

Ultraflex™ Esophageal Covered & Uncovered Stent System

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Caution

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Warning

The Ultraflex Esophageal NG Stent System is non-sterile and intended for single use only.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

The Ultraflex Esophageal Stent System should be used with caution and only after careful consideration in patients with:

- Strictures exceeding 12 cm in length
- Significant preexisting pulmonary or cardiac disease

Visually inspect the system for any sign of damage. DO NOT USE if the system has any visible signs of damage. Failure to observe this warning may result in patient injury.

MR Conditional

Non-clinical testing has demonstrated that the Ultraflex Esophageal Stent is MR Conditional. The tested Ultraflex Stents represent the longest and largest in diameter. It can be scanned safely under the following conditions:

- static magnetic field of 3 Tesla or less
- spatial gradient field of 139 T/m (13,00 Gauss/cm) or less
- maximum whole body averaged specific absorption rate (SAR) of $\leq 3.5^1$ W/kg at 1.5 T and ≤ 2.9 W/kg at 3 T for 15 minutes of continuous MR scanning.²

In non-clinical testing, the Ultraflex Esophageal Stent produced temperature rises of less than or equal to:

Static Magnetic Field	Duration	For a Single Stent	For a Pair of 100% Overlapping Stents
1.5 Tesla	15 minutes	5.80°C	4.6°C
	20 minutes	7.02°C	5.78°C
3.0 Tesla	15 minutes	9.30°C	8.75°C
	20 minutes	9.30°C	10.50°C

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at a maximum whole body averaged specific absorption rate (SAR) of 3.5 W/kg, as assessed by calorimetry for 20 minutes of MR scanning in a 1.5 Tesla Intera™ System, Philips Medical Systems, Best, The Netherlands, actively-shielded, horizontal field MR scanner and a maximum whole body averaged specific absorption rate (SAR) of 3.4 W/kg, as assessed by calorimetry for 20 minutes of MR scanning in a 3 Tesla Magnetom Trio™ System, Siemens Medical Solutions, Erlangen, Germany, active-shielded, horizontal field MR scanner.

¹ Note: The provided WBA SAR values are related to the ASTM phantom and performed tests tests as well as based on the assumption of Note 2. The WBA software displayed SAR is inappropriate to scale exact local temperature increases at implants.

² Note: Sapareto et al indicate that it takes 15 sustained minutes at 45 degrees C to cause tissue damage. Sapareto et al. "Thermal Dose Determination in Cancer Therapy," Int J Radiation Oncology Biol. Phys. Vol. 10; 787-800

The image artifact may extend up to approximately 12 mm from the device, both inside and outside the device lumen when scanned in nonclinical testing using the sequence: gradient echo with the object axis parallel to the main magnetic field in a 3 Tesla Signa™ HDx GE Medical Systems 14LX, 14.0_MS_0737.f MR system with a transmit/receive 400 mm long, 280 mm diameter head coil.

If possible, exclude the body area from radio frequency (RF) exposure where the stent is implanted with maximum continuous scan duration of 20 minutes. Measurement inaccuracies and additional safety margins should be taken into account. Before each individual MR procedure, it might be necessary to discuss the situation with regard to the patient benefit consulting medical experts and MR physicists.

Intended Use / Indications for Use

The Esophageal NG Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic **malignant tumors only**. The Covered Esophageal NG Stent System is also indicated for occlusion of concurrent esophageal fistula.

Contraindications

The Ultraflex Esophageal NG Stent System is contraindicated for:

- Placement for occlusion of esophageal fistula of any type, unless a covered stent is being used.
- Placement in esophageal strictures caused by benign tumors, as the long-term effects of the stent in the esophagus are unknown at this time.
- Placement in strictures that cannot be dilated enough to pass the endoscope or the delivery system.
- Placement of the stent's proximal end within 2 cm of the cricopharyngeal muscle.
- Placement in an esophago-jejunostomy (following gastrectomy), as peristalsis may displace stent.
- Placement in necrotic chronically bleeding tumors, if bleeding is active at the time of placement.
- Placement in polypoid lesions.
- Those patients for whom endoscopic techniques are contraindicated.
- Any use other than those specifically outlined under indications for use.

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Adverse Events

The following complications have been reported in the literature for esophageal prosthesis. These include, but are not necessarily limited to:

- **Procedural Complications**
- Bleeding
- Perforation
- Pain
- Aspiration
- Oxygen desaturation related to sedation
- Infection

Post-stent Placement Complications

- Bleeding
- Perforation
- Pain
- Stent migration
- Tumor in-growth through stent
- Tumor overgrowth around ends of stent
- Foreign body sensation
- Food bolus impaction (lavage and debriderment may be necessary on a periodic basis)
- Reflux
- Esophagitis
- Edema
- Ulceration
- Infection and Septic shock
- Fever
- Septicemia
- Recurrent dysphagia
- Fistula with trachea, bronchi, or pleural space (other than that due to normal disease progression)
- Death (other than that due to normal disease progression)
- Stent Fracture
- Tracheal compression/Airway compression

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Precaution

Read the entire Directions for Use thoroughly before using the Ultraflex Esophageal NG Stent System. The Ultraflex Esophageal NG Stent System should only be used by or under the supervision of physicians thoroughly trained in esophageal prosthesis placement. A thorough understanding of the technical principles, clinical applications, and risks associated with this procedure is necessary before using this device. Recurrence or worsening of dysphagia may occur after stent placement due to tumor in-growth or overgrowth, severe hyperplasia reaction or stent migration. Repeat endoscopy may be required.