NF™ Needle Free Transseptal **Cannula**

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

STERILE EO

MD

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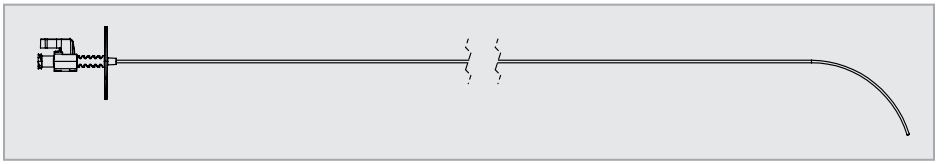

REF	Catalog Number
LOT	Lot Number
	Use-by Date
QTY	Quantity
	Inner Diameter
	Outer Diameter
	Curve
	Length
	Date of Manufacture
Rx ONLY	CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.
	Consult Instructions for Use
	Do not use if packaging is damaged
	Keep away from sunlight
	Keep dry
STERILE EO	Sterilized using ethylene oxide
MD	Medical device
UDI	Unique device identifier
	Single sterile barrier system
	Do not re-use
	Do not resterilize
	Manufacturer
	Distributor

en-Instructions for Use

The Needle Free™ Transseptal Cannula is a blunt stainless steel cannula with a plastic handle and hub designed to provide support to a transseptal introducer during a transseptal procedure. The distal end of the cannula is curved to assist in orienting the device within the heart. The outer diameter of the Transseptal Cannula is designed to mate with the inner diameter of a standard dilator. The proximal end of the Transseptal Cannula has a pointer hub to indicate the curve direction of the cannula, and a 2-way stopcock handle and luer lock connection for flushing or aspiration.

Intended Use

The Transseptal Cannula is used to support a transseptal introducer when used in conjunction with a transseptal guidewire to create the primary puncture in the interatrial septum.

Indications for Use

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

Contraindications

The use of the Transseptal Cannula 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

- 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 Cannula:

- 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

Instructions for Use

Follow standard transseptal technique:

1. Per standard technique, aspirate and flush the transseptal system (including the cannula, dilator and sheath) before and after it is inserted into the right atrium.
2. After flushing, position the stopcock handle of the cannula so that it is in the closed position.
3. Advance the Transseptal dilator fully into the Transseptal sheath.
4. Advance the Transseptal dilator and sheath assembly over the introducer guidewire to obtain venous access.
5. Remove the introducer guidewire from the dilator.
6. Aspirate and flush the dilator and ensure no air enters into the bloodstream.
7. Retract the dilator to accommodate the cannula curve which will allow the cannula curve to pass through the dilator and sheath hubs.
8. Gently advance the Transseptal Cannula into the transseptal dilator allowing the cannula hub to rotate as it is advanced so as to avoid skiving the inside wall of the dilator. The cannula will stop when the tip has reached the inside dilator tip taper.
9. Remove the protective tip cover and back the Transseptal Guidewire slowly into the guidewire tip straightener. Do not pull the Transseptal Guidewire completely out of the tip straightener.
10. Fully insert the tip straightener into the hub of the transseptal cannula.
11. Advance the Transseptal Guidewire until the tip enters the curved portion of the transseptal cannula (visible markers are provided as a guide for common commercially available transseptal introducer systems. Do not advance the guidewire beyond the tip of the dilator).
12. Tent the fossa ovalis with the transseptal cannula and dilator assembly.
13. Under visual guidance, **while tenting and maintaining constant force on the septum with the dilator**, slowly advance the transseptal guidewire through the cannula, dilator, tip, and across the interatrial septum, into the left atrium. Continue to advance into one of the pulmonary veins (The radiopaque coil on the guidewire should be seen to be within the left atrium and subsequently the pulmonary vein). **At no time should the guidewire be advanced or withdrawn when resistance is met without first determining the cause visually and taking remedial action. Confirm proper location of the transseptal guidewire prior to proceeding**.
14. The transseptal guidewire should be advanced approximately 10cm into the left atrium to ensure that the full body diameter portion of the transseptal guidewire has crossed the septum. **Advancement of the full body diameter portion into the left atrium should be observed tactilely or visually as the septum is dilated up to the full body diameter**.
15. Slowly advance the transseptal cannula, dilator and introducer sheath over the transseptal guidewire across the septum. **Do not hold or pin the transseptal guidewire when advancing the dilator. If the introducer dilator tip resists advancement through the septum with typical applied force, apply an oscillating rotation to the cannula while advancing. This will facilitate the dilator tip advancing through the septum (when a steerable introducer sheath is being used, relaxing the sheath curve shape to a straight position will facilitate the rotation and tracking over the guidewire)**. If desired, measure pressures and/or inject contrast through the cannula and dilator tip before completely advancing the cannula, dilator and introducer sheath (the transseptal guidewire must be partially retracted into the cannula in order to measure pressure through the cannula). Once the dilator tip position is confirmed in the left atrium, advance the cannula, dilator and introducer sheath over the transseptal guidewire into the left atrium. **If the introducer sheath tip resists advancement through the septum with typical applied force, apply an oscillating rotation to the introducer sheath while advancing. This will facilitate the sheath tip advancing through the septum (when a steerable introducer sheath is being used, relaxing the sheath curve shape to a straight position will facilitate the rotation and tracking over the guidewire)**.
16. Slowly remove the transseptal guidewire, cannula and dilator as a unit, leaving the introducer sheath in place. Do not remove the transseptal guidewire from the cannula without the use of a dilator. **At no time should the introducer, cannula, dilator, or guidewire be advanced or withdrawn when resistance is met without first determining the cause visually and taking remedial action.**
17. After use, the transseptal cannula 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.