

Products:

E 01 1003 Navigation headrest Universal

Manufacturer:

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



US

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



Follow the instructions for use



Marking of conformity to the European Medical Device Directive 93/42/EEC (MDD).



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



Recommended Humidity
 30% to 75% without condensation



Recommended Air pressure
 700 hPa to 1060 hPa



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.



Federal law (USA) restricts this device to sale by or on order of a physician.

1. General information

The Navigation headrest Universal is a product variant of a navigation sensor which is mountable on the OR tables. This enables the usage of the Fiagon image guided surgery system and is referred to as a 'headrest'.

The headrest is a component of the Fiagon Navigation System produced by Fiagon GmbH.



CAUTION: Read the instructions for use carefully before using the headrest.



CAUTION: Before using it, the headrest must be cleaned according to the cleaning instructions. The Navigation headrest is not sterilizable.

2. Intended purpose/Field of application



The application of the headrest is limited to the intended purpose described here.

The Navigation headrest is mounted on the OR table instead of the original headrest. It comprises of a sensor, which creates an electromagnetic field above the cushion of the Navigation headrest.

The Navigation headrest Universal 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 anrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies.
- Skull base procedures for ENT access.



Refer to the instructions for use of the OR table model for more detailed information about how to mount headrest to the corresponding table model.

The Fiagon Navigation System and its components are intended for use by healthcare professionals (physicians) only. In addition, the users must receive training. The operator, i.e., the person or facility who is responsible for the use and service of the system, must ensure that all users of the system receive an adequate briefing in accordance with valid laws and regulations. An operator is anyone who uses the system.

The Navigation headrest takes full functionality of the original headrest and houses the navigation sensor, which is a part of the Fiagon Navigation System. The instructions for use of the Fiagon Navigation system describe the proper use of the entire system in detail.



The headrest may only be used if the safety instructions of the Fiagon Navigation System and other connected devices have been followed.

i NOTE: The navigation only works in connection with the Navigation System of Fiagon GmbH. Please take carefully notice of the instructions for the use of the navigation device.



Exclusion of application

- The headrest should only be mounted to supported table models. The safety of the product cannot be guaranteed for unsupported OR tables.
- Please consult a Fiagon support representative, for first time installation on any OR table



CAUTION: The headrest must not be loaded with more than 15kg. The maximum overall body weight of the patient should not exceed 180kg.

3. Compatible Devices

The Navigation headrest Universal can only be used as a navigation sensor in connection with the Navigation Systems of Fiagon GmbH.

The headrest can either be installed to various OR table models using the specific adapters. Provided below are the specific manufacturers who provide adapter models

- Maquet
- Mizuho/Skytron
- Steris
- Eschmann
- Bертold

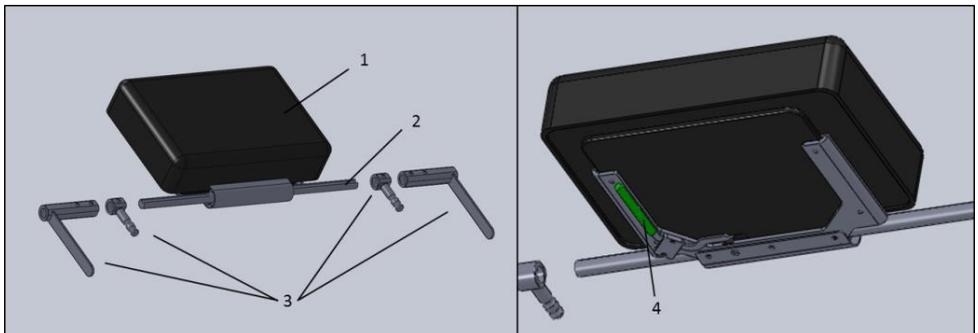
Furthermore all OR tables with siderails of the listed standards are supported:

- EUR: 25mm x 10mm
- US: $1\frac{1}{8}'' \times \frac{3}{8}''$
- UK: $1\frac{1}{4}'' \times \frac{1}{4}''$
- JPN: 32mm x 9mm

Compatible adapters are listed in the section "**specifications**".

4. Device description

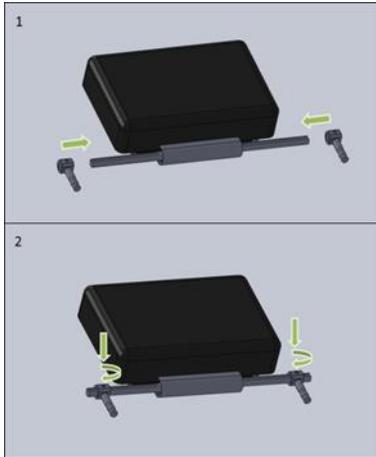
The contents of the product Navigation headrest Universal is displayed in the pictures below.



- 1: Cushion. The cushion is antistatic and removable.
- 2: Axis. The axis enables the mounting of relevant OR table adapter sets.
- 3: Adapter sets. To fix the headrest to the OR table the relevant adapter set must be mounted to the headrest first.
- 4: Lever (green color in the picture) is provided for enabling the angle set up of the headrest.

5. Bringing into service

The given example in the graphics below shows how to mount an adapter to the Navigation headrest Universal. Once an adapter that fits your OR table is mounted, the headrest can be used in this steady setup.



1: Mount the Adapter set to the axis of the Navigation headrest Universal. The screws have to face the same direction as the notch in the axis.

2: Fix the screws so that they sit tightly inside the notches. It is advisable to already set the right distance between the adapters.



Make sure that the screws rest well inside the notches so that it is impossible for the adapter to turn on the axis.

6. Installation on the OR-table

For installation on the OR-table you can either use the specific adapter for the supported table models or the Siderail-Adapter.

a. Install the headrest with specific table adapter at the OR table

In case a specific adapter is mounted, the headrest can be installed following these steps:

- 1: Make sure that the distance between the adapters fits the distance between the tables socket.
- 2: Fit the pins of the adapter into the sockets and fix them with the screw or bolt that secures the pins of the headrest inside the socket.

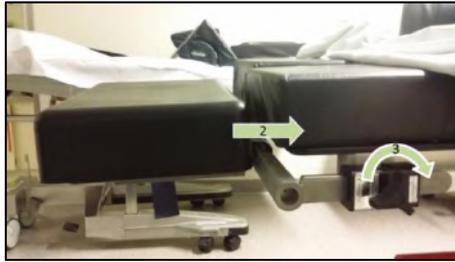


NOTE: Refer to the instructions for use of your OR table supplier for more detailed information on how to fit a headrest to your OR table.

b. Install the headrest with Siderail-Adapter at the OR table

If there is no adapter offered for a certain table, it is possible to fit the headrest to the siderail at the top end of the OR table. The procedure is described below.

- 1: Mount the Siderail-Adapter to the headrest as described in section “4. Bringing into service”.
- 2: Put the fixation clamp ready on the table’s siderails and fit the headrest’s adapter into the gap between siderails and the clamp.



3: Tighten the fixation clamp. Take care that the rails are not tilted inside the clamp. Before using the Fiagon Navigation System, the sensor must be connected to the Navigation unit.

4: Insert the plug of the sensor into the appropriate socket "sensor" (metal socket) on the Navigation unit. Note that the red marking on the plug is in the 12 o'clock position. Using too much force while trying to plug in the sensor cable in a different position may cause damage to the plug and/or the socket.

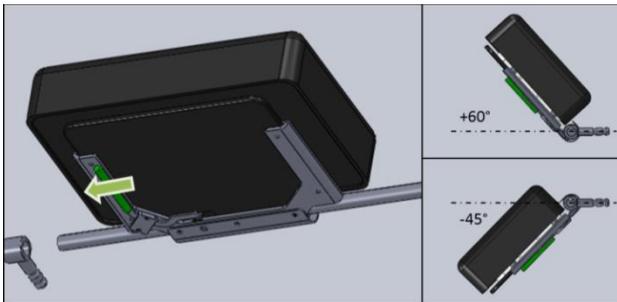


CAUTION: Note that you are inserting the plug of the headrest into a non-sterile device.

5: Once the navigation sensor is connected, you will hear a confirmation tone and the status bar will appear on the top of the Navigation screen.

c. Setting-up the angle between the headrest and the table

If necessary, it is possible to alter the angle between headrest and table. The angle can be set between $+60^\circ$ and -45° in stepwise fashion of upgrade or downgrade of 15° . The figure below shows the procedure of angle change.



To tilt the head upwards just lift the headrest. To move the head downwards it is necessary to pull the lever as illustrated above. For pulling the lever it might be needed to lift the headrest first, so that there is no load on the locking mechanism.



CAUTION: Use of hands to manoeuvre the lever should be restricted to the green zone as in the drawing. Having your hand close to the angle setting mechanism can cause injury.



CAUTION: Make sure that the mechanism rests in between every 15° step of angle adjustment. If the headrest is not resting in one of the predefined positions, the safety of the patient and personal cannot be assured.

7. After the operation



NOTE: Refer to the instructions for use of your OR table supplier for more detailed information on how to disintegrate a headrest on your OR table.



WARNING: While disintegrating the headrest, do not grab the cushion. The headrest can fall and cause damage to the system and injury to the user. The connection between cushion and headrest cannot support the weight of the headrest.

After the operation the headrest should be wiped with an alcoholic fluid to disinfect the cushion.

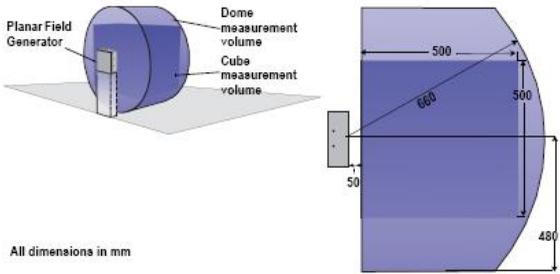


NOTE: The cushion should be covered during operation, since the biocompatibility of the material cannot be guaranteed.



NOTE: If you notice any cracks in the surface of the cushion the headrest cannot be used safely anymore until the cushion is replaced.

8. Specifications

Item	E 01 1003 Navigation headrest Universal
Compatible adapters	E 01 1913 Adapters for Maquet E 01 1914 Adapters for Steris E 01 1915 Adapters for Eschmann E 01 1916 Adapters for siderails E 01 1917 Adapters for Mizuho/Skytron E 01 1918 Adapters for Berchtold
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 + 40°C, Humidity: 30% to 75% without condensation Air pressure: 700 hPa to 1060 hPa
Storage conditions	Protected against dust, moisture and contamination. Recommended storage temperature: +15° to +35°C Humidity: 30% to 75% without condensation Air pressure: 700 hPa to 1060 hPa
Integrated sensor type	Fiagon Planar Field Generator
Dimensions (height x width x depth)	200 mm x 200 mm x 71 mm
Weight	2,6 kg (without cable)
Measurement Volume	 <p>All dimensions in mm</p>



To ensure that the instrument is intact, consult the notes regarding the transport and storage conditions as well as the use of the instrument!

9. Electrical Safety and EMC:

The Navigation headrest Universal is a part of the Fiagon Navigation System and can only be used in combination with the Fiagon Navigation unit. All Electrical safety and EMC testing has been performed with this combination. Please refer to the instructions for use of the Fiagon Navigation System for details and tables.

10. Cleaning instructions

The headrest is a reusable component.



WARNING: The headrest or parts of the headrest must not be sterilized.

Clean the headrest by hand and disinfect using an aldehyde-free disinfectant.

Do not immerse the headrest, or parts of the headrest in the disinfectant or cleaning agent.

11. Preventive Maintenance Instructions

The maintenance is done by authorized personnel only. Recommended maintenance period is 1 year and includes accuracy test according to a described procedure.