



1. Intended Use

Hot Biopsy Forceps are used for taking out biopsy specimens (tissues samples) from the human body, through endoscopes.

2. Product Description

The device is composed by a jaw, a spiral spring hose and with or without an operating handle with HF connector.

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.



Considering that device are not delivered sterilized the user must do it before the first application (See Cleaning and Sterilization)



The model with a fixed handle has a lateral connection for cleaning procedure only.

4. Handling and Operation



The device can only be used with an endoscope, a high frequency (HF) generator and an active cord.



Before inserting the device model without handle into the operating channel assemble the universal handle. During the handle assembling the Hot Biopsy Forceps cups must be closed.

4.1. Insertion into the Endoscope

The device must be passed through the endoscope operating channel with its jaws closed. Please observe compatibility between the device and the operating channel diameters.

4.2. HF active cord Connection

Connect the active cord to electricity connector at the handle and to the HF-generator.

4.3. HF Generators

The device can be connected to all licensed HF generators by using the active cord.


Always check compatibility between HF generator and active cord. In doubt contact the manufacturer of generator or your local distributor.

5. Procedure

- Place the Hot Biopsy Forceps near to the tissue to be removed out of the patient.
- Open the cups by pushing the plastic spool at the handle.
- Place the Hot Biopsy Forceps into the tissue and close the cups at the forceps by pulling back the spool.
- Apply the electric current on the hot biopsy forceps (Please observe the HF source manufacturer's instructions).
- Gently take out the tissue sample.
- Stop HF electric current and keep the forceps cups closed.
- Take the Hot Biopsy Forceps completely out of the endoscope with its cups closed.
- This tissue specimen taken will be ready for further histological examination.








 Do not touch another tissue areas when using HF electricity with the forceps cups (high risk of hurt for the patient). Do not use the rinse adapter during the HF working, but only for cleaning.

6. Storage

Please always note a 20 cm min. diameter for winding the instrument.
Always start winding the devices from the distal to the proximal end to prevent damages.

 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

G-Flex recommend to follow one of the following sequences when sterilizing the device:

- Manual Cleaning, Ultrasonic Cleaning, Automatic/Thermal Cleaning and Autoclave; or
- Manual Cleaning, Ultrasonic Cleaning, Automatic/Thermal Cleaning and Ethylene Oxide Gas Sterilization

 Either sterilize by Autoclave or by ETO. There is no need to do both.

7.1. Manual Cleaning

- The cleaning of the device should be done immediately after each use:
- Immerse the device in a suitable liquid detergent or disinfectant (Always observe the minimum diameter of 20 cm when winding the instrument and applicability of the cleaning product!).
 - Wipe the instrument with a soft towel.

7.2. Ultrasonic Cleaning

The ultrasonic cleaning facilitates the dislodging of residual material and must be done before sterilization. The ultrasonic cleaning must last for at least 30 minutes.

- Clean the device right after its use.
- Put the instrument in an ultrasonic cleaning tank always observing the winding minimum diameter 20 cm (Please observe the ultrasonic equipment manufacturer's instructions!).
- Use only tap water and the detergents which dissolve albumen, always according to ultrasonic equipment manufacturer's instructions.
- Rinse the instrument with tap water and wipe dry by using gauze pads.

7.3. Automatic / Thermal Cleaning

Alternatively or additionally to the manual cleaning, this instrument may also be cleaned in automatic / thermal cleaning machines by using approved alkaline detergents. Please refer to relevant instructions of the cleaning machine supplier.





7.4. Sterilization

7.4.1. Autoclave



Before autoclaving sterilization the instrument should be cleaned carefully as described in Manual Cleaning, Ultrasonic Cleaning and Automatic/Thermal Cleaning.



This symbol means that the product can be sterilized by autoclave according to the below parameters

Parameters:

Temperature: 134 °C / 273 °F
Pressure: 3 bar
Exposure: ≥ 18 min

Also in here the minimum 20 cm diameter for winding the instrument must be noted.



The original packages of G-FLEX are not autoclavable!

7.4.2. Ethylene Oxide Gas Sterilization



Please follow manufacturer's warnings regarding to the biological indicators

Parameters:

Temperature: 57 °C
Pressure: 1,7 bar
Exposure: max. 4 h
Relative Humidity: 50 %
Gas Concentration: 12 %
Aeration Time: 7 days in ambient temperature or 12 hours by 50-57 °C

8. 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.

9. 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.

10. Legal foundation

The Law of the European Union applied.

11. 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)





12. Symbols



Date of manufacture



Do not reuse



Caution



Use-by date



Keep away from sunlight



Autoclavable at 134°C / 273°F



Batch or lot code



Keep dry



Quantity of units per box



Non-sterile



Consult the instruction for use

