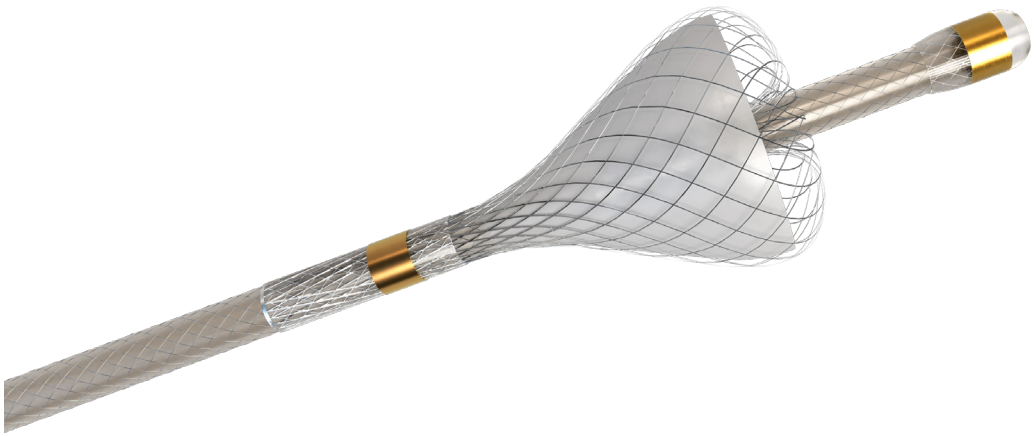
TriNav®

TriNav® FLX

with SmartValve® Technology

Instructions for Use



TriSalus LIFE SCIENCES®

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DWG-0909-00 R04

TriSalus™ TriNav® Infusion System and TriNav® FLX Infusion System: Instructions for Use

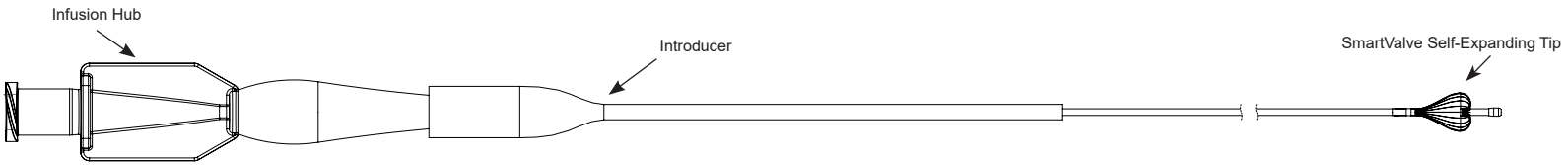
Sterile. Sterilized with ethylene oxide gas. Single use only. Nonpyrogenic. Do not resterilize.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

℞ ONLY

CAUTION: CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. FAILURE TO OBSERVE ALL WARNINGS AND PRECAUTIONS MAY RESULT IN DAMAGE TO THE DEVICE WHICH MAY NECESSITATE INTERVENTION OR RESULT IN SERIOUS ADVERSE EVENTS.

DESCRIPTION: The TriSalus TriNav and TriNav FLX Infusion Systems are 0.021" lumen microcatheters with SmartValve® Technology, a self-expanding tip at the distal end. The TriNav and TriNav FLX (Figure 1) serve as the conduit for physician-specified agents such as contrast agents, flush solutions, and embolic beads. The systems are compatible with standard guidewires with outer diameter ≤ 0.018" (0.46 mm), guide catheters with inner diameter ≥ 0.035" (0.89 mm), embolic hydrogel particles ≤ 500 µm and glass microspheres ≤ 110 µm. The TriNav and TriNav FLX have a PTFE inner liner to provide a lubricious surface for passage of physician-specified agents and other accessory devices. The device is hydrophilically coated. An optional hemostasis valve (HV) is included.

FIGURE 1. TRINAV AND TRINAV FLX INFUSION SYSTEM DIAGRAM

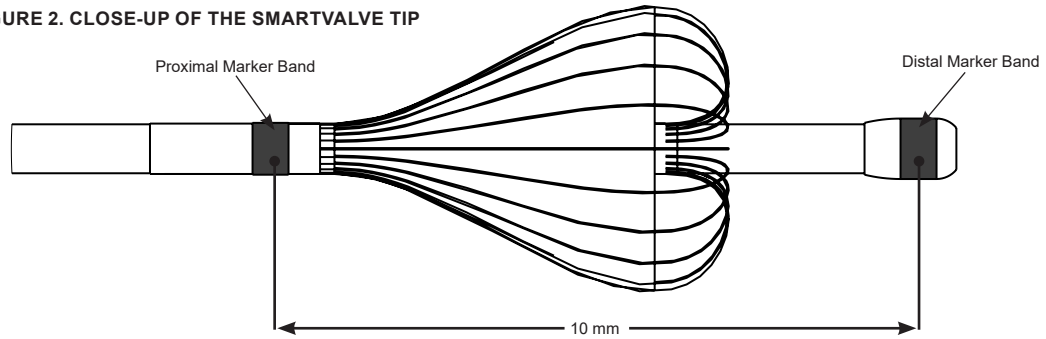


Package Contents:
(1) TriNav or TriNav FLX Infusion System
(1) Hemostasis Valve

The soft, pliable SmartValve self-expanding tip (Figure 2) is designed to improve infusion efficiency while maintaining antegrade flow during infusion. The SmartValve is self-expanding when positioned correctly in the appropriately sized vessel. The TriNav and TriNav FLX are recommended for use in vessels 1.5 mm to 3.5 mm in diameter.

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

FIGURE 2. CLOSE-UP OF THE SMARTVALVE TIP



Device Selection Guide
The following example scenarios may help with device selection and are provided for convenience only. Clinical judgement should always be employed by the practitioner.

TriNav®

• **TriNav**: Provides pushability needed to track long straight segment or long straight segment into tortuous section.

TriNav® FLX

• **TriNav FLX**: Designed for enhanced trackability, TriNav FLX features an updated catheter with a more flexible distal end, suited for cases where trackability may be challenging. Consider advancing the guide catheter further into the vasculature to provide stability to reach tortuous target anatomy.

1. Indications for Use: The TriSalus TriNav and TriNav FLX Infusion Systems are intended for use in angiographic procedures. The systems deliver radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

2. Contraindications: The TriSalus TriNav and TriNav FLX Infusion Systems are 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 TriNav when the integrity of the sterile packaging has been compromised.
- Inspect the TriNav prior to use. If the TriNav appears damaged, replace with another device.
- Do not heat, bend or attempt to shape the distal end of the TriNav. It may result in damage of the hydrophilic coating or damage to the TriNav.
- The TriNav should only be manipulated under high-quality fluoroscopic observation when within the vascular system.
- Do not use glue or other liquid embolic agents with the TriNav as ingress of the solution into the expandable tip may cause damage to the SmartValve.
- Do not deploy embolization coils through the TriNav.
- Do not advance the TriNav near or through implanted vascular devices.
- Do not advance, retract, or torque the TriNav against resistance as this could cause vessel trauma, device damage or breakage.
- Do not torque or excessively rotate the TriNav against resistance as separation of the device can occur at greater than 5 rotations with the distal tip restrained.
- Do not use a power injector to infuse agents other than contrast media, as the TriNav 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 TriNav becomes restricted, do not attempt to clear the TriNav lumen by infusion or over-pressurization. Excessive pressure could dislodge a clot or could cause the TriNav to rupture, potentially resulting in patient injury. Identify and resolve the cause of the blockage or replace with a new device before resuming infusion.

4. Precautions

- Do not store at extreme temperatures and humidity. Avoid direct sunlight.
- TriNav is intended for single patient use only. Do not re-sterilize and / or reuse.
- Handle the TriNav carefully and avoid contact with sharp instruments, plastic fittings, or abrasive surfaces that may damage the device.
- Maintain a continuous heparinized saline flush through the guide catheter to achieve optimal performance and prevent or reduce the risk of thrombus formation on the TriNav and SmartValve. 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 TriNav and the SmartValve must be completely hydrated with heparinized saline to remain lubricious. Keep these areas hydrated prior to and during use.
- Minimize handling of the SmartValve to avoid damaging it.
- Always use the provided introducer to insert the TriNav into the guide catheter to avoid damaging the SmartValve.
- Monitor the position of the TriNav tip under high quality fluoroscopic guidance using the two radiopaque marker bands located at either end of the SmartValve (see “Proximal Marker Band” and “Distal Marker Band” in Figure 2).
- Do not expose the TriNav to organic solvents (e.g. alcohol) as structural integrity and / or function of the device may be impaired.

5. Recommended Accessories

- Appropriate guide catheter with inner diameter ≥ 0.035" (0.89 mm)
- Introducer sheath
- ≤ 0.018" straight tip or curved tip guidewire
- Hemostasis Valve
- 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, the following:

- 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

Anatomic Assessment for Use of SmartValve

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

Preparation

- Remove the sterile pouch from the TriNav box and inspect for damage. If there is any damage to the pouch or the TriNav, discard and replace with a new sterile device.
- Place the appropriate introducer sheath and guide catheter using standard percutaneous technique.
- Carefully open the sterile pouch and remove the hoop from the pouch. Employ aseptic technique during removal of the TriNav from the packaging and during use.
- If desired, remove the included hemostasis valve and flush with heparinized saline. Attach the hemostasis valve to the guiding catheter to allow for continuous flush of the guide catheter with heparinized saline.
- Flush the hoop with heparinized saline to hydrate the hydrophilic coating on the outer surface of the TriNav. Flush until saline can be seen exiting the hoop near the hub.
- Prime the TriNav by flushing the infusion hub with heparinized saline until droplets of saline appear out of the distal tip.
- Prepare an appropriately sized guidewire according to the manufacturer’s instructions for use.
- Carefully insert the guidewire into the infusion hub.
- Carefully remove the infusion hub from the hub clip and remove the TriNav and the inserted guidewire from the hoop. Keep the clear, plastic introducer on the TriNav when removing the TriNav from the hoop.
- Inspect the TriNav and SmartValve thoroughly to ensure no kinks or damage. If there is any damage, replace with a new sterile device.
- Ensure that the outer surface of the TriNav remains hydrated when not in use.

SmartValve (Use/Operation)

- Throughout the procedure, confirm the guide catheter is fully hydrated to reduce potential for clotting or trapped air.
- A flush of heparinized saline through the guide catheter throughout the procedure is recommended.

Positioning

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

- Confirm the guide catheter lumen is fully hydrated prior to inserting the TriNav.
- Carefully advance the provided introducer over the SmartValve to facilitate insertion into the hemostasis valve and guide catheter hub.
- Insert the introducer through the hemostasis valve and into the hub of the guide catheter. Carefully advance the TriNav through the introducer and into the guide catheter.
- Withdraw the introducer out of the hemostasis valve.
- Tighten the hemostasis valve around the TriNav to prevent backflow while still allowing for movement of the TriNav. Avoid overtightening as it may damage the TriNav or prevent proper movement.
- Track the TriNav over the guidewire to target location.
- Contrast injections can be used to determine wall apposition and presence of antegrade flow during delivery and repositioning.

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

Diagnostic / Embolic Infusion

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

  Note: Always inject contrast through the infusion hub 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 the TriNav, reposition as needed and reassess antegrade flow.
- Once position in the desired location is confirmed, tighten the hemostasis valve to prevent movement of the TriNav. Avoid overtightening.
- Adequately flush the TriNav 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 hemostasis valve on the guide catheter.
- Open the hemostasis valve on the guide catheter.
- Under fluoroscopic guidance, withdraw the TriNav from the guide catheter.

  Warning: Do not retract the SmartValve against resistance as this could cause vessel trauma and / or device damage or breakage. If resistance is encountered, adequately flush the hemostasis valve on the guide catheter and carefully attempt to withdraw again.
- If the TriNav will be used again within the same procedure, flush the infusion hub, 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.
- 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.

Instructions for Using a Power Injector

A power injector can be used to infuse contrast media through the TriNav. 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


Do not use if package is damaged.

Not made with natural rubber latex.


Recommended Vessel Size.


Inner Diameter.


Maximum Guidewire.

Minimum Guide Catheter Inner Diameter.

Maximum Dynamic Injection Pressure.

Hemostasis Valve / Tuohy Borst Adapter Included

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