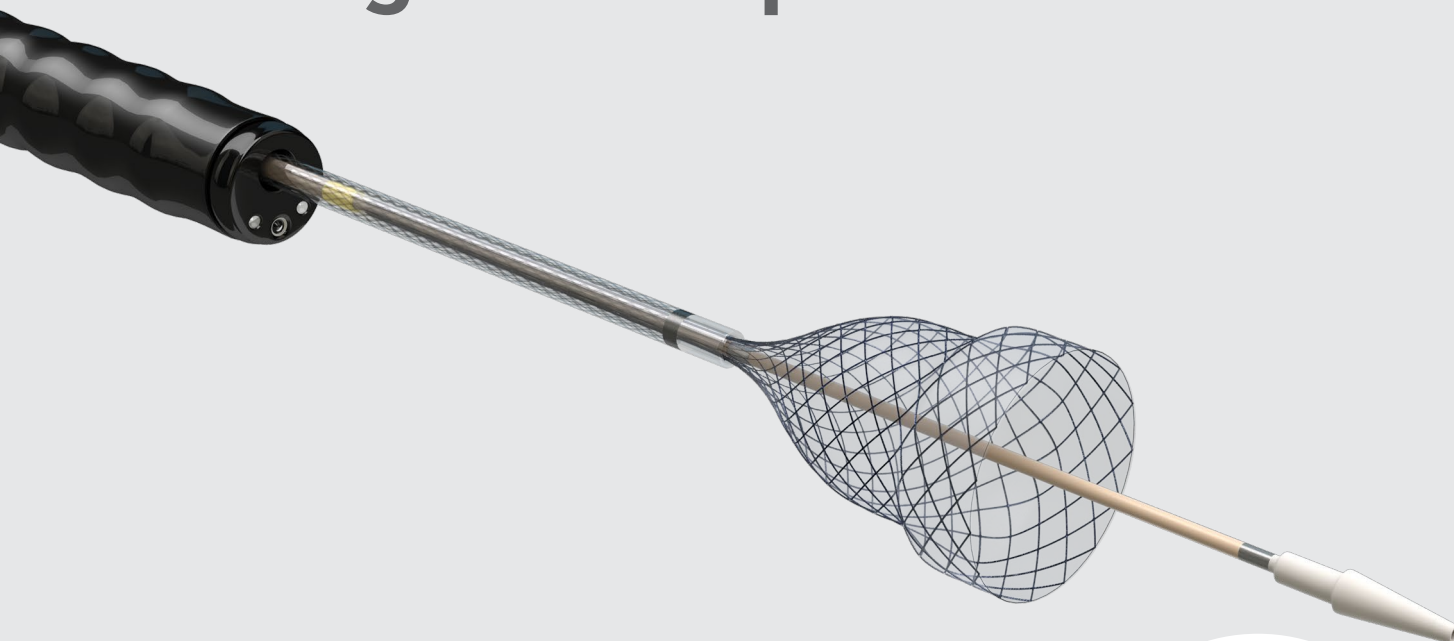


Your solution for placing esophageal stents through the scope.



TTS Esophageal Stent

Esophageal TTS 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 Esophageal TTS Stent is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistulas.

CONTRAINDICATION: The Esophageal TTS Stent is contraindicated for: • Strictures that do not allow passage of a guidewire or the introducer. • Actively bleeding tumors.

WARNINGS: The device should be used with caution and only after careful consideration in patients with elevated bleeding times or coagulopathies. • 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. • The Esophageal TTS Stent may only be repositioned immediately after deployment, during the initial placement procedure. (See 12. Instructions for Repositioning of Stents in the complete Instructions for Use). **WARNING: The stent is not intended to be removed. Attempts to remove stent after the placement procedure may cause damage to esophageal mucosa.**

PRECAUTIONS: Read the entire Instructions For Use 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 Esophageal TTS Stent is supplied sterile. Do not use if any of the packaging is opened or damaged. • The Esophageal TTS Stent is intended for single use only. Do not resterilize and/or reuse the device. • Non-clinical testing has demonstrated that the Esophageal TTS stent is MR Conditional. Please refer to the MR Imaging Information in the complete Instructions for Use.

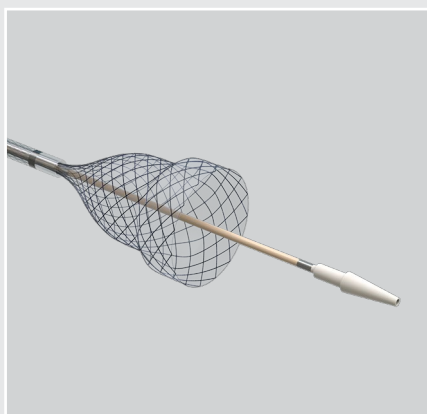
POTENTIAL COMPLICATIONS: Potential complications associated with the use of Esophageal TTS Stent may include, but are not limited to: Procedural Complications • Bleeding • Stent misplace or inadequate expansion • Pain • Death • Aspiration Post Stent Placement Complications • Bleeding • Pain • Reflux • 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-CTTS_REV1



Only available in the USA.



TAEWOONG
NITI-S™

TTS Esophageal Stent

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

- Fully/partially covered esophageal stents in a 10.5Fr delivery system
- The delivery system with conical tip is designed to navigate tight strictures and tortuous anatomies
- Retrieval string may assist with stent repositioning during the initial placement procedure
- Silicone coating designed to resist tissue in-growth
- Visible yellow marker is designed for accurate placement under endoscopic visualization
- 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
Fully Covered					
G57306	EST1806F	18	6	10.5	180
G57314	EST1808F	18	8	10.5	180
G57324	EST1810F	18	10	10.5	180
G57327	EST1812F	18	12	10.5	180
G57329	EST1814F	18	14	10.5	180
G57331	EST1815F	18	15	10.5	180
G57339	EST2006F	20	6	10.5	180
G57343	EST2008F	20	8	10.5	180
G57347	EST2010F	20	10	10.5	180
G57349	EST2012F	20	12	10.5	180
G57352	EST2014F	20	14	10.5	180
G57357	EST2015F	20	15	10.5	180

Order Number	Reference Part Number	Stent Diameter mm	Stent Length cm	Delivery System Fr	Delivery System Length cm
Partially Covered					
G57305	EST1806B	18	6	10.5	180
G57310	EST1808B	18	8	10.5	180
G57320	EST1810B	18	10	10.5	180
G57326	EST1812B	18	12	10.5	180
G57328	EST1814B	18	14	10.5	180
G57330	EST1815B	18	15	10.5	180
G57333	EST2006B	20	6	10.5	180
G57341	EST2008B	20	8	10.5	180
G57344	EST2010B	20	10	10.5	180
G57348	EST2012B	20	12	10.5	180
G57355	EST2015B	20	15	10.5	180



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