Product:
E 01 3104 FlexTube 3 Single Use

Manufacturer:
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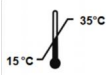
For US market only. This document is intended to provide information to an audience of the US.

Explanation of symbols

	Manufacturer / Manufacturing date
	Reference number/Order number
	Production lot /batch
	To ensure safety, follow the instructions for use
	MR UNSAFE. The system must not be used in a Magnetic Resonance Environment. It contains ferromagnetic parts and poses a clear threat to persons and equipment in the magnetic room.
	Consult instructions for use. Follow the supporting documentation
	Recommended storage temperature +15°C to +35°C
	Applied part type BF
	This is the general warning sign. It is used to alert the user to potential hazards. All safety messages that follow this sign shall be obeyed to avoid possible harm
	The device is disposable and non-reusable
	The device must not be sterilized again
	Sterilization with ethylene oxide gas
	Use by *[date]*
	Keep out of sunlight
	Keep dry
	Do not use if the package is damaged

1. General information

The product FlexTube 3 Single Use is a product variant of a navigated suction instrument for image guided surgical procedures and is referred to as ‚instrument' below.

The instrument is designed to be used with the Fiagon Navigation system. The instrument is accessory to the Fiagon navigation system produced by Fiagon GmbH.

The instrument is a single use instrument and should not be re-used.

The FlexTube 3 Single Use can only be used within the shelf life period.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION: Read the instructions for use carefully before using the instrument.

2. Indications for Use /Field of application

The application of the instrument is limited to the indications for use described here. Any misuse can lead to patient injury or damage of the instrument.

The instrument is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. It is indicated for use with the Fiagon Navigation system using electromagnetic navigation.

The instrument is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery can be identified relative to a CT or MR based model of the anatomy.

Example procedures include, but are not limited to:

- ENT Procedures;
  Transphenoidal access procedures.
- Intranasal procedures.
- Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies.
- Skull base procedures for ENT access.

The navigation system and its accessories are intended for use by healthcare professionals only. In addition, the users receive a training. The operator, i.e., the person or facility that is responsible for the use and service of the system, must ensure that all users of the system receive an adequate introduction into the system in accordance with valid laws and regulations. An operator is everyone who uses the system.

The instrument as a part of the navigation system serves as a tactile instrument. The position of the tip of the instrument and possibly the orientation of the axis are displayed in the image data. The instructions for use of the navigation system describe the proper use of the entire system in detail.

The instrument may only be used if the safety instructions of the navigation system and other connected devices have been followed.

The navigation only works in connection with the navigation system of Fiagon GmbH.

Contraindications

CAUTION: The instrument should not be used if the following contraindications exist:

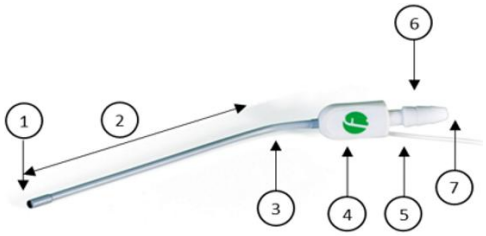
The instrument must not be exposed to MRI or used in a Magnetic Resonance Environment. The MRI exposure might magnetize the sensor. This might lead to a misleading navigation information.

3. Compatible devices

The instrument must only be used as a navigation instrument in connection with the navigation systems of Fiagon GmbH.

The instrument attaches to, and functions with, standard surgical vacuum suction systems. The maximum vacuum of the suction system should not exceed - 90 kPa.

4. Device description



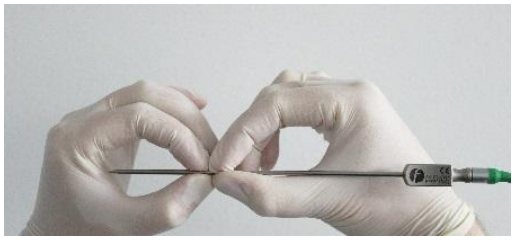
1 Suction inlet
2 Tube length
3 Bending
4 Handle with outlet
5 Cable for connection with the navigation system
6 Flexible tube outlet (6-8 mm)
7 Suction outlet

NOTE: The instrument can be bent. Note that the bending should only be accomplished manually (without using tools).

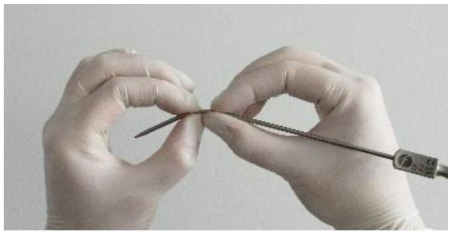
FlexTube can be bent at different locations. We recommend to bent it not more often than clinically necessary. The recommendation is 2-3 times during one operation

CAUTION: To prevent damages of the FlexTube do not bend it more than twice during an operation at the same location:

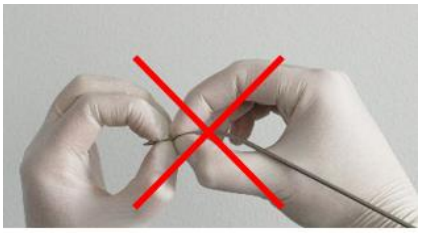
Instructions for bending:



Take the instrument in both hands. Place the thumb on the desired bending position.



Bend the instrument carefully on the thumb until you reach the desired angle. (max approx. 75°)



Do not bend the instrument at a distance of smaller than 0.6 inch (15 mm) from the tip

5. Preparation for the navigation

STERILE EO **The instrument is provided sterile.**

After taking the instrument out of the sterile packaging, place it on the instrument table.

Connect the connector of the instrument with the navigation module. (green socket for instrument). Note that the white marking at the plug is at 12 o'clock position.

CAUTION: Note that you are inserting the plug of the instrument into a non-sterile device.

Once the localizer is connected, you will hear a confirmation tone and the status display of the instrument is displayed in color. The number of remaining uses is displayed in the status indicator of the instrument on the navigation screen. The instrument is accepted and registered to the navigation system. If the indicator shows '0', the system will not accept the instrument for another surgery and prompt for an instrument change.

NOTE: Before using the navigation the patient registration has to be done according to the description of the application. The instrument is not allowed to be used for the patient registration. Consult the instructions for use of the resp. navigation application.

NOTE: If the instrument does not register at the navigation system, it cannot be used for the navigation.

NOTE: For connecting the instrument to the navigation unit via a longer distance use the extension cable instrument (accessory to the navigation unit)

6. Use of the navigation functionality

After connecting the instrument to the system, the position of the navigation point is displayed on the navigation screen (if the patient registration has been performed before)

WARNING: Do not start using the navigation information of the instrument before you have checked and verified it. Therefore, check the displayed position of the instrument on several anatomical structures after connecting the instrument. Do not use the instrument if the deviation is significant, it can lead to misinterpretation of the navigation information and thus may cause injury to the patient.

CAUTION: If the displayed position flickers, replace the instrument. There is a risk that the instrument may be damaged. The use of damaged instruments can lead to severe complications due to falsified position data.

The figure below shows the position of the navigation point on the suction instruments.

7. After the operation

After the operation disconnect the instrument from the navigation unit. Do this by pulling the plug directly. Do not pull the cable or the bend relieve. This might damage the cable.
Dispose the instrument.

CAUTION: The device must not be sterilized again.

CAUTION: The instrument is disposable and non-reusable.

8. Specifications

Type	E 01 3104 FlexTube 3 Single Use
Diameter outside	3.2 mm
Diameter inside	2.3 mm
Diameter Tip + Sensor	4.3 mm
Tube operational length l (inlet – bending)	130 mm
Shape	User defined, Malleable
Suction outlet	6 - 9 mm
Compatible suction system	The instrument attaches to, and functions with, standard surgical vacuum suction systems. The maximum vacuum of the suction system should not exceed - 90 kPa. Verified with: ATMOS Record 500
Operating conditions	Temperature: +15°C to + 35°C, Humidity: 30% to 75% without condensation Air pressure: 1060 hPa to 700 hPa
Transport conditions	Temperature: -10°C to + 40°C, Humidity: 30% to 75% without condensation Air pressure: 1060 hPa to 700 hPa Do not use the instrument if the package is broken
Storage conditions	Protected against dust, moisture and recontamination. Recommended storage temperature: +15° to +35°C Keep the instrument in a dry place. Protect from rain.
Sterilization Procedure	Sterilized by ETO

CAUTION: To ensure that the instrument is intact, pay attention to the notes regarding the transport and storage conditions as well as the notes regarding the application of the instrument!