



# INSTRUCTIONS FOR USE ENDOFIX exo

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## 1 Introduction

Please read this instructions for use to learn about the correct use of the ENDOFIX EXO 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 ENDOFIX EXO in the OR without having been instructed by an authorised person in its safe use.

### 1.1 Purpose of the document

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

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 ENDOFIX EXO.



Make sure that the rail of the operating table is secured and locked before using the device.



Always hold the endoscope firmly before releasing the TENSION SLEEVE between endoscope and ENDOSCOPE CLAMP B.



Always hold the ENDOSCOPE CLAMP 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 ENDOFIX EXO or the POWER SUPPLY. Risk of an electric shock!
	The TROLLEY is intended for the storage and transport of the ENDOFIX EXO. When using the ENDOFIX EXO to hold and move an endoscope or exoscope, the ENDOFIX EXO must be firmly connected to the tool rail of the operating table. Use on the TROLLEY is not permitted!
	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 ENDOFIX EXO 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 ENDOFIX EXO - EN 1412-190174"!
	With the exception of the ENDOSCOPE CLAMP A and B, the CONE ADAPTER, the TENSION SLEEVE and the CONTROL, the ENDOFIX EXO and the POWER SUPPLY are not suitable for machine / automated cleaning or disinfection procedures!

	Never place the ENDOSCOPE CLAMP, CONE ADAPTER, TENSION SLEEVE and CONTROL in a disinfection bath together with contaminated surgical instruments.
	After use, do not store the ENDOSCOPE CLAMP, CONE ADAPTER, TENSION SLEEVE and 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 ENDOFIX EXO emulates an arm which is capable of guiding and positioning an endoscopic camera with several degrees of movement.

An integrated DEACTIVATION PUSHBUTTON permits manual movement of the ENDOFIX EXO 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 ENDOFIX EXO is unlocked by a sterilisable CONTROL at the push of a button.

Despite its large scope of movement, the ENDOFIX EXO 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 ENDOFIX EXO. 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 ENDOFIX EXO - EN 1412-190174".

## 1.6 Intended use / Notes on product liability

*Essential Performance:*

### Stable fixation of an 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 ENDOFIX EXO 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 ENDOFIX EXO is only compatible with following HF SURGICAL EQUIPMENT:

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

The ENDOFIX EXO can not be used for argon plasma coagulation mode.

	The TROLLEY is intended for the storage and transport of the ENDOFIX EXO. When using the ENDOFIX EXO to hold and move an endoscope or exoscope, the ENDOFIX EXO must be firmly connected to the tool rail of the operating table. Use on the TROLLEY is not permitted!
	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 using the ENDOFIX EXO is the proper assembly and maintenance of the device as well the compliance with this instruction manual.

The ENDOFIX EXO 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 ENDOFIX EXO. 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 ENT, skull base and thoracic surgery.

In open surgery, the ENDOFIX EXO is used to hold and guide an incident light optic (exoscope).

*Contraindications:*

The ENDOFIX EXO must not be used outside of the fields of application detailed above. The ENDOFIX EXO may be used exclusively for holding and moving an endoscope.

The ENDOFIX EXO is not suitable for outpatient interventions where the patient is only under partial anesthesia.

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 ENDOFIX EXO has no direct clinical benefit for the patient. The ENDOFIX EXO 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 ENDOFIX EXO 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 ENDOFIX EXO 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 ENDOFIX EXO based on this instruction manual.

	<p>All components to be used in sterile condition are delivered in unsterile condition. The only exception is the disposable STERILE COVER.</p> <p>Before using the sterilisable components for the first time, it is essential that they are completely prepared in accordance with the document "Processing instructions ENDOFIX EXO - EN 1412-190174"!</p>
	<p>Operate the ENDOFIX EXO only when it has reached room temperature again after a previous storage at high or low temperatures.</p>

## 2 System Description

### 2.1 Overview



fig. 1: System overview

Number	Description
1	Arm
2	DEACTIVATION PUSHBUTTON
3	UNLOCK BUTTON for the ENDOSCOPE CLAMP
4	ENDOSCOPE CLAMP
5	CONTROL
6	Handle
7	Quick-fastener for fastening to the operating table
8	<b>Control:</b> CONTROL connection
9	<b>Supply:</b> Power supply connection

Table 1: System overview

## 2.2 System components

Component	Picture	Description
ENDOFIX EXO  (multiple patient multiple use)		The ENDOFIX EXO 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 ENDOFIX EXO 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 ENDOFIX EXO and the POWER SUPPLY.  The SUPPLY CABLE is 3.5 m long.
ENDOSCOPE CLAMP A  (multiple patient multiple use)		The ENDOSCOPE CLAMP A features a self-acting lock into the quick coupling. It picks up the endoscope at the base of the eyepiece. The ENDOSCOPE CLAMP A offers the surgeon the greatest possible freedom.  The ENDOSCOPE CLAMP A is autoclavable with a service life of min. 500 cycles.
ENDOSCOPE CLAMP B  (multiple patient multiple use)		The ENDOSCOPE CLAMP B features a self-acting lock into the quick coupling. It forms the connection between the ENDOFIX EXO and the TENSION SLEEVE. It is used when the eyepiece attachment to the endoscope is very short.  The ENDOSCOPE CLAMP B is autoclavable with a service life of min. 500 cycles.
TENSION SLEEVE  (multiple patient multiple use)		Using the ENDOSCOPE CLAMP B, the TENSION SLEEVE safely and gently accepts endoscopes with a shaft diameter of 10mm. Endoscopes with smaller shaft diameters are accommodated by the CONE ADAPTER in the TENSION SLEEVE.  The TENSION SLEEVE is autoclavable with a service life of min. 100 cycles.

Component	Picture	Description
CONE ADAPTER  (multiple patient multiple use)		The CONE ADAPTER - matching the TENSION SLEEVE – accommodates endoscopes with connection cones acc. to Karl Storz. Appropriate variants exist for different connection cones.  The CONE ADAPTER is autoclavable with a service life of min. 500 cycles.
CONTROL  (multiple patient multiple use)		The CONTROL is used to unlock the arms of the ENDOFIX EXO 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 supports for the ENDOSCOPE CLAMP, the TENSION SLEEVE, the CONE ADAPTER and the CONTROL is intended for mechanical cleaning.  The STERILISATION TRAY features flushing pipes and a Luer-Lock connector for the cleaning and disinfectant solution.
SMALL PARTS TRAY  (multiple patient multiple use)		The SMALL PARTS TRAY holds the screw of the ENDOSCOPE CLAMP A.  The SMALL PARTS TRAY is matched to the STERILISATION TRAY.
STERILE COVER  (single use)		Permits one-time sterile covering of the ENDOFIX EXO.  The STERILE COVER is sterilised with ethylene oxide and supplied sterile.
TROLLEY  (multiple patient multiple use)		The TROLLEY is intended for storage of the ENDOFIX EXO while it is not in use, and for transporting it.

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
171943	ENDOFIX EXO	ENDOFIX EXO
172035	POWER SUPPLY	POWER SUPPLY
182205	POWER CORD	POWER CORD
172054	SUPPLY CABLE	SUPPLY CABLE
182233	ENDOSCOPE CLAMP A	ENDOSCOPE CLAMP A
151686	ENDOSCOPE CLAMP B	ENDOSCOPE CLAMP B
141339	TENSION SLEEVE D10	TENSION SLEEVE D10
171927	CONE ADAPTER	CONE ADAPTER
171906	CONTROL	CONTROL
141527	STERILISATION TRAY	STERILISATION TRAY for the sterilisable parts
172097	SMALL PARTS TRAY	SMALL PARTS TRAY
110084 *	STERILE COVER PU/ 50 ea.	STERILE COVER for ENDOFIX EXO, PU with 50 pieces REF 6001-40001
242702 *	STERILE COVER PU/ 50 ea.	STERILE COVER for ENDOFIX EXO, PU with 50 pieces REF E6785
120874	TROLLEY	TROLLEY
1412-170094	Manual ENDOFIX EXO – EN	-
1412-190174	Processing instructions ENDOFIX EXO - EN	-

*Table 3: Article numbers*

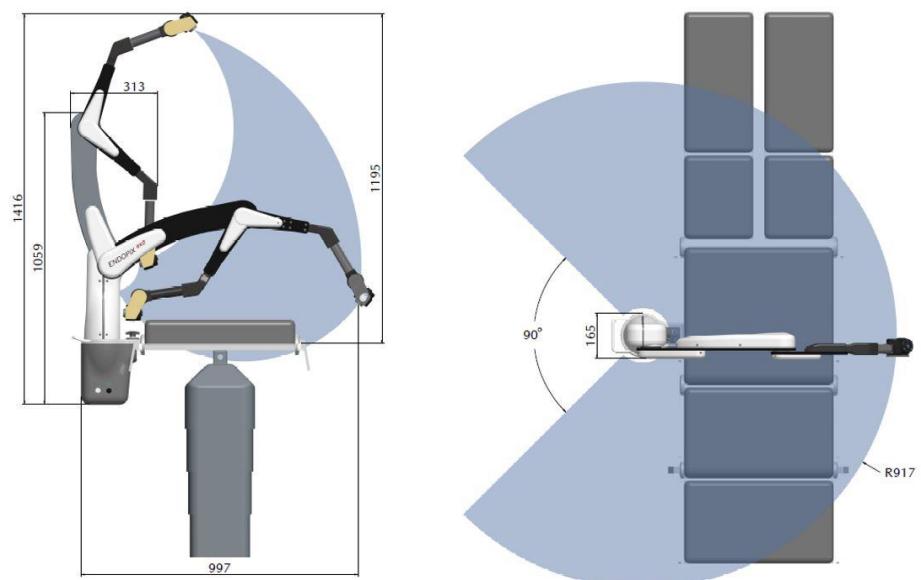
\* The two STERILE COVERS REF 6001-40001 and REF E6785 are matched to the device in terms of fit and function; due to country-specific approvals, only one STERILE COVER may be available in each case.

### 2.3 Mechanical data

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

## 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 ENDOFIX EXO 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 ENDOFIX EXO should always be transported in suitable packaging. Any position is possible during transportation.

For storage between the applications, we recommend the optional TROLLEY.

	Operate the ENDOFIX EXO only when it has reached room temperature again after a previous storage at high or low temperatures.
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## 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 MDR - 2017/745 (Medical Device Regulation)
	Date of manufacture
	Manufacturer
	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

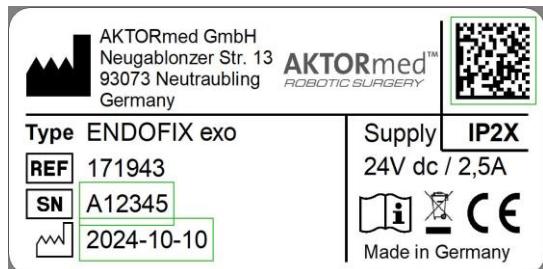


fig. 3: Name plate

## 2.10 Identification according to MDR (Medical Device Regulation)

The ENDOFIX EXO including accessories is a class I medical product. Sterile disposables are class IIs medical devices.

## 2.11 Symbols on STERILE COVER

Symbol	Description
REF	Reference number
LOT	Lot number
	Can be used until
STERILE EO	Sterilised with ethylene oxide
EC REP	Authorised representative in the European Community
CH REP	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:

AKTORmed GmbH  
Neugablonzer Str. 13  
93073 Neutraubling  
GERMANY

Web: [www.aktormed.com](http://www.aktormed.com)

eMail: [info@aktormed.com](mailto:info@aktormed.com)

Phone: +49 9401 93 20 110

### 3 Setup / Commissioning

#### 3.1 ENDOFIX EXO

Follow the following work steps to mount the ENDOFIX EXO 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
	<p>The device is lifted to the standard rail and mounted.</p>
	<p>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.</p>

Table 6: Mounting on operating table

	<p>To make the best possible use of the ENDOFIX EXO'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.</p>
	<p>Make sure that the ENDOFIX EXO is firmly locked on the rail of the operating table before using the device.</p>

*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 ENDOFIX EXO.

	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 ENDOFIX EXO 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 ENDOFIX EXO can be covered easily with the STERILE COVER.



*fig. 4: 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 ENDOSCOPE CLAMP through the opening in the elastic part of the STERILE COVER.
	Pull the ENDOSCOPE CLAMP 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 ENDOSCOPE CLAMP.

*Table 7: Prepare STERILE COVER*

*Step 4: Engage the ENDOSCOPE CLAMP and cover the ENDOFIX EXO with the STERILE COVER*

Step	Description
	<p>Move the ENDOSCOPE CLAMP with STERILE COVER to the arm from below.</p>
	<p>Insert the plug of the ENDOSCOPE CLAMP into the quick-release fastener of the extension arm until the ENDOSCOPE CLAMP audibly engages. Check the correct engagement by pulling the ENDOSCOPE CLAMP.</p>
	<p>Slip the STERILE COVER over the end of the extension arm.</p>
	<p>Pull the STERILE COVER over the extension arms.</p>
	<p>Pull the STERILE COVER down to the base plate.</p>
	<p>At this point, continue with the patient's sterile drape according to the usual procedure in your hospital.</p>

*Table 8: Obtain ENDOFIX EXO sterile*

	Only use the original STERILE COVER - REF 6001-40001, or REF E6785 - that you have purchased from the manufacturer or an authorised partner.
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### 3.2 Mounting the CONTROL to the ENDOSCOPE CLAMP

Step	Description
	Slip the CONTROL over the bracket of the ENDOSCOPE CLAMP. You can fasten the CONTROL to the bracket with the pushbutton area facing upwards or to the right.
	Connect the CONTROL to the connector „CONTROL“ on the ENDOFIX EXO.
	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 ENDOSCOPE CLAMP

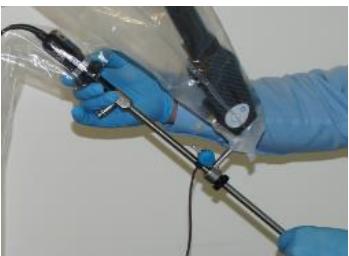
	Keep the CONTROL at least 15 cm (6 inches) away from magnetically susceptible medical devices such as pacemakers, cochlear implants or neurostimulators.
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### 3.3 Mounting the endoscope to the ENDOSCOPE CLAMP A

Step	Description
	Insert the endoscope into the ENDOSCOPE CLAMP A from below.
	Tighten the screw hand-tight.

Table 10: Mounting the endoscope to the ENDOSCOPE CLAMP A

### 3.4 Mounting the endoscope to the ENDOSCOPE CLAMP B

Step	Description
	Screw-fasten the TENSION SLEEVE loosely into the ENDOSCOPE CLAMP B.
	If you use a 10mm optical system, slip the endoscope into the prepared ENDOSCOPE CLAMP B.

Step	Description
	Tighten the TENSION SLEEVE by hand.
 	<p>If you use an optical system with a connection cone, first mount the appropriate CONE ADAPTER to the connection cone of the endoscope.</p> <p>To this effect, position it and turn it 90° clockwise.</p>
 	Now insert the endoscope into the prepared ENDOSCOPE CLAMP B and tighten the TENSION SLEEVE tight by hand.

Table 11: Mounting the endoscope to the ENDOSCOPE CLAMP B

	Only tighten the TENSION SLEEVE enough so that the endoscope can be turned easily.
---	--

## 4 Operation

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

With ENDOSCOPE CLAMP A:

Step	Description
	Press the button on the CONTROL with the thumb of your left hand to unlock the ENDOFIX EXO and set a new position for the endoscope.
	As soon as the button on the CONTROL is released, all 6 axes are locked again. You can now release the endoscope.

Table 12: Operating the ENDOFIX EXO using the ENDOSCOPE CLAMP A

With ENDOSCOPE CLAMP B:

Step	Description
	Press the button on the CONTROL with the index finger of your left hand to unlock the ENDOFIX EXO 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 13: Operating the ENDOFIX EXO using the ENDOSCOPE CLAMP B

	<p>Make sure that the blue UNLOCK BUTTON always remains oriented approximately towards the patient's head during positioning. The reaction forces of the holding arm on the leading hand are then lowest.</p>
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#### 4.1 DEACTIVATION PUSHBUTTON and status displays

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

Picture	Description
	<p>DEACTIVATION PUSHBUTTON to move the arms. The flush green LED is lit when the ENDOFIX EXO is supplied with electrical power.</p>
	<p>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 ENDOFIX EXO and has been secured to the bracket of the ENDOSCOPE CLAMP.</p>

Table 14: DEACTIVATION PUSHBUTTON and status displays

## 4.2 Weight compensation

The ENDOFIX EXO is equipped with a weight balance to compensate for the weight of the endoscope and camera head. Due to the different levers with the extension arms fully retracted and fully extended, the weight balance is still largely in place. A complete weight balance is only achieved in a middle boom position.



*fig. 5: Perfect counterbalance*

If the extension arms are positioned very close to the body of the device, there is a certain overcompensation of the weight of the endoscope and camera head.



*fig. 6: Weight balance overcompensated*

If, on the other hand, the extension arms are extended quite far, the weight balance is no longer quite adequate for the weight of the endoscope and camera head. You will then feel some weight in your hand when operating the CONTROL.



*fig. 7: Weight balance undercompensated*

#### 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
	Loosen the screw of ENDOSCOPE CLAMP A to remove the endoscope.
	Loosely turn the TENSION SLEEVE counterclockwise and pull the endoscope out of the ENDOSCOPE CLAMP B.
	Remove the CONTROL and press the blue UNLOCK BUTTON of the quick coupling in order to remove the ENDOSCOPE CLAMP.
	Dispose of the used STERILE COVER of the ENDOFIX EXO. For subsequent storage, put the ENDOFIX EXO onto the TROLLEY in upright position.

Step	Description
	Disconnect all cable connections and remove the POWER SUPPLY from the mains.
	Remove the CONE ADAPTER from the optical system. To do this, turn the CONE ADAPTER 90° counterclockwise.
	Place the protective cap onto the plug of the CONTROL.
	Remove the screw from ENDOSCOPE CLAMP A and place it in the SMALL PARTS TRAY.
	Release the TENSION SLEEVE from the ENDOSCOPE CLAMP B.
	Arrange the ENDOSCOPE CLAMP A, the CONE ADAPTER, the TENSION SLEEVE and the CONTROL on the flushing pipes of the STERILISATION TRAY. Place the ENDOSCOPE CLAMP B next to the CONTROL cable.

Step	Description
	<p>The ENDOFIX EXO can be removed from the OP table and stored on the TROLLEY.</p>

Table 15: After use

#### 4.5 Wipe disinfection

The ENDOFIX EXO 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 16: 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 ENDOSCOPE CLAMP A, ENDOSCOPE CLAMP B, CONE ADAPTER, TENSION SLEEVE and 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 ENDOFIX EXO - EN 1412-190174".

## 5 Intraoperative complications

In case of intraoperative complications not due to the use of the ENDOFIX EXO, 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
	Loosen the screw of ENDOSCOPE CLAMP A to remove the endoscope.
	Loosely turn the Tension sleeve counterclockwise and pull the endoscope out of the ENDOSCOPE CLAMP B.
	Press the DEACTIVATION PUSH BUTTON and move the ENDOFIX EXO to an upright position turned to the side.
	<p>If access to the OP site is not yet sufficient, remove the arm from the OP table completely.</p> <p>To this effect, open the OP table fastening and remove the device from the OP table rail.</p>

Table 17: Intraoperative complications

## 6 Troubleshooting

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

	Never open the ENDOFIX EXO or the POWER SUPPLY. Risk of an electric shock!
	Always contact the manufacturer's service or a representative expressly authorised by the manufacturer: <ul style="list-style-type: none"> <li>• if you are not able to solve the problem with the help of the following information or</li> <li>• if safe work is no longer ensured.</li> </ul>

Symptom	Solutions
LED on DEACTIVATION PUSHBUTTON is not lit 	Check the power supply: <ul style="list-style-type: none"> <li>• Tight fit of the SUPPLY CABLE on the ENDOFIX EXO</li> <li>• Tight fit of the SUPPLY CABLE on the POWER SUPPLY</li> <li>• Connection to the socket</li> <li>• Use another socket</li> <li>• Disconnect the POWER SUPPLY from the mains for at least 5 seconds to rectify a fault in the POWER SUPPLY</li> </ul>
The status display CONTROL is lit in orange and the CONTROL does not work 	<ul style="list-style-type: none"> <li>• The CONTROL has not been mounted onto the bracket of the ENDOSCOPE CLAMP</li> <li>• The CONTROL is only ready to operate if it is connected to the ENDOFIX EXO <u>and</u> is placed on the ferromagnetic bracket of the ENDOSCOPE CLAMP</li> </ul>
The ENDOFIX EXO cannot be unlocked via the CONTROL although it is inserted and placed on the bracket of the ENDOSCOPE CLAMP.	The CONTROL is faulty. Replace the CONTROL by a new one.

Table 18: Troubleshooting

## 7 Service

The ENDOFIX EXO 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.
- ENDOFIX EXO and accessories for external damage.



Never use the ENDOFIX EXO 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 AKTORmed 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

ENDOFIX EXO

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 ENDOFIX EXO.
	MEDICAL ELECTRICAL DEVICES are subject to special precautionary measures in regard to EMC. The ENDOFIX EXO 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 ENDOFIX EXO 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 ENDOFIX EXO 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	Device is directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations and flicker	IEC 61000-3-3	Only for Home healthcare environment.

*Table 19: Emission*

### *Immunity test levels*

Test	Limit	Electromagnetic environment - guidance
Electrostatic Discharge (IEC 61000-4-2)	Contact Discharge: $\pm 8$ kV Air Discharge: $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ 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. <b>Recommended separation distance:</b>

Test	Limit	Electromagnetic environment - guidance
		<p><math>d = 1.2VP</math> for 80 MHz to 800 MHz</p> <p><math>d = 2.3VP</math> for 800 MHz to 2,7 GHz</p> <p>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).</p>
Proximity fields from 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 induced 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. <b>Recommended separation distance:</b> $d = 1.2VP$ 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 powered from an uninterruptible power supply or battery.

Test	Limit	Electromagnetic environment - guidance
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 20: 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 ENDOFIX EXO, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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