

BIODEGRADABLE

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A Q3 Medical Company

ARCHIMEDES

Biodegradable Biliary and Pancreatic Stent



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GI PRODUCTS

CE MARK APPROVED

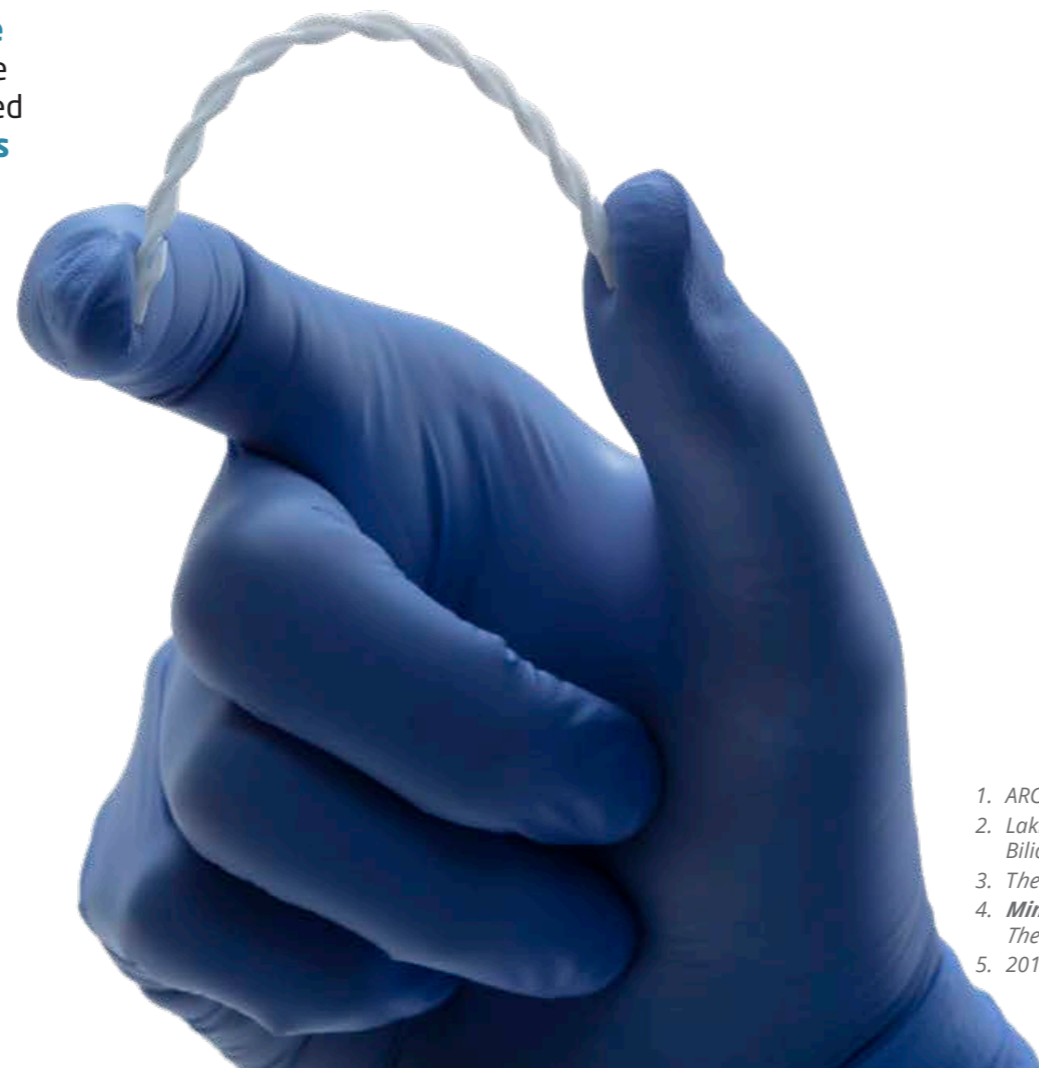
ARCHIMEDES Biodegradable Biliary and Pancreatic Stent

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 surface of the device while supporting the opening of the lumen.

Enhanced features

- > **Different degradation profiles** to cover a variety of malignant and benign underlying diseases
- > **Sinusoidal helical-channel design** to allow bile to flow on the outside of the stent
- > **Mitigation of stent occlusion** due to the degradation process of the stent materials
- > **Better simulated flow rates** than tested plastic stent predicates.
- > **Better simulated migration resistance** than tested plastic stent predicates.
- > **Equivalent crush resistance** to tested plastic stent predicates.

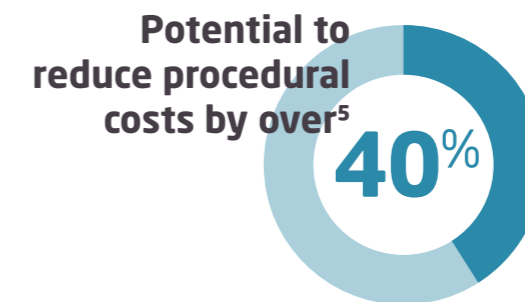
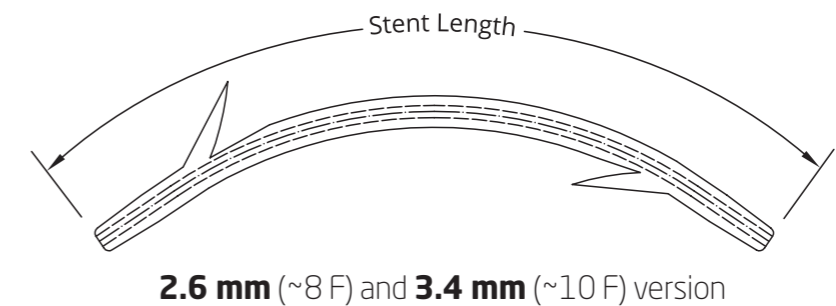
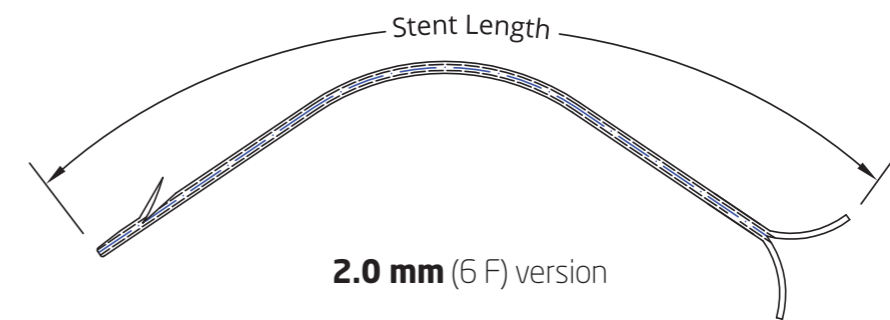
In a 53 patient single arm safety and efficacy study, bilirubin levels were **reduced by 25.6% exceeding the 20% clinical success criterion**. The quality of life score **improved from 3.7 to 7.9**. Procedural success was rated at **1.4 (good to excellent)**. And **technical success was achieved in all 53 patients**.²



DEGRADATION PROFILES

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

Stent Degradation Profiles ³	Minimal Strength Retention ⁴	Underlying diseases with obstructed biliary duct	Underlying diseases with obstructed pancreatic duct
FAST degrading stent	12 days	<ul style="list-style-type: none"> • Cholelithiasis / Choledocholithiasis • Acute biliary pancreatitis • Cholangitis • Modified anatomy procedures involving biliary and pancreatic ducts such as liver transplants, Whipples and alike 	<ul style="list-style-type: none"> • Post ERCP pancreatitis • Acute pancreatitis
MEDIUM degrading stent	20 days	<ul style="list-style-type: none"> • Cholelithiasis / Choledocholithiasis • Biliary leaks • Cystic duct leaks • Resectable CBD obstruction • Cholangitis • Modified anatomy procedures involving biliary and pancreatic ducts such as liver transplants, Whipples and alike 	<ul style="list-style-type: none"> • Pancreatic duct disruptions leaks
SLOW degrading stent	11 weeks	<ul style="list-style-type: none"> • Cholelithiasis / Choledocholithiasis • Benign biliary strictures • Malignant strictures • Biliary leaks • Cholangitis • Modified anatomy procedures involving biliary and pancreatic ducts such as liver transplants, Whipples and alike 	<ul style="list-style-type: none"> • Chronic pancreatitis • Pancreatic duct strictures



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1. ARCHIMEDES BPS Instructions for Use (IFU ARCHIMEDES BPS_02 - 093A47_200505).
2. Lakhtakia S, Yaacob N, Jarmin R, Mohamed Z, Jasminroslan E, Othman H, et al. 339 Novel Bio-Degradable Stent In Patients With Biliary Or Pancreatic Obstruction : A Pilot Study To Assess Clinical Efficacy And Safety. *Gastrointestinal Endoscopy*. 2018;87(6).
3. The different degradation profiles are designed for obstructed biliary or pancreatic ducts with various underlying diseases.
4. **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.
5. 2019 Frost & Sullivan Independent Market Research Report.

ARCHIMEDES Biodegradable Biliary and Pancreatic Stent

Fast degrading stent*		Medium degrading stent*		Slow degrading stent*	
12 days		20 days		11 weeks	
2 mm Diameter (6 F)		2 mm Diameter (6 F)		2 mm Diameter (6 F)	
Product code	Length (mm)	Product code	Length (mm)	Product code	Length (mm)
BPS20040F	40	BPS20040M	40	BPS20040S	40
BPS20060F	60	BPS20060M	60	BPS20060S	60
BPS20080F	80	BPS20080M	80	BPS20080S	80
BPS20100F	100	BPS20100M	100	BPS20100S	100
BPS20125F	125	BPS20125M	125	BPS20125S	125
BPS20150F	150	BPS20150M	150	BPS20150S	150
BPS20175F	175	BPS20175M	175	BPS20175S	175
2.6 mm Diameter (~8 F)		2.6 mm Diameter (~8 F)		2.6 mm Diameter (~8 F)	
Product code	Length (mm)	Product code	Length (mm)	Product code	Length (mm)
BPS26040F	40	BPS26040M	40	BPS26040S	40
BPS26060F	60	BPS26060M	60	BPS26060S	60
BPS26080F	80	BPS26080M	80	BPS26080S	80
BPS26100F	100	BPS26100M	100	BPS26100S	100
BPS26125F	125	BPS26125M	125	BPS26125S	125
BPS26150F	150	BPS26150M	150	BPS26150S	150
BPS26175F	175	BPS26175M	175	BPS26175S	175
BPS26200F	200	BPS26200M	200	BPS26200S	200
BPS26225F	225	BPS26225M	225	BPS26225S	225
3.4 mm Diameter (~10 F)		3.4 mm Diameter (~10 F)		3.4 mm Diameter (~10 F)	
Product code	Length (mm)	Product code	Length (mm)	Product code	Length (mm)
BPS34040F	40	BPS34040M	40	BPS34040S	40
BPS34060F	60	BPS34060M	60	BPS34060S	60
BPS34080F	80	BPS34080M	80	BPS34080S	80
BPS34100F	100	BPS34100M	100	BPS34100S	100
BPS34125F	125	BPS34125M	125	BPS34125S	125
BPS34150F	150	BPS34150M	150	BPS34150S	150
BPS34175F	175	BPS34175M	175	BPS34175S	175
BPS34200F	200	BPS34200M	200	BPS34200S	200
BPS34225F	225	BPS34225M	225	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 official 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 advancing pushing catheter in 1-2 cm increments until the stent is in desired position. For modified anatomy procedures intraoperatively, position stent manually.
4. Fluoroscopically, radiographically and or endoscopically confirm desired stent position. Inject contrast, if desired, to fluoroscopically visualize stent position.
5. After confirming stent position, gently remove guidewire from endoscope, if applicable, while maintaining position of the stent with pushing catheter.
6. Gently remove pushing catheter from accessory channel, if applicable.

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CE 1434

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