English

VENTRAX®
Delivery System

INSTRUCTIONS FOR USE

INDICATIONS AND USAGE
The product is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart.

DEVICE DESCRIPTION
The Ventrax® Delivery System is designed to provide a conduit to deliver diagnostic and therapeutic catheters to specific heart chambers and locations. It provides support for positioning and maintaining the position of catheters at specific locations in the heart. The sheath may be used for percutaneous entry. The system consists of four components: a sheath, a pigtail dilator, a straight dilator and a J-tipped Amplatz guidewire.

VENTRAX® DELIVERY SYSTEM COMPONENTS
A. 8.5F Guiding Sheath Introducer: provides a conduit to deliver diagnostic and therapeutic catheters to specific heart chambers and locations. The sheath has an integrated valve to restrict blood loss, and a sideport for flushing and withdrawing blood. The sheath is available in two different support profiles: Ventrax MS for moderate distal support, and Ventrax LS for light distal support. Selection is made based upon user preference.

B. Mating Pigtail Dilator: designed to conform to the sheath introducer inner diameter, has a tapered tip, has a pigtail at the distal end to assist aortic valve crossing, has an integrated valve to restrict blood loss, and has a sideport for flushing.

C. Mating Straight Dilator: designed to conform to the sheath introducer inner diameter and has a tapered tip. Usage of this straight dilator is optional. This straight dilator is intended to be used only when access is unsuccessful after using the mating pigtail dilator.

D. 0.035" X 220cm J-tipped Amplatz guidewire: provide path for sheath and dilator advancement.

CONTRADICTIONS
None known.

WARNINGS
1. Do not power inject contrast solution through the sheath.
2. Withdraw the dilator and sheath from the patient slowly to prevent air ingress.
3. Use on or before the last day of the expiration month that is printed on the product packaging label.
4. This device was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
5. Do not use the device if the sterile package is open or damaged.

PRECAUTIONS
1. Store in a cool dry place.
2. This device is intended for use by physicians who are trained in standard transcatheter techniques. The physician should determine which patients are candidates for procedures that require this system.
3. The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this delivery system.
4. Use caution when advancing the dilator and sheath to avoid damaging soft tissue, vasculature, or disrupting previously implanted medical devices.
5. Use standard transcatheter techniques when using Ventrax™ Delivery System product.
6. Never advance, torque, or withdraw guidewire or sheath when resistance is met. Determine cause by fluoroscopy and take remedial action.
7. When using the sheath in the presence of radio frequency ablation, care must be taken to assure all ablating elements are outside the sheath.

POTENTIAL ADVERSE EVENTS
Potential adverse events that may occur during or after a procedure using this delivery system may include, but are not limited to:
- Air embolism
- Arrhythmia
- Arteriovenous fistulae
- Bleeding
- Cardiac tamponade
- Death
- Dissection
- Endocarditis
- Hematoma
- Infection
- Local nerve damage
- Myocardial infarction
- Perforation
- Peripheral embolism
- Peripheral pulse loss
- Pseudoaneurysm formation
- Stroke
- Thrombosis
- Tissue trauma/damage
- Transient AV block
- Valve damage
- Vascular occlusion
- Vessel trauma/damage

DIRECTIONS FOR USE
1. Prepare the delivery system for use:
   - Inspect the sterile pouch and verify that it is unopened and undamaged. Do not use the components if the sterile barrier has been compromised.
   - Gently open the sterile pouch and inspect the components for damage. Do not use damaged or kinked components.
   - Flush all components with sterile saline.
2. Straighten out pigtail portion of the dilator prior to insertion through sheath valve. Insert the dilator into the sheath and advance until the dilator hub snaps into the sheath hub. Ensure the two sideports are aligned for curve orientation at the distal end of the sheath and dilator assembly.
3. Gain access to the vasculature per standard technique or hospital protocol.
4. The Amplatz guidewire is used for access. Insert the soft floppy tip of guidewire through introducer needle (not supplied). Advance guidewire with fluoroscopic guidance to the ascending aorta. Do not continue advancing or withdraw the guidewire if resistance is met. Determine the cause of resistance before proceeding.

   Maintain guidewire placement and remove introducer needle. Do not withdraw the guidewire back into the needle as this may damage the guidewire or cause harm to the patient. The needle should be removed first.

   WARNING: Use extreme caution when withdrawing PTFE coated guidewires back through a metal needle. The sharp edge of the needle may scrape the coating. It is suggested that a catheter or PTFE vessel dilator replace the access needle as soon as the guide wire has reached the appropriate position.

   Make a small incision at the puncture site with a scalpel to ease sheath introduction.
5. Straighten out the pigtail dilator and advance it over the back of the Amplatz guidewire through the access site. Continue advancing the dilator and sheath assembly over the guidewire until the desired sheath position is reached.

6. Steps if straight dilator is used:

   If resistance is felt when advancing the pigtail dilator and sheath assembly, maintain guidewire position, hold pressure on the access site, and remove the pigtail dilator and sheath assembly.

   Remove the pigtail dilator from the sheath, flush the sheath, and insert the straight dilator into the sheath until the dilator hub snaps into the sheath hub.

   Advance the straight dilator and sheath assembly over the back of the Amplatz guidewire into the vasculature and visualize with fluoroscopy until the sheath reaches the intended anatomy.

   Maintain position of the sheath and guidewire while slowly removing the straight dilator from the sheath.

   Exchange for pigtail dilator:

   Straighten out the pigtail dilator and advance it over the back of the Amplatz guidewire. Continue advancing the pigtail dilator over the guidewire until the dilator hub can be snapped into the sheath hub.

7. Hold guidewire in place and advance the pigtail dilator and sheath assembly to the ascending aorta. Withdraw the Amplatz guidewire back into the pigtail dilator to allow the pigtail curve to form. It is recommended to visualize the pigtail in an RAO fluoroscopy view and align it in an anterior orientation directed toward the left ventricle. Advance the dilator and sheath assembly through the aortic valve into the left ventricle. If resistance is met, advance the wire into the pigtail to expand the curl diameter and torque the pigtail as needed to achieve valve crossing.

   WARNING: Insertion of the pigtail dilator may result in temporary or sustained arrythmia that may require intervention.

8. While maintaining the sheath's position, separate the dilator hub from the sheath hub. After unsnapping the hubs, withdraw the dilator and guidewire.

   WARNING: Remove the dilator slowly to prevent an ingress of air.

9. Allow blood backflow to purge any air from the sheath prior to flushing or infusion and after exchanges.

10. In order to maintain the location of the sheath in the left ventricle, monitor the location of the radiopaque marker tip frequently under the fluoroscopy.

11. Introduce the properly prepared catheter through the hemostatic valve into the left ventricle.

    To prevent loss of left ventricular access, confirm the position of the radiopaque marker tip in the left ventricle with fluoroscopy prior to removal of the indwelling catheter.

12. When the procedure is complete, slowly remove the sheath.

    WARNING: Remove the sheath slowly to prevent vascular injury or ingress of air.

    After removing the sheath, achieve hemostasis per standard technique or hospital protocol.

13. Dispose of all parts including packaging according to local laws and regulations.

	Caution
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
MD	Medical Device
UDI	Unique Device Identifier
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Use by date: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
REF	Catalog number
LOT	Lot number
	Manufacturer
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
	Non-pyrogenic
	Single use
	Do not resterilize
	Keep Dry
	Keep away from sunlight
	Size
	Length
	Single sterile barrier system
STERILE EO	Sterilized Using Ethylene Oxide
	Count
	Max guide wire

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