PERFORMANCE
YOU CAN TRUST

EverFlex™ Self-expanding Peripheral Stent with
Entrust™ Delivery System
The Entrust™ Delivery System is designed to provide improved patient outcomes and procedural efficiency.

The Entrust™ delivery system was designed based on extensive physician feedback and procedural observations to develop a best-in-class delivery system that provides improved patient outcomes and economic value. It offers innovations like a 5F profile and a 150 cm catheter option with triaxial accuracy, to ensure the clinically proven EverFlex™ stent is accurately placed and offers positive procedural results.

The Entrust™ delivery system is designed to address several of the challenges currently associated with peripheral vascular stenting procedures.
Accurate stent delivery remains a challenge in endovascular procedures today.

Current stent delivery systems may not reach target lesions.

Long term clinical data in the SFA is not available for many bare metal stents.

Vascular access complications such as pseudoanerysm and major local hematoma are challenges associated with endovascular procedures.
If stents are not placed where they are intended to be delivered, it may result in unnecessary treatment of healthy tissue, need for an extra device, additional cost and time.

These challenges can lead to longer, more costly procedures, longer hospital stays, discomfort and dissatisfaction for patients.

If physicians are unable to reach target lesions with current systems, endovascular treatment options may be limited and more costly or more invasive surgical options may be employed.

It is difficult make treatment decisions due to a lack of information.
The Entrust delivery system is composed of a triaxial catheter and an isolation sheath designed to reduce friction for increased accuracy and more predictable outcomes.

The Entrust delivery system is the lowest profile SFA approved stent delivery system available in the US. Lower profile devices may:

- Reduce the incidence of major access site complications such as pseudoaneurysms and major local hematoma
- Reduce pseudoaneurysms by 5 fold over 7 F
- Reduce time to patient ambulation and discharge
- Reduce the time needed for manual compression after sheath removal

The Entrust delivery system is the only peripheral stent delivery system available in a 150 cm catheter option for extended reach.

The EverFlex stent is supported by data from the DURABILITY II study which demonstrates an excellent 3-year patency and a best-in-class fracture rate in a long and complex lesion subset.
**Indication:** The EverFlex™ Self-Expanding Peripheral Stent with Entrust™ Delivery System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 140 mm in length in the native Superficial Femoral Artery (SFA) and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 mm - 7.5 mm.

**Contraindications:** Use of the EverFlex™ Self-Expanding Peripheral Stent with Entrust™ Delivery System is contraindicated in patients with known hypersensitivity to nickel titanium; patients contraindicated for anticoagulant and/or antiplatelet therapy; patients who have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system. The EverFlex™ Self-Expanding Peripheral Stent with Entrust™ Delivery System is contraindicated for use in the carotid artery.

**Potential Adverse Events:** Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: Allergic reaction, Amputation, Arterial dissection/perforation, Bleeding disorders (including GI, lymphatic), Infection (local or systemic including bacteremia or septicemia), Pseudoaneurysm, Restenosis, Stent/Vessel Thrombosis, Surgical or endovascular intervention.

See the Instructions for Use provided with the product for a complete list of warnings, precaution, adverse events and device information.

**CAUTION:** Federal (USA) law restricts these devices to sale by or on the order of a physician.

**IMPORTANT:** Please reference the Instructions For Use (IFU) for a complete listing of indications, contraindications, warnings and precautions, adverse effects and suggested procedure.

4 Buchler, J et al. A Randomized Trial of 5 versus 7 French Guiding Catheters for Transfemoral Percutaneous Coronary Stent Implantation.