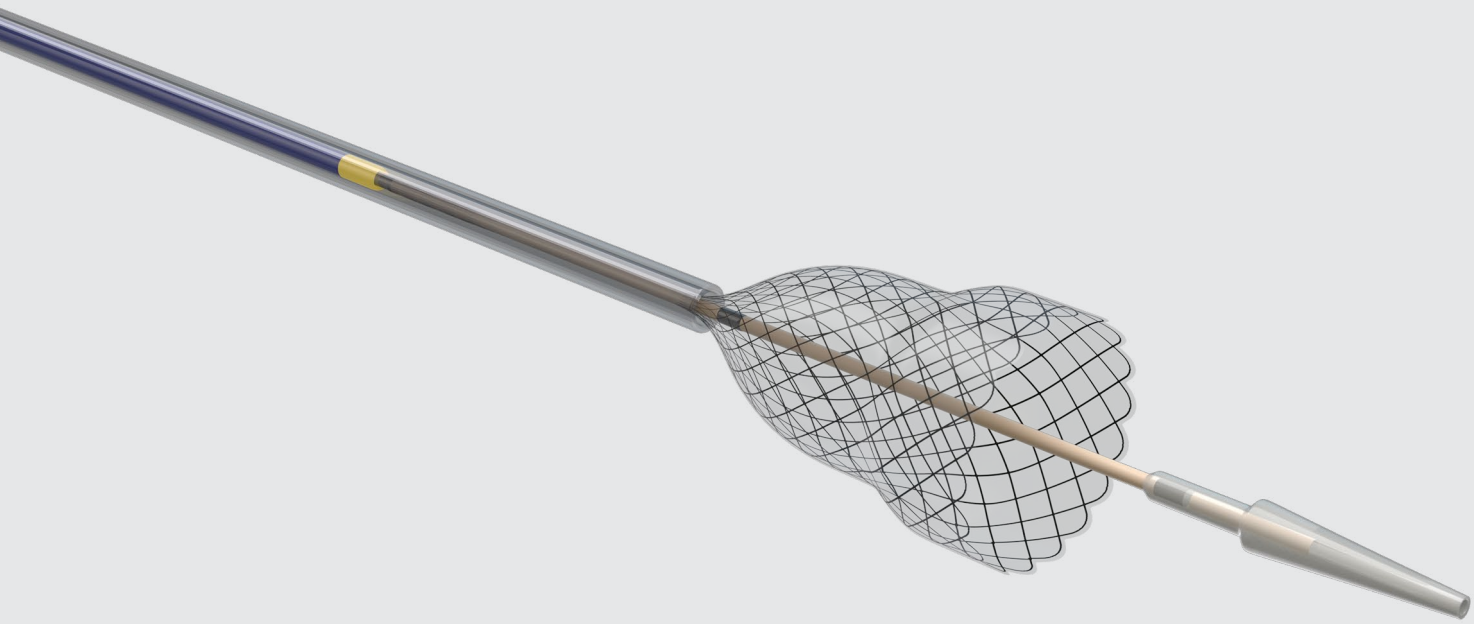


Taewoong Niti-S™

Esophageal Stent

Niti-S Esophageal 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: Niti-S Esophageal Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

CONTRAINDICATION: The Niti-S Esophageal Stent is contraindicated for: • placement in polypoid lesions. • Strictures that do not allow passage of a guidewire. • Removal or repositioning of fully deployed uncovered/bare Stents is contraindicated. (see Warnings). • Any use other than those specifically outlined under indications for use.

WARNINGS: 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. • 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. • Full Covered Stent may be repositioned immediately after deployment. (see 12. Instructions for Repositioning of Full Covered Stents **in the complete Instructions for Use**). • Uncovered/bare Stents should not be removed once fully deployed; see Contraindications.

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 stents. 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. • Care should be taken when performing dilation after the Stent has been deployed as this may result in perforation, bleeding, Stent dislodgement or Stent migration. • 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 "Use by". Do not use the device beyond the labeled use by date. • The Niti-S Stent is supplied sterile. Do not use if any of 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.

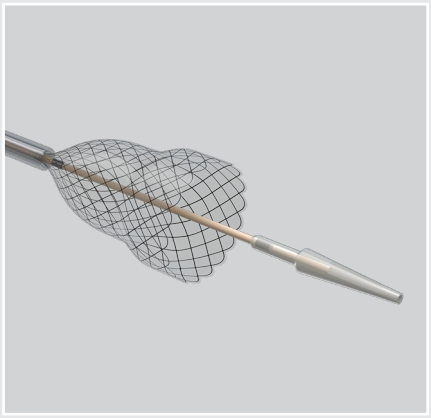
POTENTIAL COMPLICATIONS: Potential complications associated with the use of Esophageal Stent may include, but are not limited to: Procedural Complications • Bleeding • Stent misplace or inadequate expansion • Pain • Death • Aspiration Post Stent Placement Complications • Bleeding • Pain • Reflux • Perforation • Stent migration • Food bolus impaction (lavage and debridement may be necessary on a periodic basis) • Stent occlusion due to tumor in-growth through stent • Stent occlusion due to tumor over-growth around ends of stent • Fever • Ulceration • Foreign body sensation • Septicemia or Sepsis • Death (other than that due to normal disease progression) • Esophagitis • Infection • Dysphagia • Esophagobronchial fistula • Acute angulations • Aspirations • Pneumonias • Haematemesis • Airway Compressions

See Instructions for Use for full product information.

AB_TW-UE_REV2

COOK® MEDICAL

Only available in the US



Taewoong NiTi-S™ Esophageal Stent

Intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

- Fixed cell with braided configuration designed for high flexibility and optimal radial force
- Silicone coating designed to reduce tissue ingrowth and hyperplasia reaction
- Proximal and distal flanges 8 mm larger than the stent body to help minimize migration
- Visible green suture designed for repositioning
- Radiopaque markers: 4 at each end and 2 in the middle of the stent

Order Number	Reference Part Number	Stent Diameter mm	Stent Length cm	Delivery System Fr	Delivery System Length cm
Distal Release: Fully Covered					
G57334	ES1606F	16	6	16	70
G57336	ES1608F	16	8	16	70
G57338	ES1610F	16	10	16	70
G57342	ES1612F	16	12	16	70
G57346	ES1615F	16	15	16	70
G57353	ES1806F	18	6	16	70
G57356	ES1808F	18	8	16	70
G57359	ES1810F	18	10	16	70
G57361	ES1812F	18	12	16	70
G57363	ES1815F	18	15	16	70
G57365	ES2006F	20	6	20	70
G57367	ES2008F	20	8	20	70
G57369	ES2010F	20	10	20	70
G57371	ES2012F	20	12	20	70
G57373	ES2015F	20	15	20	70

Order Number	Reference Part Number	Stent Diameter mm	Stent Length cm	Delivery System Fr	Delivery System Length cm
Distal Release: Both Ends Bare					
G57332	ES1606B	16	6	16	70
G57335	ES1608B	16	8	16	70
G57337	ES1610B	16	10	16	70
G57340	ES1612B	16	12	16	70
G57345	ES1615B	16	15	16	70
G57350	ES1806B	18	6	16	70
G57354	ES1808B	18	8	16	70
G57358	ES1810B	18	10	16	70
G57360	ES1812B	18	12	16	70
G57362	ES1815B	18	15	16	70
G57364	ES2006B	20	6	20	70
G57366	ES2008B	20	8	20	70
G57368	ES2010B	20	10	20	70
G57370	ES2012B	20	12	20	70
G57372	ES2015B	20	15	20	70

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