

ReCruit™ Microcatheter

Manufacturer
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Figure 1. ReCruit™ Microcatheter

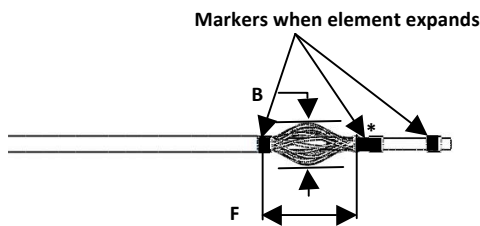
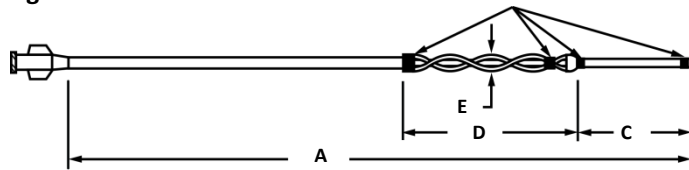
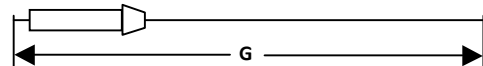


Figure 2. ReAct™ Stylet



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Device Description

The ReCruit™ Microcatheter consists of a flexible, tapered reinforced composite catheter with a braided mesh retrieval element attached to the distal region of the catheter. The inner lumen can accommodate a guidewire to aid in placement of the catheter. The catheter contains radiopaque markers to facilitate fluoroscopic visualization—a distal tip marker, markers at the proximal and distal end of the retrieval element, and circumferentially placed markers within the retrieval element. The retrieval element is deployed through the advancement of a guidewire or ReAct™ stylet through the lumen to radially expand the retrieval element. The selection of guidewire sizes in accordance with device compatibility allows for guidewires to be used for either retriever placement or for deployment of the element.

The proximal end of the catheter has a luer fitting to allow attachment of accessories and infusion of liquids through the catheter. The catheter is coated with a hydrophilic coating. The catheter is designed to be used with a guide catheter.

The catheter is offered in various retrieval element sizes to accommodate physician preferences.

The ReCruit™ Microcatheter can be used in vessel diameters ranging from 2mm to 4mm.

Each ReCruit™ Microcatheter may be packaged with a ReAct™ stylet and stylet handle. The ReAct™ stylet is a stainless steel wire with a platinum tip that may be used to activate the ReCruit Microcatheter’s retrieval element. The

ReAct™ stylet is provided in the same sterile pouch as the ReCruit™ Microcatheter.

Indications for Use

The ReCruit™ Microcatheter is designed for use with a guide catheter for the retrieval of intravascular foreign objects, such as coils, balloons, portions of catheter and/or loop wires misplaced during interventional radiological procedures in peripheral, neuro, and cardiovascular.

Potential Complications

Potential complications include, but are not limited to: hematoma at the site of entry, vessel perforation, emboli, hemorrhage, ischemia, vasospasm, and neurological deficits including stroke and death.

Precaution: To reduce the probability of coating damage in tortuous vasculature, wide lumen guide catheters are recommended for use with the ReCruit™ Microcatheter.

Compatibility

The ReCruit™ Microcatheter is compatible with the following catheters and guidewires:

- Guide catheters with minimum internal diameter 0.052 in.
- Neuro guidewires for navigation and activation as specified in table below.

Compatibility and product specifications:									
Model	Navigation Guidewire	Activation Guidewire	A (cm)	B (mm)	C (mm)	D (mm)	E (mm)	F (mm)	G (cm)
RCR214-3.0x15	0.014 in.	0.016 in.	160	3.0	8	15	1	10	180
RCR214-3.5x20	0.014 in.	0.016 in.	160	3.5	8	20	1	15	180
RCR214-4.0x25	0.014 in.	0.016 in.	160	4.0	8	25	1	20	180

Recommended Preparation Procedure

Continuous Flush

Precaution: In order to achieve optimal performance of the ReCruit™ Microcatheter, it is critical that a continuous infusion of appropriate flush solution be maintained between a) the guide catheter and the ReCruit™ Microcatheter, and b) the ReCruit™ Microcatheter and the guidewire during a procedure. Flushing aids in preventing contrast crystal formation and/or clotting on both the intraluminal device and inside the catheter lumen.

The recommended continuous flush setup as illustrated in Figure 3, requires two stopcocks, two rotating hemostatic valves (RHV) (Tuohy-Borst type), two flush lines and two 3 cc syringes. The RHVs provide a fluid tight seal and are attached to the guide catheter and ReCruit™ Microcatheter hub. The stopcocks attach to the RHV sidearm which becomes infusion ports for appropriate flush or contrast media injection.

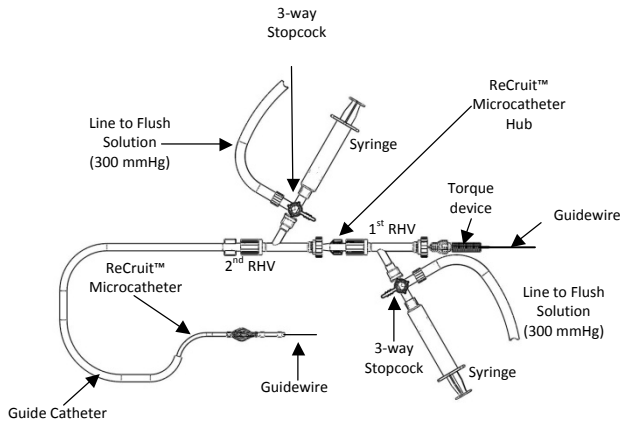


Figure 3. Example of Continuous Flush Setup

Warning

The radiopaque markers on the retrieval element and some components within the distal tip are platinum, which may be thrombogenic. It is suggested that anti-coagulants be administered when the risk of potential thrombus formation is unacceptable.

1. Connect flush-filled syringe to guide catheter RHV and flush its lumen to facilitate ReCruit™ Microcatheter insertion.
2. Attach stopcocks to sidearm of both RHVs.
3. Connect both RHVs to flush solution pressure bag. Pressure packs are convenient for this purpose. Maintain pressure above arterial pressure (approximately 300 mmHg) in order to prevent retrograde flow of blood into guide catheter or ReCruit™ Microcatheter.
Precaution: Check that all fittings are secure so that air is not introduced into guide catheter or infusion catheter during continuous flush.
4. Set up continuous flush by connecting 1st RHV to hub of ReCruit™ Microcatheter after removal from dispensing coil and after inspection. Connect 2nd RHV to guide catheter.

Removal of ReCruit Microcatheter from Dispenser Coil

The ReCruit™ Microcatheter is packaged inside a protective dispenser coil. Carefully open the sterile pouch and remove the ReCruit™ Microcatheter and the ReAct™ stylet still in its protective dispensing coils.

Precaution: Flush dispenser coil to minimize damage of the hydrophilic coating on the ReCruit™ Microcatheter prior to removal from dispenser coil. Once product is hydrated, do not allow to dry and do not reinsert product into dispenser coil.

1. Remove the hub of the ReCruit™ Microcatheter from the clip on the dispenser coil. Remove the entire ReCruit™ Microcatheter from the dispenser coil. Inspect device to ensure there is no evidence of bends, kinks, or other damage.
2. Attach 1st RHV to the ReCruit™ Microcatheter hub and gently tighten the o-ring on the RHV tight enough to stop leakage of flush solution but still allow movements of a guidewire. Flush the inner lumen with appropriate flush solution with a 3 cc syringe until fluid exits the distal region of the ReCruit™ Microcatheter.

Prepare Activation Guidewire

1. Prepare the activation guidewire according to the manufacturer’s instructions for use. Flush dispenser coil to minimize damage of the hydrophilic coating on the ReAct™ stylet prior to removal from dispenser coil.
2. Place the activation guidewire or ReAct™ stylet into the 1st RHV that is connected to the hub of the ReCruit™ Microcatheter and advance the guidewire until the tip of the guidewire meets resistance and cannot be advanced any further. This is the element activation location and when the activation guidewire or the ReAct™ stylet reaches this point the element will expand. Once the guidewire or the ReAct™ stylet is in the activated position, slide the torque device onto the proximal end of the guidewire and lock the torque device into position approximately 1 cm from the 1st RHV. Carefully inspect the retrieval element while gently pushing and pulling the guidewire or the ReAct™ stylet to verify that the retrieval element opens and closes and to verify that it is not damaged.

NOTE: When viewing the element under fluoroscopy the two middle marker bands will come together and be positioned at the distal end of the expanded element. See * in Figure 1.

Precaution: Observe all element movement in the vessels using fluoroscopy and contrast media.

3. The activation guidewire or ReAct™ stylet is now prepared.

Remove the activation guidewire or the ReAct™ stylet from the 1st RHV connected to the ReCruit™ Microcatheter. Set guidewire aside in an appropriate hydration solution.

Prepare Navigation Guidewire

1. Prepare the navigation guidewire according to the manufacturer’s instructions for use.
2. Insert the navigation guidewire into the 1st RHV connected to the ReCruit™ Microcatheter and advance the navigation guidewire until it extends beyond the tip of the ReCruit™ Microcatheter. Verify that the navigation guidewire moves freely within the ReCruit™ Microcatheter and that the element does not deploy while the navigation guidewire is positioned within the ReCruit™ Microcatheter.

Precaution: If resistance is felt or the element expands, this combination of devices should not be used. Verify that the navigation guidewire used is compatible with the ReCruit™ Microcatheter in accordance with the compatibility and product specifications chart.

Warning

Do not use the ReCruit™ Microcatheter or the ReAct™ stylet after the expiration date or if damaged in any way. Damage to the catheter, retrieval element, or stylet may cause vessel trauma or unpredictable element responses during navigation or retrieving maneuvers. Take care not to puncture gloves or sterile drapes when handling the ReCruit™ Microcatheter.

Warning

Do not reposition the activation wire’s torque device while the ReCruit™ Microcatheter is being used or position stylet handle with more than approximately 1 cm of space between

ReCruit™ Microcatheter

the RHV and and stylet handle. Doing so may cause excessive force to be applied to the distal junction of the basket causing damage to the device and can cause vascular damage or other patient injury.

Warning

Applying excessive activation force can cause serious vascular damage or other patient injury.

Flush Set up to ReCruit™ Microcatheter

1. Connect a drip line for the appropriate flush solution between the ReCruit™ Microcatheter and the guidewire using the stopcock attached to the 1st RHV on the on the ReCruit™ Microcatheter. In addition to providing a flushing port, the RHV provides a fluid tight seal between the ReCruit™ Microcatheter and guidewire or ReAct™ stylet.
2. Prepare the ReCruit™ Microcatheter for use by flushing with appropriate flush solution using a 3cc syringe.
3. Connect a drip line for the appropriate flush solution between the guide catheter and the ReCruit™ Microcatheter using the stopcock attached to the 2nd RHV on the on the guide catheter. In addition to providing a flushing port, the RHV provides a fluid tight seal between the guide catheter and the ReCruit™ Microcatheter.

Precaution: In order to achieve optimal performance of the ReCruit™ Microcatheter, it is critical that a continuous infusion of appropriate flush solution be maintained between a) the guide catheter and the ReCruit™ Microcatheter, and b) the ReCruit™ Microcatheter and guidewires or stylet during the procedure. Flushing aids in preventing contrast crystal formation and/or clotting on the guidewire or stylet and inside the catheter lumen. Inadequate flow can cause serious injury to the patient.

Warning

The ReCruit™ Microcatheter is compatible for use with contrast media, Heparin and Normal saline (0.9% Sodium Chloride Injection) at room temperature only. Use of other chemicals is not recommended.

Precaution: Check that all fittings are secure so that air is not introduced into a guide catheter or infusion during continuous flush.

Directions for Use

1. Place the appropriate guide catheter according to the guide catheter manufacturer’s instructions for use.
2. Carefully insert the ReCruit™ Microcatheter into 2nd RHV connected to the guide catheter and advance the ReCruit™ Microcatheter through the RHV of the guide catheter. Take care not to kink the ReCruit™ Microcatheter shaft. Tighten the RHV o-ring valve just enough to prevent back flow, but not enough to hinder movement of the ReCruit™ Microcatheter.

Precaution: Free movement of the guidewire or the ReAct™ stylet within the ReCruit™ Microcatheter is an important feature of the system. Whenever possible, test the system for resistance prior to use, and replace device if necessary.

Warning

Never advance, rotate or withdraw an endovascular device against resistance until cause of resistance is determined. Movement of ReCruit™ Microcatheter or guidewire or the ReAct™ stylet against resistance could dislodge a clot, perforate a vessel wall, cause vasospasm, or damage ReCruit™ Microcatheter or guidewire or the ReAct™ stylet. In severe cases, tip separation of ReCruit™ Microcatheter or guidewire may occur and this can cause vascular damage or other patient injury.

3. Using conventional catheterization techniques and fluoroscopic guidance, place the ReCruit™ Microcatheter into the selected target vessel by carefully manipulating the navigation guidewire within the ReCruit™ Microcatheter. The two can be moved together as a unit or independently.
4. Position the ReCruit™ Microcatheter with the retrieval element directly adjacent to and as close as possible to the object or foreign body to be retrieved.
5. Once positioned, remove the navigation guidewire from the ReCruit™ Microcatheter. Insert the activation guidewire into the ReCruit™ Microcatheter until the torque device approaches and is 1cm from the 1st RHV.
6. Slowly advance the torque device until the positioning marker bands are visualized on fluoroscopy and their movement towards each other is observed. Radial expansion of the element must be confirmed fluoroscopically by observing the radial expansion of four marker bands positioned at the center of the element. The element diameter should remain slightly smaller than the vessel diameter.
7. With the target object captured within the expanded element SLOWLY withdraw the activation guidewire torque device or the ReAct™ stylet handle to close the retrieval element and entrap the foreign object.
8. With foreign body securely captured SLOWLY and carefully withdraw the ReCruit™ Microcatheter and the ReAct™ stylet with the object captured to the guide catheter tip.
9. Withdraw the ReCruit™ Microcatheter and the object captured into the guide catheter and withdraw the whole system including the guide catheter.

Precaution: Do not attempt to remove the ReCruit™ Microcatheter with snared object by pulling through the guide catheter. The object may catch on the end of the guide catheter, separate from the retrieval element and return to the vasculature.

ADDITIONAL WARNINGS AND PRECAUTIONS

Precaution: Observe all element movement in the vessels using fluoroscopy and contrast media.

Warning

Before retrieval element is opened or moved, guidewire or ReAct™ stylet movement should be carefully monitored under fluoroscopy to prevent the possibility of vessel damage.

Warning

Never advance or withdraw an intraluminal device against resistance until the cause of resistance is determined by fluoroscopy.

Warning

If flow through the ReCruit™ Microcatheter becomes restricted, do not attempt to clear catheter lumen by infusion; remedy the cause of the blockage, or replace the blocked ReCruit™ Microcatheter before resuming procedure.

Warning

Pressure in excess of 100 psi may result in ruptured microcatheter.

Warning










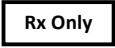
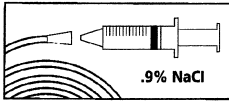
Dispose of used devices in accordance with established protocols for handling bio-hazardous materials.

- Use by “Use By” date
- Exposure to temperatures above 54°C (130°F) may damage device and accessories. Do not autoclave.
- Do not expose the device to solvents.

PACKAGING & STORAGE

- The ReCruit™ Microcatheter and the ReAct™ stylet are sterile and non-pyrogenic in unopened, undamaged packaging.
- Do not use open or damaged packages.
- Do not use if any portion of the ReCruit™ Microcatheter or the ReAct™ stylet appears damaged.
- Do not resterilize and reuse. Structural integrity and/or function may be impaired by reuse or cleaning.
- The ReCruit™ Microcatheter and the ReAct™ stylet is a delicate instrument and should be handled carefully. Do not use a device that shows signs of damage. Damage may prevent device from functioning and may cause complications.

Symbols Glossary

		Attention, see instructions for use	
	Do not reuse		Lot number
REF	Catalogue number		Contents
		Sterile (ethylene oxide)	
		Nonpyrogenic	
	Keep away from sunlight		Use By
	Prescription only- device restricted to use by or on order of a physician		
		Flush package hoop with saline before removing device	