CAGENT® VASCULAR

Serranator®

PTA Serration Balloon Catheter

℞ ONLY

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

HOW SUPPLIED

Contents supplied STERILE using ethylene oxide gas and remains sterile until the expiration date as long as packaging has not been opened or compromised. For single use only.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

CONTENTS

One (1) *Serranator*® PTA Serration Balloon Catheter

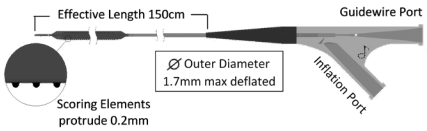
DEVICE NAME

Serranator® PTA Serration Balloon Catheter

DEVICE DESCRIPTION

The *Serranator*® PTA Serration Balloon Catheter is an over-the-wire (OTW) balloon dilatation catheter designed to perform percutaneous transluminal angioplasty (PTA) for peripheral indications as described in the Indication for Use statement. The *Serranator*® has a nylon semi-compliant balloon with three embedded external metal strips or scoring elements. The unique scoring elements are serrated, designed to modify the plaque by creating linear, interrupted scoring along the endoluminal surface. This occurs during balloon inflation and is designed to aid arterial expansion. A representation of the *Serranator*® device is shown in Figure 1.

Figure 1: *Serranator*® PTA Serration Balloon Catheter



The distal end of the catheter has two radiopaque markers that identify the balloon working length. The scoring elements are shorter than the balloon length and are positioned approximately 1 mm inside the radiopaque markers. A tapered tip enhances lesion crossing. The proximal end of the catheter has a two-port hub. The inflation port is used to inflate and deflate the balloon. The guidewire port allows passage of an exchange length 0.014" guidewire.

The nominal balloon inflation pressure and the rated burst pressure (RBP) values are listed on the product pouch labeling and compliance card insert. The working catheter length is 150cm and is designed to be used with a 6F introducer sheath (or 7F guide catheter). Table 1 indicates the available sizes of the *Serranator*®.

Table 1: *Serranator*® PTA Serration Balloon Catheter Sizes

6F Compatible		Balloon Length [mm]		
		40	80	120
Balloon Nominal OD [mm]	2.5	✓	✓	✓
	3.0	✓	✓	✓
	3.5	✓	✓	✓

LBL-0315 Rev A
DCO 0448

INTENDED USE/INDICATIONS FOR USE

The *Serranator*® PTA Serration Balloon Catheter is intended for dilatation of lesions in infrapopliteal arteries. Not for use in the coronary or neuro-vasculature.

CONTRAINDICATIONS

None known.

PRECAUTIONS

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

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

The *Serranator*® is not recommended for use in lesions which may require inflation pressures higher than those recommended for this catheter.

Prior to use, examine the *Serranator*® to verify device integrity, and to ensure that its balloon diameter and length are suitable for the treatment area.

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

Do not re-use a previously inflated device if it was completely removed.

WARNINGS

Do not use if sterile barrier is damaged. If damage is found, call your Cagent Vascular representative.

Follow all Operational Instructions. Failure to do so may result in patient injury.

To reduce the potential for air embolization, purge catheter following all Operational Instructions.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the Reference Vessel Diameter.

This product must be inserted over a guidewire. Failure to do so may result in vessel injury.

Carefully observe the guidewire exiting the guidewire port during back-loading, as the stiff portion of the guidewire could cause user injury.

Maintain device position and control at all times. Failure may result in procedure delay.

To minimize the possible introduction of air into the system, it is imperative that prior to proceeding, careful attention is paid to the maintenance of tight catheter connections and thorough aspiration and flushing of the system.

All catheter manipulations must be carefully performed using high quality fluoroscopic observation. Failure to do so could result in vessel injury.

Do not advance or retract the catheter unless the balloon is fully deflated under vacuum; confirm balloon is fully deflated prior to any movement. Failure to do so could result in vessel injury.

To reduce the potential for vessel damage, inflate the balloon slowly.

If resistance is met during manipulation, determine the cause of the resistance before proceeding. If significant resistance is met during withdrawal through the introducer sheath, extract *Serranator*® and sheath together.

Do not exceed the rated burst pressure (RBP). The RBP is based on the results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence level) will not burst at or below the RBP. Doing so may result in device burst and/or component embolization.

Never use air or any gaseous medium to inflate the balloon. Doing so may cause an air embolism.

Do not use the *Serranator*® in a newly deployed bare metal or drug-eluting stent, as the *Serranator*® has not been tested in newly deployed stents in a clinical trial. Bench testing has shown no additional risk when inserting or withdrawing the *Serranator*® through stents (i.e. no interference with stent struts, no retention of or damage to the *Serranator*®).

Do not re-sterilize and/or reuse, as this 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.

ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, those listed in Table 2:

Table 2:
Possible Adverse Effects

- Total occlusion of the treated artery
- Arterial dissection or perforation
- Arterial spasm
- Pseudo-aneurysm
- Re-stenosis of the dilated artery
- Air Embolism
- Thrombus
- Retained device components
- Hemorrhage or hematoma
- Arteriovenous fistula
- Allergic reaction to contrast medium
- Sepsis/infection

MATERIALS REQUIRED FOR USE WITH THE *SERRANATOR*®

- Femoral introducer sheath and/or guiding catheter with hemostatic valve:
  ≥6 F introducer sheath, or
  ≥7 F guide catheter
- Radiographic contrast medium diluted with normal saline solution
- Sterile, heparinized normal saline solution
- 10 ml or 20 ml syringes for flushing and balloon prep
- Inflation device (endoflator)
- Exchange length guidewire: 0.014" only

OPERATIONAL INSTRUCTIONS

***Serranator*® Selection**

Select the appropriately sized *Serranator*® based on arterial diameter and length of target lesion. The *Serranator*® diameter chosen should approximate the Reference Vessel Diameter (RVD) of the artery and length of the target lesion. A balloon to artery ratio of not more than 1:1 should be used.

***Serranator*® Preparation**

1. Inspect packaging.
2. Remove catheter from package.
3. Remove the stylet from the distal end of the catheter.
4. Remove the balloon protector by holding the catheter shaft proximal to the balloon. With the other hand, gently grasp the balloon protector and remove distally.
5. Connect a three-way stopcock to the inflation port.
6. Select an inflation device with a 10 ml or larger capacity.
7. Prepare the balloon using a contrast to sterile saline dilution ratio of approximately 1:1 or per institutional practice.
8. Connect the inflation device to the stopcock.
9. Purge the catheter by holding the inflation device with the nozzle facing downwards, and aspirate for 15-20 seconds. Turn the stopcock off to the catheter. Repeat step until air bubbles are no longer present. If air bubbles persist, discard device and contact Cagent Vascular representative.
10. Prepare the guidewire lumen by attaching a syringe to the guidewire port (Figure 1). Flush the lumen with approximately 5 ml sterile saline solution until solution exits distal tip. Remove syringe.

Use of the *Serranator*®

1. Backload the distal tip of the *Serranator*® over the pre-positioned guidewire, ensuring the guidewire exits the guidewire port.

2. Insert the *Serranator*® through the introducer sheath or guide catheter indicated on the product label.

3. Slowly advance the *Serranator*® through the introducer sheath.

4. Slowly advance the uninflated *Serranator*® across the target lesion using the two radiopaque markers as a guide for positioning.

5. Slowly inflate the *Serranator*® using the inflation device to 4 atm for 60 seconds, then assess for balloon effacement. If the balloon is not fully effaced, increase pressure to 6 atm and hold for an additional 60 seconds. If additional pressure is required, do not exceed the RBP as indicated on the Compliance Card.

6. Deflate the *Serranator*® by maintaining negative pressure using the inflation device.

7. Confirm that the *Serranator*® is fully deflated prior to repositioning or removal. Always use fluoroscopic guidance to confirm balloon is completely deflated.

8. Prior to retraction into the sheath, ensure that the *Serranator*® balloon is co-aligned with the distal sheath tip. Withdraw slowly into sheath.

9. Remove the *Serranator*® catheter.

Symbols

REF	Reference Number
LOT	Batch Code
OTW	Over The Wire
	Expiration Date
	Balloon Outer Diameter
	Balloon Length
NP	Nominal Pressure
RBP	Rated Burst Pressure
	Caution
	Instructions For Use
	Keep Dry
	Do Not Reuse
Rx ONLY	Prescription Only
	Manufacturer
STERILE EO	Sterile Using Ethylene Oxide
	Non-Pyrogenic
LATEX	Does Not Contain Latex
	Do Not Use if Package is Damaged
	Do Not Resterilize

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