



### 1. Intended Use

Biopsy Valve are intended to cover the opening of the biopsy/suction channel inlet of Olympus®, Fujinon® or Pentax® endoscopes providing access of endoscopic devices through it and helps maintaining insufflation and minimizing leakage of biomaterial from the biopsy port during a procedure.

### 2. Product Description

The device is made of a main part that can be attached to the biopsy/suction channel of the endoscope and of a lid to properly close the channel. Select the appropriate model depending on the endoscope brand.

### 3. Advices before first application

Please read carefully and follow all safety operating instructions and warnings before first application of the device.

A previous knowledge regarding handling and operation is required and essential.

Unpack the instrument carefully and examine the devices for any possibility of damage. In case of any damage or missing items contact your distributor immediately.



If the package present any damaged, the sterility of the device is not guaranteee.

### 4. Handling and Operation

- Carefully open the sterile package and refer to the label to check the compatibility with your endoscope brand.
- 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 larger valve slit / hole that can compromise leak management.
- If the lid of the Biopsy valve is opened while attached to the endoscope during a procedure, scope suction will be compromised and chances of leakage increase. Sterile gauze should be used to cover the biopsy valve if the lid must be opened for any reason.

### 5. Procedure

- Attach the valve to the biopsy/suction channel of the endoscope
- Close the lid when there is not a need to pass a device through the channel
- Open the lid and pass the device through the hole into the biopsy/suction channel

### 6. Storage

This device is delivered sterilized and in order to maintain this state until its first use it must be kept in its original sterilized package.



Do not put any objects on the instrument or its package!

Do not store the instruments near aggressive chemical products!



Do not expose the instruments to direct or indirect sunlight or other ultra-violet rays!



Keep in dry area

Complaints will not be taken under consideration if the instruments have been stored improperly.





## 7. Cleaning and Sterilization



This device is designed and warranted for single use!

## 8. Risk in case of reuse

This device is for single use only. G-Flex denied all responsibility in case of reuse. The reuse of single use device might present risk to the safety of the user or patient, due to possible uncontrolled contamination and / or unreliability of the device performance.

## 9. User

The users of G-FLEX instruments must be specialists in their fields. An appropriate and specific training for preparation, care and maintenance of the flexible instruments is required.

## 10. Repairing and complains

In health protection of our employees only disinfected or sterilized instruments will be accepted for analysis or repairing. In any case disinfection or sterilization dates and validity must be labelled outside the package. If this requirement has not been fulfilled the instruments will be returned to the sender without analysis or repairing.

## 11. Legal foundation

The Law of the European Union applied.

## 12. Product support

In case of questions or difficulties concerning our instruments please contact your local distributor or G-FLEX directly during regular working hours.

**Times available:** Monday to Friday; 9am to 5pm (MET)

## 13. Symbols



Date of manufacture



Do not use if package is damaged



Caution



Use-by date



Keep away from sunlight



Do not reuse



Batch or lot code



Keep dry



Quantity of units per box



Sterilized using ethylene oxide



Consult the instruction for use

