that a totally innovative design for two independently operated controls had to be developed. It just came to mind that the standard ratcheted grasper had a relatively bulky handle, which, at times, presented in itself some difficulty during the opening or closing of the jaws during the course of laparoscopic operations. I then pictured two ratcheted controls on a more bulky handle, each needing active release and active recapture. That, to me, spelled a very user-hostile instrument, if it could be made functional at all. A user-friendly control had to be devised if the approximator's concept had any chance for realization.

After some intense thinking, the push-button active jaw opening and passive jaw closure control emerged **(Figure 1a)**. Activation of the spring-loaded control will open the jaw, and release of the control will close the jaw and engage the tissues. This design will allow plenty of room on the handle to accommodate a second control. Furthermore, since each control can be activated easily, both controls can be activated together if desired in a simple, efficient and expeditious manner.

So, "The Approximator" was now ready in the mind but it



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Christoudias

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[45] **Date of Patent: Apr. 4, 1995**

[54] MARITSA TISSUE APPROXIMATOR AND METHOD OF USING THE SAME

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[22] Filed: Mar. 4, 1994

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[51] Int. Cl.[6] A61B 17/28

[52] U.S. Cl. 606/148; 606/205; 606/206; 606/207; 606/150; 294/19.1; 294/115; 294/87.1

[58] Field of Search 606/205, 206, 208, 150, 606/207, 148; 81/308, 309; 433/154, 155, 159; 294/19.1, 115, 87.1

[56] References Cited
U.S. PATENT DOCUMENTS

677,577	7/1901	Lancaster	606/205 X
848,126	3/1907	Roosevelt	606/205 X
1,413,896	4/1922	Brix	606/205 X
2,214,985	9/1940	Bachmann	606/208 X
5,209,747	5/1993	Knoepfler	606/208 X
5,228,451	7/1993	Bales et al.	606/205 X
5,281,230	1/1994	Heidmueller	606/205 X

Primary Examiner—Michael H. Thaler

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[57] ABSTRACT

This invention comprises an instrument for peritoneal approximation following the application of mesh in a laparoscopic herniorrhaphy or for approximating any tissues that could physically reach each other during the performance of any laparoscopic procedure. The Maritsa Tissue Approximator comprises an elongated cylinder which is divided into two elongated compartments by a central plate which extends outwardly from the bottom of the cylinder. The head of the instrument comprises the outwardly extending fixed plate and two independently controlled jaws which close separately over the fixed central plate. The jaws are pivotally mounted onto a lateral extension of the center plate by pin-means about which they rotate thus opening or closing over the fixed central plate. The rotation about the pin is caused by a control wire which extends through a compartment of the cylinder and is affixed to a pivotal member at the other end of the instrument. The two jaws are each controlled by operation of a separate pivotal member which is resiliently backed against the handle and moved in conjunction with the pressure applied thereto, thus opening or closing the jaws on the opposite end of the instrument to expeditiously move a tissue flap into approximation with the opposite flap to facilitate stapling of the incision.

9 Claims, 4 Drawing Sheets

Figure 1. The first page of the issued patent. It includes information relating to the inventor, filing date, field of search, referenced patents, patent attorney, the abstact of the invention and the main drawing of the instrument.

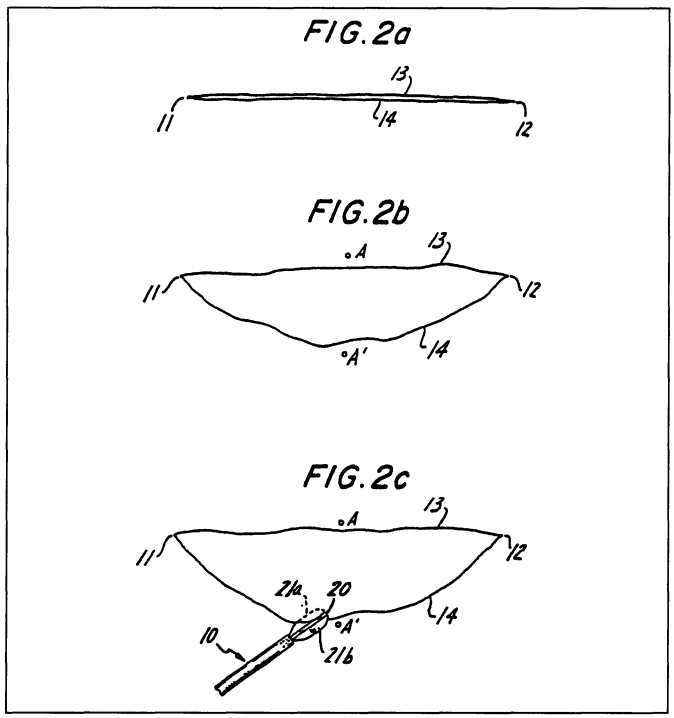


Figure 1a. The initial design of the instrument. Notice the two jaws 21a and 21b activated by push button controls 24a and 24b respectively. Both jaws engage the tissues by closing onto the central plate or jaw 20.

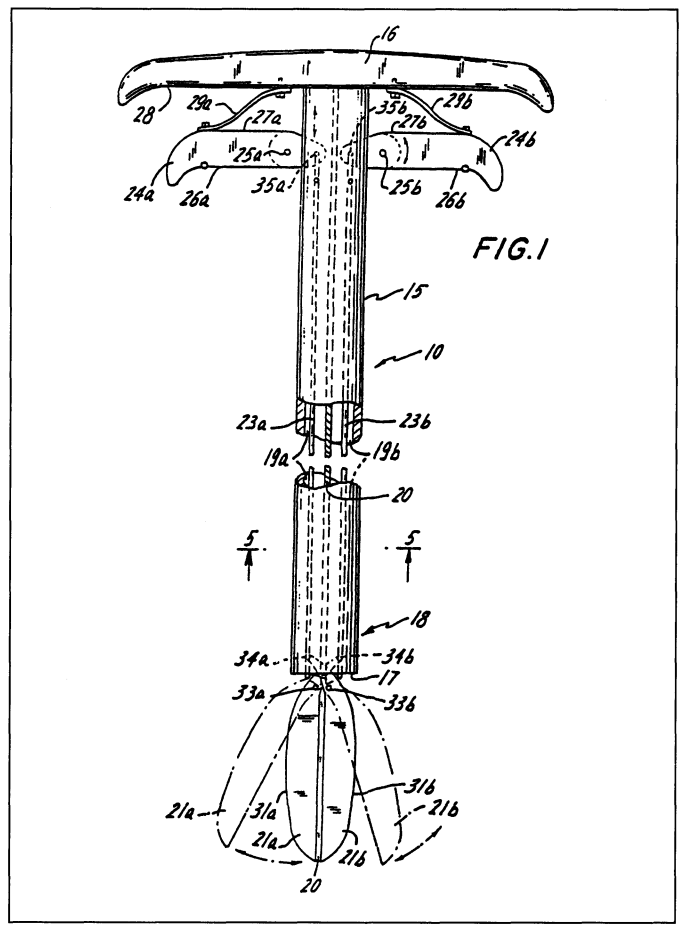


Figure 1b. The peritoneum is incised (top) and peeled from the abdominal wall (middle). The approximator engages the bottom leaf of the peritoneum in preparation to approximate it to the top leaf.

needed to be transferred onto paper to a functional level. For me, being mechanically inclined, designing the instrument was easy. It only took about one hour to complete the conceptual design of my approximator **(Figure 1a)**. Help from a mechanical engineer may of course be necessary in the event that you are unable to translate your instrument idea into a drawing.

Applying for a Patent

Certain criteria have to be met for patent eligibility. An idea, instrument or device has to be sufficiently different from prior technology. At this point, having conceptually produced a new instrument, we are ready to proceed to the next step of protecting it with a patent application, preferably with the help of a patent attorney. The patent application includes the abstract of the invention **(Figure 1)**, which describes in short the content and intent of the invention; the text **(Figure 2a, 2b)** and drawings **(Figure 1a, 1b, 1c, 1d)** follow and then, finally, the claims of the invention **(Figure 2a, 2b)**. The text includes the "background of the invention," indicating the circumstances leading to its development; a "summary of the invention" follows, which describes in short the apparatus and its function and associated advantages and objects which are further described in the "description of the drawings." A "detailed description of the invention" is a detailed account of the different instrument portions and the way the instrument is used. The most important part of the patent relates to the claims **(Figure 2b)**. This is the section where you spell out what you consider to be the new elements which make up your invention and claim them as yours. They could include the actual components of the instrument in part, the instrument as a whole and the method in which this instrument is used. In the case of the approximator, the claims are focused on the presence

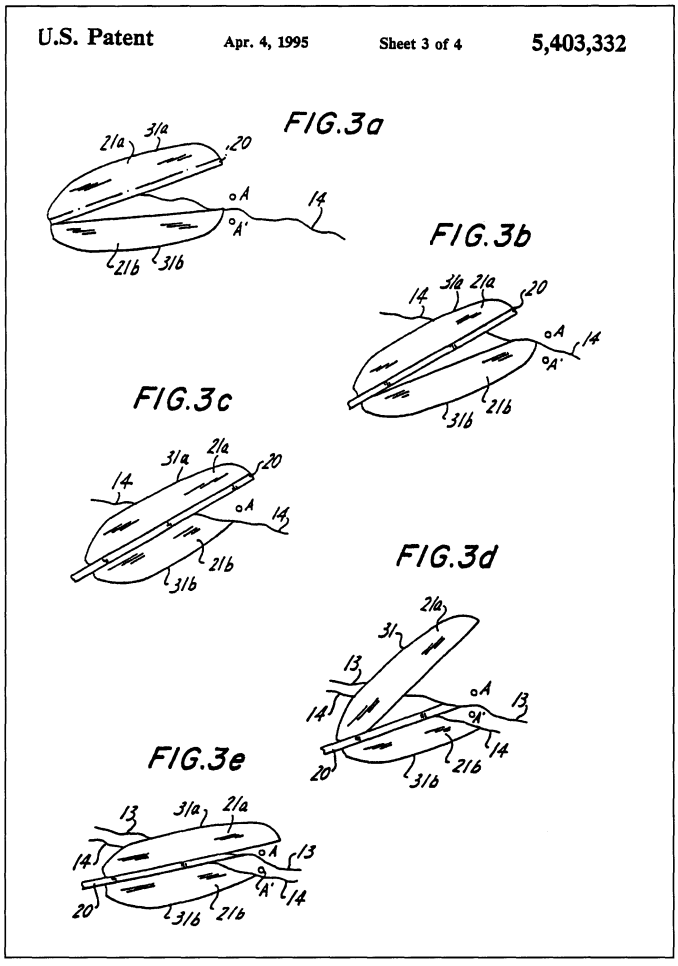


Figure 1c. The steps of tissue approximation diagrammatically using the new invention.

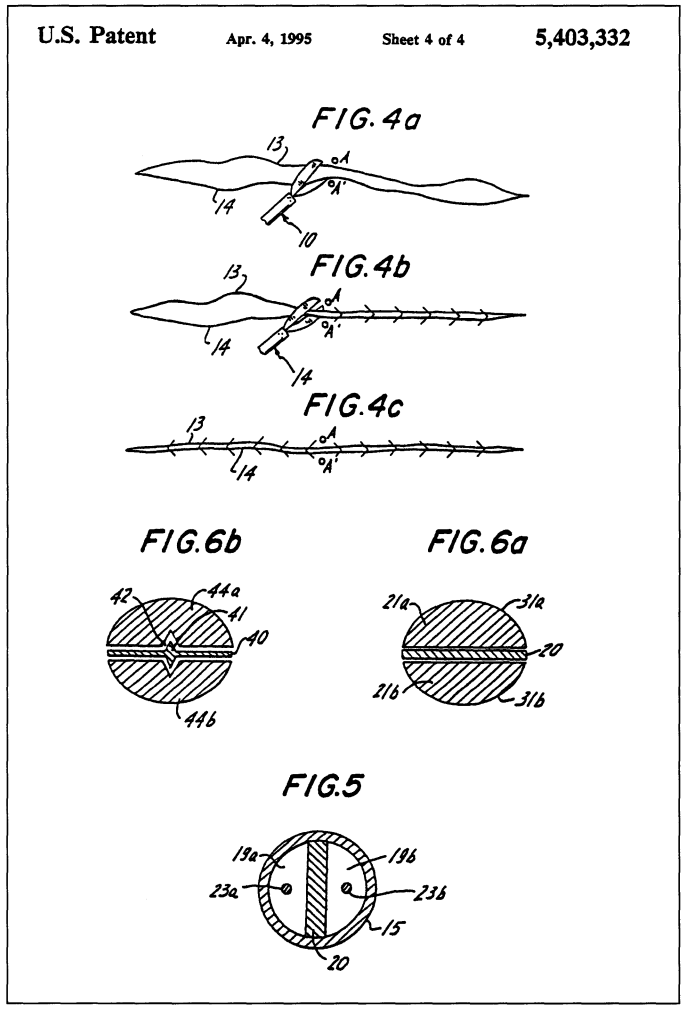
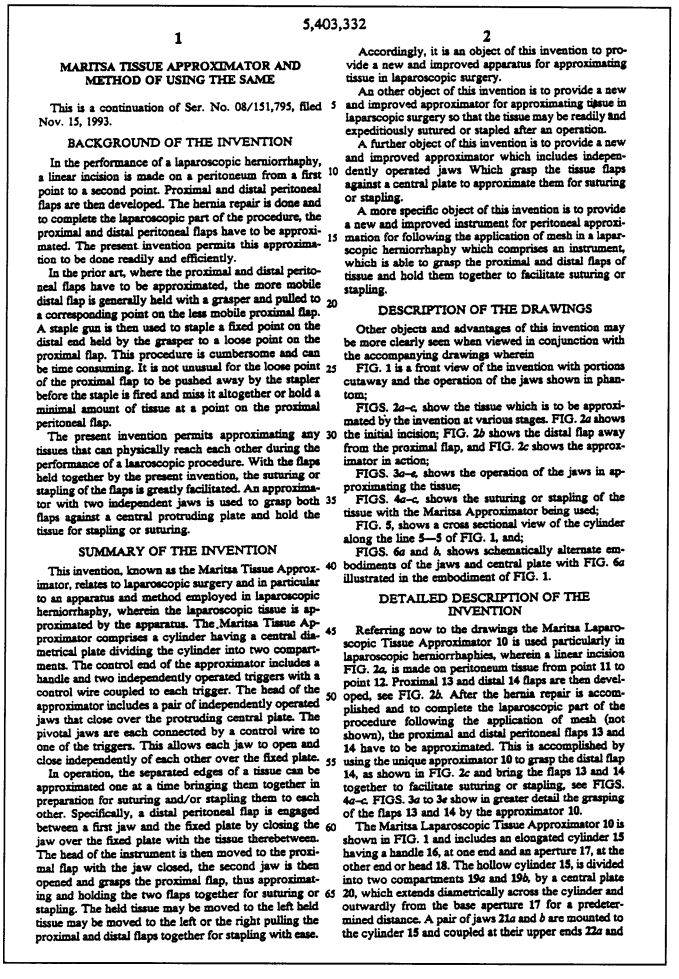


Figure 1d. Completion of the approximation and stapling of the tissue-peritoneum-continued from Figure 1b; and cross section of variations of jaw designs.

of two independently operated jaws by two independently operated controls and the method of grasping and approximating tissues with one instrument. These are features that are not present in any other instrument. The issuing of a patent, however, may prove a long, expensive and time consuming process which can take two or more years. Once the patent application is received by the patent office, the idea, instrument or device, goes on file and is protected, provided that no one else has laid claim on it before. This should be determined by a patent search, which the patent attorney can do for you, or you may be able to check it out on the Internet if you are a computer-sophisticated individual.

The First Prototype

With the patent application on file, we can now proceed to the manufacturing of the first prototype that will give flesh and blood to our idea. There are two ways to go about it. The first would be to find an instrument maker to manufacture the prototype for you. The other way would be to offer your idea, as developed to this point, to the different surgical companies and see if anyone has any interest in developing it. The first option is more expensive but it gives you more control on proceeding with the prototype development and "reduction to practice," which legally means actual application of your idea into practice.



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MARITSA TISSUE APPROXIMATOR AND METHOD OF USING THE SAME

This is a continuation of Ser. No. 08/151,795, filed Nov. 15, 1993.

BACKGROUND OF THE INVENTION

In the performance of a laparoscopic herniorrhaphy, a linear incision is made on a peritoneum from a first point to a second point. Proximal and distal peritoneal flaps are then developed. The hernia repair is done and to complete the laparoscopic part of the procedure, the proximal and distal peritoneal flaps have to be approximated. The present invention permits this approximation to be done readily and efficiently.

In the prior art, where the proximal and distal peritoneal flaps have to be approximated, the more mobile distal flap is generally held with a grasper and pulled to a corresponding point on the less mobile proximal flap. A staple gun is then used to staple a fixed point on the distal end held by the grasper to a loose point on the proximal flap. This procedure is cumbersome and can be time consuming. It is not unusual for the loose point of the proximal flap to be pushed away by the stapler before the staple is fired and miss it altogether or hold a minimal amount of tissue at a point on the proximal peritoneal flap.

The present invention permits approximating any tissues that can physically reach each other during the performance of a laaroscopic procedure. With the flaps held together by the present invention, the suturing or stapling of the flaps is greatly facilitated. An approximator with two independent jaws is used to grasp both flaps against a central protruding plate and hold the tissue for stapling or suturing.

SUMMARY OF THE INVENTION

This invention, known as the Maritsa Tissue Approximator, relates to laparoscopic surgery and in particular to an apparatus and method employed in laparoscopic herniorrhaphy, wherein the laparoscopic tissue is approximated by the apparatus. The Maritsa Tissue Approximator comprises a cylinder having a central diametrical plate dividing the cylinder into two compartments. The control end of the approximator includes a handle and two independently operated triggers with a control wire coupled to each trigger. The head of the approximator includes a pair of independently operated jaws that close over the protruding central plate. The pivotal jaws are each connected by a control wire to one of the triggers. This allows each jaw to open and close independently of each other over the fixed plate.

In operation, the separated edges of a tissue can be approximated one at a time bringing them together in preparation for suturing and/or stapling them to each other. Specifically, a distal peritoneal flap is engaged between a first jaw and the fixed plate by closing the jaw over the fixed plate with the tissue therebetween. The head of the instrument is then moved to the proximal flap with the jaw closed, the second jaw is then opened and grasps the proximal flap, thus approximating and holding the two flaps together for suturing or stapling. The held tissue may be moved to the left held tissue may be moved to the left or the right pulling the proximal and distal flaps together for stapling with ease.

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Accordingly, it is an object of this invention to provide a new and improved apparatus for approximating tissue in laparoscopic surgery.

An other object of this invention is to provide a new and improved approximator for approximating tissue in laparscopic surgery so that the tissue may be readily and expeditiously sutured or stapled after an operation.

A further object of this invention is to provide a new and improved approximator which includes independently operated jaws Which grasp the tissue flaps against a central plate to approximate them for suturing or stapling.

A more specific object of this invention is to provide a new and improved instrument for peritoneal approximation for following the application of mesh in a laparscopic herniorrhaphy which comprises an instrument, which is able to grasp the proximal and distal flaps of tissue and hold them together to facilitate suturing or stapling.

DESCRIPTION OF THE DRAWINGS

Other objects and advantages of this invention may be more clearly seen when viewed in conjunction with the accompanying drawings wherein

FIG. 1 is a front view of the invention with portions cutaway and the operation of the jaws shown in phantom;

FIGS. 2*a–c*, show the tissue which is to be approximated by the invention at various stages. FIG. 2*a* shows the initial incision; FIG. 2*b* shows the distal flap away from the proximal flap, and FIG. 2*c* shows the approximator in action;

FIGS. 3*a–e*, shows the operation of the jaws in approximating the tissue;

FIGS. 4*a–c*, shows the suturing or stapling of the tissue with the Maritsa Approximator being used;

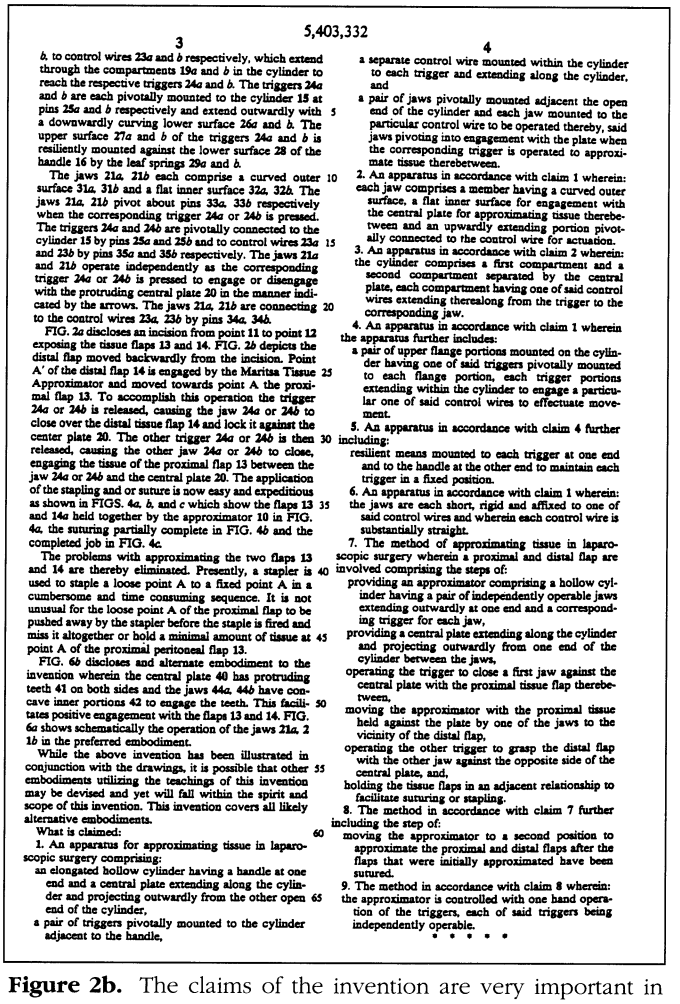
FIG. 5, shows a cross sectional view of the cylinder along the line 5—5 of FIG. 1, and;

FIGS. 6*a* and *b*, shows schematically alternate embodiments of the jaws and central plate with FIG. 6*a* illustrated in the embodiment of FIG. 1.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings the Maritsa Laparoscopic Tissue Approximator 10 is used particularly in laparoscopic herniorrhaphies, wherein a linear incision FIG. 2*a*, is made on peritoneum tissue from point 11 to point 12. Proximal 13 and distal 14 flaps are then developed, see FIG. 2*b*. After the hernia repair is accomplished and to complete the laparoscopic part of the procedure following the application of mesh (not shown), the proximal and distal peritoneal flaps 13 and 14 have to be approximated. This is accomplished by using the unique approximator 10 to grasp the distal flap 14, as shown in FIG. 2*c* and bring the flaps 13 and 14 together to facilitate suturing or stapling, see FIGS. 4*a–c*. FIGS. 3*a* to 3*e* show in greater detail the grasping of the flaps 13 and 14 by the approximator 10.

The Maritsa Laparoscopic Tissue Approximator 10 is shown in FIG. 1 and includes an elongated cylinder 15 having a handle 16, at one end and an aperture 17, at the other end or head 18. The hollow cylinder 15, is divided into two compartments 19*a* and 19*b*, by a central plate 20, which extends diametrically across the cylinder and outwardly from the base aperture 17 for a predetermined distance. A pair of jaws 21*a* and *b* are mounted to the cylinder 15 and coupled at their upper ends 22*a* and



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b, to control wires 23*a* and *b* respectively, which extend through the compartments 19*a* and *b* in the cylinder to reach the respective triggers 24*a* and *b*. The triggers 24*a* and *b* are each pivotally mounted to the cylinder 15 at pins 25*a* and *b* respectively and extend outwardly with a downwardly curving lower surface 26*a* and *b*. The upper surface 27*a* and *b* of the triggers 24*a* and *b* is resiliently mounted against the lower surface 28 of the handle 16 by the leaf springs 29*a* and *b*.

The jaws 21*a*, 21*b* each comprise a curved outer surface 31*a*, 31*b* and a flat inner surface 32*a*, 32*b*. The jaws 21*a*, 21*b* pivot about pins 33*a*, 33*b* respectively when the corresponding trigger 24*a* or 24*b* is pressed. The triggers 24*a* and 24*b* are pivotally connected to the cylinder 15 by pins 25*a* and 25*b* and to control wires 23*a* and 23*b* by pins 35*a* and 35*b* respectively. The jaws 21*a* and 21*b* operate independently as the corresponding trigger 24*a* or 24*b* is pressed to engage or disengage with the protruding central plate 20 in the manner indicated by the arrows. The jaws 21*a*, 21*b* are connecting to the control wires 23*a*, 23*b* by pins 34*a*, 34*b*.

FIG. 2*a* discloses an incision from point 11 to point 12 exposing the tissue flaps 13 and 14. FIG. 2*b* depicts the distal flap moved backwardly from the incision. Point A′ of the distal flap 14 is engaged by the Maritsa Tissue Approximator and moved towards point A the proximal flap 13. To accomplish this operation the trigger 24*a* or 24*b* is released, causing the jaw 24*a* or 24*b* to close over the distal tissue flap 14 and lock it against the center plate 20. The other trigger 24*a* or 24*b* is then released, causing the other jaw 24*a* or 24*b* to close, engaging the tissue of the proximal flap 13 between the jaw 24*a* or 24*b* and the central plate 20. The application of the stapling and or suture is now easy and expeditious as shown in FIGS. 4*a*, *b*, and *c* which show the flaps 13 and 14*a* held together by the approximator 10 in FIG. 4*a*, the suturing partially complete in FIG. 4*b* and the completed job in FIG. 4*c*.

The problems with approximating the two flaps 13 and 14 are thereby eliminated. Presently, a stapler is used to staple a loose point A to a fixed point A in a cumbersome and time consuming sequence. It is not unusual for the loose point A of the proximal flap to be pushed away by the stapler before the staple is fired and miss it altogether or hold a minimal amount of tissue at point A of the proximal peritoneal flap 13.

FIG. 6*b* discloses and alternate embodiment to the invention wherein the central plate 40 has protruding teeth 41 on both sides and the jaws 44*a*, 44*b* have concave inner portions 42 to engage the teeth. This facilitates positive engagement with the flaps 13 and 14. FIG. 6*a* shows schematically the operation of the jaws 21*a*, 21*b* in the preferred embodiment.

While the above invention has been illustrated in conjunction with the drawings, it is possible that other embodiments utilizing the teachings of this invention may be devised and yet will fall within the spirit and scope of this invention. This invention covers all likely alternative embodiments.

What is claimed:

1. An apparatus for approximating tissue in laparoscopic surgery comprising:

an elongated hollow cylinder having a handle at one end and a central plate extending along the cylinder and projecting outwardly from the other open end of the cylinder,

a pair of triggers pivotally mounted to the cylinder adjacent to the handle,

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a separate control wire mounted within the cylinder to each trigger and extending along the cylinder, and

a pair of jaws pivotally mounted adjacent the open end of the cylinder and each jaw mounted to the particular control wire to be operated thereby, said jaws pivoting into engagement with the plate when the corresponding trigger is operated to approximate tissue therebetween.

2. An apparatus in accordance with claim 1 wherein: each jaw comprises a member having a curved outer surface, a flat inner surface for engagement with the central plate for approximating tissue therebetween and an upwardly extending portion pivotally connected to the control wire for actuation.

3. An apparatus in accordance with claim 2 wherein: the cylinder comprises a first compartment and a second compartment separated by the central plate, each compartment having one of said control wires extending therealong from the trigger to the corresponding jaw.

4. An apparatus in accordance with claim 1 wherein the apparatus further includes:

a pair of upper flange portions mounted on the cylinder having one of said triggers pivotally mounted to each flange portion, each trigger portions extending within the cylinder to engage a particular one of said control wires to effectuate movement.

5. An apparatus in accordance with claim 4 further including:

resilient means mounted to each trigger at one end and to the handle at the other end to maintain each trigger in a fixed position.

6. An apparatus in accordance with claim 1 wherein: the jaws are each short, rigid and affixed to one of said control wires and wherein each control wire is substantially straight.

7. The method of approximating tissue in laparoscopic surgery wherein a proximal and distal flap are involved comprising the steps of:

providing an approximator comprising a hollow cylinder having a pair of independently operable jaws extending outwardly at one end and a corresponding trigger for each jaw,

providing a central plate extending along the cylinder and projecting outwardly from one end of the cylinder between the jaws,

operating the trigger to close a first jaw against the central plate with the proximal tissue flap therebetween,

moving the approximator with the proximal tissue held against the plate by one of the jaws to the vicinity of the distal flap,

operating the other trigger to grasp the distal flap with the other jaw against the opposite side of the central plate, and,

holding the tissue flaps in an adjacent relationship to facilitate suturing or stapling.

8. The method in accordance with claim 7 further including the step of:

moving the approximator to a second position to approximate the proximal and distal flaps after the flaps that were initially approximated have been sutured.

9. The method in accordance with claim 8 wherein: the approximator is controlled with one hand operation of the triggers, each of said triggers being independently operable.

* * * * *

Figure 2a. The text describes the new instrument and explains its function.

Figure 2b. The claims of the invention are very important in protecting your idea.

The whole process of patenting and developing a prototype can be an expensive proposition, but if one believes that the new instrument is really needed then it may be worth the expense. Of course we cannot lose sight of the fact that if the patented instrument does not eventually make it to the market, we wind up with an expensive plaque we can use to decorate the wall. The alternative is to get a surgical company interested in your idea, which can prove a frustrating process. You need to find the right person in the company who has the ability to comprehend what your idea really is and how it works. Furthermore, that person has to be interested in pursuing your idea. The "right" person of the surgical company can be the director of research and development or the director of marketing of the company. Both are generally extremely busy people involved with quite a lot of different projects and responsibilities with too little time to devote to your idea or invention. I have found this route to be very unproductive and, at times, frustrating, so I generally prefer to have my own instrument maker develop my first prototype. This gives me the freedom of decision-making and the ability to proceed with the production of the first prototype in an expeditious manner. Once the prototype is manufactured and tested in vitro, necessary modifications are done, and the instrument can be used in the operating room. By actually taking my idea to the final step of applying it in an actual procedure, it can prove whether it is functional or not. Provided the instrument does fulfill my expectations, I then have the advantage of being able to do a video presentation of my

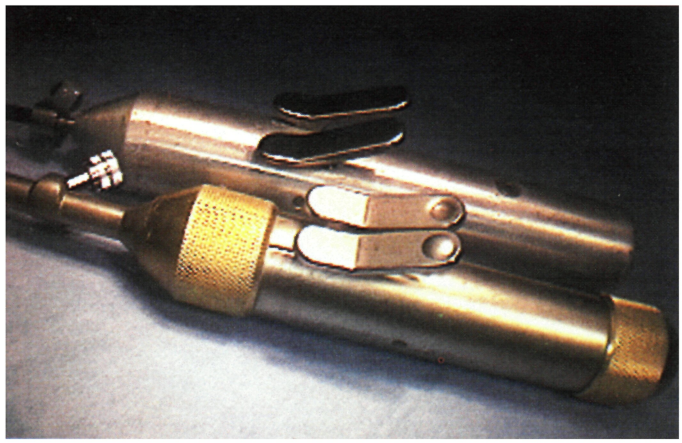

Figure 3. Handle with controls of the approximator. The first prototype (top) is more bulky than the final refined product (bottom). Notice the tactile coding with the "high" bubble control for the "golden" jaw and a "low" dimple control for the "silver" jaw on the final product.

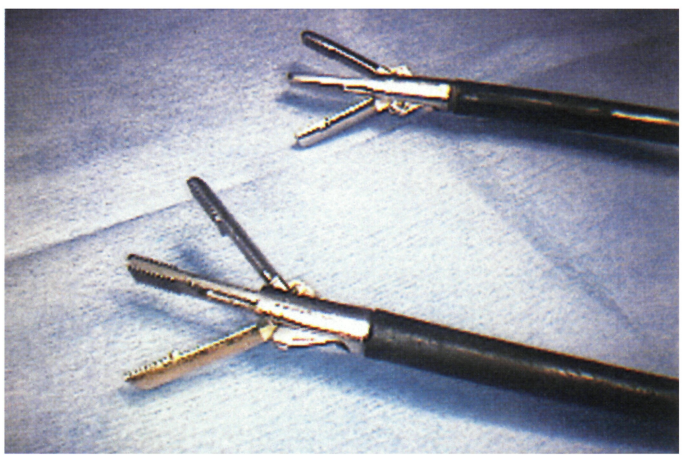

Figure 4. The jaws of the approximator. The jaws of the first prototype (top) did not have the color coding and engaging features of the final product (bottom).

invention in action and can demonstrate its function in a clear and convincing way. The video of a prototype, I believe, is much superior to any verbal or written description of what the proposed new instrument could do or, to paraphrase an old saying, if "a picture is worth a thousand words," then the video is worth a thousand pictures.

I came across an instrument maker who could produce the approximator, while attending an advanced laparoscopic course in Boston. We reached an agreement for the manufacturing of a prototype, and I proceeded to send him the plans.

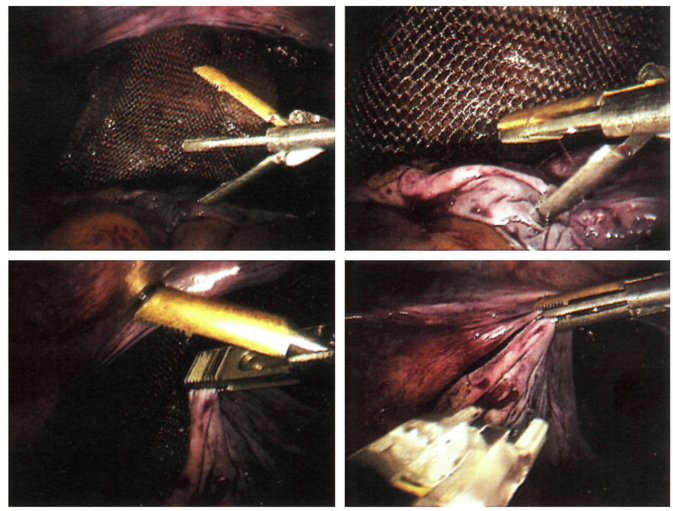

Figure 5. Approximating the peritoneum in TAPP hernia repair. **Top Left:** The mesh is secured in place and the approximator is ready to go to work. Both jaws are open. **Top Right:** The "low" dimple control is activated and the "silver" jaw opened and advanced to the most mobile peritoneal edge which will engage. **Bottom Left:** With one edge captured the approximator is directed to the corresponding point of the opposite edge and the "golden" jaw opened by activating the "high" bubble control, and readied to grasp the opposite point of the peritoneum. **Bottom Right:** In a flawless process the peritoneum is approximated precisely and ready for stapling.

At the same time an application for a "510(K)" form for Federal Drug Administration (FDA) approval of the instrument was filed by the instrument maker on my behalf. The FDA approval was received by the time the first prototype was made. Since then, new FDA regulations have waived the need for FDA approval for free hand held instruments such as the approximator. It is prudent that you consult with your patent attorney licensing it.

In two months, I had a prototype **(Figure 3, 4)** which I tested in the TAPP herniorrhaphies. It was very rewarding to see the new instrument perform just as I had hoped it would **(Figure 5)**. For the first time I breezed through the peritoneal approximation phase without frustrations.

Licensing the Instrument

I made sure that the use of the instrument was recorded on video on every occasion it was used. I then put the video clips together and contacted the appropriate persons for evaluating the instrument in different surgical companies. I explained what the instrument was about

and asked them whether they had any interest in looking at it. If they agreed to evaluate it, I proceeded to ship the actual instrument to them. The two giant companies I sent the instrument to first liked it but were not interested in developing and marketing it, probably because it could not be made into a disposable item. I then mailed it to another big company after talking to the director of research and development, and I discussed it with the director of marketing of a smaller company of mainly reusable instruments. The director of research and development of the bigger company showed immediate interest and wanted his company to enter into negotiations for licensing the instrument for development and marketing.

He talked to the director of marketing, and he was in the process of exploring the possibilities of manufacturing and marketing the instrument. After several weeks, I sent the second prototype to a smaller company. I received a call from the director of marketing the very day he received the prototype and the video. He informed me that he believed the approximator would be an "impact instrument," and his company was very interested in licensing it. Soon thereafter, we negotiated an agreement. By the time the machine of the big company was put into motion, I had already finalized an agreement with the smaller company. What I liked about the small company was that the people I was dealing with could make final decisions and give me definitive answers or commitments just as I could do for them.

Within a week, we had a written agreement which spelled out the royalties, exclusivity, timetable for production and marketing guarantees.

Production and Marketing

The instrument was redesigned with my specifications into a more refined, less bulky and easier to manipulate final product **(Figure 3, 4)**. The jaws were redesigned **(Figure 4)** to hold firmly the engaged tissues without choking and at the same time cause only minimal trauma to the tissues **(Figure 5)**. The final prototype was manufactured and given to me for evaluation. After three months of intensive use, there was one more modification needed. This final modification would allow the operator to associate the controls with the corresponding jaws. The solution was to color code the jaws, which are viewed on the monitor with corresponding tactile coding of the controls. The jaws were made into one "golden" and one "silver" **(Figure 5)** and the controls into a "high" bubble and a "low" dimple control **(Figure 3)**. The gold is always higher than the silver, and, therefore, the "high" bubble control corresponds to the golden jaw and the "low" dimple control to the silver jaw. After intensive use of the instrument in more than 60 laparoscopic herniorrhaphies and cholecystectomies, the approximator proved to be an extremely useful and helpful tool in laparoscopic surgery. It was, subsequently, produced and introduced to the national and international market.

SUMMARY

The practicing surgeon is generally the first to identify the need for a new device, instrument or technique. Identifying the need can lead to the concept of a new instrument or device. In turn, designing, patenting and developing this instrument may facilitate the performance of surgery and advance the art of surgery to a higher level. The steps that lead from concept to market of a new instrument are outlined in a concise fashion.

References:

1. The Southern Surgeons Club. A prospective analysis of 1518 laparoscopic cholecystectomies. *N Engl J Med.* 1991;324:1073-1078.

2. Krosna M, Fiocco M. Thoracoscopic pericardiectomy. *Surg Lap Endosc.* 1995;5:202-204.

3. Sarli L, Pietra N, Chua O, Costi R, Cattaneo G. Laparoscopic hernia repair: a prospective comparison of TAPP and IPOM techniques. *Surg Lap Endosc.* 1995;7:472-476.

4. Waldhausen J, Tapper D. Is laparoscopic splenectomy safe and cost effective? *Arch Surg.* 1997;8:822-824.

5. Nezhat C, Nezhat F, Nezhat C, Seidman DS. Operative laparoscopy: redefining the limits. *JSLS.* 1997;1:213-216.

6. Coller JA, Murray JJ. Equipment. In Laparoscopic Surgery. Ballantyne Leahey Modlin eds. *WB Saunders Co.* 1994:3-6.

7. Christoudias GC. Christoudias tissue approximator grasper: a step forward in minimally invasive surgery. *Surgical Technology International VII.* 1998;111-116.

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