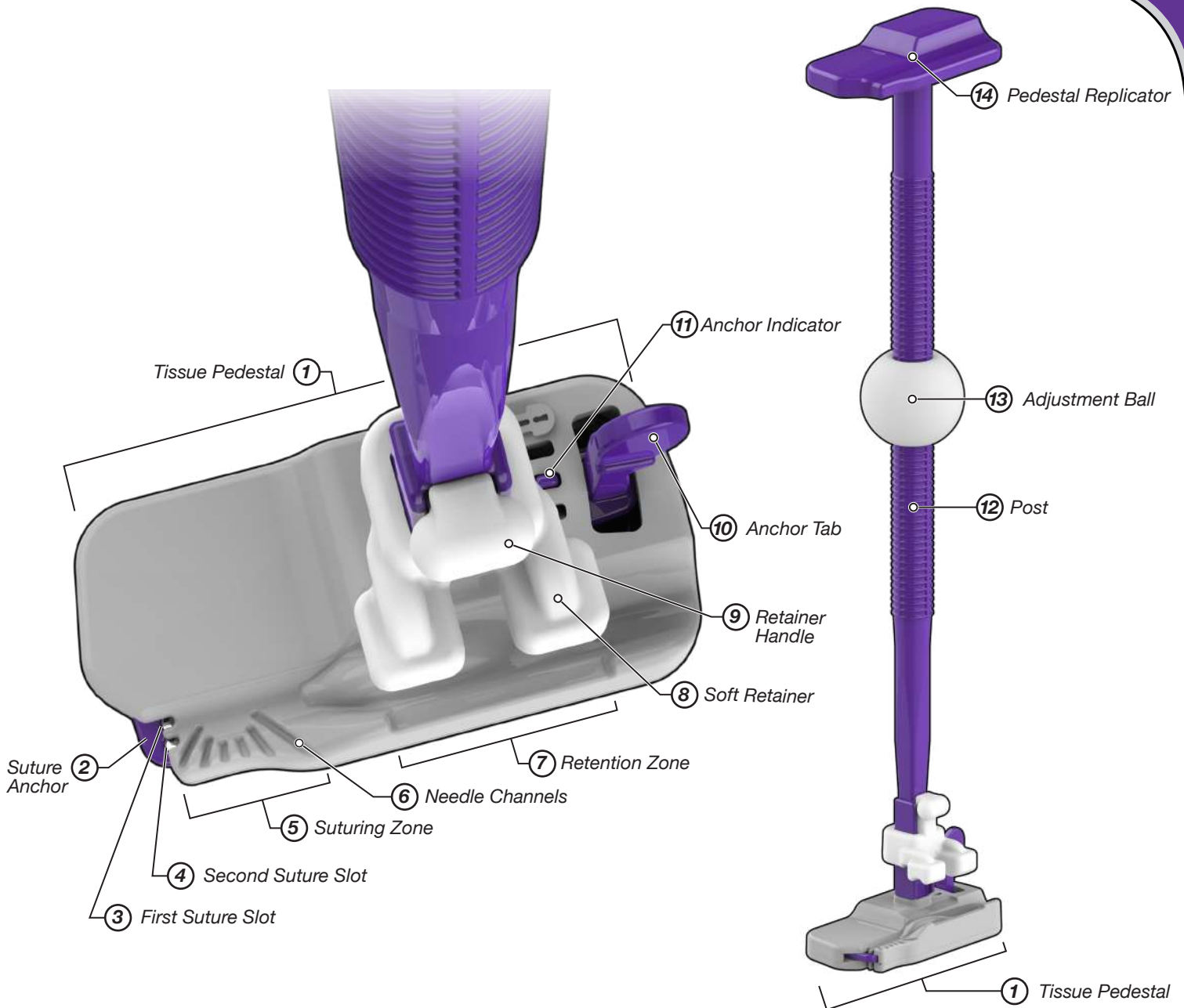


AnastoPod® DEVICE TECHNOLOGY GUIDE

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



AnastoPod® DEVICE DESCRIPTION

Each sterile package includes one single-patient-use AnastoPod® DEVICE. The tissue pedestal ① is used to hold tissue in place during suturing. The suture anchor ② can be closed to maintain tissue tension at the anastomotic site by gently holding suture within the integrated first suture slot ③ and second suture slot ④. The suturing zone ⑤ features integrated needle channels ⑥ to guide needle passage through the tissue. The retention zone ⑦ supports the tissue, which is held in place with a soft retainer ⑧ which incorporates a retainer handle ⑨. The anchor tab ⑩ is used to adjust the suture anchor from its middle, closed, and open positions as demonstrated by the anchor indicator ⑪. The post ⑫ features an adjustment ball ⑬ that is attached to a *multiSTATION® CLAMPING ADAPTER* and can be used to readily reposition the tissue pedestal. A pedestal replicator ⑭ opposite the tissue pedestal can be used to indicate the approximate position of the tissue pedestal.

INDICATIONS

The AnastoPod® DEVICE is indicated for use in the temporary retention of targeted tissue during surgery.

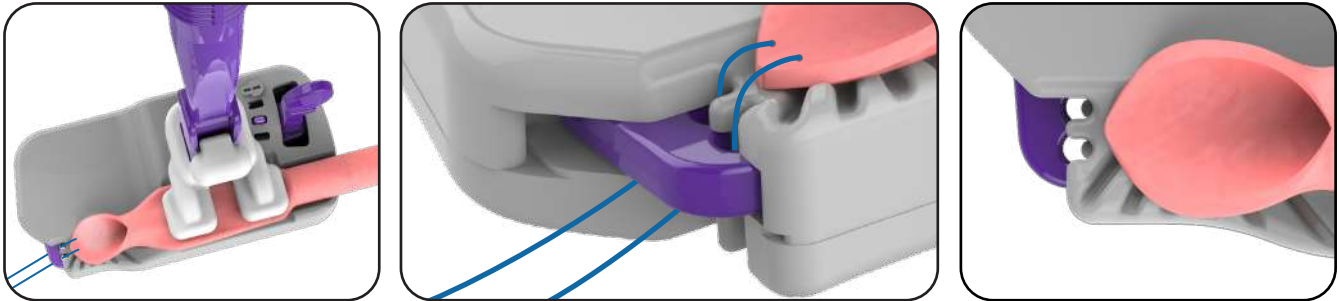
AnastoPod® DEVICE TECHNIQUE PEARLS

FIG. 2

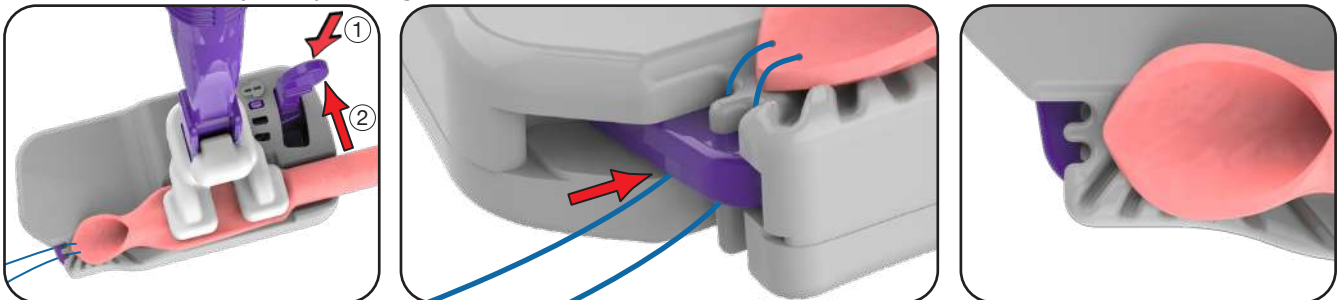
MIDDLE/CLOSED/OPEN

The anchor tab is used to set the position of the suture anchor into its middle, closed, or open positions. The suture anchor's middle position is used for passing needles through the suture slots. Pushing down and sliding the anchor toward the embossed lock icon sets the suture anchor to its closed position, which maintains tension on the suture and tissue. Pushing down and sliding the anchor tab toward the retention zone sets the suture anchor to its open position, which releases tension on the suture and tissue.

MIDDLE Ready for needle passage



CLOSED Gently compressing suture



OPEN Enables suture release from pedestal

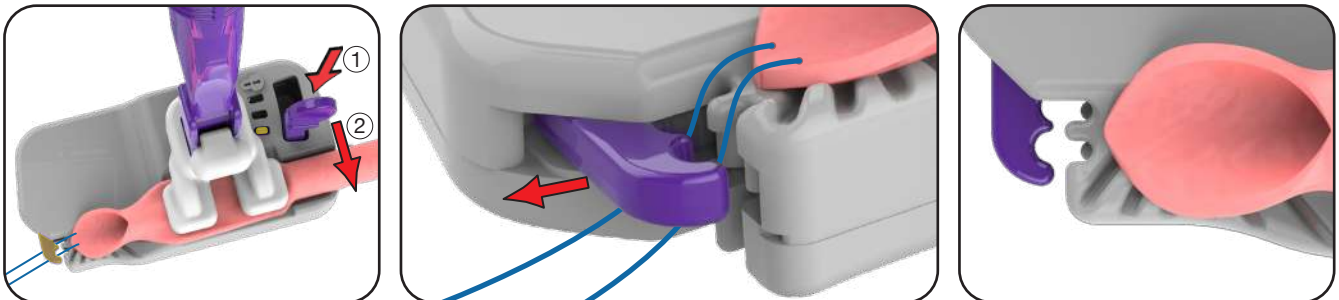
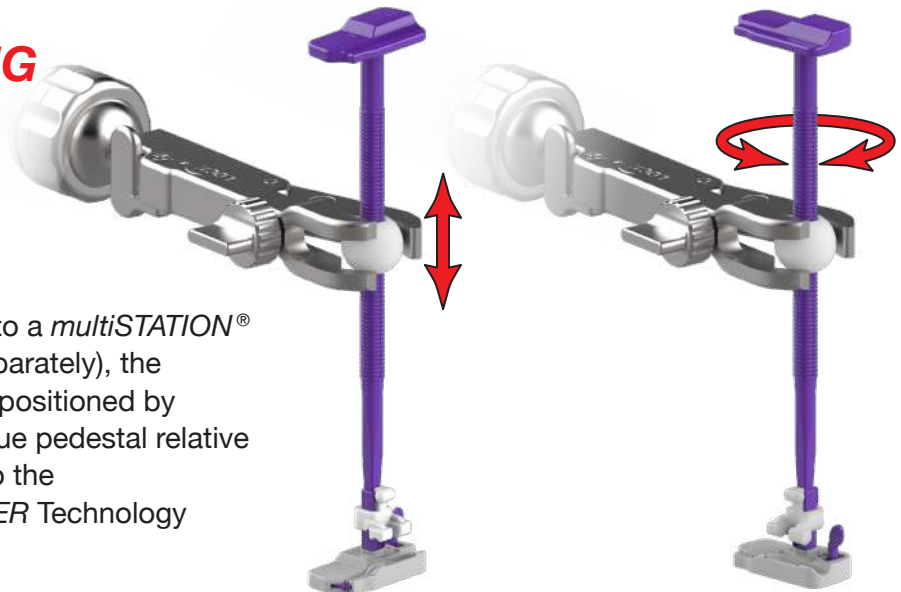


FIG. 3

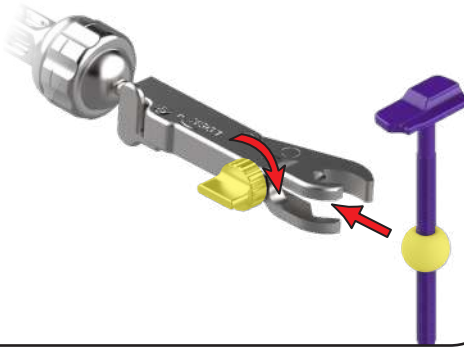
DEVICE POSITIONING

Using the adjustment ball attached to a *multiSTATION*® CLAMPING ADAPTER (available separately), the *AnastoPod*® DEVICE post can be repositioned by raising, lowering, or rotating the tissue pedestal relative to the targeted surgical site. Refer to the *multiSTATION*® CLAMPING ADAPTER Technology Guide for use instructions.



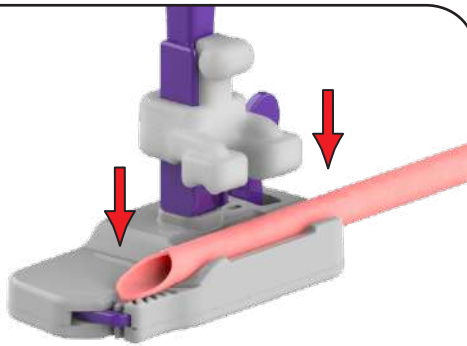
USING THE *AnastoPod*[®] DEVICE

1 ATTACH



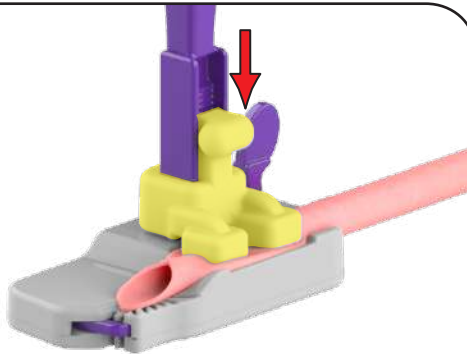
1 **ATTACH** the adjustment ball to a *multiSTATION*[®] CLAMPING ADAPTER (available separately) by placing it within the adjustable jaw and tightening the actuation thumb screw. Position the *AnastoPod*[®] DEVICE near the targeted tissue.

2 PLACE



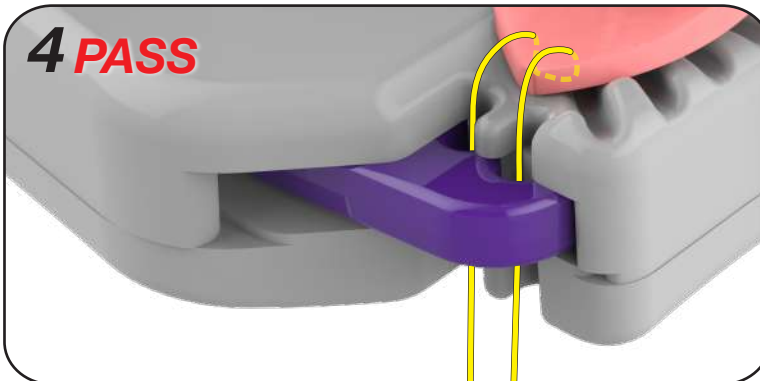
2 **PLACE** the targeted tissue onto the *AnastoPod*[®] tissue pedestal, ensuring that the tissue is properly oriented relative to the targeted anastomotic site.

3 RETAIN



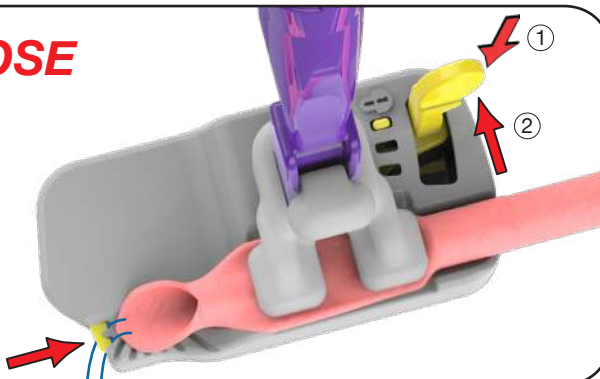
3 **RETAIN** the tissue on the tissue pedestal by lowering the soft retainer so that it is gently compressing the tissue in the retention zone.

4 PASS



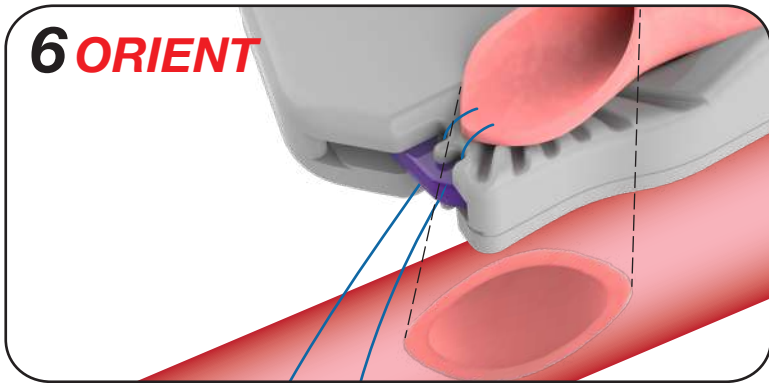
4 **PASS** the first needle through the first suture slot by taking an out-to-in tissue bite at the tip of the tissue; **PASS** the second needle through the second suture slot by taking another out-to-in tissue bite at the corresponding tissue location. **NOTE:** Ensure that the suture anchor is in its middle position while passing needles.

5 CLOSE

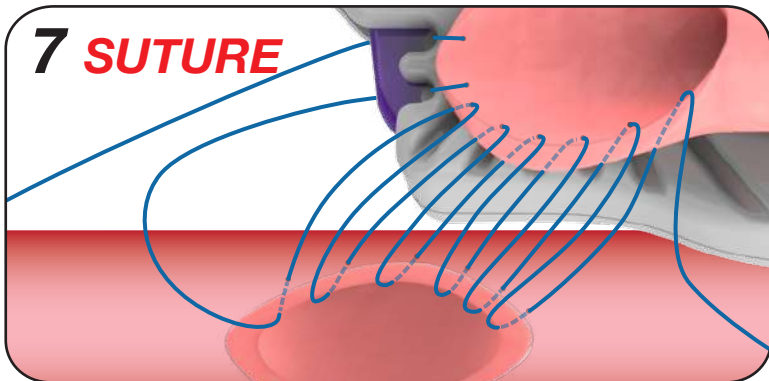


5 **CLOSE** the suture anchor by pushing down and sliding the anchor tab to the closed position, which rotates the suture anchor inward to gently hold the suture segments and maintain tension between the suture and tissue. **NOTE:** After release of the anchor tabs, ensure the anchor indicator has engaged into the slot adjacent to the lock icon.

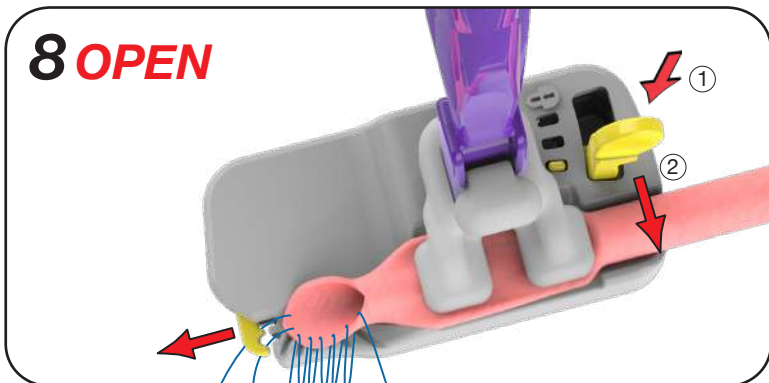
 **CAUTION:** The anchor tab must be pushed down before sliding to change its position.



6 ORIENT the tissue pedestal toward the targeted anastomotic site; ensure that the tissue held in place on the pedestal is appropriately aligned with the tissue at the target site.

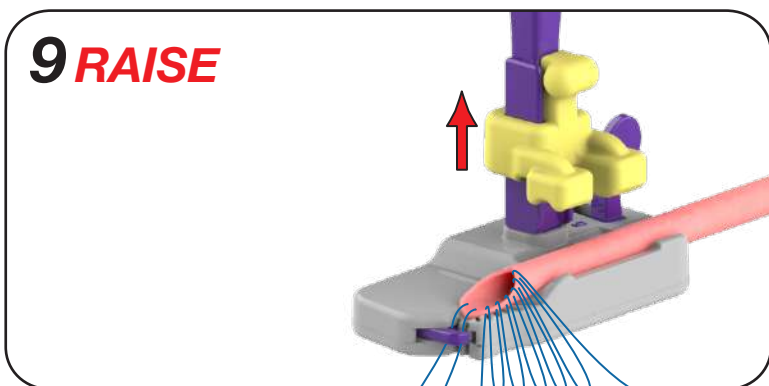


7 SUTURE the anastomosis using the surgeon's desired pattern. Shown here is the first half of a running anastomotic pattern performed using the the needle attached to the suture end closest to the target site.

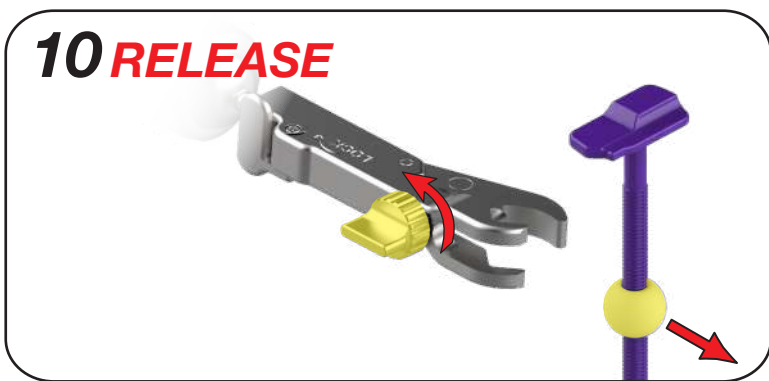


8 OPEN the suture anchor by pushing down and sliding the anchor tab to the open position, which rotates the suture anchor outward to release tension on the suture and tissue. Remove the suture from the suture slots.

CAUTION: The anchor tab must be pushed down before sliding to change its position.



9 RAISE the soft retainer up from the tissue by pulling the retainer handle from the top of the soft retainer up and sliding outward. Remove the tissue from the tissue pedestal.



10 RELEASE the adjustment ball from a *multiSTATION*[®] CLAMPING ADAPTER by loosening the actuation thumb screw and removing the *AnastoPod*[®] DEVICE from the surgical site.

ACTIONS:

- When the soft retainer of the *AnastoPod*® *DEVICE* is lowered on the tissue pedestal, the targeted tissue is secured to facilitate suturing.

CONTRAINDICATIONS:

- The *AnastoPod*® *DEVICE* is not for use in neurological procedures.

WARNINGS:






- Federal (U.S.A.) law restricts this device to sale, distribution, and use by, or on, the order of a physician.
- Users should be familiar with standard procedures and techniques for tissue retention before employing the *AnastoPod*® *DEVICE*.
- Do not reuse, reprocess, or resterilize this product. The *AnastoPod*® *DEVICE* is designed and intended for single patient use only. The performance of this product after cleaning or other reprocessing has not been validated and is not supported by LSI SOLUTIONS®. Reuse, reprocessing, or resterilization may compromise the integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Discard any open (unsealed), unused, expired, or damaged *AnastoPod*® *DEVICE*.
- Applications other than for tissue retention can result in damage to the *AnastoPod*® *DEVICE*, rendering it unsuitable for continued use.
- Do not use the *AnastoPod*® *DEVICE* to achieve hemostasis or for vessel occlusion.
- Each *AnastoPod*® *DEVICE* along with packaging, must be inspected, handled, and disposed of consistent with standard, accepted medical device disposal procedures.

PRECAUTIONS:

- Surgical procedures should only be performed by physicians having adequate training and familiarity with such techniques. In addition, medical literature should be consulted relative to techniques, complications, and hazards prior to the performance of surgical procedures. Inappropriate actions or use can lead to patient harm or death.
- Surgical instruments may vary in size from manufacturer to manufacturer. Before accessories from different manufacturers are employed together in a procedure, verify compatibility with *AnastoPod*® *DEVICE*.
- The *AnastoPod*® *DEVICE* can only be used with suture sizes and needles that allow unimpeded passage through the suture slot with its anchor tab in the middle position.
- The *AnastoPod*® *DEVICE* can accommodate tissue with a diameter up to 3.5 mm.
- Care must be taken when lowering soft retainer on targeted tissue to avoid damage to tissue.
- Avoid moving the *multiSTATION*® *CLAMPING ADAPTER* while tissue is retained on the *AnastoPod*® *DEVICE*.
- Avoid anchor tab damage due to inappropriate sliding during use. If the anchor tab is damaged during use, replace the *AnastoPod*® *DEVICE*.
- Ensure anchor indicator is fully engaged in the appropriate slot upon release of the anchor tab.

ADVERSE REACTIONS:

- No documented adverse reactions.

FIG. 4 <i>AnastoPod</i> ® PRODUCT ORDERING			SUPPLIED: STERILE
	REORDER	PRODUCT	DESCRIPTION
 x 4	REF 081420	<i>AnastoPod</i> ® <i>DEVICE</i>	(1) Box of (4) <i>AnastoPod</i> ® <i>DEVICES</i>
 x 1	REF 080519	<i>multiSTATION</i> ® <i>CLAMPING ADAPTER</i>	(1) <i>multiSTATION</i> ® <i>CLAMPING ADAPTER</i>
 x 1	REF 081000	<i>triDOC</i> ® <i>RAIL CLAMP</i>	(1) <i>triDOC</i> ® <i>RAIL CLAMP</i>
 x 1	REF 081010	<i>CLICK RELEASE</i> ™ <i>miniARM</i> ® <i>HOLDER</i>	(1) <i>CLICK RELEASE</i> ™ <i>miniARM</i> ® <i>HOLDER</i>
 x 1	REF 080950	<i>RIGID miniARM</i> ® <i>HOLDER</i>	(1) <i>RIGID miniARM</i> ® <i>HOLDER</i>



Patents: www.lsisolutions.com/patents

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Symbol Glossary: www.lsisolutions.com/symbols



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