

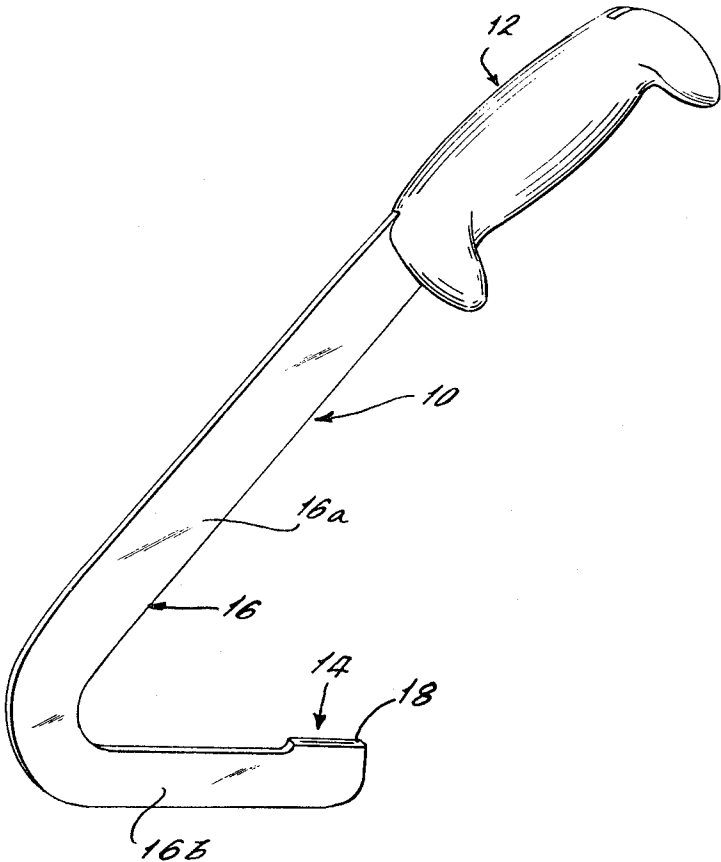
[72]	Inventor	Charles Allen McKnight 2914 Painted Valley Drive, Little Rock, Ark. 72207	1,213,334	1/1917	Chapman	145/46
			2,323,362	7/1943	Weiss	85/49X
[21]	Appl. No.	789,474	2,638,092	5/1953	Dorr	145/46X
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[45]	Patented	May 25, 1971	3,236,142	2/1966	Bradway	85/49

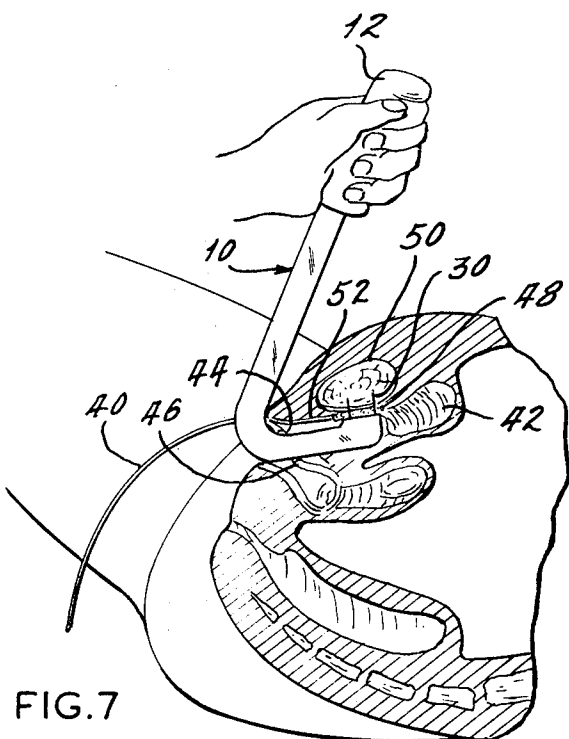
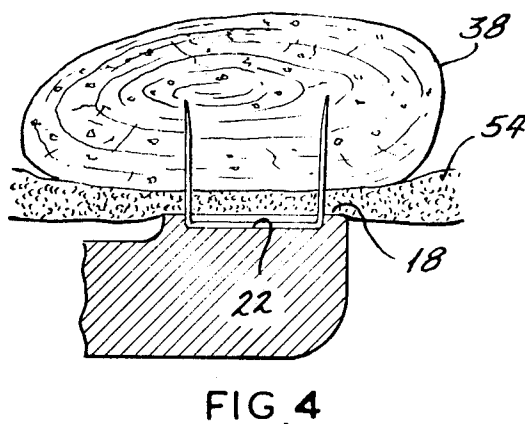
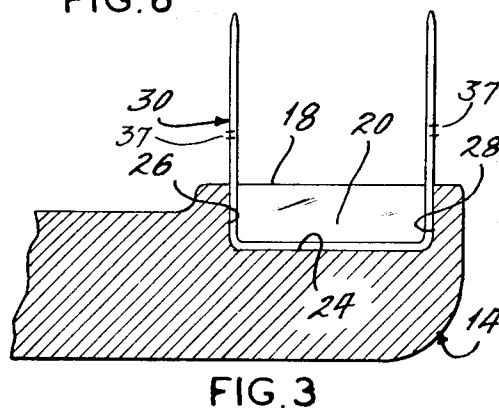
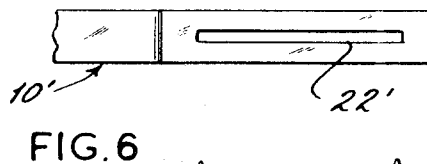
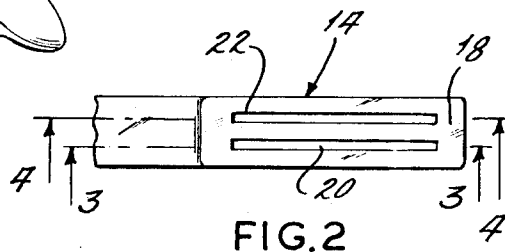
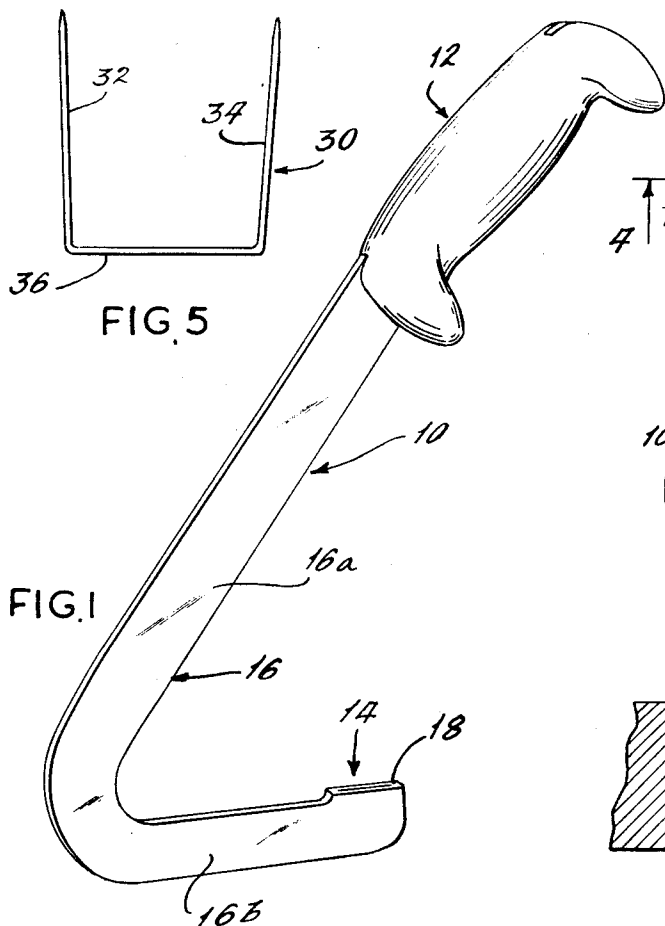
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[54]	SURGICAL INSTRUMENT
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[51]	Int. Cl. B25c 3/00
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ABSTRACT: A surgical instrument including particularly a stapling-type instrument for attaching or anchoring fleshy parts of the body to adjacent bone structure including means to facilitate such attachments in areas of the body that are relatively inaccessible and difficult to operate in.





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SURGICAL INSTRUMENT

It has been found that certain types of medical conditions can be helped by attaching fleshy portions of the body to the adjacent bone structure. This is especially true of certain kinds of conditions including particularly conditions that occur in females as an after effect of childbearing such as stress incontinence and for certain types of congenital defects, and for some conditions that result from certain types of injuries as well. Stress incontinence is one of those conditions that may occur in females after they have passed their childbearing years, particularly when they have had a number of children. Such females develop a condition where the bladder tends to sag and move away from its normal position against the interior pubic bones causing urine leakage, discomfort and embarrassment and in some instances infections of the urinary tract may also develop. In the past, these stress incontinence conditions have been relieved to some extent and with varying degrees of success by anterior vaginal repairs where meticulous attention is paid to the repair of the supports at the neck of the bladder. Special surgical procedures have also been devised, each having the common purpose of elevating the bladder neck and creating a suitable vesicourethral angle. These procedures are difficult and time consuming to perform and often have included the construction of a fascial sling or other vesicourethral suspension means. Such procedures may involve danger to some patients and are further complicated by the fact that they must be performed in areas or cavities of the body where space and access are extremely limited.

The present invention which is useful, among other things to correct stress incontinence is embodied in a relatively simple and easy to use instrument which is constructed so that it can be accurately controlled and manipulated for locating and forcing staples through body tissues into the adjacent bone structure to anchor the flesh thereto even in areas of limited space such as from a position that is accessible by entry through the mouth or other portion of the female vagina. The subject instrument is designed so that it can be used by a surgeon or other person to staple flesh to bone structure in places where it is inconvenient or impossible to see the operation as it is being performed and where the surgeon must rely on locating the parts including the body parts and the anchoring means by feel along. To this end the subject device includes means for supporting a fastener such as a staple or staplelike device while aiming or locating it in position to be driven, and means on the instrument by which controllable force can be brought to bear on the staple to drive it into a final fixed position in a patient's bone structure to anchor adjacent flesh thereto. In an actual operation this may include stapling tissue across a sagging portion of a bladder adjacent to the urethral orifice in a female to elevate the posterior urethra and to maintain the neck of the bladder in a normal or nearly normal position against the pubic bones. The present invention enables this type of repair to be accomplished in a minimum of time and with minimum of pain and expense to the patient. The operation is also relatively easy to perform especially when compared to other known operations and procedures used to correct the same condition. Furthermore, the results of tests using the present device and procedure indicates a relatively high possibility for success. It is also noteworthy that the subject instruments are relatively simple to make and use, they preferably have no moving parts, they are easily cleaned and sterilized, and relatively little training is required to master their use. Furthermore, a minimum of advanced preparation is required by the surgeon using the subject instrument thereby simplifying the surgical procedures and reducing the discomfort to the patient. Although the subject invention has special application for performing the above type of repair, it is anticipated that it will also have many other uses and applications including any application where it is desired to perform stapling operations in limited access and out-of-sight areas as for example in making rectal and genital repairs, organ transplants, and cosmetic repairs to name a few.

It is therefore a principal object of the present invention to provide simple and easy to operate means for attaching or anchoring tissue to adjacent bone structure.

Another important object is to provide means for attaching flesh to bone structure by a stapling operation.

Another object is to provide a stapling-type surgical instrument that is constructed to be used in relatively inaccessible regions of the body.

Another object is to provide means by which it is possible to accurately locate and seat a staple in bone structure or the like without being able to see to locate and drive the staple.

Another object is to provide a relatively simple and inexpensive one-piece surgical stapling instrument.

Another object is to provide similar one-piece instruments for locating and initially seating a staple and for thereafter completing the driving of the staple or staplelike device to a predetermined depth into a bone structure particularly at a location that is not readily accessible or visible to the one performing the stapling operations.

Another object is to provide a staplelike fastener particularly constructed to be used to fasten flesh to adjacent bone structure.

Another object is to provide a surgical instrument which requires relatively little training and skill to use.

Another object is to provide a surgical instrument that is relatively easy to clean and sterilize.

Another object is to simplify the surgical procedure necessary for relieving or curing stress incontinence and like conditions.

These and other objects and advantages of the present invention will become apparent after considering the following detailed specification which covers several preferred embodiments thereof in conjunction with the accompanying drawings, wherein:

FIG. 1 is a perspective view of a surgical instrument constructed according to the teachings of the present invention;

FIG. 2 is an enlarged top view of the head portion of the instrument of FIG. 1;

FIG. 3 is an enlarged cross-sectional view of the head portion of the subject instrument taken on line 3—3 of FIG. 2, said head portion being shown with a staple positioned therein;

FIG. 4 is a cross-sectional view taken on line 4—4 of FIG. 2 and showing the subject device in operative position after a staple has been driven into bone structure;

FIG. 5 is an enlarged side view showing an unstressed staple for use with the instrument of FIGS. 1—4;

FIG. 6 is an enlarged top view similar to FIG. 2 but showing a modified form of the subject instrument; and,

FIG. 7 is a view showing the subject instrument in operative position extending part way into a female vagina after preliminary surgical preparations have been made, said instrument shown being used to attach a portion of the paraurethral fibrous tissue to the adjacent posterior aspect of the pubic bone to support the bladder and urethra in positions to overcome or cure a condition of stress incontinence.

Referring to the drawing more particularly by reference numbers, number 10 refers to a surgical instrument constructed according to the teachings of the present invention. The instrument 10 can be constructed from any of a number of materials and is preferably of one-piece construction. The instrument 10 includes a handle portion 12, an operator or head portion 14, and means including a connecting portion 16 extending therebetween. In the form shown the connecting portion 16 is an elongated member that includes acutely angularly related portions 16a and 16b.

The operator or head portion 14 of the instrument 10 is shown formed on the free end of the portion 16b and includes a surface 18 positioned in opposed spaced relationship to the handle 12. In the form of the instrument shown in FIG. 2, two spaced grooves or slots 20 and 22 are formed in the surface 18 of the head portion 14. One of the grooves, shown as the groove 20 in FIG. 3, is relatively deeper than the groove 22 and is defined by a bottom surface 24 and two spaced parallel or nearly parallel end surfaces 26 and 28. The groove 20 is designed and shaped to receive and support a staple such as U-shaped staple 30 shown in FIGS. 3 and 5. The staple 30 is

shown in its unstressed condition in FIG. 5 and is defined by two spaced leg portions 32 and 34 and an integral connecting portion 36. The legs 32 and 34 in the unstressed condition of the staple are preferably not parallel to each other but instead are further from each other at their free ends than at their connected ends. This is done so that some force must be applied on the free ends to enable the staple to be positioned in the groove 20 as shown in FIG. 3, and to enable the groove 20 to hold and support the staple 30 without requiring any other holding and supporting means. The groove 20 is therefore used to hold and support the staple 30 while the staple is being set in position and forced into place as will be explained. In the preferred form of the device the staple is also made of some hard corrosive resistant material such as stainless steel, and the free ends of the legs 32 and 34 are preferably sharpened to fine points to make it relatively easy to drive the staple into bone structure or the like. It is also to be noted that in the stressed condition of the staple which is the condition shown in FIG. 3, the leg portions 32 and 34 are parallel or nearly parallel and this is the condition in which it is driven into the bone structure. Therefore, the legs will exert some sidewise pressure after it is installed to help hold it in place. However, the groove 20 (FIGS. 2 and 3) may be too deep to permit the staple to be fully or even sufficiently seated while positioned therein to prevent looseness in the attachment being made, and for this reason the second shallower groove 22 is included to provide means to complete the seating of the staple to its desired final position. It is also contemplated to make the staple legs 32 and 34 parallel and to form the end surfaces or walls 26 and 28 of the groove 20 so as to frictionally engage and hold the staple without having to stress the legs.

The grooves 20 and 22 rather than being formed in one single instrument as shown in FIG. 2, may also be formed in two separate similar instruments as illustrated in FIG. 6 which shows an instrument 10' having a single groove 22'. Having two similar instruments instead of one with two grooves may have advantages particularly when a doctor might have a difficult time being sure that he has positioned the staple in the proper groove especially in the shallower groove 22 used to complete the driving of the staple to the final desired position.

The subject instruments 10 and 10' are designed primarily as surgical instruments to be used in female surgery for anchoring the bladder to the adjacent bone structure, as already stated. To accomplish this the operating or head portion 14 thereof with a staple 30 in groove 20 is positioned extending in through a portion of the vagina of the female patient as clearly shown in FIG. 7. Before reaching this stage of the procedure, however, it is usually necessary for the doctor to have prepared one or more places for locating the subject staples which preparation will usually involve some minor surgery. The procedures for doing this are not part of this invention. Thereafter, and with the instrument in operative position as shown, the surgeon will use the fingers on one of his hands to guide and locate the pointed ends of the staples and also to prevent the pointed staple ends from causing unwanted injury to other tissues in the area. When the staple ends are properly located, the surgeon will apply force with his other hand on the handle portion 12 in a generally upwardly direction to force the staple through the tissue and into the bone structure. He is able to do this with considerable force and good control because of the leverage provided by the shape of the instrument and by the fact that he is pulling the instrument in a direction generally toward his body. After the staple has been driven in as far as possible using the deeper groove 20, it is an easy matter to free the instrument from the staple, and again using his fingers to locate the staple in the shallower groove 22, or 22' if a single groove instrument is being used. He can now complete the driving and seating of the staple to the desired final position. A typical operation will usually involve the placing of two or more staples in the manner described.

The staples 30 preferably have outwardly biased legs 32 and 34 as aforesaid and are preferably constructed of some suitable material that can be surgically sterilized and that can be

tolerated by living tissue. Stainless steel is one material that seems to offer particular advantages in this regard. Many sizes and/or other shapes for the staples other than those shown in the drawing are also possible and contemplated including staples having relatively wide flat head portions which offer some hope of providing even better support for the tissue and perhaps even less chance for a tear. Staples can also be constructed having other cross-sectional shapes and the legs of the staples may have outward protuberances 37 at various positions to provide even better engagement with the bone structure. As clearly shown in FIG. 4, the outward bias of the staple legs 32 and 34 may also cause the free ends of the staple legs to move apart slightly as the staple is driven into bone to help hold it in position and to prevent it from coming out. In FIG. 4 this outward movement is shown exaggerated for clarity, since only slight outward movement is anticipated as being desirable to help maintain the staple 30 in the bone 38.

A more specific disclosure of the actual position of the subject instrument in relation to the organs in a female during operation thereon is shown in FIG. 7. In this showing the subject instrument is being used to correct a female incontinence condition due to a sagging bladder. In this case the patient is in a lying down faceup position and the perineum is prepared as in any vaginal surgery. A catheter 40 is placed in the bladder 42 so that undesirable flow of urine can be controlled during the operative and the post operative periods. An incision 44 is cut in each side of the anterior vaginal wall 46 and an examination is made of the area around the bladder 42 by the surgeon inserting his fingers through the incisions to locate the proper places for the staples. The doctor then takes a staple 30 which has been previously sterilized, and presses the free ends of the legs 32 and 34 together slightly to enable him to insert the staple 30 into the groove 20 of the instrument 10 which has also been sterilized. The normal outward bias of the legs 32 and 34 tends to hold the staple in the groove 20 as aforesaid. With the staple 30 in the groove 20, the operator portion 14 of the instrument 10 with the staple 30 positioned therein is carefully inserted into the mouth of the vagina and the pointed ends of the staple are located at the desired positions within one of the incisions 44. The doctor then pulls the instrument 10 upwardly away from the patient thereby driving the staple 30 through the paraurethral tissue 48 and into the pubic bone 50. As the staple passes into the pubic bone 50 there is a characteristic crepitant sensation transmitted to the doctor through the instrument 10 which allows the doctor to feel the progress of the staple 30. As can be seen, the acute angle formed in the connecting portions 16a and 16b of the instrument between the handle portion 12 and the operator portion 14 is necessary to allow proper transfer of force to the staple 30 in this awkward position.

Once the staple 30 is partially driven into the pubic bone 50, the instrument 10 is released from the staple by tilting or other movement and the shallower groove 22 is placed against the staple and the operation repeated as before to complete the driving of the staple. Thereafter the instrument 10 is withdrawn from the incision 44 and loaded with another staple and reinserted into the vagina as before for locating and seating in the other previously made incision by a repeat of the foregoing procedure. In this way, the paraurethral tissue 48 is attached to the pubic bones 50 so that the paraurethral tissue 48 forms a strap or sling across the urethra 52 and across the neck of the bladder 42 to support them in proper position against the pubic bones 50.

The procedure can be varied by using the instrument 10 (or 10') to seat both staples initially and then completing the driving of the staples as a second step. An estimated force of 15 to 20 pounds is about the maximum that is usually necessary to seat and drive home each staple. When both staples are properly in position, the incisions 44 are reclosed.

The groove 22 or 22' can be made having different depths in different instruments. As shown in FIG. 4, it is the depth of the slot 22 or 22' into the surface 18 along with the resilience of the tissue 54 being stapled which determines how deep into

the bone 38 a staple 30 will ultimately be driven and hence how much space is provided between the head 36 of the staple 30 and the bone 38. There should always be a certain space between the head 36 of the staple 30 and the bone 38 so that the stapled tissue 54 will have adequate circulation and remain viable living tissue. The proper size of this space depends on the type and thickness of the tissue. Although the subject invention is primarily designed for the operative procedures described above, by varying the angle of the connecting portion 16 between the handle 12 and the operator portion 14, and by changing the size and shapes of the staples and their matching grooves in the instrument, it can be used for other procedures as well including being used in rectal repairs, cosmetic surgery and in certain types of transplants where it is desirable to attach flesh or organs to bone structure.

Thus there has been shown and described a novel surgical instrument which fulfills all of the objects and advantages sought therefor. Many changes, modifications, variations, and other uses and applications of the subject instrument will, however, become apparent to those skilled in the art after considering this specification and the accompanying drawing. All such changes, modifications, variations, and other uses and applications of the subject instrument which do not depart from the spirit and scope of the invention are deemed to be covered by the invention which is limited only by the claims which follow.

What I claim is:

1. An instrument for implanting staples having integral head and leg portions into bone and like structures comprising an elongated body having portions thereof that are acutely angularly related, a handle on one end of one of said body portions and an operative portion on one end of the angularly related other body portion such that the handle and operative portions are positioned in spaced and opposed relationship, a groove formed in the operative portion on a side thereof that faces the handle portion, said groove being shaped to cooperatively engage the head portion of the staple.

2. The instrument defined in claim 1 wherein said operative instrument portion includes a surface formed about said groove, said surface being in opposed relationship to the handle portion such that pulling force applied to the handle portion acts through the elongated body in a direction that is substantially perpendicular to said surface.

3. The instrument defined in claim 1 wherein said groove has a first groove surface positioned to engage and support the head portion of a staple to be implanted.

4. The instrument defined in claim 3 wherein said groove has end wall portions adapted to engage the staple legs adjacent to the head portion thereof to retain and support a staple positioned in the groove.

5. The instrument defined in claim 4 wherein the groove end walls are spaced apart a distance such that they exert force against the leg portions of a staple positioned in the groove in a direction to maintain the staple in the groove during implantation thereof in bone structure.

6. Means for fastening portions of living body tissue to adjacent bone structure by forcing a U-shaped staple through the tissue and into the bone structure, said means comprising an instrument for use in forcing said staples through the living body tissue and into bone structure, said instrument including spaced handle and operator portions and means including an elongated instrument body having angularly related portions connected respectively at opposite ends thereof to said handle and operator portions to maintain said portions in fixed spaced relationship, said operator portion including an anvil member having a surface thereon in spaced opposed relationship and in substantial alignment with the handle portion, and an elongated groove formed in said anvil member adjacent to said surface, said groove being constructed to cooperatively engage and support a staple while the staple is being forced

through the body tissue and into the bone structure by force applied on the handle portion in a direction away from but substantially in alignment with the operator portion of the instrument.

7. The means defined in claim 6 wherein the groove in the operator portion of said instrument is defined by spaced side and end walls constructed to cooperatively engage the staple and to prevent relative movement between the instrument and the staple during the time when the staple is forced into the bone structure.

8. The means defined in claim 7 wherein the groove is constructed so that the staple must undergo stress to be moved to a fully seated position therein.

9. Means for fastening tissue to adjacent bone structure in a living body for forcing a staple of substantially U-shape including integral head and leg portions through the tissue and into the bone structure, said means comprising an instrument for installing the staple in a living body, said instrument having a first portion including means constructed to retain and support the staple during installation thereof, and a second portion spaced from and connected to the first portion and including a handle portion, and means connecting the handle portion to the first portion, said first portion including a member having a surface facing the handle portion and a groove formed in said surface, said groove being defined by opposed side and end walls and a bottom wall extending therebetween, said groove end walls being spaced closer together than the unstressed staple leg portions adjacent to the head portion thereof so that the staple leg portions must be forced closer together than they are in their unstressed condition to install the head portion of the staple in the groove in a fully seated condition in which the head portion abuts the bottom wall of the groove.

10. The means defined in claim 9 wherein said first instrument portion includes a second groove positioned adjacent the aforesaid groove, said second groove being shallower than the aforesaid groove so that it can be used to engage the head portion of a staple that has been partially pressed into bone structure during completion of the pressing in of the staple in the bone structure to the desired depth.

11. Means for use in female surgical procedures to staple tissue to adjacent bone structure to correct certain female disorders caused by insufficient or poor support of the urethra and bladder neck by providing support therefor, the means being used to force a staple member of generally U-shape through the tissue and into the bone structure, said means comprising an instrument for implanting said staple through body tissue into adjacent bone structure, said instrument having an operator portion, a handle portion, and means including an elongated member connecting the handle portion to the operator portion in spaced and opposed relationship to each other, said operator portion having a surface formed thereon in generally opposed spaced relationship to the handle portion, a slot formed extending inwardly from said surface for supporting a staple during implantation thereof, said slot being defined by a bottom wall and adjacent spaced end and sidewall portions, the bottom wall of said slot being generally parallel to the said surface and said side and end walls having portions oriented substantially perpendicular to said surface for engaging and supporting portions of a staple positioned therein, said surface being adapted to be moved into contact with an area of the body tissue which is being attached to the adjacent bone structure during implantation of a staple to limit the penetration of the staple into the bone structure when pressure is applied through the handle portion to the staple positioned in the slot.

12. The means defined in claim 11 wherein the construction of the slot is such that the staple must undergo some stress and change in shape to be positioned therein.

13. The means defined in claim 11 wherein said slot is constructed to frictionally engage and support the staple.