



DISPOSABLE AUXILIARY WATER CONNECTOR

Instructions for Use.

Read carefully prior to use.

KEY SURGICAL

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Contains one-way valve

<u>Part Number</u>	<u>Description</u>
EN10906	Auxiliary Water Connector Jet-Kanal-Adapter

For Olympus® GI Endoscope
EVIS 145, 160, 165, 180, 185, 190, 240, 260, 290
Für Olympus® GI Endoskope
EVIS 145, 160, 165, 180, 185, 190, 240, 260, 290

INTENDED USE

The single use **Auxiliary Water Connector** is used in conjunction with irrigation tubing, intended to provide irrigation via irrigation fluids such as sterile water supplied to the Olympus® GI endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump. The **Auxiliary Water Connector** is manufactured with a one-way valve to minimize the risk of cross-contamination of the irrigation system.

WARNINGS AND PRECAUTIONS

**This device is intended to be used with Olympus® GI Endoscopes
**EXCLUDING Olympus® echoendoscopes that utilize a balloon
channel****

- This disposable medical device is intended for single patient use only.
- Never attach or reattach the **Auxiliary Water Connector** to an endoscope that is/was inside the patient and has not been reprocessed.
- The manufacturer did not design this device to be reprocessed or reused, and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of the device to ensure patient and/or user safety.
- This disposable medical device is not intended for reuse. Any institution, practitioner, or third party who reprocesses, refurbishes, remanufactures, resterilizes, and/or reuses this disposable medical device must bear full responsibility for their safety and effectiveness.
- 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 the connection or disconnection of this device. The user is responsible for adhering to Body Substance Isolation protocols.
- Do not insert this device into the patient. The device should be attached to the auxiliary water port of a flexible gastrointestinal endoscope and an irrigation source. Use proper techniques to avoid risk of aspiration of a patient.
- Always prime the auxiliary water channel or biopsy channel prior to inserting the endoscope into the patient.

DIRECTIONS FOR USE

1. Prior to clinical use, familiarize yourself with the device and read all the Instructions for Use.
2. Inspect the package for shipping or handling damage. If damage is evident, **DO NOT USE THESE DEVICES, SAVE THEM OR RETURN, AND CONTACT YOUR LOCAL PRODUCT SPECIALIST.**
3. Open the sterile pouch and attach the auxiliary water connector to the **Irrigation Tubing**. For use of the Irrigation Tubing, reference Instructions for Use of it.
4. Attach the auxiliary water connector to the auxiliary water port by screwing it onto the port (See Figure 1). When attaching the auxiliary water connector to the port, take care to ensure that the auxiliary water connector is aligned to the port and avoid excessive tightening. Misalignment or excessive tightening of the auxiliary water connector could lead to the possibility of leakage. Once the auxiliary water connector is attached to the auxiliary water port of the endoscope, attach Irrigation Tubing to the auxiliary water connector.
5. In the case there is any leakage due to misalignment or excessive tightening, please replace with a new auxiliary water connector.
6. Discard the auxiliary water connector after each patient use.

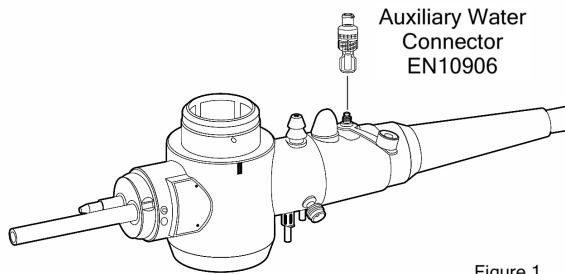


Figure 1

PRODUCT DISPOSAL

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.

WARNING

An issued or revision date for these instructions is included for the user's information. In the event that two years have elapsed between this date and product use, the user should contact the manufacturer to determine if additional information is available.

Olympus® is a registered trademark of Olympus corporation.

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EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE



Used by date



Batch or lot code



Sterilized by Ethylene Oxide



Notified body TÜV SÜD



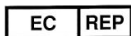
Do not re-use
Single use



Do not re-sterilize



Consult Instructions for Use



Authorized Representative in the
European Community



Do not use if package is damaged



Keep dry



Keep away from sunlight



Rx Only (U.S.A.)
Federal law (U.S.A.) restricts this
device to sale, distribution and use by
or on the order of a physician.