

GrebSet®

Micro-Introducer Kit




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GrebSet® Micro-Introducer Kit Instructions For Use

USA CAUTION

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

CAUTION

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

DEVICE DESCRIPTION

The GREBSET micro-introducer kit consists of a vascular access kit which can be converted into a diagnostic catheter. The GREBSET catheter is designed to be used for delivering guidewires and/or contrast media to vascular sites. The GREBSET catheter is compatible with ≤ 0.038 " / .965mm guidewires. Each GREBSET micro-introducer kit consists of the following components:

- Needle, consisting of either a 21G percutaneous entry needle or a 21G Trocar needle
- 0.018" guidewire
- Dilator
- Catheter with radiopaque marker band located in distal tip

INDICATIONS

The GREBSET micro-introducer kit is intended to facilitate the percutaneous placement of guidewires in the vascular system and for delivery of contrast media to vascular sites.

CONTRAINDICATIONS

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

The GREBSET catheter is contraindicated for high pressure injections.

WARNINGS

The GREBSET micro-introducer kit 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 GREBSET catheter. Doing so may harm the physical integrity of this product.

Do not exceed 300psi injection pressure with the GREBSET catheter. Exceeding the pressure rating may result in separation of the catheter, embolization or vessel damage.

COMPLICATIONS

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

- Local or systemic infection
- Hematoma
- 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 GREBSET micro-introducer kit deployment procedure should be performed by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.

Do not use the GREBSET micro-introducer kit if the packaging has been damaged.

Inspect the GREBSET 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.

The GREBSET catheter is not designed for use through an 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 GREBSET micro-introducer kit. 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 GREBSET micro-introducer kit according to the following steps:

1. Carefully inspect the GREBSET micro-introducer kit packaging and components for damage prior to use. Using sterile technique, open the pouch and transfer the packaging clip into the sterile field.
2. Remove the catheter from the packaging clip and inspect for any bends or kinks.
3. Thoroughly flush the catheter and dilator with heparinized saline.
4. Insert the dilator through the catheter and observe that the distal tip of the dilator is exposed beyond the distal tip of the catheter.
5. 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.
6. Prep skin and drape in area of anticipated puncture as required.

DEPLOYMENT PROCEDURE

Deploy the GREBSET micro-introducer kit according to the following steps:

1. Cannulate the desired vessel using the enclosed needle. If using the Trocar needle, remove the inner stylet from the needle.
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 the catheter in place.
7. Deliver radiopaque media or a ≤ 0.038 " / .965mm guidewire to selected sites through the catheter lumen as desired.

Warning: Do not exceed 300psi injection pressure with the GREBSET catheter. 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 GREBSET micro-introducer kit has been sterilized with ethylene oxide.

STERILE EO

Handle with care.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the GREBSET micro-introducer kit 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 GREBSET micro-introducer kit. Damage to the product through misuse, alteration, improper storage or improper handling shall void this limited warranty.

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PATENTS AND TRADEMARKS

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