

1 Instructions for Use

Product:

E 01 1905 Flexarm Adapter for siderail

Accessories of the medical device

Cube 4D Navigation System

Common Name of Device: Surgical navigation instrument/
Stereotactic surgery system



NOTE: The Flexarm Adapter is only to be used with the *Fiagon Navigation Sensor (A 01 1000)* as displayed on the image above

Manufacturer:

Fiagon GmbH
Neuendorfstr. 23b
16761 Hennigsdorf
Germany



Explanation of symbols



Manufacturer



Manufacturing date



Reference number/Order number



Serial number



Marking of conformity with the European Medical Devices Regulation 2017/745 (EU MDR)



Consult referenced instructions for use



Follow the supporting documentation.



Note highlighting information for the user



Caution, observe the warnings and safety information in this document.



Medical device



Unique Device Identification

1. General

Flexarm adapter for siderail is an accessory (group: Navigation sensor support) of the Cube 4D Navigation System. It serves as mounting support for the Navigation sensor (A01 1000). It is a articulating arm, which is mountable to rails 25x10 mm of OR tables or procedure chairs. It can be screwed to the Navigation sensor and holds it in position.



CAUTION: Read these Instructions for Use carefully before using the device.



NOTE: Serious incidents that occur in connection with the stated product(s) must be reported to the manufacturer and the competent authorities in accordance with country-specific guidelines. Please observe the applicable reporting deadlines and conditions in your country for reporting incidents.

1.1 Intended purpose



CAUTION: The use of the device is limited to the intended purpose of the Cube 4D Navigation System to which it is accessory.

The Cube 4D Navigation System with its components and accessories is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Cube 4D Navigation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as the paranasal sinuses, mastoid anatomy, skull base and the skull, can be identified relative to a CT or MR based model of the anatomy.

1.2 Contraindications

There are no contraindications for the use of the device as an accessory per se, but the contraindications of the complete navigation system must be considered when using navigation.



NOTE: There are no known undesirable side effects for the patient when using the Cube 4D Navigation System.

1.3 Target patient group

Patient group is not restricted in terms of age, health condition or gender.

1.4 General warnings and precautions



CAUTION: This device is intended for use by healthcare professionals only.

CAUTION: The device may only be used if the safety instructions in the instructions for use of the navigation system and the navigation sensor have been followed.

CAUTION: Before using the device for the first time, it must be cleaned according to the cleaning instructions. The Flexarm Adapter cannot be sterilized.



NOTE: The device only works for navigation with the navigation sensor mounted to it. Please take carefully notice of the instructions for use of the navigation sensor, navigation system and the navigation software.

2. Compatible devices

The Flexarm adapter can be mounted to rails of the following dimensions:

- Rail: 25 x 10 mm

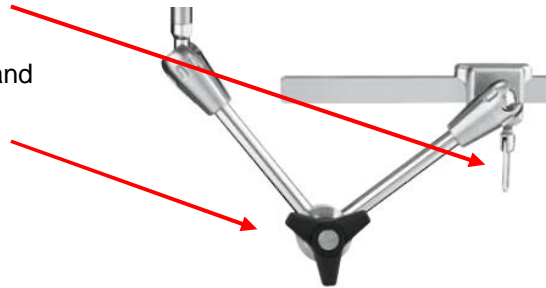
3. Device description

The Flexarm adapter consists of an articulating arm with clamp for rails (25 x 10 mm) on one end and a mounting adapter for the navigation sensor (A 01 1000).

4. Mounting of Flexarm adapter

To attach the device to the rail of 25 x 10 mm please follow the installation steps:

- I. Attach the rail clamp of the device to an appropriate position on the rail.
- II. Fix the clamp firmly with the screw.
- III. Adjust the navigation sensor to the surgical area and fix its position by tightening the articulating arm's knob.



- IV. 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.

5. After usage / disassembling

For disassembling please perform installation steps in reverse order.

6. Cleaning instructions

The device is suitable for manual cleaning and disinfection.

Material:

- CaviWipes™ (mid-level disinfectant wipe, aldehyde-free) or similar disinfectant wipes

Procedure:

1. Clean the outer surface with a disinfectant wipe, to remove debris and bacteria. Discard the used disinfectant wipe.
2. Disinfect all the components listed under 1. With a second new/unused disinfectant wipe. Leave the surface wet for around three (3) minutes. Discard the used disinfectant wipe.



CAUTION: Do not immerse the Flexarm adapter in disinfectant or cleaning agent.

7. Preventive Maintenance Instructions

The product should be inspected regularly for visible damage and wear and tear.

Check whether mechanical parts are damaged and whether the fixation of the arms and joints is firm when tightening the knob.

8. Specifications

Item	E 01 1905 Flexarm Adapter for siderail
Length of arm	400 mm
Rail size for clamp	25 x 10 mm
Weight	1,0 kg
Operating conditions	no special limitation
Transport conditions	no special limitation, store dry and protect against contamination
Storage conditions	no special limitation, store dry and protect against contamination
Compatible sensor type	Fiagon Navigation Sensor (A 01 1000)

