



Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369
USA
(888) 240-6001
(763) 656-4300
(763) 656-4250
www.vascularsolutions.com

InnerChange™ Micro-Introducer Catheter Instructions For Use

USA CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

CAUTION

The INNERCHANGE micro-introducer catheter should be used by physicians with adequate training in the use of the device.

DEVICE DESCRIPTION

The INNERCHANGE micro-introducer catheter combines a micro-introducer kit for obtaining vascular access with a hydrophilically coated diagnostic catheter. The INNERCHANGE catheter is designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. The INNERCHANGE micro-introducer catheter is compatible with $\leq 0.038"/.965\text{mm}$ guidewires. Each INNERCHANGE micro-introducer catheter consists of the following components:

- 21G percutaneous entry needle
- 0.018" guidewire
- Dilator
- Catheter with selected tip shape and attached stopcock

INDICATIONS

The INNERCHANGE micro-introducer catheter is intended for use in accessing the vascular system through a small gauge needle stick and for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.

CONTRAINDICATIONS

The INNERCHANGE micro-introducer catheter is contraindicated for use in synthetic vascular grafts due to the potential for graft perforation.

WARNINGS

The INNERCHANGE micro-introducer catheter is supplied sterile for single use only. Do not resterilize and/or reuse the device. Resterilization could change the physical characteristics of the catheter material and should not be attempted.

Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the

catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter or vessel perforation.

Do not withdraw the guidewire from the needle. If necessary, remove both the needle and guidewire as a unit to prevent the needle from damaging or shearing the guidewire.

Do not attempt to reshape the INNERCHANGE micro-introducer catheter. Doing so may harm the physical integrity of this product.

Do not exceed the pressure rating listed on the label of the INNERCHANGE micro-introducer catheter for any injection. Exceeding the pressure rating may result in separation of the catheter, embolization or vessel damage. The maximum flow rate recommended for the device is as follows (see Table 1):

Table 1: Recommended Flow Rates

Model	Catheter Size	Tip Configuration	Maximum psi rating	Maximum kPa rating
7903	5F	Cobra	1050	7239
7904	5F	Modified Hook	1050	7239
7905	5F	Pigtail	1050	7239

COMPLICATIONS

As with all catheterization procedures, complications with the INNERCHANGE micro-introducer catheter may occur. These may include:

- Local or systemic infection
- Myocardial infarction
- Cardiac arrhythmias
- Stroke and death
- Intimal disruption
- Arterial dissection
- Perforation and vessel rupture
- Arterial or venous thrombosis
- Distal embolization of blood clots and plaque
- Vessel spasm
- Arteriovenous fistula formation
- Catheter fracture with tip separation and distal embolization

PRECAUTIONS

The INNERCHANGE deployment procedure should be performed by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.

Do not use the INNERCHANGE micro-introducer catheter if the packaging has been damaged.

Inspect the catheter prior to use for any bends or kinks. Do not use a damaged catheter because vessel damage and/or inability to advance or withdraw the catheter may occur.

Exercise care when handling the catheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.

When the catheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the catheter without observing the resultant tip response.

This product is not designed for use with a separate introducer sheath. Doing so may result in difficult catheter movement.

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the INNERCHANGE micro-introducer catheter. The techniques and procedures described do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.

PREPARATIONS FOR USE

Prepare the INNERCHANGE micro-introducer catheter according to the following steps:

1. Carefully inspect the INNERCHANGE micro-introducer catheter packaging and components for damage prior to use. Using sterile technique, open the pouch and transfer the tray into the sterile field.
2. Remove the catheter from the tray and inspect for any bends or kinks.
3. Thoroughly flush the catheter and dilator with heparinized saline.
4. Check and tighten connections between the catheter, stopcock and injection system.
5. Insert the dilator through the stopcock connected to the catheter and observe that the distal tip of the dilator is exposed beyond the distal tip of the catheter.
6. Activate the hydrophilic coating on the catheter by wetting the distal end with sterile saline. For best results, keep the catheter surface wet at all times during use.
7. Prep skin and drape in area of anticipated puncture as required.

DEPLOYMENT PROCEDURE

Deploy the INNERCHANGE micro-introducer catheter according to the following steps:

1. Cannulate the vessel using the 21G needle. Needle position should be verified by observing blood return.
2. Insert the coil tip of the 0.018" guidewire through the needle into the vessel. Advance the guidewire to the required depth, leaving an appropriate amount of guidewire exposed outside of the puncture.

Warning: Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter or vessel perforation.

3. Hold guidewire in place and remove the needle.
- Warning: Do not withdraw the guidewire from the needle. If necessary, remove both the needle and guidewire as a unit to prevent the needle from damaging or shearing the guidewire.**
4. Thread the catheter and dilator together as a unit over the guidewire.
5. Advance the catheter and dilator set together through the skin tract and into the vessel.
6. Remove the dilator and guidewire after fluoroscopically confirming catheter position, leaving catheter in place.
7. Deliver radiopaque media to selected sites in the vascular system through the catheter lumen as required.

Warning: Do not exceed the pressure rating listed on the label of the INNERCHANGE micro-introducer catheter for any injection. Exceeding the pressure rating may result in separation of the catheter, embolization or vessel damage.

8. Remove the catheter and discard according to institutional practice after completing the diagnostic procedure.

PACKAGING & STORAGE

The INNERCHANGE micro-introducer catheter has been sterilized with ethylene oxide.

Handle with care.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the INNERCHANGE micro-introducer catheter is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product that has been found by Vascular Solutions, Inc. to be defective in workmanship or materials. Vascular Solutions, Inc. shall not be liable for any incidental, special or consequential damages arising from the use of the INNERCHANGE micro-introducer catheter. Damage to the product through misuse, alteration, improper storage or improper handling shall void this limited warranty.

No employee, agent or distributor of Vascular Solutions, Inc. has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Vascular Solutions, Inc.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER OBLIGATION OF VASCULAR SOLUTIONS, INC.

PATENTS AND TRADEMARKS

International and U.S. patents pending.

InnerChange™ is a trademark of Vascular Solutions, Inc.



www.vascularsolutions.com