EXALT ™ Model D
Single-Use Duodenoscope
Prescriptive Information

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.

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

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.

Warnings
- The Endoscope shaft may feel stiff. Use care during insertion or advancement and move slowly. Do not push through resistance when inserting or advancing the Endoscope, particularly at the upper and lower esophageal sphincters or when the endoscopic view is obstructed. Stop advancing and adjust the position of the Endoscope. Pushing through resistance may cause patient injury such as perforation, bleeding, or tissue damage.
- 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 user and patient.
- Do not look directly into the light emitted from the Endoscope. Doing so may result in eye injury.
- The temperature of the Endoscope's distal tip may exceed 41°C (106°F) as a result of endoscopic illumination. As surface temperatures over 41°C (106°F) may cause tissue burns, always ensure a distance appropriate for adequate viewing and utilize the minimum illumination level for the minimum length of time. Do not use stationary viewing in close proximity to the tissue or place the distal tip of the Endoscope in close proximity to the tissue for an extended length of time unless necessary.
- The articulation section should be controlled solely by the UP/DOWN and LEFT/RIGHT articulation control knobs. Never use force at the distal tip to articulate or straighten this section. Doing so may damage the Endoscope and may cause patient injury such as perforation, bleeding, or tissue damage.
- 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). Failure to do so may cause device damage and result in patient injury such as burns.

- Before use, inspect the outer surface of the portion of the Endoscope which is intended to be inserted into a patient or used during the procedure. Do not use an Endoscope that has rough surfaces, sharp edges or protrusions which may cause patient injury such as perforation or tissue damage. Cut, burned or damaged Endoscope insulation may cause unsafe currents in either patient or user .
- During air/water valve inspection described in “Test Suction and Air/Water Valves”, if bubbles are present before operating valves, inspect tubing and connection to the air/water connector. If tubing and connection has been confirmed and bubbles are still present before operating valves, see the directions for use for the Orca Air/Water Valve for further instruction. Over-insufflating the lumen may cause patient pain, injury, bleeding, and/ or perforation. Do not excessively inflate air or a nonflammable gas into the patient. This could cause gas embolism.
- When inspecting working channel and elevator function, do not use the Endoscope if the accessory device moves unexpectedly in the image. This could mean that the elevator is damaged and use of this Endoscope may lead to tissue damage and perforation.
- If the Endoscope fails any of the inspections steps, this means that the Endoscope may be damaged. Never use a damaged Endoscope as this may cause patient or user injury and/or damage to the Controller.
- Do not insert past the maximum insertion mark. Doing so may cause patient injury such as tissue damage or perforation.
- Do not use non-sterile water for irrigation. Failure to use sterile water may cause patient infection.
- Confirm that the air/water and suction tubing is connected securely before use. Failure to do so may cause lack of lens wash, insufflation, and suction functionality and may cause patient debris to be dispelled from the suction port of the single-use Endoscope. This may lead to an infection control risk.
- Articulation control knobs must always be in the neutral position and elevator must be down when inserting the Endoscope into the patient. The articulation control knobs do not naturally return to neutral and must be manually rotated to neutral. Failure to do so may cause patient injury such as perforation, bleeding, or tissue damage.
- Do not insert, advance, or operate the Endoscope without a clear, unobstructed, live endoscopic view or without confirming correct image orientation. In the event that a live endoscopic image is lost or is disrupted unexpectedly, do not advance or insert the Endoscope and do not insert, advance or actuate accessory devices. See the directions for use for the Controller for more information on how to proceed. Continuing the procedure without a live image may cause patient injury such as perforation, bleeding, or tissue damage.
- If breakage of the Endoscope is confirmed under X-ray, stop using the Endoscope immediately and disconnect it from the Controller and carefully remove the Endoscope from the patient. Failing to do so may cause patient injury such as electric shock, perforation, bleeding, or tissue damage.
- Do not view with the distal tip still and within close proximity to or touching the tissue. Doing so may cause patient injury such as tissue damage.
- Do not excessively insufflate. Doing so may cause gas embolism or other harm to the patient.
- If excessive force is required to insert the Endoscope, manipulate the elevator, or articulate the articulating section, stop the procedure and follow steps for “Removing the Endoscope from the Patient”. Using such force with the Endoscope may cause patient injury such as perforation, bleeding, or tissue damage.
- If at any point the Endoscope articulation or elevator malfunctions, stop the procedure and remove the Endoscope. Follow the steps below for “Removing the Endoscope from the Patient”. Failure to do so may cause patient injury such as perforation, bleeding, or tissue damage.
- If at any point something unexpected occurs with the Endoscope, stop the procedure and remove the Endoscope. Patient injury, user injury, or equipment malfunction may occur. Follow the steps below for “Removing the Endoscope from the Patient”.
- If suction does not stop as intended when button is no longer depressed, replace the Orca Suction Valve with a new one to prevent patient injury.

- Patient debris may be expelled through the biopsy valve during removal. Use gauze in order to prevent an infection risk.
- Do not use excessive force to remove the Endoscope. Using such force with the Endoscope may cause patient injury such as perforation, bleeding, or tissue damage. If the Endoscope cannot be withdrawn from the patient, consider removing it through surgery and take proper measures.
- During scope removal from the patient, failure to manually return the articulation control knobs to the neutral position or put the elevator in the down position may cause patient injury such as perforation, bleeding, or tissue damage. The articulation control knobs do not naturally return to neutral and must be manually rotated to neutral. If the articulation control knobs cannot be put in the neutral position or the elevator cannot be put in the down position, exercise caution when removing the Endoscope from the patient and do not use excessive force.
- Do not use any accessories other than those listed in the Compatibility section of this manual with the Endoscope in order to prevent patient injury.
- Do not perform therapy when an accessory is outside the field of view or forces the distal tip of the Endoscope against the tissue. Doing so may result in patient injury such as perforation, bleeding, or tissue damage.
- Stop the procedure and remove the Endoscope if any part of the Endoscope falls into the patient during the procedure. Be sure to remove the part per appropriate procedures. Failure to do so may cause patient injury.
- Do not insert the Endoscope when an accessory device is extended from the tip. This may lead to patient injury such as perforation, bleeding or tissue damage.
- Do not use excessive force to advance the accessory device through the working channel. Doing so may cause patient injury such as perforation, bleeding or tissue damage.
- If the elevator cannot be manipulated while accessory device is in use or movement of the accessory device is unpredictable, pull the accessory device back into the scope, manipulate the elevator, then advance the accessory device and try again. If accessory device movement is still unpredictable, the Endoscope may be damaged. Do not use this Endoscope as it may lead to patient injury such as perforation, bleeding, or tissue damage. Follow the steps below for “Removing the Endoscope from the Patient”.
- If the accessory device is unable to be removed from the Endoscope, discontinue use of the Endoscope and follow procedure to for “Removing the Endoscope from the Patient” in order to prevent patient injury.
- When using an energized accessory device, confirm that the tip of the accessory device is in the Endoscope’s field of view and that the energized component of the accessory device and the tissue are away from the distal tip of the Endoscope. Failure to do so may cause equipment damage or patient injury such as tissue damage.
- When using a high frequency accessory device with the Endoscope, patient leakage currents may be additive and result in patient injury.
- 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 user injury.
- No modification of this equipment is allowed.
- 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.

Precautions

- Do not bump, drop, bend, torque or pull any portion of the Endoscope with excessive force. Doing so may cause damage to the Endoscope and thus, failure to operate appropriately.
- Do not pull on the umbilicus while the Endoscope is in use. This may cause the umbilicus connector to be removed from the Controller leading to endoscopic image loss.
- Do not bend the insertion tube or umbilicus with excessive force. Doing so may cause harm to the internal components and Endoscope damage may result.

- Do not touch the electrical contacts of the umbilicus connector. Doing so may damage the Endoscope.
- Do not attempt to pull the image capture button. Do not press the image capture button with excessive force. Doing so may cause damage to the image capture trigger functionality.
- Take care not to spill any liquids on the Endoscope or Controller. This may cause damage to the equipment.
- Remove the Endoscope from the patient before unplugging the cable. Disconnecting the Endoscope from the Controller before removing Endoscope will result in a loss of visualization.
- Do not apply lubricant to the distal tip. It may contact the lens and damage the lens or render the Endoscope image unusable.
- Damaging the face of the umbilicus connector may result in no visualization or an unexpected loss of visualization. Handle the connector with care and inspect the face of the umbilicus connector for damage before use.
- Prior to use of a cardiac defibrillator, remove the Endoscope from the patient. Failure to remove the Endoscope from the patient may result in damage to the Controller and Endoscope due to the discharge of the cardiac defibrillator.
- Do not insert a wet umbilicus connector into the Controller as poor video performance or damage to the system may result.
- 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.
- Never attempt to clean the lens surface by any means other than depressing the water valve as this may create scratches on the lens.
- Ensure that the water container is in close proximity to the umbilicus connector so that the tubing does not become stretched or detached from the air/water port during use. Failure to do so may cause lack of lens wash, insufflation, and suction functionality and may cause patient debris to be dispelled from the suction port of the single-use Endoscope.
- For any accessory device with a sheath, failure to retract the accessory device into its sheath before/during insertion through the working channel may cause damage to the Endoscope, biopsy valve or to the accessory device.
- Do not use excessive force to advance the accessory device through the working channel. Doing so may cause damage to the working channel of the Endoscope.
- 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EXALT Endoscopic Visualization System, including cables specified by the manufacturer. Otherwise, degradation of the performances of this equipment could result.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take migration measures, such as relocating or re-orienting the equipment.
- Electromagnetic interference* (EMI) may occur on this instrument near equipment marked with the following symbol . Electromagnetic interference may occur on this instrument near other portable and mobile radio frequency (RF) communications equipment, for example, cellular phones. To check for EMI, verify the system's operation in which it will be used. Should EMI occur, employ mitigation measures like reorienting or repositioning the instrument, or shielding its location. Placing this instrument near other medical electrical equipment or mobile RF communications equipment may result in EMI, which may degrade the video image.

***NOTE:** Inspect the electromagnetic interference from external equipment by observing to verify the Endoscope system's normal operation in the configuration in which it will be used. Verify all electrical equipment is working properly before starting the procedure.

- Do not aspirate viscous fluids or solid materials. This may cause Endoscope damage or a clog. Follow the directions for use for the Orca Suction Valve for further instructions.
- Before using any accessory device, be sure to read and comply with the directions for use for that accessory device.

Potential Adverse Events

Possible complications include, but may not be limited to:

- Bleeding
- Burn
- Cholangitis
- Electric Shock
- Embolism
- Infection
- Inflammation
- Nausea / Vomiting
- Pain
- Perforation
- Tissue damage