

# CRE™ Pulmonary Balloon Dilator

## CRE PULMONARY BALLOON DILATOR

Order Number	Balloon Length (cm)	Initial Balloon O.D. (mm)	2 <sup>nd</sup> Balloon O.D. (mm)	Max. Balloon O.D. (mm)	Working Catheter Length (cm)
M00550300	5.5	12	13.5	15	75
M00550310	5.5	15	16.5	18	75
M00550320	5.5	18	19.0	20	75
M00550330	3.0	8	9.0	10	75
M00550340	3.0	10	11.0	12	75
M00550350	3.0	12	13.5	15	75

## ALLIANCE™ II INFLATION SYSTEM (Each)

Order Number	Description
M00550620	Inflation Handle
M00550601	Single-Use Syringe/Gauge Assembly

### INSTRUCTIONS FOR USE

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

### INDICATIONS

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

### CONTRAINDICATIONS

Balloon dilation 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 dilation.

Balloon dilation is contraindicated in the presence of:

- Significant active bleeding from the site of the proposed dilation,
- And/or presence of a known perforation at the site of proposed dilation,
- And/or presence of a known fistula between the tracheobronchial tree and esophagus, mediastinum or pleural space unless the dilation was being performed in preparation for the placement of a stent to treat the perforation or fistula.

### WARNINGS

Contents supplied STERILE using an ethylene oxide 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.

### POTENTIAL ADVERSE EVENTS

Potential Adverse Events that may result from a tracheobronchial dilation are, but are not limited to: bleeding, perforation, rupture (partial or complete) resulting in pneumomediastinum, pneumothorax, mediastinitis secondary to tracheal dilation, chest pain, bronchospasm, and atelectasis.

Please be aware that potential adverse events 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 Scientific  
Tel 508.650.8000  
www.bostonscientific.com

Ordering Information  
1.800.225.3226

©2007 Boston Scientific Corporation or its affiliates.  
All Rights Reserved.