E 01 3913 GuideWire 0.6 Single Use

is component of the Fiagon Navigation System

Trade Name:	Fiagon Navigation System
Common Name of Device:	Image guided surgery system

Manufacturer:
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US

Explanation of symbols

	Manufacturer / Manufacturing date
	Reference number/Order number
	Serial number
	Production lot /batch
	Content / no. of items in package
	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 pose a clear threat to persons and equipment in the magnetic room.
	Consult instructions for use
	Recommended storage temperature - +15°C to +35°C
	Application 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
	Keep out of sunlight
	Keep dry
	Do not use if the package is broken
	U.S. Federal law restricts this device to sale by or on the order of a physician.

1. General information

The product GuideWire 0.6 Single Use is a variant of a navigated probe for image guided surgical procedures with the XprESS LoProfile Multi-Sinus Dilation Tool and XprESS Multi-Sinus Dilation Tool.

The instruments are accessories to the Fiagon navigation system. It is designed to be used with the Fiagon Navigation system and the XprESS LoProfile Multi-Sinus Dilation Tool or XprESS Multi-Sinus Dilation Tool.

The XprESS LoProfile Multi-Sinus Dilation Tool and XprESS Multi-Sinus Dilation Tool are produced by Entellus Medical Inc./USA. and it is registered as a 510K device with the FDA. Its use is not subject of these instructions for use.

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

NOTE: The GuideWIre 0.6 single use can be used with the Fiagon Navigation Software, version 3.7.5.3003 or higher.

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

The Guidewire 0.6 single use should be used within one year of the manufacturing date

2. Indications for Use / Field of application

The application of the instrument is limited to the indications for use described here.

The GuideWire 0.6 Single Use 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.

It 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 such as the paranasal sinuses, mastoid anatomy, 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.
- ENT related anterior skull base procedures

The navigation system and its accessories are intended for use by healthcare professionals only. In addition, the users receive 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 navigation probe inserted into the XprESS instrument. The position of the tip of the XprESS 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.

When deploying the GuideWire 0.6 Single Use the third-party device XprESS LoProfile Multi-Sinus Dilation Tool or XprESS Multi-Sinus Dilation Tool must be used.

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 misleading navigation information.

The contraindications of the use of the XprESS LoProfile Multi-Sinus Dilation Tool / XprESS Multi-Sinus Dilation Tool and the use of the Fiagon navigation system should be respected as well.

3. Compatible devices

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

The GuideWire 0.6 Single Use is compatible to be inserted into and navigate the tip of the Multi-Sinus Dilation Tool.

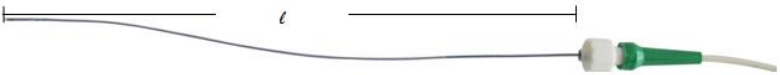
Verified devices:

- XprESS LoProfile Multi-Sinus Dilation Tool REF: LPLF-107-I
- XprESS Multi - Sinus Dilation Tool REF: JD-106

  (manufactured by Entellus Medical Inc./USA)

4. Device Description

GuideWire 0.6 Single Use

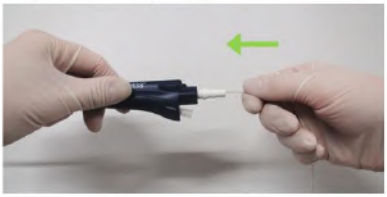


5. Preparation for the navigation

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

After taking the instrument out of the sterile packaging and Place it on the instrument table.

- Unlock the Luer-Lock and carfully pull the Guidewire out of the dispenser coil. Do not pull on the cable.
- Take the XprESS LoProfile Multi-Sinus Dilation Tool or XprESS Multi - Sinus Dilation Tool
- Insert the probe carefully into the handles through the Luer-Lock connector.
- Push the probe forward until the Luer lock connector can be locked.



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 instrument 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.

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)

NOTE: The GuideWire 0.6 Single Use should not be used for the patient registration unless it is inserted in a compatible XprESS device . Before using the instrument the patient registration has to be done according to the description of the application. Consult the instructions for use or the resp. navigation application.

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, make sure that the Luer Lock connector is securely fixed. Check the displayed position of the instrument on several anatomical structures after connecting the instrument. If the deviation is significant do not use the instrument.

CAUTION: To avoid problems with the interpretation of the navigation display, pay attention to the position of the calibrated navigation point. The displayed navigation point corresponds to the tip of the XprESS Instrument.

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.

- Straighten the XprESS Instrument shaft
- Unlock the GuideWire 0.6 Single Use from the Luer-Lock connector
- Pull the probe at the Luer Lock connector out of the handle carefully. Do not pull at the flexible tube or the cable of the GuideWire 0.6 single use.

CAUTION: The instrument is disposable and non-reusable

CAUTION: The device must not be sterilized again

8. Specifications

Type	E 01 3913 GuideWire 0.6 Single Use
Diameter outside / Length [*d*]	0.6 mm / 278 mm
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 contamination. Recommended storage temperature: +15° to +35°C Keep the instrument in a dry place Protect from rain
Sterilization Procedure	Sterilized by EtO

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!