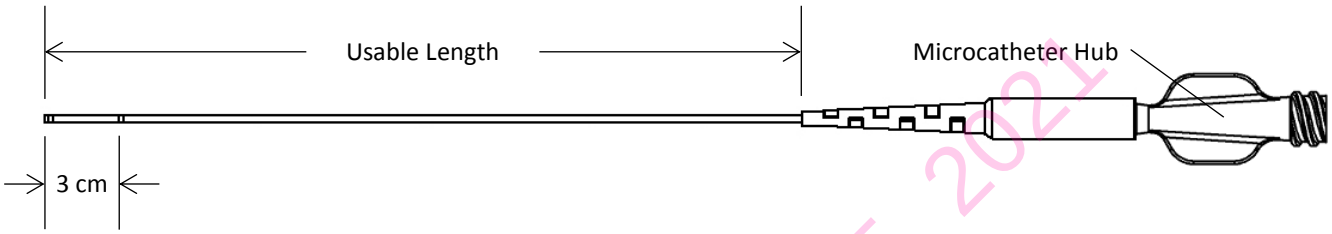
# PG Pro™ Peripheral Microcatheter

## Instructions for Use

Carefully read all instructions prior to use.

### DEVICE DESCRIPTION

The PG Pro Microcatheter is a single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the Microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the Microcatheter hub is used for the attachment of accessories.




| Usable Length | Nominal Distal Hydrophilic Coating Length | Microcatheter ID | Microcatheter OD | Guide Catheter Minimum ID | Guidewire Recommendation |
|---|---|---|---|---|---|
| 140 cm<br>165 cm | 60 cm<br>100 cm | 0.69 mm / 0.027 in. | 2.8 F / 2.8 F<br>0.92 mm / 0.94 mm | ≥ 0.038 in. / 0.97 mm Guidewire Compatible | ≤ 0.021 in. / 0.53 mm |



### CONTENTS

One PG Pro Microcatheter
One Introducer Sheath

### INDICATIONS FOR USE

The PG Pro Microcatheter is intended for the peripheral vasculature for the infusion of diagnostic and therapeutic agents.

### CONTRAINDICATIONS

There are no known contraindications.

### CAUTION

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

Do not use if pouch is opened or damaged.

This device is intended 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.

After use, dispose in accordance with hospital, administrative and/or local government policy.

**WARNINGS**

The Microcatheter should only be used by physicians who have received appropriate training in interventional techniques.

The Microcatheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.

Inspect the Microcatheter prior to use. Do not use the device if any damage or irregularities are observed.

The Microcatheter should be advanced or manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.

Infusion pressure should not exceed 8274 kPa (1200 psi) to avoid potential rupture of the Microcatheter.

The Introducer Sheath is not intended for use inside the patient body. Ensure that the Introducer Sheath is removed from the Microcatheter once the distal shaft of the Microcatheter is placed inside the patient body.

**PRECAUTIONS**

Verify Microcatheter compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.

The Microcatheter has a distal hydrophilic coating segment that should be hydrated prior to use (see Preparation for Use). If removed from the patient, the hydrophilic coating on the Microcatheter should be hydrated with heparinized saline, but not left to soak for more than 2 hours. Do not allow the coating to dry.

Exercise care in handling the Microcatheter to reduce the chance of accidental damage.

Verify that the diameter of any guidewire or accessory device that is used is compatible with the inner diameter of the Microcatheter prior to use.

Potential complications include, but are not limited to: vessel trauma, vasospasm, hematoma at the site of entry, embolism, hemorrhage, infection, vessel dissection, thrombus formation, and death.

To reduce the risk of damage or separation of the device, avoid repeated bending at the same point of the Microcatheter.

Take precaution when manipulating the Microcatheter in tortuous vasculature to avoid damage to the Microcatheter. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

**PREPARATION FOR USE**

Before removing the Microcatheter, fully hydrate the hydrophilic segment of the device by flushing heparinized saline through the dispenser tube using a syringe attached to the dispenser tube hub.

To remove the Microcatheter from the dispenser tube, gently pull the hub out from the dispenser tube. Remove the Microcatheter by pulling it from the dispenser tube. If resistance is met, repeat the flushing procedure until the Microcatheter is well hydrated and can be easily removed from the dispenser tube. Inspect the Microcatheter thoroughly to ensure it is not damaged. Do not allow Microcatheter to dry prior to introduction into the guiding catheter.

The Microcatheter is compatible with dimethyl sulfoxide (DMSO).

Note: DMSO based liquid embolic agents are not approved for use in peripheral vasculature in the USA.

## DIRECTIONS FOR USE

Prior to use, flush the Microcatheter lumen thoroughly with heparinized saline to prime the Microcatheter and provide smooth movement of the guidewire within the Microcatheter. A rotating hemostatic valve (RHV) may be attached to the Microcatheter hub and used to facilitate the flushing process.

Carefully insert the distal section of the guidewire into the Microcatheter hub (refer to the guidewire instructions for use). A guidewire insertion tool may be used to facilitate insertion of the guidewire distal tip through an RHV and into the Microcatheter hub. Advance the guidewire until the distal tip is near the distal end of the Microcatheter. Gently tighten the RHV to maintain position.

Slip the torque device over the proximal end of the guidewire to the desired location (refer to guidewire or torque device instructions for use). Secure the torque device in place by tightening the rotating knob. The torque device may be repositioned by loosening and retightening the rotating knob.

A guiding catheter is placed into the appropriate vessel and the Microcatheter/guidewire assembly is then advanced through the guiding catheter to the target vessel or vascular lesion. Set up a continuous flush of heparinized saline by connecting RHVs with pressurized flush solution lines to the hub of the guiding catheter and Microcatheter.

Loosen the guiding catheter RHV and introduce the Microcatheter/guidewire into the guiding catheter using the introducer sheath. Carefully advance the Microcatheter/guidewire to the guiding catheter distal tip. After the Microcatheter/guidewire reaches the tip of the guiding catheter, remove the introducer from the Microcatheter shaft by retracting the introducer from the RHV and peeling off the introducer. During navigation in the vasculature, advance the guidewire a short distance, then advance the Microcatheter over the guidewire and repeat until the desired site is reached. The proximal portion of the Microcatheter does not have the hydrophilic surface and may encounter resistance when this section is advanced through the RHV.

Once the desired location has been reached, the guidewire is removed from the Microcatheter. The diagnostic or therapeutic agent(s) are then prepared for delivery through the Microcatheter. Warning: Do not exceed the maximum recommended infusion pressure of 1200 psi.

Between uses, rinse the Microcatheter in a basin of heparinized saline and wipe it gently with sterile, wet gauze and place in a basin of heparinized saline or a flushed dispenser tube to keep the hydrophilic surface wet until use. Warning: Do not leave the Microcatheter soaked in saline for more than 2 hours.

| Microcatheter | Dead Space (Average) |
|---|---|
| PG Pro 140cm | 0.82 cc |
| PG Pro 165cm | 0.94 cc |

| Microcatheter | Approximate Nominal Flow Rates at 900 and 1200 psi Infusion Pressure | |
|---|---|---|
| | 100% Contrast* | |
| | 900 psi | 1200 psi |
| **PG Pro 140 cm** | 4.8 cc/sec | 5.7 cc/sec |
| **PG Pro 165 cm** | 4.2 cc/sec | 5.5 cc/sec |

*** Contrast Media: Iohexol 300 mg/mL**

## STORAGE

Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. Store the Microcatheter under controlled room temperature. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

## MATERIALS

The Microcatheter does not contain latex or PVC materials.

## SYMBOLS

| | | | |
|---|---|---|---|
| LOT | Lot Number | | Do Not Reuse |
| REF | Catalog Number | | Caution |
| CONTENTS | Contents | | Use-by Date |
| STERILE EO | Sterilized Using Ethylene Oxide | | Date of Manufacture |
| CE | CE Mark | | Manufacturer |
| EC REP | Authorized European Representative | | Non-pyrogenic |
| | Do not use if package is damaged | | Consult instructions for use |
| Rx ONLY | For Prescription Use Only | Max Guide Wire O.D. | Max Guidewire Outer Diameter |
| P max | Maximum Injection Pressure | I.D. | Inner Diameter |

**WARRANTY**

MicroVention, Inc. warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond MicroVention's control directly affect the device and the results obtained from its use. MicroVention's obligation under this warranty is limited to the repair or replacement of this device and MicroVention shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. MicroVention neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MicroVention assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.
Prices, specifications and model availability are subject to change without notice.

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