Brief Summary Document

Overview

Product

CRE™ Pulmonary Balloon Dilatation Catheter – IFU 51962798

Rx Statement

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.*

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

User Information: *Read the entire Instructions for Use before using the CRE Balloon Dilatation Catheter. The CRE Balloon Dilatation Catheter should only be used by or under the supervision of physicians thoroughly trained in endoscopic and/or fluoroscopic procedures. A thorough understanding of the technical principles, clinical applications, and risk associated with this procedure are necessary before using this device.*

Content

INTENDED USE/INDICATIONS FOR USE

The CRE Pulmonary Balloon Dilatation Catheter is intended to be used to endoscopically dilate strictures of the airway tree.

CONTRAINDICATIONS

- Balloon dilatation is contraindicated in any patient whose general medical condition and degree of respiratory failure would not allow the patient to tolerate bronchoscopy (rigid or flexible) and/or the manipulation required to accomplish balloon dilatation.
- Balloon Dilatation is contraindicated in the presence of: significant active bleeding from the site of the proposed dilatation, and/or presence of a known perforation at the site of proposed dilatation, and/or presence of a known fistula between the tracheobronchial tree and esophagus, mediastinum or pleural space unless the dilatation was being performed in preparation for the placement of a stent to treat the perforation or fistula.

WARNINGS

REUSE WARNING

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.

GENERAL WARNINGS

- If resistance is met during the procedure, do not advance the catheter without first determining the cause of resistance and taking remedial action. Failure to do so may result in patient injury.
- To prevent balloon burst and patient injury, do not exceed the inflation pressure given for the largest diameter on the catheter's hub and package label. If the balloon does rupture or a significant loss of pressure within the balloon occurs, deflate the balloon completely and carefully remove the balloon and bronchoscope together as a unit. Do not attempt to withdraw a ruptured balloon through the endoscope. Continue procedure with a new catheter.
- The balloon must be thoroughly deflated, and all fluid removed prior to withdrawal in order to prevent patient injury and/or damage to the device (approximately 10-30 seconds depending on balloon size and inflation medium).
- If excessive resistance is felt, remove the bronchoscope and balloon catheter together as a complete unit to prevent damage to body tissue, the catheter, or the endoscope.
- Use of ionic contrast medium is not recommended. Aspiration of ionic contrast medium can lead to serious patient respiratory harms.

PRECAUTIONS

- Any use for procedures, other than those indicated in these instructions, is not recommended.
- Prior to use, carefully examine the package to verify it has not been damaged during shipment.
- To ensure minimum balloon profile, do not pre-inflate, pre-test balloon, or attempt to refold balloon into protective sleeve.
- Endoscopy should be used to confirm proper placement of the catheter. This ensures that the balloon has exited the bronchoscope completely. Fluoroscopy may also be used to confirm balloon placement. Two radiopaque markers are placed under the balloon segment of the catheter to provide visual reference points for balloon positioning within the stricture.
- Do not use air or a gas medium to inflate balloon as this will result in reduced balloon effectiveness.

POTENTIAL ADVERSE EVENTS

Possible adverse events that may result from a tracheobronchial dilatation procedure include, but may not be limited to:

- Allergic reaction
- Aspiration
- Atelectasis
- Bleeding
- Bronchospasm
- Edema
- Hemorrhage
- Infection
- Inflammation
- Laceration
- Mediastinitis secondary to tracheal dilatation
- Pain
- Perforation
- Pneumatosis
- Pneumomediastinum
- Pneumothorax
- Respiratory distress/Insufficiency
- Subcutaneous/Surgical emphysema
- Tissue damage