Merit Maestro®

Microcatheters

English

INSTRUCTIONS FOR USE

DESCRIPTION: The Merit Maestro Microcatheter is available in three French size configurations. The first configuration incorporates a change in its outside diameter along its length from a 2.8F (0.93mm) proximal region to a 2.4F (0.80mm) flexible distal region of 20cm in length. This configuration employs a nominal proximal inner diameter of 0.025" with a nominal tip inner diameter of 0.020".

The second configuration maintains a 2.8F (0.93mm) diameter throughout its length, but also incorporates a 20cm flexible distal region. The I.D. of this configuration has a nominal 0.025" inner diameter in the proximal region and a distal region inner diameter of 0.024".

The third configuration maintains a 2.9F (0.96mm) diameter throughout its length, but also incorporates a 20cm flexible distal region. The I.D. of this configuration has a nominal 0.027" inner diameter in the proximal and distal regions.

The Microcatheter lumen is able to accommodate steerable guide wires. A lubricious, hydrophilic coating is applied to the distal 80cm outer surface of all catheter configurations. The Microcatheter has a radio-opaque marker at the distal tip, located approximately 1.3mm proximal of the distal limit of the tip, to facilitate fluoroscopic visualization. The proximal end of the Microcatheter incorporates a standard Luer adapter to facilitate the attachment of accessories.

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: None known

WARNINGS:

1. Due to contractual agreements, this Microcatheter is not for neurovascular use at or above the common carotid artery or at or above the vertebral artery.
2. This device is intended to be used only by physicians trained in percutaneous intravascular techniques and procedures.
3. Contents supplied sterile using an ethylene oxide (EtO) process. Do not use if sterile barrier is damaged.
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. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.
5. The infusion dynamic pressure with this Microcatheter should not exceed 800psi (5515 kPA). Infusion pressure in excess of this maximum may result in Microcatheter rupture, possibly resulting in patient injury. If flow through the Microcatheter becomes restricted, do not attempt to clear the Microcatheter lumen by infusion. The static pressure with this Microcatheter should not exceed 2068 kPa/300psi. Static pressure in excess of this maximum may result in Microcatheter rupture, possibly resulting in patient injury. Identify and resolve the cause of the blockage or replace the Microcatheter with a new Microcatheter before resuming infusion.
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. 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 injection pressure of 800psi (5515 kPA). Exceeding injection pressure beyond the maximum injection pressure may cause Microcatheter rupture. (See Instructions For Using a Power Injector)

PRECAUTIONS:

1. **℞ Only:** Federal law (U.S.A.) 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. Do not use opened or damaged packages. Use prior to the "use before" date. Store at controlled room temperature.

POTENTIAL COMPLICATIONS:

Possible complications include, but are not limited to:

Access site complications	Vascular thrombosis
Vessel perforation	Thrombis
Vessel Spasm	Ischemia
Hemorrhage	Infection
Pain and tenderness	Vessel Dissection
Embolism	Distal embolization
Allergic reaction	Death

TABLE 1: COMPATABILITY INFORMATION

Microcatheter O.D.	Nominal Microcatheter I.D.	Maximum Guide wire O.D.	Recommended guiding catheter
2.8F / 2.4F	0.020" (0.52mm)	0.018" (0.46mm)	0.040" (1.02mm) to 0.041" (1.04mm)
2.8F / 2.8F	0.024" (0.62mm)	0.021" (0.53mm)	0.040" (1.02mm) to 0.041" (1.04mm)
2.9F / 2.9F	0.027" (0.68mm)	0.021" (0.53mm)	0.042" (1.07mm) to 0.043" (1.09mm)
	EMBOLICS		
	Particles	Spherical	Coils
2.8F / 2.4F	≤ 700 um Emboli	≤ 700 um Microspheres	0.46mm / 0.018"
2.8F / 2.8F	≤ 700 um Emboli	≤ 700 um Microspheres	0.46mm / 0.018"
2.9F / 2.9F	≤ 900 um Emboli	≤ 900 um Microspheres	———

INSTRUCTIONS FOR USE: NOTE: It is recommended that the Microcatheter be used with a guiding catheter and a sheath introducer.

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. Remove the spiral holder housing the Microcatheter from its sealed 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 heparanized saline or sterile water will renew the hydrophilic effect.
5. Upon removal of the Microcatheter from the spiral holder, inspect Microcatheter to verify there is no damage prior to insertion.
6. Attach a second hemostasis valve with side-arm adapter to the Microcatheter, purge any air and flush with heparinized saline or sterile water.
7. Carefully insert guide wire into the Microcatheter and completely close the valve around the guide wire.
8. Introduce the Microcatheter and guide wire assembly into the guiding catheter via the hemostasis valve (if used). If rotating hemostatic valve is used, tighten the valve around the Microcatheter to prevent backflow, but allowing some movement through the valve by the Microcatheter.
9. 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.
10. 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.
11. Monitor Microcatheter placement and position during use.
12. To infuse, completely remove the guide wire from the Microcatheter. Connect a syringe with infusate to the Microcatheter manifold 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 below. 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.

Flow Rate Tables

Merit Maestro Catheter Size Shaft/Tip	Usable Length (cm)	Contrast Media	Iodine Content (Mg/ml)	Viscosity (cP) at 37°C	MEDRAD Flow Setting Conditions With Linear Rise @ 0.3sec Flow Rate (ml/sec)	Volume (ml)	Actual Contrast Delivery ml/sec With Safety Pressure Setting of: 5515 kPA (800 psi)	Dead Space (Priming) Volume (ml)
2.8/2.4F	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
2.8/2.8F	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
2.9/2.9F	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 (800psi)
4. Flow scale: ml/sec
5. Linear rise seconds: 0.3 sec.

Radiopaque marker

Maximum guide wire

Maximum pressure

Non-pyrogenic

Do not use if packaged is damaged

Syringe accuracy ±5%

MERITMEDICAL®

CE 0086

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