Acute Safety and Technical Results of the EverFlex™ Self-Expanding Stent with New Delivery System (ENTRUST)

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On behalf of the ENTRUST Investigators
Disclosure

Speaker name: Carl Wahlgren, MD/PhD

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company

X Other(s): Principal Investigator of the ENTRUST Study
- I do not have any potential conflict of interest
Study Device

Covidien EverFlex™ self-expanding Peripheral Stent with Entrust™ Delivery System

- 5F Entrust™ delivery system
  - One-handed triaxial shaft design
  - Ergonomic deployment handle
  - Radiopaque markers
  - Removable safety lock
  - Catheter lengths: 80, 120, and 150 mm

- EverFlex™ Peripheral Stent System
  - Self-expanding Nitinol stent
  - Spiral cell connection
  - Tantalum radiopaque markers
  - Stent diameters: 6, 7, 8 mm
  - Stent lengths: 20, 40, 60, 80, 100, 120, and 150 mm

CAUTION: Not available for sale in the USA.
Purpose: A confirmatory study to evaluate technical success and acute safety of the EverFlex™ self-expanding peripheral stent with the new Entrust™ delivery system for the treatment of symptomatic de novo or restenotic lesions in the native superficial femoral artery and/or proximal popliteal artery.

- Prospective, multi-center, non-randomized, single arm
- 34 subjects enrolled
- Clinical follow-up at 30 days post-procedure
- Independent angiographic core laboratory analysis

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ENTRUST Study Endpoints

- **Primary endpoints**
  - **Successful stent deployment**
    
    *defined as the ability to deliver the stent catheter to the desired location, implanted stent provides coverage of the lesion as intended, and stent is deployed accurately per operator assessment.*
  
  - **Absence of stent elongation**
    
    *achieved when the implanted stent length does not exceed the allowed stent length: combined nominal stent length, 10% tolerance of nominal stent length and allowed measurement error, as assessed by the angiographic core laboratory.*

- **Primary safety endpoint**

  *Device and procedure-related adverse event rate at 30 days post procedure.*
Key Inclusion and Exclusion Criteria

Inclusion Criteria
1. Stenotic, restenotic or occluded lesion(s) located in the native SFA and/or proximal popliteal artery
2. Willing to comply with all follow-up evaluations at specified times
3. Provide written informed consent prior to enrollment

Exclusion Criteria
1. Previous implantation of stent/stent graft in the target vessel
2. Hypersensitivity to nickel-titanium
3. Aneurysmal target vessel
4. Presence of an acute intraluminal thrombus at the proposed lesion site
Case Example

- **Patient information**
  - 72 year old female, non-diabetic with hypertension and hyperlipidemia
  - Total occlusion treated in the left SFA: 46.7 mm long (core lab reported)
  - 6 x 60 mm stent implanted

*Individual results may vary*
## Baseline Clinical and Lesion Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N = 34 Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs.)</td>
<td>71.5 ± 9.4</td>
</tr>
<tr>
<td>Male</td>
<td>50.0%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>29.4%</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>47.1%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>76.5%</td>
</tr>
<tr>
<td>Smoking History (current or past)</td>
<td>64.7%</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>N = 39 Lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length (mm)</td>
<td>87.1 ± 74.8 (36)*</td>
</tr>
<tr>
<td>Pre-procedure Diameter Stenosis (%)</td>
<td>90.0 ± 13.8</td>
</tr>
<tr>
<td>Any Calcification (%)</td>
<td>79.5%</td>
</tr>
<tr>
<td>Occlusions (%)</td>
<td>53.8%</td>
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</tbody>
</table>

* Lesion length data missing for 3 lesions in one subject. Subject had a long occlusion in the SFA and it was technically not feasible to measure the length for each one of the lesions.
Primary Endpoint: Successful Stent Deployment

<table>
<thead>
<tr>
<th></th>
<th>N = 45 Stents</th>
</tr>
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<tbody>
<tr>
<td><strong>Successful stent deployment</strong></td>
<td>100% (45/45)</td>
</tr>
<tr>
<td>Ability to deliver the stent catheter to the desired location</td>
<td>100.0% (45/45)</td>
</tr>
<tr>
<td>Implanted stent provides coverage of the lesion as intended</td>
<td>100.0% (45/45)</td>
</tr>
<tr>
<td>Stent is deployed accurately</td>
<td>100.0% (45/45)</td>
</tr>
</tbody>
</table>

Mean distance from desired landing point: **1.1 mm**

Mean distance of desired landing point from edge of lesion: **8.1 mm**
Primary Endpoint: Absence of Stent Elongation

Angiographic core laboratory adjudicated two stent elongations in one patient

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<th>N = 45 Stents</th>
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<tr>
<td>Absence of stent elongation</td>
</tr>
<tr>
<td>95.6% (43/45)</td>
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</table>

The absence of stent elongation rate of 95.6% exceeded the required threshold of 93.0% for success, and the endpoint was met.
Primary Safety Endpoint

Defined as the 30-day rate of device and procedure-related adverse events:

2.9% (1/34)

One event reported 14 days post-procedure:
- In-stent re-occlusion of unknown cause
- Reviewed and classified as stent thrombosis by safety officer
- Lesion revascularized by thrombectomy, angioplasty, and stenting
- Resolved without further sequelae
Summary

- Study demonstrated successful deployment of the EverFlex™ stent with Entrust™ delivery system for the treatment of symptomatic SFA and/or proximal popliteal lesions

  - High successful stent deployment rate: 100%
    - Ability to deliver stent catheter to desired location
    - Implanted stent provides coverage of lesion as intended
    - Stent deployed accurately

  - High absence of stent elongation rate: 95.6%

- Low 30-day device and procedure related adverse event rate: 2.9%

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Thank you to all the Investigators who participated in the ENTRUST Study

<table>
<thead>
<tr>
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