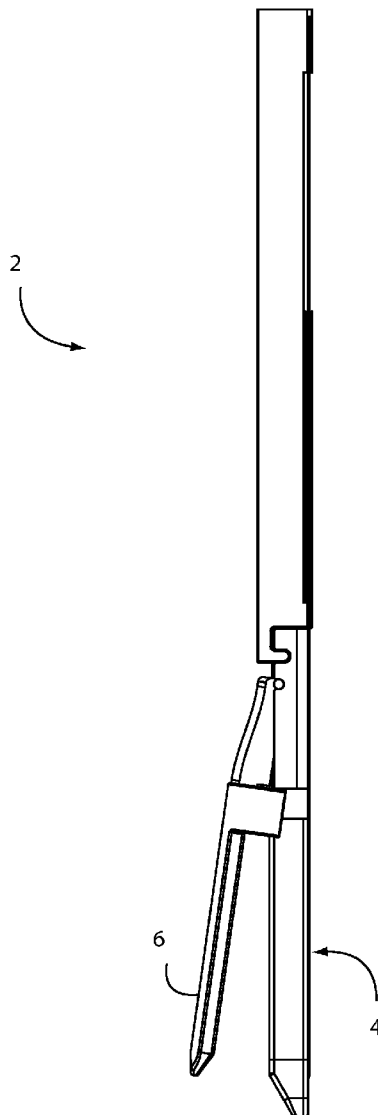


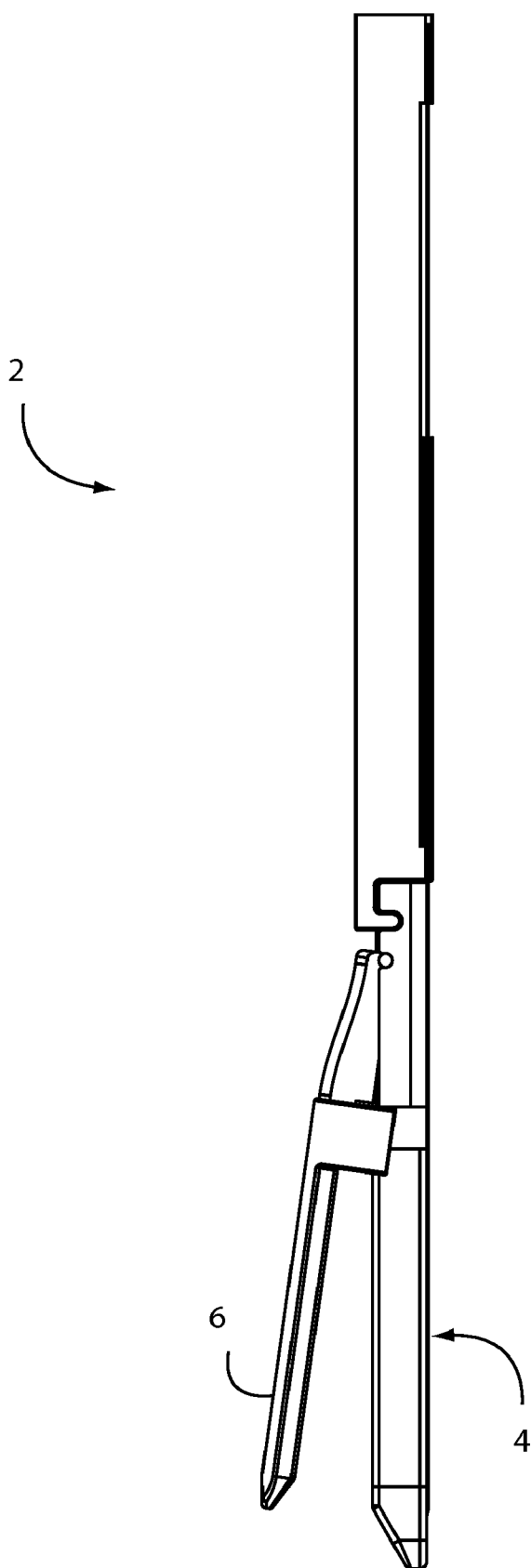


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(19) **United States**(12) **Patent Application Publication**
Manoux et al.(10) **Pub. No.: US 2012/0091183 A1**(43) **Pub. Date: Apr. 19, 2012**(54) **METHOD OF FABRICATING A STIFF ANVIL
FOR A SURGICAL INSTRUMENT****Publication Classification**(75) Inventors: **Philippe R. Manoux**, San Francisco,
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Flagstaff, AZ (US); **Bernard A.
Hausen**, Redwood City, CA (US)(51) **Int. Cl.**
A61B 17/04 (2006.01)
B23P 11/00 (2006.01)
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B23P 15/00 (2006.01)(73) Assignee: **CARDICA, INC.**, Redwood City,
CA (US)(52) **U.S. Cl. 227/175.1; 29/592; 29/428; 29/527.5**(21) Appl. No.: **13/335,581**(22) Filed: **Dec. 22, 2011**(57) **ABSTRACT****Related U.S. Application Data**(62) Division of application No. 12/489,355, filed on Jun.
22, 2009, now Pat. No. 8,087,562.

A method of manufacturing a surgical apparatus may include fabricating an anvil that includes an insert composed of a first material, the insert located within a cavity in a body composed of a second material, where the first material and the second material have different properties.





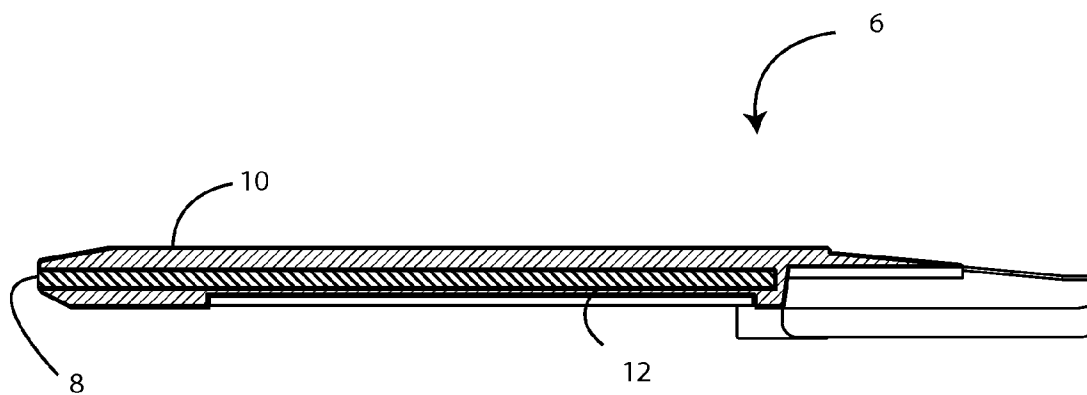


FIG. 2

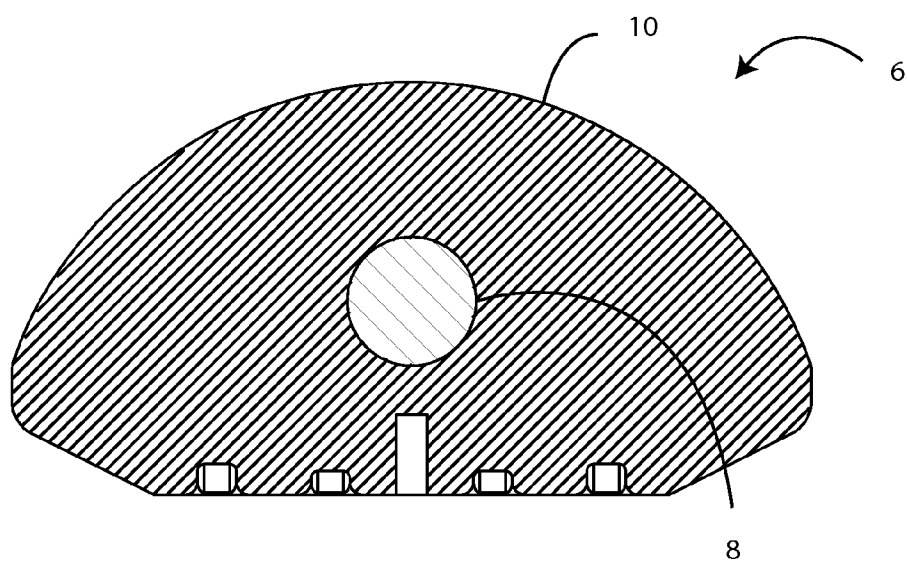


FIG. 3

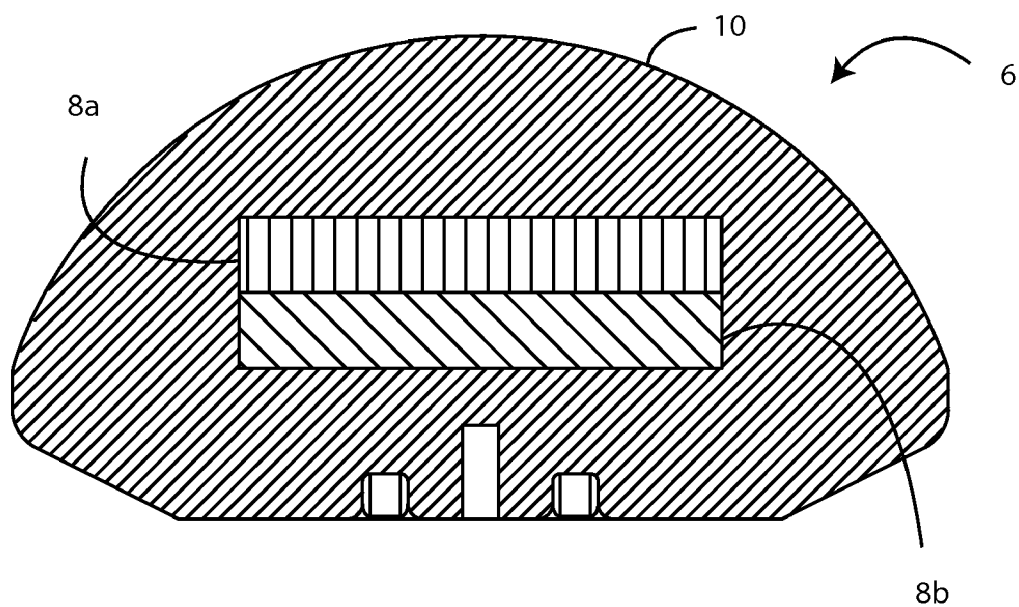


FIG. 4

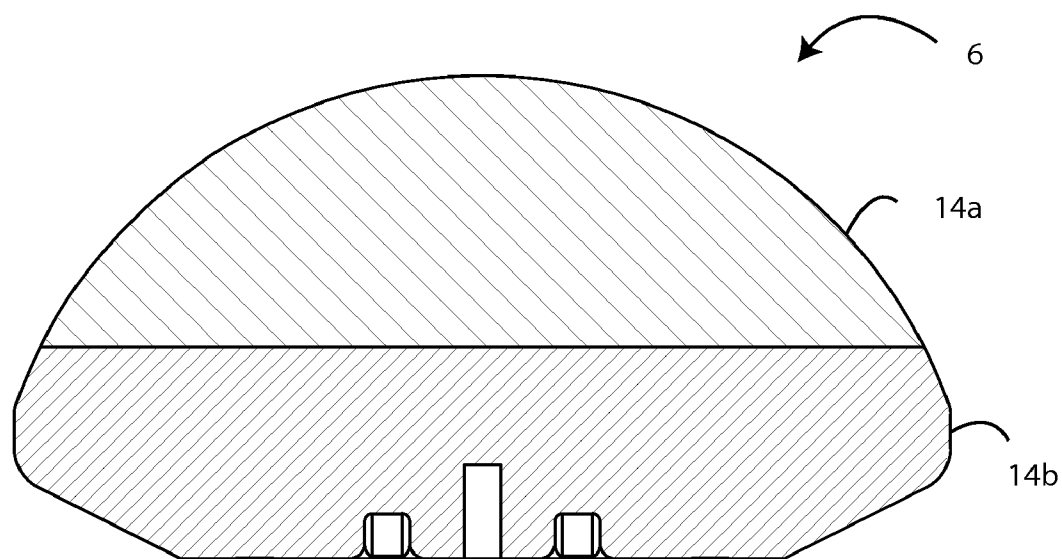


FIG. 5

METHOD OF FABRICATING A STIFF ANVIL FOR A SURGICAL INSTRUMENT

[0001] This application is a divisional of U.S. patent application Ser. No. 12/489,355, filed on Jun. 22, 2009, which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] The invention generally relates to surgical staplers and stapling.

BACKGROUND

[0003] Referring to FIG. 1, a surgical stapler 2 typically includes a staple holder 4 and an anvil 6. The staple holder 4 and anvil 6 are configured to close together and clamp tissue therebetween. After clamping, the staple holder 4 deploys a plurality of staples into that tissue. A challenge faced by most surgical staplers 2 is beam deflection. When the surgical stapler 2 clamps tissue that is sufficiently thick and/or tough, the distal end of the anvil 6 may not close completely relative to the staple holder 4. Instead, the distal end of the anvil 6 may bend away from the staple holder 4, because more force is required to compress the tissue than to cause the distal end of the anvil 6 to bend. Many attempts have been made to solve this problem. Some surgical staplers 2 utilize an “I-beam” mechanism, where the upper and lower portions of the I-beam each slide in a corresponding channel in the staple holder 4 and anvil 6. However, the I-beam takes up space in the surgical stapler 2, limits cutting and stapling operations to being performed by motion in the distal direction, and adds to the part count. Other surgical staplers 2 have been proposed that utilize exotic, highly-stiff materials to reduce or eliminate beam deflection. Stiffness is the force required to produce a unit deflection of a structure, and is related to the elastic modulus of the material from which the structure is fabricated. Strength is the ability of a structure to resist loads. However, it is a truism of material science that stiff, high-modulus materials are not high-strength materials, with the result that such materials are not practical for fabrication of an anvil 6.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0004] FIG. 1 is a side view of a surgical stapler.
- [0005] FIG. 2 is a cross-section side view of an exemplary anvil.
- [0006] FIG. 3 is a cross-section end view of the anvil of FIG. 2.
- [0007] FIG. 4 is a cross-section end view of another exemplary anvil.
- [0008] FIG. 5 is a cross-section end view of another exemplary anvil.
- [0009] The use of the same reference symbols in different figures indicates similar or identical items.

DETAILED DESCRIPTION

[0010] U.S. Patent Application Publication No. 2009/0065552, published on Mar. 12, 2009 (the “Endocutter Document”), is hereby incorporated by reference herein in its entirety. The Endocutter Document describes a surgical stapler 2 having a staple holder 4 and an anvil 6. The anvil 6 described in this document may be used in place of the anvil 6 described in the Endocutter Document, or in place of a convention anvil in any suitable surgical stapler 2.

[0011] Referring to FIGS. 2-3, an insert 8 is held within the body 10 of the anvil 6. That is, the body 10 is the part of the anvil 6 that receives the insert 8. The insert 8 may have any cross-sectional shape, such as circular, oval, rectangular, square, or any other suitable shape. The cross-sectional shape of the insert 8 may be constant, or may vary, along the length of that insert 8. The insert 8 may extend along part, or all, of the body 10 of the anvil 6. If the insert 8 extends along only part of the body 10 of the anvil 6, the insert 8 may be located at any suitable longitudinal position within the body 10 of the anvil 6. Advantageously, the insert 8 is stiffer than the body 10, and the body 10 is stronger than the insert 8. The insert 8 may be any high-modulus material, such as, for example, tungsten carbide. However, the insert 8 may be a different ceramic, metal, or any other suitable high-modulus material. The body 10 may be any high-strength material, such as, for example, 17-4 PH stainless steel. However, the body 10 may be ceramic, a different metal, or any other suitable high-strength material. Numerical analysis indicates that the use of a tungsten carbide insert 8 in conjunction with a 17-4 PH stainless steel body 10 results in an anvil 6 approximately three times stiffer than an anvil 6 composed of 17-4 PH stainless steel alone. The combination of a high-modulus insert 8 and a high-strength body 10 results in an anvil 6 that is stronger than the insert 8 alone could be, and stiffer than the body 10 alone could be. Alternately, the insert 8 may be a high-strength material, and the body 10 may be a high-modulus material. For the purposes of this document, “high-modulus” of the insert 8 or body 10 refers to a material having a higher modulus than the material from which the other is fabricated. Similarly, “high-strength” of the insert 8 or body 10 refers to a material having a higher strength than the material from which the other is fabricated.

[0012] The insert 8 and body 10 may be fabricated in any suitable manner. As one example, the insert 8 and the body 10 may be fabricated separately, and then the insert 8 may be placed into a corresponding cavity 12 within the body 10. The insert 8 may be held in place by a pressure or interference fit, by adhesive, by welding, by pinning, or by any other method, mechanism and/or structure. As another example, the body 10 may be insert-molded about the insert 8, or vice versa. Metal injection molding may be used to fabricate the body 10 about the insert 8, or to fabricate the insert 8 within the cavity 12 defined in the body 10. As another example, the body 10 may be cast about the insert 8. As another example, the insert 8 may be cast in place within the cavity 12.

[0013] Referring also to FIG. 4, a different exemplary anvil 6 may include two or more inserts 8a, 8b held within the cavity in the body 10. The inserts 8a, 8b may have any suitable cross-sectional shape. For example, each insert 8a, 8b may have a generally rectangular cross-sectional shape, where the rectangle is wider than it is tall. The inserts 8a, 8b may have substantially the same cross-sectional area and shape as one another, or may be shaped and/or sized differently from one another. For example, one of the inserts 8a, 8b may be thicker than the other. The inserts 8a, 8b each may extend substantially the same length longitudinally, and/or may be located in substantially the same longitudinal position in the anvil 6. Alternately, at least one insert 8a, 8b may be shorter than another, and/or may be located in a different longitudinal position in the anvil 6. One insert 8a may be fabricated from a high-strength material, and another insert 8b may be fabricated from a high-modulus material; such inserts 8a, 8b may be stacked relative to each other in any suitable order. If so, the body 10 may be fabricated from plastic or other material, where the anvil 6 relies on the inserts 8a, 8b for both strength or stiffness, or may be fabricated from any other material,

where the anvil 6 does not rely entirely on the inserts 8a, 8b to provide both strength and stiffness. Alternately, each insert 8a, 8b may be fabricated from a high-strength material and the body 10 may be fabricated from a high-modulus material, or vice versa.

[0014] Optionally, an upper insert 8a may be fabricated from a material that is stronger in compression than in tension, and a lower insert 8b may be fabricated from a material that is stronger in tension than compression. The upper insert 8a is further from the staple holder 4 than the lower insert 8b. The use of terms such as “upper”, “lower” and “upwards” merely refers to the orientation of figures on the page for clarity and brevity, and does not limit the arrangement of the staple holder 4 and anvil 6, nor the orientation of the anvil 6 in use. In this way, as the anvil 6 and staple holder 4, the tendency of the distal end of the anvil 6 to bend upward away from the staple holder 4 is resisted both by the tensile strength of the lower insert 8b and the ability of the upper insert 8a to withstand compression. Typically, high modulus materials are stronger in compression than in tension, so in such a configuration the upper insert 8a may be fabricated from a high-modulus material and the lower insert 8b may be fabricated from a high-strength material.

[0015] Referring to FIG. 5, a different exemplary anvil 6 may be fabricated from two separate, stacked layers 14a, 14b. In such a configuration, an insert 8 may not be utilized. However, an insert 8 may be provided in conjunction with the two layers 14a, 14b if desired; in such a configuration, the layers 14a, 14b may form the body 10 of the anvil 6, and the insert 8 is received into the cavity 12 of the body 10. The layers 14a, 14b may be fabricated from different materials and stacked in any order. As one example, an upper layer 14a may be fabricated from a high modulus material such as tungsten carbide, and a lower layer 14b may be fabricated from a high-strength material such as 17-4 PH stainless steel. As another example, the upper layer 14a may be fabricated from a high-strength material and the lower layer 14b may be fabricated from a high modulus material. The layers 14a, 14b may be fixed to one another to form a rigid anvil 6, and such fixation may be accomplished in any suitable manner, such as by adhesive, by welding, by pinning, by insert molding, or by metal injection molding. Optionally, one layer 14 may include one or more apertures (not shown) defined therein, and the other layer 14 may include one or more projections (not shown) configured to be received in those apertures. Such a configuration may facilitate the connection of the layers 14 to one another. The layers 14a, 14b each may extend along the entire length and width of the anvil 6. Alternately, at least one layer 14 may extend along less than the entire length and/or width of the anvil 6. If so, the other layer 14 may extend upward or downward to fill the remaining space. Alternately, one layer 14 may be composed of two or more separate pieces, each extending along less than all of the entire length and/or width of the anvil 6. In this way, the material properties of a particular layer 14 may be fine-tuned. The layers 14a, 14b may each be substantially the same height. Alternately, one layer 14 may be thicker than the other, depending on the desired stiffness and/or strength of the anvil 6 as a whole. As another example, the anvil 6 may be fabricated from three or more layers 14.

[0016] While the invention has been described in detail, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention. It is to be understood that the invention is not limited to the details of con-

struction, the arrangements of components, and/or the method set forth in the above description or illustrated in the drawings. Statements in the abstract of this document, and any summary statements in this document, are merely exemplary; they are not, and cannot be interpreted as, limiting the scope of the claims. Further, the figures are merely exemplary and not limiting. Topical headings and subheadings are for the convenience of the reader only. They should not and cannot be construed to have any substantive significance, meaning or interpretation, and should not and cannot be deemed to indicate that all of the information relating to any particular topic is to be found under or limited to any particular heading or subheading. Therefore, the invention is not to be restricted or limited except in accordance with the following claims and their legal equivalents.

What is claimed is:

1. A method of manufacturing a surgical apparatus, comprising:

fabricating an anvil comprising an insert composed of a first material, said insert located within a cavity in a body composed of a second material, wherein said first material and said second material have different properties.

2. The method of claim 1, wherein said first material is high-modulus and said second material is high-strength.

3. The method of claim 1, wherein said fabricating comprises

fabricating said insert; and then

metal injection molding said body about at least part of said insert.

4. The method of claim 1, wherein said fabricating comprises

fabricating said body; and then

metal injection molding said into said cavity in said body.

5. The method of claim 1, wherein said fabricating comprises

fabricating said insert; and then

insert molding said body about at least part of said insert.

6. The method of claim 1, wherein said fabricating comprises

fabricating said insert;

separately fabricating said body;

inserting said insert into said cavity; and

fixing said insert to said body.

7. The method of claim 1, wherein said first material is tungsten carbide and wherein said second material is 17-4 PH stainless steel.

8. A surgical apparatus, comprising:

an anvil, comprising

an upper layer composed of a first material; and

a lower layer composed of a second material different from said first material,

said lower layer fixed to said upper layer.

9. The surgical apparatus of claim 8, wherein said first material is high-modulus and said second material is high-strength.

10. The surgical apparatus of claim 8, wherein said first material is high-strength and said second material is high-modulus.

11. The surgical apparatus of claim 8, wherein each said layer extends along substantially all of the entire length and width of said anvil.

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