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. Applying tension to either one of the steering wires by turning the steering dial manipulates the tip direction. Once the direction of the steerable tip is determined, the steering dial lock may be used for maintaining the intended direction.

A hydrophilic coating is applied to the distal microcatheter surface. The microcatheter has radiopaque marker bands to 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.

CLINICAL BENEFITS

The Clinical Benefit of the SwiftNINJA Steerable Microcatheter is that the steerable tip may be articulated in vivo to access sub selective vasculature to infuse diagnostic, embolic, or therapeutic materials into the vessels. The ability to navigate through the vasculature without a guidewire and to articulate the catheter tip in vivo may help decrease procedure and fluoro time.

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 stop the procedure immediately. Identify the position of the steerable tip and the cause of the abnormality under fluoroscopy. Reposition the microcatheter if necessary. Should the abnormality 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 the microcatheter from the vessel to prevent vessel or product damage. Inspect the microcatheter and identify the problem. If the microcatheter remains damage free, reinsert and resume procedure. Otherwise replace the microcatheter and resume procedure.

4. Do not use a power injector to infuse agents other than contrast media, as the microcatheter may become blocked. The safety setting of the injection pressure must not exceed the maximum dynamic injection pressure. Exceeding the 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)

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 contact the metal. Contacting the metal may damage the coating and/ or decrease 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 the microcatheter and the embolic material(s) and lead to failure of embolization.

7. In the event of microcatheter fracture or separation in the vasculature, stop the procedure immediately. Carefully remove all catheters and devices, including the guiding catheter. Under fluoroscopy, confirm that there is no catheter residue in the vessels. In some cases, residue of the microcatheter shaft could remain in the guiding catheter.

8. If any air bubbles are observed in the microcatheter, remove all air bubbles with a syringe etc. prior to proceeding. Otherwise, this may lead to risk of air embolism in the vessels.

9. 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.

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

11. Make sure the guiding catheter does not slip out of the vessel while the microcatheter and/or the guide wire is inside it. If this were to happen, kinking and/or damage of the microcatheter system could occur.

12. Do not immerse, apply, or wipe the microcatheter in anything containing an organic solvent such as alcohol for disinfection. Otherwise, it may cause damage to product and/or loss of lubricity.

13. Do not attempt to shape the tip by any means other than the steering dial. Otherwise, breakage of the steerable tip and/or decline in articulation may occur.

14. Do not operate the steerable tip while a guide wire is positioned distal to the microcatheter tip, otherwise, vascular damage and/or breakage of the guide wire tip or microcatheter tip may occur.

15. 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. **RX 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 procedure 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.

11. 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.

12. Excessive tightening of a hemostatic valve onto the microcatheter shaft may result in damage to the microcatheter.

13. Read and follow the manufacturer's IFU for diagnostic, embolic, or therapeutic agents to be used with this microcatheter.

14. Store at controlled room temperature.

15. Before injecting diagnostic, embolic or therapeutic materials into the microcatheter by syringe or injector, make sure that the connections are securely attached to each other. If using a mechanical injector, utilize a connection tubing rated to the maximum pressure rating of the microcatheter, otherwise, it may cause leakage of diagnostic, embolic or therapeutic materials, and/or damage to the syringe, injector, and/or microcatheter.

16. Do not administer or insert diagnostic, embolic or therapeutic materials etc. with pressure, or insert a guide wire into the microcatheter if the microcatheter shaft is kinked or twisted. Otherwise, it may cause damage to the microcatheter.

17. Exchange microcatheters frequently during lengthy procedures that require extensive manipulation or multiple guide wire exchanges.

18. 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

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

- Embolism
- Hemorrhage
- Infection
- Ischemia
- Vascular thrombosis
- Vessel dissection
- Vessel perforation
- Vessel spasm

TABLE 1: COMPATIBILITY INFORMATION

MICROCATHETER OD	MICROCATHETER ID	MAXIMUM GUIDE WIRE OD	MINIMUM GUIDING CATHETER ID
2.6F/2.4F	0.021" (0.54 mm)	0.018" (0.46 mm)	0.038" (0.97 mm)
2.9F/2.4F	0.021" (0.54 mm)	0.018" (0.46 mm)	0.042" (1.07 mm)
EMBOLICS			
MICROCATHETER OD	**MAXIMUM PARTICLE SIZE**	**MAXIMUM SPHERICAL SIZE**	**MAXIMUM COIL SIZE**
2.6F/2.4F	≤ 710 µm	≤ 700 µm	≤ 0.018" (0.46 mm)
2.9F/2.4F	≤ 710 µm	≤ 700 µm	≤ 0.018" (0.46 mm)

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

INSTRUCTIONS FOR USE

PREPARE THE MICROCATHETER

1. Using aseptic technique, open the microcatheter sealed packaging.

2. Remove the SwiftNINJA including the microcatheter holder and lay them on the table.

3. Attach a sterile syringe filled with heparinized saline solution to the luer lock fitting of the microcatheter holder.

4. 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.

5. Remove the information card in the microcatheter hub.

6. Activate the steering /articulation feature by engaging the steering dial. Hold the 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. **Note**: If the steering dial is not engaged prior to rotating the steering dial, the steering wires may become damaged or broken.

7. Grasp the microcatheter by the hub and gently remove from the microcatheter from the microcatheter holder by pulling it straight out of the holder.

8. Upon removal of the microcatheter from the holder, inspect the microcatheter to verify there is no damage prior to insertion.

9. With the catheter straight, check that the steerable tip rotates appropriately by turning the steering dial in both directions. **Note**: 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. If a clicking sound is heard, stop applying torque because the steerable tip will not bend any further than specified.

10. Attach a syringe filled with heparinized saline to the hub of the microcatheter and flush the lumen of the microcatheter with enough solution to purge the air from inside the microcatheter.

11. If desired, carefully attach a hemostasis valve with side-arm adapter to the microcatheter. Flush with heparinized saline to purge air from the system.

12. If used, carefully insert a guide wire into the microcatheter and tighten the valve around the guide wire to prevent backflow, but allowing some movement through the valve by the guide wire.

PROCEDURAL USE

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. Properly clear and flush the guide catheter.

3. Make sure the microcatheter tip is straight, re-wet the microcatheter surface and introduce the microcatheter and guide wire (if used) assembly into the guiding catheter via the hemostasis valve (if used). **Note**: If resistance is encountered, stop, and identify the source of resistance prior to advancing the microcatheter.

4. If a rotating hemostatic valve is used on the guiding catheter, tighten the valve around the microcatheter to prevent backflow, but allowing some movement through the valve by the microcatheter.

POSITIONING OF THE MICROCATHETER WITH A GUIDE WIRE

1. 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.

2. To enhance vessel selectivity, the tip of the microcatheter may be articulated to help cannulate vessels. Pull the guide wire into the microcatheter so the guide wire is proximal to the most proximal marker band or remove guide wire from the microcatheter prior to tip articulation for wireless manipulation. **Warning**: Do not operate the steerable tip while a guide wire is positioned distal to the microcatheter tip, otherwise, vascular damage and/or breakage of the guide wire tip or microcatheter tip may occur.

3. Articulate the tip and lock the tip curve in position by sliding the small white steering lock on the handle toward the luer connector. Then advance the guide wire out the microcatheter into the vessel. **Note**: 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. If a clicking sound is heard, stop applying torque because the steerable tip will not bend any further than specified. **Note**: Unlock the steering lock and release the tip shape before advancing the microcatheter. Failure to do so could damage the vasculature. **Note**: Unlock the tip curve position before articulation as this may damage or break the locking mechanism. **Note**: When unlocking the microcatheter, it may be helpful to hold the steering dial to maintain the catheter curve. Once the catheter tip is unlocked, rotate the steering dial slowly to reduce the catheter curve. This will help prevent the microcatheter tip from straightening too quickly. Otherwise, the guide wire and/or microcatheter may be pulled out of the selected vessel.

4. If unexpected resistance is felt during movement of the guide wire and/or microcatheter, stop movement, confirm positioning with contrast under fluoroscopy. Identify the source of resistance. If the microcatheter is damaged, carefully remove all devices including the guiding catheter. Otherwise, breakage, separation, and embolism of the catheter and/or injury to the vessels can occur.

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

6. Remove the guide wire rom the microcatheter. If a tip curve is desired, manipulate the tip shape by rotating the steering dial until the desired shape is achieved. Lock the tip curve in position by sliding the small white steering lock on the handle toward the luer connector. **Note**: Unlock the steering lock and release the tip shape prior to advancing the microcatheter. Failure to do so could damage the vasculature. **Note**: Unlock the tip curve position before articulation as this may damage or break the locking mechanism. **Note**: When unlocking the microcatheter, it may be helpful to hold the steering dial to maintain the catheter curve. Once the catheter tip is unlocked, rotate the steering dial slowly to reduce the catheter curve. This will help prevent the microcatheter tip from straightening too quickly. Otherwise, the guide wire and/or microcatheter may be pulled out of the selected vessel.

7. Confirm placement of the microcatheter with contrast injection to ensure the tip is not directed toward the vessel wall, prepare diagnostic, embolic or therapeutic materials to be injected through the microcatheter.

8. 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 diagnostic, embolic, or therapeutic materials etc., do not forcibly continue the procedure. Exchange the microcatheter for a new one. Otherwise, it may cause injury to the vessels and/or damage the microcatheter.

9. To move or reposition the microcatheter, UNLOCK the steering lock by sliding the lock toward the distal tip of the steering housing to relieve tension on the tip. Use the steering dial to reposition the tip until it is straight. Move the microcatheter as desired. **Note**: Unlock the steering lock and release the tip shape prior to advancing the microcatheter. Failure to do so could damage the vasculature. **Note**: Unlock the tip curve position before articulation as this may damage or break the locking mechanism. **Note**: When unlocking the microcatheter, it may be helpful to hold the steering dial to maintain the catheter curve. Once the catheter tip is unlocked, rotate the steering dial slowly to reduce the catheter curve. This will help prevent the microcatheter tip from straightening too quickly. Otherwise, the microcatheter may be pulled out of the selected vessel. **Note**: Make sure the microcatheter is completely cleared and flushed of embolic or therapeutic materials before repositioning or removing the microcatheter.

10. Monitor the microcatheter placement and position continually during use.

POSITIONING OF THE MICROCATHETER WITHOUT A GUIDE WIRE

1. Using fluoroscopy, introduce the microcatheter into the vascular system. Advance the microcatheter to a selected vascular site.

2. Control the steerable tip by manipulating the steering dial while carefully advancing the microcatheter shaft forward through the vessels. Monitor vessel morphology, and microcatheter movement under fluoroscopy as you advance. **Note**: 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.

3. 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.

4. If unexpected resistance is felt during movement of the microcatheter, stop movement, confirm positioning with contrast under fluoroscopy. Identify the source of resistance. If the microcatheter is damaged, carefully remove all devices including the guiding catheter. Otherwise, breakage, separation, and embolism of the catheter and/or injury to the vessels can occur.

5. Final positioning is accomplished by short advances of the microcatheter until the desired position is achieved and confirmed by fluoroscopic visualization.

6. If a tip curve is desired, manipulate the tip shape by rotating the steering dial until the desired shape is achieved. Lock the tip curve in position by sliding the small white steering lock on the handle toward the luer connector. **Note**: Unlock the steering lock and release the tip shape prior to advancing the microcatheter. Failure to do so could damage the vasculature. **Note**: Unlock the tip curve position before articulation as this may damage or break the locking mechanism. **Note**: When unlocking the microcatheter, it may be helpful to hold the steering dial to maintain the catheter curve. Once the catheter tip is unlocked, rotate the steering dial slowly to reduce the catheter curve. This will help prevent the microcatheter tip from straightening too quickly. Otherwise, the guide wire and/or microcatheter may be pulled out of the selected vessel.

7. Confirm placement of the microcatheter with contrast injection to ensure the tip is not directed toward the vessel wall, prepare diagnostic, embolic or therapeutic materials to be injected through the microcatheter.

8. 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 diagnostic, embolic or therapeutic materials etc., do not forcibly continue the procedure. Exchange the microcatheter for a new one. Otherwise, it may cause injury to the vessels and/or damage the microcatheter.

9. To move or reposition the microcatheter, UNLOCK the steering lock by sliding the lock toward the distal tip of the steering housing to relieve tension on the tip. Use the steering dial to reposition the tip until it is straight. Move the microcatheter as desired. **Note**: Unlock the steering lock and release the tip shape prior to advancing the microcatheter. Failure to do so could damage the vasculature. **Note**: Unlock the tip curve position before articulation as this may damage or break the locking mechanism. **Note**: When unlocking the microcatheter, it may be helpful to hold the steering dial to maintain the catheter curve. Once the catheter tip is unlocked, rotate the steering dial slowly to reduce the catheter curve. This will help prevent the microcatheter tip from straightening too quickly. Otherwise, the microcatheter may be pulled out of the selected vessel. **Note**: Make sure the microcatheter is completely cleared and flushed of embolic or therapeutic materials before repositioning the microcatheter.

10. Monitor the microcatheter placement and position continually during use.

INSTRUCTION FOR USING A POWER INJECTOR WITH THE MICROCATHETER

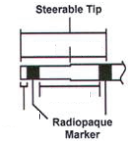
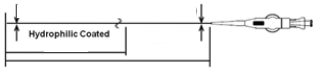
A power injector can be used to infuse a contrast media through the microcatheter using the recommended flow rates in table 1. The flow rate depends upon such factors as the viscosity of the contrast media, which varies with the type and temperature of the media, the model and setting of the power injector, and how the injector is connected to the microcatheter. The observed flow rate values indicated below are for reference only.

TABLE 2: FLOW RATES

Merit SwiftNINJA Microcatheter OD	Merit SwiftNINJA Microcatheter Usable Length (cm)	Contrast Media	Iodine Content (mg/mL)	Viscosity (cP) at 37° C	MEDRAD Flow Setting Conditions with Linear Rise @ 0.3 Sec				Dead Space (Priming Volume mL)
					Flow Rate (mL/Sec)	Volume (mL)	Pressure Setting	Actual Contrast Delivery (mL/Sec)	
2.6F/2.4F	125	Isovue (Iopamidol)	300	4.7	4.0	10	6900 kPa (1000 psi)	3.50	0.53
			370	9.4	2.0	5		2.03	
	150	Isovue (Iopamidol)	300	4.7	4.0	10	6900 kPa (1000 psi)	2.99	0.59
			370	9.4	2.0	5		1.92	
2.9F/2.4F	125	Isovue (Iopamidol)	300	4.7	6.0	10	6900 kPa (1000 psi)	5.2	0.49
			370	9.4	3.0	10		2.2	

REFERENCE DATA

1. Injector used: MEDRAD MARK V
2. Contrast Media temperature: 37°C
3. Flow scale: mL/sec
4. Linear rise seconds: 0.3 sec.

SYMBOL	DESCRIPTION
	Do not use if packaged is damaged
	Maximum Guide Wire
	Inner Diameter
	Non-pyrogenic
	Maximum Pressure
	Lock
	Unlock
	Steerable Tip Radiopaque Marker Placement
	Hydrophilic Coated
	Date of Manufacture YYYY-MM-DD
	Use By: YYYY-MM-DD
LOT	Lot Number
REF	Catalog Number
R_x ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single Use
	Do Not Resterilize
STERILE EO	Sterilized Using Ethylene Oxide
	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, call U.S.A or E.U. Customer Service
MD	Medical Device
	Manufacturer
UDI	Unique Device Identifier
	Single Sterile Barrier System
EC REP	Authorized Representative

SYMBOL	DESCRIPTION
	Unit of measurement
	For Patent Coverage, see www.merit.com/patents

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. The basic UDI-DI for the SwiftNINJA Steerable Microcatheter is 088445048754E7.

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