Products:
E 01 2002 FlexPointer
E 01 2004 FlexPointer 1.5
E 01 2300 FinePointer

are components of the Fiagon Navigation System

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

US

Manufacturer:
Fiagon GmbH
Neuendorfstraße 23b
D -16761 Hennigsdorf
Germany
Phone: +49 3302 20121 10
Fax: +49 3302 20121 15
info@fiagon.de

CE 0197

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

Explanation of symbols

	Manufacturer / Manufacturing date
REF	Reference number/ Order number
SN	Serial number
	To ensure safety, follow the instructions for use
CE 0197	Marking of conformity to the European Medical Device Directive 93/42/EEC (MDD) with the number of the notified body (0197).
MR	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
	Attention Follow the supporting documentation
	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.

1. General information

The products FlexPointer, FlexPointer 1.5 and FinePointer are product variants of a navigated pointer probe for image guided surgical procedures and are referred to as ‚*instruments*' below.

The instruments are accessories to the Fiagon navigation system produced by Fiagon GmbH.

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.

CAUTION: Before using it, the instrument must be reprocessed according to the reprocessing instructions. All instruments are delivered in NONSTERILE condition.

The instruments can be reprocessed and used 10 times. The Fiagon navigation system indicates the remaining number of uses.

2. Indications for Use / Field of application

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

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

The instrument are 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 should not be re-processes and reused after it has been used with patients with suspected Creutzfeld-Jakob disease. There is a risk of disease transmission, dispose the instrument after the operation.

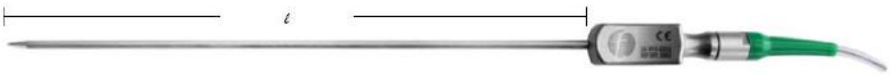
The instrument must not be exposed to MRI or used in a Magnetic Resonance Environment. The MRI exposure might magnetize the sensor. This might lead to a misleading navigation information.

3. Compatible devices

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

4. Device Description

FlexPointer



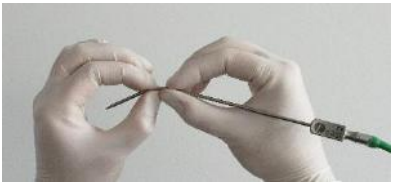
FlexPointer 1.5

NOTE: The **FlexPointer and FlexPointer 1.5** instrument can be bent. Note that the bending should only be accomplished manually (without using tools).

FlexPointer and FlexPointer 1.5 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 pointer tube **do not** bend it more than twice during an operation at the same location:

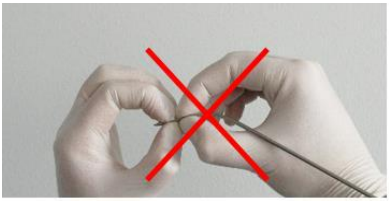
Take the instrument in both hands. Place the thumb on the desired bending position.



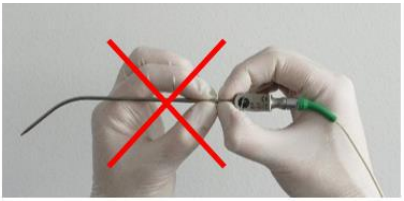
Bend the instrument carefully on the thumb until you reach the desired angle. (max approx. 75°)

CAUTION: To prevent the sensors embedded in the instrument from damage:

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



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



FinePointer

CAUTION: The **FinePointer** instruments cannot be bent.

5. Preparation for the navigation

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 instrument is connected, you will hear a confirmation tone and the status display of the instrument is displayed in color. The no 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: Before using the navigation the patient registration has to be done according to the desciption of the application. The instrument is 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. If the deviation is significant do not use the 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.

Re-process the instrument according to the reprocessing instructions on the following pages.

CAUTION: The instrument should not be re-processes and reused after it has been used with patients with suspected Creutzfeld-Jakob disease. There is a risk of disease transmission, dispose the instrument after

the operation.

8. Specifications

Type	E 01 2002 FlexPointer	E 01 2004 FlexPointer 1.5	E 01 2300 FinePointer
Diameter outside	2.8 mm	1.5 mm	1.5 mm
Length /	170 mm	152 mm	110 mm
Bendability	YES	YES	NO
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		
Storage conditions	Protected against dust, moisture and recontamination. Recommended storage temperature: +15° to +35°C		

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!

9. Reprocessing

Reprocessing instructions for reusable medical devices

General information about the products 	The instruments are intended to be used with the Fiagon navigation system. The usage of the products is described in the instructions for use of the Fiagon navigation system. **The instruments can be reprocessed and used 10 times. (see below for details)**
Warnings 	Not qualified methods for cleaning and sterilization can damage cables and instruments. Instruments are supplied unsterile and must therefore undergo the complete reprocessing cycle prior to the first use. Pay attention to the notes and user manual of the sterilizer's manufacturer as well as the chemicals used.
Restrictions on Reprocessing	**Sort out instruments that have been reprocessed 10 times.** These instructions for use come with a track chart (count sheet) to keep record of the numbers of reprocessing cycles of an instrument. Each instrument has an individual serial number, which is labeled on the handle or the shaft.

Instructions:	
Site of use:	Remove surface soiling with a non-shedding disposable towel/paper towel. Do not allow saline, blood, body fluids, bone fragments or other organic debris to dry on instruments.
Storage and transport	Immediately after use on a patient, immerse the instrument in a cleaning agent/disinfectant (alkaline, free of aldehydes). Immersion the instrument, prevents residues from drying (protein fixation). It is recommended to reprocess the instrument within 1h after use.
Preparation for reprocessing	**The instruments are reprocessed as a complete unit with cable and connector.** **Cable or connector must not be removed.**
Sorting out after 10 reprocessing cycles	**Sort out instruments that have been reprocessed 10 times.** To do so, these instructions for use come with a track chart (count sheet) to keep record of the numbers of reprocessing cycles of an instrument. Each instrument has an individual serial number, which is labeled on the handle or the shaft. When processing an instrument for the first time (brand-new), note the serial number on the first column of the track chart and check the tick box for the first reprocessing cycle. When reprocessing the same instrument the next time, check the next tick box. When receiving an instrument for reprocessing that has a fully checked track chart, it has been reprocessed 10 times. Do not reprocess the instrument. Sort out the instrument and dispose it. (see section "Disposal" for details) Hint: You can use one track chart for ten instruments.

Cleaning - automated	**Non- cannulated instruments** **“FlexPointer”, “FlexPointer 1.5”, “FinePointer”**
	Equipment: • Washer/Disinfector equipped with instrument baskets Washer type with following cycle: 5 minutes, 131°F (55°C), Injection rate, 0.64 fl.oz/gal (5 ml/l) of alkaline agent Deionized Water supply Recommendation: AMSCO® 3052 Single-Chamber Washer/Disinfector (Steris, Inc.) • Cleaning agent: Neodisher® Mediclean forte • Deionized Water • Tap water, potable water Method: 1. Rinse each instrument thoroughly under warm (approximately 91°F/ 33°C) running tap water until there is no debris or discolored fluid noticeable 2. Place instruments into instrument baskets. Take care that the instruments are separated. 3. Choose the instrument cycle in the washer. Validated: Wash: 5 minutes, 131°F (55°C), deionized water, I njection rate, 0.64 fl.oz/gal (5 ml/l) of alkaline agent (Prewash can be done additionally before the wash cycle) 4. Thermal Rinse at 194°F (90°C) for 3 minutes, deionized water
Drying	Instruments can be dried until no visible moisture is present using a clean, soft cloth for the outside of the instrument and the cable
Cleaning inspection	Inspect the instrument for visible soil or debris. Repeat the cleaning steps in case residual soil or debris was fund.
Inspection	The instrument should be inspected after cleaning and before use for surgery. Inspect the instrument visually for damage, wear and corrosion. Check also cable and connectors for damage. Sort out instruments that: • show indications of corrosion • have damaged cables or connectors • show tube denting Instruments that have been sorted out prior to their 10-cycles life time must not be used for surgery. These instruments can be disposed or returned to the dealer/manufacturer for the clarification of reason of the damage.
Maintenance	No special maintenance tasks are necessary for the instrument.

Repair, Returning instruments to the dealer/ manufacturer	Instruments are not being repaired during their life time. However, if you have sorted out an instrument during the inspection, inform the local dealer about the defect. The instrument might need to be returned to the dealer/manufacturer for the clarification of reason of the damage. Note that instruments must undergo the automated cleaning step before returning them.
Disposal	Used instruments must be disposed of as hazardous waste. Take steps to avoid risk of injury and infection. Protect against unauthorized access.
Packaging	Double pack each instrument in see-through peel pouches. Do not pack more than one instrument in a pouch. Recommended accessories: Pouches: Steriking (Healthmark Ind Co.) Size 7" x 12.5" and 8" x 15.75" Pouch item no.: .#33 and #10 Bioindicator: MesaStrip Steam biological indicator (SGM Biotech, Inc.) Steriking is registered as a 510K device (K953776) with the FDA Mesastrip is registered with the FDA
Sterilization	Method: Prevacuum steam sterilizer Sterilization parameters: Min. temperature 270°F (132°C) Full cycle time: 4 minutes Min drying time 20 minutes Recommended validated Type: Middle-sized hospital sterilizer compliant to AAMI ST8 Size: 9 STE (sterilization units) Validated load mix: 2 container of instruments and 2 packages of linen
Storage	Make sure that the package is intact prior to storing. Store the instrument protected from dust, moisture and recontamination. The integrity of the sterile barrier needs to be protected

fiagon.

Track chart (for 10 instruments)

Keep record of the number of reprocessing cycles.

Sort out instruments that have been reprocessed 10 times.

Use this track chart (count sheet) to keep record of the numbers of reprocessing cycles of an instrument. Each instrument has an individual serial number, which is labeled on the handle or the shaft.

When processing an instrument for the first time (brand-new), note the serial number on the first column of the track chart and check the tick box for the first reprocessing cycle.

When reprocessing the same instrument the next time, check the next tick box.

When receiving an instrument for reprocessing that has a fully checked track chart, it has been reprocessed 10 times. Do not reprocess the instrument.

Sort out the instrument and dispose it. (see section "Disposal" in the reprocessing instructions for details)

Hint: You can use one track chart for ten instruments.

Instrument SN no. Note here	Counter Tick a box for each time the instrument with the SN number noted on the left is entering reprocessing									
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked