Brief Summary Document

Overview

Product CRE Wireguided Balloon Dilatation Catheter – IFU 51962797

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 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.

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

- Check for proper position of the balloon catheter using endoscopic visualization. Balloon inflation in an improper location may lead to patient injury.
- 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 endoscope 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 endoscope and balloon catheter together as a complete unit to prevent damage to body tissue, the catheter, or the endoscope.

PRECAUTIONS

- Any use for procedures, other than those indicated in these instructions, is not recommended.
- The CRE Wireguided Balloon Dilatation Catheter is packaged sterile in a pouch. Before using, inspect the pouch for any breach of the package to ensure a sterile product.
- To ensure minimum balloon profile, do not pre-inflate, pre-test balloon, or attempt to refold balloon into protective sleeve.
- The CRE Wireguided Balloon Dilatation Catheter should be advanced through the endoscope using short, deliberate 2-3 cm movements to prevent inadvertent damage to the device.
- Endoscopy should be used to confirm proper placement of the catheter. Verify that the shaft segment of the catheter is within endoscopic view. This ensures that the balloon has exited the endoscope completely.
- Do not use air or a gas medium to inflate the balloon as this will result in reduced balloon effectiveness.
- Do not pull back on the catheter until the balloon is deflated completely.
- For improved withdrawal, straighten the distal end of the endoscope as much as possible. Any excess bend in the working channel will increase the force needed to withdraw the catheter through the endoscope.

POTENTIAL ADVERSE EVENTS

Possible adverse events that may result from an alimentary tract balloon dilatation procedure include, but may not be limited to:

- Allergic reaction to contrast medium
- Aspiration
- Hematoma
- Hemorrhage
- Inflammation
- Pain
- Perforation
- Respiratory distress
- Sepsis/Infection
- Tissue damage