

Ultraflex™ Esophageal NG Stent System

The Next Generation

ULTRAFLEX SINGLE-USE COVERED ESOPHAGEAL NG STENT SYSTEM – DISTAL RELEASE

Order Number	Stent O.D. (mm)	Proximal Flare O.D. (mm)	Stent Length (cm)	Covered Length (cm)
M00513730	18	23	10	7
M00513740	18	23	12	9
M00513750	18	23	15	12

Recommended Guidewire .038" Jagwire® Guidewire

ULTRAFLEX SINGLE-USE COVERED ESOPHAGEAL NG STENT SYSTEM – PROXIMAL RELEASE

Order Number	Stent O.D. (mm)	Proximal Flare O.D. (mm)	Stent Length (cm)	Covered Length (cm)
M00513840	18	23	10	7
M00513850	18	23	12	9
M00513860	18	23	15	12

Recommended Guidewire .038" Jagwire Guidewire. Visible endoscopic proximal marker.

ULTRAFLEX SINGLE-USE COVERED LARGE ESOPHAGEAL NG STENT SYSTEM – DISTAL RELEASE

Order Number	Stent O.D. (mm)	Proximal Flare O.D. (mm)	Stent Length (cm)	Covered Length (cm)
M00514200	23	28	10	7
M00514210	23	28	12	9

Recommended Guidewire .038" Jagwire Guidewire

LARGE ULTRAFLEX SINGLE-USE COVERED ESOPHAGEAL NG STENT SYSTEM – PROXIMAL RELEASE

Order Number	Stent O.D. (mm)	Proximal Flare O.D. (mm)	Stent Length (cm)	Covered Length (cm)
M00514240	23	28	10	7
M00514250	23	28	12	9

Recommended Guidewire .038" Jagwire Guidewire. Visible endoscopic proximal marker.

ULTRAFLEX SINGLE-USE NONCOVERED ESOPHAGEAL NG STENT SYSTEM – DISTAL RELEASE

Order Number	Stent O.D. (mm)	Proximal Flare O.D. (mm)	Stent Length (cm)
M00513700	18	23	7
M00513710	18	23	10
M00513720	18	23	15

Recommended Guidewire .038" Jagwire Guidewire

ULTRAFLEX SINGLE-USE NONCOVERED ESOPHAGEAL NG STENT SYSTEM - PROXIMAL RELEASE

Order Number	Stent O.D. (mm)	Proximal Flare O.D. (mm)	Stent Length (cm)
M00513800	18	23	7
M00513810	18	23	10
M00513830	18	23	15

Recommended Guidewire .038" Jagwire® Guidewire

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INSTRUCTIONS FOR USE

Refer to the operator's manual for complete instructions for use.

INDICATIONS

The Ultraflex Covered and Non-covered Esophageal NG Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic **malignant tumors only**.

The Ultraflex Covered Esophageal 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 of the delivery system.
- Placement of the stent's proximal end within 2cm 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.

WARNINGS

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

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

For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization 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 or reprocessing 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.

POTENTIAL ADVERSE EFFECTS

The potential adverse effects may include, but are not limited to:

- Procedural complications: bleeding, perforation, pain, aspiration and oxygen desaturation related to sedation;
- 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 debridement may be necessary on a periodic basis), reflux, esophagitis, edema, ulceration, 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).

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

CAUTIONS

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

**Boston
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Boston Scientific Endoscopy
Tel 508.650.8000
www.bostonscientific.com

Ordering Information
1.800.225.3226

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