

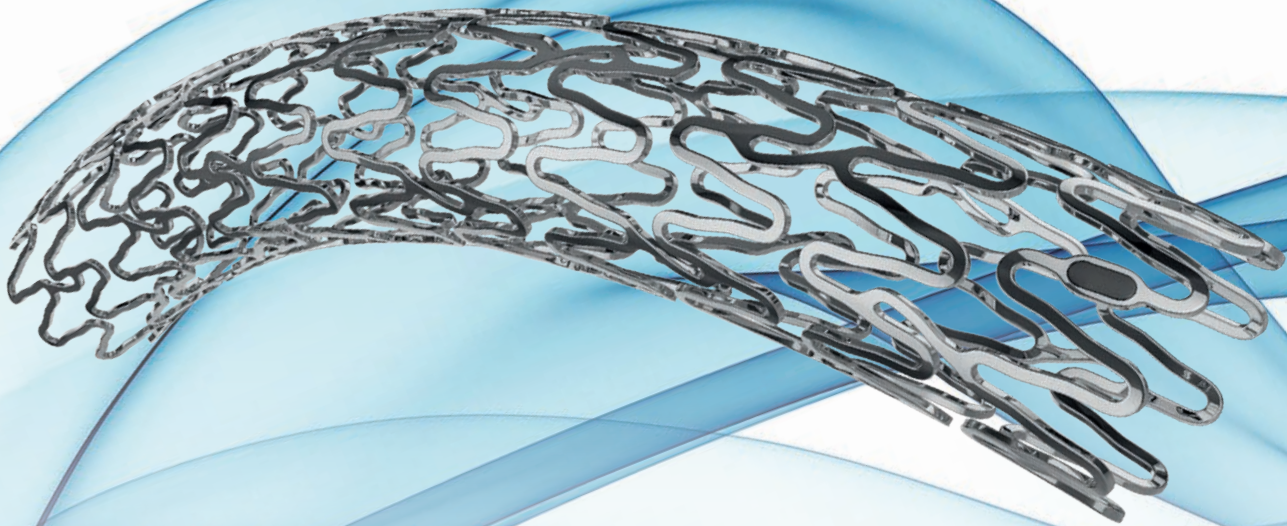
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UNITY-B

Percutaneous Balloon Expandable
Biodegradable Biliary Stent System



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The **UNITY-B** Percutaneous 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**.

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:

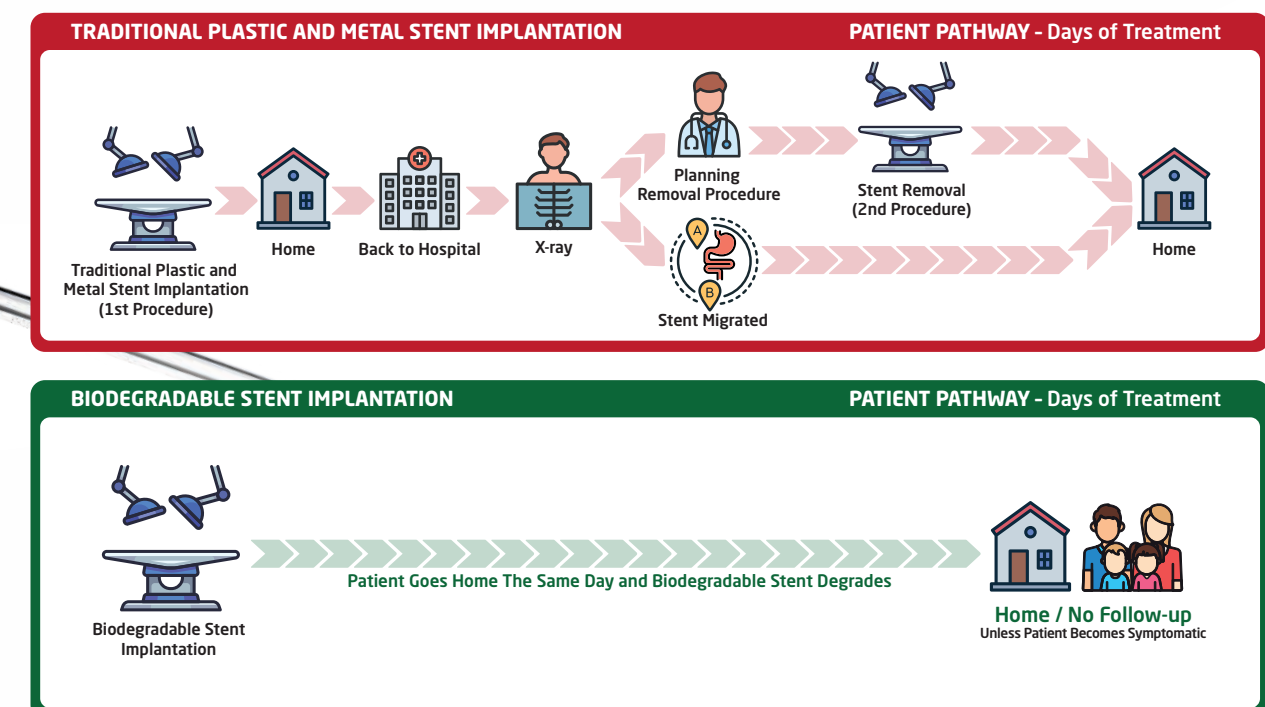
- > Can be produced in a **wide range of sizes** and placed with the **same approach** used for traditional balloon expandable metallic stents.
- > **Biodegradable nature** of the **UNITY-B** stent is intended to **mitigate stent in-growth, over-growth** and **perforation** typically seen with traditional 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

1. UNITY-B instructions for use.



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)

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
MEDIUM² 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
SLOW² 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.

 **amg International GmbH**



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