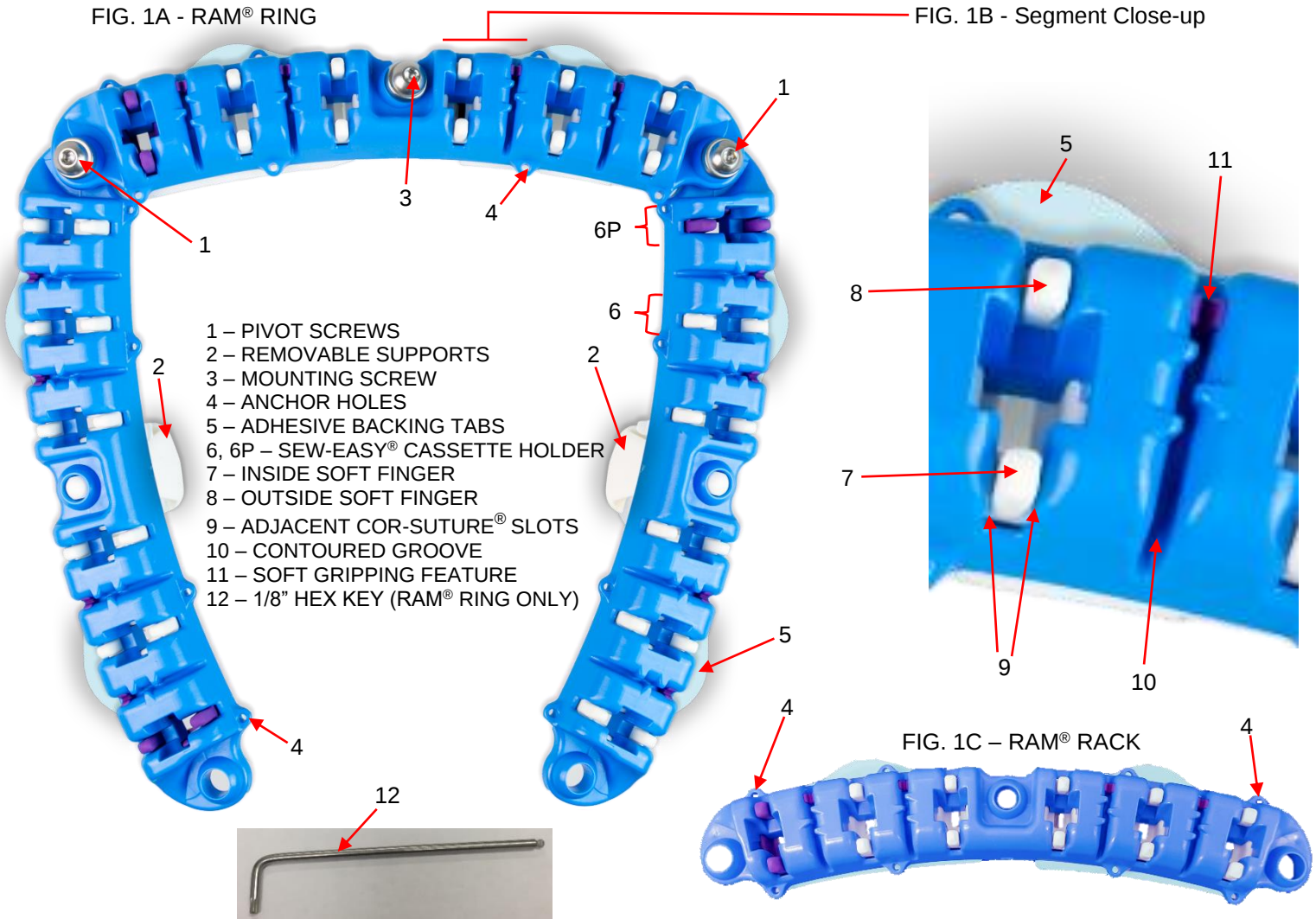


RAM® RING / RAM® RACK TECHNOLOGY GUIDE

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1A - RAM® RING

FIG. 1B - Segment Close-up



LSOLUTIONS®

RAM® RING / RAM® RACK – DESCRIPTION

Each package contains one (1) SINGLE PATIENT USE sterile RAM® RING (FIG. 1A) or RAM® RACK (FIG. 1C) suture management device. The RAM® RACK is used to hold and organize up to six SEW-EASY® Device Cassettes and their associated COR-SUTURE® surgical sutures in tissue as well as stay sutures. The RAM® RING has three RAM® RACKS coupled together by pivot screws 1, and is, therefore, used to hold and organize up to eighteen SEW-EASY® Device Cassettes. The RAM® RING comes fully assembled with removable supports 2 on the two peripheral RACKS. A mounting screw 3 may be used to attach the RAM® RING to an accessory post of a 3D® miniACCESS PORTAL (available separately). Alternately, surgical towel clamps may be used to affix the RAM® RING or RAM® RACK's anchor holes 4 to a surgical towel. As a further option, adhesive backing tabs 5 may be peeled off to affix the RAM® RING or RAM® RACK to a surgical towel or other surface. The RAM® RING has six SEW-EASY® cassette holders 6, 6P in each of the three RACKS. Each of these cassette holders has inside and outside soft fingers 7, 8 made from a flexible material. The soft fingers in one SEW-EASY® cassette holder 6P per RACK are purple, while the soft fingers in the remaining SEW-EASY® cassette holders 6 are white, contrasting with the RAM® RING and RAM® RACK's overall blue color.

For each cassette holder, suture segments from a SEW-EASY® Cassette may be held on either side of the inside and outside soft fingers in the adjacent COR-SUTURE® slots 9. Each SEW-EASY® cassette holder 6, 6P is sized to hold and easily release the tip of a SEW-EASY® Cassette after the suture segments from that Cassette have been inserted against the soft fingers in the adjacent COR-SUTURE® slots.

The RAM® RING and RAM® RACK also have twelve or four contoured grooves 10, respectively, each of which includes a soft gripping feature 11. The soft gripping features are made from a flexible purple material which defines a slot where one or more sutures may be wedged for holding until released by the user.

INDICATIONS FOR USE

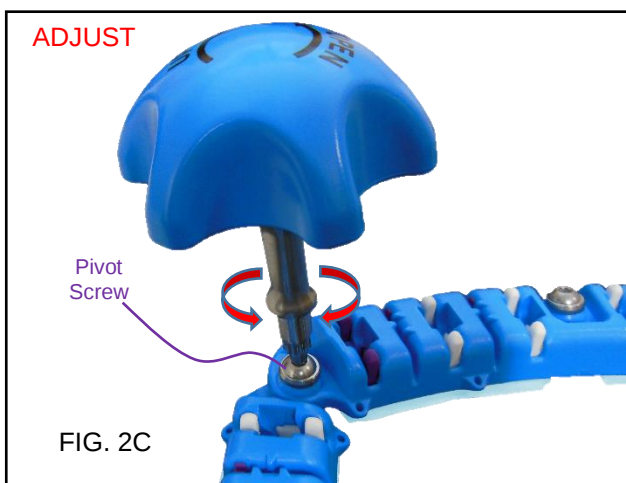
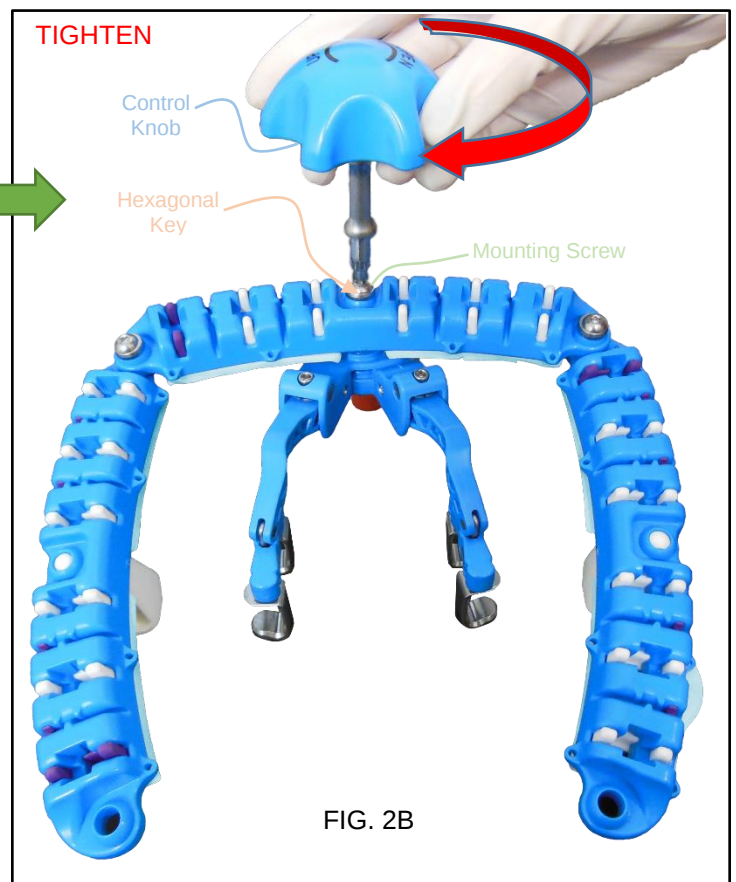
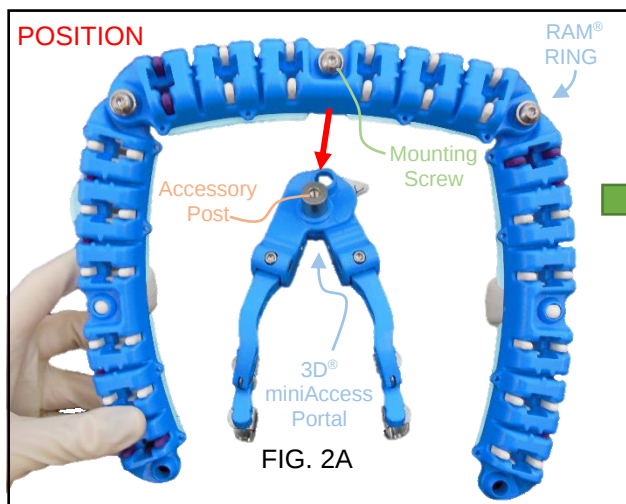
The RAM® RING and RAM® RACK are intended to organize and secure suture during surgical procedures.

POSITIONING RAM® RING / RAM® RACK

METHOD 1: Attachment to a 3D® miniACCESS PORTAL (for RAM® RING Only)

Note: The 3D® miniACCESS PORTAL is sold separately and facilitates surgical access to the thoracic cavity. It is advisable to place the 3D® miniACCESS PORTAL between ribs or tissue, adjusting its expansion arms and soft cradles to displace the ribs in desired transverse and inward or outward directions before attaching the RAM® RING to the 3D® miniACCESS PORTAL. **Be sure to read and understand the 3D® miniACCESS PORTAL Technology Guide before using the RAM® RING with the 3D® miniACCESS PORTAL.**

1. **DEPLOY**
the 3D® miniACCESS PORTAL; follow the 3D® miniACCESS PORTAL Technology Guide for instructions on this.
2. **POSITION**
RAM® RING mounting screw above the 3D® miniACCESS PORTAL accessory post. (FIG. 2A)
3. **TIGHTEN**
RAM® RING to the accessory post using the 3D® miniACCESS PORTAL control knob (FIG. 2B) or the provided 1/8" hex key.
4. **ADJUST**
peripheral RACK position with pivot screw adjustment. (FIG. 2C)



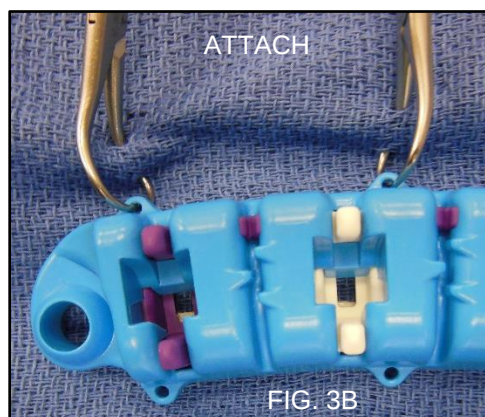
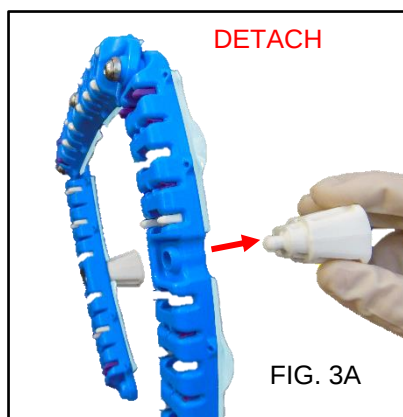
METHOD 2: Attachment with Towel Clamps

1. DETACH

both removable supports by pulling from the underside of the RAM® RING. (FIG. 3A) Note: This step is not necessary for the RAM® RACK.

2. ATTACH

tip of towel clamp through an anchor hole and secure RAM® RING or RAM® RACK to surgical towel/drape in desired location. The RAM® RING and RAM® RACK have twenty-four and eight anchor holes, respectively. Repeat with other towel clamps as needed. (FIG. 3B)



METHOD 3: Attachment with Pre-Applied Adhesive Tape

1. DETACH

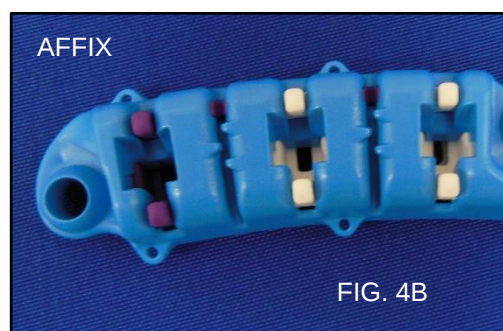
both removable supports by pulling from the underside of the RAM® RING. (FIG. 3A) Note: This step is not necessary for the RAM® RACK.

2. REMOVE

adhesive backing tab(s) to expose the pre-applied adhesive tape. Take care not to rip the adhesive backing tabs during removal. (FIG. 4A)

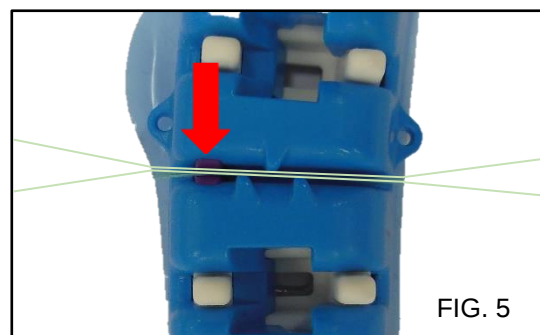
3. AFFIX

RAM® RING or RAM® RACK to surgical towel/drape or other surface at desired location. (FIG. 4B)



LOADING ACCESSORY SUTURE

As shown in FIG. 5, one or more stay sutures may be retained in the soft gripping features provided between the SEW-EASY® cassette holders.



LOADING CASSETTE HOLDERS

NOTE: The suture segments to be loaded may either 1) have their ends already loaded into a SEW-EASY® Cassette, 2) have their ends still coupled to a RAM® Suturing Device, or 3) have their ends uncoupled from any device. **Be sure to read and understand the SEW-EASY® and RAM® Technology Guides before using the RAM® RING or RAM® RACK.**

1. ALIGN

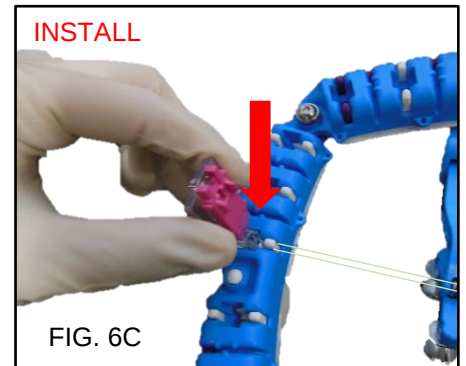
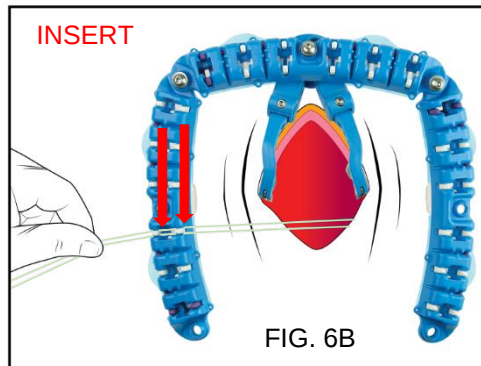
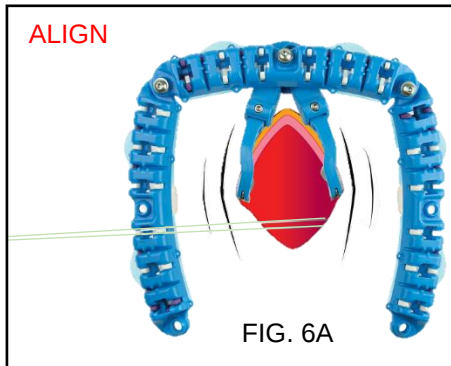
annular suture segments with desired SEW-EASY® cassette holder on the RAM® RING or RAM® RACK, using hand to hold suture under light tension and ensuring suture remains correctly oriented. (FIG. 6A)

2. INSERT

suture segments on either side of the inside and outside soft fingers as shown (FIG. 6B). Set suture tension to the tissues as desired. NOTE: If suture ends are not yet in a SEW-EASY® Cassette, load the suture ends into a SEW-EASY® Cassette before proceeding.

3. INSTALL

Cassette, tip down, into the corresponding SEW-EASY® cassette holder. The pink side of the SEW-EASY® Cassette should face the surgical field. (FIG. 6C)



UNLOADING CASSETTE HOLDERS

Each SEW-EASY® Cassette held in a RAM® RING or RAM® RACK may be engaged by a SEW-EASY® Suturing Device directly from the RAM® RING or RAM® RACK.

1. ENGAGE

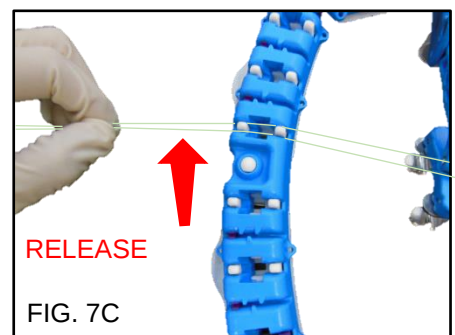
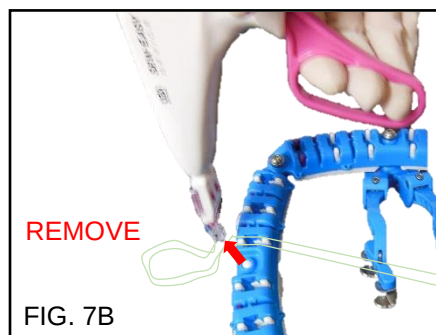
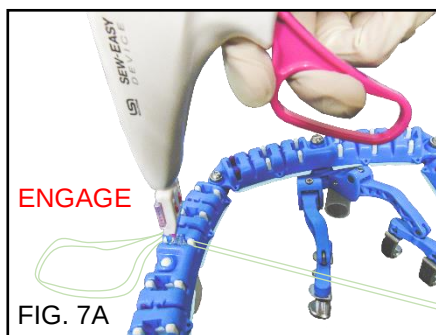
receiver end of the SEW-EASY® Suturing Device with locating pegs of the SEW-EASY® Cassette. (FIG. 7A)

2. REMOVE

SEW-EASY® Cassette from the cassette holder. (FIG. 7B)

3. RELEASE

both suture segments from the soft fingers before using the SEW-EASY® Suturing Device to place suture through a prosthesis. (FIG. 7C)

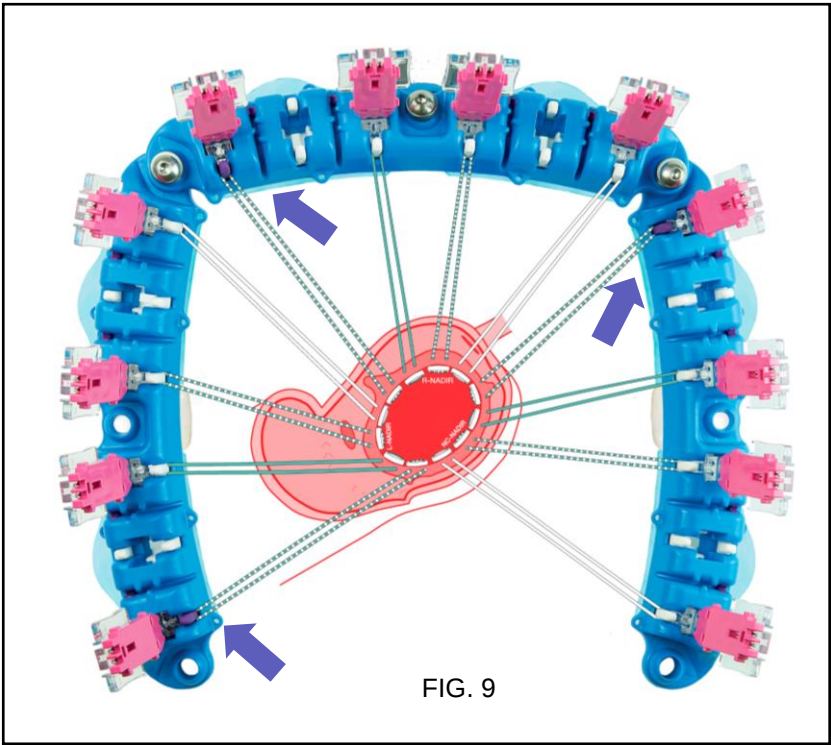


Ordering Information

FIG. 8 RAM® ACCESS PRODUCT ORDERING		
REORDER	PRODUCT	DESCRIPTION
080228	RAM® RACK Suture Management System	1 Shelf Box (3 Devices per Shelf Box)
080215	RAM® RING Suture Management System	1 Shelf Box (1 Device per Shelf Box)
110300*	3D® miniACCESS Portal	Box of 6 (1 Device per Box)
*Not CE Marked		

Pearls

- 1. Purple cassette holders can be used as reference points for sutures placed in specific anatomical locations. For example, see FIG. 9 where the purple cassette holders have been chosen to correspond with commissure stitches.



CONTRAINDICATIONS

- None known.

WARNINGS

- Federal (USA) Law restricts this device to sale, distribution and use by, or on, the order of a physician.
- Minimally invasive surgical procedures should only be performed by physicians having adequate training and familiarity with endoscopic techniques. In addition, medical literature should be consulted relative to techniques, complications and hazards prior to the performance of minimally invasive procedures.
- Read and become familiar with all instructions, warnings, and precautions before using this product.
- **Do not resterilize.** The RAM® RING and RAM® RACK are designed and intended for single patient use only. Do not reuse, reprocess, or resterilize this product. The performance of the RAM® RING and RAM® RACK after cleaning or other reprocessing has not been verified and is not supported by LSI Solutions, Inc. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Do not use if package or product is damaged. Discard any open (unsealed), unused, expired, or damaged product.
- It is the responsibility of the user to dispose of the device in accordance with local regulations and hospital procedures.
- The RAM® RING and RAM® RACK should only be used by appropriately trained health care professionals.

PRECAUTIONS

- Do not use devices if they do not satisfactorily perform their intended function or if they have physical damage. Avoid mechanical shock or overstressing the devices.
- Any foreign body inadvertently left in a patient, including a hex key, a 3D® miniACCESS PORTAL, or a control knob, may be associated with serious complications, such as infection, bleeding, discomfort, wound complications, etc.
- Before instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that function is not compromised.



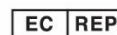
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