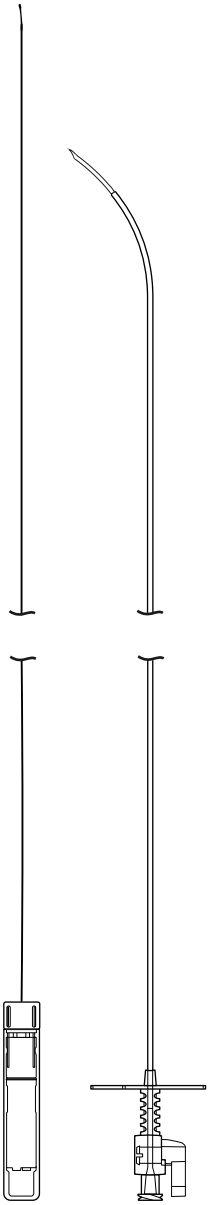
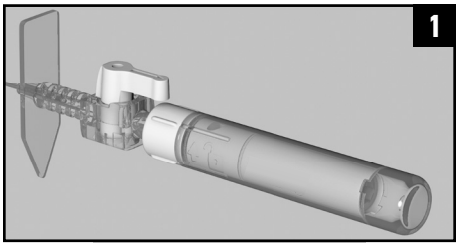
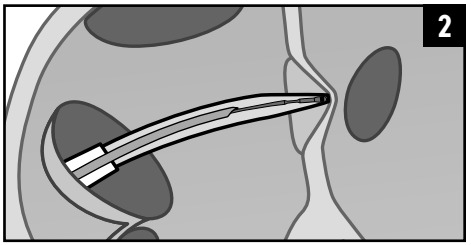
SafeSharp™ Transseptal Needle

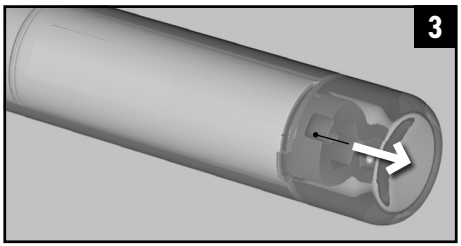
INSTRUCTIONS FOR USE

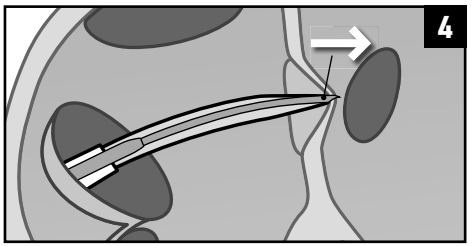
Pressure® Products
ACCESSING THE HEART OF INNOVATION

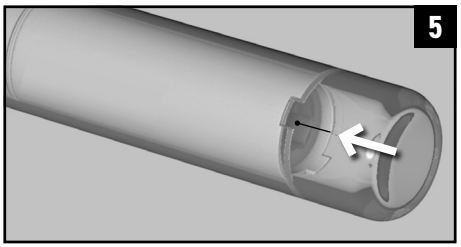


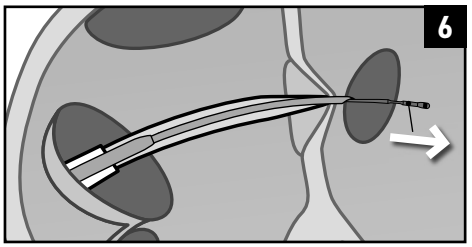












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Do not re-use | Do not resterilize | Do not use if packaging is damaged and consult Instructions | Keep dry | Keep away from sunlight | Sterilized with ethylene oxide | Medical device | Unique device identifier

Rx ONLY **CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.**

en-Instructions for Use

The SafeSharp Transseptal Needle™ consists of a stainless-steel cannula with a proximal plastic handle and hub, a distal curve to facilitate positioning, and an offset beveled tip designed to puncture the interatrial septum with minimal force during a transseptal procedure. The proximal end of the Transseptal Needle has a pointer hub to indicate the distal curve direction, and a 2-way stopcock handle and Luer lock connection for flushing or aspiration. A stylet assembly inserted into the transseptal needle consists of an elongated .018" diameter nitinol wire with an intermediate .013" diameter section, a bulbous distal tip, and a proximal clear plastic handle with an internal mechanism configured to both provide feedback on the position of the stylet tip as well as to maintain the stylet tip in the extended position to reduce the possibility for further penetration of the needle tip after the initial crossing of the septum.

INTENDED USE

The Transseptal Needle is used to create the primary puncture in the interatrial septum during a transseptal procedure to gain access to the left side of the heart.

INDICATIONS FOR USE

The Transseptal Needle is used to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access. The Transseptal Needle is intended for single use only.

CONTRAINDICATIONS

The use of the Transseptal Needle is contraindicated in patients with the following conditions.

- Distorted anatomy due to congenital heart disease or other causes
- Aneurysmal septum
- Significant chest or spine deformity
- The inability to lie flat
- Left atrial thrombus or tumor
- Dilated aortic root
- Previous patch repair of the interatrial septum
- Known or suspected myocardial infarction within the last two weeks
- Unstable angina
- Recent pulmonary emboli
- Recent cerebral vascular accident (CVA)
- Patients who cannot tolerate anticoagulation therapy
- Patients with an active infection

WARNINGS AND PRECAUTIONS

- Do not use needle without stylet
- Do not insert a guidewire, including a transseptal guidewire, into the needle
- Do not use without echocardiography for image guidance
- Do not alter this device in any way
- Single-Use Only: Do not re-use this device. After use thorough cleaning of biological and foreign material is not possible. Adverse patient reactions may result from the re-use of this device.
- Store in a cool, dark, and dry place
- Prolonged exposure to temperatures above 30° C (86° F) may damage the product
- Do not use if the package is open or damaged in any way

ADVERSE EVENTS

In addition to all the complications associated with any transseptal cardiac catheterization, the following can occur during the use of the Transseptal Needle:

- Puncture of the atrial free wall
- Puncture of the aorta
- Puncture of the inferior vena cava
- Puncture of the coronary sinus
- Tamponade
- Hemothorax
- Arterial embolism from thrombus at the puncture site
- Pulmonary embolism
- Stroke
- Death
- Atrial arrhythmias
- Residual atrial septal defects
- Thromboembolism
- Valvular damage
- Intimal tear
- Hematoma at the vascular access site
- Disturbances in conduction system such as SA or AV node

STYLET ASSEMBLY DESCRIPTION AND OPERATION:

[Figure 1] The stylet handle green plunger is not visible. The SafeSharp Transseptal Needle™ is ready to be advanced as the stylet tip is protruding from the needle tip.

[Figure 3] The stylet handle green plunger is visible. The stylet handles internal green plunger advances into the proximal clear outer housing to provide a visual indication of the stylet being pushed into the needle tip during puncture.

[Figure 5] The stylet handle green plunger suddenly disappears. Upon the needle tip puncturing the septum, the distal stylet tip crosses the septum, and the green plunger disappears with a tactile and audible click once the needle tip has crossed the septum.

PREPARATION OF SYSTEM BEFORE USE

Follow standard transseptal technique:

1. **Caution is to be used when handling the transseptal needle to prevent injury due to the sharp needle tip. Any manual forming of the needle curve must not intefere with the distal smaller diameter needle portion to avoid kinking the needle.**
2. Flush the SafeSharp Transseptal Needle™. **Caution is to be used when handling the transseptal needle with the stylet removed to prevent injury due to the sharp needle tip.** After flushing, insert the stylet into the transseptal needle and fully attach it to the needle hub by rotating the ribbed Luer adapter clockwise.
3. Flush the transseptal dilator and sheath.
4. Insert the transseptal needle into the transseptal dilator. **Ensure that the stylet handle is fully engaged onto the needle hub and the stylet is protruding from the sharp needle tip before inserting into the dilator hub. Handle with care to prevent injury due to the sharp needle tip. Caution is to be used when inserting the needle into the dilator to avoid skiving the dilator. if resistance is met, withdraw the transseptal needle and flush the needle and dilator. Re-insert the needle.**
5. Retract the needle assembly so that the tip of the **stylet** is 0.5 cm within the tip of the dilator.
6. Measure and record the distance from the pointer flange to the dilator hub.
7. **The distance between the pointer flange and the dilator hub must be maintained during the procedure to ensure that the needle AND distal stylet tip does not extend beyond the dilator tip.**
8. Remove the needle from the dilator and the stylet from the needle. Flush the needle and reinsert and fully attach the stylet handle to the needle hub. Flush the dilator again.

INSTRUCTIONS FOR USE

Follow the standard transseptal technique:

1. Obtain femoral venous access.
2. Insert the introducer guidewire into the superior vena cava.
3. Advance the transseptal sheath and dilator over the introducer guidewire and into the superior vena cava. Make sure the dilator tip is pointed medially once in the superior vena cava.
4. Remove the introducer guidewire and per standard technique, aspirate and flush the transseptal system (including the dilator and sheath) before and after it is inserted into the right atrium.
5. Separate the sheath and dilator by withdrawing the dilator by a distance sufficient to accommodate the needle curve. **Ensure that the stylet handle is fully engaged onto the needle hub and the stylet is protruding from the sharp needle tip before inserting into the dilator hub** [see Figure 1].
6. Insert the needle and stylet into the dilator, letting the needle rotate freely as it advances. **Caution is to be used when inserting the needle into the dilator to avoid skiving. If resistance is met, withdraw the transseptal needle and aspirate the needle and dilator. Re-insert the needle.**
7. Reconnect the sheath and dilator after the needle curve is advanced beyond the hemostasis valve hub of the sheath. Maintain position in the superior vena cava and do not advance the dilator.
8. Advance the transseptal needle until the pointer flange is at the same distance recorded during preparation from the hub of the dilator.
9. Remove the stylet assembly by rotating the ribbed luer adapter counterclockwise from the transseptal needle hub. **Caution is to be used when handling the transseptal needle with the stylet removed to prevent injury due to the sharp needle tip.** Do not discard the stylet.
10. Attach a syringe to the needle hub and aspirate until blood return is observed, then discard the syringe.
11. Flush the needle with clean heparinized saline, ensuring no air enters the bloodstream.
12. After flushing, re-insert the stylet assembly into the transseptal needle and fully attach to the needle hub by rotating the ribbed luer adapter clockwise.
13. Confirm that the needle AND stylet tip are located 0.5 cm inside the dilator tip.
14. Slowly drag the assembly preventing any movement of the assembly parts relative to one another. Be sure to maintain the orientation of the needle pointer.
15. Confirm that the dilator tip has engaged the fossa ovalis [see Figures 1 & 2]. **Ensure the dilator is in the correct location on the fossa ovalis using echocardiography image guidance before advancing the needle. Ensure that the stylet tip is fully positioned inside the dilator tip and that the 2-way stopcock handle is in its fully open position to allow free movement of the stylet wire.**
16. Once the location is confirmed, advance the SafeSharp Transseptal Needle™ across the septum until it is fully engaged with the dilator. If resistance is met, re-confirm the anatomic landmarks. The stylet assembly provides both a visual and tactile indication of the needle tip puncture [see Figures 3 & 4]. The stylet handle internal green plunger is visible as the needle is advanced against the septum and disappears with a tactile and audible click once the needle tip has crossed the septum [see Figures 5 & 6].
17. **Confirm proper puncture location and entry into the left atrium using echocardiography image guidance. Do not continue to advance the SafeSharp Transseptal Needle™ upon entry into the left atrium as it can cause trauma to the heart wall or vasculature.**
18. **If pericardial or aortic entry occurs, do not advance the dilator over the needle. Withdraw the needle and monitor the vital signs of the patient.**
19. Advance the sheath and dilator assembly over the needle while maintaining a fixed position of the SafeSharp Transseptal Needle™ until the needle is inside the dilator tip. **Do not advance the SafeSharp Transseptal Needle™ into the left atrium with the dilator as it can cause trauma to the heart wall or vasculature.**
20. While maintaining the position of the needle and dilator, advance the sheath over the dilator.
21. **Air embolism may occur when withdrawing objects from the sheath. Take precautions to prevent air from entering.**
22. Withdraw the transseptal needle from the dilator. **Handle with care to prevent injury due to the sharp needle tip.** Attach a syringe to the dilator and aspirate. Continue aspirating blood while holding the sheath in position and withdrawing the dilator.
23. Once the dilator is removed, aspirate blood through the stopcock on the sheath and then flush, taking precautions to avoid air bubbles.
24. After use, the transseptal needle may be a potential biohazard. **Handle with care.** Disposal should be performed in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.