Products:
E 01 2003 RegistrationPointer

is component of the Fiagon Navigation System

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

US

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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
REF	Reference number/ Order number
SN	Serial number
	To ensure safety, follow the instructions for use
CE	Marking of conformity to the European Medical Device Directive 93/42/EEC (MDD).
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
15°C 35°C	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 RegistrationPointer is a navigated pointer probe for performing non-steril registration for image guided surgical procedures. The instrument is part of the Fiagon Navigation – Extended instrument set ENT, which is designed to be used with the Fiagon Navigation system. The instrument is an accessory 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 RegistrationPointer is not suitable for sterilization. They need to be disinfected before using according to the reprocessing instructions.

2. Indications for Use / Field of application

The RegistrationPointer is for Non-steril registration procedure only. **It must not be used in the surgical field after steril draping of the patient.**

The Fiagon Navigation - Extended Instrument Set ENT 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 Fiagon Navigation – Extended Instrument Set ENT 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 RegistrationPointer as a part of the navigation system serves as a tactile instrument for the patient registration. The position of the ball 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.

MR UNSAVE: 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

RegistrationPointer

5. Preparation for the navigation

After taking the instrument out of its 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: The instrument is to be used for the patient registration. Before using the navigation the patient registration has to be done according to the desciption of the application. 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 pages 6 and 7

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 2003 RegistrationPointer
Diameter outside	2.8 mm Ball tip 5.0 mm
Length (ℓ)	35 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
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 instructions

The RegistrationPointer is a reusable component.

WARNING: The RegistrationPointer must not be sterilized

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. (see below for details)**
Warnings 	Not qualified methods for cleaning and disinfection 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 manufacturer as well as the chemicals used.
Restrictions on Reprocessing	**Not suitable for sterilization.**

Detailed instructions for reprocessing the RegistrationPointer:	
Preparation for reprocessing	**The instruments are reprocessed as a complete unit with cable and connector.** **Cable or connector must not be removed.**
Cleaning and disinfection	Materials: - CaviWipes™ (intermediate-level disinfectant towelettes, aldehydes free) or equivalent disinfectant towelettes Method: 1. Clean exterior surfaces of the instrument (handle, barb, tip, cable) and outer face of connector,with a first towelette to remove debris and bioburden, discard used towelette. 2. Disinfect surface of all above mentioned parts with a second new/unused towelette. Leave surface wet for three (3) minutes, discard used towelette.
Cleaning inspection	Examine surfaces for visible soil/detergent/debris. If residual soil or debris are still visible on the instrument after reprocessing, all cleaning and disinfection steps should be repeated.
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 2-years life 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 cleaning steps 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 (Point of Use / Protective Wraps:)	After cleaning and disinfection, place the instrument into protective wrapping. 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 or equivalent pouch Make sure that the package is intact prior to storing. Steriking is registered as a 510K device (K953776) with the FDA
Storage	Make sure that the package is intact prior to storing. Store the instrument protected from dust, moisture and recontamination.