Transseptal **Needle**

STERILE EO

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

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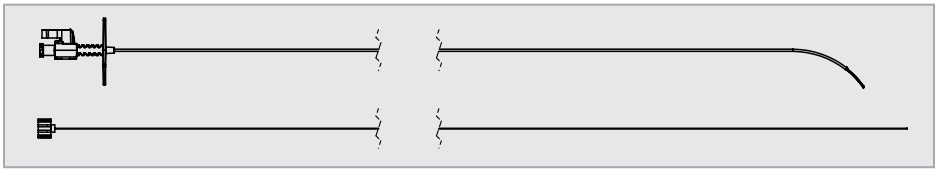
ACCESSING THE HEART OF INNOVATION



en-Instructions for Use

The Transseptal Needle consists of a stainless steel cannula with a proximal plastic handle and hub, and a distal needle bevel designed to puncture the interatrial septum 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.

The distal end of the needle is curved to facilitate positioning within the heart. A stylet inserted within the transseptal needle is designed to guide the needle when advancing through the dilator.

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
- Significant chest or spine deformity
- The inability to lie flat
- Ongoing anticoagulation
- 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 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 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 package is open or damaged in any way

Adverse events

In addition to all of 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

Preparation Before Use

Follow standard transseptal technique:

1. Remove the stylet and flush the transseptal needle. After flushing, re-insert the stylet into the transseptal needle and lock to the needle hub.
2. Per standard technique, aspirate and flush the transseptal system (including the dilator and sheath) before and after it is inserted into the right atrium.
3. Insert the transseptal needle into the transseptal dilator.
4. **Caution is to be used when inserting in the dilator to avoid skiving of 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 just 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 assembly 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 lock the stylet. Flush the dilator again.

Instructions for Use

Follow 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 aspirate and flush the dilator.
5. Separate the sheath and dilator by withdrawing the dilator by a distance sufficient to accommodate the needle curve. Lock the stylet on the hub of the transseptal needle and insert the needle into the dilator, letting the needle rotate freely as it advances. **Caution is to be used when inserting in 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.**
6. Reconnect the sheath and dilator after the needle curve is advanced beyond the hemostasis valve hub of the sheath. Maintain position in the super vena cava and do not advance the dilator.
7. Advance the needle and stylet until the pointer flange is at the distance recorded during preparation from the hub of the dilator.
8. Remove the stylet and set it aside. Do not discard the stylet.
9. Aspirate the transseptal needle until blood return is observed and discard.
10. Flush the transseptal needle and close the stopcock.
11. Confirm the needle tip is located inside the dilator.
12. 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.
13. Confirm the dilator tip has engaged the fossa ovalis. **Ensure the dilator is in the correct location on the fossa ovalis before advancing the needle.**
14. Once the location is confirmed, advance the needle across the septum. If resistance is met, re-confirm the anatomic landmarks.
15. **If pericardial or aortic entry occurs, do not advance the dilator over the needle. Withdraw the needle and monitor vital signs of patient.**
16. Advance the sheath and dilator assembly over the needle while maintaining a fixed position of the needle.
17. Withdraw the needle into the dilator until it is just inside the dilator tip.
18. While maintaining the position of the needle and dilator, advance the sheath over the dilator.
19. **Air embolism may occur when withdrawing objects from the sheath. Take precautions to prevent air from entering.**
20. Withdraw the transseptal needle from the dilator. Attach a syringe to the dilator and aspirate. Continue aspirating blood while holding the sheath in position and withdrawing the dilator.
21. Once the dilator is removed, aspirate blood through the stopcock on the sheath and then flush, taking precautions to avoid air bubbles.
22. After use, the transseptal needle may be a potential biohazard. Handle and dispose of it in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

REF	Model Number
LOT	Lot Number
	Use Before
	Quantity
	Inner Diameter
	Outer Diameter
	Curve
	Length
	Manufacturing Date
Rx ONLY	CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.
	Consult technical manual!
	Do not use if packaging is damaged!
	Keep away from sunlight
	Keep dry
15° C 30° C	Temperature limitation
STERILE EO	Sterilized with ethylene oxide
	Single use only. Do not reuse!
STERILIZE	Do not resterilize!
	Manufacturer
	Distributor
CE	European approval mark. This product conforms with the EC directive 93/42/EEC relating to medical products. It is therefore designated with the CE mark. The product can be used in all European Union countries as well as in countries that recognize the above-mentioned directive.
EC REP	European Representative