

SPEAKER: CRE, Controlled Radial Expansion Balloon Dilator and Alliance II Inflation System.

The CRE pulmonary balloon comes in two lengths, 3 centimeters and 5.5 centimeters, and several diameters ranging from 8 millimeters through 20 millimeters. The CRE pulmonary balloon is made of a material called Pebax. Pebax allows for the balloon to be strong and durable during dilation. The CRE pulmonary balloon inflates to three distinct sizes at three distinct pressures. A key feature of the CRE balloon is its rounded-shoulder design which allows for visualization of the dilation through the balloon as it occurs, which is also known as balloon endoscopy.

The Alliance II Integrated Inflation Handle is a nonsterile reusable tool used with a sterile, single-use Alliance II Syringe Gauge Assembly, sold separately, designed to simplify inflation and deflation of balloon dilatation catheters.

Inspect the Alliance II Integrated Inflation Handle for damage and utility. Pump the handle lever to insure the device's ability to move in the direction indicated by the arrows. The syringe gauge assembly component of the Alliance II Integrated Inflation System is ETO sterilized in a sealed tray. Carefully examine the unit to verify that neither the contents nor the sterile package has been damaged during shipment.

Turn the lever on Alliance II Inflation System handle upward, neutral position. Snap the syringe into both fin slots on the handle. Move the plunger forward. Turn the lever to the red arrow, deflate position. Pump the handle to fill the syringe with 35 ccs of water.

Turn the lever to the green arrow, in-flight position. Angle the gun upward. Pump the handle to purge the air from the syringe. Attach the CRE balloon catheter to the syringe at the lower connection. Turn the lever back to the red arrow. Pump the handle until it stops removing air from the catheter, creating negative vacuum. Remove the protective sleeve from the balloon.

To insert the CRE pulmonary dilation balloon over the guidewire, first, with the introducer in place, pass the pulmonary jagwire through the flexible bronchoscope, positioning the pulmonary jagwire through the stricture. Next, remove the flexible bronchoscope while leaving the pulmonary jagwire in place, doing a scope exchange over the wire. Once the bronchoscope has been removed over the pulmonary jagwire, you can reinsert the

bronchoscopy into the airway alongside the pulmonary jagwire. Once the flexible bronchoscope is in position next to the pulmonary jagwire, backload the CRE pulmonary balloon over the pulmonary jagwire. The second method of inserting the CRE pulmonary dilation balloon, if the physician chooses, is over the wire through a rigid bronchoscope.

Endoscopically place the balloon in the stricture. Angle the gun downward to purge air bubbles in the syringe. Turn the lever to the green arrow, in-flight 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. Hold the specified pressure at each diameter for desired time.

Turn the lever to the red arrow, deflate position. Pump the handle until it stops deflating.