1 Instructions for Use

Products:
E 01 2900 PointerShell 4 mm
E 01 2901 PointerShell 5 mm
E 01 2902 PointerShell 3 mm
E 01 2904 PointerShell Universal

are components of the Cube Navigation System

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

Manufacturer:
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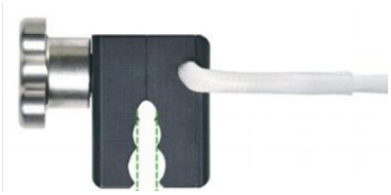
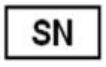


For US market only. This document is intended to provide information to an audience of the US.

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.


CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

1. General information

The products PointerShell 3mm, PointerShell 4 mm, PointerShell 5 mm, PointerShell Universal are product variants for the navigation of shavers or surgical instruments without motor in the handle and are referred to as ‘PointerShells’ below.

The instruments are accessories of the Cube Navigation System produced by Fiagon GmbH.

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 PointerShells can be reprocessed and used 10 times. The Cube Navigation System indicates the remaining number of uses.

2. Indications for Use / Field of application

The application of the instrument is limited to the indications for use described here.

The instruments are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. They are indicated for use with the Cube Navigation System using electromagnetic navigation.

The instruments are 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 PointerShell devices are intended to be used as an attachment to the shaft of shaver blades or other surgical instruments without being in contact with the surgical area.

The navigation system and its accessories are intended for use by healthcare professionals only. In addition, the users receive 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.

In the navigation system, the PointerShell is used to display the current position of the instrument, to which the shell is attached in a preoperative radiological image data of the patient. The position of the 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 details.

Refer to the application note Navigation with PointerShell for training.

The PointerShells 3mm, 4mm, 5mm and Universal have a calibration pit that can be used for the calibration of a second PointerShell navigated instrument. The instruction for use of the navigation system describes 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.

The patient registration cannot be carried out by the PointerShell 3mm, 4mm, 5mm and Universal. Use an instrument that is recommended by Fiagon GmbH.

Contraindications

CAUTION: The PointerShell should not be used if the following contraindications exist:

The instrument should not be re-processed and reused after it has been used on patients with suspected Creutzfeldt-Jakob disease. In case, there is a risk of disease transmission, dispose the instrument after the operation.

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 misleading navigation information.

Furthermore, the contraindications of the instrument to be navigated must be taken into consideration as well.

3. Compatible devices

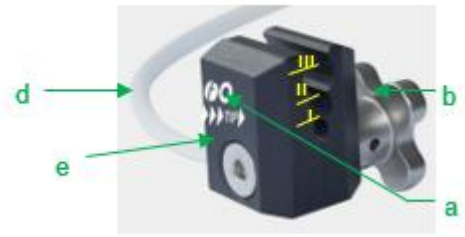
The PointerShell can be operated on instruments that are suitable and approved for surgeries mentioned above and that meet the requirements stated in the specifications.

The instrument can only be used as a navigation instrument in connection with the navigation systems of Fiagon GmbH.

Device Description

E 01 2900/ E 01 2901/ E 01 2902 - PointerShell 4 mm/ 5 mm/ 3 mm

E 01 2904 – PointerShell Universal



Position I: for instruments with a shaft diameter 2,5 - 3,3 mm

Position II: for instruments with a shaft diameter 3,4 - 4,3 mm

Position III: for instruments with a shaft diameter 4,4 - 5,0 mm

Description:
a Calibration pit (K) **b** Locking screw/screw for fixation **c** Identification of the inner diameter of the PointerShell **d** Cable for connection with the navigation system **e** Identification of the direction for the surgical instrument

4. Preparation for the navigation

After taking the PointerShell out of the sterile packaging, place it on the instrument table.

NOTE: The PointerShell 3mm,4mm,5mm and Universal cannot be used for the patient registration. Before using the instrument, the patient registration has to be done according to the description of the application. Consult the instructions for use of the resp. navigation application.

Mounting

Prior to use, the PointerShell must be locked to the instrument that shall be navigated:

- Select the PointerShell (Diameter type) that fits to the shaft of the instrument that shall be equipped.
- Before the PointerShell is attached to an instrument, it must be ensured that the surface is clean and dry.
- Before each use, check if the thread can move freely.
- Push the PointerShell onto the instrument with the CE marking facing forward.
- Insert the tip of the instrument from the direction with the CE marking which is present on one end of the PointerShell (applicable for PointerShell 3 mm, 4 mm, 5 mm). For PointerShell Universal, the mounting direction is provided.
- Lock the PointerShell to the instrument with the locking screw. The screw must be tightened firmly.

CAUTION: Check for the secure fixation of the PointerShell before every use.

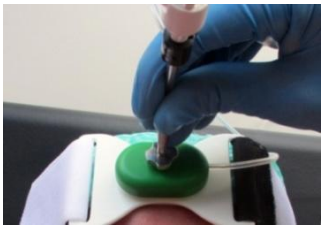
CAUTION: The PointerShell mounted on an instrument shaft reduces the applicable length of the instrument by approximately 15 mm and therefore the range of the instrument may be limited compared to use without a PointerShell. The PointerShell at the proximal end of the instrument shaft can injure the patient's nasal entrance if the instrument is inserted deep (e.g., sphenoid bone). Please make sure that you do not insert the instrument so far that the proximally attached PointerShell is in contact with the nasal entrance.

Calibrating

After mounting PointerShell, insert the connector of the attachment into the appropriate socket on the navigation unit. Note that the white marking at the plug aligns with the marking at the socket.

Once the PointerShell is connected, you will hear a confirmation tone and the status display of the instrument is displayed in color. The message "Check tool" is displayed on the progress bar.

Place the tip of the instrument onto the calibration pit of the patient localizer. Keep the instrument, including the PointerShell, in one position until the progress bar is displayed and completed. If the calibration of the PointerShell was successful, you will hear a confirmation tone.



The PointerShell is now calibrated to navigate the instrument. The navigated point is the point that has touched the calibration tip.

Check the displayed position of the instrument on several anatomical structures. If the deviation is significant, the registration of the PointerShell must be rejected and repeated.

If a registration failed, you can reject it and repeat the process anytime by touching the calibration pit of the patient localizer.

Before a new instrument is navigated by means of the PointerShell, a new calibration is necessary. Start with the new calibration only after the PointerShell has been locked in place on the new instrument.

CAUTION: Do not start an operation before the calibration has been checked.

NOTE: If the PointerShell does not register at the navigation system, it cannot be used for the navigation**.**

5. Use of the navigation functionality

After connecting the PointerShell to the system, the position of the navigation point of the PointerShell is displayed on the navigation screen (if the patient registration has been performed before).

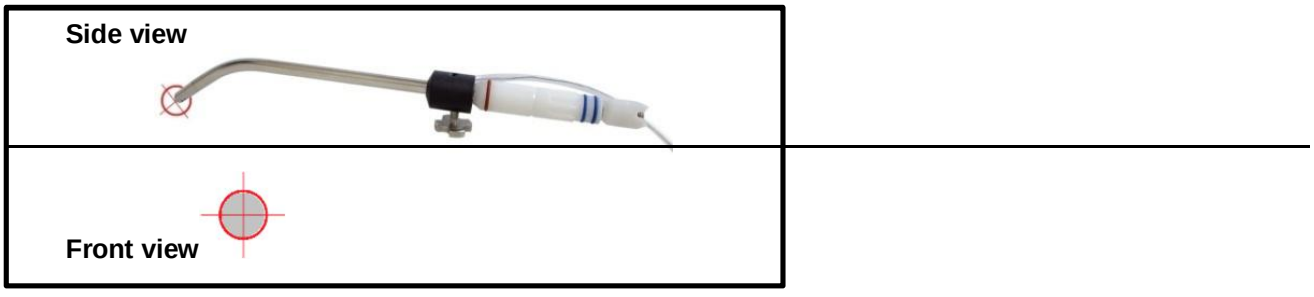
CAUTION: Do not start using the navigation information of the instrument before you have checked and verified it. Therefore, check the displayed position of the instrument on several anatomical structures after connecting the instrument. If the deviation is significant, do not use the instrument.

CAUTION: Make sure that the tip of the instrument is accurately held in place on the calibration pit of the second PointerShell or of the patient localizer.

CAUTION: If the PointerShell slips or turns during the use on the navigated instrument, the PointerShell must be newly calibrated immediately.

NOTE: Note that the PointerShell navigated instrument cannot be used for the patient registration.

The figures below show the position of the navigation point on the tip of a shaver.



CAUTION: To avoid problems with the interpretation of the navigation display, pay attention to the position of the calibrated navigation point. The displayed navigation point corresponds to the part (tip) of the instrument that was held onto the calibration pit during calibration.

6. 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 in these instructions for use.

CAUTION: The instrument should not be re-processed and reused after it has been used with patients with suspected Creutzfeldt-Jakob disease. In case there is a risk of disease transmission, dispose the instrument after the operation.

7. Specifications

REF	PointerShell 4 mm E 01 2900	PointerShell 5 mm E 01 2901	PointerShell 3 mm E 01 2902	PointerShell Universal E 01 2904
To be used with	· For rigid cylindrical instruments, e.g. Bien Air Shaver, Storz or Gyrus/ Olympus shaver blades with a shaft diameter from 3,5 to 4 mm and a bending angle from 0° to 40° · For instruments without motor that have an appropriate geometry	· For rigid cylindrical instruments, e.g. Medtronic Shaver with a shaft diameter from 4.7 to 5 mm and a bending angle from 0° to 40° · For instruments without motor that have an appropriate geometry	· For rigid cylindrical instruments, e.g. Bien Air Shaver with a shaft diameter from 2.5 to 3.4 mm and a bending angle from 0° to 40° · For instruments without motor that have an appropriate geometry	· For rigid cylindrical instruments with a shaft diameter from 2.5 to 5 mm · For instruments without motor that have an appropriate geometry
Note	Patient registration cannot be carried out in connection with the PointerShell.			
Applicable length	The PointerShell mounted on an instrument shaft reduces the applicable length of the instrument by approximately 15 mm. See also Chapter 4.			
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° 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!

8. Reprocessing

Reprocessing instructions for reusable medical devices

General information about the products 	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. **The instruments can be reprocessed and used 10 times. (see below for details)**
Warnings 	Not qualified methods for cleaning and sterilization 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 sterilizer's manufacturer as well as the chemicals used.
Restrictions on Reprocessing	**Sort out instruments that have been reprocessed 10 times.** These instructions for use come with a track chart (count sheet) to keep record of the numbers of reprocessing cycles of an instrument. Each instrument has an individual serial number, which is labeled on the handle or the shaft.

Instructions:	
Site of use:	Remove surface soiling with a non-shedding disposable towel/paper towel. Do not allow saline, blood, body fluids, bone fragments or other organic debris to dry on instruments.
Storage and transport	Immediately after use on a patient, immerse the instrument in a cleaning agent/disinfectant (alkaline, free of aldehydes). Immersion of the instrument prevents residues from drying (protein fixation). It is recommended to reprocess the instrument within 1h of use.
Preparation for reprocessing	**The instruments are reprocessed as a complete unit with cable and connector.** **Cable or connector must not be removed.**
Sorting out after 10 reprocessing cycles	**Sort out instruments that have been reprocessed 10 times.** To do so, these instructions for use come with a track chart (count sheet) to keep record of the numbers of reprocessing cycles of an instrument. Each instrument has an individual serial number, which is labeled on the handle or the shaft. When processing an instrument for the first time (brand-new), note the serial number on the first column of the track chart and check the tick box for the first reprocessing cycle. When reprocessing the same instrument the next time, check the next tick box. When receiving an instrument for reprocessing that has a fully checked track chart, it has been reprocessed 10 times. Do not reprocess the instrument. Sort out the instrument and dispose it. (see section "Disposal" for details) Hint: You can use one track chart for ten instruments.

Cleaning	**"PointerShell"**
	Equipment: · Brush · Washer/Disinfector equipped with instrument baskets Washer type with following cycle: 5 minutes, 131°F (55°C), Injection rate, 0.64 fl.oz/gal (5 ml/l) of alkaline agent Deionized Water supply Recommendation: AMSCO® 3052 Single-Chamber Washer/Disinfector (Steris, Inc.) · Cleaning agent: Neodisher® Mediclean forte · Deionized Water · Tap water, potable water Method: 1. Rinse each instrument thoroughly under warm (approximately 91°F/ 33°C) running tap water until there is no debris or discolored fluid noticeable 2. Dilute the concentrated cleaning agent with tap water at 30 ml/l and maintain at room temperature. 3. Apply the cleaning solution (at 20-25°C) manually with a brush. 4. Rinse the instrument under hot running tap water until all residues of the cleaning agent and visible surface soiling are removed. 5. Place instruments into instrument baskets. Take care that the instruments are separated. 6. Choose the instrument cycle in the washer. Validated: Wash: 5 minutes, 131°F (55°C), deionized water, I injection rate, 0.64 fl.oz/gal (5 ml/l) of alkaline agent (Prewash can be done additionally before the wash cycle) 7. Thermal Rinse at 194°F (90°C) for 3 minutes, deionized water
Drying	Instruments can be dried until no visible moisture is present using a clean, soft cloth for the outside of the instrument and the cable
Cleaning inspection	Inspect the instrument for visible soil or debris. Repeat the cleaning steps in case residual soil or debris was found.
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 10-cycles life time 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 lifetime. 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 automated cleaning step before returning them.
Disposal	Used instruments must be disposed as hazardous waste. Take steps to avoid risk of injury and infection. Protect against unauthorized access.
Packaging	Double pack each instrument in see-through peel pouches. 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 Bioindicator: MesaStrip Steam biological indicator (SGM Biotech, Inc.) Steriking is registered as a 510K device (K953776) with the FDA Mesastrip is registered with the FDA
Sterilization	Method: Prevacuum steam sterilizer Sterilization parameters: Min. temperature 270°F (132°C) Full cycle time: 4 minutes Min drying time 20 minutes Recommended validated Type: Middle-sized hospital sterilizer compliant to AAMI ST8 Size: 9 STE (sterilization units) Validated load mix: 2 container of instruments and 2 packages of linen
Storage	Make sure that the package is intact prior to storing. Store the instrument protected from dust, moisture and recontamination. The integrity of the sterile barrier needs to be protected

Track chart (for 10 instruments)

Keep record of the number of reprocessing cycles.

Sort out instruments that have been reprocessed 10 times.

Use this track chart (count sheet) to keep record of the numbers of reprocessing cycles of an instrument. Each instrument has an individual serial number, which is labeled on the handle or the shaft.

When processing an instrument for the first time (brand-new), note the serial number on the first column of the track chart and check the tick box for the first reprocessing cycle.

When reprocessing the same instrument the next time, check the next tick box.

When receiving an instrument for reprocessing that has a fully checked track chart, it has been reprocessed 10 times. Do not reprocess the instrument.

Sort out the instrument and dispose it. (see section “Disposal” in the reprocessing instructions for details)

Hint: You can use one track chart for ten instruments.

Instrument SN no. Note here	Counter Tick a box for each time the instrument with the SN number noted on the left is entering reprocessing									
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked
	1	2	3	4	5	6	7	8	9	10	Dispose the instrument when all boxes of the line are ticked