

CRE™ Fixed Wire Balloon Dilator

Prescriptive Information

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

Intended Use/Indications for Use

Intended for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus.

Contraindications

None known.

Warnings

Do not exceed the inflation pressure given.

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is 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.

Check for proper positioning of the balloon catheter using endoscopic visualization. Balloon inflation in an improper location may lead to patient injury.

Potential Adverse Events

Potential adverse events may result from an esophageal balloon dilation procedure and include, but are not limited to perforation; hemorrhage; hematoma; septicemia/infection; and an allergic reaction to contrast medium.

Please be aware that potential adverse events may arise even with the proper use of medical devices. Accordingly, this device should 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.