Orca®
Single Use Air/Water, Suction, Valve Set

OrcaPod™
Single Use Air/Water, Suction, & Biopsy Valve Set with Water Jet Valve

ADVERSE EVENTS
None known.

HOW SUPPLIED
The device is supplied sterile and intended for single use only. The packaging and device should be inspected prior to use. 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, dark place. See product label for expiration date.

CONTRAINDICATIONS
Contraindications include those specific to any endoscopic procedure.

ORCA SUCTION VALVE
WARNING
Avoid aspirating solid matter or thick fluids; instrument channel, suction channel or suction valve clogging can occur. If the suction valve clogs and suction cannot be stopped, disconnect the suction tube from the suction connector on the endoscope. Turn the suction pump OFF, detach the suction valve and remove the solid matter or thick fluids.

When aspirating, maintain the suction pressure at the lowest level necessary to perform the procedure. Excessive suction pressure could cause aspiration of and/or injury to the mucous membrane. In addition, patient fluids could leak or spray from the biopsy valve, posing an infection control risk.

When aspirating, ensure the biopsy valve is in the closed position. An uncapped biopsy valve can reduce the efficacy of the suction system and may leak or spray patient debris or fluids, posing an infection control risk.

OPERATIONAL INSTRUCTIONS
1. Open the sterile pouch and remove the tray from the pouch.
2. Remove the suction valve from the tray and align the two plastic ridges on the underside of the suction valve with the two holes in the suction cylinder.
3. Advance the shaft into the cylinder until a snap is felt to ensure secure attachment.
4. Depress the suction valve prior to the procedure to confirm proper function.
5. Depress the suction valve to aspirate excess fluids or other debris obscuring the endoscopic image.
6. Remove and discard the suction valve after each procedure prior to reprocessing the endoscope.

ORCA AIR/WATER VALVE
WARNING
If the sterile water level in the water container is too low, then air, not water will be supplied. In this case, turn the airflow regulator on the processor OFF and add sterile water to the water bottle with a new sterile water bottle.

If air/ water feeding does not stop, turn the airflow regulator on the processor OFF and replace the air/water valve clogs and suction cannot be stopped, disconnect the suction tube from the suction connector on the endoscope. Turn the suction pump OFF, detach the suction valve and remove the solid matter or thick fluids.

If the lid of the vacuum chamber is not tightened to the endoscope, air can enter the suction system and may leak or spray patient debris or fluids, posing an infection control risk.

OPERATIONAL INSTRUCTIONS
1. Remove the Orca Air/Water valve from the tray.
2. Advance the shaft into the cylinder until a snap is felt to ensure secure attachment.
3. Cover the air/water valve's hole to feed air from the air/water nozzle at the distal end of the handle. Confirm proper function prior to procedure.
4. Depress the air/water valve to feed water onto the objective lens. Confirm proper function prior to procedure.
5. Remove and discard the air/water valve after each procedure prior to reprocessing the endoscope.

ORCAPOD™
DEVICE DESCRIPTION
The OrcaPod is an endoscope channel support kit containing the Orca® Air/Water and Suction Valves, Seal® Single Use Biopsy Valve and Hydra® Disposable Auxiliary Water Jet Connector.

CONTENTS
Package contents include:
(1) Orca Air/Water Valve
(1) Orca Suction Valve
(1) Seal Single Use Biopsy Valve
(1) Hydra Disposable Auxiliary Water Jet Connector (If Included)

HOW SUPPLIED
The device is supplied sterile and intended for single use only. The packaging and device should be inspected prior to use. 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, dark place. See product label for expiration date.

SEAL SINGLE USE BIOPSY VALVE
DEVICE DESCRIPTION
The Seal Single Use Biopsy Valve is an endoscopic biopsy valve that fits on the working channel/portal of endoscopes to facilitate device passage and maintain insufflation during endoscopic procedures. The attached cap should remain closed during the endoscopic procedure unless larger devices need to be passed.

INDICATIONS FOR USE
The Seal Single Use Biopsy Valve provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

CONTRAINDICATIONS
Contraindications include those specific to any endoscopic procedure.

WARNINGS
When irrigation is used, ensure proper techniques to avoid aspiration in the patient.

Do not use a sharp or pointed object to prime the biopsy valve prior to use.

Do not leave a device hanging from the valve. Doing so can cause the creation of a larger valve slit / hole that can compromise leak management.

If the lid of the Seal Single Use Biopsy Valve is opened while attached to the endoscope during a procedure, scope suction will be compromised and chances of leakage increase. Gauze should be used to cover the biopsy valve if the lid must be opened for any reason.

Exposure to bodily fluids may occur during connection or disconnection of these devices; adherence to Body Substance Isolation protocols is the responsibility of the user.

ADVERSE EVENTS
None known.

OPERATIONAL INSTRUCTIONS
Caution: The biopsy valve cannot be used with ultrasonic endoscopes with UC in the model number, or with dual channel endoscopes with 2T in the model number.

The Seal Single Use Biopsy Valve is designed to allow passage of a 3.2 mm device with the cap closed and once the device is removed to seal security.

1. Remove the Seal Single Use Biopsy Valve from the pouch.
2. Place the Seal Single Use Biopsy Valve on the endoscope channel inlet.
3. Insert devices as needed through the Seal Single Use Biopsy Valve by aligning the device with the endoscope inlet and advancing slowly in a straight manner.

Caution: If the diameter of the accessory is greater than 3.2 mm open the cap for instrumentation.
4. Remove and discard the Seal® Single Use Biopsy Valve after each procedure prior to reprocessing the endoscope.
5. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

**HYDRA® DISPOSABLE AUXILIARY WATER JET CONNECTOR**

**DEVICE DESCRIPTION**

The Hydra Disposable Auxiliary Water Jet Connector is a disposable auxiliary irrigation port connector for endoscopes which is used in conjunction with Hydra irrigation tubing. The Hydra Disposable Auxiliary Water Jet Connector is comprised of a female luer connection, a backflow prevention check valve, and a threaded endoscope connection.

**INDICATIONS FOR USE**

The Hydra Disposable Auxiliary Water Jet Connector is used in conjunction with Hydra irrigation tubing (tubing and accessories to accommodate various endoscopes and irrigation pumps) and is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.

**CONTRAINDICATIONS**

Contraindications include those specific to any endoscopic procedure.

**WARNINGS**

- Never attach or reattach the Hydra Auxiliary Water Jet Connector to an endoscope that is/was inside the patient and has not been reprocessed.
- Do not insert this device into the patient. The device should be attached to the auxiliary water port of a flexible gastrointestinal endoscope and to an irrigation source.
- Always prime the auxiliary irrigation port prior to inserting the endoscope into the patient.
- The Hydra Disposable Auxiliary Water Jet Connector is intended for use with Hydra Irrigation Tubing only. Use of this device with any other irrigation tubing could potentially impact performance.

**OPERATIONAL INSTRUCTIONS**

1. Prior to clinical use, familiarize yourself with the device.
2. Open the sterile pouch and attach the Hydra Disposable Auxiliary Water Jet Connector to the endoscope’s auxiliary water jet port.
3. After the Hydra Disposable Auxiliary Water Jet Connector is connected to the endoscope’s auxiliary water jet port, connect the appropriate irrigation tubing set to the Hydra Disposable Auxiliary Water Jet Connector.
4. After connecting the system (Hydra Disposable Auxiliary Water Jet Connector and appropriate irrigation tubing) to the endoscope and prior to inserting the endoscope into the patient, ensure that the tubing, water jet connector, and endoscope channel are primed by activating the foot pedal for water flow.
5. When the procedure is completed turn off the irrigation pump before disconnecting the Hydra irrigation system from the endoscope.
6. Discard the Hydra Disposable Auxiliary Water Jet Connector after each patient use.

**WARRANTY**

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use. BSC’s obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments used in conjunction with an irrigation pump.

**LEGAL MANUFACTURER**

Manufactured for: Boston Scientific Corporation
330 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-327-1001

**LEGAL MANUFACTURER**

© 2018 Boston Scientific Corporation or its affiliates. All rights reserved.