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ARROW®

Single Suture Staple Device
Rx only.

Indications for Use:
The Single Suture Staple Device permits needle free catheter securement to patient.

Contraindications:
None known.

⚠ *General Warnings and Precautions*

Warnings:
1. **Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.**
2. **Read all package insert warnings, precautions and instructions prior to use. Failure to do so may result in severe patient injury or death.**

Precautions:
1. **Do not alter any kit/set component during insertion, use or removal.**
2. **Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.**
3. **Use standard precautions and follow institutional policies for all procedures including safe disposal of devices.**

A Suggested Procedure: Use sterile technique.
1. Insert vascular catheter per hospital/agency protocol.
2. Remove staple applicator from storage cup.
3. Position thumb and index finger of dominant hand on indented surface of staple anchoring device.
4. Pass staple point through eye of catheter suture hub (refer to Figure 1).

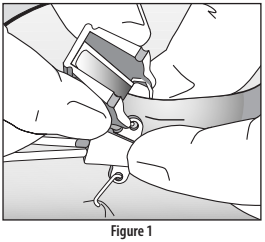

Figure 1

5. Tent skin and position with hub eye between staple opening.

⚠ **Warning: Do not place staple over catheter body or extension lines except at indicated anchoring location to minimize the risk of damage to catheter.**

6. Firmly squeeze anchoring device together to close staple and secure catheter to skin (refer to Figure 2).

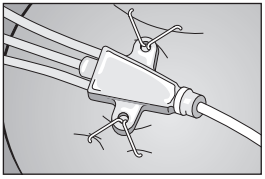

Figure 2

7. Repeat procedure through other suture eyes, if applicable.
8. Discard anchoring device upon completion.
9. Continue procedure per catheter manufacturers' instructions or dress insertion site according to hospital protocol.

MR Conditional Advisory:

MRI Information:
Non-clinical testing demonstrated that Staples are MR Conditional. Patients can be scanned safely immediately after placement under the following conditions:
- static magnetic field of 3.0 Tesla or less
- spatial gradient magnetic field of 720 Gauss/cm or less

MRI-Related Heating:
In non-clinical testing, Staples produced the following temperature rise during MRI performed for 15 minutes of scanning (i.e., per pulse sequence) in a 3.0 Tesla MR system (3.0 Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI):
- highest temperature change +1.6°C

Therefore, MRI-related heating experiments for the Staple at 3.0 Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

MR Artifacts:
MR image quality may be compromised if the area of interest is in exact same area or relatively close to position of the Staple. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on gradient echo pulse sequence) extends approximately 15 mm relative to size and shape of the Staple.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	365 mm^2	227 mm^2	782 mm^2	680 mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

For reference literature concerning patient assessment, clinician education, insertion technique, and potential complications associated with this procedure, consult standard textbooks, medical literature, and Arrow International LLC website: www.teleflex.com

A pdf copy of this IFU is located at **www.teleflex.com/IFU**

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