Alliance™ II Inflation System

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

The Alliance™ Integrated Inflation/Litho Handle is indicated for inflation and deflation of balloon dilation catheters while simultaneously monitoring balloon catheter pressures and for the crushing of biliary calculi when used with the Trapezoid™ RX Wireguided Retrieval Basket.

Contraindications

The Alliance II System (Syringe/Gauge Assembly and Alliance II Inflation Handle) is indicated for inflation and deflation of balloon dilatation catheters while simultaneously monitoring balloon catheter pressures.

Warnings

The Alliance II System (Syringe/Gauge Assembly and Alliance II Inflation Handle) is indicated for inflation and deflation of balloon dilatation catheters while simultaneously monitoring balloon catheter pressures.

For the Alliance II Integrated Inflation/Litho Handle:
Contents supplied NON STERILE. Do not use if damaged. If damage is found, contact your Boston Scientific representative.

For Alliance II Syringe / Gauge Assembly:

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.

Syringe for single patient 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.

Potential Adverse Events

For the Alliance II Integrated Inflation/Litho Handle:
Contents supplied NON STERILE. Do not use if damaged. If damage is found, contact your Boston Scientific representative.

Please be aware that potential adverse events may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

Cautions

For Alliance II Integrated Inflation/Litho Handle:
Precaution: A thorough understanding of the technical principles, clinical applications, and risks associated with balloon dilatation and/or ERCP and techanical lithotripsy is necessary before using this product.
Inspect the Alliance II Integrated Inflation / Litho Handle for damage and utility. Pump the handle lever to ensure the device's ability to move in the direction indicated by the arrows. The Syringe/Gauge Assembly component of the Alliance II Integrated Inflation/Litho System is supplied 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. DO NOT USE if damaged. Immediately return the damaged product to Boston Scientific.

For Alliance II Syringe / Gauge Assembly,
Precautions:
• Carefully read these instructions before using this product.
• If this product is being used along with other manufacturer's components, also read their instructions for use.
• A thorough understanding of the technical principles, clinical applications, and risks associated with balloon dilatation is necessary before using this product

Cautions 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.