



# D Biliary Stent

## Niti-S Biliary Stent

**CAUTION:** U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

**INDICATION FOR USE:** The Niti-S Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

**CONTRAINDICATION:** The Niti-S Biliary Stent is contraindicated; • Strictures that do not allow passage of a guidewire. • Patients for whom endoscopic techniques are contraindicated. • Any use other than those specifically outlined under indications for use. • Patient with bleeding disorder. • Patient with ascites. • Biliary obstruction preventing either endoscopic or percutaneous cholangiography • Patients with coagulopathy

**WARNINGS:** The safety and effectiveness of this device for use in the vascular system has not been established. • The device should be used with caution and only after careful consideration in patients with elevated bleeding times, coagulopathies, or in patients with radiation colitis or proctitis. • Stents cannot be repositioned after complete deployment. • Chemoradiation therapy or radiotherapy alone may lead to tumor shrinkage and subsequent stent migration. • The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity. • Do not expose the introducer system to organic solvent (e.g. Alcohol) • Do not use with Ethiodol or Lipiodol contrast media.

**PRECAUTIONS:** Read the entire User's Manual thoroughly before using this device. It should only be used by or under the supervision of physicians thoroughly trained in the placement of biliary stent. A thorough

understanding of the techniques, principles, clinical applications and risk associated with this procedure is necessary before using the device. • Care should be taken when removing the introducer system and guidewire immediately after stent deployment since this may result in stent dislodgement if the stent has not been adequately deployed. • The packaging and the device should be inspected prior to use. • Do not attempt to reload deployed stents onto the introducer system. • Use of fluoroscopy is recommended to ensure correct placement of the device. • Check the expiration date "Expiration Date". Do not use the device beyond the labeled use by date. • The Niti-S Stent is supplied sterile. Do not use if the packaging is opened or damaged. • The Niti-S Stent is intended for single use only. Do not resterilize and/or reuse the device. • MRI Compatible: The Niti-S Stent will not present an additional risk or hazard to a patient in a 1.5 tesla MRI environment or less.

**POTENTIAL COMPLICATIONS:** Potential complications associated with the use of Biliary Stent may include, but are not limited to: Procedural Complications • Bleeding • Stent misplace or inadequate expansion • Pain • Death • Intestinal perforation Post Stent Placement Complications • Bleeding • Pain • Perforation • Bowel impaction • Stent migration • Stent occlusion • Stent occlusion due to tumor in-growth through stent • Stent occlusion due to tumor over-growth around ends of stent • Tumor In-growth • Peritonitis • Sludge occlusion • Fever • Ulceration • Foreign body sensation • Septicemia • Acute Cholecystitis • Pancreatitis • Cholangitis/Cholestasis • Death (other than that due to normal disease progression) • Constipation • Diarrhea • Infection • Liver abscess

**See instructions for use for full product information.**

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Only available in the USA.



**TAEWOOONG**  
**NITI-S™**

## D Biliary Stent

Indicated for the palliation of malignant strictures in the biliary tree.

- Unfixed cell with weave configuration designed to provide optimal radial and axial force to maintain patency in tortuous anatomy
- Radiopaque markers: 3 at each end and 2 in the middle of the stent
- Low foreshortening rate\*

Order Number	Reference Part Number	Stent Diameter mm	Stent Length cm	Delivery System Fr	Delivery System Length cm
<b>Endoscopic Approach</b>					
G57304	BD0804	8	4	8	180
G57307	BD0805	8	5	8	180
G57308	BD0806	8	6	8	180
G57309	BD0807	8	7	8	180
G57311	BD0808	8	8	8	180
G57312	BD0809	8	9	8	180
G57313	BD0810	8	10	8	180
G57315	BD0812	8	12	8	180

Order Number	Reference Part Number	Stent Diameter mm	Stent Length cm	Delivery System Fr	Delivery System Length cm
<b>Endoscopic Approach</b>					
G57316	BD1004	10	4	8	180
G57317	BD1005	10	5	8	180
G57318	BD1006	10	6	8	180
G57319	BD1007	10	7	8	180
G57321	BD1008	10	8	8	180
G57322	BD1009	10	9	8	180
G57323	BD1010	10	10	8	180
G57325	BD1012	10	12	8	180

\*Data on file at Cook Medical.



USA Website: [cookmedical.com](http://cookmedical.com)  
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