Boston Scientific

Renegade™ STC 18

Microcatheter

Boston Scientific (Master Brand DFUTemplate 8in x 8in Global, 90106041AK) DFU, MB, Renegade STC 18, Global, 90961082-01A

Renegade™ STC 18

Microcatheter

℞ ONLY

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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single 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.

DEVICE DESCRIPTION

The Renegade STC 18 Microcatheter incorporates a taper in its outside diameter along its length from the 3.0F (1.00 mm) proximal stiff region to the 2.4F (0.80 mm) flexible distal region. The I.D. of the microcatheter is 0.021 in (0.53 mm) minimally in the proximal and distal regions. The microcatheter lumen is able to accommodate steerable guidewires that are ≤ 0.018 in (0.47 mm) in diameter. The outer surface of the microcatheter's distal segment is coated with Hydro Pass™ Hydrophilic Coating. The Renegade STC 18 Microcatheter has a radiopaque marker at the distal tip to facilitate fluoroscopic visualization. The distal tip of the microcatheter is steam shapeable. The proximal end of the microcatheter incorporates a standard luer adapter to facilitate the attachment of the accessories. A steam shaping mandrel and a rotating hemostatic valve (RHV) are included.

Table 1. Compatibility Information

Interface compatibility between the microcatheter and any accessory devices, or diagnostic, embolic or therapeutic agents should be carefully considered before use. Consult table below.

		EMBOLICS		
Guidewire	**Guiding Catheter**	**Coils**	**Particles**	**Spherical**
Max Dia. 0.018 in (0.47 mm)	Min. 0.96 mm (0.038 in) OD Guidewire compatible	0.018 in (0.47 mm)	≤ 500 Microns Results based on testing conducted using Contour™ PVA Embolic Particles	≤ 700 Microns Results based on testing conducted using Contour SE™ Microspheres

Contents

(1) Renegade STC 18 Microcatheter

(1) Rotating Hemostatic Valve

(1) Shaping Mandrel

INTENDED USE/INDICATIONS FOR USE

The Renegade STC 18 Microcatheter is intended for peripheral vascular use. The microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous 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. Diagnostic, embolic, therapeutic agents to be used in accordance with specifications outlined by the manufacturer.

CONTRAINDICATIONS

None Known.

WARNING

The infusion pressure with this microcatheter should not exceed 6895 kPa (1000 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 2070 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.

The Renegade STC 18 Microcatheter is not intended for use in the coronary vasculature or the neurovasculature.

PRECAUTIONS

- This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
- Prior to use, carefully examine the unit to verify that the sterile package or product has not been damaged in the shipment.
- Prior to a procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity.
- Inspect the microcatheter prior to use for any bends or kinks. Any catheter damage may decrease the desired performance characteristics.
- Exercise care in handling of the catheter during a procedure to reduce the possibility of accidental breakage, bending, or kinking.
- 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.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire against resistance may result in separation of the microcatheter or guidewire tip, damage to the microcatheter or guidewire tip, or vessel perforation.
- Extensive guidewire manipulation during lengthy procedures and the use of embolic agents may require the exchange of new microcatheters in place of the used microcatheters.
- 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.
- Excessive tightening of a hemostatic valve onto the microcatheter shaft may result in damage to the microcatheter.

ADVERSE EVENTS

The Adverse Events include, but are not limited to:

- Vessel trauma
- Embolism
- Hemorrhage/Hematoma
- Vasospasm
- Infection
- Air embolism
- Allergic reaction

CONTINUOUS FLUSH

To achieve optimal performance, it is recommended that continuous flow of appropriate flush solution be maintained between a) the Renegade STC 18 Microcatheter and guiding catheter, and b) the Renegade STC 18 Microcatheter and any intraluminal device. Continuous flushing aids in preventing contrast crystal formation and/or thrombosis on the intraluminal device and inside the guiding catheter and microcatheter lumens.

The recommended continuous flush set-up is shown in Figure 1.

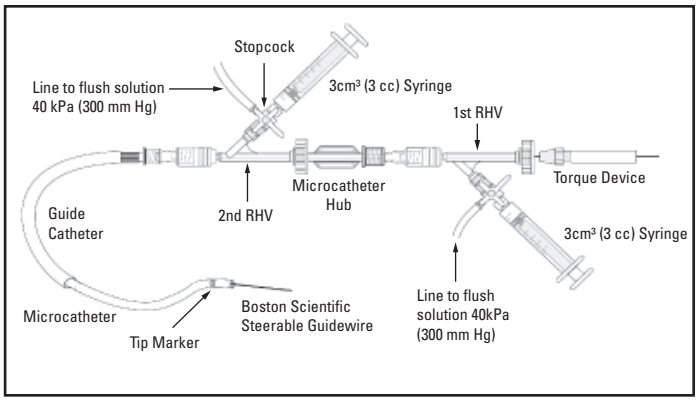

Figure 1. Example of Continuous Flush Setup

HOW SUPPLIED

Store in a cool, dry, dark place.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

PREPARATION FOR USE

For pre-curved microcatheters, gently remove shape retention mandrel prior to removing the microcatheter from carrying hoop.

Before removing the microcatheter from the carrier hoop, flush the carrier hoop with heparinized saline to activate the hydrophilic coating. The luer fitting attached to the carrier hoop may facilitate the flushing of the hoop. If difficulty in removing the product from the carrier hoop occurs, repeat injection or place in heparinized saline bath.

INSTRUCTIONS FOR USE

1. Flush the lumen of the catheter with heparinized saline and inspect for leaks.
2. Gently remove the microcatheter from the carrier hoop and inspect the catheter prior to use to verify that it is undamaged. (See Preparation For Use)
3. Carefully remove the guidewire from its packaging and prepare the guidewire according to manufacturer's instructions.
4. It is recommended that the Renegade™ STC 18 Microcatheter be used with a guiding catheter that is 0.96 mm (0.038 in) guidewire compatible (with a minimum internal diameter of 1.1 mm (0.042 in)) and a sheath introducer. A rotating hemostatic valve (Tuohy-Borst type) used in conjunction with the guiding catheter will provide a fluid-tight seal around the microcatheter.
5. Carefully insert and advance the guidewire into the microcatheter. A guidewire introducer may be used to facilitate the introduction of guidewires into catheter hubs or hemostatic valves.
6. Place the appropriate guiding catheter using standard technique. A rotating hemostatic valve may be connected to the guiding catheter luer adapter to continuously flush the guiding catheter with saline (a pressure pack is convenient for this purpose).
7. Introduce the microcatheter and wire assembly through the hemostatic valve. Tighten the valve around the microcatheter to prevent backflow, but allowing some movement through the valve by the microcatheter.
8. Advance the guidewire and microcatheter to a selected vascular site by alternately advancing the guidewire and then tracking the microcatheter over the guidewire.
9. To infuse, completely remove the guidewire from the microcatheter. Connect a syringe with infusate or introduce embolic materials to the microcatheter manifold luer, and infuse as required. The following are functional characteristics of flow through the microcatheter.

For all agents, please refer to manufacture's instructions for use.

Table 2. Operational Information

	Usable Length (cm)	Dead Space Volume ml (cc)	Max Infusion Pressure [kPa (psi)]	100% Non-Ionic Contrast 300 ml/sec
Renegade STC 105	105	0.36	6895 (1,000)	2.6
Renegade STC 130	130	0.42	6895 (1,000)	2.3
Renegade STC 150	150	0.48	6895 (1,000)	2.2

STEAM SHAPING MANDREL INSTRUCTION FOR USE

If desired, the tip of the microcatheter may be steam shaped using the steam shaping mandrel provided.

1. Insert the mandrel into the microcatheter's distal lumen and bend to the desired shape.
2. Shape catheter by holding mandrel/catheter assembly no closer than 25.4 mm (1 in) from a steam source. Multiple shaping is not recommended.
3. Cool tip in saline and remove the mandrel.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose**. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments**.