medifa
the medical factory

Body support system

Art.-no. 81361, 61361_1, 61361_2
61361_3, 61361_4

User manual

CE

Version: 1.0

we care.

Table of contents

1. Important information

1.1 Revision history

Version	Date	Reason for change to the publication
1.0	04/2020	Erstausgabe

1.2 CE marking

This product is a class 1 medical device according to the European Directive 93/42/ EEC on medical devices. This corresponds to the version of this directive valid at the time it was placed on the market.

1.3 Conformity

The manufacturer declares that this product complies with the main requirements according to MDD Appendix 1. The manufacturer also declares that a conformity assessment procedure, according to MDD Appendix 7, (and required for Class-1 products) was carried out and documented by a CE marking.

1.4 Manufacturer and distributor

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1.5 Copyright notice

2. Foreword

The company medifa thanks you for purchasing the product. The body support system is a product that combines design, functionality and comfort with the highest quality associated with German manufacturing.

The medifa products are manufactured to have a long and trouble-free lifespan.
The development, design and production at medifa have been certified to comply with DIN EN ISO 9001 and DIN EN ISO 13485. These products comply with the requirements of the Medical Devices Act and bear the CE mark.

The product consists exclusively of high-quality materials with a high service life.
We are always available to help if you have any questions.

3. Understanding these operating instructions

ATTENTION

Please read and observe these operating instructions.
This operating instructions must have been read and understood fully by the operating personnel before initially commissioning the product, this applies particularly to the chapter Safety instructions and user obligations. If necessary, in-house training for technical qualifications may be carried out by a qualified person. The operating instructions must be closely followed and available at the place of use.

ATTENTION

This product is safe to use!
Any remaining residual hazards are indicated at the affected locations in the operating instructions.
Follow these instructions!

3.1 List of abbreviations

Abbreviation	Description
CE	European Community (from the French “Communauté Européenne”)
DIN	German Institute for Standardization
EN	European Standard
EWG	European Economic Community
MDD	Medical Device Directive
ISO	International Organization for Standardization
OP	Operations (surgery)

4. Symbols in use

These operating instructions use various warning, notice and safety symbols to highlight information of particular relevance.

Safety instructions

DANGER

DANGER indicates a hazardous situation which, if not avoided, will result in death or serious injury.

WARNING

WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

CAUTION indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

ATTENTION

Notice about a harmful situation; possible consequences: the device itself or surrounding objects could be damaged.

5. Safety instructions and user obligations

Keep these operating instructions close to the product so that the information can be accessed later! These operating instructions are an integral part of the product and must be transferred when the location or personnel changes. These operating instructions must also be easily accessible to all users of the product at all times.

5.1 General safety instructions

WARNING

Danger for the patient!
Do not change this medical product! The manufacturer assumes no liability resulting from changes made.

- All work with or on the product (installation, commissioning, operation, maintenance, decommissioning, transport or disposal) may only be carried out by trained medical or nursing staff.
- The product must only be used for the purposes specified in the Proper and intended usage!
- The values specified in Technical specifications must be complied with whenever the product is being used.
- The body support system must be attached correctly according to the assembly instructions. Failure to follow the instructions may cause the system to become unstable, thus preventing the product from performing its protective function.
- The product may only be mounted on standard rails with the dimensions 10x25 mm.

5.2 Steps to take before each use in the OP

All mechanical components of the product must be checked for proper functionality and integrity before each use!
Do not use defective or damaged products!

5.3 Infection control

- Follow all regulations for cleaning and disinfection!
- Follow the cleaning and disinfection procedures described in these operating instructions!
- Only cleaned and disinfected devices and equipment may be handed over to a service technician or the manufacturer for repair work!

5.4 Maintenance and repair

The product is maintenance-free.
Wear caused by use as well as ageing can affect the safety relevant functions of the product. Check the condition of the product before each use. The product must no longer be used if damage has been identified.

Repairs
Repairs may only be carried out by the medifa technical support or by personnel who have been authorized, trained and certified by medifa.The company medifa is not liable for any damages due to neglected inspections, inadequate repair, improper maintenance or changes made to the product!
For servicing work, please contact the medifa technical support department.

6. Proper and intended usage

This product is an body support system. It is an accessory of the medifa 8000.
The medifa 8000 and the standard accessories are intended exclusively for human medical purposes.

The body support system in conjunction with the X-ray operating table is intended for the following uses:
- Positioning of patients from the induction of anaesthesia to the operation and the discharge of the anaesthesia. In doing so the body support system serves to support the patient‘s body..

The body support system for the medifa 8000 consists of the holder and one of the different body supports.

Holder:
- Art.-no. 81361: Holder of body supports

Body supports:
- Art.-no. 61361_1: Body support for pubis, sacrum and sternum
- Art.-no. 61361_2: Body support for side and shoulder
- Art.-no. 61361_3: Body support for back and buttocks
- Art.-no. 61361_4: Supporting roll

The product may only be used and operated responsibly and in a controlled manner by trained medical and nursing staff. The manufacturer of other persons authorised by the manufacturer shall carry out the training for the operating and care personnel.

In order to ensure proper and intended usage of the product, these operating instructions for the arm rest and the X-ray table must be followed! Any other usage is considered improper and unintended! The supplier/manufacturer is not liable for personal injury or property damage as a result of improper operations or usage.

7. Rating plates

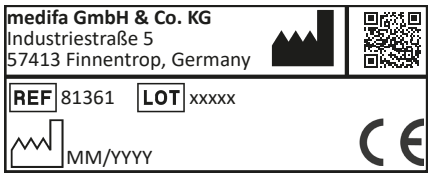


Abb. 1: Typenschild 81361

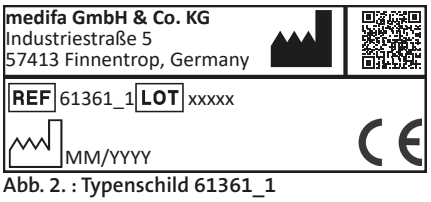
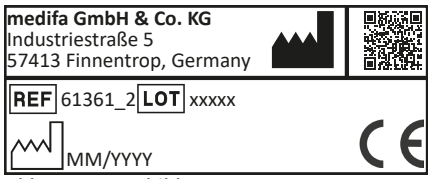


Abb. 2. : Typenschild 61361_1



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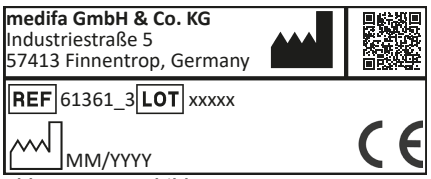


Abb. 4. : Typenschild 61361_3

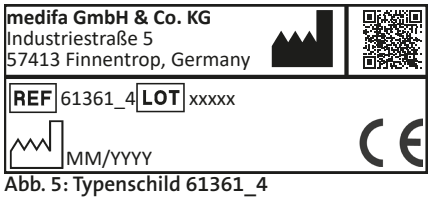


Abb. 5: Typenschild 61361_4

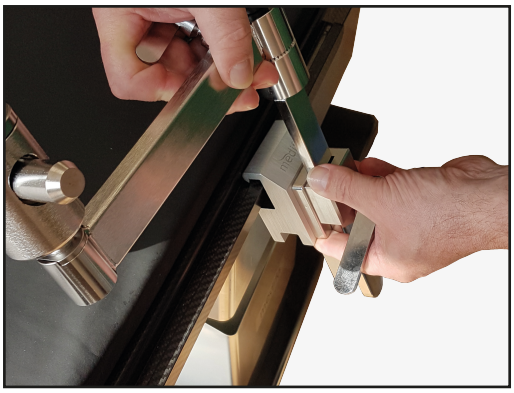
Elements / symbols	Description
	Manufacturer specifications and contact information
REF	Article number
LOT	Batch number
	QR code
	Date of manufacture
CE	This product is declared to be compliant with Directive 93/42/EEC.

8. Assembly and adjustment

8.1 Inspection of the product for damage

Make sure that all parts of the product are mechanically in order. The metal and the plastic parts must not have sharp edges or any kind of damage.

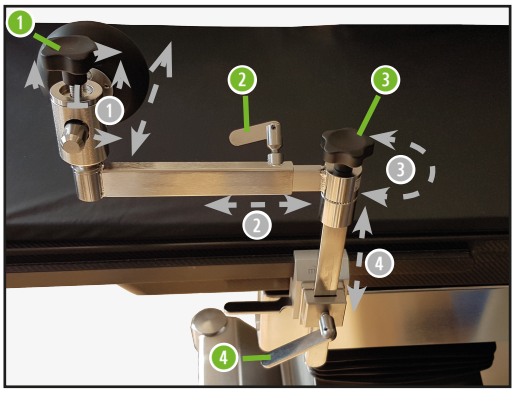
8.2 Attaching the holder of body supports



1. Hook the clamp into the carbon standard rail at the desired position from top to bottom.

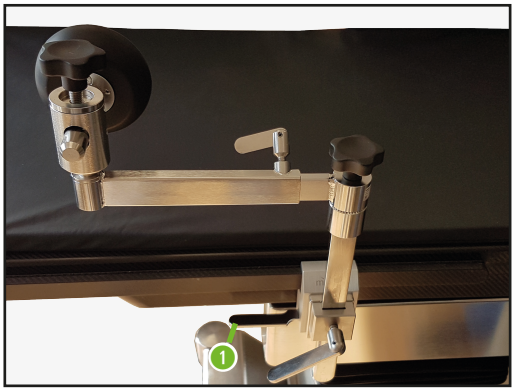
2. Fix the locking lever [1] of the holder of body supports.

8.3 Adjusting the body support system



1. By loosening the star knob screw [1], the body support can be swivelled, removed and inserted and replaced by another body support.
2. The length of the holder can be adjusted by loosening the locking element [2].
3. By loosening the star knob screw [3] the body support system can be swivelled.
4. The height of the bracket can be adjusted by loosening the locking element [4].

8.4 Removing the body support system



1. Release locking element [1] (point lever downwards).

2. Remove the holder upwards.

9. Care instructions

CAUTION

Risk of personal injury!
Only cleaned and disinfected products and devices may be handed over to a service technician for maintenance and repair work!

ATTENTION

Danger: incorrect care may damage property!
- Improper cleaning products can damage the surface!
- When cleaning the product, do not use scouring cleansers or detergents and disinfectants containing halide or peracetic acid.
- For the plastic parts, do not use alcoholic or solvent-based (flammable) cleaning/disinfecting agents!

The cleaning products for the cleaning and disinfection must comply with the applicable national regulations for the medical sector and/or be listed by the German Society for Hygiene and Microbiology / Association for Applied Hygiene.
Clean contaminated products immediately! The cleaning/disinfection is limited to a regular wiping (not dipping!) using the appropriate substance.

9.1 Cleaning

For cleaning stainless steel and plastic parts, use a pH-neutral or slightly alkaline all-purpose cleaner with surfactants for cleaning-active components. If parts are heavily contaminated, use concentrated cleaner and then wipe with clear water.

9.2 Disinfecting

For disinfecting, follow the instructions of the disinfectant manufacturer!
Surface disinfectants based on alcohol or aldehyde are suitable for disinfecting the stainless steel parts. For the plastic parts, only use aldehyde-based surface disinfectants. Alcohol-based agents can damage the surface..

9.3 Drying

After cleaning and disinfecting, remove excess moisture with a dry cloth.

9.4 Disposal

Dispose of all cleaning and disinfectant residues in a proper and environmentally friendly manner!

10. Technical specifications

10.1 Maße und Gewichte

Dimensions: Art.-no. 81361	Length: 325 mm
	Wide: 280 mm
Upholstery dimensions	Art.-no. 61361_1: Ø: 100 mm
	Art.-no. 61361_2/3: L x B: 220 x 110 mm
	Art.-no. 61361_4: L x Ø: 190 x 100 mm
Tare weight	Art.-no. 81361: 2,3 kg
	Art.-no. 61361_1 : 0,3 kg
	Art.-no. 61361_2/3: 0,5 kg
	Art.-no. 61361_4: 1,5 kg

10.2 Classification

Medical device class	I

12. Pictograms on the transport packaging

There are several handling symbols on the transport packaging.

Elements / symbols	Description
	Protect the transport packaging against moisture.
	Read the operating instructions.
	Protect from sunlight.
	Date of manufacture
	Follow the instructions for disposal.
	QR code

ATTENTION

Danger of damage to property
The packaging is not weatherproof! Please observe the storage instructions.

11. Disposal

The body support system and packaging must be recycled in an environmentally friendly manner. The disposal of individual parts must also be carried out in an environmentally friendly manner (i.e. according to the relevant legal regulations)!

For more information about the proper disposal of used products, please contact medifa Technical Support, your local dealer or the appropriate national authority.

The company medifa will take back old products, defective devices, or products no longer in use.
Contact medifa Technical Support for more details.

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