

CRE™ Balloon Dilatation Catheter and Alliance™ II Integrated Inflation/Lithotripsy Device

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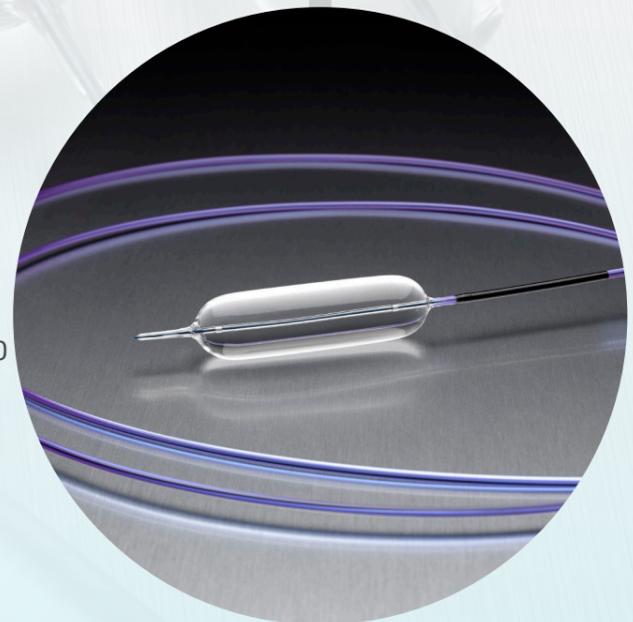
Set up

1. Turn the lever on Alliance II Integrated Inflation/Lithotripsy Device handle upward (neutral position). Snap the syringe into both fin slots on the handle. Move the plunger forward.
2. Turn the lever to the red arrow (deflate position). Pump the handle to fill the syringe with 35cc of water.
3. Turn the lever to the green arrow (inflate position). Angle the gun upward. Pump the handle to purge the air from the syringe.
4. Attach the CRE Balloon Dilatation Catheter to the syringe at the Luer connection.
5. Turn the lever back to the red arrow. Pump the handle until it stops removing air from the catheter (creating negative vacuum).
6. Remove the protective sleeve from the balloon.
7. DO NOT pre-inflate or pre-test the balloon.



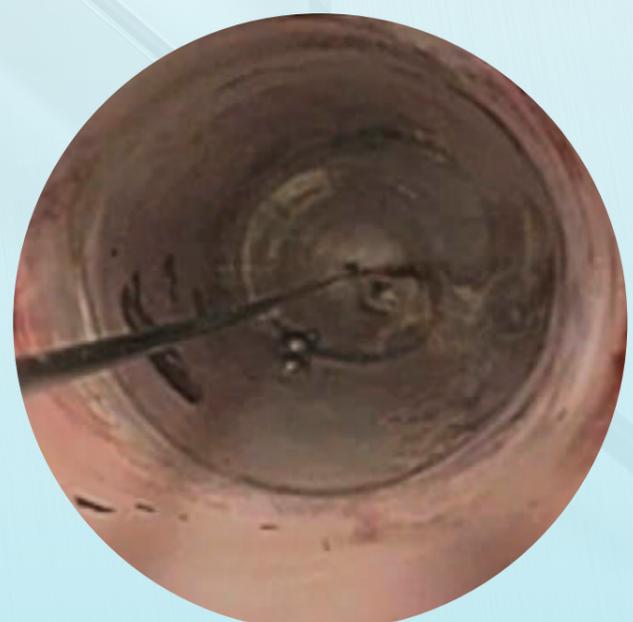
Use

1. Endoscopically place the balloon in the stricture.
2. Angle the gun downward to purge air bubbles in syringe.
3. Turn the lever to the green arrow (inflate position). Pump the handle to inflate the balloon to the stated pressure corresponding to the desired diameter (See balloon catheter 'tag' for pressures and diameters).
4. Hold the specified pressure at each diameter for desired time.
5. Assess the stricture.
6. Turn the lever to the red arrow (deflate position). Pump the handle until it stops deflating.



Balloon Endoscopy – Direct Stricture Visualization through Rounded Shoulders of the CRE Balloon

1. Position the CRE Balloon Dilatation Catheter within target stricture and inflate as instructed above.
2. Advance the scope against the balloon, then pull the balloon back gently to ensure contact.
3. Secure the catheter against the scope handle to avoid losing the position of the image.
4. Using the scope dials, angle the optical lens towards the balloon.
5. Irrigate with water to magnify the image and help create a seal between the scope and the balloon.
6. Observe the tissue affect during the dilation procedure.



This overview is provided for illustrative purposes only and is intended only as a brief summary of how the operational steps during a procedure using the CRE Radial Expansion Balloon Dilator are generally performed. Please refer to the Directions for Use for complete instructions.

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Indications, Contraindications, Warnings and Instructions for Use 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.

CAUTION: The law restricts this device to sale by or on the order of a physician. Information for the use only in countries with applicable health authority product registrations.

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