

CRE™ Fixed Wire Balloon Dilatation Catheter

Prescriptive Information

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

Caution/Rx Only:

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

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.

Device Description

The CRE Fixed Wire Balloon Dilatation Catheter is capable of 3 distinct and progressively larger size diameters via controlled radial expansion. Specific balloon sizes are printed on each package and hub label.

UPN	Balloon OD Ø		Inflation Pressure	
	mm	F	ATM	kPA
M00558330	6-7-8	18-21-24	3-6-10	304-608-1013
M00558340	8-9-10	24-27-30	3-5.5-9	304-557-912
M00558350	10-11-12	30-33-36	3-5-8	304-507-811
M00558360	12-13.5-15	36-40.5-45	3-4.5-8	304-456-811
M00558370	15-16.5-18	45-49.5-54	3-4.5-7	304-456-709
M00558380	18-19-20	54-57-60	3-4.5-6	304-456-

Intended Use/Indications For Use

The CRE Fixed Wire Balloon Dilatation Catheter is intended for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus.

Contraindications

None known.

Precautions

- The CRE Fixed Wire Balloon Dilatation Catheter should only be used by or under the supervision of physicians trained in endoscopic balloon dilatation. A thorough understanding of the technical principles, clinical applications, and risks associated with balloon dilatation is necessary before using these devices.
- If resistance is met during the procedure, do not advance the catheter without first determining the cause of resistance and taking remedial action.
- The CRE Fixed Wire Balloon Dilatation Catheter is designed for use with endoscopes having a minimum working channel size of 2.8 mm.
- The CRE™ Fixed Wire Balloon Dilatation Catheter is supplied sterile by method of ethylene oxide (EO). If catheter package is opened or damaged prior to use, do not use the catheter and contact Boston Scientific for replacement.
- Any use of this device, other than those indicated in these instructions, is not recommended.

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Adverse Events

Possible adverse events that may result from an esophageal balloon dilatation procedure include, but may not be limited to:

- Perforation
- Hemorrhage
- Hematoma
- Sepsis/infection
- Allergic reaction to contrast medium

Warranty

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.