

CRE™ RX Biliary Balloon Dilatation Catheter

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 RX Biliary 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	Inflated Balloon OD		Balloon Dilation Length	Inflation Pressure	
	mm	F	cm	ATM	kPA
M00558860	6-7-8	18-21-24	5.5	3-6-10	304-608-1013
M00558870	8-9-10	24-27-30	5.5	3-5.5-9	304-557-912
M00558880	10-11-12	30-33-36	5.5	3-5-8	304-507-811
M00558890	12-13.5-15	36-40.5-45	5.5	3-4.5-8	304-456-811
M00558900	15-16.5-18	45-49.5-54	5.5	3-4.5-7	304-456-709
M00558910	18-19-20	54-57-60	5.5	3-4.5-6	304-456-608
M00558920	8-9-10	24-27-30	3	3-5.5-9	304-557-912
M00558930	10-11-12	30-33-36	3	3-5-8	304-507-811
M00558940	12-13.5-15	36-40.5-45	3	3-4.5-8	304-456-811

The CRE™ RX Biliary 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. The catheter is multi-lumen. The guidewire lumen begins at the distal tip of the catheter, travels under the black sleeve where it exits at the proximal end of the black sleeve. This lumen is used to pass the catheter over a 0.035 in (0.89 mm) guidewire to provide for the rapid exchange feature. The lumen marked "Balloon" is the balloon inflation lumen. The lumen marked "Injection," at the proximal end of the catheter, can be used for contrast fluid injection for fluoroscopic visualization of the bile duct. There is a FloSwitch™ Adapter connected to the hub of the "Injection" lumen. The FloSwitch Adapter is to remain closed until distal dye contrast injections are required. Two radiopaque markers are placed under the balloon segment of the catheter to provide visual reference points for balloon positioning within the papilla.

CRE™ RX Biliary Balloon Dilatation Catheter

Intended Use/Indications for Use

The CRE RX Biliary Balloon Dilatation Catheters are indicated for use in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy. The CRE RX Biliary Balloon Dilatation Catheters may be used for injection of contrast medium for fluoroscopic visualization of the bile ducts.

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 Sphincter of Oddi with or without sphincterotomy 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 RX Biliary 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
- inflammation
- hematoma
- sepsis/infection
- air embolism
- allergic reaction to contrast medium
- pain and tenderness

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.**