PRESCRIPTIVE INFORMATION

CRE™ Wireguided Balloon Dilatation Catheter

Boston Scientific
Advancing science for life™

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
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 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 Wireguided 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.

	Balloon OD Ø		Inflation Pressure	
UPN	**mm**	**F**	**ATM**	**kPA**
180 cm				
M00558390	6-7-8	18-21-24	3-6-10	304-608-1013
M00558400	8-9-10	24-27-30	3-5.5-9	304-557-912
M00558410	10-11-12	30-33-36	3-5-8	304-507-811
M00558420	12-13.5-15	36-40.5-45	3-4.5-8	304-456-811
M00558430	15-16.5-18	45-49.5-54	3-4.5-7	304-456-709
M00558440	18-19-20	54-57-60	3-4.5-6	304-456-608
240 cm				
M00558450	6-7-8	18-21-24	3-6-10	304-608-1013
M00558460	8-9-10	24-27-30	3-5.5-9	304-557-912
M00558470	10-11-12	30-33-36	3-5-8	304-507-811
M00558480	12-13.5-15	36-40.5-45	3-4.5-8	304-456-811
M00558490	15-16.5-18	45-49.5-54	3-4.5-7	304-456-709
M00558500	18-19-20	54-57-60	3-4.5-6	304-456-608

The CRE Wireguided Balloon Dilatation Catheter is designed to pass through the working channel of an endoscope and accept a 0.035 in (0.89 mm) guidewire through its guidewire lumen. This catheter comes packaged with a 0.035 in (0.89 mm), floppy tip guidewire preloaded in the guidewire lumen. The guidewire is 25 cm longer than the balloon catheter with the excess length extending from the hub end of the catheter.

A guidewire locking device is attached to the guidewire hub of the catheter. The locking device will be packaged in the "OFF" or unlocked position. The guidewire may only be advanced or removed from the catheter when the switch on the locking device is in the "OFF" position. The guidewire may be held in place within the catheter by moving the switch to the "ON" position.

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Intended Use/Indications for Use

The CRE™ Wireguided Balloon Dilatation Catheters are intended for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. The recommended application is printed on the package label.

Contraindications

None known.

Precautions

- Balloon dilatation catheters should be used by or under the supervision of physicians thoroughly trained in endoscopic balloon dilatation. A thorough understanding of the technical principles, clinical application, and risks associated with balloon dilatation of the alimentary tract 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 Wireguided 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 for procedures, other than those indicated in these instructions, is not recommended.

Adverse Events

Possible adverse events that may result from an alimentary tract 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.**

ENDO-477302-AA June 2017