Merit Maestro®

Microcatheter

INSTRUCTIONS FOR USE

DESCRIPTION

The Merit Maestro 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 1.3 mm proximal to the catheter tip to facilitate fluoroscopic visualization. The proximal end of the microcatheter incorporates a standard Luer adapter for attachment of accessories.

ACCESSORIES

The Merit Maestro Microcatheter may be packaged with a tip straightener and male luer lock syringes. Syringe(s), Access Needle, Guidewire Dilator, Catheter Sheath Introducer, Guiding Catheter and a Guidewire are required for use but not supplied with the microcatheter.

INTENDED PURPOSE

The Maestro Microcatheter is intended for the peripheral vascular infusion of diagnostic, embolic and/or therapeutic materials.

INDICATIONS FOR USE

The Maestro 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 Maestro Microcatheters exhibit an indirect clinical benefit to patients as they facilitate infusion of diagnostic, embolic, or therapeutic materials into vessels.

CONTRAINDICATIONS

None known

INTENDED PATIENTS

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

INTENDED USERS

Placement and access of the Maestro Microcatheter are only intended to be used by physicians trained in percutaneous intravascular techniques and procedures.

WARNINGS

1. Due to contractual agreements, the Maestro Microcatheter is not for neurovascular use at or above the common carotid artery or at or above the vertebral artery.
2. There is insufficient clinical data to support the use in the coronary or cerebral vasculature.
3. Sterile if package is unopened and undamaged.
4. 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.
5. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.
6. 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)
7. 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.
8. Microcatheter advancement beyond the end of the guide wire may result in vessel trauma.
9. 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.

PRECAUTIONS

1. **℞ 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, 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. Syringe accuracy is +/- 5%.

POTENTIAL COMPLICATIONS

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

- Dissection
- Embolism
- Foreign body in patient
- Hemorrhage
- Infection
- Inflammatory reaction
- Perforation
- Thrombus formation
- Vasoconstriction

Table 1: Compatibility Information

Microcatheter OD	Microcatheter ID	Maximum Guide Wire OD	Minimum Guiding Catheter ID
2.8F / 2.1F	0.018" (0.46 mm)	0.016" (0.41 mm)	0.040" (1.02 mm)
2.8F / 2.4F	0.020" (0.52 mm)	0.018" (0.46 mm)	0.040" (1.02 mm)
2.8F / 2.8F	0.024" (0.62 mm)	0.021" (0.53 mm)	0.040" (1.02 mm)
2.9F / 2.9F	0.027" (0.69 mm)	0.021" (0.53 mm)	0.042" (1.07 mm)
Embolics			
Microcatheter OD	**Maximum Particle Size**	**Maximum Spherical Size**	**Maximum Coil Size**
2.8F / 2.1F	≤ 500 µm Emboli	≤ 700 µm Microspheres	≤ 0.016" (0.41 mm)
2.8F / 2.4F	≤ 700 µm Emboli	≤ 700 µm Microspheres	≤ 0.018" (0.46 mm)
2.8F / 2.8F	≤ 700 µm Emboli	≤ 700 µm Microspheres	≤ 0.018" (0.46 mm)
2.9F / 2.9F	≤ 1000 µm Emboli	≤ 900 µm Microspheres	N/A*

* Coils should not be used in the 2.9F / 2.9F Maestro Microcatheters

NOTE: Embolic compatibility is for reference only. Read and follow the embolic manufacturers IFU for compatibility.

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 hoop 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: The surface of the microcatheter may become dry after removal from the holder. Additional wetting with heparinized saline or sterile water will renew the hydrophilic effect.
5. Attach a syringe filled with heparinized saline or sterile water to the hub of the Microcatheter.
6. Inject enough solution to purge the air from the inside of the Microcatheter.
7. Upon removal of the microcatheter from the hoop, inspect the microcatheter to verify there is no damage prior to insertion.
8. 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.
9. Carefully insert guide wire into the microcatheter and completely close the valve (if used) around the guide wire.
10. 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.
11. 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.

12. 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.
13. Monitor microcatheter placement and position during use.
14. 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 Maestro Micro-catheter Size Shaft/Tip	Merit Maestro Micro-cath-eter 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/2.1F	110	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	5.22 2.45	0.63
	130	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	4.58 2.00	0.70
	150	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	4.31 1.87	0.76
2.8F/2.4F	110	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	5.55 2.54	0.63
	130	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	5.14 2.21	0.70
	150	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	4.60 2.00	0.76
2.8F/2.8F	110	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	5.57 2.63	0.63
	130	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	5.07 2.37	0.70
	150	ISOVUE (Iopamidol)	300 370	4.7 9.4	6.0 3.0	10 10	4.70 2.18	0.77
2.9F/2.9F	110	ISOVUE (Iopamidol)	300 370	4.7 9.4	7.0 4.0	10 10	6.82 3.44	0.69
	130	ISOVUE (Iopamidol)	300 370	4.7 9.4	7.0 4.0	10 10	6.26 3.40	0.77
	150	ISOVUE (Iopamidol)	300 370	4.7 9.4	7.0 4.0	10 10	5.59 3.20	0.85

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.

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 UDIDI.

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 Merit Maestro Microcatheter is 088445047256DB.

SYMBOL	DESCRIPTION
	Date of Manufacture: YYYY-MM-DD
	Use By: YYYY-MM-DD
LOT	Lot Number
REF	Catalog Number
Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single use
	Do Not Resterilize
STERILE EO	Sterilized using ethylene oxide
	Non-pyrogenic
	Caution
	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 E.U. Customer Service
	Max guide wire
	Maximum pressure
	Radiopaque marker
MD	Medical Device
	Single Sterile Barrier System
UDI	Unique Device Identifier
EC REP	Authorized Representative in European Community
	Manufacturer
	Keep away from Sunlight
	Keep Dry

MERIT MEDICAL®

CE 2797

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