

Table 1 – Specifications

Model Number	8800	8801	8802
Length, cm	80cm	120cm	145cm
Required Guidewire Diameter	0.014 in. / 0.036mm	0.014 in. / 0.036mm	0.014 in. / 0.036mm
Required Guidewire Minimum Length For Exchange	160cm	240cm	290cm
Minimum Introducer Size	4F (0.053 in. I.D.)	4F (0.053 in. I.D.)	4F (0.053 in. I.D.)
Distal Hydrophilic Coating	Yes	Yes	Yes

INDICATIONS

The PiggyBack is intended to be used with guidewires to access the peripheral vasculature and to facilitate placement of interventional devices.

CONTRAINDICATIONS

None.

WARNINGS

Do not advance the PiggyBack without a guidewire in place. Advancement of the PiggyBack without a guidewire in place may result in intimal damage, arterial dissection or perforation.

The PiggyBack is supplied sterile for single use only. Do not reuse, reshape or re-sterilize the device. Re-sterilization or reshaping may change the physical characteristics of the 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 PiggyBack against resistance may result in separation of the device or guidewire tip, damage to the device or vessel perforation.

Never deploy the PiggyBack into an artery unless a 0.014" guidewire is already in place or a 0.014" guidewire is preloaded in the PiggyBack. Vessel perforation or damage may result.

Never advance the PiggyBack beyond the distal end of the 0.014" guidewire. Vessel perforation or damage may result.

Never deliver devices over the PiggyBack without first confirming that the device is securely locked onto the 0.014" guidewire. Vessel perforation or damage may result.

Never advance the proximal lock of the PiggyBack into the patient. Verify that the lock is visible outside of the patient prior to delivering devices over the PiggyBack. Advancing the lock of the PiggyBack into the patient may result in device migration.

COMPLICATIONS

As with all catheterization procedures, complications may occur when using the PiggyBack. These may include:

- local or systemic infection
- intimal disruption
- arterial dissection
- perforation and vessel rupture
- arterial thrombosis
- distal embolization of blood clots and plaque
- myocardial infarction
- arterial spasm
- catheter fracture with tip separation and distal embolization

PRECAUTIONS

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

Do not use the PiggyBack if the packaging has been damaged.

Inspect the PiggyBack prior to use for any bends or kinks. Do not use a damaged PiggyBack because vessel damage and/or inability to advance or withdraw the PiggyBack or 0.014" guidewire may occur.

Precautions to prevent or reduce clotting should be taken when any device is used in the vascular system. Use of systemic heparinization and heparinized sterile solution should be considered.

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

The 0.014" guidewire should not be loaded into the proximal end of the PiggyBack (i.e. the sliding lock). Damage and/or inability to advance the 0.014" guidewire may occur.

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the PiggyBack. 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.

Each PiggyBack includes the following components:

- Single-use disposable PiggyBack wire converter in dispenser coil

Other materials required but not provided are:

- ≥4F introducer sheath
- 0.014" guidewire
- Sterile saline (for hydrating hydrophilic coating and flushing)

PREPARATIONS FOR USE

1. Carefully inspect the PiggyBack packaging and components for damage prior to use.
2. Utilizing sterile technique, remove the dispenser coil from the pouch and transfer it into the sterile field.
3. Hydrate the hydrophilic coating by injecting saline through the coil until saline exits the other end of the coil.
4. Remove the PiggyBack from the dispenser coil and inspect for any bends or kinks.

DEPLOYMENT PROCEDURE

The following PiggyBack deployment steps assume a standard catheterization protocol using the following items: ≥4F introducer sheath and *in situ* 0.014" guidewire of the appropriate length.

WARNING: Never deploy the PiggyBack into an artery unless a 0.014" guidewire is already in place or a 0.014" guidewire is preloaded in the PiggyBack. Vessel perforation or damage may result.

1. Backload the PiggyBack over the 0.014" guidewire. Under fluoroscopic guidance, advance the PiggyBack until the radiopaque marker band is in the desired location on the 0.014" guidewire in the vessel leaving at least 2cm of the distal guidewire exposed.



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PiggyBack™ Wire Converter

Instructions For Use

USA CAUTION

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

CAUTION

The PiggyBack wire converter (PiggyBack) should be used by physicians with adequate training in the use of the device.

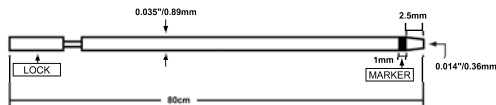
DEVICE DESCRIPTION

The PiggyBack is a 0.035" outer diameter catheter that can be delivered over and locked onto a 0.014" guidewire to allow subsequent delivery of catheters with a 0.035" wire lumen. The PiggyBack can either be delivered over a 0.014" guidewire *in situ* or can be preloaded onto a 0.014" guidewire before it is placed intravascular.

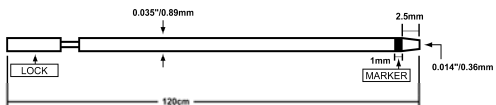
The proximal end of the PiggyBack contains a sliding lock that maintains position of the PiggyBack on the 0.014" guidewire while maintaining an outer diameter of 0.035".

The PiggyBack has a hydrophilic coating on the distal portion of the catheter and a radiopaque marker band located approximately 2.5mm from the distal tip.

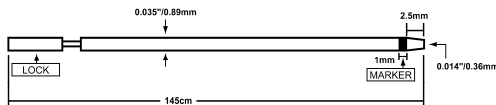
Model 8800



Model 8801

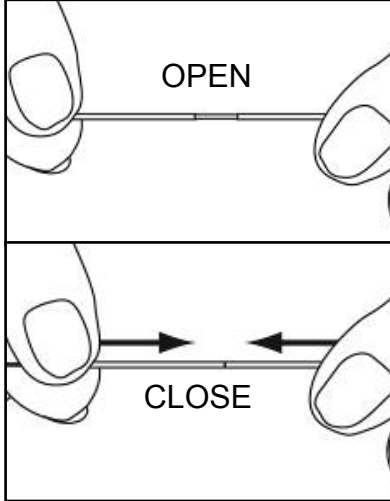


Model 8802



WARNING: Never advance the PiggyBack beyond the distal end of the 0.014" guidewire. Vessel perforation or damage may result.

2. Lock the PiggyBack onto the 0.014" guidewire by firmly pushing the sliding lock together, which will cover the exposed stainless portion completely (see figure A below). Verify the locked position by pulling the guidewire while holding the PiggyBack stable. The PiggyBack is now fixed to the 0.014" guidewire and may be used to deliver 0.035" devices.



WARNING: Never deliver devices over the PiggyBack without first confirming that the device is securely locked onto the 0.014" guidewire. Vessel perforation or damage may result.

WARNING: Never advance the proximal lock of the PiggyBack into the patient. Verify that the lock is visible outside of the patient prior to delivering devices over the PiggyBack. Advancing the lock of the PiggyBack into the patient may result in device migration.

3. To unlock the PiggyBack from the 0.014" guidewire, pull on both sides of the sliding lock to expose the stainless steel. The PiggyBack may now be removed from the 0.014" guidewire.

PACKAGING & STORAGE

The PiggyBack has been sterilized with ethylene oxide.

STERILE EO

Handle with care.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the PiggyBack 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 which 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 PiggyBack. 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.

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PATENTS AND TRADEMARKS

International and U.S. patents pending.

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