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# EXALT™ Model D

FOR USE WITH THE EXALT CONTROLLER

## Single-Use Duodenoscope

### Rx ONLY

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

### WARNING

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.

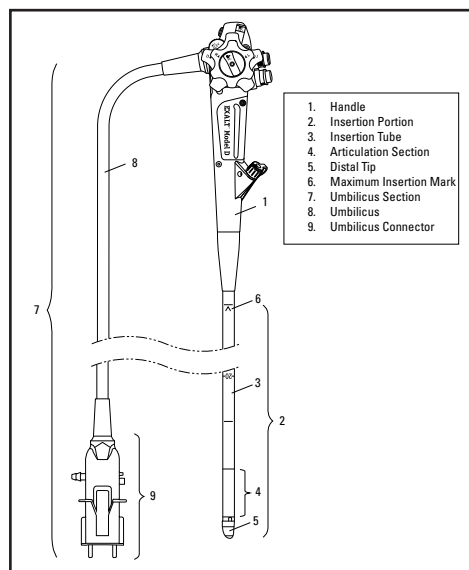
### DEVICE DESCRIPTION

The EXALT Model D Single-Use Duodenoscope (hereafter referred to as the Endoscope) is a sterile, single-use Endoscope that facilitates access to the duodenum, delivery of accessories, and live video when connected to an EXALT Controller (hereafter referred to as the Controller).

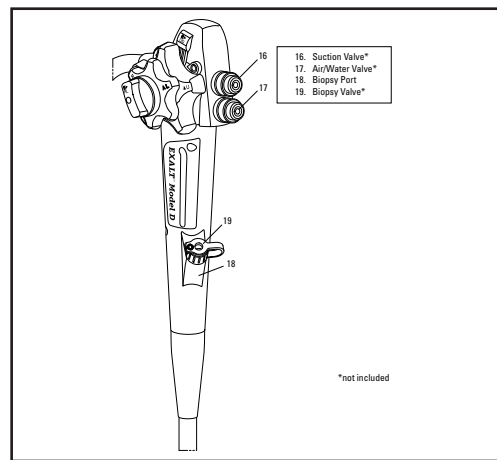
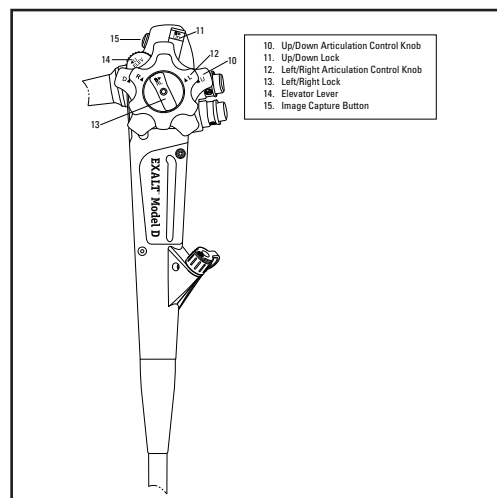
### Features and Controls

The Endoscope includes the following features and controls:

Figure 1.



Figures 2 and 3. Main features of the Endoscope

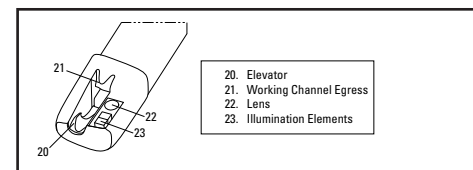


- **Handle:** The handle enables the user to operate the Endoscope. The handle includes: articulation control knobs and locks, an elevator lever, suction and air/water valves, an image capture button, and a biopsy port.
- **UP/DOWN articulation control knob:** Rotating this knob toward the user (▲ U direction) causes the articulating section of the Endoscope to bend up. Rotating this knob away from the user (▲ D direction) causes the articulating section to bend down.
- **UP/DOWN lock:** Moving this locking lever in the direction of the arrow 🔒 ➡ locks the UP/DOWN articulation control knob and the articulating section in the current position.
- **LEFT/RIGHT articulation control knob:** Rotating this knob toward the user (▲ L direction) causes the articulating section of the Endoscope to bend left. Rotating this knob away from the user (▲ R) causes the articulating section to bend right.
- **LEFT/RIGHT lock:** Moving this locking knob in the direction of the arrow 🔒 ➡ locks the LEFT/RIGHT articulation control knob and articulating section in the current position.
- **Elevator lever:** Bring the elevator up by advancing the elevator lever in the direction of the arrow (◀U). Bring the elevator down by moving the elevator lever opposite the direction of the arrow (◀U).
- **Suction valve:** Depressing this valve activates suction. Refer to the directions for use for the Orca™ Suction Valve for further description and intended use. The Endoscope shall only be used in conjunction with the Orca sterile single-use suction valve (not included).
- **Air/Water valve:** Depressing this valve delivers water to the distal tip to clear the field of view. Covering the hole of this valve provides insufflation. Refer to the directions for use for the Orca Air/Water Valve for further description and intended use. The Endoscope shall only be used in conjunction with the Orca sterile single-use air/water valve (not included).
- **Image capture button:** Depressing this button will trigger capture of the live image. Refer to the instructions supplied with the Controller for more information on this functionality.
- **Biopsy port:** The biopsy port is the point of insertion for accessories.
- **Biopsy valve:** The biopsy valve covers the biopsy port of the Endoscope. Refer to the directions for use for the RX Locking

Device and Biopsy Cap System (Olympus™ / FujiFilm™ G5 Series Brand Endoscope Compatible) or Seal™ Biopsy Valve for further description and intended use. The Endoscope shall only be used in conjunction with the RX Locking Device and Biopsy Cap System (Olympus / FujiFilm G5 Series Brand Endoscope Compatible) or Seal single-use biopsy valve (not included).

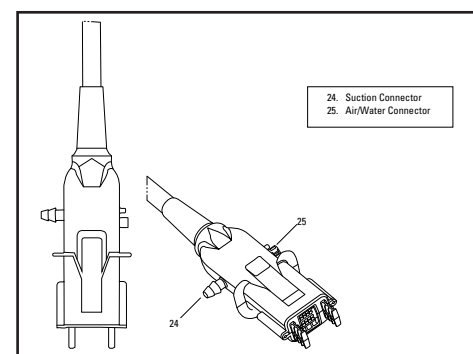
- **Insertion portion:** The insertion portion includes the insertion tube, articulation section and the distal tip (including the elevator).
- **Insertion tube:** The flexible insertion tube includes a working channel to provide suction and to allow for passage of endoscopic accessories. It also includes channels for lens wash and insufflation.
- **Articulation section:** This section articulates when the articulation control knobs are rotated.
- **Maximum insertion mark:** The insertion tube should not be inserted into the patient's mouth beyond this point.
- **Distal tip:** The distal tip includes the egress points for the working channel, elevator, lens wash and insufflation. It also includes the image sensor and lens and illumination elements.
- **Elevator:** The elevator articulates in response to the movement of the elevator lever and can be used to adjust endoscopic accessories and lock the guidewire.

Figure 4.



- **Umbilicus Section:** The umbilicus section includes the umbilicus and umbilicus connector which contains connections for suction, air and water.
- **Umbilicus:** Connects the handle to umbilicus connector.
- **Umbilicus connector:** Connects the Endoscope to the Controller.
- **Suction connector:** Connects to the suction source via tubing.
- **Air/Water connector:** Connects to the air/water supply via tubing of the Hydra™ Water Bottle Cap. Refer to the directions for use for the Hydra Water Bottle Cap for further description and intended use. The Endoscope shall only be used in conjunction with the Hydra Water Bottle Cap (not included).

Figure 5.



### Operating Principle

The Endoscope works in conjunction with the Controller.

- Two knobs and one lever on the handle assist in navigation, delivery and removal of accessory devices:
  - UP/DOWN articulation control knob manipulates the bending section in the UP/DOWN directions
  - LEFT/RIGHT articulation control knob manipulates the bending section in the LEFT/RIGHT directions
  - Elevator lever controls the articulation of the elevator
- The air/water and suction valves on the handle can be used to support visualization as necessary.
- The image capture button on the handle can be depressed to initiate a live image capture trigger signal.
- Endoscopic accessory devices will be advanced through the biopsy port as indicated.

- The distal tip includes the imaging sensor and lens, illumination elements, the elevator, a port to provide insufflation and lens wash, and a working channel for accessory device passage and application of suction.

#### Articulation Section

The articulating section bends in four directions as controlled by the two articulation control knobs on the handle.

#### User Information

The Endoscope and these instructions are intended for use by physicians trained in endoscopic retrograde cholangiopancreatography (ERCP). A thorough understanding of the techniques, principles, clinical applications and risks associated with ERCP is suggested before using this Endoscope.

#### Contents

- EXALT™ Model D Single-Use Duodenoscope

Ensure the package contains the components listed above.

#### MODEL NUMBERS

EXALT Model D Single-Use Duodenoscope	M00542420 M00542421
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#### SPECIFICATIONS

The Endoscope specifications are summarized in Table 1.

**Table 1. Endoscope specifications**

Specifications	Value
Direction of view	Backward side viewing 5°
Field of view	108°
Articulation Angle	Up: 120° Down: 90° Left: 90° Right 110°
Maximum elevator articulation angle (with guidewire)	≥80°
Distal end outer diameter	15.1mm
Insertion tube outer diameter	11.3mm
Working length	1240mm
Working channel inner diameter	4.2mm
Degree of protection against electric shock	TYPE BF applied part

#### 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
- Bleeding
- Infection
- Tissue damage
- Burn
- Electric Shock
- Embolism
- 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 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 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).
- 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 operator.
- 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 expelled 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. 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".
- 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.

- If suction does not stop as intended when button is no longer depressed, replace the Orca Suction Valve with a new one.
- 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 open surgery and take proper measures.
- During scope removal from the patient, failure to put the articulation control knobs in the neutral position or the elevator in the down position may cause patient injury such as perforation, bleeding, or tissue damage. 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.
- 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.
- Do not use any accessories other than those listed in the Compatibility section of this manual with the Endoscope.
- 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.
- 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.
- Before using any accessory device, be sure to read and comply with the directions for use for that accessory device.
- 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".
- 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.
- 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

- 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 gastrectomy II 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.

## CONFORMANCE TO STANDARDS

### Essential Performance Statement

Per IEC 60601-1 and applicable collateral and particular standards, the Endoscope does not have any functions that would present an unacceptable risk if failure occurred.

### HOW SUPPLIED

Device supplied sterile in a pouch. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

### Handling and Storage

Store in a cool, dry, and dark place.

### DEVICE COMPATIBILITY

The Endoscope is compatible with Orca™ Suction and Air/Water Valves, the RX Locking Device and Biopsy Cap System (Olympus™ / FujiFilm™ G5 Series Brand Endoscope Compatible), the Seal™ Biopsy Valve, and Hydra™ Water Bottle Caps. Additionally, the Endoscope is compatible with Boston Scientific accessory devices that are compatible with a 4.2mm working channel, have a minimum working length of 180cm and (for energized devices) have a Maximum Accessory Voltage Rating: 3800 V peak (7600 V peak-to-peak).

**Note:** Be sure to follow all instructions and inspections for any accessory or accessory device according to its directions for use.

## OPERATIONAL INSTRUCTIONS

The intended use environment is the endoscopy suite or operating room at a hospital.

### Unpack and Inspect the Endoscope

Open and remove the Endoscope (still in its sterile packaging) from any shipping packaging and then perform the following visual and operational checks:

1. Check the expiration date on the Endoscope package. Do not use the Endoscope if it is beyond the expiration date.
2. Ensure the sterile packaging is intact and shows no signs of damage, holes, or tears. If the packaging shows any type of damage, do not use the Endoscope.
3. Remove the Endoscope from its sterile package and check it for signs of damage. If you observe damage, do not use the Endoscope.
4. Inspect the entire surface of the insertion portion visually and tactilely. Examine the handle, insertion tube, and bending section. Ensure no components are loose or broken. During inspection, do not touch the lens surface. If you observe any loose or broken components, do not use the Endoscope.
5. Visually inspect the distal end for damage including dents, protrusions, tears and holes. Also inspect for foreign material/debris. If you observe damage or any debris, do not use the Endoscope. During inspection, do not touch the lens surface.
6. Rotate the articulation control knobs located on the handle and visually confirm articulation of the articulating section as the articulation control knobs are rotated. If knobs are not functioning, do not use the Endoscope.
7. Articulate the UP/DOWN articulation control knob to the UP direction and lock the knob using the UP/DOWN lock lever. Confirm that the articulation section remains locked in position. Repeat the confirmation in the DOWN direction. If the articulation section does not remain locked, confirm that the UP/DOWN lock lever is fully engaged. If lock is not functioning, do not use the Endoscope.
8. Articulate the LEFT/RIGHT articulation control knob to the LEFT direction and lock the knob using the LEFT/RIGHT lock knob. Confirm that the articulation section remains locked in position. Repeat the confirmation in the RIGHT direction. If the articulation section does not remain locked, confirm that the LEFT/RIGHT lock knob is fully engaged. If lock is not functioning, do not use the Endoscope.
9. Raise and lower the elevator control lever fully in both directions and visually confirm responsiveness of the elevator. If elevator is not functioning, do not use the Endoscope.
10. Visually examine the umbilicus for kinks or damage. Visually inspect the umbilicus connector for damage. If any damage or debris is observed, do not use the Endoscope.

## Attaching the suction and air/water valves

1. Refer to the directions for use for the Orca Suction and Air/Water Valves for proper inspection and placement of Orca Valves. Be sure to follow all instructions and consider all warnings and precautions.

## Attaching the biopsy valves

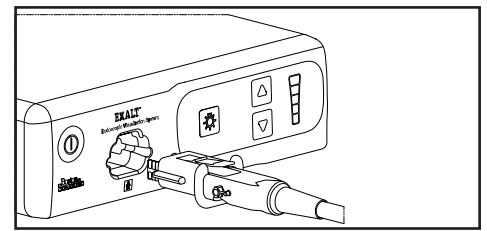
1. Refer to the directions for use for the proper inspection and placement of the RX Locking Device and Biopsy Cap System (Olympus / FujiFilm G5 Series Brand Endoscope Compatible) or Seal Biopsy Valve. Be sure to follow all instructions and consider all warnings and precautions.

## Connect the Endoscope to the Controller and check the Image

Attach the Endoscope to the Controller and adjust the image following these steps:

1. Power on the Controller following the instructions supplied with the Controller.
2. When the monitor used with the Controller displays the "cable connect screen," plug the Endoscope umbilicus connector (locking tab facing up) into the receptacle on the front panel of the Controller (Figure 6). Push the umbilicus connector in until the locking tab engages.
3. Verify a live image is present on the screen. If live image is not present, refer to the instructions supplied with the Controller.
4. Press the image capture button on the handle. Confirm that the image capture indication is shown on the screen and that you maintain a live image. If the image capture indication is not shown, refer to the instructions supplied with the Controller.

**Figure 6. Inserting the umbilicus connector into the Controller receptacle**



## Attach Suction and Air/Water Tubing

1. Connect the air/water tubing of the Hydra™ Water Bottle Cap set to the air/water connector of the Endoscope. Refer to the directions for use for the Hydra Water Bottle Cap for proper inspection and connection. Be sure to follow all instructions and consider all warnings and precautions.
2. Connect a suction source to the Endoscope suction connector.

## Test Suction and Air/Water Valves

1. Fully submerge distal tip in sterile water and confirm there are no bubbles present.
2. Set insufflator to HIGH and apply insufflation by covering the air/water valve and visually confirm that there are bubbles.
3. Remove distal tip from water.
4. Cover and depress the air/water valve and test lens wash function. Visually confirm flow of water across the lens.
5. Fully submerge distal tip in sterile water and depress the suction valve. Confirm that water is aspirated.
6. Confirm valves return to their initial position when the valves are released.

## Test Working Channel and Elevator Function

1. If an accessory device is to be used, insert the accessory device through the working channel and advance the accessory device down the Endoscope.

**NOTE:** The elevator must be raised when the accessory device is passing through the Endoscope.

2. Advance the accessory device through the tip until it makes contact with the elevator.
3. Confirm visualization in the endoscopic image.
4. Manipulate the elevator lever while viewing the accessory device on the endoscopic image. Confirm that the accessory device is moving as expected in the image.

## WARNING

Failure of any of the above inspections 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.

## Preparation and Insertion of the Endoscope

**NOTE:** A medical-grade, water soluble lubricant may be applied to the insertion tube and articulations section. Do not allow any lubricant to contact the distal tip.

1. Position bite block in patient's mouth.
2. With the articulation control knobs in a neutral position and the elevator down, insert the Endoscope into the patient.
3. Manipulate the articulation control knobs as necessary under visualization to navigate the Endoscope to the desired location in the digestive tract.
4. If required, adjust the image brightness as necessary to obtain the best image. (Refer to the instructions supplied with the Controller to learn more about adjusting image brightness).
5. As necessary, provide insufflation, use suction and use lens wash to clear the field of view.

## Inserting an Endoscopic Accessory Device into the Single-Use Endoscope

1. Prepare an accessory device for use following the instructions provided with the accessory device.
2. Raise the elevator by advancing the elevator lever in the UP direction (▲U).
3. If the accessory device is able to be extended or retracted, be sure that the tip of the accessory device is retracted into its sheath before inserting the accessory device from the scope. Do not extend the accessory device at any point during insertion through the working channel.
4. Advance the accessory device slowly through the scope. When the accessory device reaches the elevator, lower the elevator so that the accessory device may be advanced slowly under visualization.
5. Lower the elevator by moving the lever down (opposite of the ▲U direction) while utilizing the live video image to bring the accessory device into the field of view.

**NOTE:** If the elevator is completely down, the accessory device may not be seen under visualization.

6. When the accessory has come into view, manipulate the elevator slowly to confirm predictable movement of the accessory device in the endoscopic image.
7. With direct visualization of the accessory, move it to the desired location to perform the preferred technique.
8. After accessory device use is complete, remove the accessory device through the working channel. If the accessory device is able to be extended or retracted, be sure that the tip of the accessory device is retracted into its sheath before removing the accessory device from the scope per the steps for "Removing an Accessory Device from the Endoscope".

## Locking the guidewire

1. A guidewire may be locked by moving the elevator lever in the UP direction (▲U).

## Removing an Accessory Device from the Endoscope

1. While observing the live video, withdraw the accessory into the distal tip of the Endoscope. Use gauze to pull the accessory device through the biopsy valve.
2. Slowly withdraw the accessory from the Endoscope. If you feel resistance, investigate the source of the resistance before continuing to withdraw the accessory.
3. Removal and exchange of accessories may be performed throughout the course of the procedure.

## Removing the Endoscope from the Patient

1. Ensure the articulation lock is released and the articulation control knobs are returned to the neutral position.
2. Ensure the elevator is in the down position.
3. Ensure all accessory devices have been removed from the Endoscope.
4. Slowly withdraw the Endoscope from the patient.
5. Shut down air/water sources.
6. Disconnect air/water tubing and suction tubing from the air/water and suction connectors.

7. Depress the locking tab on the umbilicus connector and simultaneously pull the connector outward to disconnect.
8. Power down the Controller.

## Disposal of the Endoscope and Packing Materials

Dispose of the Endoscope per standard biohazard hospital protocol. Dispose of the packaging materials following the relevant regulations and laws in your country.


## WARRANTY

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