English

Merit Pursue™
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.

The Pursue Microcatheter may be packaged with the following components:
- Tip straightener
- Male Luer lock Syringe

INTENDED PURPOSE / INDICATIONS FOR USE
Intended Purpose: The Pursue microcatheter is intended for the peripheral vascular infusion of diagnostic, embolic and/or therapeutic materials.

Indications: The Pursue microcatheter is indicated for use in patients requiring peripheral vascular infusion of diagnostic, embolic and/or therapeutic materials for the treatment or diagnosis of disease and/or lesions, preoperative intervention, or hemostasis as determined by clinician assessment.

CLINICAL BENEFITS
The Pursue Microcatheter exhibit an indirect clinical benefit to patients as it facilitates infusion of diagnostic, embolic, or therapeutic materials into vessels.

INTENDED USERS
Patients: The Microcatheter Family is intended for use in adult patients requiring controlled and selective infusion of diagnostic, embolic, or therapeutic materials into peripheral vasculature.

Physicians: The Microcatheter Family is intended to be used only by physicians trained in percutaneous intravascular techniques and procedures.

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

WARNINGS
1. There is insufficient clinical data to support the use in the coronary or cerebral vasculature.
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. ℞ **ONLY** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
2. Ensure embolic or chemical material compatibility with microcatheter prior to use. Compatible materials are listed in Table 1.
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 before" date.
16. Store at controlled room temperature.
17. Remove the stylet from the catheter before removing the catheter from the spiral holder.

    WARNING: After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.

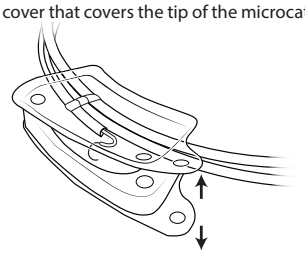
POTENTIAL COMPLICATIONS
Possible complications (in alphabetical order) include, but are not limited to:
- Dissection
- Embolism
- Foreign body in patient
- Hemorrhage
- Infection
- Inflamatory reaction
- Perforation
- Thrombus formation
- Vasoconstriction

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	

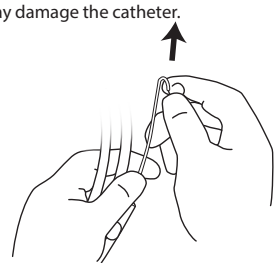
INSTRUCTIONS FOR USE
NOTE: It is recommended that the microcatheter be used with a guiding catheter.
1. Place the appropriate guiding catheter using standard technique. A rotating hemostasis valve may be connected to the guiding catheter Luer adapter to continuously flush the guiding catheter with saline.
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)	5515 kPa (800 psi)	
2.8F/1.7F	110	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	3.0 1.5	0.42
	130	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	2.6 1.3	0.50
	150	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	2.4 1.2	0.53
2.9F/2.0F	110	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	4.3 2.4	0.50
	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 1.9	0.63

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
	Caution
	Do Not Use If Package is Damaged and Consult Instruction for Use
REF	Catalog number
LOT	Lot Number
MD	Medical Device
UDI	Unique Device Identifier
	Single use
STERILIZE	Do not resterilize
	Consult Instructions for Use For electronic copy scan QR code, or go to www. merit. com/ifu and enter IFU ID Number. For printed copy available within seven days, call U.S.A or EU Customer Service
STERILE EO	Sterilized using ethylene oxide
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single Sterile Barrier System
	Use by date: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
	Manufacturer
EC REP	Authorized Representative in European Community
	Non-pyrogenic
	Max guide wire
	Maximum pressure
	Radiopaque marker
	Keep away from sunlight
	Keep dry

For a copy of this device's current European Summary of Safety and Clinical Performance (sscp), please go to the European database on medical devices (Eudamed), https://ec.europa.eu/tools/eudamed where it is linked to the basic UDI-DI. Pending availability of the Eudamed site, the SSCP may also be accessed at the following link: http://www.merit.com/sscp/

The basic UDI-DI for the Pursue Microcatheter is 088445048813DW.

In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

CE 2797

MERIT MEDICAL®

www.merit.com

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