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Disposable Biopsy Valve IFU

This product is not made with natural rubber latex

INTENDED USE:

The biopsy valve – sterile is used to cover the opening to the biopsy/suction channel inlet of a Olympus® and Fujinon® (G5 series and newer) gastrointestinal endoscope. The biopsy valve – sterile provides access for endoscopic device passage and exchange, helps maintain insufflation and minimizes leakage of biomaterial from the biopsy port throughout the gastrointestinal endoscopic procedure.

WARNINGS AND PRECAUTIONS:

- 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 attempt to reuse, reprocess, refurbish, remanufacture, or resterilize this device. Boke Endo Medical did not design this device nor is it intended to be reused, reprocessed, refurbished, remanufactured, or resterilized. Performing such activities on this disposable medical device presents a safety risk to patients (i.e. compromised device integrity, cross-contamination, infection).
- Do not leave a device hanging from the valve. Doing so can cause the creation of larger valve slit / hole that can compromise leak management.
- If the lid of the Boke biopsy valve - sterile is opened while attached to the endoscope during a procedure, scope suction will be compromised and chances of leakage increase. A sterile 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.

DIRECTIONS FOR USE (BY PRODUCT NUMBER):

1. Securely place the biopsy valve onto the biopsy/suction channel opening of Olympus (excluding Olympus linear EUS endoscopes) or G5 series and newer Fujinon gastrointestinal endoscope.
2. This biopsy valve does not accommodate a luer-lock syringe for irrigation purposes without an irrigating adaptor.

Product Disposal:

After use, this product may be a potential biohazard which presents a risk of cross-contamination. 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 Boke Endo Medical to determine if additional information is available.