Brief Summary Document

Overview

Product Orca™ Air/Water and Suction Valves, Orca Pod™ – IFU 52140077

Rx Statement

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.*

Content

INTENDED USE/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.

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.

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 AND PRECAUTIONS

ORCA AIR/WATER AND SUCTION VALVES

- 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.

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.

ORCA™ SUCTION VALVE

- 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.

ORCA™ AIR/WATER VALVE

- 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.

SEAL SINGLE USE BIOPSY VALVE

- 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.

HYDRA™ DISPOSABLE AUXILIARY WATER JET CONNECTOR

- 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.

PRECAUTIONS

SEAL SINGLE USE BIOPSY VALVE

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.

If the diameter of the accessory is greater than 3.2 mm open the cap for instrumentation.

ADVERSE EVENTS

None known.