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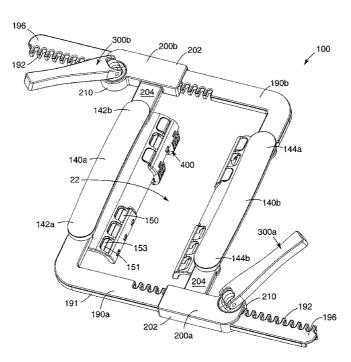
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#### (54) Title: SURGICAL ACCESS DEVICE



(57) Abstract: A surgical access device (100) utilizing two side members (140a, 140b) carrying repositionable tissue engaging flanges (400) and two lateral members (190a, 190b) that are pivotably hinged to the side members by a bayonet hinge mechanism that allows variable amounts of retraction at either end of the retractor.



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

#### SURGICAL ACCESS DEVICE

#### FIELD OF THE INVENTION

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The present invention provides an improved surgical access device of the type used to gain access to an internal cavity of a patient's body.

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#### BACKGROUND OF THE INVENTION

Surgeons frequently need to gain access to patients' body cavities to perform various procedures. One way to gain access to such a cavity is to perform invasive surgery where the cavity is opened fairly widely from the exterior to allow the surgeon ready access to the interior of the cavity. For example, in most traditional heart surgery, the patient's sternum is split and the overlying tissue is cut back to allow the surgeon to place both hands in the chest cavity. Such procedures traditionally employ a retractor to maintain the incision in an open configuration during surgery.

A wide variety of surgical retractors are known in the art. Most surgical retractors are intended to allow a surgeon to forcibly urge tissue out of the way to enable unfettered access to the underlying anatomical structures. For example, United States Patent No. 4,765,311 issued to Kulik et al. (the teachings of which are hereby incorporated by reference), shows a "wound retractor" that comprises a split tube. Each of the two tube halves are carried on holders which can be moved apart from one another to retract the tissue and provide access to the abdominal cavity. United States Patent No. 1,157,202 issued to Bates, teaches a retractor which is used to retract the sides of an incision in the abdominal wall. The retractor includes four separate retractile elements which are arranged about an oval frame. The tissue can be pulled apart to expand the size of the opening of the incision by pulling the retractile elements away from one another.

United States Patent No. 5,125,396 issued to Ray (the teachings of which are incorporated herein by reference), suggests a surgical retractor which comprises two separate arcuate blades. A separate ring carries each of these arcuate blades. By turning

these two rings with respect to one another, one can move the blades with respect to one another to open a generally cylindrical passageway through the patient's tissue.

When opening up the chest cavity for performing coronary bypass surgery, following the typical incision through the sternum, it is desirable to retract the layers of tissue to the minimum degree possible. Minimal retraction causes less trauma to other areas of the patient's body, resulting in less pain and faster overall healing time. Coronary bypass surgery typically involves the coronary arteries on the caudal side of the heart (*i.e.*, the apical side of the heart). Because coronary bypass surgery usually does not require access to the cranial parts of the chest cavity, a lesser amount of retraction is ideally required toward the cranial regions of the chest cavity than is required toward the caudal regions of the chest cavity. Other procedures, such as open heart valve replacement or repair, require a greater amount of retraction across the entire chest cavity, to expose both the cranial and caudal regions of the heart.

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When performing surgical procedures in the thoracic cavity, access is gained by making an incision between the ribs. This area is referred to as the intercostal space. The ribs are attached posteriorly to the spine and anteriorly to the sternum. This creates a bowing of the rib and non-uniformity of the distance of the intercostal space. A procedure in which a section of a lung, or the entire lung is removed may require non-parallel retraction of the ribs to address the bowing of the ribs and variance of the intercostal space. Ideally, this retraction is minimized to lessen trauma, specifically the breakage or removal of ribs. Non-parallel retraction is presently only performed by the use of two surgical retractor devices placed at opposite ends of the intercostal incision and opened independently of each other.

Thus, what is needed is a single surgical retractor allowing for non-parallel retraction when required, and parallel retraction in other instances.

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#### **SUMMARY OF THE INVENTION**

The Present Invention contemplates both a surgical access device and a method of gaining surgical access to a body cavity. In accordance with one embodiment of the

invention, a surgical device for accessing a body cavity comprises first and second longitudinally opposed side members, each of the side members having first and second ends. A first lateral member adjustably connects the first end of the first side member to the second end of the second side member, with at least one of the side member ends being moveable along a length of the first lateral member, thereby permitting adjustment of the lateral distance between the first end of the first side member and second end of the second side member. Likewise, a second lateral member adjustably connects the second end of the first side member to the first end of the second side member, with at least one of the side member ends being moveable along a length of the second lateral member, thereby permitting adjustment of the lateral distance between the second end of the first side member and first end of the second side member. At least one transversely extending repositionable flange is releasably attached to each side member.

In another embodiment, the Present Invention also comprises the first and second side members being pivotably articulated to the first and second lateral members by a bayonet hinge mechanism.

#### BRIEF DESCRIPTION OF THE DRAWINGS

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- Fig. 1 shows a perspective view of an embodiment of the invention in parallel retracting configuration.
  - Fig. 2 shows a perspective view of the first side member shown in Figs. 1 and 19.

- Fig. 3 shows a perspective view of the second side member shown in Figs. 1 and 19.
- Fig. 4 shows a plan view of the lower surface of the lower plate of the first side 30 member.
  - Fig. 5 shows a plan view of the lower surface of the lower plate of the second side member.

Fig. 6 shows a plan view of the upper surface of the first lateral member shown in Figs. 1 and 19.

- Fig. 7 shows a plan view of the upper surface of the second lateral member shown in Figs. 1 and 19.
  - Fig. 8 shows a plan view of the lower surface of the first lateral member.
  - Fig. 9 shows a plan view of the lower surface of the second lateral member.
  - Fig. 10 shows a perspective view from the lower surface of the first carriage.
  - Fig. 11 shows a perspective view from the lower surface of the second carriage.
- Fig. 12 shows an end view of the first carriage.

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- Fig. 13 shows an end view of the second carriage.
- Fig. 14 shows a disassembled perspective view of the mating gear assembly.
- Fig. 15 shows an assembled perspective view of the first mating gear assembly.
- Fig. 16 shows an assembled perspective view of the second mating gear assembly.
- Fig. 17 shows a perspective view of a tissue engaging flange.
  - Fig. 18 shows a side view of a tissue engaging flange.
- Fig. 19 shows a perspective view of the assembled surgical access device configured for non-parallel retraction.

# DETAILED DESCRIPTION OF THE INVENTION INCLUDING A BEST MODE

#### **Definitions**

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"Bayonet Hinge" as used herein, unless otherwise defined, refers to the pivoting articulation between a side member and a carriage and the pivoting articulation between a side member and a lateral member. The carriage has an essentially perpendicular extension terminating in a hook. The hook defines a slot extending into the body of the extension, the slot terminating at a concavity facing toward the opening of the slot. A peg extends perpendicularly away from the hook a distance less than the width of the hook. The hook of the carriage is designed to articulate with and form a hinge capable of pivoting against a side member. Both end portions of each side member comprise a cylindrical post extending between upper and lower plates. A beam perpendicularly disposed between the plates forms an "I" configuration if viewed from an end perspective separates upper and lower plates. The length of the beam is less than the length of the upper and lower beams, to allow for the post to extend between the plates. The upper plate is solid and raised proximally (i.e., extends away from the patient's body) when the surgical access device is in use by the physician. The lower plate is parallel and distal to the upper plate and has an arcuate channel extending partially around the lower plate. To complete articulating the channel with the side member requires first placing the hook around the post, with the carriage and side member disposed in parallel planes to each other. The raised peg on the perpendicular extension of the carriage is aligned with and fits into the arcuate channel and guides the carriage in a pivoting motion with respect to the side member, while maintaining the carriage and side member in a parallel planar disposition to each other. The lateral members utilize a similar configuration as the carriage to articulate with the side member. The lateral member is essentially a bar having a first leg with an extended length and a second leg of shorter length attached to one end of the first leg at approximately a right angle. The second leg is configured in a similar manner to the perpendicular extension of the carriage (i.e., the hook and peg arrangement is designed to articulate with the post and arcuate channel of the side member to provide a pivoting arrangement).

"Caudal" as used herein, unless otherwise defined, refers to the inferior or lower part of the human body (*i.e.*, toward the feet).

"Cranial" as used herein, unless otherwise defined, refers to the superior or upper part of the human body (*i.e.*, toward the head).

"Lower" as used herein, unless otherwise defined, refers to the direction toward the interior of the patient's body.

"Inside" as used herein, unless otherwise defined, refers to the space defined by the articulated and assembled surgical access device and bounded by the first side member, second side member, first carriage, second carriage, first lateral member and second lateral member.

"Kit" as used herein, unless otherwise defined, refers to a set of elements in unassembled form, which when assembled forms a surgical access device.

"Upper" as used herein, unless otherwise defined, refers to the direction away from the interior of the patient's body.

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"Outside" as used herein, unless otherwise defined, refers to the space outside the area created by the articulated and assembled surgical access device and bounded by the first side member, second side member, first carriage, second carriage, first lateral member and second lateral member.

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#### Nomenclature

22 Access Port

100 Surgical Access Device

138a Inside Edge of First Side Member

138b Inside Edge of Second Side Member

140a First Side Member

140b Second Side Member

142a	First End of First Side Member	
142b	Second End of First Side Member	
144a	First End of Second Side Member	
144b	Second End of Second Side Member	
150	Aperture	
151	Shelf	
152	Upper Plate	
153	Upper Surface of Shelf	
154	Upper Surface of Upper Plate	
156	Lower Surface of Upper Plate	
158	First Post	
160	Lower Plate	
162	Upper Surface of Lower Plate	
164	Lower Surface of Lower Plate	
168	Second Post	
172	First Arcuate Channel	
174	Second Arcuate Channel	
186	Upper Surface of Lateral Member	
188	Lower Surface of Lateral Member	
190a	First Lateral Member	
190b	Second Lateral Member	
191	Width of Lateral Member	
192	Teeth on Lateral Member	
196	Free End of Lateral Member	
200a	First Carriage	
200b	Second Carriage	
202	Body of Carriage	
204	Extension	
206	Channel	
208	Projection	
210	Bearing	
212	Terminal End of Carriage Extension	
214	Hook on Carriage	
216	Top Side of Carriage	
	142b 144a 144b 150 151 152 153 154 156 158 160 162 164 168 172 174 186 188 190a 190b 191 192 196 200a 200b 202 204 206 208 210 212 214	

	217	Closed End of Slot		
	218	Bottom Side of Carriage		
	220	Upper Surface of Carriage		
	222	Lower Surface of Carriage		
5	224	Slot (Carriage)		
	226	Peg (Carriage)		
ſ	250	First leg of Lateral Member		
	252	Second Leg of Lateral Member		
	254	Terminal End of First Leg		
10	256	Terminal End of Second Leg		
	270	Hook (Lateral Member)		
	272	Slot (Lateral Member)		
	273	Closed End of Slot		
	274	Peg (Lateral Member)		
15	276	Trough		
	300a	First Mating Gear Assembly		
	300b	Second Mating Gear Assembly		
	302	Mating Gear		
	304	Upper Disc		
20	306	Lower Disc		
	308	Gear Teeth		
	310	Raised Portion of Mating Gear		
	312	Aperture in Raised Portion		
	314	Gear Handle		
25	315	Free End of Gear Handle		
	316	Projections On Gear Handle		
	317	Attached End of Gear Handle		
	318	Apertures in Gear Handle Projections		
	320	Pin		
30	400	Flange		
	402	Upper End of Flange		
	403	Offset Portion of Flange		
	404	Lower End of Flange		
	405	Portion Extending in Retraction Direction		

406 Length of Flange

408 Width of Flange

410 Leading Edge of Flange

#### 5 Construction

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Figures 1 and 19 illustrate an embodiment of the present invention. The assembled surgical access device 100 defines an access port 22 which extends therethrough. This access port 22 can take any desired shape or dimension to achieve a particular clinical objective. For example, the access port 22 can be circular, elliptical, rectangular, or deltoid. In Figure 1, the access port 22 is shown as being rectangular, while in Figure 19, the access port 22 is shown as being deltoid. The dimensions of the access port 22 vary significantly depending on the body cavity being accessed and the reason for such access. If the surgeon is attempting to gain access to a patient's thoracic cavity through an incision through the intercostal space, typical dimensions of the access port 22 for an adult patient will be on the order of 2.5 inches (about 6.3 cm) long by 1.5 inches wide. If the surgeon is attempting to perform a sternotomy, typical dimensions of the access port 22 for an adult patient will be on the order of 6 inches long by 1.5 to 6 inches wide (to provide an asymmetric incision). The dimensions would decrease proportionately for a child.

As shown in Fig. 1, one embodiment of the Present Invention comprises first 140a and second 140b longitudinally extending opposed side members, each having a first end 142a, 144a and a second end 142b, 144b. The first end 142a of the first side member 140a is pivotably attached to the first lateral member 190a by means more fully discussed below. The first lateral member 190a extends through the first carriage 200a in a slidable manner more fully discussed below. An extension 204 extends perpendicularly from the first carriage 200a and is pivotably attached to the second end 144b of the second side member 140b. In a similar manner the first end 144a of the second side member 140b is pivotably attached to the second lateral member 190b by means more fully discussed below. The second lateral member 190b extends through the second carriage 200b in a slidable manner more fully discussed below. An extension 204 extends perpendicularly from the second carriage 200b and is pivotably attached to the second end 142b of the first side member 140a. Viewed from any side of itself, the assembled Present Invention

presents mirror images of itself. The mirror image nature of the Present Invention is further reflected in that similar parts are identical and therefore completely interchangeable. For example, the first 140a and second 140b side members are identical as are first 190a and second 190b lateral members. Finally, the first 200a and second 200b carriages are also identical with each other and interchangeable as are first 300a and second 300b mating gear assemblies. The feature of identical similar parts adds to the simplicity of the design by eliminating any ambiguity following sterilization when reassembling the surgical access device 100 prior to use.

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As shown in Figs. 2 and 3, the first 140a and second 140b side members, which are identical in all respects and completely interchangeable with each other, comprise an upper plate 152 having a length, a width, a first end 142a, 144a, a second end 142b, 144b an upper surface 154 and a lower surface 156. A lower plate 160 is attached to the upper plate 152 in a generally parallel planar manner. The lower plate 160 has an upper surface 162 and a lower surface 164. A first post 158 extends in a generally perpendicular manner between the upper surface 162 of the lower plate 160 and the lower surface 156 of the upper plate 152 proximate the first end 142a, 144a of the first and second side member 140a, 140b. In a similar manner a second post 168 extends in a generally perpendicular manner between the upper surface 162 of the lower plate 160 and the lower surface 156 of the upper plate 152 proximate the second end 142b, 144b of the first 140a and second 140b side members. A first arcuate channel 172 and a second arcuate channel 174 extend into the lower plate 160 from the upper surface 162. In a preferred embodiment, the first 172 and second 174 arcuate channels extend completely through the lower plate 160 for simplicity of manufacture and more importantly, improved sterilizability. In an alternate embodiment, however, the first 172 and second 174 arcuate channels could also comprise a groove extending into but not through the lower plate 160 from the upper 162 or lower 164 surface as design contingencies dictate. As best shown in Fig. 4, the first arcuate channel 172 is concentric with the first post 158 and begins at the first end 142a, 144a of the first 140a and second 140b side members and arcs toward the inside edge 138a, 138b of the first 140a and second 140b side members. In a similar manner (as best shown in Fig. 5), the second arcuate channel 174 is concentric with the second post 168 and begins at the second end 142b, 144b of the first 140a and second 140b side member and arcs toward the inside edge 138a, 138b of the first 140a and second 140b side member. In one embodiment, a plurality of longitudinally arranged

apertures 150 designed to hold and secure one or more tissue engaging flanges 400 during use of the surgical access device 100 are defined proximate the inside edge 138a, 138b of the first 140a and second 140b side member. Each aperture 150 defines an associated shelf 151 that is attached to the lower plate 160 and terminates toward the first 138a or second 138b inside edge of the first 140a or second 140b side member, respectively.

The upper plate 152 defines a substantially consistent thickness along its length. This permits the surgeon to attach a plurality of surgical accessories (not shown) to the surgical access device 100 during surgery. This greatly increases the efficiency of the surgical team during an operation by permitting the surgical accessories (not shown) to be fixed in place during the operation, thus freeing up space and allowing fewer personnel in the immediate operating area. Such devices (not shown) include suction/irrigation probes (suckers), beating heart stabilizers, malleable instrument arms, diaphragm retractors, valve instrument retractors (primarily for mitral valve), cautery pencil holders, illumination probes and sternal approximators. Suture pads (not shown) can also be attached to the upper plate 152. The suture pads give the physician the ability to suture to the tissue and then suture or re-suture anywhere along the length of the suture pad to achieve the appropriate retraction. By being able to have sutures attached at any location along the length of the first 140a and second 140b side members, the suture pads essentially provide an infinite number of connection locations, enabling a physician to reorient the sutured tissue by moving the suture to a different location on the pad to alter the direction the suture is pulling. In use, the physician will pass the suture through the patient's tissue and through one of the suture pads or may tie a knot at each end to hold the suture in place, as is conventional.

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As shown in Figs. 6 and 7, the first 190a and second 190b lateral members comprise a first leg 250 and a second leg 252, and have an upper surface 186 and a lower surface 188 and a width 191. First lateral member 190a and second lateral member 190b are identical in all respects and are thus completely interchangeable. First leg 250 has a longitudinal dimension and a terminal end 254. Second leg 252 has a longitudinal dimension and a terminal end 256. In one embodiment, first leg 250 defines a greater longitudinal dimension than does second leg 252. It is possible, however, that uses for the surgical access device 100 may exist wherein the second leg 252 would need to be longer than the first leg 250. Accordingly, it is not critical that first 190a and second

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190b lateral members have a first leg 250 longer than the second leg 252. Thus, combinations of various lengths of the first leg 250 and second leg 252 are contemplated and within the scope of the invention. Veterinary applications on large animals such as horses and cattle require lateral members having greater dimensions than would a human application. Likewise, pediatric applications in human beings would require smaller sized lateral members than would adults. In a preferred embodiment, the first 250 and second 252 legs are fixedly attached to each other at an approximate angle of ninety degrees. Other angles, however, would also work and are contemplated by and within the scope of the Present Invention. A plurality of regularly spaced teeth 192 are disposed along the length of the first leg 250. The teeth 192 are sized to mate with first 300a and second 300b mating gear assemblies as shown in Figs. 15 and 16. A hook 270 is disposed proximate the terminal end 254 of the second leg 252. The hook 270 defines a slot 272 that in a preferred embodiment extends toward, is substantially parallel with the first leg 250 and terminates at a closed end 273 facing away from the terminal end 254 of the first leg 250. As best shown in Figs. 8 and 9, peg 274 extends perpendicularly from the lower surface 188 of the first 190a and second 190b lateral members. The peg 274 extends from the lower surface 188 of the first 190a or second 190b lateral member so as to be received by the first arcuate channel 172 in an essentially parallel planar relationship with the first end 142a, 144a of the first side member 140a or second side member 140b. The tolerance between the first 190a or second 190b lateral member and first 140a or second 140b side member, guided in an arcing motion by the peg 274 extending into the first arcuate channel 172 results in a pivotable hinge between the first 190a or second 190b lateral member and the first end 142a, 144a of the first 140a or second 140b side member. As best shown in Figs. 8 and 9, an off-center trough 276 is defined on the lower surface 188 of the first 190a and second 190b lateral members and runs parallel with the longitudinal dimension of the first 190a and second 190b lateral member.

As best shown in Figs. 10 and 11, first 200a and second 200b carriages are identical in all aspects and therefore completely interchangeable with each other. First 200a and second 200b carriages comprise a body 202 having a top side 216, a bottom side 218, an upper surface 220 and a lower surface 222. A channel 206 extends through the body 202 and is configured and arranged to slidably accept the first leg 250 of the first 190a or second 190b lateral member. A bearing 210 is defined by the body 202 and is configured and arranged to receive a first 300a or second 300b mating gear assembly as

will be discussed in greater detail below. An off-center projection 208 runs the length of and is in parallel alignment with the channel 206. An extension 204 extends from the top side 216 of the body 202 in a perpendicular manner and has a terminal end 212. A hook 214 is defined at the terminal end 212 of the extension 204. A slot 224 runs substantially parallel with the top side 216 of the body 202 and terminates at a closed end 217 facing the bearing 210. A peg 226 proximate the closed end 217 of the slot 224 extends perpendicularly toward the lower surface 222 of the carriage 200a, 200b. The particular configuration and arrangement of the extension 204, slot 224 and peg 226 enable the carriage 200a, 200b to be removably and pivotably hinged to the second post 168 proximate the second end 142b, of the first side member 140a, or to the second post 168 proximate the second end 144b of the second side member 140b in only one way. Put another way, it is impossible to attach the first 200a or second 200b carriage to the second end 142b, 144b of the first 140a or second 140b side member in any way other than a pivotable parallel planar way. When the first 200a or second 200b carriage is attached to the second end 142b, 144b of the first 140a or second 140b side member, the channel 206 is positioned to slidably receive the first leg 250 of the first 190a or second 190b lateral member due to the off-center alignment of the trough 276 and projection 208. This allows the slot 272 of the first 190a or second 190b lateral member to attach to the first end 142a, 144a of the first 140a or second 140b side member with the first leg 250 extending toward the opposing side member 140a or 140b. Finally, in a preferred embodiment, the length of the extension 204 is similar to the length of the second leg 252 of the first 190a and second 190b lateral members. Similarity of length of the second leg 252 ensures the ability of the assembled surgical access device 100 to be able to perform parallel retraction, if desired. It is contemplated by and therefore within the scope of the invention to have the length of the extension 204 of the first carriage 200a be different than the length of the extension 204 of the second carriage 200b. It is also contemplated by and therefore within the scope of the invention to have different lengths for each of the extensions 204 of the first 200a and second 200b carriages and each of the second legs 252 of the first 190a and second 190b lateral members.

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Fig. 14 shows the disassembled first 300a and second 300b mating gear assemblies. The first 300a and second 300b mating gear assemblies comprise a mating gear 302 defining an upper disc 304 and a lower disc 306. Two gear teeth 308 sized and spaced to mate with the teeth 192 on the first 190a and second 190b lateral members are

defined by the length of the gear teeth 308 is of a length slightly greater than the width 191 of the first 190a and second 190b lateral members. A raised portion 310 extends from the upper disc 304 and defines an aperture 312 therethrough. The outer diameter of the upper disc 304 and lower disc 306 is slightly smaller than the inner diameter of the bearing 210 defined by the body 202 of the first 200a or second 200b carriage. A gear handle 314 defines a free end 315 and an attached end 317. A pair of centered projections 316 extend longitudinally from the attached end 317 and define apertures 318.

Figs. 15 and 16 show the assembled first 300a and second 300b mating gear assemblies. The first 300a and second 300b mating gear assemblies are identical in all aspects and therefore completely interchangeable with each other. The gear handle 314 is pivotably attached to the raised portion 310 of the mating gear 302 by means of a pin 320 extending through the gear handle projection 316 apertures 318 and through the raised portion aperture 312. The rack and pinion system defined by the first 190a and second 190b lateral members, and first 300a and second 300b mating gear assemblies provides a mechanism for increasing the mechanical advantage of a force applied to the first 200a and second 200b carriage to move it along the first 190a or second 190b lateral members. Turning of the gear handle 314 will move the carriage 200a, 200b laterally along the lateral member 190a, 190b, with the gear ratio of the mating gear 302 and teeth 192 determining the mechanical advantage. The two cylindrical gear teeth 308 provide a locking mechanism wherein in the position of the first 200a or second 200b carriage can be locked in a desired position on the first 190a or second 190b lateral member. The 200a or second 200b carriage is locked into position when the gear teeth 308 are aligned with the teeth 192 of the first 190a or second 190b lateral member with the gear handle 314 at an angle so as to extend parallel with the first 190a or second 190b lateral member. Put another way, this geometry results in a locked position every 180 degrees, or a linear movement of the pitch of the gear (in this embodiment 0.26" along the travel of the teeth 192 of the first 190a or second 190b lateral member.

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As explained in greater detail below, the assembled surgical access device 100 is configured and arranged to receive and hold a plurality of tissue engaging flanges 400. As best shown in Figs. 17 and 18, the flange 400 comprises an upper end 402, a lower end 404, a length 406 and a width 408. In one embodiment, the distal end 404 defines a

portion 405 extending in the direction of retraction. In a further embodiment, the upper end 402 defines an offset portion 403 that extends in the direction of retraction. The offset portion 403 is sized so as to be received within an aperture 150. When the flange 400 is inserted into the aperture 150, the offset portion 403 will rest against the upper surface 153 of the shelf 151. This ensures that during retraction the flange 400 will lever against the upper surface 153 of the shelf 151, enabling the leading edge 410 of the flange 400 to firmly exert force against the retracted tissue without becoming dislodged. Finally, it is contemplated by and within the scope of the invention that the length 406 of the flanges 400 can be varied to accommodate the needs of a particular surgeon or surgical procedure. While in one embodiment the flanges 400 are releasably attached to the side members 140a, 140b by the alignment of the offset portion 403 and the shelf 151, other methods (not shown) for attachment are also contemplated by and therefore within the scope of the invention. For example, a stainless steel flange (not shown) could also be used that would be repositionably fastenable to several positions along the inside edge 138a, 138b of the first 140a and second 140b side members using a fastener mechanism, such as a screw (not shown). An additional mechanism comprises a clamping mechanism (not shown).

#### Materials

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First 140a and second 140b side members, first 190a and second 190b lateral members, first 200a and second 200b carriages, and first 300a and second 300b mating gear assemblies are preferably constructed from 17-4 PH metal injection molded stainless steel. 17-4 stainless steel is preferred due to its resistance to corrosion, surface hardness (wear resistance), and strength. In an alternate embodiment, first 140a and second 140b side members, first 190a and second 190b lateral members, first 200a and second 200b carriages, and first 300a and second 300b mating gear assemblies could also be machined from stainless steel. Stainless steel offers the advantages of relatively low cost, great strength, biocompatibility and endurance. In a further embodiment, the first 140a and second 140b side members, first 190a and second 190b lateral members, first 200a and second 200b carriages, and first 300a and second 300b mating gear assemblies could also be made of various plastics such as polycarbonate and ABS provided the first 190a and second 190b lateral members are reinforced with stainless steel to resist bending.

The flanges **400** are preferably made from injection molded polycarbonate plastic with a barium sulfate load for radiopacity. Radiopacity is a desirable characteristic in the flanges **400** in the event one remains behind in the patient following completion of surgery. Other plastic materials such as ABS with a barium sulfate load are also suitable and therefore contemplated by and within the scope of the invention. In one embodiment, the flanges are disposable and come ready to use in a sterilized package.

#### Assembly

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As explained in detail above, the design of the Present Invention ensures that the various components can be articulated together in only one way. While the following description of the assembly process discusses the process in terms such as "first side member 140a being attached to first lateral member 190a", etc. it should be remembered that in all cases regarding the intended articulation of the various components of the invention, where first and second parts are specified, the first and second parts are identical to and interchangeable with each other. Assembly of the components as described below need not take place in any particular order, thus the order to be described should be regarded as exemplary and not limiting the scope of the invention.

The first lateral member 190a and first side member 140a are placed in similar planar positions. The slot 272 of the first lateral member 190a is aligned so as to engage the first post 158 proximate the first end 142a of the first side member 140a. The first lateral member 190a is slid toward the first post 158 until the closed end of the slot 273 contacts the first post 158. The peg 274 of the first lateral member 190a is simultaneously slid into the first arcuate channel 172. The first lateral member 190a can now be pivoted toward the inside edge 138a of the first side member 140a so that the first lateral member 190a extends away from the inside edge 138a of the first side member 140a. The first carriage 200a is fitted with the first mating gear assembly 300a and aligned with the upper surface 220 facing the assembler so that the slot 224 faces away from the first lateral member 190a. The channel 206 is aligned with the free end 196 of the first lateral member 190a and the first mating gear assembly 300a rotated until the gear teeth 308 mesh with the teeth 192 on the first lateral member 190a. The first mating gear assembly 300a is continued to be rotated until the first carriage 200a rests at a position on the first leg 250 of the first lateral member 190a where at least

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the free end 196 of the first leg 250 extends from the first carriage 200a. Next, the second post 168 at the second end 144b of the second side member 140b is aligned with the slot 224 of the first carriage 200a, simultaneously aligning the peg 226 of the first carriage 200a with the second arcuate channel 174 of the second side member 140b. The second side member 140b is slid toward the second post 168 until the closed end of the slot 217 contacts the second post 168. The second side member 140b is now pivoted toward the inside edge 138a of the first side member 140a. Following this step, the second lateral member 190b is aligned with the first post 158 proximate the first end 144a of the second side member 140b. Next, the second lateral member 190b is slid toward the first post 158 of the second side member 140b until the closed end 273 contacts the first post 158, while simultaneously aligning the peg 274 of the second lateral member 190b with the second arcuate channel 174 of the second side member 140b. At this point, the second lateral member 190b is pivoted toward the inside edge 138b of the second side member 140b until it is substantially perpendicular to the second side member 140b. The second carriage 200b is aligned with the second end 142b of the first side member 140a so that the second post 168 at the second end 142b of the first side member 140a is aligned with the slot 224 of the second carriage 200b, simultaneously aligning the peg 226 of the second carriage 200b with the second arcuate channel 174 of the first side member 140a. The second carriage 200b is fitted with the second mating gear assembly 300a and aligned with the upper surface 220 facing the assembler so that the slot 224 faces toward the second lateral member 190b. The channel 206 is aligned with the free end 196 of the second lateral member 190b and the second mating gear assembly 300b rotated until the gear teeth 308 mesh with the teeth 192 on the second lateral member 190b. The second mating gear assembly 300b is continued to be rotated until the second carriage 200b rests at a position on the first leg 250 of the second lateral member 190b where at least the free end 196 of the first leg 250 extends from the second carriage 200b. At least one flange 400 is attached to each of the first side member 140a and second side member 140b. In a preferred embodiment, the placement of the flanges 400 is symmetrical (i.e., equal numbers of flanges 400 are placed at the mirror image aperture 150 on the opposite side member 140a or 140b). This completes assembly of the surgical access device 100.

Use

For purposes of illustration, the following discussion is based on retraction as would be used in performing open-chest heart surgery.

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Following preoperative procedures, an incision is made into the patient. Several layers of tissue will normally need to be incised to gain access to the anatomical site where the operation is to occur. When all tissue layers are incised, the sterilized, assembled surgical access device 100 is carefully inserted into the incision. It is important that the length 406 of the flange 400 is sufficiently long that the lower end 404 of the flange 400 extends into the body at a point deeper than the tissue to be retracted. To minimize trauma to the patient, the first 300a and second 300b mating gear assemblies are rotated by the surgeon or technician causing retraction only to the minimum extent required.

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As shown Fig. 19, the illustrated design permits the first end 142a of the side member 140a to be moved away from or toward the second end 144b of the second side member 140b along the first lateral member 190a without requiring any movement of the second end 142b of the first side member 140a toward the first end 144a of the second side member 140b. Alternatively, the second end 142b of the first side member 140a can be moved with respect to the first end 144a of the second side member 140b along the second lateral member 190b without requiring any movement of the previously discussed half of the surgical access device 100.

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For example, the surgical access device 100 may be initially deployed with both carriages 200a, 200b locked as described above against movement with respect to the associated lateral member 190a, 190b and with the side members 140a, 140b positioned immediately adjacent another in a parallel manner. The gear handle 314 of the first carriage 200a can be lifted upwardly from the locked position and rotated to move the first carriage 200a with respect to the first lateral member 190a. The first end 142a of the first side member 140a will pivot with respect to the second leg 252 of the first lateral member 190a about the first post 158 of the first side member 140a. The second end 144b of the second side member 140b will pivot with respect to the terminal end 212 of the carriage extension 204 about the second post 168 of the second side member 140b.

Once the carriage 200a has been moved the desired distance toward the free end 196 of the first lateral member 190a, the gear handle 314 may be pushed downwardly toward the substantially parallel planar position to lock the carriage 200a in place on the first lateral member 190a. Due to the mirror image nature of the invention, the procedure described above works equally well when applied to the other side of the surgical access device 100 (i.e., second end 142b of first side member 140a toward first end 144a of second side member 140b). Differential retraction at each end of the surgical access device 100 is thus possible, resulting in a wide variety of retraction possibilities. Following completion of the surgical procedure, the gear handles 314 are unlocked, and the surgical access device 100 re-retracted to the insertion configuration, and removed from the patient.

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What is claimed is:

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1. A surgical device for accessing a body cavity, comprising:

- (a) first and second longitudinally extending opposed side members, each of the side members having a first end and a second end;
- (b) a first lateral member adjustably connecting the first end of the first side member to the second end of the second side member, at least one of the side member ends being moveable along a length of the first lateral member, thereby permitting adjustment of the lateral distance between the first end of the first side member and second end of the second side member;
- (c) a second lateral member adjustably connecting the second end of the first side member to the first end of the second side member, at least one of the side member ends being moveable along a length of the second lateral member, thereby permitting adjustment of the lateral distance between the second end of the first side member and first end of the second side member; and
- (d) at least one transversely extending repositionable flange releasably attached to each side member.
- 2. The surgical access device of claim 1 wherein the first and second side members are pivotably articulated to the first and second lateral members by a bayonet hinge mechanism.
- 25 **3.** The surgical access device of claim 2 wherein pivotable articulation between the first and second side members and the first and second lateral members occurs in substantially a single plane.
- 4. The surgical access device of claim 1 wherein a first carriage attaches the first lateral member to the second end of the second side member and a second carriage attaches the second lateral member to the second end of the first side member.

5. A surgical device for accessing a body cavity, comprising:

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(a) first and second opposed side members, each of the side members having a first end and a second end;

- (b) a first lateral member adjustably connecting the first end of the first side member to the second end of the second side member, at least one of the side member ends being moveable along a length of the first lateral member, thereby permitting adjustment of the space between the first end of the first side member and the second end of the second side member;
- (c) a second lateral member adjustably connecting the second end of the first side member to the first end of the second side member, at least one of the side member ends being moveable along a length of the second lateral member, thereby permitting adjustment of the space between the second end of the first side member and the first end of the second side member; and
  - (d) wherein the first and second side members are pivotably attached to the first and second lateral members by a bayonet hinge mechanism.
  - 6. The surgical access device of claim 5 wherein pivotable articulation between the first and second side members and first and second lateral members occurs in substantially a single plane.
  - 7. The surgical access device of claim 5 further including at least one transversely extending repositionable flange releasably attached to each side member.
- 25 **8.** The surgical access device of claim 5 wherein a first carriage attaches the first lateral member to the second end of the second side member and a second carriage attaches the second lateral member to the second end of the first side member.
- 9. The surgical device of claim 2 or 5 wherein the bayonet hinge mechanisms permit operable attachment of each end of the side members to only one end of the lateral members.

10. A surgical device for accessing a body cavity, comprising:

(a) first and second opposed mirror image side members, each side member having a first end, a second end, an inside edge and an outside edge, comprising;

- (i) an upper plate having a length, a width, a first end, a second end, and upper and lower surfaces,
- (ii) a lower plate having a length, a width, an inner edge, an outer edge, an upper surface, a lower surface, the lower plate a plurality of apertures disposed along the length of the lower plate proximate the inner edge adapted to releasably receive and hold tissue engaging flanges,
- (iii) a first post attaching the lower surface of the upper plate and the upper surface of the lower plate in spaced relationship proximate the first ends of the upper and lower plates,
- (iv) a second post attaching the lower surface of the upper plate and the upper surface of the lower plate in spaced relationship proximate the second ends of the upper and lower plates,
- (v) a first arcuate channel in each side member, concentric with the first post, portside to a point greater than a quarter turn around the post; and
- (vi) a second arcuate channel in each side member, concentric with the second post, portside to a point greater than a quarter turn around the post;
- (b) a first lateral member adjustably connecting the first end of the first side member to the second end of the second side member, at least one of the ends being moveable along a length of the first lateral member, thereby permitting adjustment of the space between the first end of the first side member and the second end of the second side member, the first lateral member comprising;
  - (i) a bar having a first leg with a length and a terminal end and a second leg with a length having a terminal end, the first and second legs being disposed to each other at an angle,
  - (ii) a plurality of regularly spaced gear teeth disposed along the length of the first leg,

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(iii) an off-center linear trough or projection disposed on an upper or lower surface of the first leg extending along at least a portion of the length of the first leg,

- (iv) a hook defining a slot disposed proximate the terminal end of the second leg, and
- (v) a peg protruding from an upper or lower surface of the second leg proximate the slot;
- (c) a second lateral member adjustably connecting the second end of the first side member to the first end of the second side member, at least one of the ends being moveable along a length of the first lateral member, thereby permitting adjustment of the space between the second end of the first side member and the first end of the second side member, the second lateral member comprising;
  - (i) a bar having a first leg with a length and a terminal end and a second leg with a length having a terminal end, the first and second legs being disposed to each other at an angle,
  - (ii) a plurality of regularly spaced gear teeth disposed along the length of the first leg,
  - (iii) an off-center linear trough or projection disposed on an upper or lower surface of the first leg extending along at least a portion of the length of the first leg,
  - (iv) a hook defining a slot disposed proximate the terminal end of the second leg, and
  - (v) a peg protruding from an upper or lower surface of the second leg proximate the slot;
- (d) a first carriage, comprising;
  - (i) a carriage body having a length, a channel extending through the length of the body, configured and arranged to accept the first leg of the first lateral member therethrough, and a bearing with an off-center trough or projection within the channel mated to the trough or projection of the first leg of the first lateral member, whereby only a single spatial orientation of the first lateral member relative to the first carriage allows passage of the first leg of the first lateral member through the channel in the first carriage, and

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(ii) a perpendicular extension terminating in a hook, defining a slot disposed proximate a terminal end of the extension;

(e) a second carriage, comprising;

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- (i) a carriage body having a length, a channel extending through the length of the body, configured and arranged to accept the first leg of the second lateral member therethrough, and a bearing with an off-center trough or projection within the channel mated to the trough or projection of the first leg of the second lateral member, whereby only a single spatial orientation of the second lateral member relative to the second carriage allows passage of the first leg of the second lateral member through the channel in the second carriage, and
- (ii) a perpendicular extension terminating in a hook, defining a slot disposed proximate a terminal end of the extension;
- (f) a first mating gear disposed in the bearing in the first carriage for mating with the teeth disposed on the first leg of the first lateral member whereby the lateral position of the first lateral member with regard to the side member can be varied when the gear is rotated; and
- (g) a second mating gear disposed in the bearing of the second carriage for mating with the teeth disposed on the first leg of the second lateral member whereby the lateral position of the second lateral member with regard to the side member can be varied when the gear is rotated.
- 11. The surgical access device of claim 10 wherein the lower plate of the first and second members further comprises a plurality of apertures, the apertures defining recessed portions extending from the lower plate so as to provide a shelf extending in the inside direction, coplanar and continuous with the lower surface of the lower plate and terminating so as to provide an opening through the lower plate.
  - 12. The surgical access device of claim 10 wherein the tissue engaging flange comprises an extended finger defining proximal and distal ends, a longitudinal dimension, a thickness and a width, the distal end having portions angled toward the outside edge, the proximal end defining a portion angled to the outside edge of

the lower plate when inserted in the lower plate and having a lesser thickness and a narrower width than the width of the aperture so as to be insertable through the selected aperture from the outer surface of the lower plate, wherein upon insertion the proximal end rests against the shelf such that when retraction force is applied to the inserted flange, the flange is firmly secured to the side member by being levered against the shelf.

- 13. A kit assemblable to form a surgical access device for accessing a body cavity, comprising:
  - (a) a first longitudinally extending side member having a first end and a second end:
  - (b) a second longitudinally extending side member having a first end and a second end:
  - (c) a first lateral member;
- (d) a second lateral member;

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- (e) at least one transversely extending repositionable flange releasably attachable to each side member;
- (f) wherein the first lateral member is configured and adapted to pivotably attach to the first end of the first side member and the second end of the second side member, with at least one of the first end or the second end being movable along a length of the first lateral member, thereby permitting adjustment of the lateral distance between the first end of the first side member and the second end of the second side member; and
- (g) wherein the second lateral member is configured and adapted to pivotably attach to the second end of the first side member and the first end of the second side member, with at least one of the first end or the second end being movable along a length of the second lateral member, thereby permitting adjustment of the lateral distance between the second end of the first side member and the first end of second side member.
- 14. The kit of claim 13 wherein the first and second side members can be pivotably articulated to the first and second lateral members by a bayonet hinge mechanism when assembled.

15. The kit of claim 14 wherein pivotable articulation between the first and second side members and the first and second lateral members can occur in substantially a single plane when assembled.

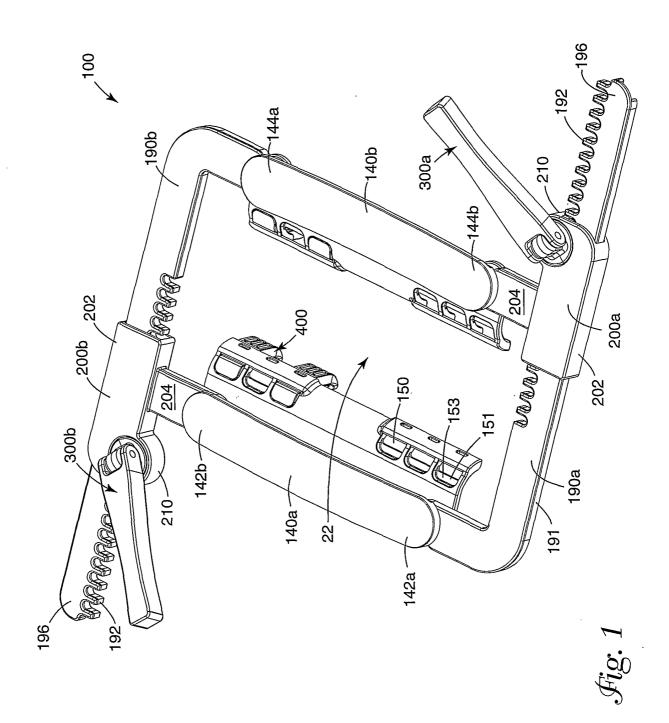
- The kit of claim 13 wherein a first carriage can attach the first lateral member to the second end of the second side member and a second carriage can attach the second lateral member to the second end of the first side member.
- 17. A kit assemblable to form a surgical access device for accessing a body cavity, comprising:
  - (a) a first side member having a first end and a second end;
  - (b) a second side member having a first end and a second end;
  - (c) a first lateral member;

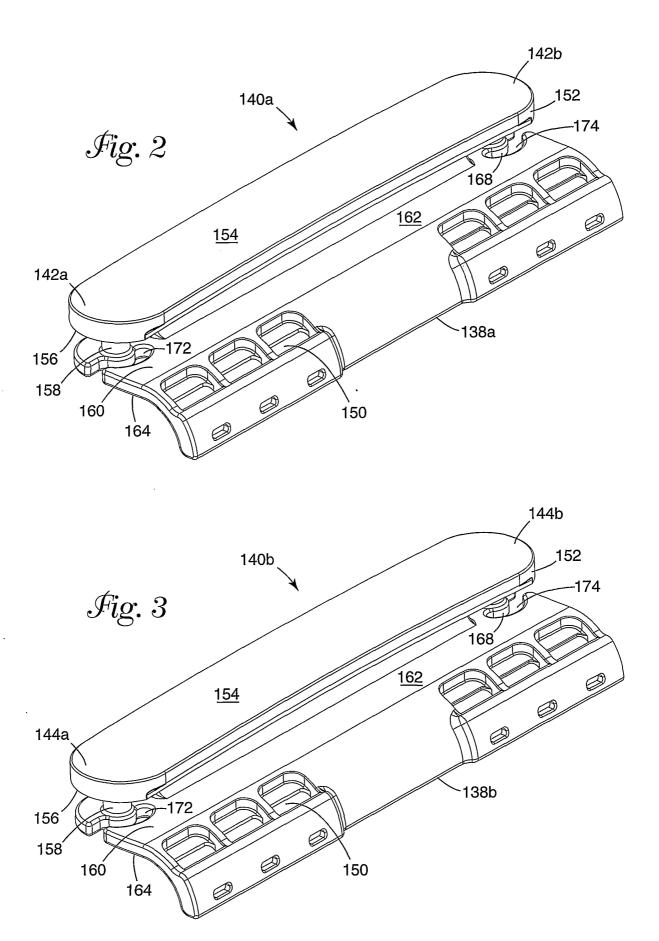
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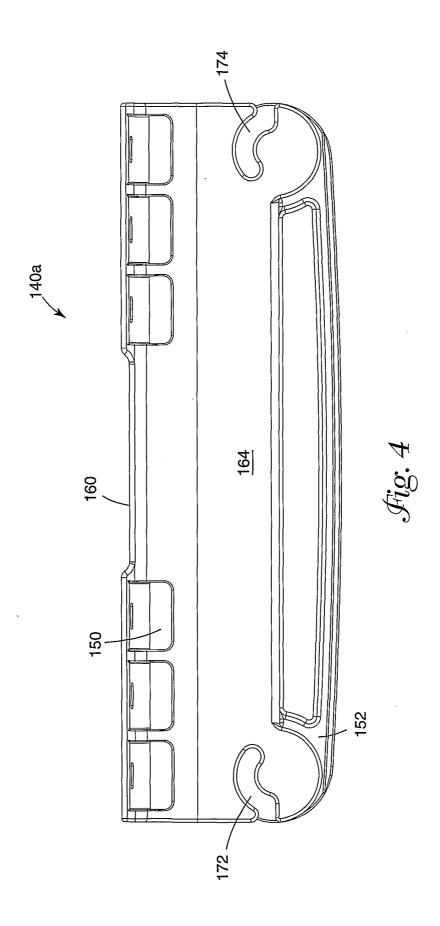
- (d) a second lateral member;
- 15 (e) at least one transversely extending repositionable flange releasably attachable to each side member;
  - (f) wherein the first lateral member is configured and adapted when assembled to pivotably attach to the first end of the first side member and the second end of the second side member, with at least one of the first end or the second end being movable along a length of the first lateral member, thereby permitting adjustment of the lateral distance between the first end of the first side member and the second end of the second side member:
  - (f) wherein the second lateral member is configured and adapted when assembled to pivotably attach to the second end of the first side member and the first end of the second side member, with at least one of the first end or the second end being movable along a length of the second lateral member, thereby permitting adjustment of the lateral distance between the second end of the first side member and the first end of second side member; and
- 30 (g) wherein the first and second side members are pivotably attachable to the first and second lateral members by a bayonet hinge mechanism when assembled.

18. The kit of claim 17 wherein pivotable articulation between the first and second side members and the first and second lateral members can occur in substantially a single plane when assembled.

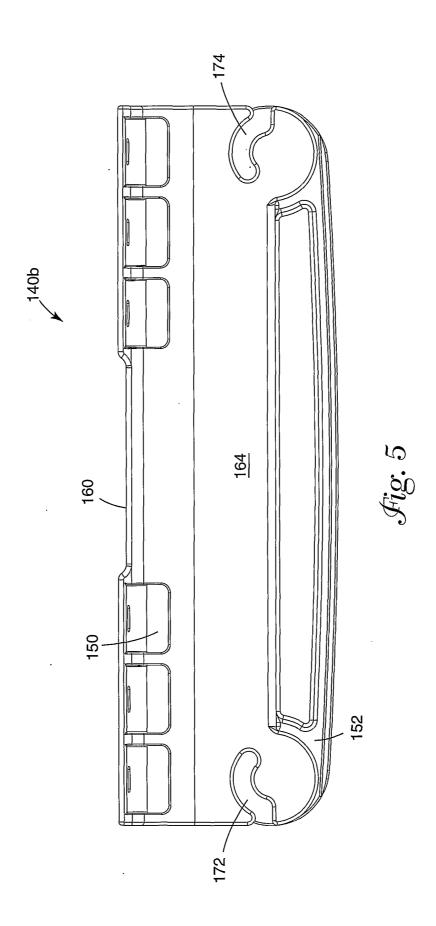
The kit of claim 17 wherein a first carriage can attach the first lateral member to the second end of the second side member and a second carriage can attach the second lateral member to the second end of the first side member when assembled.

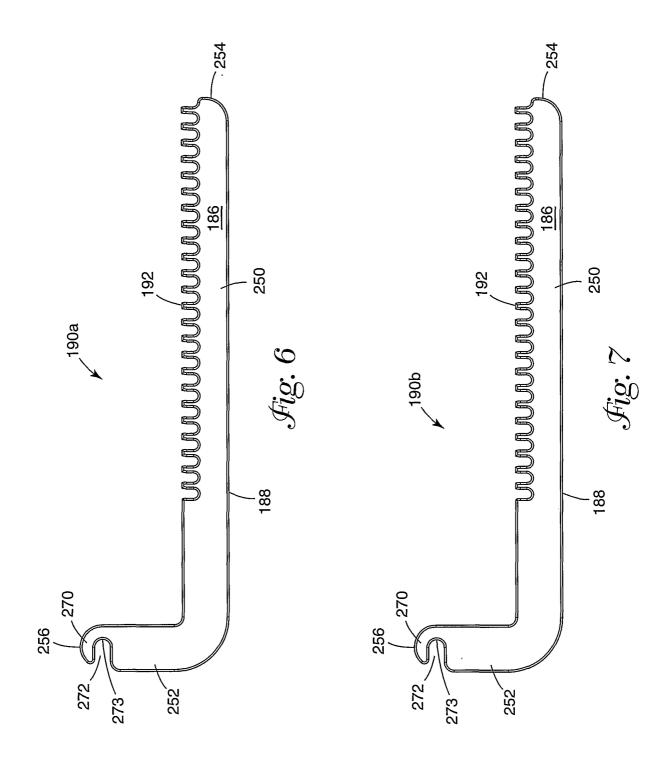


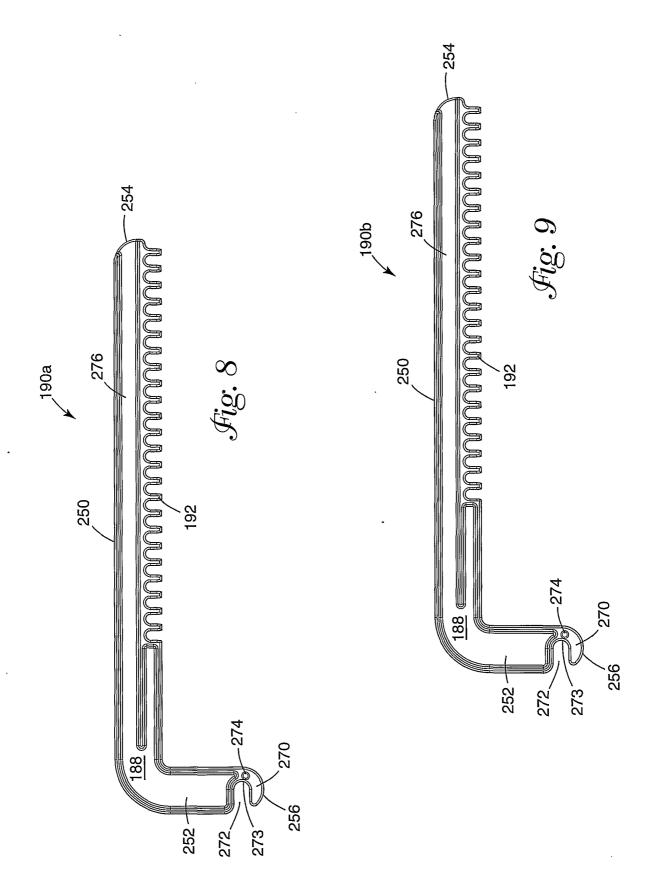


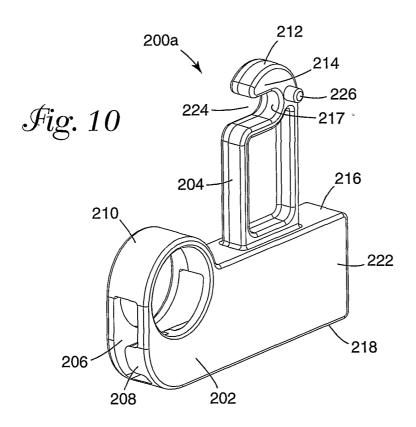


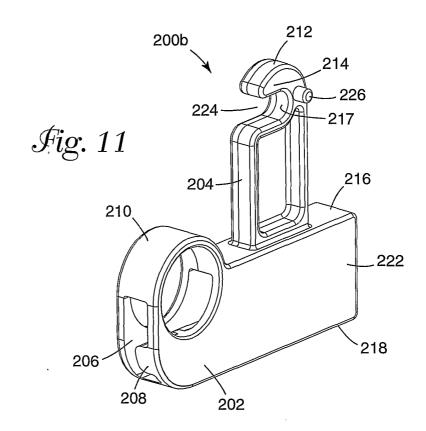
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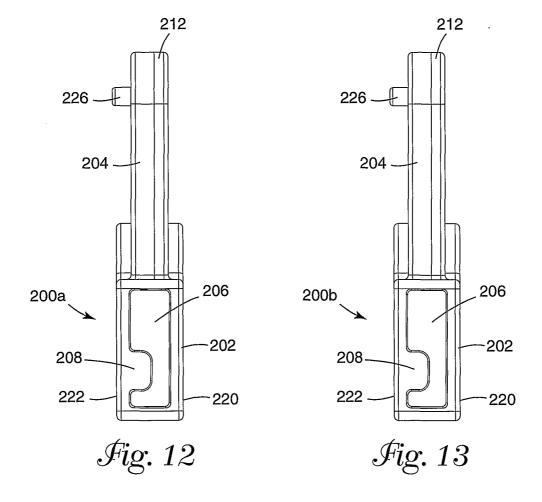


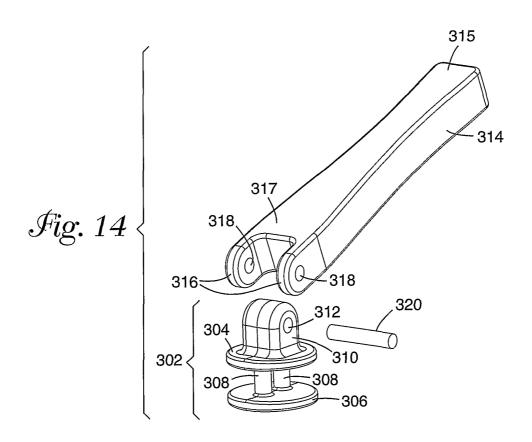


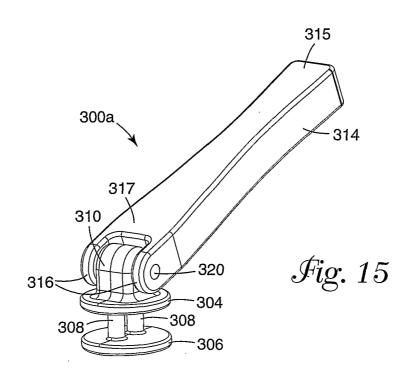




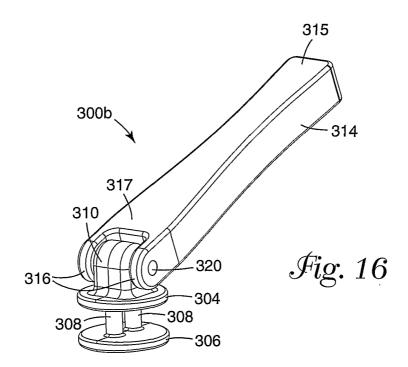
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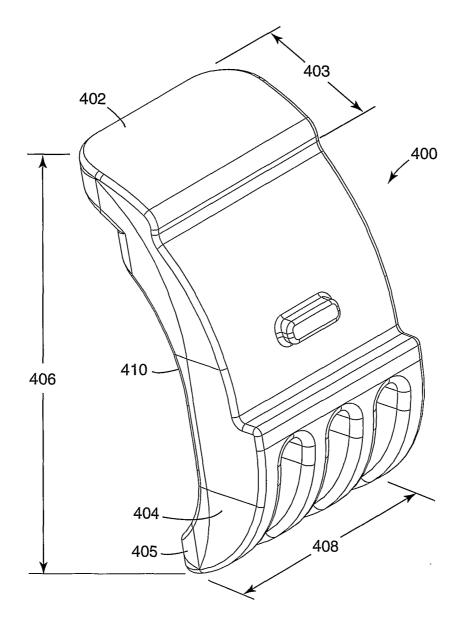


Fig. 17

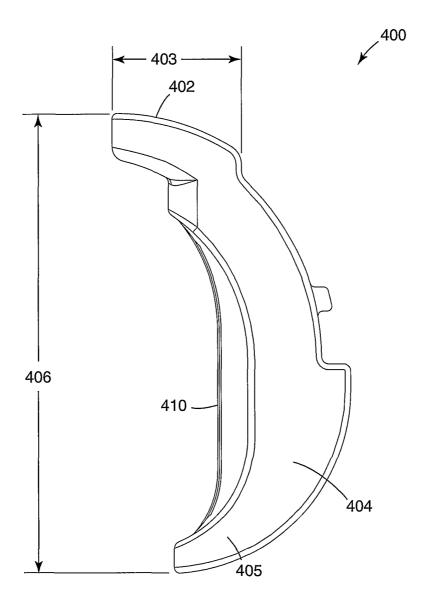
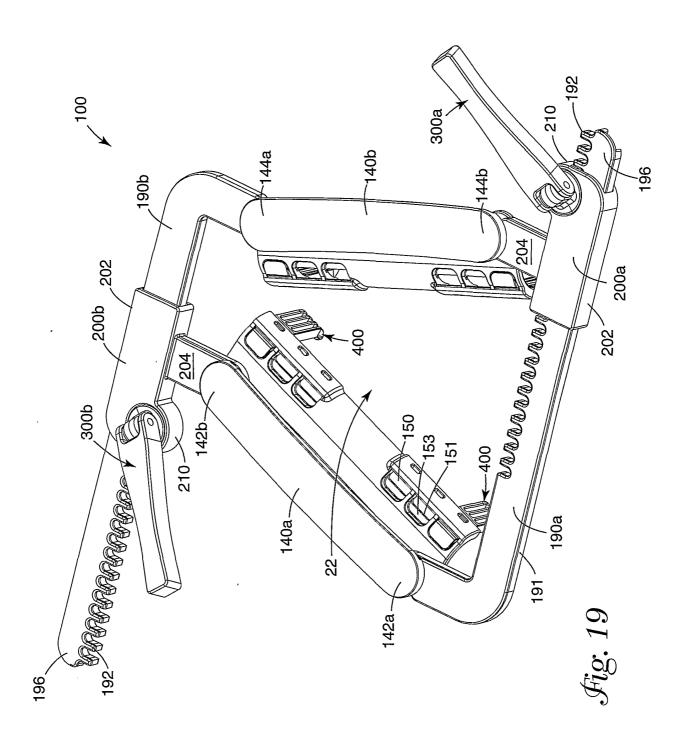


Fig. 18

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#### INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/10898

A. CLASSIFICATION OF SUBJECT MATTER  IPC(7) : A61B 1/32 US CL : 600/233							
	US CL:600/233 According to International Patent Classification (IPC) or to both national classification and IPC						
B. FIEL	DS SEARCHED						
Minimum d	ocumentation searched (classification system followed	l by classification symbols)					
U.S. : 600/227, 231-233							
Documentat	tion searched other than minimum documentation to the	extent that such documents are included i	n the fields searched				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)							
C. DOCUMENTS CONSIDERED TO BE RELEVANT							
Category*	Citation of document, with indication, where ap	Relevant to claim No.					
X	US 1,707,689 A (SLOAN) 02 April 1	1-9, 13-19					
X	US 3,038,468 A (RAEUCHLE) 12 Ju:	1-9, 13-19					
X	US 1,963,173 A (MORIN) 19 June 19	1, 4					
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Furtl	her documents are listed in the continuation of Box C	. See patent family annex.					
* Sp	pecial categories of cited documents:	"T" later document published after the int date and not in conflict with the app					
	ocument defining the general state of the art which is not considered be of particular relevance	the principle or theory underlying the					
"E" ea	rlier document published on or after the international filing date	"X" document of particular relevance; the considered novel or cannot be considered.					
"L" do	comment which may throw doubts on priority claim(s) or which is ted to establish the publication date of another citation or other	when the document is taken alone					
sp	ecial reason (as specified)  cument referring to an oral disclosure, use, exhibition or other	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination					
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Washington, D.C. 20231  Facsimile No. (703) 305-3230  Telephone No. (703) 308-3588							
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