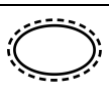
FLEX Vessel Prep™ System

INSTRUCTIONS FOR USE

Glossary of symbols used on labeling

Symbol	Description of the Symbol	Standard	Title of symbol and reference number
	Manufacturer's catalog number, so that the medical device can be identified	ISO 15223-1:2021	Catalog number (5.1.6)
	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021	Batch code (5.1.5)
	Indicates a medical device that is intended for one single use only	ISO 15223-1:2021	Do not reuse (5.4.2)
	Indicates a medical device that is not to be resterilized.	ISO 15223-1:2021	Do not resterilize (5.4.2)
	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1:2021	Sterilized using ethylene oxide (5.2.2)
	Indicates the date after which the medical device is not to be used.	ISO 15223-1:2021	Use-by date (5.1.4)
	Indicates the need for the user to consult the instructions for use.	ISO 15223-1:2021	Consult instructions for use (5.4.3)
	Indicates a medical device that needs protection from light sources.	ISO 15223-1:2021	Keep away from sunlight (5.3.2)
	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1:2021	Keep dry (5.3.4)
	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1:2021	Do not use if package is damaged (5.2.8)
	U.S. and Foreign Patents pending	Not Applicable	Not Applicable
	Prescription use only	21 CFR 801 Title 21 FDA Medical Devices Part 801 Labeling	801.109(b)(1)
	Indicates the medical device manufacturer VentureMed Group, Inc. 2800 Campus Drive Suite 50 Plymouth, Minnesota 55441 US TEL: (763)-951-0280 www.venturemedgroup.com	ISO 15223-1:2021	Manufacturer (5.1.1)
	Authorized Representative in the European Union MedNet EC-REP GmbH Borkstraße 10 48163 Münster, Germany	ISO 15223-1:2021	Indicates the Authorized representative in the European Community (5.1.2)
	CE Marked per the Medical Device Directive 93/42/EEC of the European Union. The Notified Body is BSI (ID#2797)	MDD 93/42/EEC	Compliance with MDD 93/42/EEC
	Indicates a single sterile barrier system with protective packaging outside	ISO 15223-1:2021	Single sterile barrier system with protective packaging outside (5.2.14)
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1:2021	Caution (5.4.4)
	Indicates the item is a medical device	ISO 15223-1:2021	Medical device (5.7.7)
	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021	Unique device identifier (5.7.10)

INSTRUCTIONS FOR USE

These instructions apply to all FLEX Vessel Prep System lengths listed below.

CONTENTS: One (1) FLEX Vessel Prep™ System.

REF	Length
FSC 4-120	120 cm
FSC 4-75	75 cm
FSC 4-40	40 cm

℞ ONLY: 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.

DO NOT USE IF PACKAGE IS OPEN OR DAMAGED, UNINTENTIONALY OPENED BEFORE USE, AND IF PACKAGING IS EXPOSED TO ENVIRONMENTAL CONDITIONS OUTSIDE OF STORAGE REQUIREMENTS.

STERILE EO Sterilized with ethylene oxide gas. Non-pyrogenic.

I. DEVICE NAME

The device name is FLEX Vessel Prep™ System.

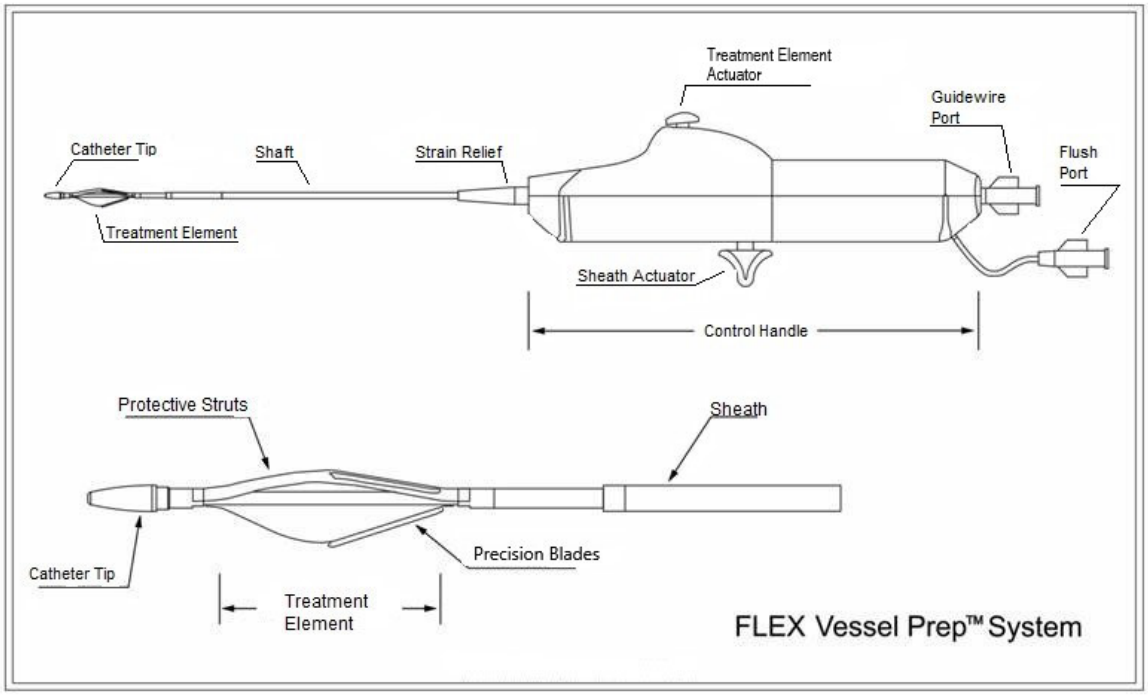


Figure 1

II. DEVICE DESCRIPTION/TECHNICAL DESCRIPTION

The FLEX Vessel Prep™ System™ is an over-the-wire sheathed catheter with a three-strut treatment element near the distal tip as shown in Figure 1.

The FLEX Vessel Prep™ System is advanced over a 0.014" or 0.018" guidewire until distal to the lesion to be treated. The Treatment Element is unsheathed and expanded. The Treatment Element consists of three independent flexible struts, each with a precision blade, mounted on the proximal end. As the device is pulled back in a retrograde fashion through the target lesion, the Treatment Element "flexes" providing continuous engagement along the lesion to create controlled-depth micro-incisions.

The Flex Vessel Prep™ catheter is available in 3 lengths, 120cm, 75cm, and 40cm. The device has a 2mm crossing profile and is compatible with 6 French introducer sheaths. It is recommended to use a 150 cm+ guidewire with the 40cm/75cm product and a 300cm guidewire with the 120cm product.

The device consists of three integrated components. The Control Handle, which contains a Guidewire Port for guidewire insertion, a Flush Port to flush with saline to remove air from the device, the Sheath Actuator and Treatment Element Actuator.

The Sheath Actuator is located on the flat surface of the handle below the word FLEX. When the Sheath Actuator is pulled back and held in place, the sheath covering the Treatment Element is retracted and the Treatment Element is exposed. A click verifies the sheath is fully retracted.

The Treatment Element Actuator is located on the curved aspect of the handle, above the word FLEX. When the Treatment Element Actuator is pulled back and held in place, the Treatment Element expands the 3 flexible struts of the Treatment Element.

The Reinforced Braided Shaft, which is enclosed within a clear polymer sheath, provides strength to enhance deliverability and torque performance of the device.

The distal end of the device contains a radiopaque marker to aid in positioning the catheter and the Treatment Element.

The Treatment Element as shown in Figure 2 consists of three precision blades, 10 thousandths of an inch (0.010") in height and mounted on the proximal end of each of the three independent flexible struts. The expansion of the Treatment Element allows the three precision blades to independently engage the lesion.

During the retrograde pull-back of the device, each strut of the protective Treatment Element "flexes" independently to provide continuous engagement along and through complex lesions to create controlled-depth micro-incisions along the length of the lesion. These micro-incisions modify the plaque in the lesion and enable dilatation of the target lesion using percutaneous angioplasty balloons at lower inflation pressures, minimizing barotrauma to the vessel.

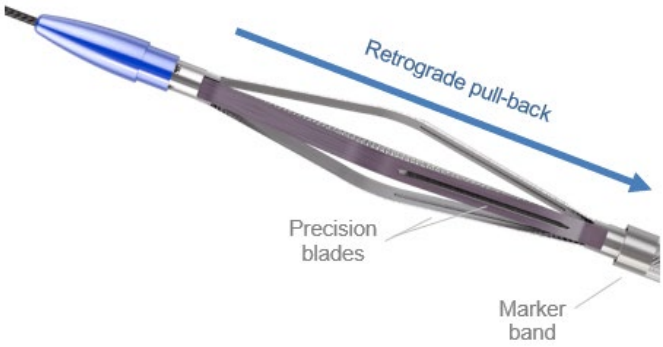


Figure 2

III. INDICATIONS FOR USE/INTENDED USE

The FLEX Vessel Prep™ System is indicated 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. The device also is indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature.

IV. CONTRAINDICATIONS

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

V. WARNINGS

Never advance the catheter while the Treatment Element is expanded.

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

The expanded diameter of the Treatment Element should approximate the reference vessel diameter to minimize the risk of vessel damage.

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

Do not advance or withdraw the device from the lesion site unless the Treatment Element 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 Vessel Prep™ System in or near a recently deployed bare metal stent or drug-eluting stent. The FLEX Vessel Prep™ System has not been tested for post-dilatation of stents or in lesions distal to freshly deployed stents in clinical studies.

Use the device 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 the package is opened or damaged.

Prior to use, the device 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 Vessel Prep™ System through the recommended introducer sheath indicated on the product label.

VII. ADVERSE EFFECTS/RESIDUAL RISKS

Possible adverse effects/residual risks include the following:

- Additional Intervention
- Arterial dissection or perforation
- Arteriovenous fistula
- Bleeding
- Delayed Procedure
- Embolism
- Hemorrhage or hematoma
- Pain and discomfort
- Patient Fever
- Patient Infection
- Patient Septicemia
- Patient Toxicity
- Prolonged Procedure
- Pseudo-Aneurysm
- Retained device components
- Surgery
- Thrombus
- User Dissatisfaction
- Vessel Trauma (includes Arterial spasm)

VIII. MATERIALS REQUIRED FOR USE WITH THE FLEX Vessel Preparation™ Catheter :

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

- Introducer sheath: 6 French
- Sterile heparinized normal saline (referred to as normal saline throughout IFU)
- 10-cc and 20-cc syringes for flushing
- Guidewire: 0.014" or 0.018" only
- Other equipment, as needed, for interventional procedures

IX. INSTRUCTIONS FOR USE

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

1. Prepare the FLEX Vessel Prep™ System by irrigating the Guidewire Port with normal saline. Observe fluid exiting the blue catheter tip.

2. To irrigate the Flush Port, pull back on the Sheath Actuates to expose the Treatment Element. A click verifies the Sheath is fully retracted. Attach the syringe to the Flush Port and irrigate with normal saline until fluid is observed exiting at the distal tip of the catheter shaft.

3. Un-sheath the Treatment Element by pulling back on the Sheath Actuator.

4. Pull back the Element Actuator to ensure Treatment Element expansion occurs.

5. Release Element actuator.

6. Re-sheath the Treatment Element 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 VP™ catheter is loaded onto the guidewire and advanced distally past the area of the vessel to be treated.

12. The Sheath is retracted by pulling back on the Sheath Actuator, locking the Sheath into place. A click verifies the Sheath is fully retracted, exposing the Treatment Element. Freedom of the Treatment Element can be visually verified via fluoroscopy by ensuring the radiopaque marker is positioned proximal to and free of the Treatment Element.

    Note: If the Treatment Element is in a relatively non-diseased portion of the vessel with a lumen greater than 2 mm, the Treatment Element may be seen to have a degree of expansion under fluoroscopy as the Treatment Element engages the lesion.

13. The Treatment Element Actuator is retracted and held in place to allow for expansion of the Treatment Element. This allows the three Precision Blades mounted on Protective Struts to contact the vessel segment to create micro-incisions. More pronounced deflection of the Treatment Element Actuator towards the back of the Control Handle allows for a larger diameter of the Treatment Element. Relaxation or forward deflection towards the front of the Control Handle allows for a smaller Treatment Element.

    Caution: To minimize lateral wall pressure and shear forces on the inner surface of the vessel, use the smallest amount of force necessary to allow for contact of the Precision Blades with the vessel.

14. The device is slowly pulled back over the 0.018" guidewire, or 0.014" guidewire in a retrograde manner (~1-2mm/s). The Treatment Element Actuator controls the diameter of the Treatment Element. The appropriate diameter allows contact with the vessel wall, which can also be determined by the fluoroscopic image of the Treatment Element diameter relative to the native vessel diameter. The Treatment Element diameter adjusts as the device is pulled back.

    Note: During pullback, the Treatment Element may be seen flexing to accommodate the morphology of the stenosis. It is important to continue to hold both Actuators in place during the pullback and maintain visual verification that the Treatment Element remains free of the radiopaque marker. Otherwise, it is possible for the Sheath to recapture the Treatment Element preventing its expansion.

    Caution: If the device is not able to be pulled back, the Treatment Element Actuator should be pushed forward to minimize the Treatment Element diameter through that segment of the vessel. Advancing the Sheath Actuator towards the front of the Control Handle also can recapture the Treatment Element.

15. When the desired length of the diseased vessel has been incised, the Treatment Element Actuator is pushed forward/released which allows the Treatment Element to decrease in size to attain its smallest diameter.

16. The Sheath Actuator is unlocked by pushing it forward to capture and re-sheath the Treatment Element.

17. Based on the clinical judgment of the interventionalists, the device can once again be advanced distal to the area to be treated. The Control Handle can be rotated 30-90 degrees and steps 12 through 16 can be repeated a second time for a total of six longitudinal micro-incisions, respectively.

18. The FLEX Vessel Prep™ System is then removed by first re-sheathing the Treatment Element, then withdrawing the catheter back through the Introducer Sheath over the Guidewire, which is left in place.

19. Following completion of the procedures, angiography is performed to document vessel patency, luminal gain and absence of perforation, thrombosis, or embolization.

20. The length of the vessel that underwent the FLEX Vessel Preparation™ procedure is then ready for subsequent treatment at the discretion of the operator.

21. At the discretion of the operator, adjunct therapy to maintain adequate luminal gain can be used (PTA, stent). Selection should be calibrated to the lesion length and reference vessel diameter and used in accordance with its approved instructions for use.

X. REFERENCES

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

XI. SAFE DISPOSAL INFORMATION

After use, discard the device in accordance with local environmental regulations for biohazard material.

XII: REPORTABILITY

Report any serious incident that has occurred in relation to the FLEX Vessel Prep System to VentureMed Group via contact information specified below and the authority having jurisdiction in locale.

XIII. 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 VP® 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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Revision History		
Revision	**Details**	**Date**
P	eCopy of IFU available on VentureMed website	2022-02
Q	Updated to include any residual risks per Regulation (EU) 2017/745 Annex I Chapter III, 23.1 (g)	2022-06
R	Incorporate new 75cm length - orderable number FSC 4-75	2022-06