The LIFESTENT® 5F Vascular Stent System is designed to be used via a femoral access site. The ULTRA SCORE™ Focused Force PTA Balloon is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries and for the treatment of obstructive lesions of the femoral, iliac, and popliteal arteries.

The CROSSER® Recanalization System is indicated to facilitate the intraluminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy. The CROSSER® Recanalization System is contraindicated for use in carotid arteries.

The LUTONIX® 035 Drug Coated Balloon PTA catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions up to 180 mm in length. The low profile solutions to enable a 5F ProSeries™ Low Profile crossover device. DO NOT attempt to break, damage, or disrupt the stent after placement. Cases of stent fracture have been reported in clinical use of the LIFESTENT® Vascular Stent.

The UltraScore and UltraVerse are trademarks and/or registered trademarks of C. R. Bard, Inc., or an affiliate.

Low profile solutions to enable a 5F procedure from various access sites.

The ProSeries™ Advantage
- Established Technologies
- Low crossing profiles
- Designed to reduce arteriotomy size
- Enables alternative access sites

Low Profile Proven Design

Potential adverse events that may occur include, but are not limited to:
- Hypotension/hypertension
- Incorrect positioning of the stent requiring further stenting or retrieval of the stent
- Arteriovenous fistula
- Arrhythmia
- Bypass surgery
- Death related/unrelated to procedure
- Coronary ischemia
- Arterial occlusion/thrombus
- Arterial occlusion/restenosis of the treated artery

Potential Adverse Events:
- Cases of stent fracture occurred have been reported in clinical use of the LIFESTENT® Vascular Stent. Cases of stent fracture may not be apparent immediately after stent placement or during system flushing but are visible via angiography or OCT if performed following repeat dilatation of endothelialized stents. Cases of stent fracture occurred have been reported in clinical use of the LIFESTENT® Vascular Stent. Cases of stent fracture may not be apparent immediately after stent placement or during system flushing but are visible via angiography or OCT if performed following repeat dilatation of endothelialized stents.

Procedures:
- The device is intended for use in patients with normal renal function. The device should not be used in patients with creatinine clearance less than 30 mL/min.

For more detailed information and instructions for use, please consult the package insert.
The LIFESTENT® 5F Vascular Stent System is designed to be used via a femoral access site. The CROSSER® Recanalization System is indicated to facilitate the intraluminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy. The CROSSER® Stent Elongation or stent foreshortening are potential consequences as a result of not following the deployment techniques other than those indicated by the Instructions For Use are advised against. During system flushing, observe that saline exits at the catheter tip. The delivery system is not designed for use with power injection systems. Recrossing a partially or fully deployed stent with overlapping in the middle (P2) and distal popliteal artery (P3) has not been established. Operator failure to keep the device straight may impede the optimal deployment of the implant, potentially resulting in an elongated or foreshortened implant. The long-term outcomes following repeat dilatation of endothelialized stents are unknown. The safety and effectiveness of stent placement of the stent or stent delivery system.

**Indications:**
- The LIFESTENT® 5F Vascular Stent Systems are contraindicated for use in:
  - Coronary ischemia; arterial occlusion/thrombus, arterial occlusion/restenosis of the treated vessel; arteriovenous fistula; arrhythmia; bypass surgery; death related/unrelated to procedure; coronary artery bypass graft; restenosis; septicemia/bacteremia; stent fracture; stent migration; stroke; surgical intervention.
  - Vasospasm; venous occlusion/thrombosis; respiratory arrest; restenosis; septicemia/bacteremia; stent fracture; stent migration; stroke; surgical intervention.

**Contraindications:**
- Femoral access site

**Precautions:**
- These devices are designed for use in patients with femoral arterial access having a history of chronic total occlusion. Use in patients having a history of prior peripheral arterial interventions with impaired blood flow is recommended. The device is a blood pressure measurement to be used in conjunction with the patient’s clinical history and physical examination. The device is also recommended for your doctor’s initial assessment and lab recording of the preprocedural situation. The catheter used in this procedure is a low profile catheter designed for femoral access.

**Low Profile Proven Design**

**CROSSER® Recanalization System**

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- Enables alternative access sites

**CardioStent® 5F Vascular Stent System**

**Instructions:**
- To maintain the Integrity of the Stent System, accurately track inflation on and off guidewire tracking up to 240 mm in length. Deployment of the device should be done using a low profile system with a low profile catheter to maintain a low profile profile.

**Pharmacology:**
- The LIFESTENT® Vascular Stent is indwelling for approximately 6 months. Use of the device may result in a small amount of blood flow through the tissue. The device is also recommended for your doctor’s initial assessment and lab recording of the preprocedural situation. The catheter used in this procedure is a low profile catheter designed for femoral access.

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**LIFESTENT® 5F Vascular Stent System**

Complete a 5F procedure with the low profile LIFESTENT® 5F Vascular Stent System.

**Proven Stent Design**

The only stent design that is FDA-approved for the SFA and full popliteal artery.

**Proven Clinical Results**

The LIFESTENT® Vascular Stent Systems, in varying sizes, have been studied in more than ten clinical trials globally.

**Innovative Triaxial Delivery System**

Designed for ease of use, deployment control, and precise placement accuracy.

**GEOALIGN® Marking System**

Designed to reduce radiation exposure by minimizing fluoroscopy time.

**Access site complications (ASCs) have been reported to occur in up to 11% of peripheral vascular interventions.**

**Literature suggests that access site complications may be minimized by reducing sheath profile.**

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**6F 1F SMALLER**

**Low profile, 5F Triaxial Delivery System**

**Dual-Speed Thumbwheel**

**Ergonomic Handle**

**Unique Helical Struts and Angled Bridges**

**Engineered for bending, compression, and torsion**

**Radiopaque markers on all sizes**

**GEOALIGN® Marking System**

Designed to reduce radiation exposure by minimizing fluoroscopy time.

**RESILIENT TRIAL**

- Level 1, sustained effectiveness over PTA out to 3 years.

**POPLITEAL ARTERY STUDY (ETAP)**

- Level 1, double the primary patency of PTA out to 2 years.

**LONG LESION DATA**

- High primary patency at 12 months in lesions up to 240 mm.

**ADDITIONAL TRIALS**

- RESILIENT II Trial, E-TAGUSS Trial, STELLA Trial, Retrospective Analysis of LIFESTENT® Vascular Stent Systems in the Treatment of Long-Segment Lesions, CONTINUUM Trial, REALITY I/II/III Trials, and RELIABLE Trial.

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The only stent design that is FDA-approved for the SFA and full popliteal artery.

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**LONG LESION DATA**

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**ADDITIONAL TRIALS**

- RESILIENT II Trial, E-TAGUSS Trial, STELLA Trial, Retrospective Analysis of LIFEStent® Vascular Stent Systems in the Treatment of Long-Segment Lesions, CONTINUUM Trial, REALITY I/II/III Trials, and RELIABLE Trial.
Complete a 5F procedure with the low profile LifeStent® 5F Vascular Stent System

Access site complications (ASCs) have been reported to occur in up to 11% of peripheral vascular interventions 1, 2, 3. Literature suggests that access site complications may be minimized by reducing sheath profile 4, 5, 6.

The only stent design that is FDA-approved for the SFA and full popliteal artery 8.

The only stent design that is FDA-approved for the SFA and full popliteal artery.

The LifeStent® Vascular Stent Systems, in varying sizes, have been studied in more than ten clinical trials globally.

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5F ProSeries™

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LIFESTENT® 5F Vascular Stent System

Indications:
- The LIFESTENT® 5F Vascular Stent System is designed to be used via a femoral access site in the treatment of symptomatic de novo or restenotic lesions up to 240 mm in length in the native superficial femoral or popliteal arteries with reference vessel diameters ranging from 4.0 - 7.0 mm.

Contraindications:
- The LIFESTENT® 5F Vascular Stent System is contraindicated for use in carotid arteries.

Warnings:
- Stent elongation or stent foreshortening are potential consequences as a result of not following the deployment techniques other than those indicated by the Instructions For Use are advised against.

Precautions:
- The device is intended for use by physicians who have received appropriate training.

For more information, please consult the package insert for detailed safety information and instructions for use.

LifeStent® | 5F Vascular Stent System

GEOALIGN® Marking System

Indications:
- The GEOALIGN® Marking System is intended to facilitate the intraluminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy. The GEOALIGN® Marking System is indicated for use in the treatment of in-stent restenosis.

Contraindications:
- The GEOALIGN® Marking System is contraindicated for use in carotid arteries.

Warnings:
- Failure to keep the device straight may impede the optimal deployment of the stent or stent delivery system. The device is also recommended for use when deploying the stent as manipulation of the delivery system may, in rare instances, cause stent fractures. The device is intended for use with the LIFESENSE® 2000 and GEOMETRIX™ 5F ProSeries® Balloon Dilatation Catheters.

Precautions:
- The device is intended for use in patients with known latent coronary artery bypass graft disease.

For more information, please consult the package insert for detailed safety information and instructions for use.

LifeStent® | 5F Vascular Stent System

ULTRAVERSE® 035 PTA Dilatation Catheter

Indications:
- The ULTRAVERSE® 035 PTA Dilatation Catheter is intended to dilate stenoses in the peripheral arteries, to treat obstructive lesions of native synthetic AV fistulae and/or re-expand endoluminal stent native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post dilatation of balloon expandable stents, self-expanding stents, and stent grafts in the peripheral vasculature.

Contraindications:
- The ULTRAVERSE® 035 PTA Dilatation Catheter is contraindicated for use in carotid arteries.

Warnings:
- Failure to keep the device straight may impede the optimal deployment of the stent or stent delivery system. The device is also recommended for use when deploying the stent as manipulation of the delivery system may, in rare instances, cause stent fractures.

Low Profile Proven Design