**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 1-2 cm 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.
The ARCHIMEDES Stent is a Biodegradable Biliary and Pancreatic Stent intended to be used to drain obstructed biliary or pancreatic ducts. 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.”

### DEGRADATION TABLE

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

<table>
<thead>
<tr>
<th>Stent Degradation Profiles</th>
<th>Minimal Strength Retention</th>
<th>Potential Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast degrading stent</td>
<td>12 days</td>
<td>E.g. Acute biliary pancreatitis</td>
</tr>
<tr>
<td>Medium degrading stent</td>
<td>20 days</td>
<td>E.g. Biliary leaks; Cystic duct leaks; Pancreatic duct disruptions/leaks</td>
</tr>
<tr>
<td>Slow degrading stent</td>
<td>11 weeks</td>
<td>E.g. Benign biliary strictures; Malignant stricture; Chronic pancreatitis; Pancreatic duct strictures</td>
</tr>
</tbody>
</table>

* Minimal Strength Retention is defined by the presence of at least 10% of an initial strength parameter.
** The different degradation profiles are designed for but not limited to the listed potential applications. The suitable Degradation Profile of the stent must be chosen by a clinical professional, always taking the underlying disease and the condition of the individual patient into account.

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.