UNITY-B Biodegradable Balloon Expandable Stent System

**Stent Sizes**

<table>
<thead>
<tr>
<th>Diameter (mm)</th>
<th>17</th>
<th>27</th>
<th>37</th>
<th>57</th>
<th>77</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.00</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>6.00</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>7.00</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>8.00</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>9.00</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>10.00</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

* Sizing release dates may vary after CE approval depending on availability and approval ranges.

**Test Description**

<table>
<thead>
<tr>
<th>SIS Size</th>
<th>Max (mm)</th>
<th>French compatibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0 x 57</td>
<td>2.40</td>
<td>8</td>
</tr>
<tr>
<td>10.0 x 57</td>
<td>2.59</td>
<td>8</td>
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**CE MARK PENDING**

THE FUTURE IN GI PRODUCTS

amg international a bioresorbable gi company

UNITY-B Biodegradable Balloon Expandable Stent System

Biodegradable Stent System

17 | 27 | 37 | 57 | 77
5.00 | X | X | X | X | X
6.00 | X | X | X | X | X
7.00 | X | X | X | X | X
8.00 | X | X | X | X | X
9.00 | X | X | X | X | X
10.00 | X | X | X | X | X

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**CE MARK PENDING**

THE FUTURE IN GI PRODUCTS
The UNITY-B Biodegradable Balloon Expandable Stent System is designed to replace self-expanding metallic stents (SEMS) with the added benefit of biodegradation to minimize the complications associated with metal stents such as perforation, stent-in-growth, stent-over-growth and the inability to remove metal stents.

UNITY-B is a hybrid biodegradable stent that:
- Functions like a metallic stent
- Can be used in non conforming strictures
- Can be over-dilated without fracturing
- Has minimal recoil and foreshortening
- Does not require in advance preparation of the stricture
- Can be placed with the same traditional approach used for a normal metallic or DES stent
- Can be easily produced in a wide range of sizes

UNITY-B OmniLink

**Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>UNITY-B</th>
<th>UNITY VS MAIN COMPETITOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crossing Profile (mm)</td>
<td>2.20 – 2.40 (mean 2.30)</td>
<td>2.22 – 2.27 (ø10 mm)</td>
</tr>
<tr>
<td>Foreshortening, max at NP (%)</td>
<td>0.9% (RBP) ø10 mm</td>
<td>2.30% (RBP) ø10 mm</td>
</tr>
<tr>
<td>Maximum Recoil of the expanded stent at NP (%)</td>
<td>3.1% (NP) ø10 mm</td>
<td>3.14% (NP) ø10 mm</td>
</tr>
</tbody>
</table>

**Enhanced features:**

- Initial surface degradation allows for bile flow and "self-cleaning" of biofilm
- Minimizes stent-in-growth
- Minimizes stent-over-growth
- Minimizes stent perforation (no COF)
- The issue of stent removal is eliminated

BILIARY

amg has combined the same natural symbiotic design into its UNITY-B Stent where its proprietary magnesium alloy acts as the bone or skeleton and the polymer outer acts as the muscle.

PERIPHERAL

By finding the right balance for the combination of these materials one can produce a implant that works in the same mechanical form as its historical metallic version with the added benefit of being biodegradable and leaving nothing behind.

CORONARY

**ADVANTAGES**

- Uniform expansion of the stent with no cracks to maximum diameter (4.4 mm).
- Measurements resulted to almost zero foreshortening.
- Fluoroscopic visibility can be improved by radiopaque markers.
- Very low recoil which ranged between 1.98% and 1.13%.

Enhanced features:

- Initial surface degradation allows for bile flow and "self-cleaning" of biofilm
- Minimizes stent-in-growth
- Minimizes stent-over-growth
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The Skeletal portion of the system servers as the main support structure for the body.

The Muscles keep bones in place and also play a role in the movement of bones.