

INSTRUCTIONS FOR USE JOYSTICK for SOLOASSIST II

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1308-180088-07

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1 Introduction

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

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

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.
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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.
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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 JOYSTICK.

	The JOYSTICK is designed exclusively for use with the SOLOASSIST II camera guidance system. Do not use the JOYSTICK with other equipment.
	Observe the safety instructions in these operating instructions as well as the operating instructions for the SOLOASSIST II.
	The device is not intended for the operation in explosive areas. Ensure a sufficient distance to highly flammable gases (e.g. O ₂ , anaesthetic gases).

	Keep the JOYSTICK at least 15 cm (6 inches) away from magnetically susceptible medical devices such as pacemakers, cochlear implants or neurostimulators.
	Only put the JOYSTICK into operation after it has returned to room temperature during the previous reprocessing process.
	All serious incidents related to the product must be reported to the manufacturer and the competent authority in the country concerned.
	Avoid tripping hazards when connecting the cables.
	Never insert the JOYSTICK, JOYSTICK-RH, MOUNT-1A, MOUNT-1B, MOUNT-2A, MOUNT-2B, ADAPTER-1 and ADAPTER-2 into a disinfectant bath together with contaminated surgical instruments.
	Do not store the JOYSTICK, JOYSTICK-RH, MOUNT-1A, MOUNT-1B, MOUNT-2A, MOUNT-2B, ADAPTER-1 and ADAPTER-2 in a common container with contaminated surgical instruments after use.
	JOYSTICK, JOYSTICK-RH, MOUNT-1A, MOUNT-1B, MOUNT-2A, MOUNT-2B, ADAPTER-1 and ADAPTER-2 are delivered non-sterile. Before first use, it is essential that the sterilisable components are completely prepared in accordance with the "Processing instructions JOYSTICK - EN 1308-190145".

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 JOYSTICK is the input device for the SOLOASSIST II. It enables the surgeon to adjust the position of the endoscope and thus the field of view at the touch of a button.

The JOYSTICK is preferably attached to the handle of the instrument guided on the left. Alternatively, the JOYSTICK-RH can be attached to the handle of the right-hand instrument. There are different ways of attaching the JOYSTICK to the differently shaped instrument handles (see chapter 3.1 "JOYSTICK and instrument handle").

The JOYSTICK can be used either as a stand-alone input device or parallel to a connected voice control.

Sterilisation in the fractionated vacuum process at 134° places a high load on the material. Therefore, all recyclable components have a limited service life despite the use of selected materials. More information can be found in the processing instructions "Processing instructions JOYSTICK - EN 1308-190145" under "Reusability".

The product works with software. You can find out more in document 1515-240319 (Cybersecurity label – Soloassist), which is available on request.

1.6 Intended use / Notes on product liability

JOYSTICK, JOYSTICK-RH, MOUNT-1A, MOUNT-1B, MOUNT-2A, MOUNT-2B, ADAPTER-1 and ADAPTER-2 are accessories of the SOLOASSIST II. Do not use the JOYSTICK with other equipment.

Environment:

O.R. Room. JOYSTICK, JOYSTICK-RH, MOUNT-1A, MOUNT-1B, MOUNT-2A, MOUNT-2B, ADAPTER-1 and ADAPTER-2 are used in a sterile environment during surgery.



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:

The correct installation and maintenance of the JOYSTICK as well as the observance of the instructions for use are mandatory prerequisites for the use of the JOYSTICK. In addition, the instructions for use of the SOLOASSIST II must be observed.

The operation of the JOYSTICK is primarily performed by the surgeon performing the procedure. The surgeon must have sufficient experience in the use of minimally invasive surgical techniques and have been instructed in the use of the JOYSTICK. Operation may only be carried out by instructed personnel. The instruction must be documented.

Application:

Enter direction commands to control the SOLOASSIST II.

Contraindications:

The restrictions on the use of the SOLOASSIST II apply.

The manufacturer only considers himself responsible for the safety-related properties, reliability and performance if

- the user has been fully instructed in the correct use of the equipment.
- Assembly, new settings, modifications or repairs may only be carried out by the manufacturer or by an institution expressly authorised to do so by the manufacturer.
- the device is used under the specified ambient conditions in rooms used for medical purposes whose electrical installation complies with the provisions of VDE 0100-710 or IEC 60364-7-10.
- the device is used in full compliance with these instructions for use.

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

Please check the JOYSTICK 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 JOYSTICK 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 JOYSTICK based on this instruction manual.

	JOYSTICK, JOYSTICK-RH, MOUNT-1A, MOUNT-1B, MOUNT-2A, MOUNT-2B, ADAPTER-1 and ADAPTER-2 are delivered non-sterile. Before first use, it is essential that the sterilisable components are completely prepared in accordance with the "Processing instructions JOYSTICK - EN 1308-190145".
	Only put the JOYSTICK into operation after it has returned to room temperature during the previous reprocessing process.

2 System Description

2.1 Overview



fig. 1: Overview

Number	Description
1	JOYSTICK
2	JOYSTICK-RH
3	MOUNT-1A
4	MOUNT-1B
5	MOUNT-2A
6	MOUNT-2B
7	ADAPTER-1
8	ADAPTER-2

Table 1: Overview

2.2 System components

Component	Picture	Description
JOYSTICK (multiple patient multiple use)		The SOLOASSIST II can be controlled with the autoclavable JOYSTICK. It is attached to the handle of the left-guided surgical instrument to allow the surgeon to adjust the endoscopic view during preparation. The following components MOUNT-1A, MOUNT-1B, ADAPTER-1, ADAPTER-2, MOUNT-2A and MOUNT-2B are available for attachment to the differently pronounced handles. The JOYSTICK can be prepared for a maximum of 150 cycles.
JOYSTICK-RH (multiple patient multiple use)		The SOLOASSIST II can be controlled with the autoclavable JOYSTICK-RH. It is attached to the handle of the right-guided surgical instrument to allow the surgeon to adjust endoscopic vision during preparation. The following components MOUNT-1A, MOUNT-1B, ADAPTER-1, ADAPTER-2, MOUNT-2A and MOUNT-2B are available for attachment to the differently pronounced handles. The JOYSTICK-RH can be prepared for a maximum of 150 cycles.
MOUNT-1A (multiple patient multiple use)		The MOUNT-1A fits most surgical handles and is the standard mount for the JOYSTICK and JOYSTICK-RH. The MOUNT-1A can be prepared for at least 500 cycles.

Component	Picture	Description
MOUNT-1B (multiple patient multiple use)		The MOUNT-1B fits on surgical handles that are particularly thickly designed. The MOUNT-1B can be prepared for at least 500 cycles.
ADAPTER-1 (multiple patient multiple use)		The ADAPTER-1 is specially designed for the strongly rounded handles of the company Aesculap. First clip the ADAPTER-1 onto the handle and attach the JOYSTICK using the MOUNT-1A. The ADAPTER-1 has a limited service life of maximum 100 preparation cycles.
ADAPTER-2 (multiple patient multiple use)		The ADAPTER-2 is specially designed for the strongly rounded handles of the Olympus company. First clip the ADAPTER-2 onto the handle and secure the JOYSTICK using the MOUNT-1B. The ADAPTER-2 has a limited service life of maximum 100 preparation cycles.
MOUNT-2A (multiple patient multiple use)		The MOUNT-2A is intended to be used as an attachment for handles with a latching mechanism. The MOUNT-2A is threaded onto the instrument shaft and attached to the handle with the SCREW. The MOUNT-2A can be reprocessed at least 500 times.
MOUNT-2B (multiple patient multiple use)		The MOUNT-2B is intended to be used as an attachment for handles with a latching mechanism. It is longer than the MOUNT-2A. The MOUNT-2B is threaded onto the instrument shaft and attached to the handle with the SCREW. The MOUNT-2B can be reprocessed at least 500 times.

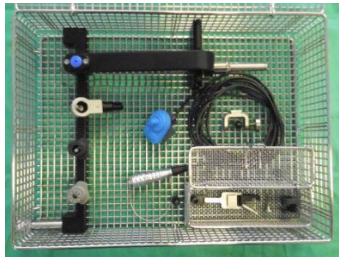
Component	Picture	Description
STERILISATION TRAY (multiple patient multiple use)		The STERILISATION TRAY with holder for all components of the SOLOASSIST II is intended for machine cleaning. The integrated SMALL PARTS TRAY additionally holds the ADAPTER-1 and 2, the MOUNT-2A and 2B, as well as the SCREW of the MOUNT-2A and 2B to be removed during cleaning.

Table 2: system components

Overview accessories and spare parts:

For orders, please contact the manufacturer directly or your responsible representative.

Only use original accessories. The use of accessories not approved by the manufacturer may endanger the patient or cause damage to the device.

Article number	Article name	Name
172091	JOYSTICK-LH	JOYSTICK
182198	JOYSTICK-RH	JOYSTICK-RH
172066	MOUNT-1A	MOUNT-1A
172065	MOUNT-1B	MOUNT-1B
161822	ADAPTER-1	ADAPTER-1
172088	ADAPTER-2	ADAPTER-2
172067	MOUNT-2A	MOUNT-2A
172068	MOUNT-2B	MOUNT-2B
172081	SCREW	SCREW for MOUNT-2A and MOUNT-2B (spare part)
182168	O-RING	O-RING for the protective cap on the plug of the JOYSTICK and JOYSTICK-RH (spare part)
172099	STERILISATION TRAY	STERILISATION TRAY with SMALL PARTS TRAY
172097	SMALL PARTS TRAY	SMALL PARTS TRAY
1308-180088	Manual JOYSTICK – EN	-
1308-190145	Processing instructions JOYSTICK – EN	-
1206-140108	Manual SOLOASSIST II – EN	-

Table 3: Article numbers

2.3 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

2.4 Storage and transport

The JOYSTICK and its system components should always be transported in suitable protective packaging. The position during transport is arbitrary.

	Operate the JOYSTICK only when it has reached room temperature again after a previous storage at high or low temperatures.
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2.5 Symbols used on the name plates / labels

Symbol	Description
	Observe the instructions for use
	Follow the instructions for use
	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

2.6 Name plate

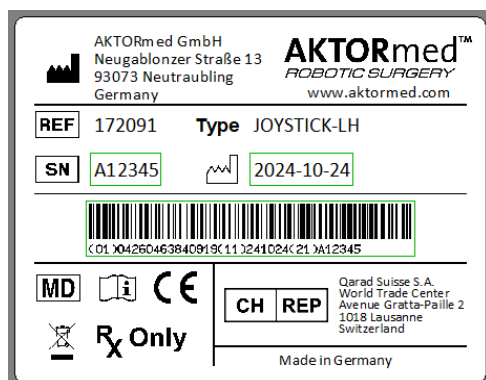


fig. 2: nameplate

2.7 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
eMail: info@aktormed.com
Phone: +49 9401 93 20 110

3 Assembly / Commissioning

3.1 JOYSTICK and instrument handle

The JOYSTICK can be mounted to the instrument handle using the following steps and put into operation for subsequent use.

Mounting with MOUNT-1A:

Step	Description
	Slide the JOYSTICK onto the MOUNT-1A and make sure that the screw is pointing towards the cable.
	Attach the JOYSTICK with the MOUNT-1A to the instrument handle and tighten the screw for secure attachment.

Table 5: Mounting with MOUNT-1A

	The JOYSTICK is preferably used on the instrument handle, which is operated by the surgeon with the left hand. Usually it is a handle with pliers as instrument. If the user wants to guide the instrument with the pliers to the right, this is possible using the JOYSTICK-RH. All described fastenings for the JOYSTICK apply analogously to the JOYSTICK-RH.
	Ensure that the JOYSTICK is firmly attached to the instrument handle.
	Keep the JOYSTICK at least 15 cm (6 inches) away from magnetically susceptible medical devices such as pacemakers, cochlear implants or neurostimulators.

Mounting with ADAPTER-1:

Step	Description
	Slide the JOYSTICK onto the MOUNT-1A and make sure that the screw is pointing towards the cable. Turn the screw to the left until the end stop is reached.
	Attach the ADAPTER-1 to the leg of the Aesculap instrument handle. The flattening with the serial number points, as shown in the picture, to the left.
	Place the JOYSTICK with the MOUNT-1A over the ADAPTER-1 and tighten the screw for secure attachment.

Table 6: Mounting with ADAPTER-1

Mounting with MOUNT-1B:

Step	Description
	Slide the JOYSTICK onto the MOUNT-1B and make sure that the screw is facing the cable.

Step	Description
	Attach the JOYSTICK with the MOUNT-1B to the instrument handle and tighten the screw for secure attachment.

Table 7: Mounting with MOUNT-1B

Mounting with ADAPTER-2:

Step	Description
	Slide the JOYSTICK onto the MOUNT-1B and make sure that the screw is facing the cable. Turn the screw to the left until the end stop is reached.
	Attach the ADAPTER-2 to the leg of the Olympus instrument handle. The flattening with the serial number points, as shown in the picture, to the left. If the JOYSTICK-RH is used, the flattening with the serial number of the ADAPTER-2 must point to the right rather than to the left as shown in the picture.
	Place the JOYSTICK with the MOUNT-1B over the ADAPTER-2 and tighten the screw for secure attachment.

Table 8: Mounting with ADAPTER-2

Mounting with MOUNT-2A or MOUNT-2B:

Step	Description
	Remove the MOUNT-2A or 2B and the small screw from the SMALL PARTS TRAY.
	Insert the small screw and turn it until you reach the opening as shown in the picture.
	Slide the JOYSTICK onto the MOUNT-2A or 2B and make sure that the small screw points in the direction of the cable. When using the JOYSTICK-RH, the cable points in the opposite direction to the small screw.
	Insert the shaft of the instrument through the lug of the MOUNT-2A or 2B and slide the JOYSTICK backwards until it reaches the instrument handle.
	Attach the MOUNT-2A or 2B to the finger ring of the instrument handle. Tighten the small screw for secure attachment.

Table 9: Mounting with MOUNT-2A or 2B

3.2 Electrical connection

Step	Description
	Connect the JOYSTICK or the JOYSTICK-RH to the "Control" connector on the SOLOASSIST II.

Table 10: Electrical connection

4 Operation

If the SOLOASSIST II is adjusted by motor using the JOYSTICK, **the tip of the endoscope** moves on the surface of an imaginary sphere in space. This means that the image section **can be changed intuitively during the operation**.

Assignment of the control buttons on the JOYSTICK

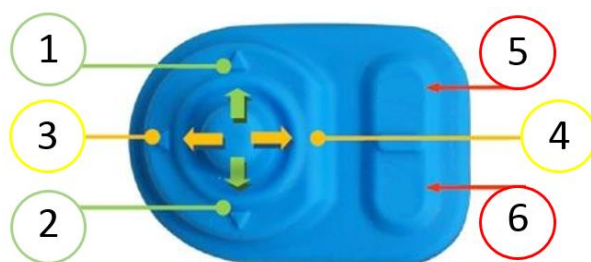


fig. 3: Buttons on the Joystick

Button	Description
1	Move image up
2	Move image down
3	Move image to the right
4	Move image to the left
5	Zoom out
6	Zoom in

Table 11: Movements

	It is also possible to move the image diagonally, e.g. to the top right. Press the JOYSTICK diagonally in the desired direction.
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All movement directions are based on the monitor image. Ensure the anatomically correct setting of the image horizon.

Corresponding movements of the endoscope within the trocar

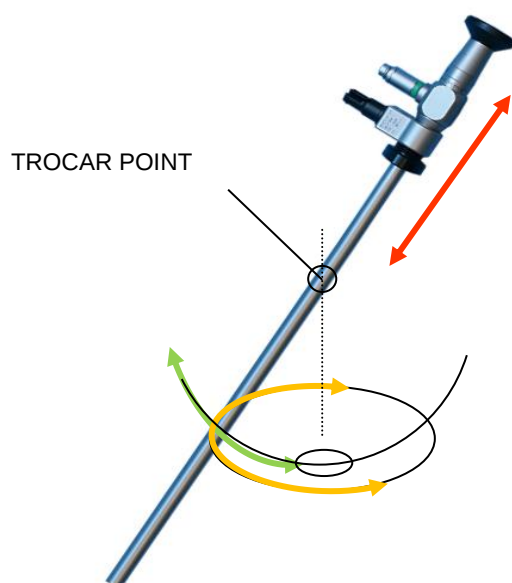


fig. 4: Endoscope movement



Operation with the JOYSTICK is only available after a TROCAR POINT has been saved on the SOLOASSIST II. See SOLOASSIST II user manual.

The endoscope position can be changed at any time by operating the JOYSTICK or manually on the SOLOASSIST II. Refer to the SOLOASSIST II operating instructions.

5 Ending the application

Step	Description
	Remove the JOYSTICK from the instrument handle. Loosen the screw on the MOUNT-1A or 1B, or the small screw on the MOUNT-2A or 2B.
	Unplug the JOYSTICK from the SOLOASSIST II.
	If applicable, disconnect the JOYSTICK from the MOUNT-1A or 1B.
	If applicable, disconnect the JOYSTICK from the MOUNT-2A or 2B.
	If applicable, remove the small screw from the MOUNT-2A or 2B.

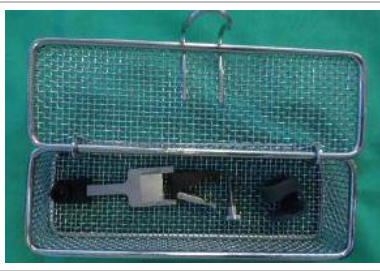
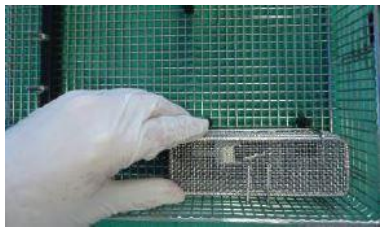
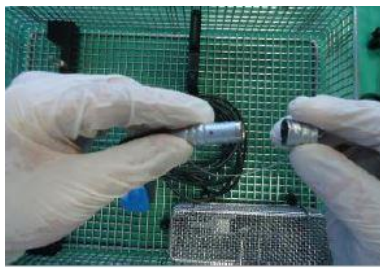
Step	Description
	If applicable, remove the ADAPTER-1 or 2 from the instrument handle.
	Place the MOUNT-2A or 2B, the small screw and the ADAPTER-1 or 2 in the SMALL PARTS TRAY.
	Place the SMALL PARTS TRAY in the STERILISATION TRAY of the SOLOASSIST II.
	Place the JOYSTICK or the JOYSTICK-RH in the STERILISATION TRAY and place the protective cap on the plug.
	Now insert the MOUNT-1A or 1B loosely into the STERILISATION TRAY.
	Complete the STERILISATION TRAY with the remaining components of the SOLOASSIST II.

Table 12: Ending the application
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6 Troubleshooting

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

	Never open SOLOASSIST II or the POWER SUPPLY. Danger of 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	Solution
The LED „JOYSTICK“ lights up 	The JOYSTICK is defective or has exceeded its service life of 150 reprocessing cycles. Replace the JOYSTICK with a new one.
The LED „JOYSTICK“ flashes 	The JOYSTICK has been used more than 140 times and is nearing the end of its life. The JOYSTICK can be used a maximum of 150 times and is then automatically deactivated. Replace the JOYSTICK.
The LED „JOYSTICK“ blinks 	The JOYSTICK has been used more than 145 times and is nearing the end of its life. The JOYSTICK can be used a maximum of 150 times and is then automatically deactivated. Replace the JOYSTICK.
The movement does not follow the expected path. The image does not move in the expected direction.	The TROCAR POINT may not be set correctly. Replace the TROCAR POINT (see SOLOASSIST II Instructions for Use).

Table 13: Troubleshooting

7 Service

The JOYSTICK is basically maintenance-free. However, regular checks are essential to ensure safe operation over the lifetime of the unit.

Perform the following checks before each use of the JOYSTICK:

- Check the JOYSTICK cable for damage.
- Check JOYSTICK and accessories for external damage.

	Do not use the JOYSTICK if you notice any damage. Call the service responsible for you.
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7.1 Disposal / Recycling

The manufacturer confirms that the product

JOYSTICK

complies with 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 EEA

For more information, see document no. 1308-190128 (Recycling Pass Joystick).

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



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