

CRE™ Pulmonary Balloon Dilatation Catheter

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

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 patient 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.

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

Never use air or a gas medium to inflate balloon.

To prevent balloon burst, do not exceed the inflation pressures given for the largest diameter on the catheter's hub and package label. If the balloon does rupture or a significant loss of pressure within the balloon occurs, deflate the balloon completely and carefully remove the balloon.

The balloon must be thoroughly deflated and all fluid removed prior to withdrawal (approximately 10-30 seconds depending on balloon size and inflation medium).

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

Intended Use

The CRE Pulmonary Balloon Dilatation Catheter is intended to be used to endoscopically dilate strictures of the airway tree.

Contraindications

- Balloon dilatation is contraindicated in any patient whose general medical condition and degree of respiratory failure would not allow the patient to tolerate bronchoscopy (rigid or flexible) and/or the manipulation required to accomplish balloon dilatation.
- Balloon Dilatation is contraindicated in the presence of:
 - significant active bleeding from the site of the proposed dilatation,
 - and/or presence of a known perforation at the site of proposed dilatation,
 - and/or presence of a known fistula between the tracheobronchial tree and esophagus, mediastinum or pleural space unless the dilatation was being performed in preparation for the placement of a stent to treat the perforation or fistula.

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Cautions

If resistance is met during the procedure, do not advance the catheter without first determining the cause or resistance and taking remedial action.

Do not preinflate, pretest balloon, or attempt to refold balloon into protective sleeve.

Balloon dilatation catheters should be used by or under the supervision of physicians thoroughly trained in bronchoscopic balloon dilatation. A thorough understanding of the technical principles, clinical application, and risks associated with balloon dilatation of the airway tree is necessary before using this device.

Endoscopy should be used to confirm proper placement of the catheter. This ensures that the balloon has exited the bronchoscope completely. Fluoroscopy may also be used to confirm balloon placement. Two radiopaque markers are placed under the balloon segment of the catheter to provide visual reference points for balloon positioning within the stricture.

If excessive resistance is felt, remove the bronchoscope and balloon catheter together as a complete unit to prevent damage to body tissue, the catheter, or bronchoscope.

Any use for procedures, other than those indicated in these instructions, is not recommended.

Potential Adverse Events

Possible adverse events that may result from a tracheobronchial dilatation procedure include, but may not be limited to:

- Bleeding
- Perforation
- Rupture (partial or complete) resulting in
- Pneumomediastinum
- Pneumothorax
- Mediastinitis secondary to tracheal dilatation
- Chest pain
- Bronchospasm
- Atelectasis