INSTRUCTIONS FOR USE
RoboFIX®

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1412-240368-02

Issued copies of this document are not subject to revision. We reserve the right to make modifications to the devices for the purpose of technical progress or product improvements without prior notification.

1 Introduction

Please read this instructions for use to learn about the correct use of the RoboFIX® before using it for the first time.

Keep the instructions for use close to the site of operation and ensure that the user can access it at all times.

	Never use the RoboFIX® in the OR without having been instructed by an authorised person in its safe use.
	Observe not only these instructions for use, but also the instructions for use of the joimax® endoscope used.

1.1 Purpose of the document

This document tells you how to handle the RoboFIX®. In conjunction with the instructions by our trained specialists, it allows you to safely handle the RoboFIX®.

This document has been created for anyone put in charge with the setup, operation and cleaning of the device.

1.2 Notes on this document

Notes to avoid damage to property:

	This symbol is found in front of notes to assist the user, to facilitate the use of the device or to prevent faults.

Safety information to avoid risk of injury:

	This symbol indicates safety information. Non-compliance with the corresponding information may lead to damage or even injuries for the patients and / or the user.

Words written in CAPITAL LETTERS indicate parts or accessories of the system as well as important terms regarding their use.

1.3 Important notes on the safe handling (summary)

The incorrect operation or non-compliance with precautionary measures may cause serious incidents, injuries of patients or damage to persons or material.

Therefore, use this instruction manual to fully inform yourself about the correct operation and handling of the RoboFIX®.

	Make sure that the rail of the operating table is secured and locked before using the device.
	Always hold the ADAPTER HOLDER firmly before unlocking it by pressing the UNLOCK BUTTON.

	The device is not intended for the operation in explosive areas. Ensure a sufficient distance to highly flammable gases (e.g. O2, anaesthetic gases).
	Never open the RoboFIX® or the POWER SUPPLY. Risk of an electric shock!
	All serious incidents related to the product must be reported to the manufacturer and the competent authority in the country concerned.
	Do not use a STERILE COVER if you can detect damage to the packaging or the STERILE COVER itself!
	Do not use a STERILE COVER whose expiry date has expired!
	Keep the CONTROL at least 15 cm (6 inches) away from magnetically susceptible medical devices such as pacemakers, cochlear implants or neurostimulators.
	Check the configuration for any possible collision with parts of the operating table before using the device. The maximum transverse tilt depends on the respective operating table.
	The quick clamping for the docking to the operating table is designed for a maximum Trendelenburg position of 30°. Never exceed that range.
	Avoid tripping hazards when connecting the cables.
	Operate the RoboFIX® only when it has reached room temperature again after a previous storage at high or low temperatures.
	Pull the power plug of the POWER SUPPLY in order to completely disconnect this device from the mains. Make sure that the POWER SUPPLY can be accessed at any time.
	Disconnect the POWER SUPPLY from the mains for at least 5 seconds to rectify a fault in the POWER SUPPLY.
	Modifications to the device are not permitted.
	All components to be used in sterile condition are delivered in unsterile condition. The only exception is the disposable STERILE COVER. Before using the sterilisable components for the first time, it is essential that they are completely prepared in accordance with the document "Processing instructions RoboFIX® - EN 1412-240370"!
	With the exception of the CONTROL, the RoboFIX® and the POWER SUPPLY are not suitable for machine / automated cleaning or disinfection procedures!

	Never place the CONTROL in a disinfection bath together with contaminated surgical instruments.
	After use, do not store the CONTROL in the same container with contaminated surgical instruments.

1.4 Modifications

Subject to technical modifications!

Both the device and the instructions for use are developed and improved on a continuous basis. Some illustrations may therefore slightly differ from the actual delivery condition.

These instructions for use have been prepared with the utmost care. We are not liable for mistakes and printing errors!

Your improvement suggestions in regard to our products or these instructions for use are always welcome. Please contact the address provided in this instructions for use or your competent sales partner.

1.5 General product description

The RoboFIX® emulates an arm which is capable of guiding and positioning an endoscopic camera with several degrees of movement. Only endoscopes from joimax® can be used.

An integrated DEACTIVATION PUSHBUTTON permits manual movement of the RoboFIX® at the push of a button.

The system presents a large scope of movement in order to provide the user with ample access to the situs.

In order to reposition a guided endoscopic camera, the RoboFIX® is unlocked by a sterilisable CONTROL at the push of a button.

Despite its large scope of movement, the RoboFIX® is light-weight and compact and is fastened directly to the OP table by means of a quick-acting clamp. Thus, repositioning with reference to the patient is not necessary even if the OP table is moved in the meantime.

Constant availability and a large degree of re-usability were key issues during development of the RoboFIX®. This is why only a STERILE COVER is required for safe use.

Sterilisation in fractionated vacuum at 134° requires the material in question to be extremely robust. Thus, all components being conditioned have a limited service life, despite selected materials being used. You can find more information on this in the document "Processing instructions RoboFIX® - EN 1412-240370".

1.6 Intended use / Notes on product liability

Essential Performance:

Stable fixation of of a joimax® endoscope

The system holds an endoscope in a fixed position, which was adjusted by the user. This will also be assured when power is lost.

Environment:

Operating room. The RoboFIX® must be firmly attached to the operating table during use. It is not permitted to "place it on" or on an equipment cart, side table, or similar.

During HF Surgery, the RoboFIX® is only compatible with following HF SURGICAL EQUIPMENT:

- Power Cut mode capability of 300 W
- Coagulation mode capability of 120 W

The RoboFIX® can not be used for argon plasma coagulation mode.

	The device is not intended for the operation in explosive areas. Ensure a sufficient distance to highly flammable gases (e.g. O2, anaesthetic gases).

User Group:

A mandatory requirement for the use of the RoboFIX® is the proper assembly and handling of the device, as well as compliance with these instructions for use and the instructions for use of the joimax® endoscope used.

The RoboFIX® is used primarily by the surgeon performing the operation. He must have sufficient experience in the use of minimally invasive operating techniques and received instructions in the handling of the RoboFIX®. The device may be operated exclusively by instructed personnel. The instruction is to be documented.

Application:

Holding and guiding the endoscopic camera for minimally invasive intervention in spine surgery.

Only suitable endoscopes from joimax® can be used.

The suitable combinations of endoscope and camera head are determined jointly by the companies AKTORmed and joimax®.

Contraindications:

The RoboFIX® must not be used outside of the fields of application detailed above. The RoboFIX® may only be used to hold and move a joimax® endoscope.

The contraindications of the endoscopes used also apply to the use of the RoboFIX®.

The manufacturer will only consider himself liable for the safety-related characteristics, reliability and performance if

- the user has been fully instructed in the proper use of the device.
- the readjustments, modifications or repairs are performed exclusively by the manufacturer or an institution expressly authorised by the manufacturer.
- the device is used under the specified environmental conditions in rooms used for medical purposes in which the electrical installation meets the requirements of the VDE 0100-710 or IEC 60364-7-10 standard.
- the device is used entirely in accordance with this instruction manual.

Clinical Benefit:

The RoboFIX® has no direct clinical benefit for the patient. The RoboFIX® offers the user the following clinical benefits:

- Stable and steady image of the endoscope during the surgical procedure
- Allows the surgeon to work with both hands
- No more ergonomically unfavourable static holding of the endoscope required

Warranty:

The manufacturer issues a 12 month warranty on the performance of the product. The period of validity of this warranty is limited to claims that have been immediately asserted in writing within the named period after the invoice date - if applicable, with a reference to repairs stating the invoice number. Legal warranty claims are not restricted by this warranty.

If you did not purchase the product directly from the manufacturer, please contact your sales partner for the processing of the warranty.

This warranty covers only defects that have not been caused by normal wear, misuse, improper handling, external influences, deficient or incorrect preparations, or force majeure.

All warranty claims will be lost if the user itself or a non-authorized repair shop has carried out repairs or modifications on the product.

Liability claims arising from the improper use or from a combination with other devices or accessories can not be asserted.

	All serious incidents related to the product must be reported to the manufacturer and the competent authority in the country concerned.

1.7 Receiving inspection

Please check the RoboFIX® and the enclosed accessories immediately upon receipt for possible transport damage and defects.

Claims for damages can be asserted only if the seller or the freight forwarder is immediately informed. A damage report has to be prepared immediately. The damage report must be submitted directly to the manufacturer or the representative of the manufacturer so that the claims for damages can be reported to the insurance company.

When a device is returned to the manufacturer, use, if possible, the original packaging. The following accompanying documents are to be enclosed: Name and address of the owner, ID and serial number (see name plate) as well as a description of the defect.

1.8 Initial operation

The operator may operate the RoboFIX® only after the manufacturer or the supplier:

- has performed a functional test of the devices at the place of operation and
- has instructed the persons responsible for the operation in the proper handling of the RoboFIX® based on this instruction manual.

	All components to be used in sterile condition are delivered in unsterile condition. The only exception is the disposable STERILE COVER. Before using the sterilisable components for the first time, it is essential that they are completely prepared in accordance with the document "Processing instructions RoboFIX® - EN 1412-240370"!
	Operate the RoboFIX® only when it has reached room temperature again after a previous storage at high or low temperatures.

2 System Description

2.1 Overview

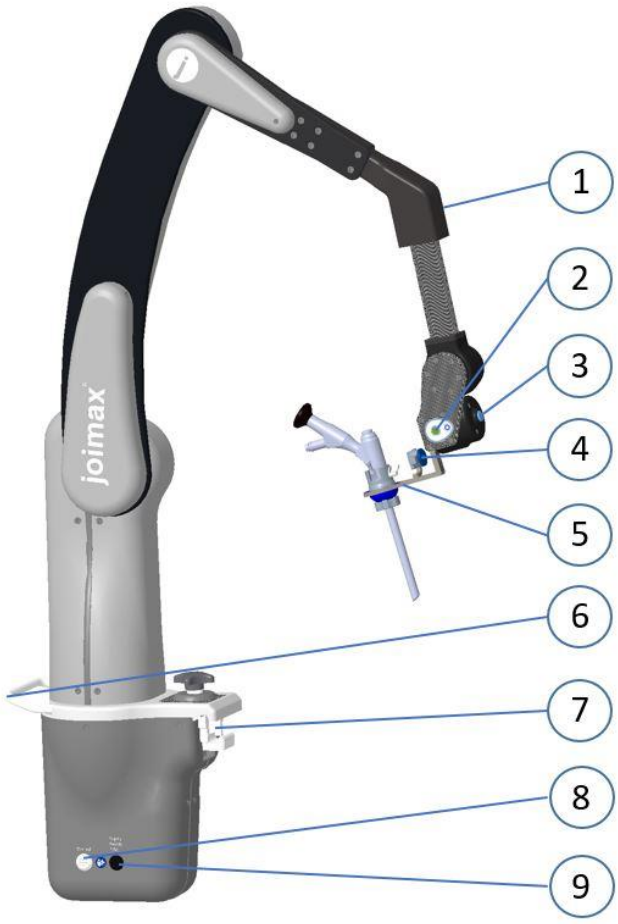


fig. 1: System overview

Number	Description
1	Arm
2	DEACTIVATION PUSHBUTTON
3	UNLOCK BUTTON for the ADAPTER HOLDER
4	CONTROL
5	ADAPTER HOLDER for the joimax® adapter system
6	Handle
7	Quick-fastener for fastening to the operating table
8	**Control:** CONTROL connection
9	**Supply:** Power supply connection

Table 1: System overview

2.2 System components

Component	Picture	Description
RoboFIX® (multiple patient multiple use)		The RoboFIX® is the support for the endoscope and is fastened to the OP table by means of a quick coupling.
POWER SUPPLY (multiple patient multiple use)		The POWER SUPPLY supplies the RoboFIX® with the required operating voltage and has been designed for a wide range of input voltages. Only use the original POWER SUPPLY.
POWER CORD (multiple patient multiple use)		The POWER CORD supplies the POWER SUPPLY with AC current. Use exclusively the POWER CORD supplied with the equipment or country specific POWER CORDS.
SUPPLY CABLE (multiple patient multiple use)		The SUPPLY CABLE is used to establish the electrical connection between the RoboFIX® and the POWER SUPPLY. The SUPPLY CABLE is 3.5 m long.
ADAPTER HOLDER (multiple patient multiple use)		The ADAPTER HOLDER engages automatically in the quick-release fastener of the RoboFIX®. The ADAPTER HOLDER is an accessory for joimax® endoscopes. Please contact us if you have any questions about the endoscopes and their accessories: joimax® GmbH Amalienbadstrasse 41, RaumFabrik 61 76227 Karlsruhe, Germany +49 721 255 14 0 www.joimax.com

Component	Picture	Description
CONTROL (multiple patient multiple use)		The CONTROL is used to unlock the arms of the RoboFIX® at the push of a button. The CONTROL is autoclavable and has a lifetime of up to 150 cycles.
STERILISATION TRAY (multiple patient multiple use)		The STERILISATION TRAY with holder for the CONTROL is intended for machine cleaning. The STERILISATION TRAY is equipped with a rinsing tube and Luer-Lock connection for the cleaning and disinfectant solution.
STERILE COVER (single use)		Permits one-time sterile covering of the RoboFIX®. The STERILE COVER is sterilised with ethylene oxide and supplied sterile.

Table 2: System components

Overview accessories and spare parts:

For orders, please contact the manufacturer or your sales partner directly.

Only use original accessories. The use of accessories not approved by the manufacturer can lead to a patient hazard or damage to the device.

Article number	Article name	Description
242791	RoboFIX®	RoboFIX® Support Arm
172035	POWER SUPPLY	POWER SUPPLY
182205	POWER CORD	POWER CORD
172054	SUPPLY CABLE	SUPPLY CABLE
171906	CONTROL	CONTROL
242794	STERILISATION TRAY	STERILISATION TRAY for the CONTROL
110084	STERILE COVER PU/ 50 ea.	STERILE COVER for RoboFIX®, PU with 50 pieces REF 6001-40001
1412-240368	Manual RoboFIX® – EN	-
1412-240370	Processing instructions RoboFIX® - EN	-

Table 3: Article numbers

2.3 Mechanical data

Weight	12 kg
Dimensions (W x H x D)	165 x 1059 x 313 mm
Safe working load	1,1 kg

Connection to the operating table Quick-fastener, suitable for European and US standard rails

Range of motion:

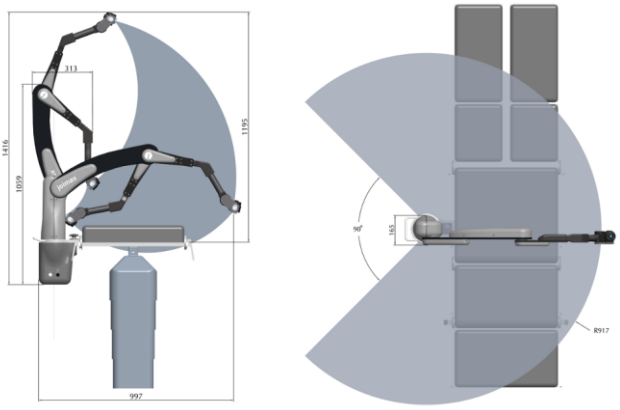


fig. 2: Range of motion

	Positions outside of the illustrated range of movement cannot be reached. To avoid this, position the arm as centrally as possible within the OP field.

The RoboFIX® is equipped with a counterbalance to compensate for the weight of the endoscope and camera head. When using joimax® endoscopes, the ideal distance from the vertical axis of the RoboFIX® to the endoscope has been found to be around 60 to 75 cm (600 to 750 mm). Take this into account when positioning the RoboFIX® on the operating table (see chapter 3.1).

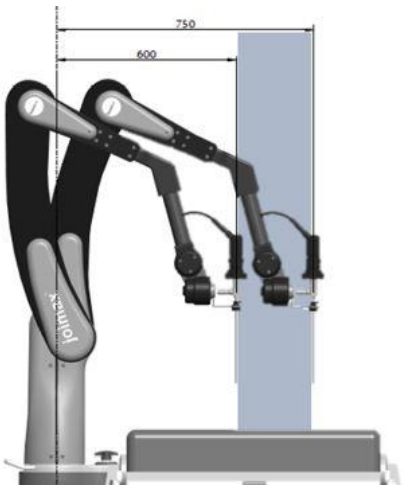


fig. 3: Positioning for ideal weight compensation

2.4 Electrical data

POWER SUPPLY	Type BET-0624M, Bicker Elektronik GmbH
Input voltage	100 - 240V~; 50-60Hz
Max. power input	60W
Output voltage	24 V DC
Protection class	II
Operating mode	continuous
Mains fuses	none

	Pull the power plug of the POWER SUPPLY in order to completely disconnect this device from the mains. Make sure that the POWER SUPPLY can be accessed at any time.
	Disconnect the POWER SUPPLY from the mains for at least 5 seconds to rectify a fault in the POWER SUPPLY.

2.5 Important performance characteristics

Essential performance features of the RoboFIX® are:

- The system hold an endoscope in a fixed position, which was adjusted by the user. This must also be assured when power is lost.
- The system allows the user to reposition the endoscope at the push of a button. In case of power failure or other failures, this function may not be available.

2.6 Environmental conditions

for transport and storage

Temperature	-20°C to +70°C
Relative air humidity	10% to 90%, non-condensing
Air pressure	700 hPa to 1060 hPa

for the operation

Temperature	+15°C to +37°C
Relative air humidity	10% to 85%, non-condensing
Air pressure	700 hPa to 1060 hPa

2.7 Storage and transport

The RoboFIX® should always be transported in suitable packaging. Any position is possible during transportation.

	Operate the RoboFIX® only when it has reached room temperature again after a previous storage at high or low temperatures.

2.8 Symbols used on the name plates / labels

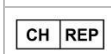
Symbol	Description
	Observe the instructions for use
	Follow the instructions for use
Control	Connection for the CONTROL
Supply	Power supply
Type	Construction type
	Device conforms to the regulation EU MDR - 2017/745 (Medical Device Regulation)
	Date of manufacture
	Manufacturer
	Distributor
	Model number
	Serial number
	Reference number
Rx only	Sale only on instruction of a physician (US federal law)
	Authorised representative in Switzerland
	Medical Device
	Dispose products marked with this symbol separately with electric and electronic devices. The disposal is carried out by the manufacturer within the EU for free.

Table 4: Symbols on nameplate and label

2.9 Name plate

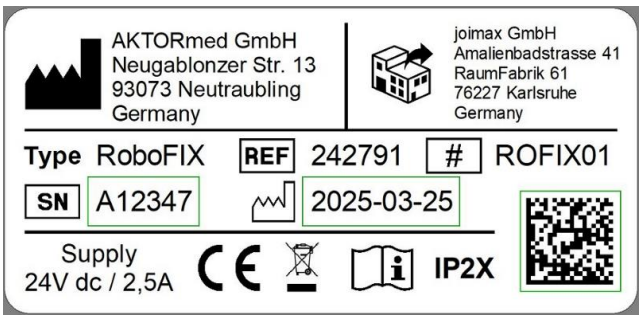


fig. 4: Name plate

2.10 Identification according to MDR (Medical Device Regulation)

The RoboFIX® including accessories is a class I medical product. Sterile disposables are class Is medical devices.

2.11 Symbols on STERILE COVER

Symbol	Description
	Reference number
	Lot number
	Can be used until
	Sterilised with ethylene oxide
	Authorised representative in the European Community
	Authorised representative in Switzerland
	Do not use if packaging is damaged
	Do not re-sterilise
	Do not reuse
	Free of latex
	Manufacturer

Table 5: Symbols on STERILE COVER

2.12 Contact

If you have any further questions in connection with the product, please contact:

joimax® GmbH
Amalienbadstrasse 41, RaumFabrik 61
76227 Karlsruhe, Germany

Web: www.joimax.com
Phone: +49 721 255 14 0

3 Setup / Commissioning

3.1 RoboFIX®

Follow the following work steps to mount the RoboFIX® to the operating table and to put it into operation for the following application. This is usually done **before** the patient is washed and covered with sterile drapes.

Step 1: Mount it to the operating table

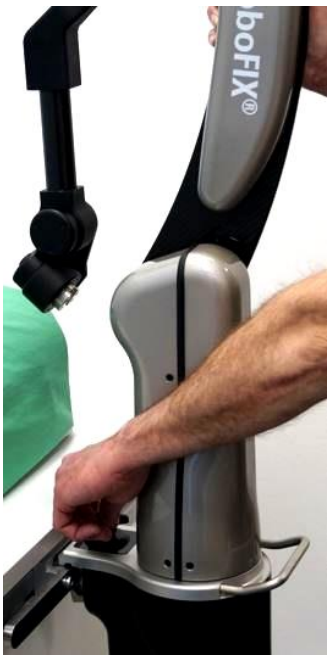
Step	Description
	The device is lifted to the standard rail and mounted.
	Once the device is placed on the standard rail of the operating table, align it perpendicular to the operating table and tighten the clamp screw by hand.

Table 6: Mounting on operating table

	To make the best possible use of the RoboFIX®'s range of motion, we recommend checking the accessibility of the operating field after installation. The position on the operating table can now still be corrected.
	Make sure that the RoboFIX® is firmly locked on the rail of the operating table before using the device.

Step 2: Establish the electrical connection

Connect the POWER CORD to the POWER SUPPLY and then plug the POWER CORD into a suitable wall outlet. Connect the SUPPLY CABLE to the POWER SUPPLY and then connect the SUPPLY CABLE to the input jack of the RoboFIX®.

	Pull the power plug of the POWER SUPPLY in order to completely disconnect this device from the mains. Make sure that the POWER SUPPLY can be accessed at any time.
	Disconnect the POWER SUPPLY from the mains for at least 5 seconds to rectify a fault in the POWER SUPPLY.
	Use only the original POWER SUPPLY, POWER CORD and SUPPLY CABLE.
	Avoid tripping hazards when connecting the cables.

The RoboFIX® is ready to operate once the green LED on the DEACTIVATION PUSHBUTTON is lit. Now you can move the arms by pressing the DEACTIVATION PUSHBUTTON into a position in which the RoboFIX® can be covered easily with the STERILE COVER.

fig. 5: Operational readiness

Step 3: Prepare STERILE COVER

⚠	Do not use a STERILE COVER if you can detect damage to the packaging or the STERILE COVER itself!
⚠	Do not use a STERILE COVER whose expiry date has expired!

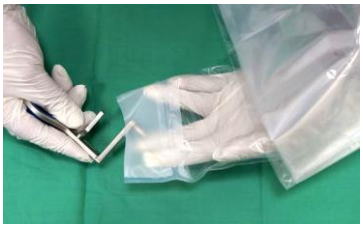
Step	Description
	Take a STERILE COVER from the packaging and keep it ready.
	Open the folded STERILE COVER centrally (adhesive mark with green arrow).
	Put one hand into the STERILE COVER. Insert the plug of the ADAPTER HOLDER through the opening in the elastic part of the STERILE COVER.
	Pull the ADAPTER HOLDER with the elastic part through the STERILE COVER.
	Pull the elastic front end of the STERILE COVER until it is centred on the bar of the ADAPTER HOLDER.

Table 7: Prepare STERILE COVER

Step 4: Engage the ADAPTER HOLDER and cover the RoboFIX® with the STERILE COVER

Step	Description
	Move the ADAPTER HOLDER with STERILE COVER to the arm from below.
	Insert the plug of the ADAPTER HOLDER into the quick-release fastener of the extension arm until the ADAPTER HOLDER audibly engages. Check the correct engagement by pulling the ADAPTER HOLDER.
	Slip the STERILE COVER over the end of the extension arm.
	Pull the STERILE COVER over the extension arms.
	Pull the STERILE COVER down to the base plate.
	Continue with the sterile draping of the patient at this point.

Table 8: Obtain RoboFIX® sterile

	Use only the original STERILE COVER – REF 6001-40001 - which you have bought from the manufacturer or an authorised partner.

Step 5: Apply patient cover

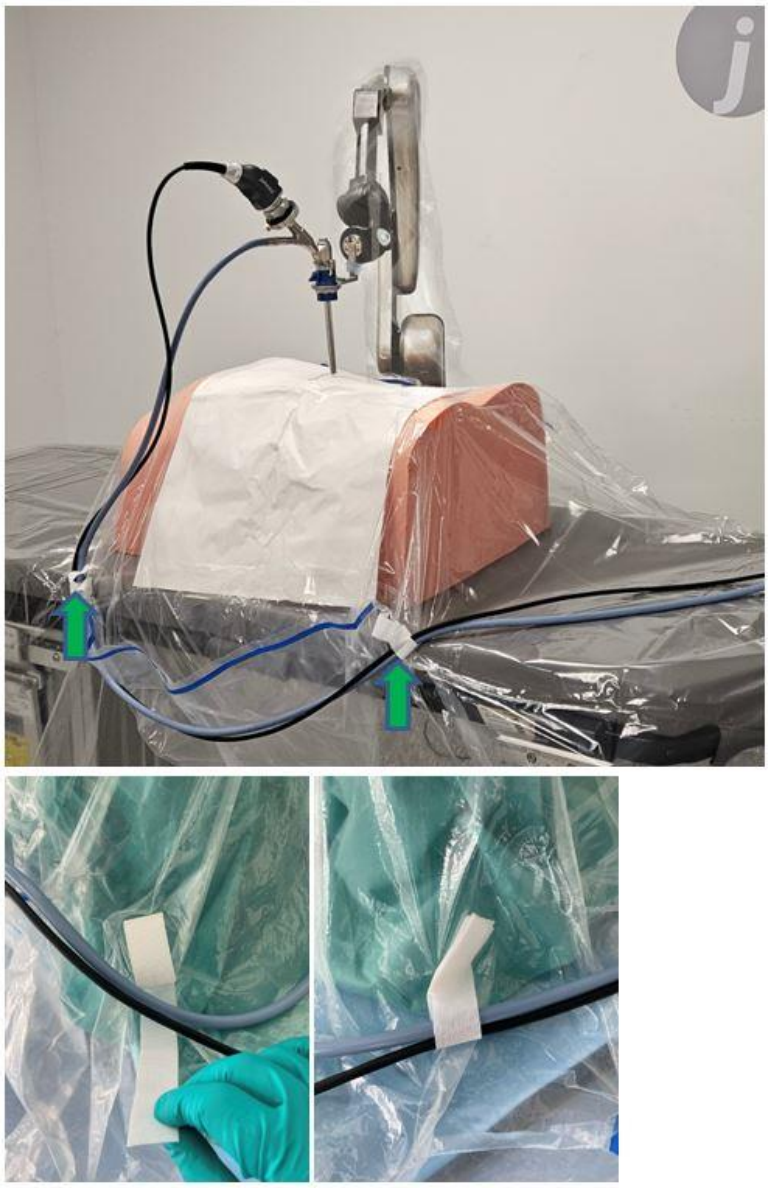


fig. 6: Apply patient cover and fix cables

Disinfect the skin and cover the patient with a sterile drape.

The patient cover REF JMHID3224 (patient in prone position) and the patient cover REF JMVID3224 (patient in lateral position) from joimax® are available for this purpose.

Attach the cold light guide and the camera head cable to the patient cover later using the Velcro fasteners after you have attached the endoscope to the RoboFIX® (see chapter 3.3).

Fixing the cables not only ensures a tidy operating theatre environment, but also provides the necessary strain relief for the endoscope.

3.2 Mounting the CONTROL to the ADAPTER HOLDER

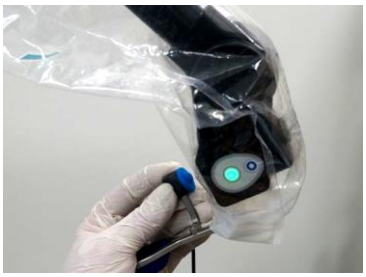
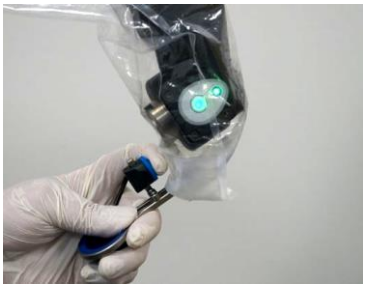
Step	Description
	Slip the CONTROL over the bracket of the ADAPTER HOLDER. You can initially attach the CONTROL to the bracket as shown, but you can also change the orientation of the blue pushbutton panel later.
	Connect the CONTROL to the connector „CONTROL“ on the RoboFIX®.
	The status LED next to the DEACTIVATION PUSHBUTTON indicates that the CONTROL is ready to operate.
	The arm can be moved by pressing the CONTROL.

Table 9: Mounting the CONTROL to the ADAPTER HOLDER

⚠	Keep the CONTROL at least 15 cm (6 inches) away from magnetically susceptible medical devices such as pacemakers, cochlear implants or neurostimulators.

3.3 Mounting the endoscope to the ADAPTER HOLDER

Proceed as described in the corresponding instructions for use of the joimax® endoscope.

Then attach the cold light guide and the camera head cable to the patient cover (see image in chapter 3.1, step 5).

4 Operation

The RoboFIX® is operated by unlocking all 6 axes and subsequent manual positioning using the CONTROL.

Step	Description
	Press the button on the CONTROL with the index finger of your left hand to unlock the RoboFIX® and set a new position for the endoscope.
	As soon as you release the button on the CONTROL, all 6 axes are locked again. You can now release the endoscope.

Table 10: Operating the RoboFIX® with the CONTROL

4.1 DEACTIVATION PUSHBUTTON and status displays

The RoboFIX® features a lit DEACTIVATION PUSHBUTTON which can be used to vary the position before and after surgery even without the CONTROL.

Picture	Description
	DEACTIVATION PUSHBUTTON to move the arms. The flush green LED is lit when the RoboFIX® is supplied with electrical power.
	Status display for the CONTROL. The LED (also green) displays the CONTROL's readiness for operation. The CONTROL is operative if it is connected to the RoboFIX® and has been secured to the bracket of the ADAPTER HOLDER.

Table 11: DEACTIVATION PUSHBUTTON and status displays

4.2 Weight compensation

The RoboFIX® is equipped with a counterbalance to compensate for the weight of the endoscope and camera head. When using joimax® endoscopes, the ideal distance from the vertical axis of the RoboFIX® to the endoscope has been found to be around 60 to 75 cm (600 to 750 mm). Take this into account when positioning the RoboFIX® on the operating table (see chapter 3.1).

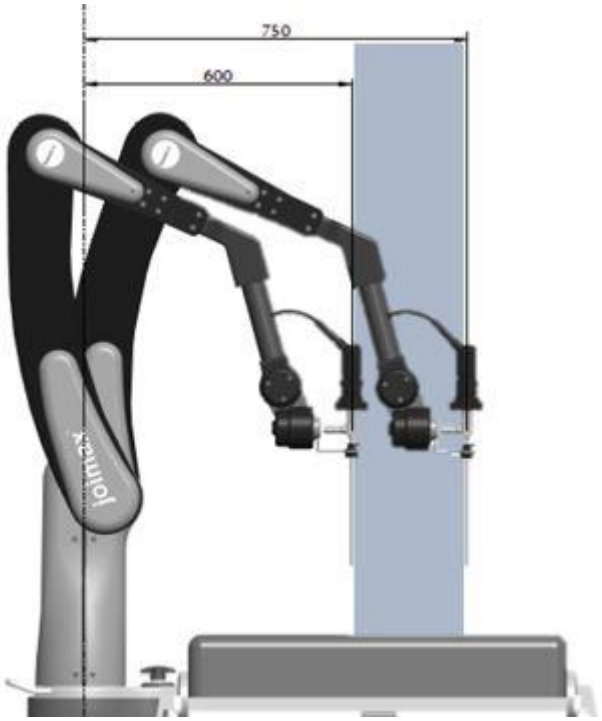
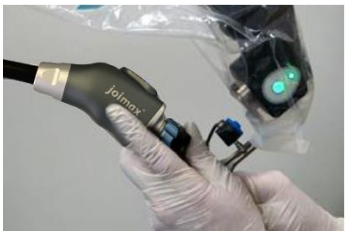


fig. 7: Ideal distance between endoscope and RoboFIX®

4.3 Cleaning the endoscope (optical system)

Operate the CONTROL and carefully move the endoscope out of the body orifice to clean the optics.
After cleaning, carefully reposition the endoscope in the situs.

4.4 Ending the application

Step	Description
	Remove the endoscope used from the ADAPTER HOLDER. Proceed as described in the instructions for use of the endoscope.

Step	Description
	Remove the CONTROL and press the blue UNLOCK BUTTON of the quick coupling in order to remove the ADAPTER HOLDER.
	Dispose of the used STERILE COVER of the RoboFIX®. Place the RoboFIX® in an upright position for subsequent storage.
	Disconnect all cable connections and remove the POWER SUPPLY from the mains.
	Place the protective cap onto the plug of the CONTROL.
	Place the CONTROL on the rinsing tube of the STERILISATION TRAY.

Step	Description
	Loosen the clamping screw and remove the RoboFIX® from the operating table.

Table 12: After use

4.5 Wipe disinfection

The RoboFIX® has been successfully tested with the following disinfectants for wipe disinfection with regard to the material compatibility of the surfaces.

You can perform wipe disinfection with the disinfectants mentioned here and similar disinfectants with regard to the active substances contained.

Use a soft cloth to apply the disinfectant and follow the manufacturer's instructions regarding the exposure time of the disinfectant used.

disinfectant	agent	mass concentration in 100 g solution:
Microbac (cloths)	Benzyl-C12-18-Alkyldimethylammoniumchlorid	0,4 g
	Didecyldimethylammoniumchlorid	0,4 g
Meliseptol HBV (cloths)	1-Propanol	50 g
	Didecyldimethylammoniumchlorid	0,075 g
Incidin Liquid	2-Propanol	35 g
	1-Propanol	25 g
Isopropanol	2-Propanol	63,1 g

Table 13: Disinfecting agents

4.6 Reprocessing

The STERILISABLE ARM COMPONENTS must be cleaned, disinfected and sterilised before each use; this applies in particular to the first use after delivery, as all STERILISABLE ARM COMPONENTS are delivered non-sterile (cleaning and disinfection after removal of the protective transport packaging; sterilisation after appropriate packaging).

The term "STERILISABLE ARM COMPONENTS" includes the CONTROL. Effective cleaning and disinfection is an indispensable prerequisite for effective sterilisation.

Within the scope of your responsibility, please observe the sterility during use. For details on the reprocessing of STERILISABLE ARM COMPONENTS please refer to the separately available processing instructions "Processing instructions RoboFIX® - EN 1412-240370".

5 Intraoperative complications

In case of intraoperative complications not due to the use of the RoboFIX®, it may still be in order to remove the device as fast as possible from the OR surroundings in order to have better access to the patient.

Proceed as follows:

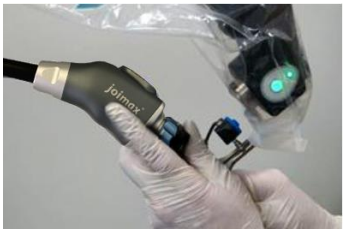
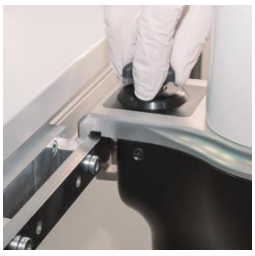
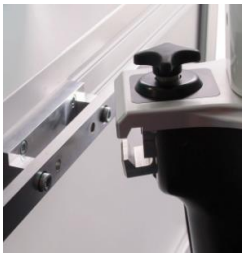
Step	Description
	Remove the endoscope used from the ADAPTER HOLDER. Proceed as described in the instructions for use of the endoscope.
	Press the DEACTIVATION PUSH BUTTON and move the RoboFIX® to an upright position turned to the side.
 	If access to the OP site is not yet sufficient, remove the arm from the OP table completely. To this effect, open the OP table fastening and remove the device from the OP table rail.

Table 14: Intraoperative complications

6 Troubleshooting

In case the RoboFIX® does not behave as expected, the following hints should enable you to solve simple problems yourself.

⚠	Never open the RoboFIX® or the POWER SUPPLY. Risk of an electric shock!

❗	Always contact the manufacturer's service or a representative expressly authorised by the manufacturer: • if you are not able to solve the problem with the help of the following information or • if safe work is no longer ensured.

Symptom	Solutions
LED on DEACTIVATION PUSHBUTTON is not lit 	Check the power supply: • Tight fit of the SUPPLY CABLE on the RoboFIX® • Tight fit of the SUPPLY CABLE on the POWER SUPPLY • Connection to the socket • Use another socket • Disconnect the POWER SUPPLY from the mains for at least 5 seconds to rectify a fault in the POWER SUPPLY
The status display CONTROL is lit in orange and the CONTROL does not work 	• The CONTROL has not been mounted onto the bracket of the ADAPTER HOLDER • The CONTROL is only ready to operate if it is connected to the RoboFIX® and is placed on the ferromagnetic bracket of the ADAPTER HOLDER
The RoboFIX® cannot be unlocked via the CONTROL although it is inserted and placed on the bracket of the ADAPTER HOLDER.	The CONTROL is faulty. Replace the CONTROL by a new one.

Table 15: Troubleshooting

7 Service

The RoboFIX® is basically maintenance-free. However, regular inspections and safety tests are imperative in order to ensure a reliable operation over its lifetime.

7.1 Handover certificate

The manufacturer or a representative expressly authorized by the manufacturer will commission the device upon delivery.

7.2 Regular inspections

Perform the following checks before each use of the device:

– Check POWER CORD for damage.

– RoboFIX® and accessories for external damage.

	Never use the RoboFIX® if you detected any damage. Contact the corresponding service.

7.3 Annual safety-related inspection

A regular maintenance is not required. However, the manufacturer requires a specialist or a hospital technician to carry out a precautionary safety inspection on a regular basis in order to ensure a reliable operation over its lifetime. This inspection must be carried out at least once a year.

No special requirements or precautions have to be considered for a precautionary inspection. During the inspection, the following tests have to be performed in accordance with section 5 of the DIN EN 62353:

- 5.2 Inspection

- 5.3.2 Measurement of the protective conductor resistance, where applicable

- 5.3.3 Measurement of the leakage currents

- 5.3.4 Measurement of the insulation resistance

The test results are to be fully documented in a test report according to section 6 of the DIN EN 62353. The test report can be taken from section F of the standard.

In case of a malfunction, please contact the joimax® Service or the respective service partner. In addition to an accurate description of the error, please also always indicate the product identification number and serial number as shown on the name plate of the device.

7.4 Disposal / Recycling

The manufacturer confirms that the product

RoboFIX®

meets the following guidelines:

- Waste electrical and electronic equipment (WEEE) 2012/19/EC,
- Electrical and Electronic Equipment Act - ElektroG,
- as well as the legal requirements of the member states of the ECC

Further information can be found in document no. 1412-170030 (Recycling pass).

	Due to the risk of an infection through contaminated products, they have to be treated prior to the disposal.
	Make sure that contaminated disposable products are disposed separately.
	The national regulations are to be complied when the product or its components are disposed of or recycled.

8 EMC

	Portable and mobile HF communication devices such as cell phones can interfere with MEDICAL ELECTRICAL DEVICES. Do not operate such devices in the direct vicinity of the RoboFIX®.
	MEDICAL ELECTRICAL DEVICES are subject to special precautionary measures in regard to EMC. The RoboFIX® may be installed and operated only in accordance with the EMC information contained in this manual.
	Disconnect the POWER SUPPLY from the mains for at least 5 seconds to rectify a fault in the POWER SUPPLY.
	The RoboFIX® or the associated POWER SUPPLY may not be placed directly adjacent to other equipment or stacked with other equipment. If it is necessary to operate the device close to other equipment and stacked with other equipment, the RoboFIX® should be monitored in order to check the proper operation with this arrangement.

Guidelines and manufacturer's declaration - Electromagnetic emissions

Emission

Test	Limit	Electromagnetic environment - guidance
Conducted emission	CISPR 11, Group 1, Class B	Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emission	CISPR 11, Group 1, Class B	
Voltage fluctuations and flicker	IEC 61000-3-3	Device is directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Only for Home healthcare environment.

Table 16: Emission

Immunity test levels

Test	Limit	Electromagnetic environment - guidance
Electrostatic Discharge (IEC 61000-4-2)	Contact Discharge: ±8 kV Air Discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM field (IEC 61000-4-3)	80-2700 MHz; 1kHz AM 80 %; 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Test	Limit	Electromagnetic environment - guidance
		Recommended separation distance: d = 1.2√P for 80 MHz to 800 MHz d = 2.3√P for 800 MHz to 2,7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Proximity fields form RF wireless communications equipment (IEC 61000-4-3)	385 MHz; Pulse Modulation: 18 Hz; 27 V/m 450 MHz, Pulse Modulation: 18 Hz: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; 5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 30 cm.
Electrical fast transients / bursts (IEC 61000-4-4)	Power lines: 2 kV; 100 kHz repetition frequency Signal lines: 1 kV; 100 kHz repetition frequency	Mains power quality should be that of a typical environment.
Surges (IEC 61000-4-5)	L-N: 1kV at 0°, 90°, 180°, 270°	Mains power quality should be that of a typical environment.
Conducted disturbances inducted by RF fields (IEC 61000-4-6)	0.15-80 MHz; 1kHz AM 80 %; 3 Vrms , 6 Vrms in ISM band	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d = 1.2√P for 150 kHz to 80MHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Rated power frequency magnetic fields (IEC 61000-4-8)	30 A/m, 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips / Voltage interruptions (IEC 61000-4-11)	0 % UT for 0.5 cycle at 8 phase angles 0 % UT for 1 cycle at 0° 70 % UT for 25/30 cycles at 0° 0 % UT for 250/300 cycles 0°	Mains power quality should be that of a typical environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is

Test	Limit	Electromagnetic environment - guidance
		powered from an uninterruptible power supply or battery.
Immunity to proximity magnetic fields (IEC 61000-4-39)	134.2 kHz; Pulse Modulation: 2.1 kHz; 65 A/m 13.56 MHz; Pulse Modulation: 50 kHz; 7.5 A/m	-
Immunity to HF Surgical equipment emissions (IEC 60601-2-2, Annex BB)	HF Mode: Cut – 300 W and Coagulation – 120 W	-

Table 17: Immunity test level

⚠	Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
⚠	Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RoboFIX®, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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