



The *Serranator*® Alto PTA Serration Balloon Catheter

The *Serranator*® Alto PTA Serration Balloon Catheter (Figure 1) is an over-the-wire balloon dilatation catheter designed to perform percutaneous transluminal angioplasty for peripheral vasculature as described in the indications for use statement. The *Serranator*® Alto has a nylon semicompliant balloon with four embedded external serrated metal strips. The serrated strips are designed to create linear, interrupted scoring (Figure 2) along the endoluminal surface during balloon angioplasty.

INDICATIONS FOR USE

The *Serranator*® Alto PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, iliofemoral, and popliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature. The *Serranator*® Alto received 510(k) clearance from the US Food and Drug Administration in February 2017.

The *Serranator*® Bass, currently in development, will be intended for below-the-knee arteries.

PRODUCT SPECIFICATIONS

- 0.018" guidewire compatible
- 6 F sheath compatible
- Semicompliant balloon
- 150 cm catheter length
- 4.0, 5.0, and 6.0 mm balloon diameters
- 40, 80, and 120 mm balloon lengths

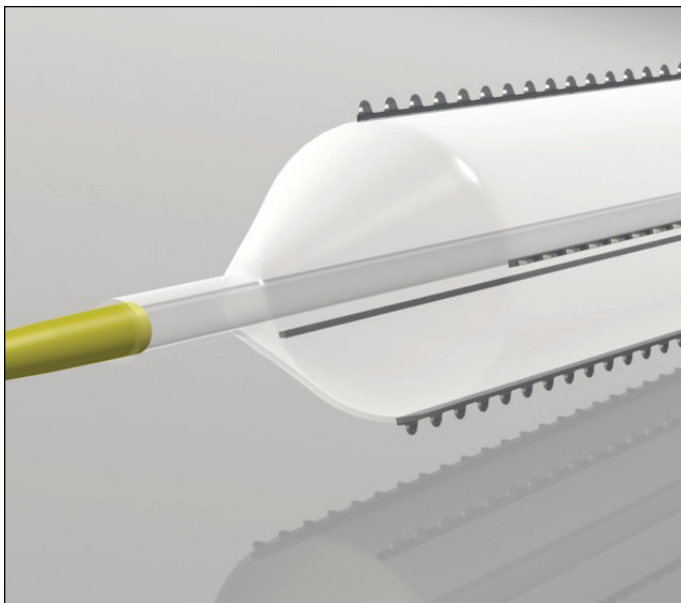


Figure 1. Close-up of the *Serranator*® Alto balloon and its four embedded external metal serrated strips.

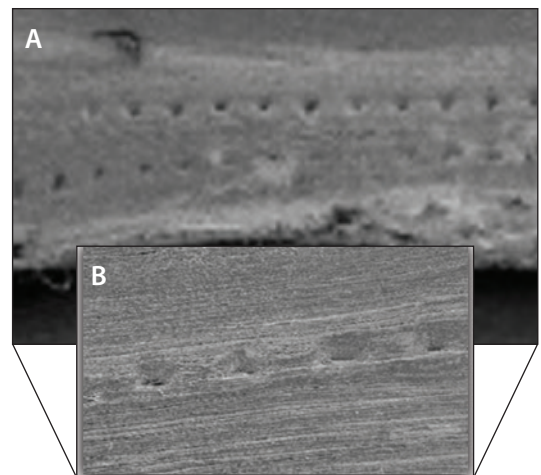


Figure 2. Scanning electron microscopy (SEM) images approximately 5X (A) and 10X (B) of porcine femoral artery surface 7 days after *Serranator*®. Linear, interrupted serrations demonstrate controlled media exposure, circumferential expansion (between each serration), and neointimal healing.