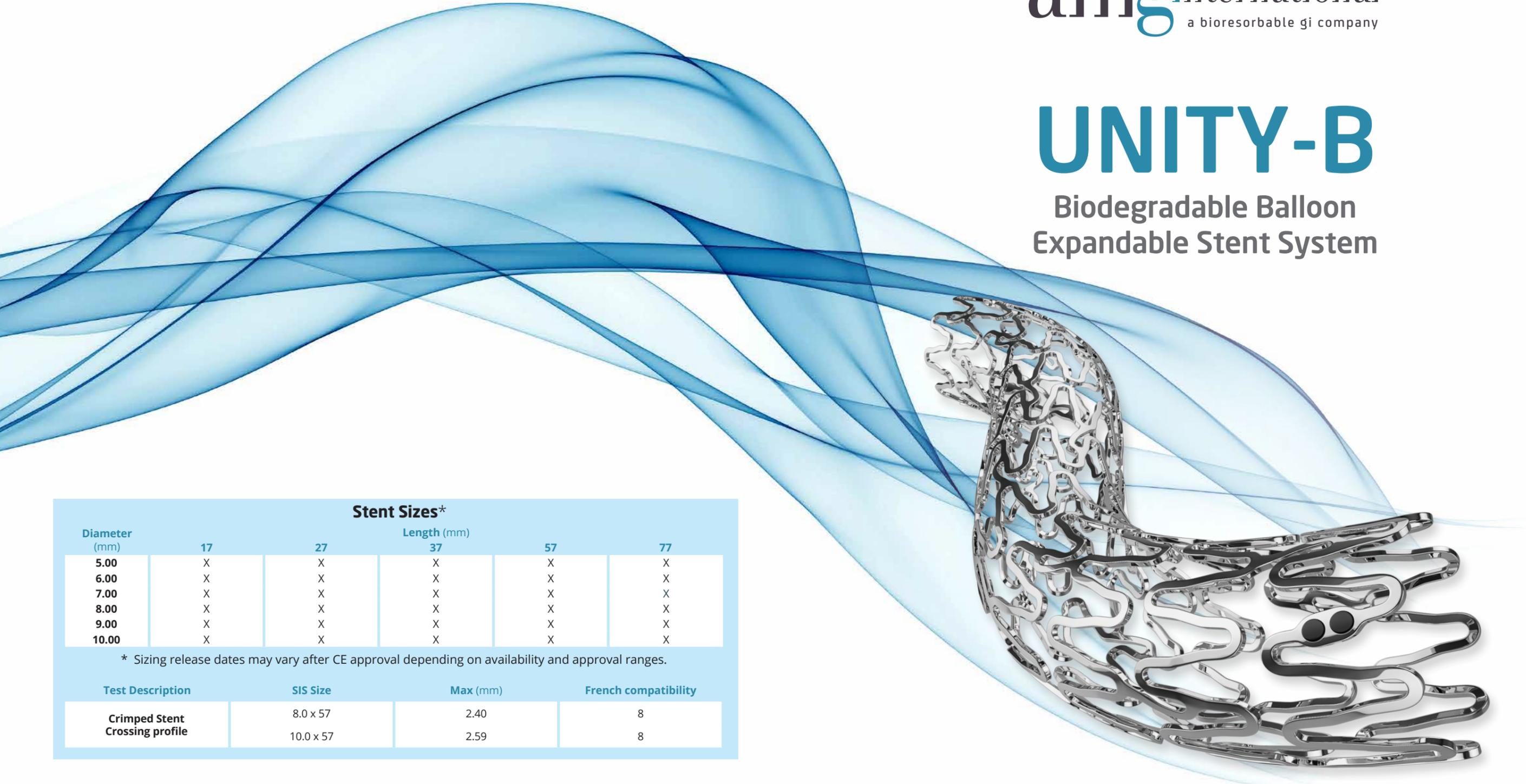


BIODEGRADABLE

UNITY-B Biodegradable Balloon Expandable Stent System

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UNITY-B Biodegradable Balloon Expandable Stent System



Diameter (mm)	Stent Sizes*				
	Length (mm)				
	17	27	37	57	77
5.00	X	X	X	X	X
6.00	X	X	X	X	X
7.00	X	X	X	X	X
8.00	X	X	X	X	X
9.00	X	X	X	X	X
10.00	X	X	X	X	X

* Sizing release dates may vary after CE approval depending on availability and approval ranges.

Test Description	SIS Size	Max (mm)	French compatibility
Crimped Stent Crossing profile	8.0 x 57	2.40	8
	10.0 x 57	2.59	8

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THE FUTURE IN
BIORESORBABLE
GI PRODUCTS

Q³Medical GROUP OF COMPANIES

Manufactured by
QualiMed Innovative Medizinprodukte GmbH
Boschstraße 16 | D-21423 Winsen | Germany | www.qualimed.de

Status - April 2017
PS Unity-B_01
Made in Germany

CE MARK PENDING

UNITY-B Biodegradable Balloon Expandable Stent System

THE FUTURE IN
BIORESORBABLE
GI PRODUCTS

The **UNITY-B** Biodegradable Balloon Expandable Stent System is designed to replace self-expanding metallic stents (SEMS) with the **added benefit of biodegradation** to **minimize the complications** associated with metal stents such as perforation, stent-in-growth, stent-over-growth and the inability to remove metal stents.

COMPARISON DATA*

Characteristics

Crossing Profile (mm)
Foreshortening, max at NP (%)
Maximum Recoil of the expanded stent at NP (%)

UNITY-B

2.20 - 2.40 (mean 2.30)
0.9% (RBP) ø10 mm
3.1% (NP) ø10 mm

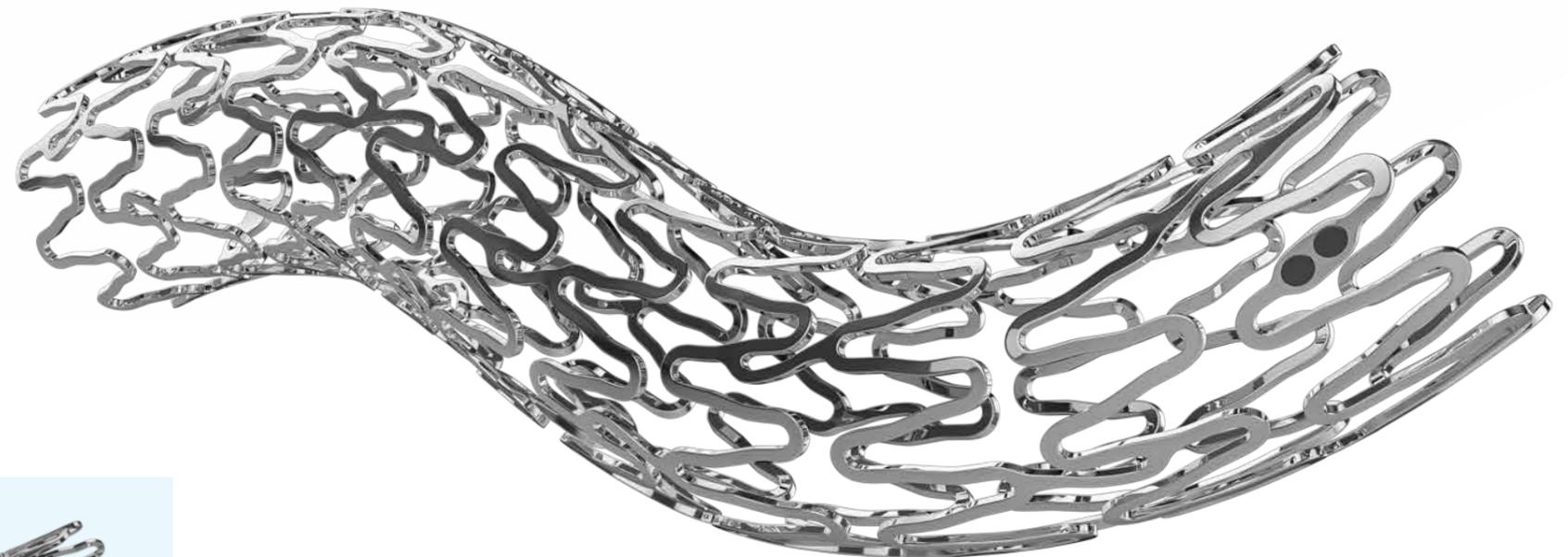
UNITY VS MAIN COMPETITOR

OmniLink

2.22 - 2.27 (ø10 mm)
2.30% (RBP) ø10 mm
3.14% (NP) ø10 mm

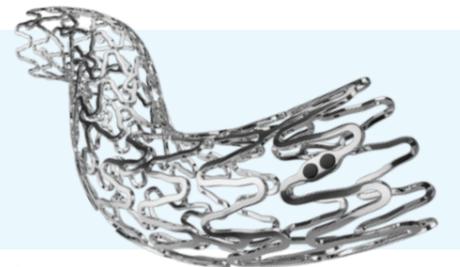
UNITY-B is a hybrid biodegradable stent that:

- ✦ Functions like a metallic stent
- ✦ Can be used in non conforming strictures
- ✦ Can be over-dilated without fracturing
- ✦ Has minimal recoil and foreshortening
- ✦ Does not require in advance preparation of the stricture
- ✦ Can be placed with the same traditional approach used for a normal metallic or DES stent
- ✦ Can be easily produced in a wide range of sizes



BILIARY

amg has combined the same natural symbiotic design into its UNITY-B Stent where its proprietary magnesium alloy acts as the bone or skeleton and the polymer outer acts as the muscle.



PERIPHERAL

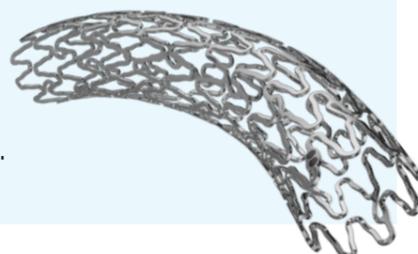
By finding the right balance for the combination of these materials one can produce a implant that works in the same mechanical form as its historical metallic version with the added benefit of being biodegradable and leaving nothing behind.



CORONARY

ADVANTAGES

- ✦ Uniform expansion of the stent with no cracks to maximum diameter (4.4 mm).
- ✦ Measurements resulted to almost zero foreshortening.
- ✦ Fluoroscopic visibility can be improved by radiopaque markers.
- ✦ Very low recoil which ranged between 1.98% and 1.13%.



Enhanced features:

- ✦ Initial surface degradation allows for bile flow and "self-cleaning" of biofilm
- ✦ Minimizes stent-in-growth
- ✦ Minimizes stent-over-growth
- ✦ Minimizes stent perforation (no COF)
- ✦ The issue of stent removal is eliminated

The Skeletal portion of the system serves as the main support structure for the body.



The Muscles keep bones in place and also play a role in the movement of bones.