



50736128-01

2018-10
< en >

Orca[®]

Single Use Air/Water, Suction, Valve Set

OrcaPod[™]

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

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.

Note: The OrcaPod components & Orca Air/Water and Suction Valves are to be used with Olympus[®] 160, 180 and 190 gastrointestinal endoscopes.

ORCA AIR/WATER AND SUCTION VALVES

DEVICE DESCRIPTION

The Orca Air/Water and Suction Valves are endoscopic channel accessories that attach to the Air/Water and Suction ports on the endoscope handle to control the amount of air/water flow and suction of an endoscope.

CONTENTS

Package contents include:

- (1) Orca Air/Water Valve
- (1) Orca Suction Valve

INDICATIONS FOR USE

The Orca Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI (gastrointestinal) endoscopic procedure.

The Orca Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.

WARNINGS AND PRECAUTIONS

- Inspect package for damage. If package is damaged or opened sterility may be compromised. Do not use if product is damaged or opened.
- Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques.
- Consult the medical literature relative to complications, hazards and techniques prior to the performance of any endoscopic procedure.

- Use proper aseptic techniques to avoid contamination during device setup.
- Exposure to bodily fluids may occur during connection or disconnection of the device. The user is responsible for adhering to Body Substance Isolation protocols.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state and federal laws and regulations.

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

WARNINGS

- 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

WARNINGS

- 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 container until it reaches the specified water level or replace the water bottle with a new sterile water bottle.
- If air/water feeding does not stop, turn the airflow regulator on the processor or CO₂ insufflator OFF and replace the air/water valve with a new one.

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 endoscope. 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 port 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 securely.

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.

- Remove and discard the Seal® Single Use Biopsy Valve after each procedure prior to reprocessing the endoscope.
- 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

- Prior to clinical use, familiarize yourself with the device.
- Open the sterile pouch and attach the Hydra Disposable Auxiliary Water Jet Connector to the endoscope's auxiliary water jet port.
- 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.
- 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.
- When the procedure is completed turn off the irrigation pump before disconnecting the Hydra irrigation system from the endoscope.
- 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 reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Olympus is a trademark of the Olympus Corporation.



Catalog Number



Consult instructions for use.



Contents



EU Authorized Representative



Legal Manufacturer



Lot



Recyclable Package



Use By



Australian Sponsor Address



Argentina Local Contact



For single use only. Do not reuse.



Do Not Resterilize



Do not use if package is damaged.



Sterilized using ethylene oxide.



EU Authorized Representative

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND



Australian Sponsor Address

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666



Argentina Local Contact

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg



Legal Manufacturer

Manufactured for:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001



Do not use if package is damaged.



Recyclable Package

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