BIODEGRADABLE

Q3 Medical GROUP

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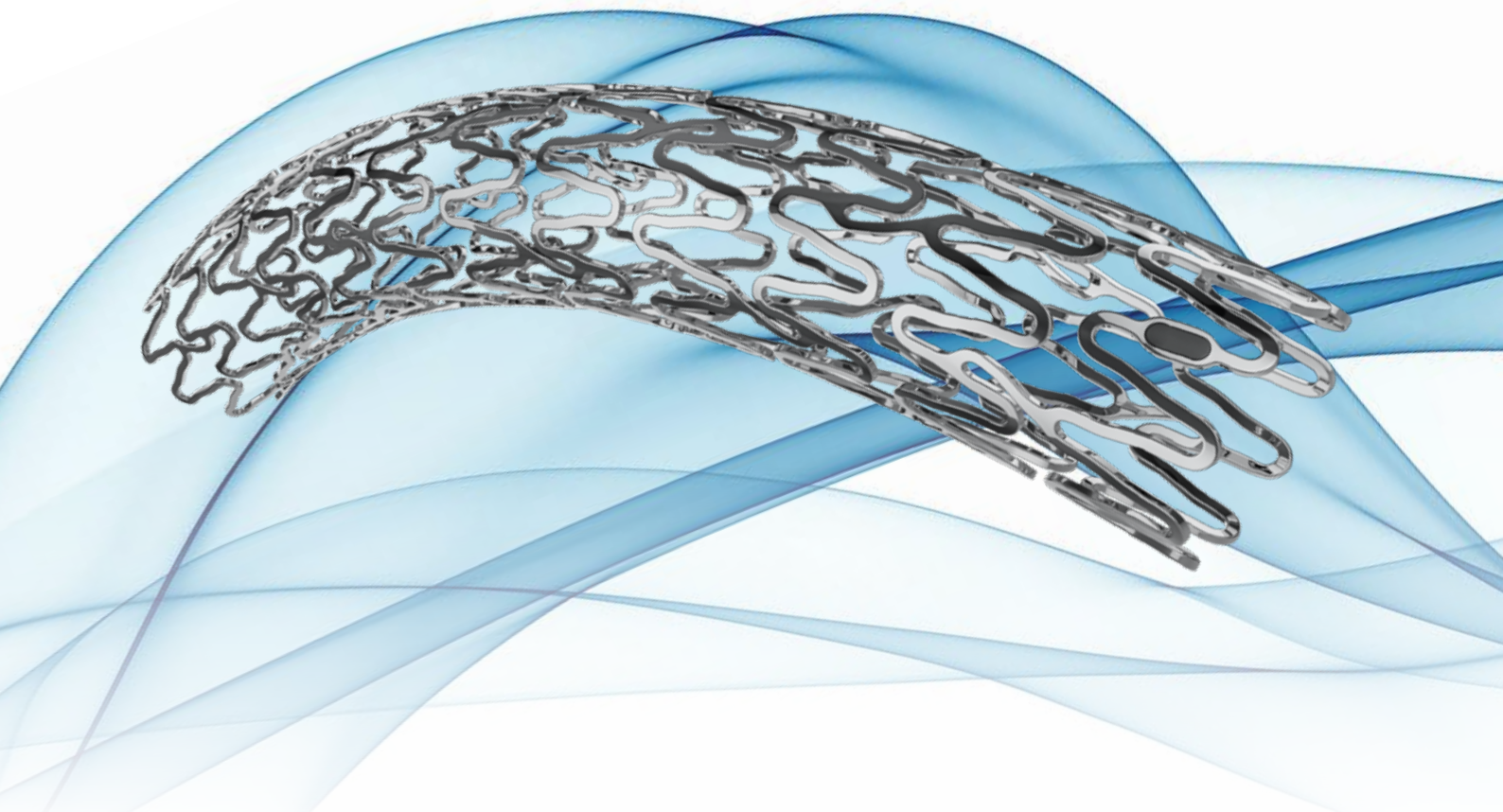
# UNITY-B

## Percutaneous Balloon Expandable Biodegradable Biliary Stent System



BIODEGRADABLE SOLUTIONS

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# UNITY-B

**Percutaneous Balloon Expandable Biodegradable Biliary Stent System**

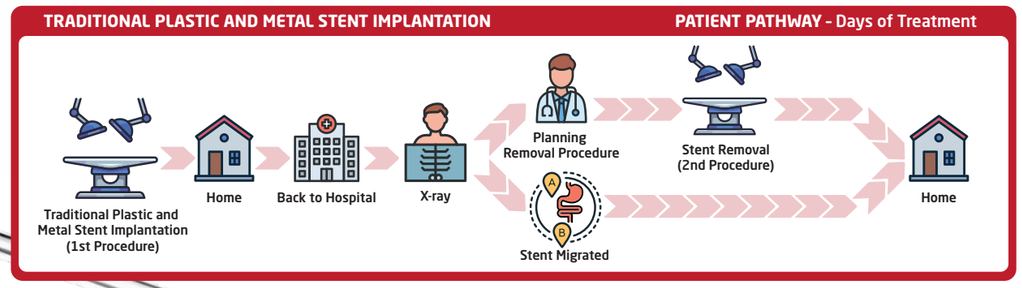
BIODEGRADABLE SOLUTIONS

The **UNITY-B** Percutaneous Balloon Expandable Biodegradable Biliary Stent System is designed to be used to help drain obstructed bile ducts[1] with the **added benefit of biodegradation** to potentially **minimize the complications associated with traditional metal stents.**

## 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 short comings found in 1st generation biodegradable technology.



## 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 | | | |

## Device Specifications

| | |
|---|---|
| Description | Percutaneous 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) |

1. UNITY-B instructions for use.

# UNITY-B

## Percutaneous Balloon Expandable Biodegradable Biliary Stent System

## Ordering Information

| | UCL (cm) | Balloon Ø (mm) | Balloon Length (mm) | Stent Length (mm) | Guidewire | Catalogue Number |
|---|---|---|---|---|---|---|
| **FAST** DEGRADING 1 - 3 Months[1] | 80 | 8 | 60 | 57 | 0.035” | 08 MBXb 08057A |
| | | 9 | | | | 08 MBXb 09057A |
| | | 10 | | | | 08 MBXb 10057A |
| | 120 | 8 | 60 | 57 | 0.035” | 12 MBXb 08057A |
| | | 9 | | | | 12 MBXb 09057A |
| | | 10 | | | | 12 MBXb 10057A |
| | 150 | 8 | 60 | 57 | 0.035” | 15 MBXb 08057A |
| | | 9 | | | | 15 MBXb 09057A |
| | | 10 | | | | 15 MBXb 10057A |

| | UCL (cm) | Balloon Ø (mm) | Balloon Length (mm) | Stent Length (mm) | Guidewire | Catalogue Number |
|---|---|---|---|---|---|---|
| **MEDIUM**[2] DEGRADING 3 - 6 Months[1] | 80 | 8 | 60 | 57 | 0.035” | TBD |
| | | 9 | | | | TBD |
| | | 10 | | | | TBD |
| | 120 | 8 | 60 | 57 | 0.035” | TBD |
| | | 9 | | | | TBD |
| | | 10 | | | | TBD |
| | 150 | 8 | 60 | 57 | 0.035” | TBD |
| | | 9 | | | | TBD |
| | | 10 | | | | TBD |

| | UCL (cm) | Balloon Ø (mm) | Balloon Length (mm) | Stent Length (mm) | Guidewire | Catalogue Number |
|---|---|---|---|---|---|---|
| **SLOW**[2] DEGRADING 6+ Months[1] | 80 | 8 | 60 | 57 | 0.035” | TBD |
| | | 9 | | | | TBD |
| | | 10 | | | | TBD |
| | 120 | 8 | 60 | 57 | 0.035” | TBD |
| | | 9 | | | | TBD |
| | | 10 | | | | TBD |
| | 150 | 8 | 60 | 57 | 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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