FLEX Scoring Catheter®

INSTRUCTIONS FOR USE

Identification of symbols used on product labeling:

	Catalogue Number – Reference Number
	Lot Number
	Do not Reuse – Single use
	Do not re-sterilize
	Sterile, Ethylene Oxide Gas
	Use by – Expiration
	Consult instructions for use
	Keep away from sun/heat
	Keep dry
	Do not use if package Is damaged
	US and foreign patents issued and pending
	Prescription use only
	VentureMedGroup, INC. 2865 N. Reynolds Road, Suite 220A Toledo, Ohio 43615 TEL: (419)-725-1001 www.venturemedgroup.com
	Authorized Representative: MedNet GmbH Borktraße 10 48163 Muenster, Germany

INSTRUCTIONS FOR USE

FLEX Scoring Catheter® or FLEX®

Catalog #:	Length	Anatomy
FSC 4-120	120 cm	Fem-pop
FSC 4-40	40 cm	AV fistulae

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

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE: FAILURE TO OBSERVE ALL WARNINGS AND PRECAUTIONS MAY RESULT IN COMPLICATIONS.

NOTE: These instructions apply to all FLEX Scoring Catheter® diameters and lengths.

STERILE: Sterilized with ethylene oxide gas. Non-pyrogenic. **DO NOT USE IF PACKAGE IS OPEN OR DAMAGED.**

CONTENTS: One (1) FLEX Scoring Catheter®

STORAGE: Store in a dark, dry, cool place.

I. DEVICE NAME

The device name is FLEX Scoring Catheter®.

II. DEVICE DESCRIPTION

The FLEX Scoring Catheter® is an over the wire sheathed catheter with a three strut scoring element near the distal tip. The sheath is retracted using the sheath actuator control on the catheter handle. The scoring element is expanded to engage plaque deposits on the arterial wall via the scoring basket actuator. A flushing port is located on the handle for flushing the device with saline prior to operation in the patient. The other lumen permits the use of a guidewire to facilitate advancement of the catheter to and through the stenosis to be scored. The product is offered on an over-the-wire (OTW) delivery platform.

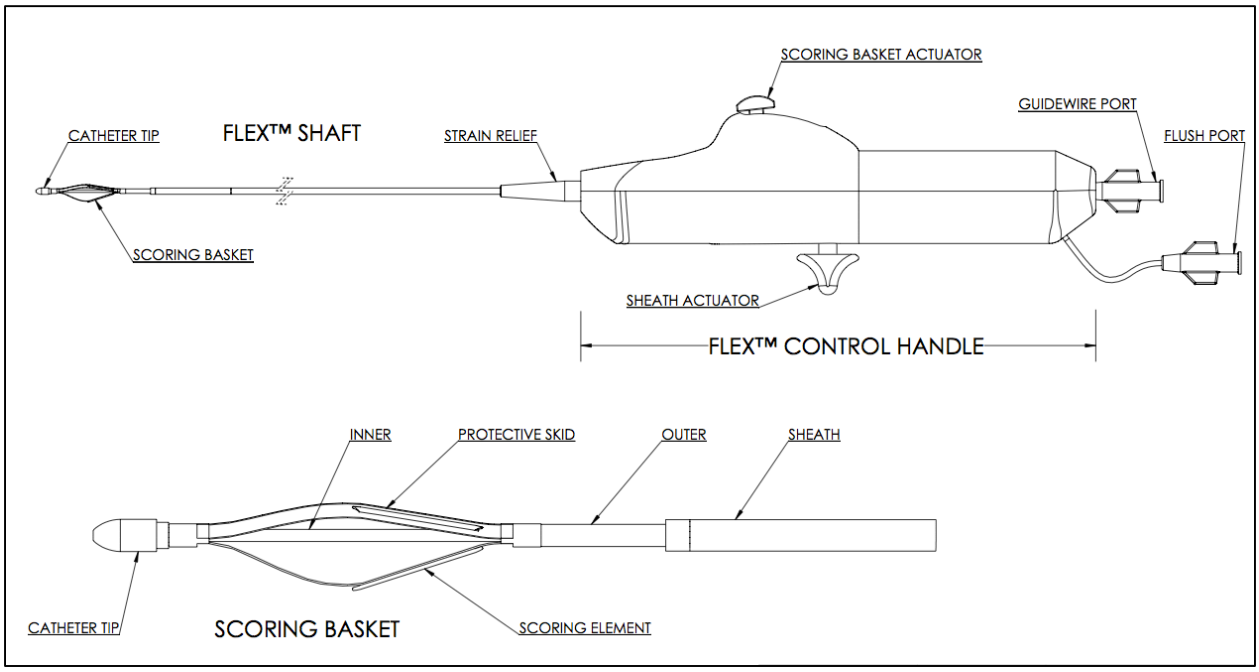
The distal end of the catheter contains the tri-element (three strutted) scoring elements. The struts create focal concentrations that glide along the arterial wall scoring plaque during the procedure and assisting in the luminal expansion of stenotic arteries.

The catheter has radiopaque markers at the distal end to aid in positioning the catheter.

The catheter is compatible with 0.018” and 0.014” guidewires and 6F introducer sheaths.

The device consists of three integrated components:

- FLEX® Control handle
  - Guidewire port
  - Flush port
  - Sheath actuator
  - Scoring basket actuator
- Catheter shaft
  - Distal tip
  - Scoring basket
- FLEX® scoring basket
  - Scoring arms (3)
  - Scoring element (3 each, one per arm)
  - Protective skid.



III. INDICATIONS

The FLEX Scoring Catheter® is intended for use with percutaneous transluminal angioplasty (PTA) catheters to facilitate dilation of stenoses in the femoral and popliteal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

IV. CONTRAINDICATIONS

Not for use in the cerebrovascular, coronary, renal or mesenteric vasculature.

V. WARNINGS

This device is intended for single (one) use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.

The expanded diameter of the scoring basket should approximate the inner diameter of the vessel just proximal and distal to the stenosis, in order to reduce potential vessel damage.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation.

WARNING: Never advance the catheter while the basket is expanded.

Do not advance or retract the catheter from the lesion site unless the basket is fully retracted into the catheter sheath. If resistance is met during deployment in the lesion, determine the cause of the resistance before proceeding.

Proceed with caution when using the FLEX Scoring Catheter® in or near a recently deployed bare metal stent or drug eluting stent. The FLEX® has not been tested for post-dilatation of stents or in lesions distal to freshly deployed stents in clinical studies. Use the catheter prior to the “Use Before” (expiration) date specified on the package.

VI. PRECAUTIONS

A thorough understanding of the principles, clinical applications and risks associated with PTA is necessary before using this product.

Any use for procedures other than those indicated in these instructions is not recommended.

This device is not recommended for use in reference vessel diameters smaller than 4.0mm

This device is not recommended for use in highly calcified lesions.

Do not use if package is opened or damaged.

Prior to scoring, the catheter should be examined to verify functionality, device integrity and to ensure that its size and length are suitable for the specific procedure for which it is to be used.

During and after the procedure, the appropriate anti-coagulants, anti-platelet agents and vasodilators should be administered to the patient according to the institutional practice for peripheral angioplasty of similar arteries.

Pass the FLEX® catheter through the recommended introducer sheath indicated on the product label.

VII. ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, the following:

- Arterial spasm
- Arterial dissection or perforation
- Embolism
- Thrombus
- Retained device components
- Hemorrhage or hematoma
- Arteriovenous fistula

VIII. MATERIALS REQUIRED FOR USE WITH THE FLEX SCORING CATHETER®:

WARNING: Use single use items only. Do not resterilize or reuse.

- Femoral introducer sheath:
  - $\geq$ 6 F
- Hemostatic valve
- Radiographic contrast medium
- Sterile heparinized normal saline
- 10-cc and 20-cc syringes for flushing and follow-on balloon prep
- Inflation device
- Guidewire:
  - 0.014” or 0.018” only
- Guidewire introducer
- Guidewire torque device
- Manifold (for pressure monitoring and contrast injection), extension pressure tubing

IX. INSTRUCTIONS FOR USE

Prior to use of the FLEX Scoring Catheter®, carefully examine for damage and confirm device integrity. Do not use if catheter has bends, kinks, missing components or other damage. Do not use if inner package is open or damaged.

1. Prepare the FLEX® device by irrigating the FLEX® guidewire port lumen with normal saline.
2. Irrigate FLEX® flush port with normal saline until normal saline is observed exiting at the catheter shaft distal tip.

3. Unsheathe FLEX® scoring basket by pulling back on the sheath actuator (bottom lever).
4. Pull back the scoring basket actuator (top lever) to ensure that the distal scoring basket expansion occurs.
5. Release scoring basket actuator.
6. Resheath FLEX® scoring basket by pushing sheath actuator forward.
7. Premedicate patients with anti-coagulants and vasodilators according to institutional protocol for PTA procedures.
8. Perform peripheral angiogram in the view best demonstrating the target lesion prior to device deployment.
9. Utilizing standard fluoroscopic technique, the femoral arterial segment to be treated is crossed using standard technique and a 0.014" or 0.018" guidewire is positioned distally to the segment to be treated.
10. Embolic protection device may be deployed at the discretion of the operator.
11. The FLEX® catheter is loaded onto the guidewire and advanced distally past the area of the femoral popliteal artery to be treated.
12. The catheter sheath is retracted by pulling back on the sheath actuator, locking the sheath into place. A click verifies that the sheath is fully retracted, exposing the distal scoring basket. Freedom of the distal scoring basket is also ensured by movement of the radiopaque catheter shaft marker. Note: If the distal scoring basket is in a relatively undiseased portion of the artery with a lumen greater than 2 mm, the basket will be seen to have a degree of expansion under fluoroscopy.
13. The distal scoring basket actuator is pulled back towards the back part of the handle to allow for expansion of the distal scoring basket. This allows for the scoring elements to contact the arterial segment to be scored. More pronounced deflection of the thumb control towards the back of the handle allows for a larger diameter of the basket. Relaxation or forward deflection towards the front of the handle allows for a smaller diameter basket.

    Caution: To minimize lateral wall pressure and shear forces on the inner surface of the artery, use the smallest amount of force necessary to allow for contact of the scoring elements with the artery.
14. The device is withdrawn over the 0.018" guidewire, or 0.014" guidewire. The distal scoring basket actuator is either pulled back to increase the scoring basket diameter or deflected forward to decrease the scoring basket diameter. The appropriate basket diameter to allow contact with the arterial wall can also be determined by the fluoroscopic image of the basket diameter in reference to the native artery diameter. The scoring basket diameter is constantly adjusted as the device is withdrawn.

    Caution: If the device is not able to be withdrawn, the distal scoring basket actuator should be pushed forward to minimize basket diameter through that

segment of the artery. Advancing the sheath retraction mechanism towards the front of the handle can also recapture the scoring basket.

15. When the desired length of the diseased artery has been scored, the distal scoring basket actuator is advanced towards the front of the handle which allows the basket to decrease in size to attain its smallest diameter.
16. The sheath actuator is unlocked by advancing it toward the front of the handle. This also allows for capture and resheathing of the distal scoring basket.
17. Based on clinical judgment of the interventionalists, the device can once again be advanced distally passed the area to be treated. The handle can be rotated 30-90 degrees and steps 6 and 7 can be repeated a second time for a total of 6 longitudinal scorings, respectively.
18. The FLEX Scoring Catheter® is then removed by first re-sheathing the scoring basket, then withdrawing the catheter back through the introducer sheath over the guidewire, which is left in place.
19. The length of the artery that underwent scoring is subjected to standard balloon angioplasty. Balloon selection should be calibrated to the lesion length and reference vessel diameter.
20. Completion angiography is then performed to document vessel patency, luminal gain and absence of perforation, thrombosis or embolization.
21. Embolic protection devices are optional based on lesion characteristics and run-off assessment.
22. At the discretion of the operator, adjunct therapy to maintain adequate luminal gain can be used (balloon, stent).

X. REFERENCES

The physician should consult recent literature on current medical practice regarding arterial scoring, balloon dilatation and PTA procedures.

XI. DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

There is no expressed or implied warranty, including any implied warranty of merchantability or fitness for a particular purpose, on the FLEX® product(s) described in this publication. Under no circumstances shall VentureMed Group be liable for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has the authority to bind VentureMed Group to any representation or warranty except as specifically set forth herein.

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By Biomerics, Brooklyn Park, MN

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