

ENT Navigation Electromagnetic

Instructions for use Navigated instruments and trackers

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1 General information

1.1 Manufacturer



ErgoSurg GmbH
Gleissenweg 1
85737 Ismaning
Germany

1.2 Support & Feedback

If you cannot find the information you need in this guide, or if you have any questions, problems with our products, or suggestions for improvement, please contact our support team.

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2 Legal

2.1 Copyright

The content of these operating instructions is protected by copyright. Copying or publishing these operating instructions, either in whole or in part, is prohibited without the express written permission of the manufacturer.

2.2 CE marking



This medical device is CE marked in accordance with the Medical Device Directive (MDD) 93/42/EEC. If the CE mark is followed by an identification number, this indicates the competent notified body:

- Patient Tracker (Item No. 435001)
- Pointer, angled (Item No. 433001)
- Pointer, curved (Item No. 433002)



This medical device is CE marked in accordance with the Medical Device Regulation (MDR) 2017/745. If the CE mark is followed by an identification number, this indicates the competent notified body:

- Shaver Tracker (Item No. 435003)

3 Symbols

Please read these instructions carefully and follow them closely. The terms Warning, Caution, and Note have specific meanings. Wherever they are used in the instructions, the following text should be read carefully to ensure safe and efficient use. For clear emphasis, these terms are preceded by a pictogram.



WARNING: Warning indicates a hazard to the patient or personnel. Failure to observe a warning may result in injury to the patient or personnel.



CAUTION: Caution indicates that certain measures must be taken to prevent damage to the instrument.



NOTE: Notes contain specific information on operation or explain important information.



Manufacturer



Date of manufacture



Item number



Serial number



Quantity



Medical device



Unique product identification



Air pressure limitation



Follow the instructions for use or follow the electronic instructions for use



Temperature limitation



Humidity limitation



Fragile, handle with care



Store in a dry place



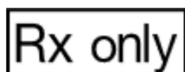
Not sterile



Caution



Data matrix code



Rx-only

4 Intended use

4.1 Scope



These instructions for use describe the safe and proper use of the following electromagnetically navigated instruments and trackers (hereinafter referred to as instruments):

- | | |
|-------------------|-------------------|
| • Patient Tracker | (Item No. 435001) |
| • Pointer, angled | (Item No. 433001) |
| • Pointer, curved | (Item no. 433002) |
| • Shaver Tracker | (Item No. 435003) |

These instructions supplement the instructions for the ENT navigation system and the ENT Navigation software package and should only be used in conjunction with them. The reprocessing of the instruments and trackers is described in the separate reprocessing instructions.

- Instructions for Use ENT Navigation Electromagnetic (Item No. 439301)
- Instructions for Use ENT Navigation Software (Item No. 448301)
- Reprocessing Instructions Navigated Instruments and Trackers (Item No. 440301)

4.2 Intended use

The ENT navigation system is a positioning aid for instrument navigation in ENT, skull base, and cranial surgery under visual control.

It consists of a planning and treatment program in which an instrument is navigated on the basis of radiological image data (obtained by CT, MRI, or CBCT/DVT). The radiological data is presented depending on the position of the instrument, and the position of the instrument is superimposed on the radiological data.

The two pointers mentioned above serve as electromagnetically navigated probing instruments without contact with the central nervous system.

The Patient Tracker is used to detect the patient's position using the electromagnetic navigation system. For this purpose, it is fixed to the patient during the procedure.

The shaver tracker enables the position and location of compatible Karl Storz shaver attachments and sinus drills (see instructions for use of the installed ENT Navigation software package) to be determined without contact with the central nervous system.

Any use other than that specified and expressly described in these instructions for use is not permitted.

4.3 Compatibility

The electromagnetic navigated instruments and trackers mentioned may only be used in conjunction with the electromagnetic ENT navigation systems from ErgoSurg (item number 439001) and Karl Storz (item number 40820001E/40820001).

The Patient Tracker can be attached to the patient using the following products:

- 3M Tegaderm Film, 10 cm x 12 cm, 1626W
- Karl Storz, headband for Patient Tracker, single use, 40800083
- Karl Storz, headband for Patient Tracker, reusable, 40800084
- Karl Storz, bone anchor, 40800100
- Karl Storz, adhesive pad, non-sterile, 40820085
- Karl Storz, adhesive pad, sterile, 40820084

The Shaver Tracker is compatible with a range of Karl Storz shaver attachments and sinus drills (see the instructions for use of the installed ENT Navigation software package) when used with the DrillCut-X® II shaver handpiece, 40712050. The ENT Navigation software package is compatible from version 6.2.1 onwards.

4.4 User qualification

The user of the navigation system, as well as the surgical staff and other personnel involved, must have received training authorized by the manufacturer and distributor in order to operate the navigation system safely and effectively and to be allowed to use the navigation system on a patient. The requirements for such training may vary depending on the applicable legal regulations at the place of use. The operator of the navigation system must ensure that the user receives adequate instruction in the navigation system in accordance with the applicable local laws.

4.5 Contraindications



WARNING: The navigation system must never be used if there are clinical or medical reasons against its use. The navigation system must not be used if, in the opinion of a responsible physician, such use would endanger the patient, e.g., due to the patient's general condition.



WARNING: The navigation system may only be used if the operation can also be performed conventionally.



WARNING: The navigation system must be used with visual control of the navigated instrument at the surgical site.



WARNING: The navigation system must not be used on patients suffering from Creutzfeldt-Jakob disease. If the navigation system is nevertheless used on such a patient, it must be disposed of in accordance with the applicable regulations. In this case, the operating license expires immediately.



WARNING: The navigation system should not be used if the user has dyschromatopsia (color blindness), especially red-green color blindness or color weakness.



WARNING: The products described in this user manual must not be used with other accessories, materials, or components unless they have been expressly declared compatible by the manufacturer. A list of compatible products is included in this user manual. For safety reasons, unauthorized modifications or alterations to the products are prohibited.

5 Safety instructions



WARNING: Failure to follow these instructions for use and all instructions for use of the products used in combination may result in injury to patients, users, and third parties, as well as damage to the product. Read all relevant instructions for use carefully and always follow the instructions described. Check the function of the products used in combination.



WARNING: Incorrect use of medical instruments may result in injury to patients. Users of medical instruments must have the appropriate medical qualifications and be familiar with their use.



WARNING: Incorrectly assembled and damaged instruments can cause injury to the patient. Instruments and accessories used in conjunction with them must be checked immediately before and after each use to ensure that they are in perfect condition, fully functional, and free of unintended rough surfaces, sharp corners, burred edges, protruding parts, and that they are complete. Missing or broken components must not be left in the patient.

6 Handling

It is recommended to check the suitability of the products for the planned procedure before use. Always handle instruments with care to avoid damage:

- Do not kink the instrument cable.
- Always grasp the plug when disconnecting an instrument from the Electromagnetic Tracking Unit. Do not pull on the instrument cable itself.
- Avoid stretching the instrument cable.
- Only connect to the designated sockets on the device.
- Do not expose to strong magnetic fields, especially MRI machines.

- Do not place directly on the field generator.
- Do not place the instrument cable in the immediate vicinity (<30 mm) of the field generator cable during operation.



WARNING: Overloading due to excessive force can lead to breakage, bending, and malfunction of the medical device and to injury to the patient or user. Do not overload instruments. Do not bend bent instruments back into their original position.

6.1 Connecting the instruments



NOTE: When connecting the instrument to the Electromagnetic Tracking Unit, check that it is securely seated by gently pulling on the plug before use.

Connect the EM-navigated instruments to the sockets marked with the numbers "1" to "4" on the front of the Electromagnetic Tracking Unit. A status light above each socket indicates the connection status:

- off: no instrument connected/detected
- orange: instrument connected but not initialized
- green: instruments initialized

To initialize the instruments, switch to "Surgery Mode" on the navigation system.



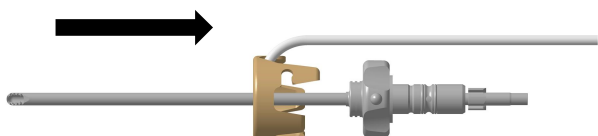
NOTE: The color of the cable's anti-kink sleeve indicates the function of the instruments

yellow: Pointer
white: Patient Tracker
gray: Shaver Tracker

6.2 Mounting the Shaver Tracker

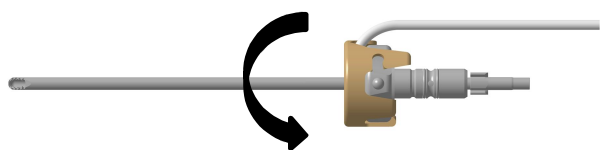


CAUTION: The Shaver Tracker can only be attached in the mounting direction shown. Forcing it to mount in the opposite direction may damage the Shaver Tracker and/or the shaver blade.



Remove the Shaver Tracker from its sterile packaging.

Slide the Shaver Tracker over the distal end of the shaver attachment.



Turn the Shaver Tracker toward the orientation pin on the adjustment wheel.



The locking tab of the Shaver Tracker must engage noticeably with the orientation pin.

6.2.1 Status display of the instruments

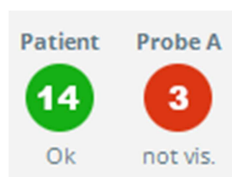


During navigation, the status display of the instruments is shown at the top left edge of the workflow bar. This shows the status of the instruments currently connected to the Electromagnetic Tracking Unit.

The colors have the following meanings:

Gray	"Not connected"	No instrument is connected
Red	"Not detectable"	The instrument is outside the working range or cannot be detected by the electromagnetic measuring system.
Yellow	"Not registered"	The instrument is detected by the measuring system, but is not registered.
Green	"OK"	The instrument is detected and registered or does not require registration.

6.2.2 Instrument usage cycles



The status display shows the status of an instrument's usage counter within the circles. An instrument displays 1 when it is used for the first time. Each time an instrument is used in a navigated surgery, the usage counter is increased by 1.

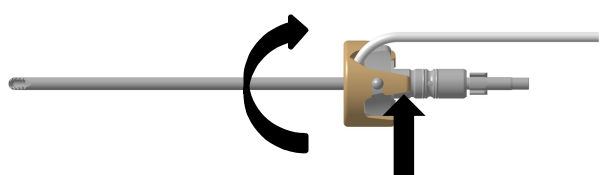


NOTE: Navigated instruments can be connected/disconnected as often as desired during an uninterrupted navigated procedure without increasing the usage counter.

6.3 Disassembly of the Shaver Tracker



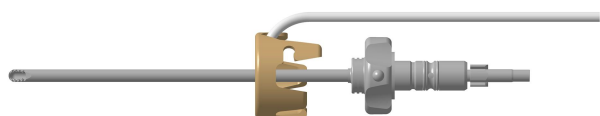
CAUTION: The tracker can only be released in the direction shown. Forcing it in the opposite direction may damage the tracker and/or the shaver blade.



Loosen the Shaver Tracker by turning it away from the orientation pin on the adjustment wheel. To do this, press against the locking tab.



Pull the Shaver Tracker toward the distal end of the shaver attachment.



7 Reprocessing

All medical products used during surgical procedures in a sterile patient environment must be cleaned and sterilized before each surgical use. This applies in particular to the first use after delivery of non-sterile packaged products.

The reprocessing of the instruments covered in these instructions for use is described in separate reprocessing instructions.

8 Limitation of reprocessing

The end of the product's service life is largely determined by wear and tear, the reprocessing procedures, the chemicals used, and any damage caused by use. ErgoSurg has validated a cycle count of 30, provided that the product is used and reprocessed properly and professionally.

9 Conditions of use and storage

	Temperature	Relative humidity	Air pressure
Storage	-10 °C to +50 °C	10% to 90	70 kPa to 106 kPa
Application	+10 °C to +40 °C	30% to 70	70 kPa to 106 kPa

10 Disposal

No special measures are required for disposal. Observe the applicable local and national laws and regulations when disposing of the product.

11 Customer service

If you have any questions or problems, please contact ErgoSurg Customer Service. To ensure that your inquiry is processed quickly, please send the product with the following information:

- Item number (REF)
- Serial number (SN) or (LOT)
- As detailed a description of the fault as possible

To protect your staff and ErgoSurg employees, the product (and any accessories) must be thoroughly cleaned and sterilized before shipping. If this is not possible due to urgency, the product must be prepared as far as possible and labeled accordingly.

For safety reasons, ErgoSurg GmbH may refuse to repair dirty or contaminated products.

12 Emergency number

In the event of an incident in accordance with Regulation (EU) 2017/745 Article 2 or the Medical Device User Reporting and Information Regulation (MPAMIV) § 2, please report it to us at the following telephone number:

+49 (0) 89 322094-63

Thank you for your support!