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SURGICAL TISSUE THICKNESS MEASURING INSTRUMENT

5 The invention relates to a surgical tissue
thickness measuring instrument and more particularly
to such an instrument for use in conjunction with
a surgical stapling instrument to determine the
size of the staple to use and the proper gap to
which the instrument should be set.

10 In the past decade there has been an increasing
number of surgeons using staples in lieu of conven-
tional sutures in many internal organ procedures
ranging from the esophagus to the rectum. This
15 trend is due largely to the fact that the use of
staples is much easier and a number of difficult
procedures are rendered much simpler through the
use of staples. Perhaps of even greater importance,
however, is the fact that the use of staples is a
20 very much faster procedure, substantially reducing
the time required for suturing and, therefore, the
length of time the patient must be maintained in a
state of anesthesia.

25 Along with the above noted advantages, surgical
stapling procedures also present certain problems.
For example, it is necessary to select the proper
staple size for the thickness of the tissue to be
joined. Furthermore, it is quite possible that even
if the proper staple size is selected, the staple
30 could be formed in the tissue either too tightly or

too loosely. If the surgical staples are formed too tightly, the blood supply needed for the healing process is cut off and the tissue will become necrotic. On the other hand, if the staples are
5 formed too loosely, then hemorrhaging and/or leakage can occur. Both too tightly and too loosely formed staples can cause serious problems and complications.

It is precisely these problems, inherent in surgical stapling, that cause the need for an
10 instrument to measure the thickness of tissue to be joined by surgical staples. Surgical staples are available in various sizes. Many surgical stapling instruments are provided with means enabling the adjustment of the gap between the cartridge or
15 head containing the staples and the anvil against which the staples are formed, thereby determining the amount by which the staples are clinched. If the thickness of the tissue to be joined is known, appropriately sized staples can readily be selected
20 and the above noted gap can be properly set.

The very nature of living tissue makes it somewhat difficult to measure because of its soft, elastic and resilient properties. Studies have been conducted to determine the optimum healing pressure,
25 for example, for intestinal tissue. The optimum healing pressure varies with various types of tissue. Lung tissue, for example, is quite different from intestinal tissue. Therefore, the tissue measuring device of the present invention would have to be
30 designed to apply the optimum healing pressure during the tissue measuring operation for the particular type of tissue being measured. This can

readily be done and the same principles and mode of operation of the tissue measuring instrument of the present invention would be involved with each type of tissue.

5 For purposes of an exemplary showing, the tissue measuring instrument of the present invention will be described in its application to the measurement of the thickness of intestinal tissue. Prior art workers have developed various types of intraluminal anastomosis surgical stapling instruments. Exemplary, but nonlimiting, examples of such instruments are taught in U.S. Patent 3,552,626, copending application Serial No. 890,262, filed March 27, 1978 in the name of Carl T. Becht and entitled INTRALUMENAL ANASTOMOSIS SURGICAL STAPLING INSTRUMENT. These instruments join the tubular body parts substantially in end-to-end relationship, engaging the tubular parts internally and removing excess portions of the tubular parts adjacent the annular set or sets of staples implanted by the instrument, through the use of a cylindrical scalpel or the like. These instruments are adapted to use cylindrical cartridges of staples of one or more sizes and are provided with means to preset the gap between the staple containing cartridge and an annular anvil member against which the staples are formed. The adjacent tubular body parts to be joined together are located within the gap. The tissue measuring instrument of the present invention is intended to be used with such exemplary surgical stapling instruments provided with gap setting means (as for example that taught in the last mentioned copending application), the calibration

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of which is identical to that of the tissue measuring instrument.

5 The tissue measuring instrument of the present invention attaches to the tissue with a clamping action, making the actual tissue thickness measurement independent of the surgeon. The instrument, during the measuring process, will clamp on the tissue to be measured with a force substantially equivalent to the above mentioned optimum healing pressure. This is true over a predetermined range of tissue thicknesses. The instrument has at least one scale and indicator means by which the tissue thickness can be readily and directly read by the surgeon. The clamping jaws of the instrument are so configured as to provide easy engagement thereby of intestinal tissue where access is limited. The instrument may be provided with a second scale from which the diameter of the intestinal lumens can be determined for selection of a cylindrical staple cartridge of the proper diameter.

20 According to the invention there is provided a pliers-like tissue thickness measuring instrument for surgical purpose comprising first and second opposed tissue engaging jaws, first and second elongated handles pivotally joined together, said first handle terminating in said first jaw and said second handle terminating in said second jaw, said handles being so configured as to shift said jaws away from each other over a predetermined working range of separation when said handles are pivoted toward each other, resilient means to urge said jaws toward each other with a substantially constant predetermined force throughout said working range, a pair of arcuate members extending from the free end of said first handle in side-by-side parallel

5 spaced relationship toward the free end of said second
handle, a single arcuate member extending from said
free end of said second handle toward said free end
of said first handle, said single arcuate member
10 having a first portion slidable between said pair
of arcuate members of said first handle and a
second portion slidable along those edges of said
pair of members furthest from said jaws when said
handles are shifted toward and away from each other,
15 to shift said jaws away from and toward each other,
each of said pair of members bearing a scale
representing said working range, said second portion
of said single member having a pair of indicators
each cooperating with one of said scales to give a
20 direct reading of the distance between said jaws.

By way of example, an embodiment of the present
invention will now be described with reference to the
accompanying drawings, in which:

20 Figure 1 is a side elevational view of one
embodiment of the tissue measuring instrument of the
present invention.

Figure 2 is a front elevational view of the
embodiment of Figure 1 as seen from the left in
that Figure.

25 Figure 3 is a rear elevational view of the
instrument of Figure 1 as seen from the right in
that Figure.

Figure 4 is a cross sectional view taken along
section line 4-4 of Figure 1.

30 Figure 5 is a side elevational view similar to
Figure 1 and illustrating the use of the instrument
of Figure 1.

35 Figure 6 is a fragmentary cross sectional view
similar to Figure 4 and illustrating the provision
of a laterally offset jaw.

A first embodiment of the tissue measuring instrument of the present invention is illustrated in Figures 1 through 6, wherein like parts have been given like index numerals. Reference is first made to Figures 1 through 4. The instrument itself is generally indicated at 1 and comprises a first jaw 2 having a rearward extension in the form of a first handle element 3 and a second jaw 4 having a rearward extension in the form of a handle element 5. At their forward ends, jaws 2 and 4 terminate in planar tissue engaging surfaces 2a and 4a, respectively.

As will be evident from Figure 2, the jaws 2 and 4 have a thickness of approximately one-third the thickness of their respective handles 3 and 5. The first jaw 2 and handle 3 have a downwardly depending central portion 6 with a transverse perforation 6a therethrough. The second jaw 4 and its handle 5 have a pair of upstanding members or bifurcations 7 and 8, having transverse coaxial perforations 7a and 8a, respectively. The downwardly depending element 6 of first jaw 2 and its handle 3 is adapted to be located between upstanding members 7 and 8 of second jaw 4 and its handle 5 with perforations 6a, 7a and 8a coaxial. A pivot pin 9 is located in these perforations thereby pivotally joining first jaw 2 and its handle 3 to second jaw 4 and its handle 5.

The handle 3 of first jaw 2 has an elongated groove or depression 10 formed on its inside surface.

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BEST MODE OF CARRYING OUT THE INVENTION

A first embodiment of the tissue measuring instrument of the present invention is illustrated in Figures 1 through 6, wherein like parts have been given like index numerals. Reference is first made to Figures 1 through 4. The instrument itself is generally indicated at 1 and comprises a first jaw 2 having a rearward extension in the form of a first handle element 3 and a second jaw 4 having a rearward extension in the form of a handle element 5. At their forward ends, jaws 2 and 4 terminate in planar tissue engaging surfaces 2a and 4a, respectively.

As will be evident from Figures 1 and 2, the jaws 2 and 4 have a transverse thickness approximately one-third that of their respective handles 3 and 5. The first jaw 2 and handle 3 have a downwardly depending central portion 6 with a transverse perforation 6a therethrough. The second jaw 4 and its handle 5 have a pair of upstanding members or bifurcations 7 and 8, having transverse coaxial perforations 7a and 8a, respectively. The downwardly depending element 6 of first jaw 2 and its handle 3 is adapted to be located between upstanding members 7 and 8 of second jaw 4 and its handle 5 with perforations 6a, 7a and 8a coaxial. A pivot pin 9 is located in these perforations thereby pivotally joining first jaw 2 and its handle 3 to second jaw 4 and its handle 5.

The handle 3 of first jaw 2 has an elongated groove or depression 10 formed on its inside surface.

This depression 10 is shown in Figures 1 and 4.

At the rearward end of depression 10 an upstanding stud 11 is formed. Handle 5 of second jaw 4 has a similar longitudinally extending groove or depression 12 formed on its inside surface (see Figure 1).

At the rearward end of depression 12 an upstanding stud 13 is located, the stud 13 being similar to stud 11 of handle 3. A leaf spring 14 is located between handles 3 and 5. The end 14a of spring 14 is located in the depression 10 of handle 3 and has a perforation 15 formed therein. The stud 11 extends

through the perforation 15, as shown in Figures 1 and

4. The end 14b of spring 14 is similarly located

in the groove or depression of handle 5. Spring end 14b has a perforation 16 therein through which stud 13 extends. It will be evident that spring 14

will remain in place between handles 3 and 5 by virtue of the fact that its ends 14a and 14b are located in handle grooves or depressions 10 and 12 and are engaged by studs 11 and 13, respectively.

The spring 14 urges handles 3 and 5 apart, thus urging jaws 2 and 4 and their tissue engaging surfaces 2a and 4a together. Figures 1 through 3 illustrate the tissue measuring instrument in its normal condition when not in use.

Handle 3, at its distal end, has a pair of downwardly depending elements 17 and 18. As can most clearly be determined from Figure 4, the elements 17 and 18 are of substantially triangular cross section. Their facing surfaces 17a and 18a are in parallel spaced relationship. Their exterior surfaces

17b and 18b slope rearwardly and toward each other. Outside surface 17b of element 17 carries indicia in the form of a scale, generally indicated at 19. Exterior surface 18b of element 18 is provided with indicia in the form of an identical scale, generally indicated at 20.

The second handle 5 has an upstanding arcuate member 21. As can most easily be seen in Figure 4, the member 21 has a rearward triangular edge having one surface 21a substantially coplanar with the surface 17b of element 17 and a second surface 21b substantially coplanar with surface 18b of element 18. The member 21 also has a thin web-like body portion 21c which fits just nicely between the surfaces 17a and 18a of elements 17 and 18. The surface 21a of element 21 carries an indicator line 22 cooperating with the scale 19 of element 17 (see Figures 1 and 3). Similarly, the surface 21b carries an indicator line 23 identical to indicator line 22 and adapted to cooperate with the scale 20 of element 18. The scales 19 and 20 are expanded at least about 3:1 for ease of reading. In the embodiment illustrated the scales 19 and 20 are expanded 4:1.

To complete the structure, the handle 3 may be serrated as at 3a so that it can be conveniently and firmly grasped in non-slip fashion by the hand of the surgeon. The handle 5 may be similarly serrated as at 5a. Optionally, the handle 3 may be provided with another scale, generally indicated at 24 in Figure 1. The scale 24 runs longitudinally of handle 3 along its side. The other side of handle 3 may be provided with an identical scale (not shown) so that the instrument can be viewed from either side during use. The scale 24 enables the surgeon to make a quick

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determination of the diameter of a tubular body element to be stapled, as will be described hereinafter.

Studies have been conducted to determine the optimum healing pressure for sutured intestinal tissue. This pressure is known to be approximately 8 g/mm^2 . In the exemplary application with respect to which the tissue measuring instrument is herein being described, it has been found adequate in the measurement of intestinal tissue to design the instrument to be capable of measuring tissue thickness over a range of from 0 to 4 mm. It will be noted from Figures 1 and 3 that scales 19 and 20 extend over this range. The spring 14 is designed to be a constant bias spring causing jaw surfaces 2a and 4a to measure tissues located therebetween at a pressure of 8 g/mm^2 at $1/2$ the working range (i.e., at 2 mm separation between the surfaces) and for all practical purposes exerting this same pressure throughout the working range of from 0 to 4 mm. The jaws 2 and 4 are so configured that their surfaces 2a and 4a will be parallel at $1/2$ the working range (i.e., a 2 mm separation between the surfaces) to assure maximum accuracy of the tissue thickness measurement. The instrument 1 may be made of any material (including plastic, metal, combinations thereof, or the like) suitable for a surgical environment and capable of being sterilized by autoclave, ethylene oxide, irradiation or other standard methods.

Figure 6 is a fragmentary view similar to that of Figure 4. The embodiment shown in Figure 6 differs from that of Figure 4 in that the jaw

(indicated at 2b in Figure 6) is angled laterally. It will be understood that in such an embodiment the other jaw would be similarly angled. The instrument of the present invention, provided with such angled jaws, would be used in constricted areas where access is limited to insure adequate visibility.

The instrument having been described, its use may be set forth as follows. The surgeon, grasping the instrument 1 in a pliers-like fashion, squeezes handles 3 and 5, causing jaws 2 and 4 to open against the action of constant bias spring 14. For purposes of this description, the instrument will be described in its application to the tissue thickness measurement of an intestinal lumen 25 shown in Figure 5. The jaws 2 and 4 are located about the intestinal lumen 25 as shown and, thereafter, the pressure applied to instrument handles 3 and 5 by the surgeon is released. Spring 14 will cause jaw surfaces 2a and 4a to exert a pressure on lumen 25 of about 8 g/mm^2 . Since the surgeon is no longer applying pressure to handles 3 and 5, the direct thickness reading in millimeters on scales 19 and 20 in conjunction with indicator lines 22 and 23, respectively, is wholly independent of the surgeon. The arrangement of scales 19 and 20 is such that the direct measurement reading can be observed from either side of the instrument, or from the rear thereof.

It will be understood that in the procedure illustrated in Figure 5 a double thickness of the intestinal lumen tissue is being measured. If two substantially identical lumens are to be joined together by the surgical stapling instrument, this

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reading can be used directly, being considered the sum of the tissue thickness of the two lumens to be joined. If the two lumens to be joined are of tissue of different thicknesses, each lumen can be measured in the manner shown in Figure 5 and the resulting reading divided by 2. This will give a tissue thickness measurement for each individual lumen. The resulting thickness measurements are then added to determine the proper staple height and the proper gap to set between the instrument staple containing cartridge or head and the anvil. When necessity dictates, a single tissue thickness reading can be taken directly by inserting one of jaws 2 and 4 into the hollow interior of the lumen.

As indicated above, the instrument may be provided with the scale 24 along both sides of handle 3. It will be understood that an identical scale could be provided along both sides of handle 5, as well, as a matter of convenience. To measure the diameter of the lumen 25, the lumen, in flaccid state, is laid along the surface of handle 3 with one edge at the 0 mark of scale 24. The scale is then read at the position of the other edge of the lumen. The actual measurement in this instance is a measurement of about $1/2$ the circumference of the lumen, which is proportional to the lumen diameter. The numbers appearing on scale 24 indicate the various circular cartridge or head diameters available for use with the intraluminal anastomosis surgical staple instrument, since the cartridge or head during the procedure is located within one of the lumens to be joined. This procedure makes the selection of proper staple cartridge or head size a simple matter, eliminating any guess work.



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CLAIMS

1. A pliers-like tissue thickness measuring instrument for surgical purpose comprising first and second opposed tissue engaging jaws, first and second elongated handles pivotally joined together, said first handle terminating in said first jaw and said second handle terminating in said second jaw, said handles being so configured as to shift said jaws away from each other over a predetermined working range of separation when said handles are pivoted toward each other, resilient means to urge said jaws toward each other with a substantially constant predetermined force throughout said working range, a pair of arcuate members extending from the free end of said first handle in side-by-side parallel spaced relationship toward the free end of said second handle, a single arcuate member extending from said free end of said second handle toward said free end of said first handle, said single arcuate member having a first portion slidable between said pair of arcuate members of said first handle and a second portion slidable along those edges of said pair of members furthest from said jaws when said handles are shifted toward and away from each other to shift said jaws away from and toward each other, each of said pair of members bearing a scale representing said working range, said second portion of said single member having a pair of indicators each cooperating with one of said scales to give a direct reading of the distance between said jaws.



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2. An instrument as claimed in claim 1 wherein said working range is from 0 to 4 mm and said resilient means is such as to cause said first and second jaws to exert a substantially constant pressure of tissue therebetween of 8 g/mm² throughout said working range whereby said instrument can be used to measure the thickness of intestinal tissue.

3. An instrument as claimed in claim 1 or claim 2 wherein at least one of said handles has a scale marked on at least one side thereof, said scale being so devised as to give a diameter reading of a tubular body organ laid therealong in flaccid state.

4. An instrument as claimed in claim 1, claim 2 or claim 3 wherein said resilient means comprises a constant bias leaf spring located between said handles with its ends affixed to said handles.

5. A tissue thickness measuring instrument substantially as hereinbefore described with reference to and as shown in the accompanying drawings.

The text of the specification has been reproduced by photocopying the applicants original typescript. It may contain a few amendments which are difficult to read. The original typescript containing these amendments may be inspected on the premises of the Patent Office