

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

## Caution

Cautions can be found in the product labeling supplied with each device.

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

The use of silicone oil and silicone lubricant spray can damage the coating of the stent.

Avoid contacting the stent with sharp instruments which may cause possible tearing.

Do not apply laser to the stent.

## Warning

Contents supplied NON STERILE. Do not use if damaged. If damage is found, call your Boston Scientific representative.

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.

Do not use magnetic resonance imaging (MRI) on patients whom have had a Dynamic™ (Y) Stent placed.

The operating physician should provide the patient with an identification card indicating that a Dynamic (Y) Stent has been placed. Emergency intubation for a patient with a Dynamic (Y) Stent may be difficult and every effort should be made to alert the medical professional treating the patient. In an emergency some common endotracheal tube designs may not be adequate for proper intubation. Instructions to not inflate the endotracheal tube cuff or to use a tube without a cuff (if available) should be given. A cricothyrotomy may be warranted in such cases.

Do not use on patients with:

- Operable stenosis
- Mature, open tracheostoma
- Patients who need artificial respiration because of indications other than stenosis
- Compression of airway by vascular anomalies (e.g. aortic aneurysm)

## Intended Use/Indications for Use

The Dynamic (Y) Stent is intended to maintain patent airways in tracheal stenosis and seal tracheo-esophageal fistulas.

## Indications

- Airway complications such as anastomosis and stenosis following lung transplantation
- Tracheo-malacia
- Tracheo-esophageal fistula

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

## Contraindications

- None in life threatening emergencies
- Laryngeal obstruction
- Bilateral paralysis of recurrent laryngeal nerve
- Patent tracheal stoma
- Need for artificial ventilation

## Note

In Computer Tomography, the metal struts will cause a distorted image (artifact).