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653405

**PATENT REQUEST AND NOTICE OF ENTITLEMENT**

We **ETHICON, INC.**

of **U.S. Route #22, Somerville, NEW JERSEY 08876, U.S.A.**

being the Applicant and Nominated Person, request the grant of a patent for an invention entitled **ENDOSCOPIC SUTURE CLIP** which is described in the accompanying standard complete specification.

Convention priority is claimed from the following basic application:

| <b>Basic Applicant</b>                             | <b>Application Number</b> | <b>Application Date</b> | <b>Country</b> | <b>Country Code</b> |
|--|---------------------------|-------------------------|----------------|---------------------|
| Chao C. Chen;<br>William Zwaskis<br>and Mark Ortiz | 717,134                   | 18 June 1991            | U.S.A.         | US                  |

Chao C. Chen; William Zwaskis and Mark Ortiz are the actual inventors of the invention.

The nominated person is the assignee of the invention from the inventors. As part of the assignment, the nominated person is entitled to rely on the basic application.

The basic application was the first application made in a Convention country in respect of the invention the subject of this request.

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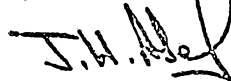
Attorney Code:

**GH**

DATED this 4th day of June 1992

S029856 04/06/92

**ETHICON, INC.**  
By their Patent Attorney



**GRIFFITH HACK & CO.**



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(54) Title  
ENDOSCOPIC SUTURE CLIP

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(56) Prior Art Documents  
US 4476865  
US 4418694  
US 4346869

(57) Claim

1. An endoscopic surgical clip comprising first and second leg members joined at their proximal ends by resilient hinge means and terminating at their distal ends in latch means, each leg member having an outer surface and a clamping inner surface, the clamping inner surface being in opposition to the clamping inner surface of the other leg member, the outer surface of each leg member being configured to be accepted by the jaws of an endoscopic clip applier;

wherein the clamping inner surface of the first leg member has a convex radius of curvature extending transversely across at least a portion of the width of the first leg member, and the clamping inner surface of the second leg member has a concave radius of curvature extending transversely across at least a portion of the width of the second leg member, with the radius of curvature of the clamping inner surface of the first leg member being smaller than the radius of curvature of the clamping inner surface of the second leg member, and the

(11) AU-B-18027/92

-2-

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radius of curvature of the clamping inner surfaces of the first and second leg members being complementary so as to minimize the gap which is created between the clamping inner surfaces when the clip is in a clamped position.

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**ORIGINAL  
COMPLETE SPECIFICATION  
STANDARD PATENT**

Invention Title:            **ENDOSCOPIC SUTURE CLIP**



The following statement is a full description of this invention, including the best method of performing it known to us:



**GH&CO REF: P04089-LH:RPW:RK**

TITLE OF THE INVENTION

ENDOSCOPIC SUTURE CLIP

BACKGROUND OF THE INVENTION

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This invention relates generally to a surgical clip. More particularly, it relates to such a clip suitably adapted to replace a suture knot during endoscopic surgery.

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As medical and hospital costs continue to increase, surgeons are constantly striving to develop advanced surgical techniques. Advances in the surgical field are often related to the development of operative techniques which involve less invasive surgical procedures and reduce overall patient trauma. In this manner, the length of hospital stays can be significantly reduced, and therefore the hospital and medical costs can be reduced as well.

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One of the truly great advances in recent years to reduce the invasiveness of surgical procedures is endoscopic surgery. Endoscopic surgery involves the use of an endoscope, which is an instrument permitting the visual inspection and magnification of any cavity of the body. The endoscope is inserted through a cannula after puncture through the wall of the body cavity with a trocar, which is a sharp-pointed instrument. The surgeon can then perform diagnostic and therapeutic procedures at the surgical site with the aid of specialized instrumentation designed to fit through additional cannulas providing small diameter openings into the desired body cavity as may be required.

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An age-old procedure which surgeons are required to perform to repair or reconstruct traumatized bodily tissue is suturing. Fortunately, medical instruments have been recently designed to allow a surgeon to manipulate a suture, or suture and needle combination, through the small diameter opening of a cannula. However, the ability to tie an appropriately placed suture knot has become troublesome and problematical.

Therefore, in response to this problem, surgeons have sought alternatives to conventional knot-tying techniques which would be suitable during endoscopic surgery. Among these alternatives include the use of hemostatic clips, which are designed to ligate blood vessels and other tubular members, to replace suture knots. Such hemostatic clips are described, for example, in U.S. Patent Nos. 4,418,694 and 4,476,865. These clips can be readily applied with a clip applier which is designed to function through the small opening of a cannula. Unfortunately, the force required to displace these clips from the suture is inadequately low. As a result, hemostatic clips of the type shown in the art are unsuitable for general endoscopic surgery needs.

In view of the deficiencies of the prior art for creating a useful alternative to tying a suture knot, what is desired within the medical community is a device suitable for application using endoscopic techniques which can successfully replace the suture knot. More specifically, what is needed is a clip particularly adapted for replacing a suture knot during endoscopic surgery, and which exhibits adequate clamping force to function effectively.

The present invention provides an endoscopic surgical clip comprising first and second leg members joined at their proximal ends by resilient hinge means and terminating at their distal ends in latch means, each leg member having an outer surface and a clamping inner surface, the clamping inner surface being in opposition to the clamping inner surface of the other leg member, the outer surface of each leg member being configured to be accepted by the jaws of an endoscopic clip applier;

wherein the clamping inner surface of the first leg member has a convex radius of curvature extending transversely across at least a portion of the width of the first leg member, and the clamping inner surface of the second leg member has a concave radius of curvature extending transversely across at least a portion of the width of the second leg member, with the radius of curvature of the clamping inner surface of the first leg member being smaller than the radius of curvature of the clamping inner surface of the second leg member, and the radius of curvature of the clamping inner surfaces of the first and second leg members being complementary so as to minimize the gap which is created between the clamping inner surfaces when the clip is in a clamped position.

Thus, the clip is of the type comprising first and second leg members joined at their proximal ends by resilient hinge means and terminating at their distal ends in latch means. Each leg member has an outer surface and a clamping inner surface. The clamping inner surface is disposed in opposition to the clamping inner surface of the other leg member. The outer surface of each leg member is configured to be accepted by the jaws of a clip applier.

The improvement in the clip design specifically relates to the clamping inner surfaces of the first and second leg members. The clamping inner surface of the first leg member has a convex radius of curvature extending transversely across at least a portion of the width of the first leg member. The clamping inner surface of the second leg member has a concave radius of



curvature extending transversely across at least a portion of the width of the second leg member. The radius of curvature of the clamping inner surface of the first leg member is smaller than the radius of curvature of the clamping inner surface of the second leg member. Additionally, the radius of curvature of the clamping inner surfaces of the first and second leg members are complementary so as to minimize the gap which is created between the clamping inner surfaces when the clip is in a clamped position.

The clip of this invention is adapted to act as a knot clip in those applications requiring the replacement of a suture knot during endoscopic surgery. The clip, when clamped about a suture, exhibits a clamping force significantly greater than the clamping force exhibited by conventional clips disclosed in the art. This significantly increased clamping force allows the clip to function effectively for the application relating to the replacement of a suture knot.

Notwithstanding any other forms which may fall within the scope of the present invention, preferred forms of the present invention will now be described, by way of example only, with reference to the accompanying drawings wherein:

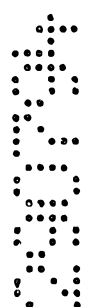
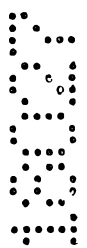
Figure 1 is a greatly enlarged view in perspective of a clip in accordance with the present invention;

Figure 2 illustrates the clip of Figure 1 clamped about a suture;

Figure 3 is a cross-sectional view taken along line 5-5 of Figure 2;

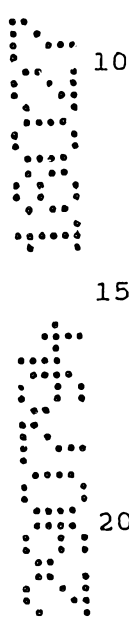
Figure 4 illustrates an endoscopic clip applier for endoscopically clamping a suture with a clip according to the invention.

Referring to Figure 1, there is shown a preferred surgical clip 60 of the present invention. The clip has first and second leg members 40 and 41, respectively. The leg members are connected at their proximal ends by a hinge section 43. The hinge section according to at least preferred forms of the present



invention is resilient; i.e., it has elastic memory and acts as a spring which assists in the packaging of the clip as well as the handling and placement of the clip. First leg member 40 terminates at its distal end in a hook member 44. Hook member 44 has two opposed arms 49 extending perpendicularly from first leg member 40. Each opposed arm 49 terminates with a protrusion means 50, which is disposed perpendicularly from arm 49 and lying substantially in the same plane as that of leg member 40. Each protrusion means 50 has a beveled protrusion end surface 53 to assist in deflecting the arms of the clip when the clip is closed. The second leg member 41 terminates at its distal end in latch member 47. Latch member 47 has two shoulder regions 48 with beveled regions 54 complementary to beveled protrusion end surfaces 53 so as to assist in the deflection of the arms 49 when the clip is closed.

First leg member 40 has a clamping inner surface 46 which has a convex radius of curvature extending transversely and uniformly across the width of first leg member 40. The second leg member 41 has a clamping inner surface 45 which has a concave radius of curvature extending transversely and uniformly across the width of second leg member 41. The radius of curvature of clamping surface 45 is smaller than, and complementary to, the radius of curvature of clamping surface 46. Ideally, the radii of curvature for the respective clamping surfaces of the leg members are configured to minimize the gap between the clamping surfaces which forms when the clip is in a clamped position. Although the particular embodiment shown in Figures 1-3 has the radius of curvature extending transversely across the entire width of the leg member, the radius of curvature may



extend across only a portion of the width of the leg member if there is a corresponding increase in the radius of curvature over that portion of the leg member which is curved.

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Disposed on the outer surface of each leg member are cylindrical bosses 51 and 52 to manipulate the clip in a suitable clip applier, preferably an endoscopic clip applier. Referring now to Figures 1 and 2, a suture can be clamped by urging leg members 40 and 41 toward each other by applying force in the direction of the arrows at cylindrical bosses 51 and 52. As force is applied, shoulder end regions 54 contact protrusion end surfaces 53 and deflect arms 49 of hook member 44 as the two leg members are pivoted about the resilient hinge 43 and closed about a suture 53. Closure is complete when shoulder regions 48 are disposed in tight contact on top of protrusion means 50 so as to firmly lock latch member 47 within hook member 44.

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As is clearly shown in the cross-sectional view of Figure 3, suture 53 conforms to the radii of curvature of complementary clamping surfaces 45 and 46, thereby being crimped within the clip. This crimped suture configuration advantageously increases the length of suture 53 which is securely clamped by the clip. Therefore, the pull force required to disengage suture 53 from the clip increases significantly.

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The clips within the scope of the present invention are suitably adapted for endoscopic applications to replace a conventional suture knot. This can be accomplished as illustrated in Figure 4. Referring now to Figure 6, there is shown a clip applier 70 having a long,

5 small-diameter longitudinal member 76. Longitudinal member 76 is adapted to be inserted into a conventional trocar 71 through trocar cannula 77. The trocar is used to provide an opening through bodily tissue 72 for access to the surgical site. The clip applicator 70 has jaws 73 at its distal end which are configured in such a manner as to facilitate grasping the outer surface of the legs of the clip 74. Clip applicator 70 is maneuvered within the surgical site to place clip 74 about suture 75 which is to be clamped.

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15 The clips of the invention can be made of any biocompatible material using conventional fabrication methods. The clips can be composed of various biocompatible metals, e.g. titanium and tantalum, and polymeric materials. Preferably, the clips are made of bioabsorbable polymeric materials such as homopolymers and copolymers of glycolide, lactide and para-dioxanone. The preferred means for fabricating clips from bioabsorbable polymeric materials is to inject a suitable polymer melt into an appropriately designed mold at process conditions conventionally employed for such polymer systems. After the polymer melt cools, the molded polymer shaped in the mold to meet the design criteria of the clip can be readily released from the mold. The molded clip can then be sterilized using conventional methods to render the clip suitable for surgical applications.

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30 The description of this preferred embodiment should not be construed in any way to limit the scope of the claimed invention. Numerous additional embodiments within the scope and spirit of the invention will become readily apparent to those skilled in the art.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An endoscopic surgical clip comprising first and second leg members joined at their proximal ends by resilient hinge means and terminating at their distal ends in latch means, each leg member having an outer surface and a clamping inner surface, the clamping inner surface being in opposition to the clamping inner surface of the other leg member, the outer surface of each leg member being configured to be accepted by the jaws of an endoscopic clip applicator;

wherein the clamping inner surface of the first leg member has a convex radius of curvature extending transversely across at least a portion of the width of the first leg member, and the clamping inner surface of the second leg member has a concave radius of curvature extending transversely across at least a portion of the width of the second leg member, with the radius of curvature of the clamping inner surface of the first leg member being smaller than the radius of curvature of the clamping inner surface of the second leg member, and the radius of curvature of the clamping inner surfaces of the first and second leg members being complementary so as to minimize the gap which is created between the clamping inner surfaces when the clip is in a clamped position.

2. An endoscopic clip as claimed in claim 1 wherein the clamping inner surface of the first leg member has a convex radius of curvature extending transversely across the entire width of the first leg member, and the clamping inner surface of the second leg member has a concave radius of curvature extending transversely across the entire width of the second leg member.

3. An endoscopic clip as claimed in claim 2 wherein the radii of curvature of the clamping inner surfaces of the first and second leg members are uniform.



4. An endoscopic clip as claimed in any one of the preceding claims wherein the outer surface of each leg member includes a cylindrical boss to facilitate engagement of the clip by the jaws of the endoscopic clip applier.
5. An endoscopic surgical clip substantially as herein described with reference to the accompanying drawings.

Dated this 18th day of July 1994

ETHICON, INC.

By their Patent Attorneys  
GRIFFITH HACK & CO.

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ABSTRACT

An improved surgical clip having first and second leg members joined at their proximal ends by resilient hinge means and terminating at their distal ends in latch means. Each leg member has an outer surface and a clamping inner surface. The outer surface of each leg member is configured to be accepted by the jaws of a clip applier. The improvement in the clip design specifically relates to the design of the clamping inner surface of each leg member of the clip. The clamping inner surface of the first leg member has a convex radius of curvature extending transversely across at least a portion of the width of the first leg member, and the clamping inner surface of the second leg member has a concave radius of curvature extending transversely across at least a portion of the width of the second leg member. The radius of curvature of the clamping inner surface of the first leg member is smaller than, and complementary to, the radius of curvature of the clamping inner surface of the second leg member.

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