Treat below-the-knee from the radial artery

For additional information on the Sublime™ Radial Access .014 RX PTA Dilatation Catheter, please contact us at: info@sublimeradial.com

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

INDICATIONS FOR USE
The Sublime™ Radial Access .014 RX PTA Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA dilation of peripheral vasculature stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

CONTRAINDICATIONS
The Sublime™ Radial Access .014 RX PTA Dilatation Catheter is contraindicated for use in the coronary arteries and the neurovasculature.

TEST METHODS
Kink Resistance: The proximal segment* of each device was made into a loop and placed into kink resistance test fixture mandrel. Visual inspection of kink was administered. If no kink occurred, the devices were made into the next smallest size loop and placed in the mandrel. This was continued until a kink was visually observed on the test device and the mandrel radius at which the kink occurred was recorded. *Measured 6 cm from strain relief on catheter.

Track Force: Each device was tested using a radial track model and MSI™ track tester water heater with water temperature of 37° ±2°C. Each device was advanced through the radial track model and the average force in grams was measured.

Pushability: Each device was tested using an MSI™ track tester water heater with water temperature of 37° ±2°C. Each device was advanced through the track tester into a distal load cell and the maximum proximal and distal forces were measured and a percentage difference between the proximal and distal force was calculated.

Crossability: Each device was tested using a lesion containment fixture and MSI™ track tester water heater with water temperature of 37° ±2°C. A guidewire was used to cross the mock lesion. Each device was advanced through the track tester where the catheter tip was proximal to the lesion. The catheter was then advanced through the lesion and maximum force (gf) and average force (gf) was measured.

Comparison Testing
a. Average measurements from bench testing by Surmodics, Inc. Sublime™ Radial Access .014 RX PTA Dilatation Catheter (Surmodics, Inc.) N=5; Crosperio RX (0.014) PTA Dilatation Catheter (Terumo Medical Corp.) N=5; Ultraverse™ RX PTA Dilatation Catheter (Becton, Dickinson and Company) N=5; Coyote™ Monorail Balloon Dilatation Catheter (Boston Scientific) N=5; RapidCross™ PTA RX Balloon Dilatation Catheter (Medtronic, Inc.) N=5. Data on file. Bench test results may not necessarily be indicative of clinical performance.

b. Average measurements from bench testing by Surmodics, Inc. Sublime™ Radial Access .014 RX PTA Dilatation Catheter (Surmodics, Inc.) N=5; Crosperio RX (0.014) PTA Dilatation Catheter (Terumo Medical Corp.) N=5. Data on file. Bench test results may not necessarily be indicative of clinical performance.

c. Average measurements from bench testing by Surmodics, Inc. Sublime™ Radial Access .014 RX PTA Dilatation Catheter (Surmodics, Inc.) N=5; Crosperio RX (0.014) PTA Dilatation Catheter (Terumo Medical Corp.) N=5; Ultraverse™ RX PTA Dilatation Catheter (Becton, Dickinson and Company) N=5. Bench test results may not necessarily be indicative of clinical performance.

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Treat below-the-knee from the radial artery
The 250 cm Sublime™ Radial Access .014 RX PTA Dilatation Catheter provides the industry's longest working length to facilitate treatment of above- or below-the-knee arteries using a transradial approach.

The Sublime™ Radial Access .014 RX PTA Dilatation Catheter combines a proprietary shaft design with a 250 cm Serene™ hydrophilic coating technology designed to provide exceptional pushability, trackability, and crossability in an RX platform.

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