

1 Instructions for Use

Product:

E 01 2003 RegistrationPointer

is component of the Cube Navigation System

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

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



Serial number



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.



Note to the user to adhere to and consult the referenced Instructions for Use of other system components or 'Application Notes'



Attention
Follow the supporting documentation



Indicates the temperature limits to which the medical device can be safely exposed



Indicates the humidity limits to which the medical device can be safely exposed



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 product RegistrationPointer is a navigated pointer probe for performing non-sterile registration for image guided surgical procedures. The instrument is part of the extended instrument set ENT, which is designed to be used with the Cube Navigation System. The instrument is an accessory to the Cube 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 NON-STERILE 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-sterile registration procedure only. It must not be used in the surgical field after sterile draping of the patient.

The 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 Cube Navigation System using electromagnetic navigation.

The 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;
Transsphenoidal 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-processed and reused after it has been used with patients with suspected Creutzfeldt-Jakob disease. There is a risk of disease transmission, dispose the instrument after the operation.



MR UNSAFE: 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 unit. Note that the white marking at the plug aligns with the marking at the socket.



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 description 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.

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 done)



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 5 and 6.



CAUTION: The instrument should not be re-processed and reused after it has been used with patients with suspected Creutzfeldt-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 (λ)	35 mm
Operating conditions	Temperature: +15°C to + 35°C, Humidity: 30% to 75% without condensation Air pressure: 700 hPa to 1060 hPa
Transport conditions	Temperature: -10°C to + 50°C, Humidity: 10% to 90% without condensation Air pressure: 700 hPa to 1060 hPa
Storage conditions	Protected against dust, moisture and recontamination. Storage temperature: -10°C to + 50°C, Storage humidity: 10% to 90% without condensation Storage air pressure: 700 hPa to 1060 hPa





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.

<p>General information about the products</p> 	<p>The instruments are intended to be used with the Cube Navigation System. The usage of the products is described in the instructions for use of the Cube Navigation System.</p> <p>The instruments can be reprocessed. (see below for details)</p>
<p>Warnings</p> 	<p>Not qualified methods for cleaning and disinfection can damage cables and instruments.</p> <p>Instruments are supplied unsterile and must therefore undergo the complete reprocessing cycle prior to the first use.</p> <p>Pay attention to the notes and user manual of the manufacturer as well as the chemicals used.</p>
<p>Restrictions on Reprocessing</p>	<p>Not suitable for sterilization.</p>

<p>Detailed instructions for reprocessing the RegistrationPointer:</p>	
<p>Preparation for reprocessing</p>	<p>The instruments are reprocessed as a complete unit with cable and connector.</p> <p>Cable or connector must not be removed.</p>
<p>Cleaning and disinfection</p>	<p>Materials:</p> <ul style="list-style-type: none"> - CaviWipes™ (intermediate-level disinfectant towelettes, aldehydes free) or equivalent disinfectant towelettes <p>Method:</p> <ol style="list-style-type: none"> 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.
<p>Cleaning inspection</p>	<p>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.</p>
<p>Inspection</p>	<p>The instrument should be inspected after cleaning and before use for surgery.</p> <p>Inspect the instrument visually for damage, wear and corrosion.</p> <p>Check also cable and connectors for damage.</p> <p>Sort out instruments that:</p> <ul style="list-style-type: none"> • show indications of corrosion • have damaged cables or connectors • show tube denting <p>Instruments that have been sorted out prior to their 2-years life must not be used for surgery.</p> <p>These instruments can be disposed or returned to the dealer/manufacturer for the clarification of reason of the damage.</p>

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Maintenance	No special maintenance tasks are necessary for the instrument.
Repair, Returning instruments to the dealer/ manufacturer	<p>Instruments are not being repaired during their lifetime. However, if you have sorted out an instrument during the inspection, inform the local dealer about the defect.</p> <p>The instrument might need to be returned to the dealer/manufacturer for the clarification of reason of the damage.</p> <p>Note that instruments must undergo the cleaning steps before returning them.</p>
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:)	<p>After cleaning and disinfection, place the instrument into protective wrapping. Do not pack more than one instrument in a pouch.</p> <p>Recommended accessories:</p> <p>Pouches: Steriking (Healthmark Ind Co. Size 7" x 12.5" and 8" x 15.75" Pouch item no.: #33 and #10 or equivalent pouch</p> <p>Make sure that the package is intact prior to storing.</p> <p>Steriking is registered as a 510K device (K953776) with the FDA</p>
Storage	<p>Make sure that the package is intact prior to storing.</p> <p>Store the instrument protected from dust, moisture and recontamination.</p>

