Modifications BeGraft Peripheral

Modifications / Performance Comparison

Sebastian Büchert
January 27th, 2016
The development of the Medical Device Industry in Hechingen

Vascular Surgery

Intensive Care

Cardiology

Extracorporeal Lung Assist

Open Heart Surgery

Cardiology

Percutaneous Circulatory Support

Dialysis Catheters

Mechanical Heart Compression

Interventional Cardiology/Radiology
# Product Launch History

<table>
<thead>
<tr>
<th>Year</th>
<th>Product Launch History</th>
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</thead>
<tbody>
<tr>
<td>2009</td>
<td>Matrix Expansion (4.5 – 5.0 mm)</td>
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<tr>
<td>2010</td>
<td>Be smooth</td>
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<tr>
<td>2011</td>
<td>Be graft</td>
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<td>2012</td>
<td>Be graft</td>
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<td>2013</td>
<td>Be graft</td>
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<td>2014</td>
<td>Be graft</td>
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Sebastian Büchert  
January 27th, 2016
Indication

The BeGraft Peripheral Stent Graft System is indicated for intraluminal chronic placement in iliac and renal arteries for:
- Restoring and improving the patency
- Treating aneurysms, acute perforations, acute ruptures and fistulas
BeGraft Peripheral Modifications

Three Stent Design Modifications were implemented

1. **Fixation of Graft Material:**

   Identical fixation of ePTFE covering from the inside of the stent at both stent ends.

   **Reason:** increase the “inherent safety by design” of the implant in order to avoid detachment of the graft material (e.g. during introducer- and / or lesion-access, thereby acting in contrary to the IfU – e.g. using a too small introducer sheath).

![Old Design](image1)

![Modified Design](image2)
BeGraft Peripheral Modifications

Three Stent Design Modifications were implemented

2. **Connector Width**:

Increase the connector width by approx. 20%.

*Reason*: slight increase of the longitudinal stiffness of the stent. It was orally communicated to Bentley InnoMed that in case of “reasonably foreseeable misuse” (off-label use, e.g. use in combination with fenestrated aortic endoprostheses), that this property of the stent could be optimised in order to increase the longitudinal stability.
BeGraft Peripheral Modifications

Three Stent Design Modifications were implemented

3. **Thickness of Graft Material:**

Increase the thickness of the ePTFE covering by factor 2

Reason: improve the mechanical stability for on-label use and for “reasonably foreseeable misuse” (off-label use, e.g. use as bridging stent graft in branched aortic endoprostheses).

![Old Design](image1)

![Modified Design](image2)
Trackability

- Competitor A (Ø10 x 59mm) - 12.29 N
- BeGraft Peripheral (Ø10 x 57mm) - 1.59 N
- Competitor B (Ø10 x 58mm) - 4.83 N
Foreshortening

Percentage change of the stent length from crimped length to the final expanded stent length after balloon removal

\[
\text{% stent foreshortening} = \frac{\text{stent length (crimped)} - \text{stent length (expanded)}}{\text{stent length (crimped)}} \times 100
\]

**Competitor A**
(Ø10 x 59mm) - 11.1%

**BeGraft Peripheral**
(Ø10 x 57mm) - 4.7%

**Competitor B**
(Ø10 x 58mm) - 8.0%
Expanded Stent Flexibility

- **Competitor A (Ø10 x 59mm)**: 1.35
- **BeGraft Peripheral (Ø10 x 57mm)**: 0.80
- **Competitor B (Ø10 x 58mm)**: 1.14
Radial Force (Flat Plate)

Nominal exp. diameter

50% diameter reduction

<table>
<thead>
<tr>
<th>Competitor A (Ø10 x 59mm)</th>
<th>BeGraft Peripheral (Ø10 x 57mm)</th>
<th>Competitor B (Ø10 x 58mm)</th>
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</thead>
<tbody>
<tr>
<td>0.23</td>
<td>0.26</td>
<td>0.15</td>
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January 27th, 2016
Kink Resistance

BeGraft    Competitor A    Competitor B