SENTREHEART®

TENSURE™ SUTURE TIGHTENER

80-02

Carefully Read All Instructions Prior To Use.

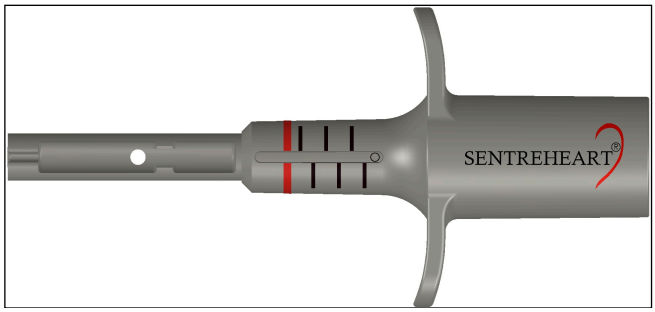
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

PACKAGING & STORAGE:
The TenSURE Suture Tightener is sterile (using ethylene oxide gas) in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged.

Handle with care. Do not store in excessive heat; a cool dry place is recommended. After use, this product may be a potential biohazard. Handle and dispose of all such devices in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

INDICATIONS:
The TenSURE Suture Tightener may be used with the LARIAT Suture Delivery Device while deploying the pre-tied suture loop from the device. The TenSURE provides tensile feedback to the user during suture deployment.

DESCRIPTION:
The TenSURE Suture Tightener is a single-use, sterile device. The device is comprised of a plastic handle and a pre-tensioned spring shaft that allows for tensile feedback. It may be used after the LARIAT Suture Delivery Device has placed a pre-tied suture loop.



COMPLICATIONS:
When used as directed, no adverse effects are expected with use of this device.

WARNINGS:
- Never retract the TenSURE Suture Tightener if the red Suture Release Tab is not securely loaded into the device.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Do not tighten beyond the red mark on the Suture Tightener as this may cause damage to the suture.
- Ensure all instrumentation is free of the closure site prior to pulling with the TenSURE Suture Tightener to prevent other instrumentation from becoming captured during tightening.

PRECAUTIONS:
- Care should be taken to avoid damage when handling the device. Do not use if the device is visibly damaged or deformed.

INSTRUCTIONS FOR USE
1. Carefully inspect the TenSURE Suture Tightener and the packaging prior to use. Do not use a device that is damaged in any way or if its packaging is damaged.
2. Insert the red Suture Release Tab connected to the end of the pulled suture on the LARIAT device into the TenSURE Suture Tightener. Be sure to align the Suture Release Tab within the grooves in the suture Tightener. (See FIG. 1)

CAUTION: The red tab must be properly aligned within the grooves in the Suture Tightener.

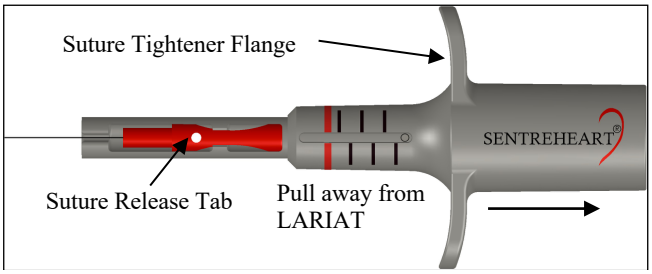


FIGURE 1

3. Grasping the TenSURE Suture Tightener with 2 fingers on the flange, pull the Suture Tightener away from the LARIAT until adequate suture tightening is achieved. This step may be repeated as necessary. The scale on handle indicates 1 lb increments, with the red mark indicating 7 lb.

CAUTION: Do not tighten beyond the red mark on the Suture Tightener as this may cause damage to the suture. (See Fig. 2)

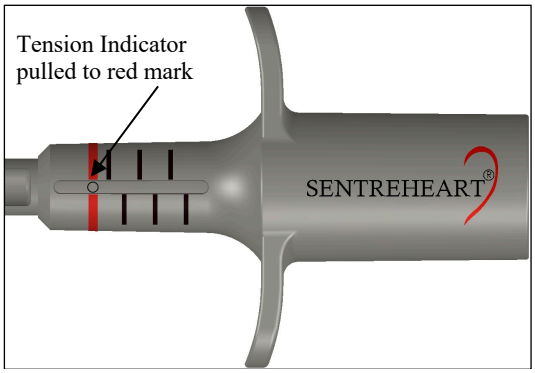


FIGURE 2

CAUTION: Pull the Suture Tightener straight back from the handle of the LARIAT Suture Delivery Device to avoid damage to the suture.

4. Dispose of the TenSURE Suture Tightener device as appropriate in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Catalog Number:	REF
Batch Code:	LOT
Use By:	
Contents of the package:	CONTENTS
Do Not Reuse:	
Do Not Resterilize:	
Do not use if packaging is damaged:	
Keep Away From Sunlight:	
Keep Dry:	
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician:	
Caution: consult accompanying documents:	
Consult Instructions For Use:	
Sterilized using ethylene oxide:	STERILE EO

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EC REP

CE Mark: Indicates conformance with European Council Directive 93/42/EEC

CE 2797