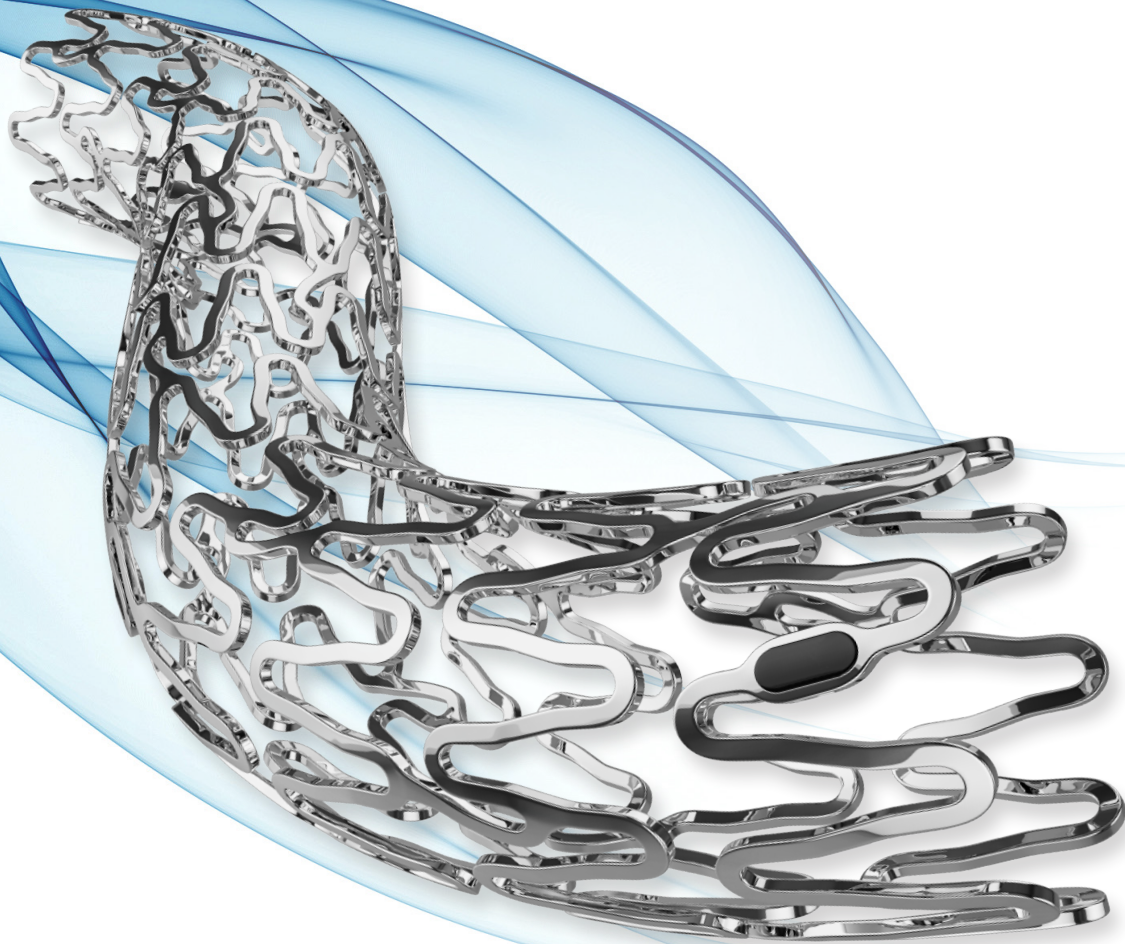


ENDOSCOPIC  
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# UNITY-B

Endoscopic Balloon Expandable  
Biodegradable Biliary Stent System



THE FUTURE IN  
BIODEGRADABLE™  
GI PRODUCTS

CE MARK PENDING

# UNITY-B Endoscopic Balloon Expandable Biodegradable Biliary Stent System

THE FUTURE IN  
**BIO**DEGRADABLE™  
 GI PRODUCTS

The **UNITY-B** Endoscopic Biodegradable Balloon Expandable Biliary Stent System is designed to be used to help drain obstructed bile ducts<sup>1</sup> 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 1<sup>st</sup> 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 <sup>2</sup>	2.62 mm
Crossing profile (mean)	2.52 mm	2.54 mm <sup>2</sup>	2.56 mm
Foreshortening at NP (max)	0.1%	1.3% <sup>2</sup>	2.5%
Recoil at NP (max / mean)	4.3% / 3.4%	3.1% / 1.7% <sup>2</sup>	1.9% / 0%
Recoil at RBP (max / mean)	7.3% / 4.1%	6.8% / 3.45% <sup>2</sup>	6.3% / 2.8%

Specification of crossing profile for all diameters: < 2.67mm

## Device Specifications

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

1. UNITY-B instructions for use.  
 2. Approximate data for product sizes in development

## Indication for Use:

> The UNITY-B Endoscopic Balloon Expandable Biodegradable Biliary Stent System is used to drain obstructed bile ducts.

## Ordering Information

	Balloon Ø (mm)	Balloon Length (mm)	Stent Length (mm)	UCL (cm)	Guidewire	Catalogue Number
<b>FAST</b> DEGRADING 1 - 3 Months <sup>1</sup>	8	60	57	190	0.035"	19 MBXb 08057A
	9 <sup>2</sup>					19 MBXb 09057A <sup>2</sup>
	10					19 MBXb 10057A

	Balloon Ø (mm)	Balloon Length (mm)	Stent Length (mm)	UCL (cm)	Guidewire	Catalogue Number
<b>MEDIUM<sup>2</sup></b> DEGRADING 3 - 6 Months <sup>1</sup>	8	60	57	190	0.035"	TBD
	9					TBD
	10					TBD

	Balloon Ø (mm)	Balloon Length (mm)	Stent Length (mm)	UCL (cm)	Guidewire	Catalogue Number
<b>SLOW<sup>2</sup></b> DEGRADING 6+ Months <sup>1</sup>	8	60	57	190	0.035"	TBD
	9					TBD
	10					TBD

## In Development<sup>2</sup>

Balloon Ø (mm)	Stent Length (mm)				UCL (cm)	Guidewire	
5	17	27	37	57	77	190	0.035"
6							
7							
8							
9							
10							

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