SUBLIME™ RADIAL ACCESS GUIDE SHEATH

INDICATIONS FOR USE
The Guide Sheath is intended to introduce therapeutic or diagnostic devices into the vasculature, excluding the coronary and neurovasculature.

COMPARISON TESTING
a. Average measurements from bench testing by Surmodics, Inc. R2P™ Destination Slender™ Guiding Sheath, 6 Fr (Terumo Medical Corp.) N = 5; Sublime™ Radial Access Guide Sheath, 5 Fr (Surmodics, Inc.) N = 5; Sublime™ Radial Access Guide Sheath, 6 Fr (Surmodics, Inc.) N = 5. Data on file. Bench test results may not necessarily be indicative of clinical performance.

TEST METHOD for Kink-resistance: Each test device was made into a loop and placed into a kink resistance test fixture mandrel. Visual inspection of kink was administered. If no kink occurred, the devices were made into a smaller 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.

TEST METHOD for Torque: Each test device was placed into calibrated torque test instrument. Devices were clamped into the torque test instrument on the distal end and rotated via the proximal hub. Devices were rotated clockwise one full rotation and maximum torque force on torque sensor was recorded.

TEST METHOD for Radial Strength: Each test device was compressed between two flat plates. Force was measured at a fixed percent compression of the shaft diameter.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

Sublime™ Radial Access .014 RX PTA Dilatation Catheter

INDICATIONS FOR USE
The Sublime™ Radial Access .014 and .018 RX PTA Dilatation Catheters are 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 and .018 RX PTA Dilatation Catheters are contraindicated for use in the coronary arteries and the neurovasculature.

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.

TEST METHOD for 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 tracked 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.

TEST METHOD for 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.

TEST METHOD for 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.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

Sublime™ Radial Access .018 RX PTA Dilatation Catheter

INDICATIONS FOR USE
The Sublime™ Radial Access .014 and .018 RX PTA Dilatation Catheters are 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 and .018 RX PTA Dilatation Catheters are contraindicated for use in the coronary arteries and the neurovasculature.

COMPARISON TESTING
a. Average measurements from bench testing by Surmodics, Inc. Sublime™ Radial Access .018 RX PTA Dilatation Catheter (Surmodics, Inc.) N = 5; Crostella® RX (0.018) PTA Dilatation Catheter (Terumo Medical Corp.) N = 5; Ultraverse™ RX PTA Dilatation Catheter (Becton, Dickinson and Company) N = 5; Sterling™ .018 Balloon Dilatation Catheter (Boston Scientific) N = 5; Crostella® OTW (0.018) PTA Dilatation Catheter (Terumo Medical Corp.) 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 .018 RX PTA Dilatation Catheter (Surmodics, Inc.) N = 5; Crosstella® .018 RX PTA Balloon Dilatation Catheter (Terumo) N = 5; Sterling™ .018 Balloon Dilatation Catheter (Boston Scientific) N = 5. Data on file. Bench test results may not necessarily be indicative of clinical performance.

TEST METHOD for 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 tracked 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.

TEST METHOD for 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.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician. Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

REFERENCES (from pages 14-17)

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