

# CRE™ Wireguided Balloon Dilators

## CRE SINGLE-USE WIREGUIDED ESOPHAGEAL/PYLORIC BALLOON DILATORS

Order Number	Inflated O.D. (mm)	Inflated O.D. (Fr)	Balloon Length (cm)	Inflation Pressures (ATM)	Minimum Working Channel (mm)	Catheter Size (Fr)	Working Length (cm)	Unit
M00558390	6-7-8	18-21-24	5.5	3-6-10	2.8	7.5	180	Each
M00558400	8-9-10	24-27-30	5.5	3-5-9	2.8	7.5	180	Each
M00558410	10-11-12	30-33-36	5.5	3-5-8	2.8	7.5	180	Each
M00558420	12-13.5-15	36-40.5-45	5.5	3-4.5-8	2.8	7.5	180	Each
M00558430	15-16.5-18	45-49.5-54	5.5	3-4.5-7	2.8/3.2*	7.5	180	Each
M00558440**	18-19-20	54-57-60	5.5	3-4.5-6	2.8/3.2*	7.5	180	Each

Recommended Inflation Device: Alliance II Integrated Inflation System Re-usable Handle

\* Requires a 2.8mm Olympus® Brand Endoscope channel or a 3.2mm Pentax® or Fujinon® Brand Endoscope channel

\*\*Esophageal application only

This product contains no detectable latex.

## SINGLE-USE WIREGUIDED ESOPHAGEAL/PYLORIC/COLONIC BALLOON DILATATION CATHETERS

Order Number	Inflated O.D. (mm)	Inflated O.D. (Fr)	Balloon Length (cm)	Inflatable Pressures (ATM)	Minimum Working Channel (mm)	Catheter Size (Fr)	Working Length (cm)	Unit
M00558450	6-7-8	18-21-24	5.5	3-6-10	2.8/3.2*	7.5	240	Each
M00558460	8-9-10	24-27-30	5.5	3-5-9	2.8/3.2*	7.5	240	Each
M00558470	10-11-12	30-33-36	5.5	3-5-8	2.8/3.2*	7.5	240	Each
M00558480	12-13.5-15	36-40.5-45	5.5	3-4.5-8	2.8/3.2*	7.5	240	Each
M00558490	15-16.5-18	45-49.5-54	5.5	3-4.5-7	2.8/3.2*	7.5	240	Each
M00558500	18-19-20	54-57-60	5.5	3-4.5-6	2.8/3.2*	7.5	240	Each

Recommended Inflation Device: Alliance II Integrated Inflation System Re-usable Handle

\* Requires a 2.8mm Olympus® Brand Endoscope channel or a 3.2mm Pentax® or Fujinon® Brand Endoscope channel

\*\*Esophageal or Colonic application only

This product contains no detectable latex.

### INSTRUCTIONS FOR USE

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

### INDICATIONS

Indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract.

### CONTRAINDICATIONS

None known.

### WARNINGS

Do not exceed the inflation pressure given.

Contents supplied STERILE using an ethylene(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.

### POTENTIAL ADVERSE EVENTS

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

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

### TRADEMARKS

Olympus is a trademark of Olympus America Inc. Pentax is a trademark of the Pentax Corporation. Fujinon is a trademark of Fujinon Inc. (USA).

Boston Scientific  
Tel 508.650.8000  
www.bostonscientific.com

Ordering Information  
1.800.225.3226

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