TriNav®

TriSalus™ TriNav® Infusion System
with SmartValve® Technology

Instructions for Use

TriSalus LIFE SCIENCES®

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TriSalus™ TriNav® Infusion System: Instructions for Use

with SmartValve® Technology

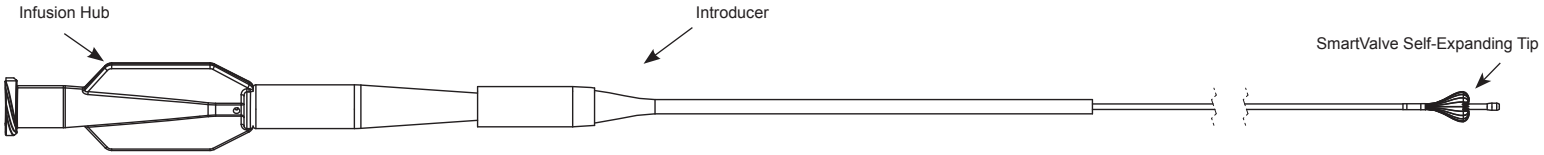
Sterile. Sterilized with ethylene oxide gas. Single use only. Do not resterilize.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

℞ ONLY

CAUTION: CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. FAILURE TO OBSERVE ALL WARNINGS AND PRECAUTIONS MAY RESULT IN COMPLICATIONS.

DESCRIPTION: The TriSalus™ TriNav® Infusion System is a 0.021" lumen microcatheter with SmartValve® Technology, a self-expanding tip at the distal end. The TriNav (Figure 1) serves as the conduit for physician-specified agents such as contrast agents, flush solutions, and embolic beads. It is compatible with standard guide wires up to 0.018", and embolic hydrogel particles 500µm or less in size and glass microspheres 110µm or less in size. The TriNav has a PTFE inner liner to provide a lubricious surface for passage of physician-specified agents and other accessory devices. The device is hydrophilically coated.

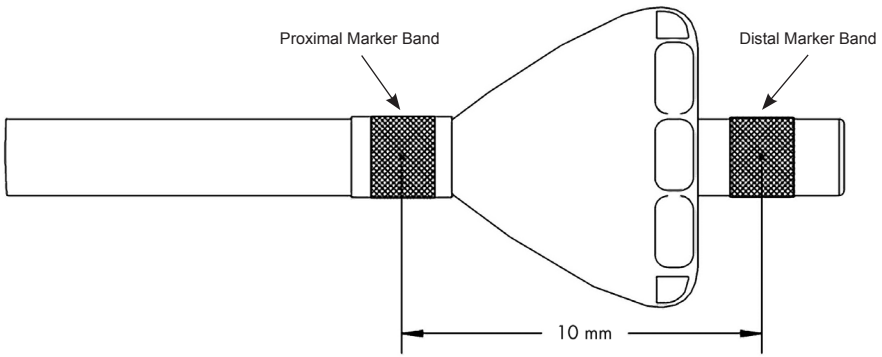
FIGURE 1. TRINAV INFUSION SYSTEM DIAGRAM



The soft, pliable SmartValve (Figure 2) is designed to improve infusion efficiency while maintaining antegrade flow during infusion. It will self-activate when positioned correctly in the appropriate size vessel. Refer to the product label for vessel size recommendation.

There are two radiopaque markers located at the distal end of the TriNav to aid in positioning of the SmartValve self-expanding tip.

FIGURE 2. CLOSE-UP OF THE SMARTVALVE



1. Intended Use: The TriSalus™ TriNav™ Infusion System is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

2. Contraindications: The TriSalus™ TriNav™ Infusion System is not intended for use in the vasculature of the central nervous system (including the neurovasculature) or central circulatory system (including the coronary vasculature).

3. Warnings

- Do not use the product after the "Use By" date specified on the package.
- Only physicians possessing sufficient training, skill and experience in the principles, clinical applications, complications, and side effects commonly associated with similar or same techniques should perform vascular interventional procedures.
- Do not use a device where the integrity of the sterile packaging has been compromised.
- Inspect the device prior to use. If the device appears damaged, replace with another device.
- Do not heat, bend or attempt to shape the catheter tip. It may result in abrasion of the hydrophilic coating or damage to the catheter.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation.
- Do not deploy embolization coils through the device.
- Do not advance the device near or through implanted vascular devices.
- Do not advance, retract, or torque the device against resistance as this could cause vessel trauma, device damage or breakage. If resistance is encountered while navigating the device, assess for vasospasm and treat accordingly. Flush the infusion lumen and gently attempt to navigate again. If resistance is still encountered, carefully pull the entire infusion system back into the guiding catheter and remove from the patient.
- The device is compatible with solutions containing embolic agents, specifically hydrogel beads ≤ 500 µm and glass beads ≤ 110 µm.
- The maximum guide wire diameter for the device is 0.018" (0.46 mm).
- Do not use a power injector to infuse agents other than contrast media, as the catheter may become blocked.
- The maximum dynamic injection pressure during power injection should not exceed 8274 KPa / 1200 psi / 82 atm/bar. The static pressure should not exceed 2068 KPa / 300 psi / 20 atm/bar. Static pressure in excess of this maximum may result in device rupture.
- If flow through the device becomes restricted, do not attempt to clear the catheter lumen by infusion. Identify and resolve the cause of the blockage or replace with a new device before resuming infusion.

ENGLISH

4. Precautions

- Do not store at extreme temperatures and humidity. Avoid direct sunlight.
- This device is intended for single patient use only. Do not re-sterilize and/or reuse.
- Handle the device carefully to avoid contact with sharp instruments, plastic fittings, or abrasive surfaces that may damage the device.
- Maintain a continuous heparinized saline flush to achieve optimal device performance and prevent or reduce the risk of thrombus formation on the catheter and self-expanding tip. The use of systemic heparinization to reduce the risk of thromboembolic complications should be considered for some patients, such as those with known hypercoagulable conditions.
- The surface of the distal portion of the device and the self-expanding tip must be completely hydrated with heparinized saline to remain lubricious. Keep these areas hydrated prior to and during use. Minimize handling of the self-expanding tip to avoid damaging it.
- Always use the provided introducer to insert device into guide catheter to avoid damaging the self-expanding tip.
- Monitor the position of the catheter tip under image guidance using the two radiopaque marker bands located at either end of the self-expanding tip (see "Proximal Marker Band" and "Distal Marker Band" in Figure 1).
- Do not expose the delivery system to organic solvents (e.g. alcohol) as structural integrity and / or function of the device may be impaired.

5. Recommended Accessories

- Appropriate guiding catheter (of minimum inner diameter stated on the product label) and sheath introducer
- 0.014" (0.36 mm), 0.016" (0.41 mm), 0.018" (0.46mm) straight tip or curved tip, guide wire
- Heparinized saline or equivalent flushing solution
- Luer lock syringes

6. Adverse Events:

Possible complications associated with angiographic procedures (either during or after the procedure) include, but are not limited to:

- Access site complications
- Inability to treat
- Leak of therapeutic agents
- Aneurysms
- Vessel dissection or perforation
- Vascular Thrombosis
- Embolism
- Necrosis
- Infection
- Creation of vascular shunts
- Non-target delivery of therapeutic agents
- Allergic reaction or Hypersensitivity
- Vasospasm

7. Directions for Use Preparation

- Remove the sterile pouch from the device box and inspect for damage. If there is any damage to the pouch or the device, discard and replace with a new sterile device.
- Place the appropriate sheath introducer and guiding catheter using standard percutaneous technique. Attach a Tuohy Borst adapter to the guiding catheter to allow for continuous flush of the guiding catheter with heparinized saline.
- Carefully open the sterile pouch and remove the coiled dispenser tube from the pouch. Employ aseptic technique during removal of the device from the packaging and during use.
- Flush the coil dispenser tube with heparinized saline to hydrate the hydrophilic coating on the outer surface of the catheter. Flush until saline can be seen exiting the tubing near the hub.
- Prime the catheter by flushing the infusion hub of the device with heparinized saline until droplets of saline appear out of the distal tip.
- Prepare an appropriately sized guide wire according to the manufacturer's instructions for use. Carefully insert the guide wire into the infusion hub.
- Carefully remove the infusion hub from the hub clip and remove the catheter and the inserted guide wire from the coil dispenser tube.
- Inspect the device and self-expanding tip thoroughly to ensure that it is not kinked or otherwise damaged. If there is any damage, replace with a new sterile device.

Positioning

- Confirm the guiding catheter lumen is fully hydrated prior to inserting the device.
- Carefully advance the provided introducer over the self-expanding tip to facilitate insertion into the Tuohy Borst adapter and guide catheter hub.
- Insert the introducer through the Tuohy Borst and into the guide catheter hub.
- Carefully advance the device through the introducer and into the guide catheter. Withdraw the introducer out of the Tuohy Borst.
- Tighten the Tuohy Borst adapter around the catheter to prevent backflow while still allowing for movement of the microcatheter through the Tuohy Borst, avoid over-tightening.
- Track the device over the guidewire to target location.

  Note: It is important to adequately flush the infusion lumen throughout the procedure to prevent backflow of blood into the device lumen.

  Warning: Do not advance, retract, or torque the device against resistance as this could cause vessel trauma, device damage or breakage. If resistance is encountered while navigating the device, assess for vasospasm and treat accordingly. Flush the infusion lumen and gently attempt to navigate again. If resistance is still encountered, carefully pull the entire infusion system back into the guiding catheter and remove from the patient.

Diagnostic / Embolic Infusion

- Remove the guide wire. Inject with contrast to confirm infusion location and apposition of tip to vessel wall under fluoroscopy. If repositioning is needed, reinsert the guidewire and reposition as needed.

  Note: Always inject contrast through the infusion port to confirm location prior to infusion. Confirm that contrast can be injected freely without excess pressure prior to infusion of embolic agents.
- Confirm antegrade flow. If antegrade flow is less than desired, flush infusion hub of device, reposition as needed and reassess antegrade flow.
- Once position in the desired location is confirmed, tighten the Tuohy Borst to prevent movement of the device. Do not overtighten.
- Adequately flush the device with heparinized saline prior to initial introduction of therapeutic agents. If vasospasm is present in target vasculature, treat accordingly prior to infusing therapeutic agents.
- Infuse diagnostic, embolic or therapeutic agents according to the manufacturer's Instructions for Use.

Device Retraction

- Flush the Tuohy Borst on the guiding catheter.
- Open the Tuohy Borst on the guiding catheter.
- Under fluoroscopic guidance, withdraw the device from the guiding catheter.

  Warning: Do not retract the self-expanding tip against resistance as this could cause vessel trauma and/or device damage or breakage. If resistance is encountered, adequately flush the Tuohy Borst on the guiding catheter and carefully attempt to withdraw again.
- If the device will be used again within the same procedure, flush the infusion port, and keep it soaked in heparinized saline solution. Do not leave the self-expanding tip collapsed in the introducer for an extended period of time in the introducer.
- After use, dispose in accordance with hospital, administrative and/or local government policy.

  Caution: This device is intended for single patient use only. Do not re-sterilize and/or reuse.

Anatomic Assessment for Use of SmartValve

- The recommended target vessel diameter for SmartValve is 1.5-3.5 mm. Pre-procedural review of imaging and potential target vessel diameter measurement is recommended.

SmartValve (Use/Operation)

- Throughout the entire procedure, confirm the guiding catheter is fully hydrated to reduce potential for clotting or trapped air.
- A flush of heparinized saline through the side port of the guiding catheter throughout the procedure is recommended.
- Prior to repositioning or use in an alternate location, an injection of contrast may be used to determine wall apposition and presence of antegrade flow.

SmartValve Deployment in Complex Vasculature

- For tortuous vessels or those with acute angle origins, consider exchange over wire using endhole catheter to aide in the positioning of SmartValve.
- Consider alternative guiding catheters and alternative wires with varying degrees of stiffness to help navigate SmartValve to the target location.

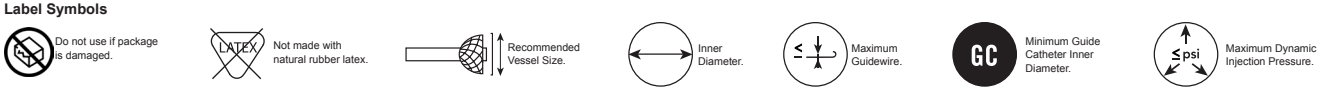
Instructions for Using a Power Injector

A power injector can be used to infuse contrast media through the device. The flow rate depends upon factors such as the viscosity of the contrast media, which varies with the type and temperature of the media, the model and setting of the power injector, and how the injector is connected to the device. The observed flow rate values indicated below are for reference only.

Catheter ID	Usable Length	Dead Space Volume (mL)	Infusion Medium	Viscosity (cP)	Actual Flow Rate at 1200 psi / 8274 kPa (mL/sec)
0.021"	120 cm	0.37	Omnipaque 300 (Iodine 300 mg/mL)	6.3	2.6
	150 cm	0.44	Omnipaque 300 (Iodine 300 mg/mL)	6.3	2.1

Injector Used: MEDRAD Mark V Provis Contrast Media Temperature: 37 °C

Label Symbols



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