BIODEGRADABLE

ARCHIMEDES

Biodegradable Biliary and Pancreatic Stent

amg international
A Q3 Medical Company

Fast degrading stent*

12 days

2 mm Diameter (6 F)

Product code	Length (mm)
BPS20040F	40
BPS20060F	60
BPS20080F	80
BPS20100F	100
BPS20125F	125
BPS20150F	150
BPS20175F	175

2.6 mm Diameter (~8 F)

Product code	Length (mm)
BPS26040F	40
BPS26060F	60
BPS26080F	80
BPS26100F	100
BPS26125F	125
BPS26150F	150
BPS26175F	175
BPS26200F	200
BPS26225F	225

3.4 mm Diameter (~10 F)

Product code	Length (mm)
BPS34040F	40
BPS34060F	60
BPS34080F	80
BPS34100F	100
BPS34125F	125
BPS34150F	150
BPS34175F	175
BPS34200F	200
BPS34225F	225

Medium degrading stent*

20 days

2 mm Diameter (6 F)

Product code	Length (mm)
BPS20040M	40
BPS20060M	60
BPS20080M	80
BPS20100M	100
BPS20125M	125
BPS20150M	150
BPS20175M	175

2.6 mm Diameter (~8 F)

Product code	Length (mm)
BPS26040M	40
BPS26060M	60
BPS26080M	80
BPS26100M	100
BPS26125M	125
BPS26150M	150
BPS26175M	175
BPS26200M	200
BPS26225M	225

3.4 mm Diameter (~10 F)

Product code	Length (mm)
BPS34040M	40
BPS34060M	60
BPS34080M	80
BPS34100M	100
BPS34125M	125
BPS34150M	150
BPS34175M	175
BPS34200M	200
BPS34225M	225

Slow degrading stent*

11 weeks

2 mm Diameter (6 F)

Product code	Length (mm)
BPS20040S	40
BPS20060S	60
BPS20080S	80
BPS20100S	100
BPS20125S	125
BPS20150S	150
BPS20175S	175

2.6 mm Diameter (~8 F)

Product code	Length (mm)
BPS26040S	40
BPS26060S	60
BPS26080S	80
BPS26100S	100
BPS26125S	125
BPS26150S	150
BPS26175S	175
BPS26200S	200
BPS26225S	225

3.4 mm Diameter (~10 F)

Product code	Length (mm)
BPS34040S	40
BPS34060S	60
BPS34080S	80
BPS34100S	100
BPS34125S	125
BPS34150S	150
BPS34175S	175
BPS34200S	200
BPS34225S	225

** PLEASE NOTE that the suitable degradation profile of the stent to treat the obstructed biliary or pancreatic duct must be chosen by a clinical professional, always taking the underlying disease and the condition of the individual patient into account.*

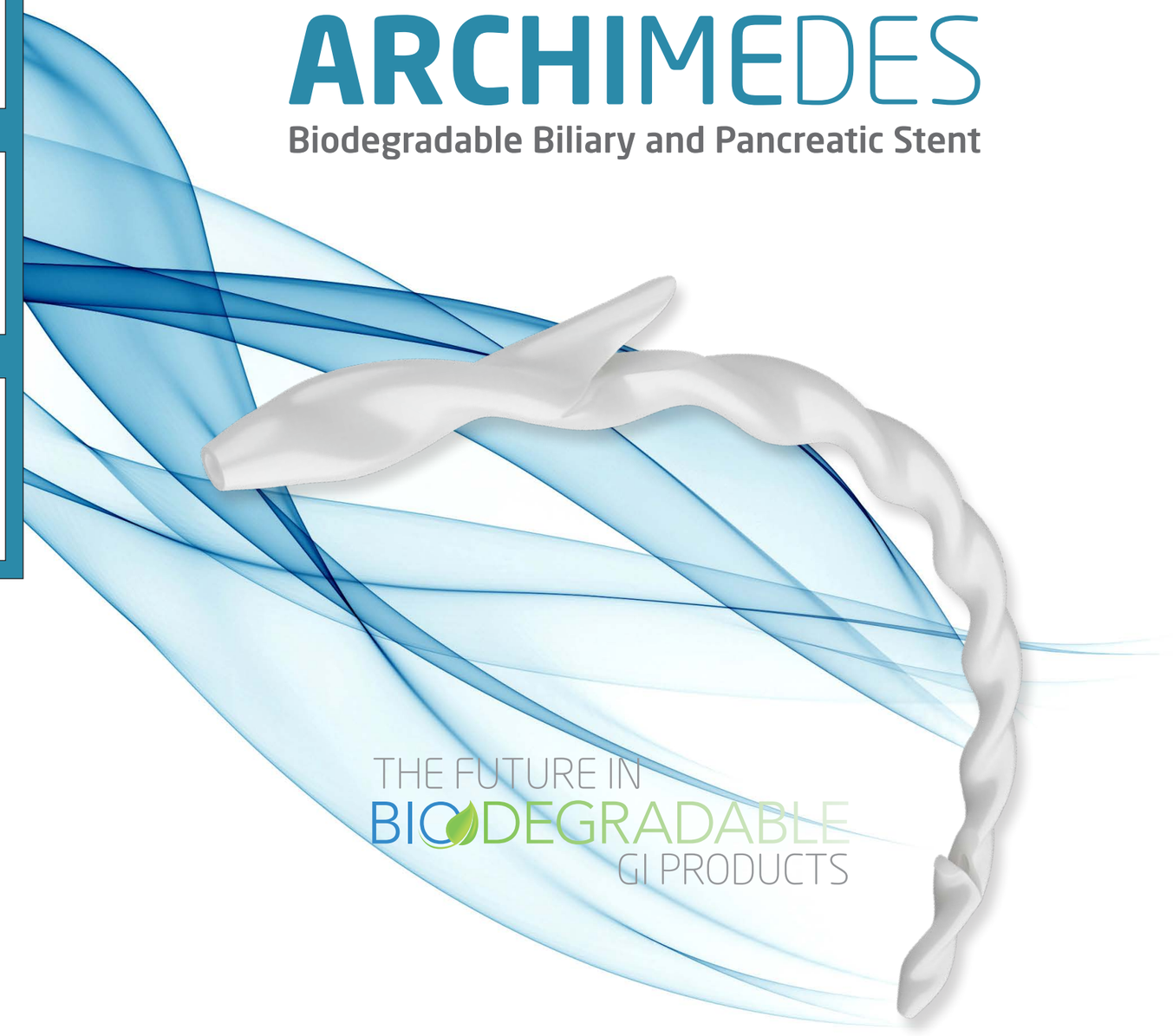
***The product offical name is** ARCHIMEDES BPS Biodegradable Pancreaticobiliary Stent*

INTENDED USE / INDICATION: This device is used to drain obstructed biliary or pancreatic ducts and is indicated for obstructed biliary or pancreatic ducts.

Instructions For Use:

1. Ensure full extension of anti-migration struts.
2. Load introducer sleeve over one end of stent.
3. Introduce introducer sleeve and stent onto a pre-positioned guidewire.
4. Advance pushing catheter in 1-2cm increments until the stent is in desired position.
5. Fluoroscopically and endoscopically confirm desired stent position. Inject contrast, if desired, to fluoroscopically visualize stent position.
6. After confirming stent position, gently remove guidewire from endoscope while maintaining position of the stent with pushing catheter.
7. Gently remove pushing catheter from accessory channel.

ARCHIMEDES
Biodegradable Biliary and Pancreatic Stent



THE FUTURE IN BIODEGRADABLE GI PRODUCTS

amg international
A Q3 Medical Company

amg International GmbH | Boschstraße 16 | D-21423 Winsen | Germany

Phone +49 4171 6905 57-0
Fax +49 4171 6905 57-11
Email info@amggastro.com
Web www.amggastro.com

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CE MARK APPROVED

ARCHIMEDES Biodegradable Biliary and Pancreatic Stent

The **ARCHIMEDES** Stent is a **Biodegradable Biliary** and **Pancreatic** Stent intended to be used to drain obstructed biliary or pancreatic ducts.[1] The patented helical design of the stent **allows for bile to flow** on the outer extremity of the device while supporting the opening of the lumen.

- > **Three degradation profiles** address all potential biliary and pancreatic drainage applications
- > Potential to **reduces cost, morbidity,** and **complication rates** by eliminating subsequent stent removal procedure
- > **Proximal** and **distal flaps** help minimize migration
- > **Anatomically shaped** for enhanced positioning
- > **Tapered tip** facilitates smooth cannulation
- > **Helical bile channels** allow for anatomical bile flow

" In a 53 patient single arm safety and efficacy study, bilirubin levels were **reduced by 25.6% exceeding the 20% clinical success criterion.** The quality of life score **improved from 3.7 to 7.9.** Procedural success was rated at **1.4 (good to excellent).** And **technical success was achieved in all 53 patients.** "

THE FUTURE IN BIODEGRADABLE GI PRODUCTS

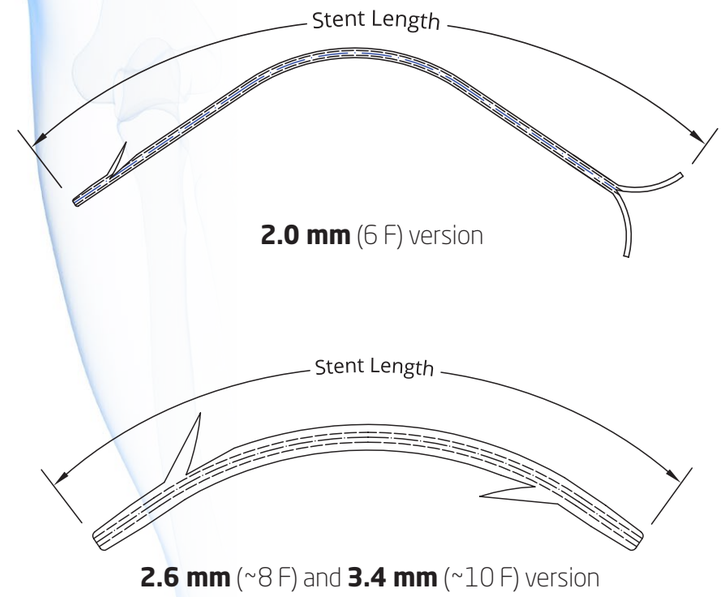
DEGRADATION TABLE

Recommendation for the use of ARCHIMEDES Stent degradation profiles to potential underlying diseases

Stent Degradation Profiles*	Minimal Strength Retention**	Underlying diseases with obstructed biliary duct	Underlying diseases with obstructed pancreatic duct
Fast degrading stent	**12 days**	• Cholelithiasis / Choledocholithiasis • Acute biliary pancreatitis • Cholangitis	• Post ERCP pancreatitis • Acute pancreatitis
Medium degrading stent	**20 days**	• Cholelithiasis / Choledocholithiasis • Biliary leaks • Cystic duct leaks • Resectable CBD obstruction • Cholangitis	• Pancreatic duct disruptions / leaks
Slow degrading stent	**11 weeks**	• Cholelithiasis / Choledocholithiasis • Benign biliary strictures • Malignant strictures • Biliary leaks • Cholangitis	• Chronic pancreatitis • Pancreatic duct strictures

** The different degradation profiles are designed for obstructed biliary or pancreatic ducts with various underlying diseases.*

*** Minimal Strength Retention is defined by the presence of at least 10% of an initial strength parameter. The Stent remains intact with no breaks, tested in a simulated degradation model.*



2.0 mm (6 F) version

2.6 mm (~8 F) and **3.4 mm** (~10 F) version

[1] Hepatic, Cystic, Common Bile, and Pancreatic resulting from malignancy of the liver, pancreas, duodenum, biliary tree or from various benign disease.

[2] Based on global plastic stents procedure estimates placed annually, the ARCHIMEDES Biodegradable Stent has the potential to reduces cost, morbidity and complication rates by eliminating subsequent stent removal procedure.