



## 1. Intended Use

Bougie Dilator Sets are intended for dilation of digestive tract and cardia.

## 2. Product Description

The device is made of 6 bougies that have a smooth distal tip that gradually increase in diameter to reach the final outer diameter of 5, 7, 9, 11, 13 or 15 mm. Each bougie contain a radiopaque marker.

## 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)

## 4. Handling and Operation

- Please carefully read the instructions for use before use.
- The users should be the well trained physicians.
- It is the unsterilized product, and can be reused. The thorough cleaning and sterilization before use is needed. The surface of bougies should be cleaned with flowing water, and the inner hole should be washed with syringe. The guide wire should be cleaned with ultrasonic washer. The sterilization method should be referenced the standard of endoscope cleaning and sterilization technical operation.
- The dilatation should be slow and careful and the diameter of the bougies should be suitable. Do not use the bougie with large diameter directly.
- Do not use it if the bougie has the condition of cracking, rigidity, abrasion, or permanent deformation.

## 5. Procedure

- The device is delivered non-sterile and should be sterilized before use.
- When using the bougies, the physicians should check the condition of the stenosis of esophagus or cardia and select one suitable bougie, the diameter of which should be a little larger than the stenosis part.
- Under X-ray, the guide wire should be inserted through the endoscopy channel until the flexible spring of the guide wire head goes into the gastric cavity.
- (Whether the flexible spring is in gastric cavity or not can be judged through the curved forms of the flexible spring) and then the endoscope should be drawn back and the guide wire should be left.
- The bougie goes along with the guide wire through the stenosis part of the patient to dilate the stenosis.
- The diameter of bougies should be selected from small to large size to dilate the stenosis step by step.

## 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



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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. Contraindications

This device is not recommended for patients whose esophageal anastomose is narrow and tumour is confirmed of relapse; patients whose esophageal anastomose is narrow in 3 weeks after esophageal operation, patients of acute irritation after esophageal burning; patients of seriously high blood pressure; patients of coronary heart disease or lacking of lung function, etc. The details should be determined by physicians.

## 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



Autoclavable at 134°C / 273°F



Batch or lot code



Keep dry



Non-sterile



Quantity of units per box



Consult the instruction for use

