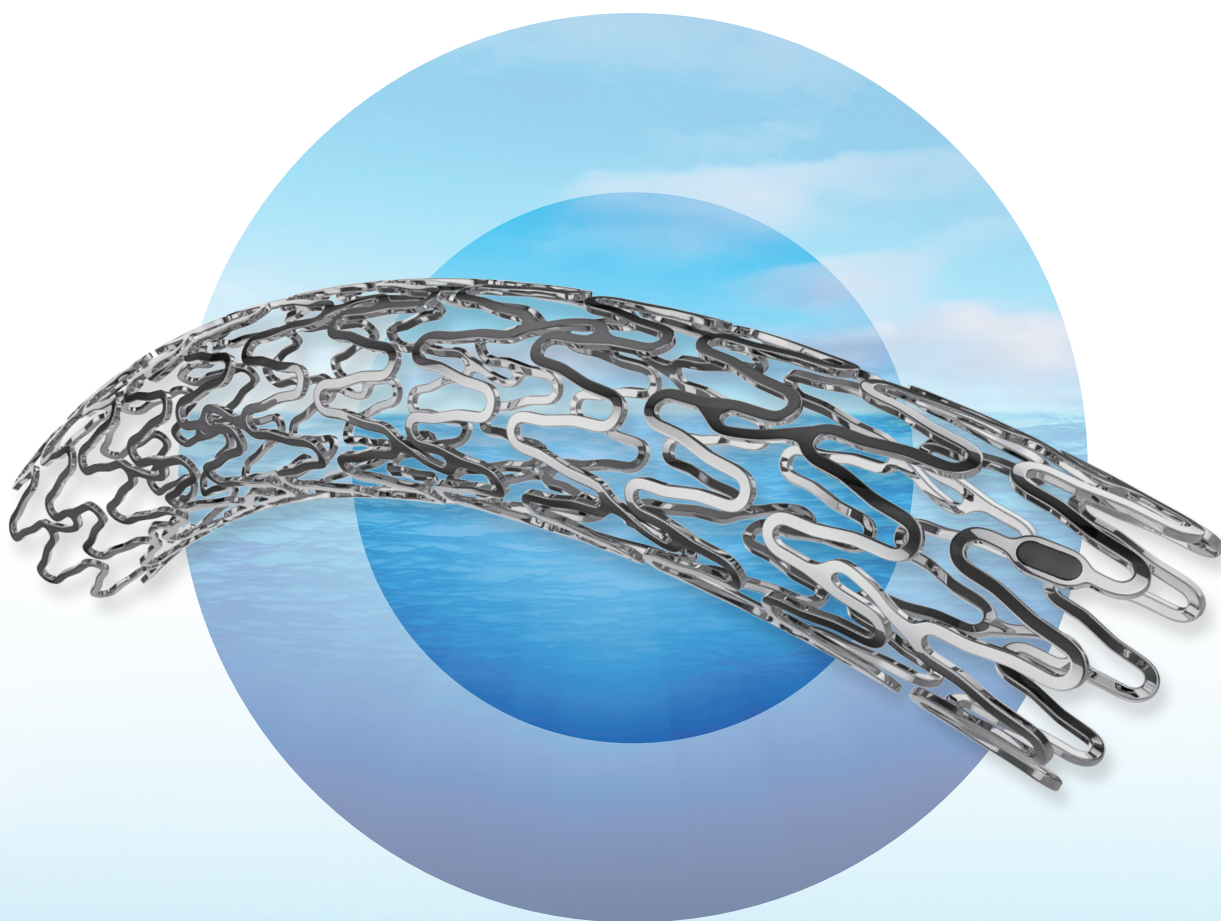


BIODEGRADABLE

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UNITY-B

Percutaneous Balloon Expandable
Biodegradable Biliary Stent System



QualiMed®

A Q3 Medical Company

CE MARK PENDING



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 shortcomings 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**.

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	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.
2. Approximate data for product sizes in development

UNITY-B Percutaneous Balloon Expandable Biodegradable Biliary Stent System

Indications for Use:

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

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.