



Infusion Catheter and Accessories

INSTRUCTIONS FOR USE

**READ ALL INSTRUCTIONS, PRECAUTIONS AND WARNINGS BEFORE
USE. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS**

CAUTION

This device should be used only by trained physicians familiar with techniques and possible complications involved with angiography and percutaneous interventional radiological procedures.

Rx Only

Federal (USA) law restricts this device to use by or under the direction of a physician



Read instructions with careful attention to caution symbols prior to using this product.

STERILE EO

This product is sterile and non-pyrogenic. Sterilized using ethylene oxide gas.



Single use ONLY. Do not re-sterilize or reuse.

CONTENTS

One (1) IsoFlow™ Infusion Catheter with protective sheath, one (1) 1cc infusion plunger syringe, one (1) 1cc balloon inflation plunger syringe, one (1) rotating hemostasis valve (RHV), one (1) 3-way stopcock, one (1) 1-way stopcock.

DEVICE DESCRIPTION

The Vascular Designs IsoFlow™ Infusion Catheter System includes the components shown in Fig 1.

The IsoFlow™ Infusion Catheter is a multi-lumen dual balloon catheter designed to isolate a specific treatment region from blood flow while allowing infusion of fluids into the region and perfusion of blood past the region. The exterior surface of the distal 120cm catheter length is treated with a hydrophilic coating. The distal working region of the catheter is depicted in Fig 2.

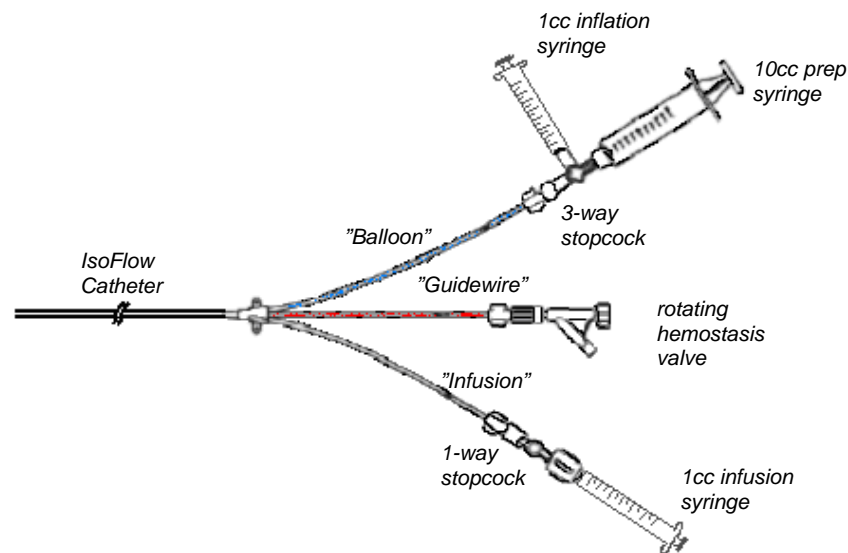


Fig 1. IsoFlow™ Infusion Catheter System components

The 2.4F IsoFlow™ Infusion Catheter System is intended to be used with guide catheters 4F (0.050") and larger, along with a 0.010" guide wire (neither shown) for positioning the catheter in the desired region. A standard Y-adaptor RHV provides for guide wire entry and saline flush into the main guide wire / bypass lumen of the catheter. Radiopaque markers at the distal tip and between the two balloons allow for final position adjustment under fluoroscopy guidance.

The two compliant balloons are inflated simultaneously using radiopaque fluid delivered via a single inflation lumen. A 1cc syringe is provided for precise inflation under fluoroscopic guidance.

A 1cc plunger syringe is provided to deliver physician specified infusion fluid through either the labeled infusion lumen or the labeled guidewire lumen via a 1-way stopcock connection. The mixture of infusion and radiopaque agents is delivered directly to the target region between the balloons, or out the distal tip respectively.

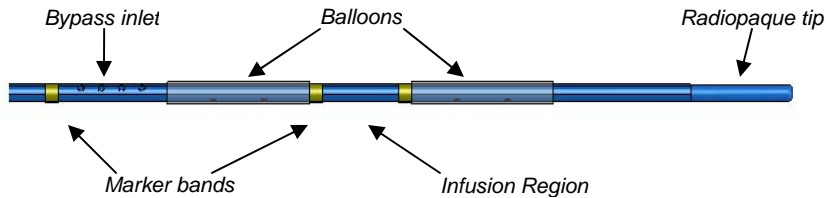


Fig 2. IsoFlow™ Infusion Catheter Distal Working Region

For infusion out of the sideport holes, retracting the guide wire to the radiopaque marker band proximal to both balloons allows blood to bypass the isolated target region via holes connecting the guide wire / bypass lumen with the catheter exterior. Complete removal of the guidewire allows delivery from the distal tip.

Refer to the product label for dimensional information.

All components of the catheter system are provided sterile. Each device is intended for single use. Do not reuse or attempt to re-sterilize any component of the system.

INDICATIONS FOR USE

The Vascular Designs IsoFlow™ Infusion Catheter System is designed for controlled and selective infusion of physician-specified fluids into selected vasculature by means of temporary occlusion of a target region of the vessel with simultaneous perfusion of blood past the isolated region. The device can be used in adult or pediatric patients whose target vessels are between 1.5 and 4 mm diameter. The device also has the ability to deliver physician specified fluids out the distal tip with or without inflation of the balloons. See Figure 3 for infusion delivery options.

CONTRAINDICATIONS

- None known

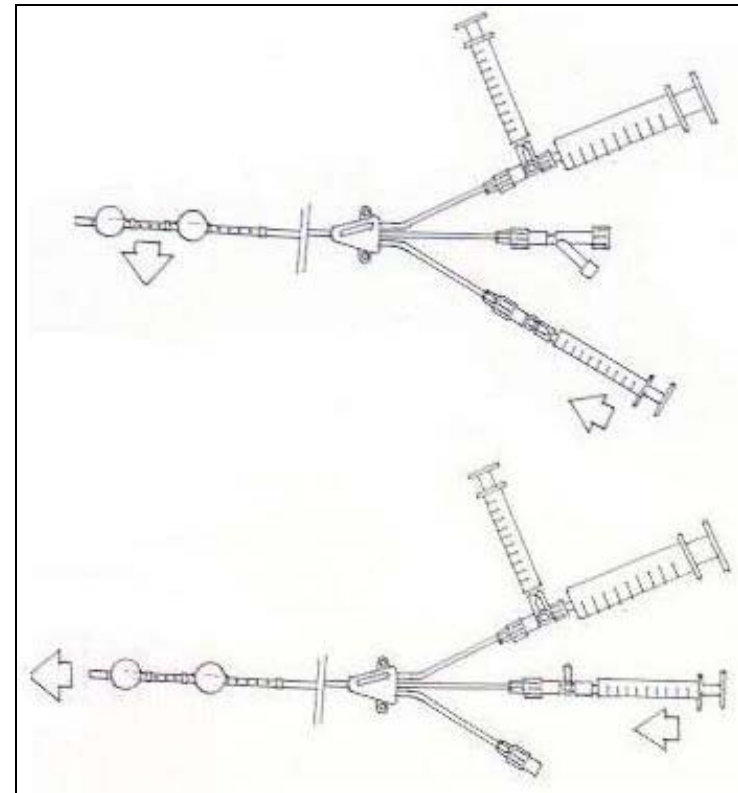


Fig 3. IsoFlow™ Infusion catheter - options for infusion

WARNINGS

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death.

Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

The infusion dynamic pressure with this catheter should not exceed

200 psi/13.7atm/bar. Infusion pressure in excess of this maximum may result in catheter rupture, possibly resulting in patient injury.

If flow through the catheter becomes restricted, do not attempt to clear the catheter lumen by infusion. Identify and resolve the cause of the blockage or replace the catheter with a new catheter before resuming infusion.

Do not attempt to use device if package has been opened or damaged.

Vessel dimensions should be verified prior to inflation to ensure they do not exceed the maximum balloon diameter listed on the label. Maximum inflation volume pertains to the dual balloon system, not a single balloon.

Do not advance the catheter against resistance until source of resistance is identified via fluoroscopy.

Do not re-insert catheter tip into introducer once it has been removed.

Remove air from the balloons, balloon inflation lumen and infusion lumen according to 'Directions For Use'.

Before retrieving the IsoFlow™ Infusion Catheter back through the guide catheter, always confirm via fluoroscopy that the balloons are fully deflated to prevent complications.

PRECAUTIONS

Handle the catheter with care. Hold onto the manifold/junction while removing from protective sheath. Inspect the catheter for bends, kinks or other damage prior to use.

Use only the recommended balloon inflation medium of 50:50 solution by volume of contrast medium and normal, sterile saline (e.g. Hypaque® -50).

For precise visualization of vessel occlusion, the infusion fluid mixture should contain at minimum 20% by volume contrast medium.

During the procedure, ensure that there is adequate blood flow distal to the catheter. Additional blood or blood products may be infused down the guidewire lumen if additional volume is desired.

Precautions should be taken to reduce the possibility of thrombosis formation during the procedure, such as systemic heparinization or limiting treatment time.

The IsoFlow™ Infusion Catheter has not been tested for protracted use in the vascular system.

Store the IsoFlow™ Infusion Catheter System in a cool, dry place.

Refer to the package insert of the physician-specified fluid media for indications, contraindications, side effects and precautions.

POTENTIAL COMPLICATIONS

Vessel perforation, damage or trauma
Hemorrhage or hematoma
Vascular thrombosis
Drug reactions
Allergic reaction to contrast medium
Infection

COMPATIBILITY

The maximum outer diameter of the IsoFlow™ Infusion Catheter is 0.046". It is intended to be used with guide catheters 4F and larger. The catheter is compatible with 0.010" guide wires.

SUPPLIES

The following supplies will need to be available and prepared for the procedure (not provided with the IsoFlow™ Infusion Catheter System)

- Guide catheter (4F or larger) with guide wire
- Catheter guide wire (0.010")
- Heparinized normal saline
- Angiographic imaging supplies (e.g. radiopaque contrast medium)
- 10cc syringe for flushing guide wire lumen
- 10cc syringe for balloon preparation and deflation

DIRECTIONS FOR USE

Package Integrity and System Prep

1. Check to ensure package has not been opened or damaged.
2. Open sealed pouch and remove tray. Gently remove protective coil with catheter from tray. Remove device from protective coil.
3. Inspect catheter before use to verify condition, contour, and size are as desired.
4. Attach Accessories
 - a. Attach the 1-way stopcock to the INFUSION branch tubing.
 - b. Attach the 3-way stopcock to the BALLOON branch tubing.
 - c. Attach the Rotating Hemostasis Valve (RHV) to the GUIDEWIRE branch tubing.
5. Prepare prescribed infusion fluid mixture by mixing with at least 20% (by volume) contrast medium.



A radiopaque infusion fluid mixture is necessary for precise control of balloon inflation and visualization of vessel occlusion.

6. Prepare balloon inflation fluid by mixing contrast media with normal, sterile saline (50:50 by volume) or use a pre-mixed 50% contrast medium.



Use of anything but recommended balloon inflation media could result in balloon damage, non-uniform balloon inflation or reduced visibility.

7. Locate and fill a standard 10cc syringe (not provided) with about 5cc of balloon inflation media and attach syringe to 3-way stopcock on "Balloon" port as indicated in Fig 1.
8. Set the valve OFF position to the unused port where the 1cc syringe will attach.
9. Pull a vacuum with the 10cc syringe while maintaining the syringe tip and distal catheter tip in a downward position. Hold vacuum pressure for 20-30 seconds while air is removed from balloon lumen. Release plunger to allow media passively into balloon lumen. Do not infuse.

10. Repeat the last step at least two more times to ensure proper evacuation of air from the catheter shaft and balloon.
11. Set the 3-way stopcock valve to OFF position to the balloons. Attach the 1cc balloon inflation syringe to the unused port on the 3-way stopcock using standard practice for fluid connections.

Balloon Prep

12. Transfer the maximum labeled inflation volume for the identified vessel size from the 10cc syringe into 1cc syringe.
13. Set the valve to the OFF position to the 1cc syringe. Using the 10cc syringe, pull a vacuum for 30 seconds.
14. Release the vacuum and allow the fluid to flow passively into the inflation lumen.
15. Set the valve OFF position to the 10cc syringe. Using the 1cc syringe, gradually inflate the balloons to max inflation volume. Fix the pressure by turning stop cock OFF to balloons.

NOTE: Do not allow all of the inflation volume to enter one balloon. Constrain the balloon that inflates first between fingers to allow equal inflation of second balloon.

16. Inspect balloons absence of air emboli. If air emboli exist, repeat Steps 8-14.

NOTE: If air bubbles are present, it may be helpful to gently tap the balloons, catheter shaft and proximal attachments to release air emboli into the syringe.

17. Set the valve OFF position to the 1cc syringe. Using the 10cc syringe, fully deflate the balloons.
18. Set the valve OFF position to the balloons and set aside with the distal end of catheter wet with saline until insertion into patient.

Infusion Prep

19. Fill the 1cc infusion syringe (provided) with the infusion fluid mixture and attach the syringe to the 1-way stopcock on the "Infusion" port as indicated in Fig 1.

20. Set the 1-way stopcock valve to the ON position and flush the infusion lumen until fluid exits the infusion side ports between the balloons.
21. While advancing the infusion fluid, set the 1-way stopcock valve to the OFF position.

Introduction of Guide Catheter, Guide Wire, and IsoFlow™ Infusion Catheter

22. Introduce the guide catheter and position at the pre-selected vessel per standard practice.
23. Attach a standard 10cc syringe (not provided) to the rotating hemostasis Y connector and flush the Y connector and catheter guide wire / bypass lumen with heparinized normal saline using standard practice until fluid exits proximal and distal ends of the catheter.
24. Continue flushing guide wire lumen during 0.010" guide wire insertion up to catheter tip.
25. With the guide catheter already inserted, introduce the IsoFlow™ Infusion Catheter into the vasculature using standard practice. Under fluoroscopy, guide the catheter into position within the selected vessel. Radiopaque marker bands identify the region between the balloons and the distal tip.
26. Ensure that the 1cc syringe is filled with the appropriate amount of balloon inflation fluid and set the 3-way stopcock valve OFF position to the 10cc syringe port.

NOTE: Determine the vessel size in the treatment segment using standard practices. Refer to Table 1 for guidance on the amount of inflation fluid for balloon inflation and vessel occlusion.



Do not inflate the balloons beyond the maximum inflation volume. Balloons should never be inflated with a pressure-based inflation device.

Table 1. Guidance for Balloon Inflation Volume

Vessel ID/Balloon OD (mm)	Balloon Inflation Volume (cc)
1.5	< 0.1
2.0	0.1
2.5	0.2
3.0	0.2
3.5	0.3
4.0	0.3
Maximum balloon inflation volume	0.4

27. Slowly inflate the balloons while delivering a small amount of infusion fluid mixture into the vessel by pushing the syringe plunger. Under fluoroscopy, verify blood flow past the balloon region. Complete inflation is achieved when flow of infusion fluid mixture is not visible distal to balloon region. Close the 3-way stopcock to maintain balloon inflation diameter.



Verification of position and diameter of the balloons must be monitored under fluoroscopy during inflation.

28. Retract guide wire tip proximal to bypass marker band to initiate bypass blood flow.

NOTE: Verification of distal perfusion via bypass lumen should be monitored under fluoroscopy while balloons are inflated

29. Infuse isolated region by pushing the infusion syringe plunger.

NOTE: Do not use excessive force to depress plunger. Applied pressure should not exceed 200psi, which is consistent with typical use of 1cc syringe.

NOTE: Selection of drugs/agents or other fluids and associated infusion amounts, rates and times are at the discretion of the physician.



Do not exceed maximum inflation volume in balloons



Fluoroscopic visualization of the infusion zone during fluid infusion is necessary to monitor device performance and vessel behavior.

30. At the completion of the infusion cycle, deflate balloons with a vacuum on the 10cc syringe while visualizing the balloons via fluoroscopy, and evaluate the vessel using standard practices. If additional treatment is required, the IsoFlow™ Infusion Catheter may be repositioned and treatment repeated at the discretion of the physician.
31. When treatment is complete, remove the catheter and guide catheter using standard removal procedures.

DISPOSAL

Dispose of contaminated device, components and packaging materials using standard hospital procedures and universal precautions for biohazardous waste.

SYMBOLS

	Do not reuse
	Lot Number
	Read Instructions before use
	No Latex Present
	CE Mark
	Manufactured
	Date
	Prescription Only
	Use By Date



Made in U.S.A

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IsoFlow is a trademark of Vascular Designs, Inc.

U.S. and Foreign patents pending.

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