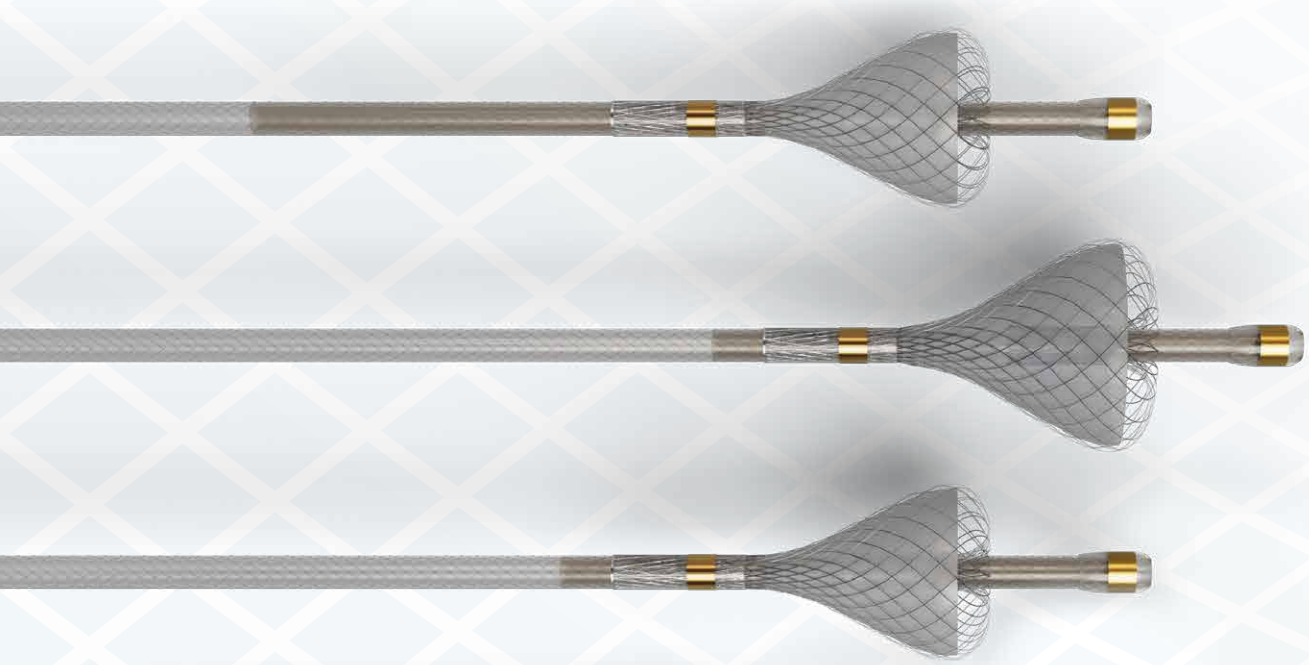
TriNav®
INFUSION SYSTEM

TECHNICAL USER GUIDE



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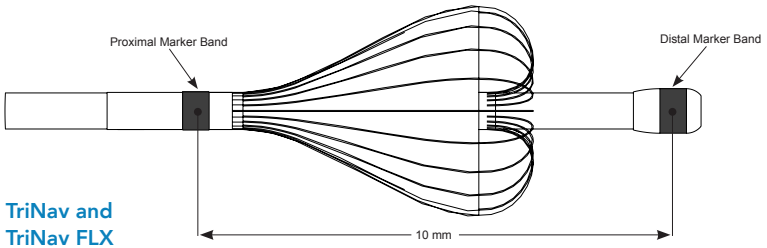
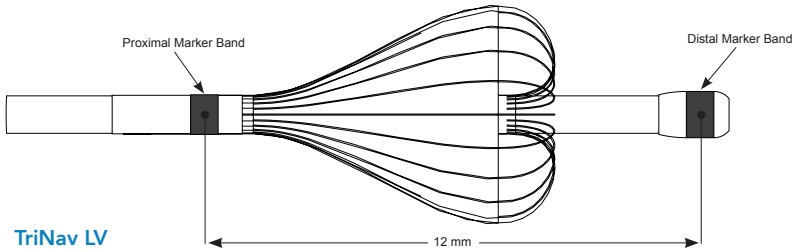
GUIDANCE ON SELECTING THE APPROPRIATE TRINAV PRODUCT

Once target vessel is identified, recommend performing angiographic run to measure vessel size and assess anatomy and tortuosity to help select appropriate TriNav product.

	TriNav® Recommended for 1.5mm-3.5mm vessels		TriNav® FLX Recommended for 1.5mm-3.5mm vessels		TriNav® LV Recommended for 3.5mm-5.0mm vessels	
Product Code	**TNV-21120-35**	**TNV-21150-35**	**FLX-21120-35**	**FLX-21150-35**	**TVM-25120-50**	**TVM-25150-50**
Length	120 cm	150 cm	120 cm	150 cm	120 cm	150 cm
Inner Diameter	0.021 in		0.021 in		0.025 in	
Minimum Base TriNav ID	0.035 in		0.035 in		0.048 in	
Proximal Outer Diameter	2.4 F		2.4 F		2.9 F	
Maximum Guidewire Diameter	0.018 in		0.018 in		0.018 in	
Distance Between SmartValve® Marker Bands	10 mm		10 mm		12 mm	
Bead Size Compatibility	Hydrogel ≤ 500 µm Glass ≤ 110 µm		Hydrogel ≤ 500 µm Glass ≤ 110 µm		Hydrogel ≤ 500 µm Glass ≤ 110 µm	
Distal Tip Design	Standard		Flexible		Standard	
Merit Medical FLO50™ Hemostasis Valve included (not required for use)	No		Yes		Yes	



TriNav and TriNav FLX



TriNav LV

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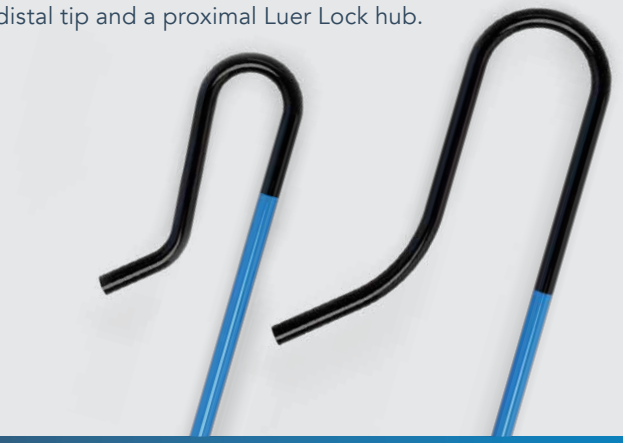
RECOMMENDED ACCESSORIES

- Appropriate sheath introducer and guide catheter with a minimum inner diameter
  - ≥ 0.035" (0.89 mm) for TriNav and TriNav FLX
  - ≥ 0.048" (1.22 mm) for TriNav LV
- 0.014" (0.36 mm), 0.016" (0.41 mm), 0.018" (0.46 mm) straight tip or curved tip guidewire
- Hemostasis Valve
- Heparinized saline or equivalent flushing solution
- Luer Lock syringes

TRIGUIDE® GUIDING CATHETER

The TriGuide® Guiding Catheter is a 5F, single lumen, braided catheter with a soft distal tip and a proximal Luer Lock hub.



TGC-48065-Axis TGC-48065-Sim1

TRINAV LV GUIDE CATHETER COMPATABILITY

TriNav LV is compatible with guide catheters with an inner diameter of 0.048" or greater throughout, including any taper. Below is a list of common guide catheters that are compatible with TriNav LV. The list is not exhaustive.

Manufacturer / Brand	ID*	Length
TriSalus TriGuide	5F 0.048"	65cm
Cordis Vista Brite Tip	5F 0.056"	100cm, 125cm
Cook Flexor Ansel Guiding Sheath	4F/0.060" 5F/0.074"	45cm, 55cm, 90cm
Medtronic Launcher	5F 0.058"	100cm, 110cm
Terumo Optitorque (Sarah and Jacky Radial)	5F 1.22mm	110cm
Terumo Pinnacle Destination Sheath	5F 0.076"	45cm

*Manufacturer's labeled size

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OPTIONAL ACCESSORY: POWER INJECTOR

A power injector may be used to infuse contrast media through the TriNav. The flow rate depends upon factors such as the viscosity of the contrast media, the model and setting of the power injector, and how the injector is connected to the TriNav. The observed flow rate values below are for reference only.

Product	TriNav / TriNav FLX		TriNav LV	
Length	120 cm	150 cm	120 cm	150 cm
TriNav ID	0.021"		0.025"	
Dead Space Volume (mL)	0.37	0.44	0.52	0.61
Infusion Medium	Omnipaque 300 (Iodine 300 mg/mL)			
Viscosity (cP)	6.3			
Actual Flow Rate at 1200 psi / 8274 kPa (mL/sec)	2.6	2.1	3.6	3.3

Warning: Do not use a power injector to infuse agents other than contrast media through the TriNav, as the catheter may become blocked.

If there are difficulties injecting contrast with a power injector, such as the MEDRAD® Mark 7, consider infusion medium viscosity, temperatures and power injector settings among other factors as described in the TriNav Infusion System Instructions for Use. Please also refer to the power injector Instructions for Use.

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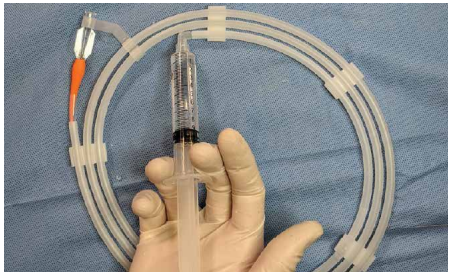
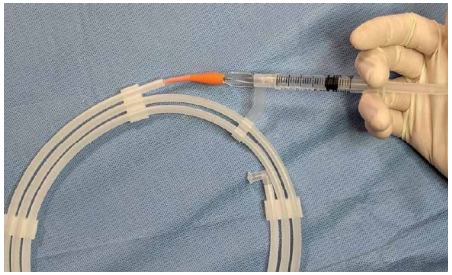
Helpful Hints

HYDRATING TRINAV® AND TRINAV® FLX



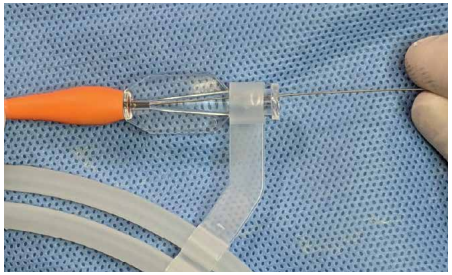
STEP 1

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 tubing near the hub.



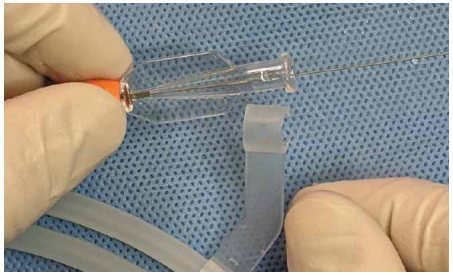
STEP 2

Prime the TriNav by flushing the infusion hub with heparinized saline until droplets of saline appear out of the distal tip.



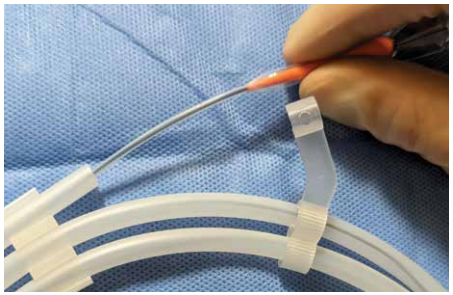
STEP 3

Prepare an appropriately sized guidewire according to the manufacturer's Instructions for Use. Carefully insert the guidewire into the infusion hub.



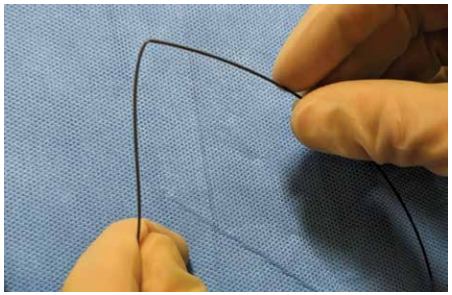
STEP 4

Carefully remove the infusion hub from the hub clip. Remove the TriNav and the inserted guidewire from hoop, taking care not to damage the TriNav. Keep the clear plastic introducer on the TriNav when removing it from the hoop.



STEP 5

Hold introducer and strain relief on the proximal end of the TriNav and pull as one unit to remove from the coil.



Warning: Avoid kinking the catheter

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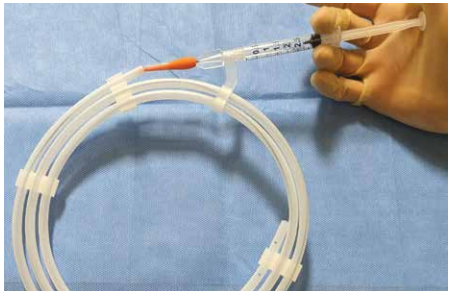
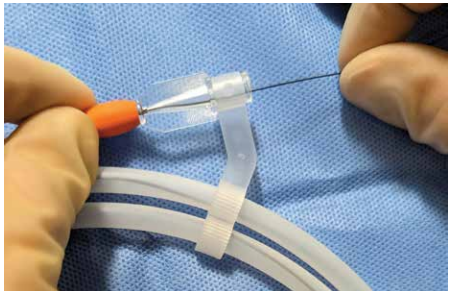
HYDRATING THE TRINAV® LV



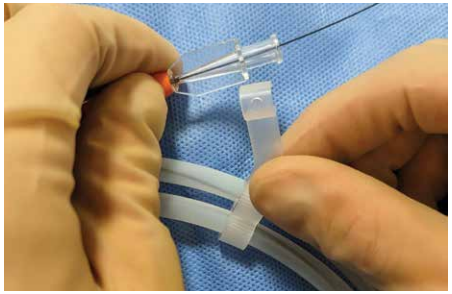
STEP 1

Prime the TriNav by flushing the infusion hub with heparinized saline until droplets of saline appear out of the distal tip.



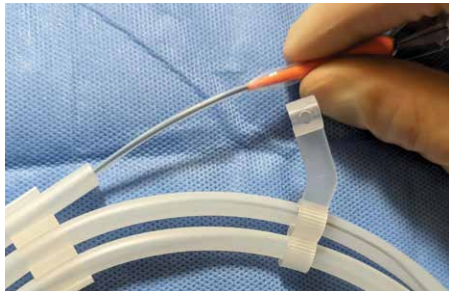
STEP 2

Prepare an appropriately sized guidewire according to the manufacturer's Instructions for Use. Carefully insert the guidewire into the infusion hub.



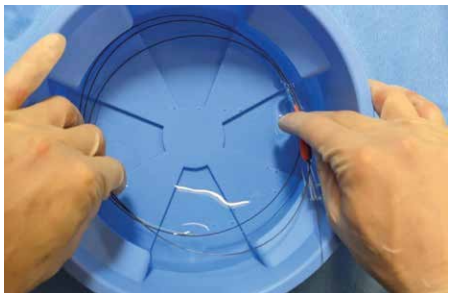
STEP 3

Carefully remove the infusion hub from the hub clip and remove the TriNav and the inserted guidewire from the hoop, taking care not to damage the TriNav. Keep the clear plastic introducer on the TriNav when removing it from the hoop.



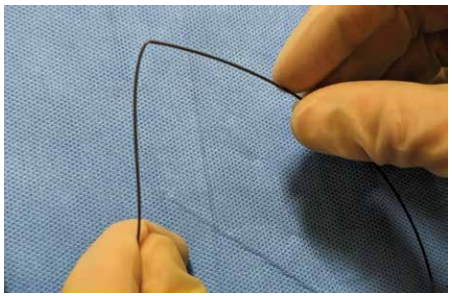
STEP 4

Hold the Introducer and strain relief on the proximal end of the TriNav. Pull as one unit and remove from the coil.



STEP 5

Immerse the system in a basin of heparinized saline to hydrate the outer surface.



Warning: Avoid kinking the catheter

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KEY CONSIDERATIONS FOR TRINAV HYDRATION

Understanding the Importance of Hydration:

- Hydrating the TriNav helps the coating become more lubricous, a process that takes 10-15 seconds.
- Proper hydration is crucial to maintain the coating's effectiveness to ensure intended performance.
- Keep the TriNav hydrated in a heparinized saline bath when not in use.
- Maintaining proper hydration of the TriNav may improve trackability, may help reduce the likelihood of thrombus formation, and supports clinician satisfaction.

RECOMMENDED WORKFLOW FOR HYDRATION

1. Hydration in the Bowl
   (**TriNav**, **TriNav FLX** & **TriNav LV Infusion Systems**)
   Hydrating the TriNav in a bowl is highly recommended to ensure thorough and sustained hydration. Avoid placing the hydrated TriNav on a table, as it can dry out quickly. Leave TriNav in hydration bowl until ready for use.
2. Hydration in the Hoop
   (**TriNav** and **TriNav FLX Infusion Systems** only)
   Flush the hoop with heparinized saline to help the coating become more lubricous on the outer surface of the TriNav. Flush until saline can be seen exiting the tubing near the hub.

BEST PRACTICES

- Always hydrate the TriNav immediately prior to insertion to help ensure intended functionality.
- If the TriNav is removed during the procedure, it should be placed in a bowl of heparinized saline to ensure it is re-hydrated prior to use.
- Follow a strict workflow to prevent drying after the initial hydration.
- Reinforce these steps with all technical staff to maintain consistency and reliability.

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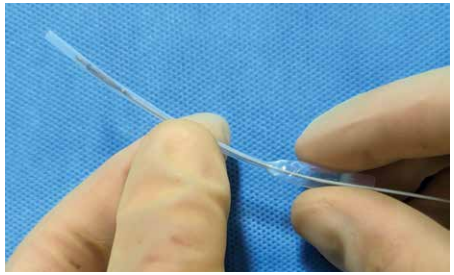
Helpful Hints

INSERTION INTO GUIDE CATHETER

Maintain a continuous flush of heparinized saline through the guide catheter throughout the procedure. Continuous flushing using an IV drip bag is recommended. Intermittent flushing by hand using a syringe attached to the y-connector of the hemostasis valve can also be performed.

STEP 1

Flush and attach the included hemostasis valve to the guide catheter to maintain a continuous flush of heparinized saline. Ensure the catheter lumen is fully hydrated before inserting the TriNav.

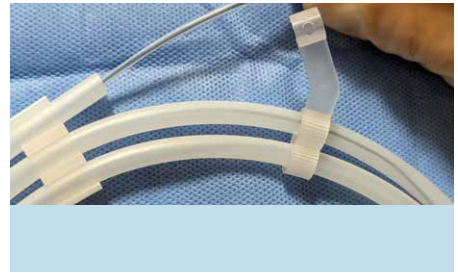


STEP 2

Carefully advance the provided introducer over the SmartValve self-expanding tip to facilitate insertion into the hemostasis valve and guide catheter hub.

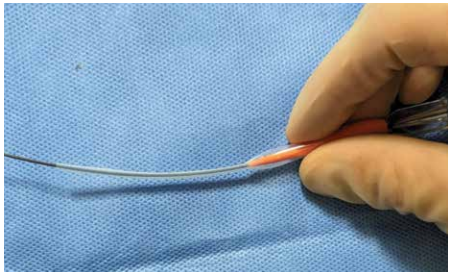
STEP 3

Insert the introducer as far as possible through the hemostasis valve and into the guide catheter hub.



STEP 4

Carefully advance the TriNav through the introducer and into the guide catheter.



STEP 5

Withdraw the introducer from the hemostasis valve and move it to the end of the TriNav to the orange strain relief.

STEP 6

Tighten the hemostasis valve around the TriNav to prevent backflow while still allowing for movement of the TriNav through it. Avoid over-tightening as it may damage the TriNav.

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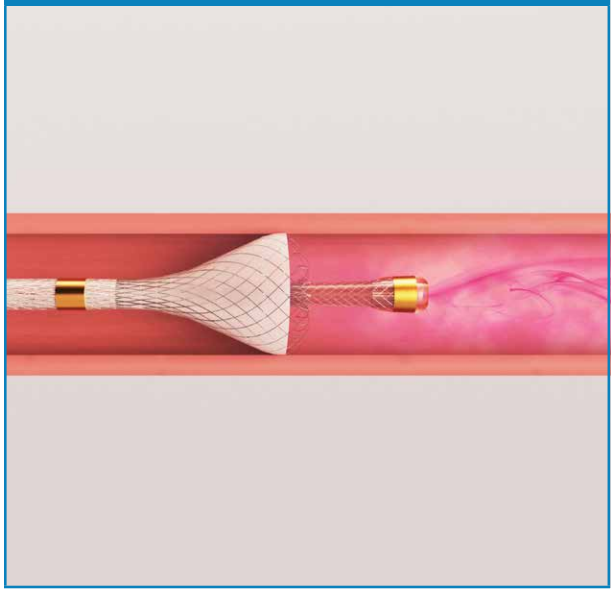
Helpful Hints

TRACK TRINAV TO TARGET LOCATION

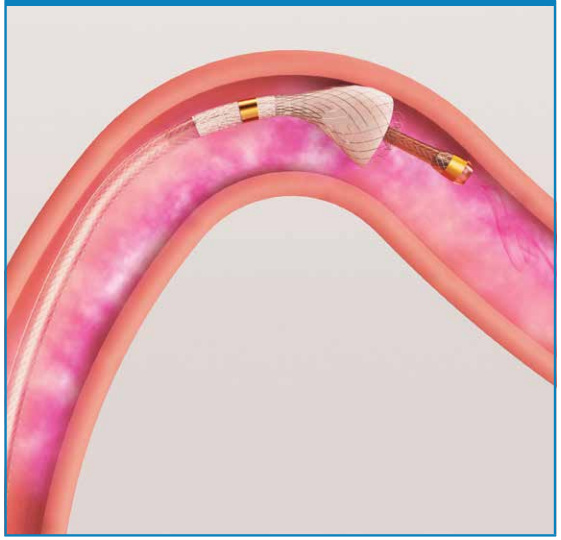
1. Track the TriNav over the guidewire to the target location. A landing zone of 10 mm to 12mm of relatively straight vessel is optimal for wall apposition of the SmartValve.
2. When target vessel location is reached, confirm placement and wall apposition of the SmartValve, so that the marker bands appear in the center of the vessel.
3. If wall apposition is not achieved in that position, recommend repositioning the SmartValve so it's not in a curve or over a bifurcation.

Good Wall Apposition

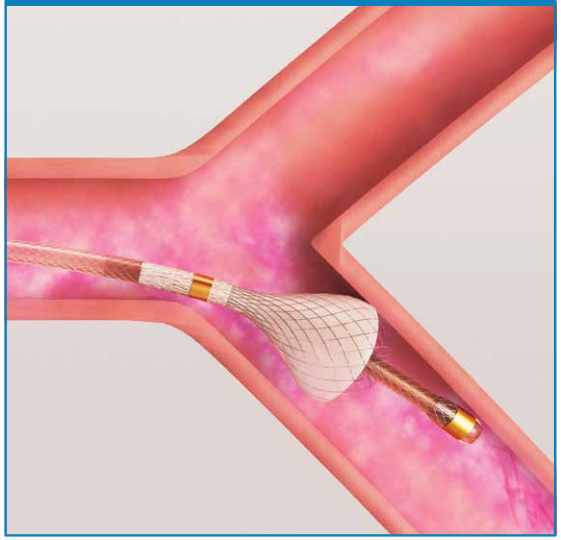


EXAMPLES OF POOR WALL APPOSITION

Sharp Curve



Bifurcation



Note: There are two radiopaque markers on the distal end of the TriNav. The proximal band indicates the most proximal edge of the SmartValve, and where protection from reflux starts. Position the proximal marker band distal to any vessels requiring protection during infusion.

Warning: Do not advance, retract, or torque the TriNav against resistance as this could cause vessel trauma, TriNav damage, or breakage. If resistance is encountered while navigating the TriNav, assess for vasospasm and treat accordingly. 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 it from the patient.

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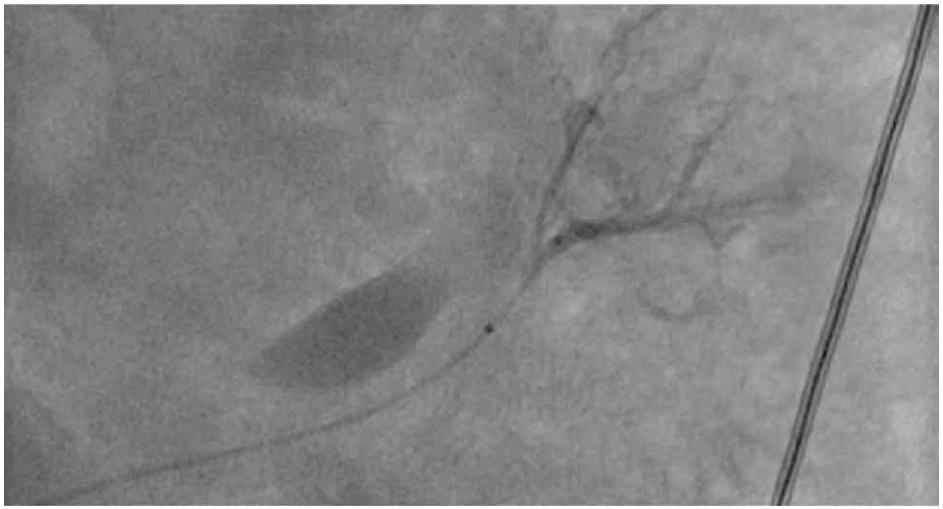
Helpful Hints

CONFIRM SMARTVALVE® PLACEMENT

1. Once the SmartValve is positioned in the desired location, tighten the hemostasis valve to prevent movement of the TriNav. Avoid overtightening.
2. Remove the guidewire.
3. Inject with contrast to confirm the infusion location and the apposition of the SmartValve to the vessel wall under fluoroscopy. If repositioning is needed, reinsert the guidewire before adjusting the placement. Always inject contrast through the infusion hub to confirm its location prior to infusion. Confirm that the contrast can be injected freely without excess pressure.
4. Confirm antegrade flow. If the antegrade flow is less than desired, flush the infusion hub of the TriNav, reposition, and reassess antegrade flow.
5. Adequately flush the TriNav with heparinized saline prior to the initial introduction of therapeutic agents.
6. Infuse diagnostic, embolic, or therapeutic agents according to the manufacturer's Instructions for Use.



Warning: If vasospasm is present in the target vasculature at any point during the procedure, treat accordingly prior to infusing therapeutic agents.

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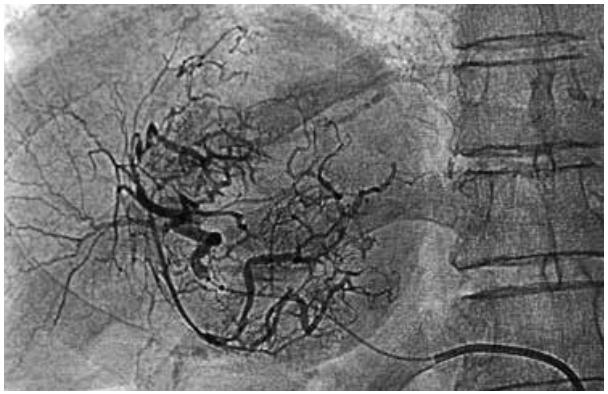
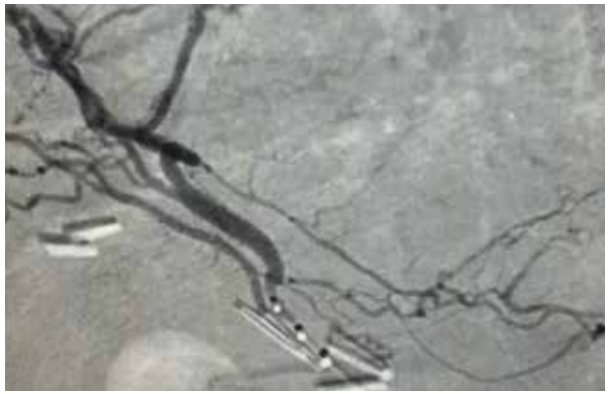
Helpful Hints

INFUSION ENDPOINTS

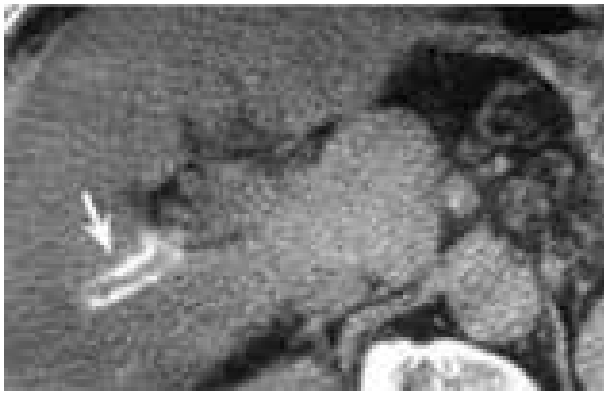
Prepare agent according to the manufacturer's instructions.



A Full delivery of physician-prescribed agent



B Development of an intrahepatic collateral vessel leading away from the target tumor[1,2]



C Visualization of the portal vein[1]

Note: Images are for reference only. Determination of the infusion endpoint is at the sole discretion of the physician.

1. Titano et al Study Design: A retrospective, single-center study included 88 treatment-naive patients with solitary HCC tumors <6.5 cm who underwent treatment utilizing either SIS (n = 18) or standard EH microcatheters (n = 70). Twenty-three patients (5 SIS, 18 EH) received a liver transplant during the study, with 1 SIS and 6 EH patients excluded from the tumor necrosis analysis for receiving subsequent therapies prior to transplant. A pathologist performed a blinded review of the liver explant specimens to assess tumor necrosis and treatment distribution. Pathological analysis of explanted livers showed greater concentrations of microspheres within the tumor relative to the surrounding tissue in SIS explants (88.7 ± 10.6%) versus the EH explants (55.3 ± 32.7%) (p = 0.002). Titano JJ, et al. Cardiovasc Intervent Radiol. 2019;42:560-568.

2. Kim AY et al Study Design: Single center retrospective evaluation of patients who underwent DEE-TACE for HCC, delivered with SIS. Treatment response rates were assessed using the modified Response Evaluation Criteria in Solid Tumors criteria. A total of 22 patients with 39 separate HCC lesions underwent 28 treatments with SIS. Ten patients (45%) underwent de novo treatment with SIS whereas 12 patients (55%) were previously treated with a microcatheter. Complete response was demonstrated in 32% of patients and 54% of lesions after a single treatment session with the SIS. Overall disease response was demonstrated in 91% of patients and 85% of lesions after a single treatment. No grade 3 or higher elevation of alkaline phosphatase or total bilirubin was seen at follow up. Kim AY, et al. PLoS One. 2017;12(9):e0183861. DOI: 10.1371/journal.pone.0183861.

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Helpful Hints

TRINAV RETRACTION

- Flush the hemostasis valve connected to the guide catheter.
- Open the hemostasis valve connected to the guide catheter.
- Under fluoroscopic guidance, withdraw the TriNav from the guide catheter.
- 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 SmartValve self-expanding tip collapsed in the introducer for an extended period of time.

Warning: Do not retract the SmartValve self-expanding tip against resistance as this could cause vessel trauma and/or TriNav damage, or breakage. If resistance is encountered, adequately flush the hemostasis valve connected to the guide catheter and carefully attempt to withdraw them.

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TROUBLESHOOTING

Difficult or unable to infuse

- Assess for vasospasm. Address as required.
- Flush with 10-20 cc of saline.
- If applicable, examine for impingement along the Y-90 infusion lines.
- Check the hub for clumping or clogging.
- Confirm embolic sphere size compatibility.

Reflux appears at the target location

- Assess for vasospasm. Address as required.
- Confirm the TriNav is appropriately sized for the target vessel.
- Reposition the tip and reassess.
- If reflux still appears, remove the TriNav and assess the condition of the SmartValve.

Stasis develops almost immediately

- Assess for vasospasm. Address as required.

Resistance is encountered when pulling the TriNav back into the guide

- Do not withdraw against resistance as this could cause vessel trauma or TriNav damage.
- Assess for vasospasm. Address as required.
- Flush the guide catheter to expel any blood from the lumen.
- If unable to resolve, withdraw the TriNav and guide catheter from the patient as a single unit.

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TIPS TO IMPROVE TRACKABILITY*

Understanding trackability:
Trackability is influenced by many factors that contribute to overall system stability such as the following:

Physician delivery technique

Catheter design:
- Diameter
- Material
- Pushability versus Flexibility

Micro guidewire stiffness and size:
Stiffer wire or more wire purchase à may allow for more pushability past obstacles. Softer wire or less wire purchase may allow for more flexibility to navigate tortuous vessels.

Guide catheter placement:
Advancing the guide catheter can provide more purchase, which may help anchor the guide catheter in an area where vasculature can provide additional support.

Vascular anatomy (tortuosity, landing zones, etc.)
For tortuous vessles or those with acute origins, consider selecting TriNav FLX or getting access with a traditional microcatheter, then exchanging over-the-wire to position the SmartValve.

Proper hydration techniques:
Increasing hydration and maintaining a continuous flush through the guide catheter may improve trackability

TIPS THAT MAY IMPROVE SIR-SPHERES® Y-90 RESIN MICROSPHERES DELIVERY

- A 50/50 solution is often successful, but any dilution will help reduce the likelihood of clogging
- Always refer to the SIR-Spheres device labeling for complete use instructions

*These tips are presented for convenience purposes only, and clinical judgment should always be employed by the practitioner. These tips are not intended to supplement or supersede the Instructions for Use. Please always refer to the Instructions for Use for complete usage guidance.

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TriNav®
INFUSION SYSTEM

Indications for Use: The TriNav, TriNav FLX, and TriNav LV Infusion Systems are intended for use in angiographic procedures. They deliver radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.[1,2,3]

Contraindications: The TriNav, TriNav FLX, and TriNav LV Infusions 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).[1,2,3]

Rx Only. For the safe and proper use of the TriNav, TriNav FLX, and TriNav LV Infusion Systems, refer to their individual Instructions for Use.

1. TriSalus™ TriNav® Infusion System, Instructions for Use.
2. TriSalus™ TriNav® FLX Infusion System, Instructions for Use.
3. TriSalus™ TriNav® LV Infusion System, Instructions for Use.

For Customer Service, + 1 888 321 5212

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