G-FLEX® simple and performing
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Instruction For Use

REUSABLE GUIDING CATHETER, PUSHER AND STENT APPLICATION SYSTEM

CE 0120

AUTOCLAVABLE 134°C 273°F

STERILE EO

1. Intended Use

Reusable Guiding Catheter, Pusher and Stent Application System are intended to place transpapillary biliary stents in patients with biliary obstructions via endoscopes.

2. Product Description

The device is made of an inner guiding catheter with stainless steel marker at the distal end and a Y connector at the proximal end. They also have an outer pusher with stainless steel marker at the distal end and a Luer-lock adapter at the proximal end.

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 guarantee.

4. Handling and Operation

The device can only be used with a duodenoscope and a guide wire.

The device is not suitable for placing Pigtail- or Double-Pigtail-Stents

Endoscopic sphincterotomy and selective duct cannulation prior to guide wire placement is recommended. (Please observe HF-generator and sphincterotome manufacturer's instructions).

5. Procedure

- Steer the tip of the duodenoscope close to the papilla.
- Insert the guide wire through the operating channel into the biliary duct and pass the stenosis.
- Use the included positioning sleeve for easier introducing by sliding it to the proximal end of the stent. So the rear flap will fit back into it.
- Ensure that the Luer-Lock connection between pusher and guiding catheter is firmly closed. Loosen the sealing cap at the Y-adapter.
- Place the biliary stent on to the device by sliding it over the distal end of guiding catheter up to the pusher.
- Now introduce the loaded the device over the proximal end of the guide wire into the operating channel. Positioning sleeve does not fit to the channel and will stay outside.
- Advance the device under constant fluoroscopic control carefully until the radiopaque metal tip of the guiding catheter passes the stenosis.
- Closing the sealing cap at the Y-adapter prevents movement of the guide wire inside of the guiding catheter. Contrast injection is possible through the Luer-Lock-Port at the Y-adapter.
- Open up the Luer-Lock connection between guiding catheter and pusher and advance the biliary stent to its final position by moving forward the pusher carefully. ATTENTION: Keep guiding catheters position while placing the stent !

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CE 0120 AUTOCLAVABLE 134°C 273°F STERILE EO

- Pull back the guiding catheter and guide wire into the operating channel. Prevent movement of the stent by keeping the pusher in its last position. After that the stent will return to its original shape.
- Finally, remove pusher, guiding catheter and guide wire out of the duodenoscope.

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.

CE 0120

AUTOCLAVABLE 134°C 273°F

STERILE EO

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.

AUTOCLAVABLE 134°C 273°F 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.
T**imes available**: Monday to Friday; 9am to 5pm (MET)

CE 0120

AUTOCLAVABLE 134°C 273°F

STERILE EO

12. 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		Quantity of units per box
	Sterilized using ethylene oxide		Consult the instruction for use		