

Microcatheter

INSTRUCTIONS FOR USE

DESCRIPTION

The Merit Pursue™ Microcatheter is a microcatheter with a flexible distal region. A hydrophilic coating is applied to the distal 80 cm outer surface. A radiopaque marker is located approximately 0.6 mm proximal to the microcatheter tip to facilitate fluoroscopic visualization. The proximal end of the microcatheter incorporates a standard luer adapter for attachment of accessories.

These may be packaged with the following components:

- Tip straightener
- Male Luer lock syringes

INDICATIONS FOR USE

The microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels.

The catheter should not be used in the cerebral vessels.

CONTRAINDICATIONS

There are no known contraindications with the use of this product.

WARNINGS

1. This device is intended to be used only by physicians trained in percutaneous intravascular techniques and procedures.
2. Sterile if package is unopened and undamaged.
3. For single patient 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.
4. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.
5. Do not use a power injector to infuse agents other than contrast media, as the microcatheter may become blocked. The safety setting of injection pressure must not exceed the maximum dynamic injection pressure of 5515 kPa (800 psi). Exceeding injection pressure beyond the maximum injection pressure may cause microcatheter rupture possibly resulting in patient injury. If flow through the microcatheter becomes restricted, do not attempt to clear the microcatheter lumen by infusion. Identify and resolve the cause of the blockage or replace the microcatheter with a new microcatheter before resuming infusion. (See Instructions For Using a Power Injector)
6. Make sure that the guiding catheter does not slip out of the vessel. If the guiding catheter should leave the vessel when the microcatheter and/or the guide wire is moved, this may result in the damage of the microcatheter system.
7. Microcatheter advancement beyond the end of the guide wire may result in vessel trauma.
8. Appropriate anticoagulation therapy should be administered in consideration of the conditions of the patient. Pre-clinical testing shows variable amounts of thrombus formation on the device surface in the absence of anticoagulation.

PRECAUTIONS

1. **Rx Only** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
2. Ensure embolic material compatibility with microcatheter prior to use.
3. Always monitor infusion rates when using the microcatheter
4. When injecting contrast for angiography, ensure that the microcatheter is not kinked or occluded.
5. The microcatheter has a lubricious hydrophilic coating on the outside of the catheter. It must be kept hydrated prior to removal from its carrier and during the actual procedure in order to be lubricious. This can be accomplished by attaching the Y-connector to a continuous saline drip.
6. Prior to a procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity.
7. Inspect the microcatheter prior to use for any bends or kinks. Any microcatheter damage may decrease the desired performance characteristics.
8. Exercise care in handling of the microcatheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.
9. When the microcatheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the microcatheter without observing the resultant tip response.
10. Exchange microcatheters frequently during lengthy procedures that require extensive manipulation or multiple guide wire exchanges.
11. Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the microcatheter or guide wire against resistance may result in separation of the microcatheter or guide wire tip, damage to the microcatheter, or vessel perforation.
12. Because the microcatheter may be advanced into narrow subselective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal.
13. Excessive tightening of a hemostatic valve onto the microcatheter shaft may result in damage to the catheter.
14. Read and follow the manufacturer's IFU for diagnostic, embolic, or therapeutic agents to be used with this microcatheter.
15. Use prior to the "use by" date.
16. Store at controlled room temperature.
17. Remove the stylet from the catheter before removing the catheter from the spiral holder.
18. Syringe accuracy is +/- 5%.

POTENTIAL COMPLICATIONS

Possible complications (in alphabetical order) include, but are not limited to:

- Access site complications
- Allergic reaction
- Death
- Dissection
- Embolism
- Foreign body in patient
- Hemorrhage
- Infection

- Inflammatory reaction
- Ischemia
- Pain and tenderness
- Perforation
- Thrombus formation
- Vasoconstriction
- Vessel spasm

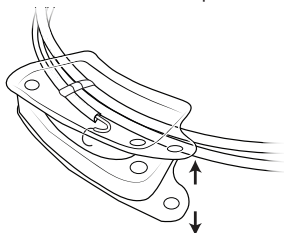
Table 1: Merit Pursue Compatibility Information

| Microcatheter OD | Microcatheter ID | Maximum Guide Wire OD | Minimum Guiding Catheter ID |
|------------------|------------------|------------------------------|-----------------------------|
| 2.8F / 1.7F | 0.016" (0.40 mm) | 0.014" (0.36 mm) | 0.040" (1.02 mm) |
| 2.9F / 2.0F | 0.020" (0.50 mm) | 0.018" (0.46 mm) | 0.042" (1.07 mm) |
| Embolics | | | |
| Microcatheter OD | Particles | Spherical | Maximum Coil Size |
| 2.8F / 1.7F | ≤ 500 μm Emboli | ≤ 500 μm Microspheres | 0.014" (0.36 mm) |
| 2.9F / 2.0F | ≤ 710 μm Emboli | ≤ 700 μm Microspheres | 0.018" (0.46 mm) |
| Chemical | | | |
| Cisplatin | Cyanoacrylate | DMSO (Dimethyl Sulfoxide) | Doxorubicin |
| Ethanol | Irinotecan | Lipiodol | |

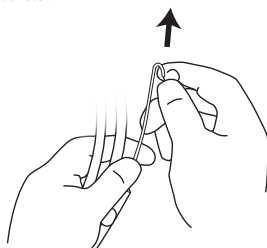
INSTRUCTIONS FOR USE

NOTE: It is recommended that the microcatheter be used with a guiding catheter.

1. Place the appropriate guiding catheter using standard technique. A rotating hemostasis valve may be connected to the guiding catheter luer adapter to continuously flush the guiding catheter with saline.
2. Utilizing sterile technique, carefully open the pouch and remove the microcatheter holder from the packaging.
3. Attach a syringe filled with heparinized saline solution or sterile water to the luer lock fitting of the microcatheter holder.
4. Inject enough solution to wet the microcatheter surface entirely. This will activate the hydrophilic coating on the microcatheter surface.
NOTE: Steps 5 and 6 are for catheters with a 45° or Swan Neck tip shape.
5. Remove the protective cover that covers the tip of the microcatheter.



6. Remove the tip retention stylet from the catheter.
WARNING: Failure to remove the stylet prior to removing the microcatheter from the microcatheter holder may damage the catheter.



7. Attach a syringe filled with heparinized saline solution or sterile water to the hub of the microcatheter.
8. Inject enough solution to purge any air from the inside of the microcatheter.
9. Remove the microcatheter from the microcatheter holder.
NOTE: The surface of the microcatheter may become dry after removal from the microcatheter holder. Additional wetting with heparinized saline or sterile water will renew the hydrophilic effect.
10. Upon removal of the microcatheter from the microcatheter holder, inspect the microcatheter to verify there is no damage prior to insertion.
11. If desired, attach a second hemostasis valve with side-arm adapter to the microcatheter, flush with heparinized saline or sterile water to purge any air.
12. Carefully insert guide wire into the microcatheter and completely close the valve (if used) around the guide wire.
13. Introduce the microcatheter and guide wire assembly into the guiding catheter via the hemostasis valve (if used). If a rotating hemostatic valve is used, tighten the valve around the microcatheter to prevent backflow, but allowing some movement through the valve by the microcatheter.
14. Using fluoroscopy, introduce the microcatheter and guide wire assembly into the vascular system, making sure the guide wire is always ahead of the microcatheter. Advance the guide wire and microcatheter to a selected vascular site by alternatively advancing the guide wire and then tracking the microcatheter over the guide wire.
Note: To facilitate microcatheter handling, the proximal portion of the microcatheter is uncoated to ensure a non-slip grip.

15. Final positioning is accomplished by short advances of the guide wire and microcatheter until the desired position is achieved and then confirmed by fluoroscopic visualization.

16. Monitor microcatheter placement and position during use.

17. To infuse, completely remove the guide wire from the microcatheter. Connect a syringe with infusate to the microcatheter luer, and infuse as required.

INSTRUCTION FOR USING A POWER INJECTOR WITH THE MICROCATHETER







A power injector can be used to infuse a contrast media through the microcatheter. Observe the warnings and cautions given above. The flow rate depends upon such factors as the viscosity of the contrast media, which varies with the type and temperature of the media, the model and setting of the power injector, and how the injector is connected to the microcatheter. The observed flow rate values indicated below are for reference only.

Table 2: Flow Rates

| Merit Pursue Microcatheter Size Shaft/Tip | Usable Length (cm) | Contrast Media | Iodine Content (mg/mL) | Viscosity (cP) at 37°C | MEDRAD Flow Setting Conditions With Linear Rise @ 0.3 Sec | | Actual Contrast Delivery mL/Sec with Safety pressure Setting of: | Dead Space (Priming) Volume (mL) |
|---|--------------------|--------------------|------------------------|------------------------|---|-------------|--|----------------------------------|
| | | | | | Flow Rate (mL/Sec) | Volume (mL) | | |
| 2.8F/1.7F | 110 | ISOVUE (Iopamidol) | 300 370 | 4.7 9.4 | 6.0 | 10 | 3.0 | 0.42 |
| | | | | | 3.0 | 10 | 1.5 | |
| | 130 | ISOVUE (Iopamidol) | 300 370 | 4.7 9.4 | 6.0 3.0 | 10 10 | 2.6 1.3 | 0.50 |
| 2.9F/2.0F | 110 | ISOVUE (Iopamidol) | 300 370 | 4.7 9.4 | 6.0 | 10 | 4.3 | 0.50 |
| | | | | | 3.0 | 10 | 2.4 | |
| | 130 | ISOVUE (Iopamidol) | 300 370 | 4.7 9.4 | 6.0 3.0 | 10 10 | 3.9 2.0 | 0.57 |
| 150 | ISOVUE (Iopamidol) | 300 370 | 4.7 9.4 | 6.0 3.0 | 10 | 10 | 3.7 | 0.63 |
| | | | | | 10 | 10 | 1.9 | |

REFERENCE DATA

1. Injector used: MEDRAD MARK V
2. Contrast Media temperature: 37°C
3. Injection pressure monitor/ limit setting: 5515 kPa (800 psi)
4. Flow scale: mL/sec
5. Linear rise seconds: 0.3 sec.

| Symbol | Designation |
|---|---|
| Rx Only | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. |
|  | Caution: Consult accompanying documents. Read instructions prior to use. |
|  | Do not use if package is damaged |
|  | Non-pyrogenic |
|  MAX GUIDE WIRE | Maximum diameter guide wire |
|  | Maximum pressure |
| STERILE EO | Sterilized using Ethylene Oxide |
|  | Radiopaque marker |



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