SwiftNINJA® Steerable Microcatheter

INSTRUCTIONS FOR USE

DESCRIPTION:

The Merit SwiftNINJA® is a microcatheter with a steerable/articulating distal tip. Articulation is achieved via a steering dial at the proximal handle which allows the operator to manipulate the tip up to 180 degrees in opposing directions. The steering dial and steerable tip are connected via two operating wires. The wires are located on both lateral walls of the microcatheter shaft with a connection point on the distal microcatheter. Tension is applied to either one of the wires by turning the steering dial for manipulation of the tip direction. Once the direction of steerable tip is determined, the steering dial lock may be used for maintaining the intended direction.

The microcatheter lumen is able to accommodate steerable guide wires. A hydrophilic coating is applied to the distal 80 cm microcatheter surface. The microcatheter has two radiopaque marker bands, the first located approximately 0.5 mm proximal to the distal tip and the second approximately 14 mm from the distal tip. The marker bands facilitate fluoroscopic visualization. The proximal end of the microcatheter incorporates a standard Luer adapter for attachment of accessories.

INDICATIONS FOR USE:

The microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the sub selective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. The microcatheter should not be used in the cerebral vessels.

CONTRAINDICATIONS:

None known

WARNINGS:

1. This device is intended to be used only by physicians trained in percutaneous intravascular techniques and procedures. Operators should be well trained in microcatheter use and embolization procedures.
2. Advancement of the microcatheter beyond the guide wire may result in vessel trauma.
3. If any abnormality is observed in the microcatheter movement or if the steerable tip is inserted into a location other than the target site, stop the procedure immediately. Identify the position of the steerable tip and the cause of the miss-direction under fluoroscopy. Reposition the microcatheter if necessary. Should the abnormality still remain, stop insertion, relieve any tension on the steerable tip by unlocking the steering dial lock and articulate to a straight tip via the steering dial. Carefully remove all the devices including microcatheter from the vessel to prevent vessel or product damage. Inspect the microcatheter and identify problem. If the microcatheter remains damage free reinsert and resume procedure. Otherwise replace the microcatheter and resume procedure.
4. The infusion dynamic pressure with this microcatheter should not exceed 6,900 kPa/1,000 psi. 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 2,068 kPa/300 psi. 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.
5. Avoid passing the microcatheter through a metal lumen such as a stent if possible. If used with metal, use caution during advancement to ensure that the microcatheter does not come in contact with the metal which may damage the coating and/ or decline the lubricity.
6. Do not use a guide wire to help insert embolic material(s). Otherwise, it may cause entrapment of the guide wire between the lumen of microcatheter and the embolic material(s) and lead to failure of embolization.
7. In the event of catheter fracture or separation in the vasculature, stop the procedure immediately. Carefully remove all catheters and devices, including the guiding catheter. Confirm that there is no catheter residue in the vessels under fluoroscopy. In some cases, residue of microcatheter shaft could remain in the stopcock of the guiding catheter because of operation of the stopcock during insertion.
8. In the event that expansion of the microcatheter wall is observed during injection of medication, contrast media, or embolics into the microcatheter by syringe or injector, stop the procedure immediately. Otherwise, the microcatheter may fracture. If any air bubbles are observed in the connector of the microcatheter, remove all air bubbles with a syringe etc. Otherwise, this may lead to risk of air embolism in the vessels. Replace the microcatheter with a new microcatheter prior to proceeding.
9. If any unexpected resistance is felt or if flow through the microcatheter becomes restricted during administration or insertion of embolic materials, medications, or contrast media do not attempt to clear the microcatheter lumen by forced infusion. Identify and resolve the cause of the blockage or replace the microcatheter with a new microcatheter before resuming infusion, otherwise damage to the vessel or product can occur.
10. The static pressure with this microcatheter should not exceed 2,068 kPa/300 psi. Static pressure in excess of this maximum may result in microcatheter rupture, possibly resulting in patient injury.
11. Contents supplied sterile using an ethylene oxide (ETO) process.
12. Sterile if package is unopened and undamaged.
13. 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.
14. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.
15. 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 kinking and/or damage of the microcatheter system.
16. 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 6,900 kPa/1,000 psi. Exceeding injection pressure beyond the maximum dynamic injection pressure may cause microcatheter rupture. (See Instructions for Using a Power Injector)
17. Do not immerse, apply, or wipe microcatheter in any medication containing an organic solvent such as alcohol for disinfection. Otherwise, it may cause damage to product and/or loss of lubricity.
18. If a guiding catheter with a stopcock is used, do not operate the stopcock during insertion of microcatheter, otherwise, damage or fracture may occur.
19. Do not attempt to manually pre shape the microcatheter tip by heat, a metal shaping tool, pinching, bending or crushing, otherwise, breakage of steerable tip and/or decline in articulation may occur.
20. Do not operate the steerable tip while a guide wire is positioned distal to the microcatheter tip, otherwise, vascular damage and/ or breakage of wire tip or microcatheter tip may occur.

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, occluded, or directed toward the vessel wall.
5. The microcatheter has a lubricious hydrophilic coating on the outside of the microcatheter. 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. 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. Because the microcatheter may be advanced into narrow sub selective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal.
11. Excessive tightening of a hemostatic valve onto the microcatheter shaft may result in damage to the microcatheter.
12. Read and follow the manufacturer's IFU for diagnostic, embolic, or therapeutic agents to be used with this microcatheter.
13. Do not use opened or damaged packages.
14. Use prior to the "use before" date.
15. Store at controlled room temperature.
16. Before injecting medication and/or contrast media into the microcatheter by syringe or injector, make sure that the two connectors are securely attached to each other. If using a mechanical injector utilize a connection tubing rated to the maximum pressure rating 6,900 kPa/1,000 psi otherwise, it may cause leakage of medication and/or contrast media, and/or damage to the syringe, injector, and/or microcatheter.
17. Do not administer or insert embolic materials, medication, and contrast media etc. with pressure, or insert a guide wire into microcatheter if the microcatheter shaft is kinked or twisted. Otherwise, it may cause damage to microcatheter.
18. Exchange microcatheters frequently during lengthy procedures that require extensive manipulation or multiple guide wire exchanges.
19. Do not rotate the microcatheter more than 5 full rotations in the straight position if the tip does not rotate as microcatheter damage may occur.

POTENTIAL COMPLICATIONS:

Possible complications include, but are not limited to:

Access site complications	Vessel occlusion	Aneurysm
Embolism	Vessel Spasm	Pseudoaneurysm
Vessel perforation	Ischemia	Blood pressure fluctuation
Pain and tenderness	Hemorrhage	Irregular heart rhythms
Infection	Vessel Dissection	Thrombis
Shock	Allergic reaction	Death
Distal embolization	Vascular thrombosis	

PREPARE THE MICROCATHETER:

1. Using aseptic technique open microcatheter sealed packaging.
2. Attach a sterile syringe filled with heparinized saline solution to the luer lock fitting of the microcatheter holder.

3. Inject enough solution to wet the entire microcatheter surface to activate the hydrophilic coating. **Note:** The surface of the microcatheter may become dry after removal from the holder. Additional wetting with heparinized saline will renew the hydrophilic effect.
   a. Grasp microcatheter by hub and gently remove from transportation tubing.
   b. Upon removal of the microcatheter from the holder, inspect microcatheter to verify there is no damage prior to insertion.
4. Activate the steering /articulation feature by engaging the steering dial. Hold handgrip and gently pull the white steering dial toward the luer connector until an audible clicking sound is heard.

Note: Check that a clicking sound is heard and Steerable Tip moves appropriately

5. Image target vasculature through the guide catheter with contrast media to determine vasculature pathways and site for embolization.
6. Attach a hemostasis valve with side-arm adapter to the microcatheter, purge any air and flush with heparinized saline.
7. Carefully insert guide wire into the microcatheter and completely close the valve around the guide wire.

PROCEDURAL USE:

1. Properly clear and flush the guide catheter.
2. Make sure the microcatheter tip is straight, re-wet the microcatheter surface and introduce the microcatheter and guide wire assembly into the guiding catheter via the hemostasis valve (if used).
3. 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. **Note:** If resistance is encountered, stop and identify source of resistance prior to advancing microcatheter. **Note:** To facilitate microcatheter handling, the proximal portion of the microcatheter is uncoated to ensure a non-slip grip.
4. Using fluoroscopy, introduce the microcatheter assembly into the vascular system and advance the assembly to a selected vascular site. **Note:** To facilitate microcatheter handling, the proximal portion of the microcatheter is uncoated to ensure a non-slip grip.

POSITIONING OF MICROCATHETER WITH THE GUIDE WIRE:

1. If a guide wire was used to advance the catheter through the guide catheter lumen, pull back guide wire 30 cm or remove guide wire from the catheter prior to tip articulation for wireless manipulation.
2. 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.

3. Control the steerable tip by manipulating the steering dial while carefully advancing the microcatheter shaft forward through the vessels. Gradually check vessel morphology under fluoroscopy as you advance.
4. A tension limiter is built in the steering dial to prevent the articulation wires from being broken. Application of torque larger than specified activates the tension limiter, which makes the steering dial spin freely and generates a clicking sound. In that case, do not apply torque anymore because the steerable tip will not bend any further than specified.
5. If unexpected resistance is felt during movement of the microcatheter, stop movement, confirm positioning with contrast under fluoroscopy. Identify source of resistance. If the microcatheter is damaged, carefully remove all devices including the guiding catheter. Otherwise, breakage, separation and retention of the catheter and/or injury to the vessels can occur. **Note:** Pull wire back approximately 30 cm prior to attempting articulation of the microcatheter distal tip.
6. 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.
7. Confirm the guide catheter placement is closest to target embolization site. Reconfirm the vasculature pathway to the target embolization site. Under fluoroscopy, use the steering dial to carefully manipulate the microcatheter tip as necessary to reach the target embolization site.
8. If tip curve is desired, manipulate tip shape by rotating the steering dial until desired shape is achieved. Lock the tip curve into position by sliding the small white steering lock on the handle toward the luer connector. **Note:** Be sure to unlock the steering lock to release shape prior to attempting movement.
9. Confirm placement of the microcatheter with contrast injection to ensure the tip is not directed toward the vessel wall, prepare embolic materials or medications to be injected through the microcatheter.
10. Remove the guide wire from the microcatheter. Ensure the microcatheter lumen is open by injecting contrast to confirm final positioning. Utilizing standard techniques, inject materials to the target location until objective is met. **Note:** If any unexpected resistance is felt during administration or insertion of embolic materials, medication, and contrast media etc., do not forcibly continue the procedure. Exchange microcatheter for another one. Otherwise, it may cause injury to the vessels and/or the microcatheter.
11. To move or reposition the microcatheter, prior to attempting movement, UNLOCK the steering lock by sliding the lock toward the distal tip of the steering housing to relieve tension on the tip. Use steering dial to reposition tip until it is straight. Move the microcatheter as desired. **Note:** Make sure the microcatheter is completely cleared and flushed of contrast media and/or embolic materials before proceeding to next step.
12. Monitor the microcatheter placement and position continually during use.

POSITIONING OF MICROCATHETER WITHOUT THE GUIDE WIRE:

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. Manipulate the steering dial of the operating portion according to the vessel morphology and guide the steerable tip toward the target site. Monitor the microcatheter movement under fluoroscopy.
3. Control the steerable tip by manipulating the steering dial while carefully advancing the microcatheter shaft forward through the vessels. Gradually check vessel morphology under fluoroscopy as you advance.
4. A tension limiter is built in the steering dial to prevent the articulation wires from being broken. Application of torque larger than specified activates the tension limiter, which makes the steering dial spin freely and generates a clicking sound. In that case, do not apply torque anymore because the steerable tip will not bend any further than specified.
5. In the case where there is difficulty in reaching the target site, it is recommended to use a guide wire in combination with the microcatheter. It may enhance the vessel selectivity.
6. After reaching the target site, administer and/or inject an embolic material, medication, and/or contrast media through the connector.
7. To complete the procedure, manipulate the steering dial to free the steerable tip from any tension and straighten its curve. Do not continue to hold the dial.
8. Carefully remove the microcatheter under fluoroscopy. Otherwise, it may cause breakage of microcatheter and/or damage to vessels.

INSTRUCTION FOR USING A POWER INJECTOR WITH THE MICROCATHETER:

A power injector can be used to infuse a contrast media through the microcatheter using the recommended flow rates in table 1. 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

			Linear Rise Setting 0.3 sec			Actual Contrast Delivery mL/sec with Safety Pressure setting of		
Merit SwiftNINJA Microcatheter Size Shaft/Tip	Usable Length (cm)	Contrast Media	Iodine Content (Mg/mL)	Viscosity (cP) at 37°C	Flow Rate (mL/ sec)	Volume (mL)	6,900 kPA (1,000 psi)	Dead Space (Priming volume) (mL)
2.9F/2.4F	125	Isovue (Iopamidol)	300	4.7	6.0	10	5.2	0.49
2.9F/2.4F	125	Isovue (Iopamidol)	370	9.4	3.0	10	2.2	0.49

REFERENCE DATA

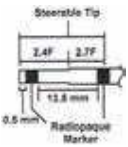
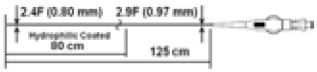
1. Injector used: MEDRAD MARK V
2. Contrast Media temperature: 37°C
3. Injection pressure monitor/ limit setting: 6,900 kPa/1,000 psi
4. Flow scale: mL/sec
5. Linear rise seconds: 0.3 sec.

COMPATIBILITY INFORMATION

Catalog Number	I.D. Inches & (mm)	O.D. Proximal (F/mm)	OD Distal (F/mm)	Max Guide wire	Max Microsphere size	Max Coil Size	Recommended Guide	Cath Vol.
MIV-20500	0.021″ (0.54 mm)	2.9F (0.97 mm)	2.4F (0.80 mm)	0.018″ (0.46 mm)	700 µm	0.018″	0.042" - 0.043" (1.07 mm - 1.09 mm)	0.49 mL

EMBOLIC SIZING

Particles	Spherical	Coils
≤ 710 µm Embolic	≤ 700 µm Microsphere	0.018″/ 0.46 mm

	Do not use if packaged is damaged
	Maximum Guide Wire
	Maximum Inner Diameter
	Non-pyrogenic
	Maximum Pressure
	Steerable Tip Radiopaque Marker Placement
	Hydrophilic Coated

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