



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

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

### **Warnings**

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. 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. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

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

The EXALT Model D Single-Use Duodenoscope is intended for use with the EXALT Controller, for endoscopy and endoscopic surgery within the duodenum.

### **Contraindications**

Contraindications associated with the use of this device include:

- Patients for whom ERCP is medically contraindicated.

### **Adverse Events**

Possible complications include, but may not be limited to:

- Perforation
- Infection
- Burn
- Embolism
- Bleeding
- Tissue damage
- Electric Shock
- Inflammation

### **Warnings**

- Do not use the Endoscope in the presence of flammable fluids or gases such as alcohol or oxygen. Doing so may result in fire and burns to the operator and patient.
- Do not use the Endoscope with any medical electrical equipment that does not comply with IEC 60601-1, and any applicable collateral and particular standards (e.g. IEC 60601-1- 2, IEC 60601-2-2, IEC 60601-2-18).
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Before using any accessory device, be sure to read and comply with the directions for use for that accessory device.
- Before using any high frequency accessory device, check the compatibility with the Endoscope and Controller. Always follow the associated instructions for use including all safety criteria.
- Only use the Endoscope in conjunction with the EXALT™ Controller. Connection to any other system may cause Endoscope or property damage or operator injury.

### **Precautions**

- Use the Endoscope with caution in patients who have surgically altered anatomy for example following a Billroth II reconstruction or with known strictures. These conditions may prevent passage of the scope.
- There is no guarantee that instruments selected solely using maximum insertion portion width and working length will be compatible in combination.
- There is no guarantee that instruments selected solely using the minimum instrument channel width will be compatible in combination.