ENDOSCOPIC
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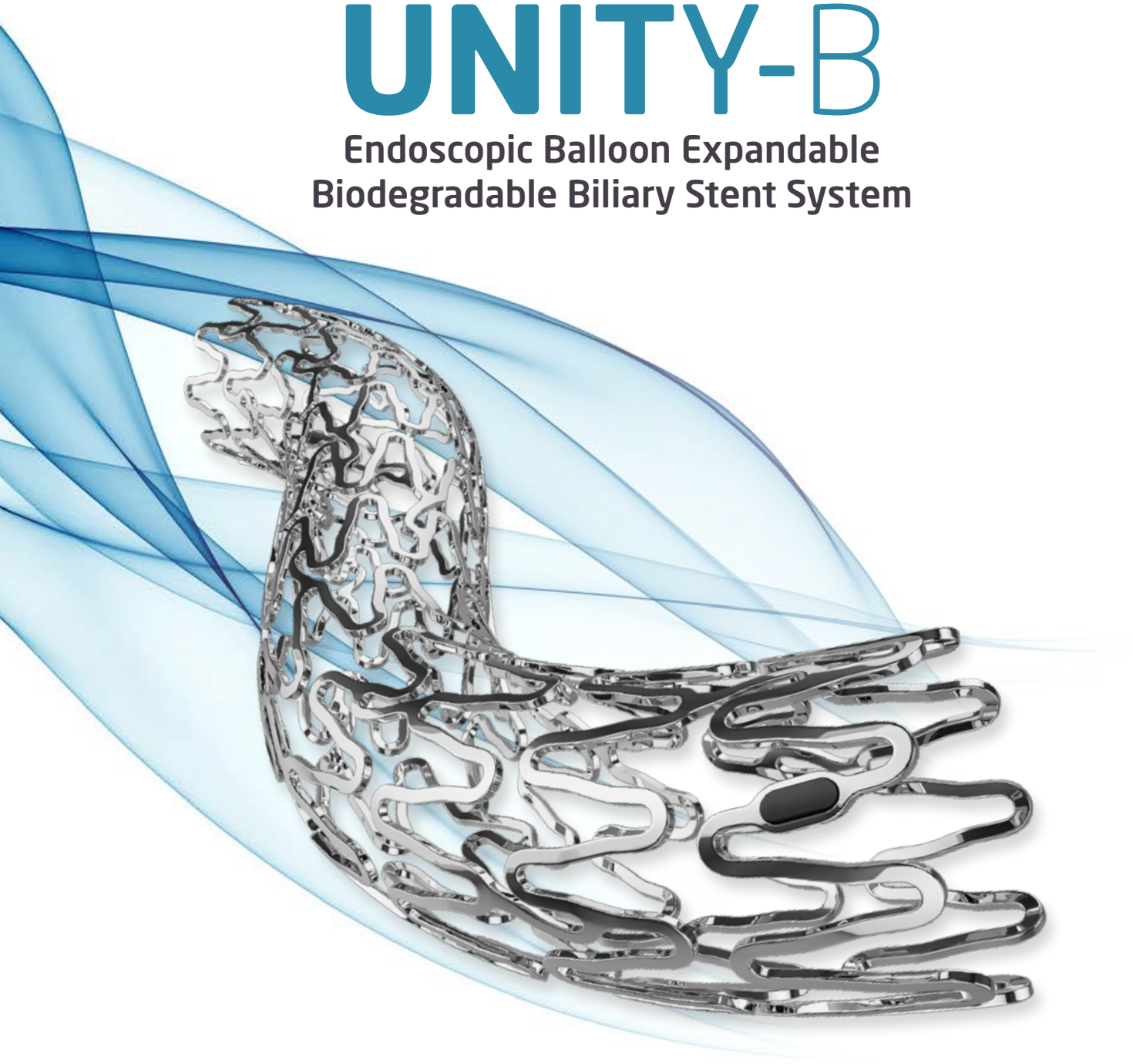
UNITY-B

Endoscopic Balloon Expandable Biodegradable Biliary Stent System



THE FUTURE IN
BIODEGRADABLE™
GI PRODUCTS

CE MARK APPROVED

UNITY-B

Endoscopic Balloon Expandable Biodegradable Biliary Stent System

THE FUTURE IN BIODEGRADABLE™ GI PRODUCTS

The **UNITY-B** Endoscopic Biodegradable Balloon Expandable 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]	2.62 mm
Crossing profile (mean)	2.52 mm	2.54 mm[2]	2.56 mm
Foreshortening at NP (max)	0.1%	1.3%[2]	2.5%
Recoil at NP (max / mean)	4.3% / 3.4%	3.1% / 1.7%[2]	1.9% / 0%
Recoil at RBP (max / mean)	7.3% / 4.1%	6.8% / 3.45%[2]	6.3% / 2.8%
Specification of crossing profile for all diameters: < 2.67mm			

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)

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

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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
FAST DEGRADING 1 - 3 Months[1]	8	60	57	190	0.035“	19 MBXb 08057A
	9[2]					19 MBXb 09057A[2]
	10					19 MBXb 10057A

	Balloon Ø (mm)	Balloon Length (mm)	Stent Length (mm)	UCL (cm)	Guidewire	Catalogue Number
MEDIUM[2] DEGRADING 3 - 6 Months[1]	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
SLOW[2] DEGRADING 6+ Months[1]	8	60	57	190	0.035“	TBD
	9					TBD
	10					TBD

In Development[2]

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

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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051300 Made in Germany