

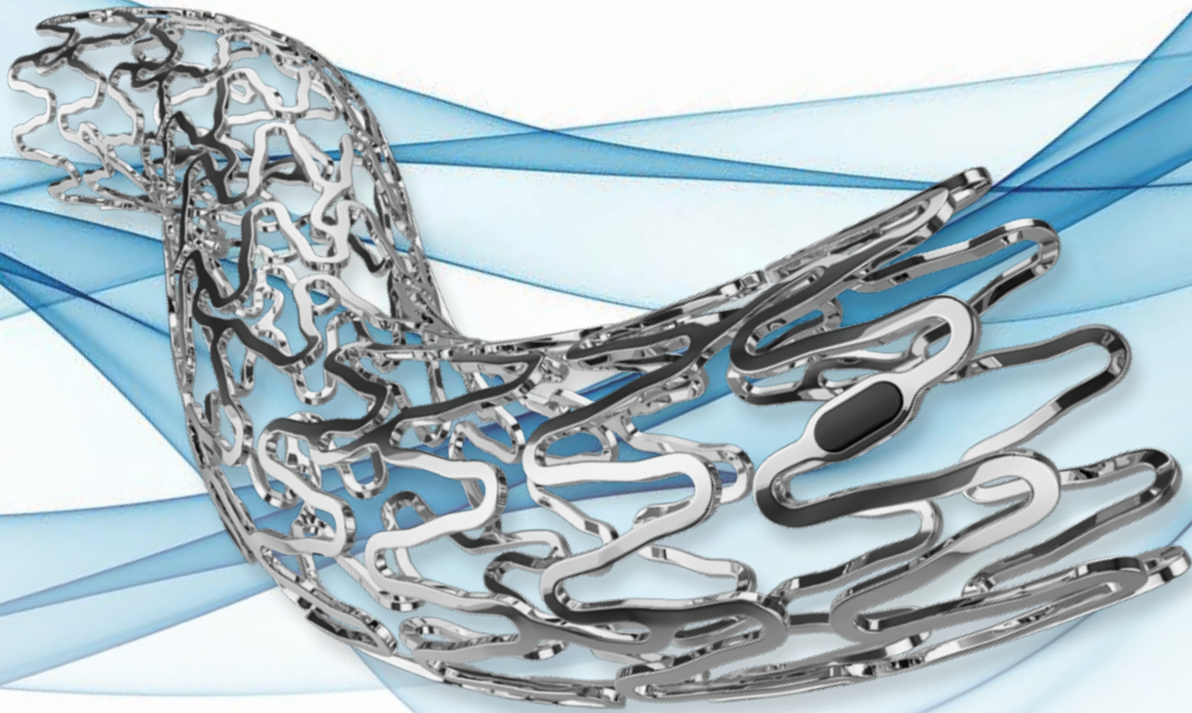
BIODEGRADABLE

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CREATING VALUE BY HELPING PEOPLE

UNITY-B

Endoscopic Balloon Expandable
Biodegradable Biliary Stent System



BIO  **DEGRADABLE**
SOLUTIONS

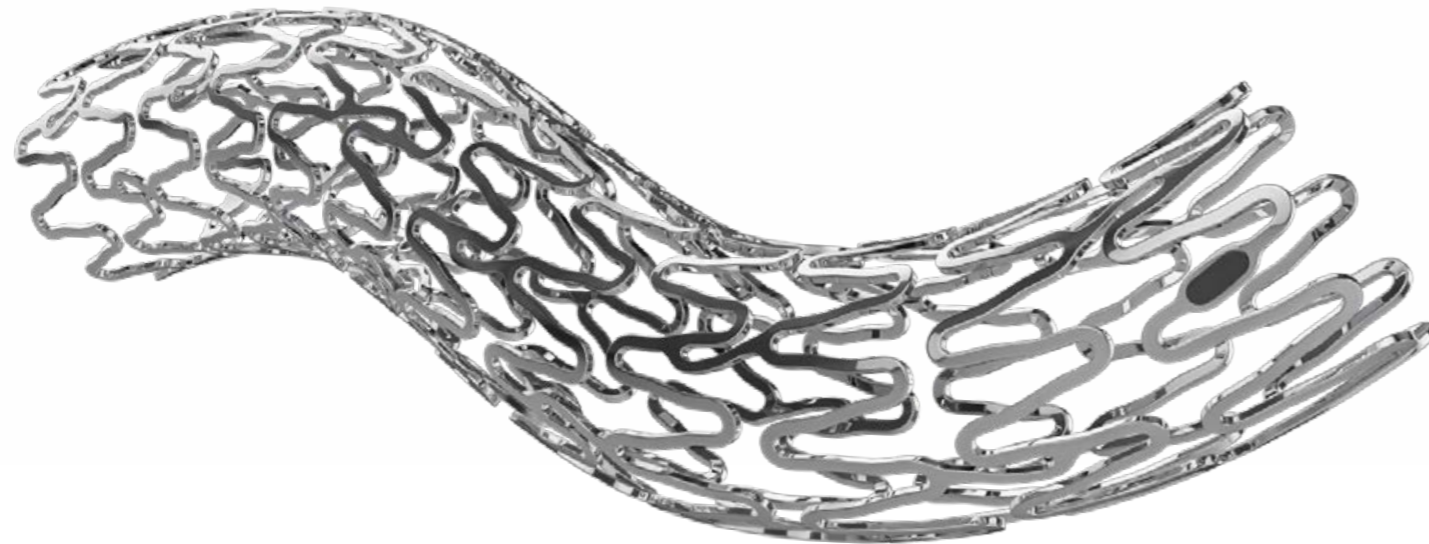
CE MARK APPROVED

UNITY-B

Endoscopic Balloon Expandable Biodegradable Biliary Stent System

BIODEGRADABLE SOLUTIONS

The **UNITY-B** Endoscopic Balloon Expandable Biodegradable Biliary Stent System is designed to be used to help drain obstructed bile ducts¹ with the **added benefit of biodegradation** to potentially **minimize the complications associated with traditional metal stents**.



Enhanced Features:

- > Can be produced in a **wide range of sizes** and placed with the **same approach** used for traditional balloon expandable metallic stents.
- > **Biodegradable nature** of the UNITY-B stent is intended to **mitigate stent in-growth, over-growth** and **perforation** typically seen with traditional metallic stents.
- > Intended to **eliminate the need for stent removal or replacement**.
- > Potential to be used in **non-conforming strictures** and designed to be **over-dilated** for luminal wall conformance without fracturing.

Stent Technical Data

| Characteristics | 8.0 mm | 9.0 mm | 10.0 mm |
|----------------------------|-------------|--------------|-------------|
| Crossing profile (max) | 2.60 mm | 2.61 mm | 2.62 mm |
| Crossing profile (mean) | 2.52 mm | 2.54 mm | 2.56 mm |
| Foreshortening at NP (max) | 0.1% | 1.3% | 2.5% |
| Recoil at NP (max / mean) | 4.3% / 3.4% | 3.1% / 1.7% | 1.9% / 0% |
| Recoil at RBP (max / mean) | 7.3% / 4.1% | 6.8% / 3.45% | 6.3% / 2.8% |

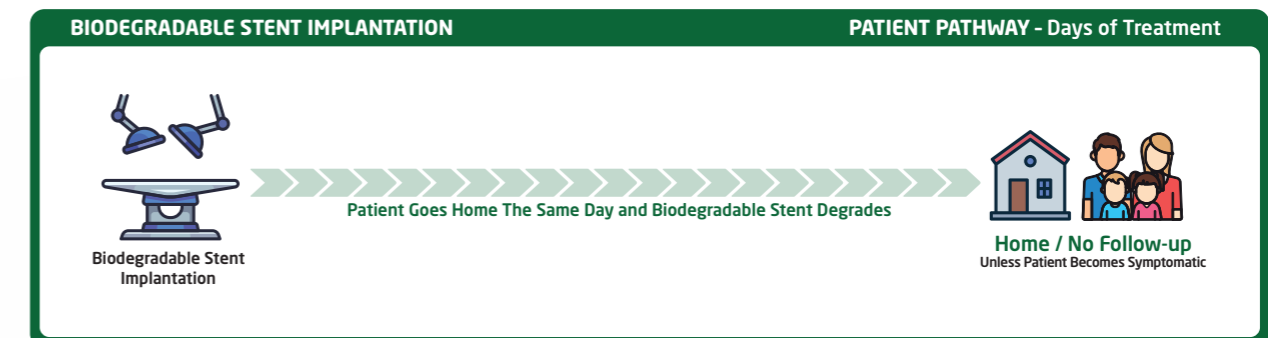
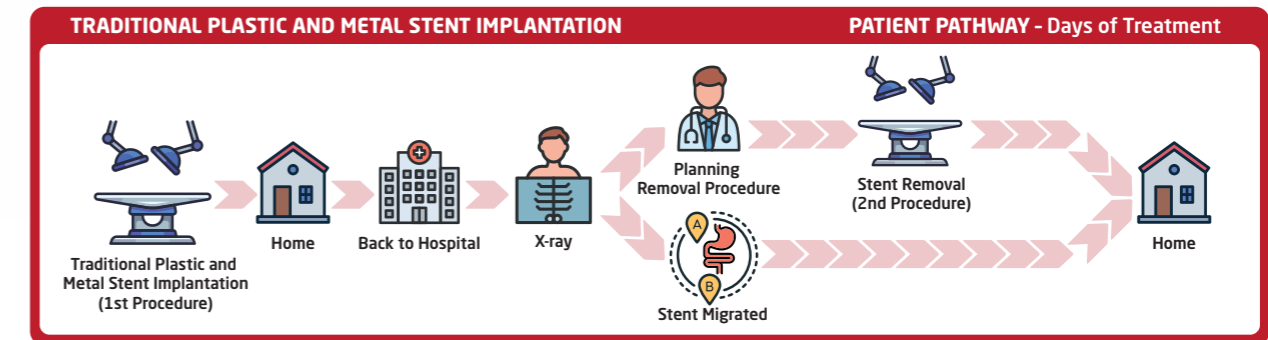
Specification of crossing profile for all diameters: < 2.67mm

1. UNITY-B instructions for use.

Musculoskeletal Stent System

The **UNITY-B** biodegradable stent was designed based on the functionality of **Musculoskeletal System** (Bone and Muscle) where the magnesium mimics the bone and the polymer the muscle.

The **Skeletal** (Magnesium) portion of the system serves as the main support structure while the **Muscle** (Polymer) helps to support movement and stability potentially eliminating many of the shortcomings found in 1st generation biodegradable technology.



Device Specifications

| | |
|----------------------------|--|
| Description | Endoscopic Balloon Expandable Biodegradable Biliary Stent System |
| Balloon Characteristic | Semi-Compliant |
| Recommended Guidewire | 0.035" (0.89 mm) |
| French Compatibility | 8 F |
| Entry Tip Profile | min 0.95 mm ± 0.15 mm |
| Nominal Pressure | 9 bar |
| Rated Burst Pressure (RBP) | 10 bar |
| Radiopaque Stent Marker | 2 markers on each side (distal and proximal) |

UNITY-B

Endoscopic Balloon Expandable Biodegradable Biliary Stent System

Ordering Information

| | Balloon Ø (mm) | Balloon Length (mm) | Stent Length (mm) | UCL (cm) | Guidewire | Catalogue Number |
|--|----------------|---------------------|-------------------|----------|-----------|------------------|
| FAST DEGRADING 1 - 3 Months ¹ | 8 | 60 | 57 | 190 | 0.035" | 19 MBXb 08057A |
| | 9 | | | | | 19 MBXb 09057A |
| | 10 | | | | | 19 MBXb 10057A |
| MEDIUM ² DEGRADING 3 - 6 Months ¹ | 8 | 60 | 57 | 190 | 0.035" | TBD |
| | 9 | | | | | TBD |
| | 10 | | | | | TBD |
| SLOW ² DEGRADING 6+ Months ¹ | 8 | 60 | 57 | 190 | 0.035" | TBD |
| | 9 | | | | | TBD |
| | 10 | | | | | TBD |

1. Degradation times are estimated and are subject to change based on patient anatomy and biochemistry.
2. Not currently available / product and sizes currently in development are subject to change.



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