



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

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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### ***Intended Use/ Indications For Use***

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

### ***Adverse Events***

None known

### ***Precaution***

A thorough understanding of the technical principles, clinical applications, and risks associated with balloon dilatation and/or ERCP and mechanical 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.**