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Instructions for use UniLeg leg support

101.0369.0 (with side fin)

101.0678.0 (without side fin)

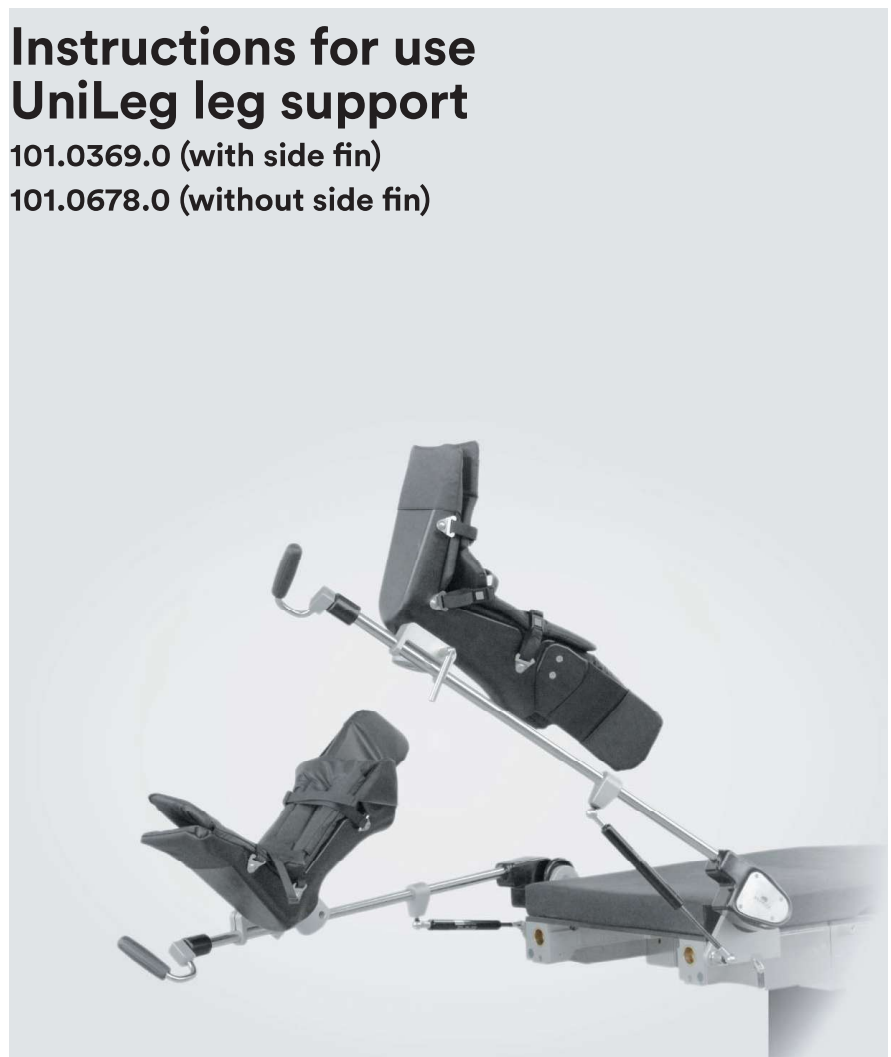


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These instructions for use

General

Addressees

These instructions for use must be read and observed by all persons who use, operate or clean this accessory. These instructions for use also contain information for those involved in storing, transporting, installing or disposing of the accessory at the end user's premises.

To be able to use the described accessory safely, the provisions of these instructions for use must be observed. National and local regulations take precedence over the provisions of these instructions for use. Please observe in particular warnings, ambient conditions, installation instructions, operating instructions, inspection regulations and maintenance instructions, as well as the standards listed in these instructions for use.

Information updates

These instructions for use reflect the state of knowledge at the time of printing and make no claim to completeness. The information provided in these instructions for use may be outdated due to the ongoing technical development of our devices. However, all information is regularly updated in revisions.

Illustrations

Illustrations in these instructions for use are not necessarily to scale.

Storage

Keep these instructions for use at the place of use of the accessory.

Tolerances

Minor deviations from the values set out in these instructions for use are caused by design factors and do not represent defects.

Performance characteristics

Performance characteristics of this accessory can be found in the "Intended use" chapter of these instructions for use.

Text symbols

A triangle before the text means:

- ▶ Execute this work step.
- ▷ Execute this partial work step.

A square before the text means:

- This is the result of the previous action.

A bullet point before the text means:

- This is part of an itemisation.

Warnings

The warnings contained in these instructions for use are graded according to the severity, type and probability of possible conse-

quences. They are classified according to the following definitions.

Warnings in chapters

Warnings relevant to the respective chapter can be found at the start of each chapter and apply to the entire contents of the chapter.

DANGER

“DANGER” refers to a hazardous situation which could result in serious injury or death if it is not avoided. Serious injuries are irreversible injuries requiring permanent and regular medical care.

WARNING

“WARNING” refers to a hazardous situation which could result in moderate to serious injury if it is not avoided. This includes reversible injuries requiring care or examination by a medical professional.

CAUTION

“CAUTION” refers to a hazardous situation which could result in slight to moderate injury if it is not avoided. This includes reversible injuries not requiring medical care.

NOTE

“NOTE” refers to information not relating to personal injury, e.g. information relating to damage to property.

RECOMMENDATION

Recommendations are information that helps readers use the device better, longer and more safely.

Warnings in the text

The warnings

 **DANGER**

 **WARNING**

 **CAUTION**

NOTE and

RECOMMENDATION

can be found in the text and refer to the subsequent action or situation. They have the same significance as the “warnings in chapters” as well as the same signal word and the same signal colour (see above).

Example:

 **WARNING** Risk of injury!

Accessories that have not been properly attached can suddenly come undone during use and could cause serious injury to patients, nursing staff and third parties! Therefore, always thoroughly tighten the fastening elements before use!

Responsibility of the manufacturer

SCHMITZ u. Söhne GmbH & Co. KG and the fitters, installers or importers commissioned by it only consider themselves responsible for the basic safety, reliability and performance of this accessory if

- assembly, extensions, corrective adjustments, changes or repairs are performed only by appropriately trained personnel,
- the electrical installation of the room concerned corresponds to the applicable requirements and
- the accessory is used exactly as described in the instructions for use,
- the accessory is used as intended,
- the accessory is used in sound condition.

Expected service life

Devices by SCHMITZ u. Söhne GmbH & Co. KG have an “expected service life” (as per IEC 60601-1:2005 + amendment:2006 + amendment:2007 + A1:2012) of 10 years, unless otherwise stated.

Technical changes

It is not permitted to modify this accessory without the consent of the manufacturer.

Replacement parts

Only use original replacement parts by SCHMITZ u. Söhne GmbH & Co. KG.

Important safety information

This accessory is state-of-the-art and was built according to recognised safety rules. Nevertheless, risks to the life and limb of users or third parties may occur, or this accessory and other assets may be adversely affected by the use of this accessory.

If the following measures are not observed, dangerous or life-threatening injuries to

patients, nursing staff and third parties may occur. The measures outlined in this chapter are subject to any other regulations that may be applicable in your country and organisation, including regulations regarding the cleaning of medical devices or patient positioning.

Attaching the leg support

Attach securely

Accessories (such as this device) can suddenly come loose during use and cause serious injury if it is poorly attached, worn out or damaged.

- ▶ When mounting this accessory, always ensure that it is properly attached, and check its condition.

A gas spring is not a carrying handle!

Using the gas spring on this accessory as a carrying handle can damage it!

It can bend or buckle as a result! This will stop it from working properly!

- ▶ Therefore, do not carry this accessory by the gas spring!

Positioning patients

Cover the pads!

- ▶ Cover the pads with a suitable sterile underlay.

No contact with electroconductive parts!

The use of HF surgical devices or defibrillator devices can easily result in serious accidents! Without appropriate safety precautions, HF surgical devices and defibrillator devices can cause severe electric shocks to patients and bystanders on the operating table! These can cause life-threatening injuries to patients!

- ▶ Place an electrically insulated underlay on the lying surface before putting the patient on the operating table!
- ▶ Make sure that the patient does not come into contact with electroconductive parts, especially when changing the patient's position.
- ▶ Observe the instructions for use in the user manual of the high-frequency surgical device / defibrillator device!

Observe the load limit

If loaded excessively, a material failure of this accessory may cause damage. This may cause patients to suffer serious injury.

- ▶ Do not place loads greater than the safe working load (as per Tab. 8 on page 39) on this accessory!

Position properly

Improper positioning of patients may impair their respiration, nervous system and circulatory system.

- ▶ The nursing staff are responsible for ensuring that the patients are positioned in such a way that no threats are posed to respiration, the nervous system or the circulatory system. This applies in particular to anaesthetised or unconscious patients.

Operation

Adjust carefully

This accessory could collide with body parts or other objects during adjustment, causing injury or damage.

- Make sure that there is sufficient clearance when performing adjustments!

Combining with accessories

Situation-dependent operator duties apply when you combine this device with accessories. There are two basic situations:

Situation	Operator's duties
1. The accessories used are listed in the "Approved accessories" chapter of these instructions for use. Load limits are also specified here.	This accessory has been tested and approved by SCHMITZ u. Söhne GmbH & Co. KG in combination with the device described in these instructions for use. The combination created satisfies the normative requirements. You do not need to take any further action in this respect. Some instructions for use for the combined devices restrict the use of the combination. (Examples include safe working load or permitted attachment point on the main device.) Observe these restrictions!
2. The accessories used are NOT listed in the "Approved accessories" chapter of these instructions for use.	For these accessories, you must provide evidence yourself that combining them with the device described in these instructions for use complies with the specifications of the standard. You can find the requirements and test procedures in IEC 60601-1:2005 + amendment:2006 + amendment:2007 + A1:2012, Section 16. These include ensuring that the accessories are undamaged and fail-safe.

Tab. 1
Operator's duties for the accessory used

When mounting accessories, always check the condition of the accessory, and make sure that it is attached securely!
Observe the guidelines in the instructions for use of the accessory!

Observe the load limits

Every accessory has its own approved patient weight, which may differ from that of another accessory or the main device. (These main devices include, for example, operating tables, examination chairs and patient stretchers.) Overloading can cause parts of the patient's body to suddenly fall off the chair. This may

lead to severe and even life-threatening injuries, particularly during treatment!

- ▶ Do not place loads greater than the lowest approved patient weight on the main device and accessories! (The approved patient weight of a device can be found in the "Technical Data" chapter of the respective instructions for use.)

Cleaning and disinfecting

Clean after use!

When used, pads absorb infectious germs which can spread to other users. As a result, patients can contract infections. It is also important to remember that infectious germs multiply extremely quickly in unclean and undisinfected residues.

- ▶ Therefore, clean and disinfect the pad after use!

Replace damaged pads.

Damaged pads (e.g. slit or torn) often contain stubborn infectious germs from normal use. These germs cannot be completely removed even by means of thorough disinfection. Upon contact with injuries or open skin areas, the infectious germs can be transferred to the bloodstream of the patient and third parties.

- ▶ Always replace damaged pads immediately!

Check

Checklist

This accessory requires regular inspection.

- ▶ Perform a visual and functional check regularly according to the device-specific checklist provided in these instructions for use.

Vigilance

Report serious incidents!

Serious incidents, which occur in connection with the accessory described, must also be reported to the manufacturer.

Repairing

Clean first.

During its use, this accessory comes into contact with materials that carry pathogens or harmful substances (e.g. bodily fluids). During repair works, minor injuries in particular can lead to infections.

- Thoroughly clean this accessory prior to performing repair work!

Do not use the leg support

Carrying out technical work to this accessory while it is in use can result in personal injury.

- Do not carry out any repair work, maintenance or inspections while this accessory is in use!

Disposal

Clean first.

During its use, this accessory comes into contact with materials that carry pathogens or harmful substances (e.g. bodily fluids). During repair works, minor injuries in particular can lead to infections.

- Thoroughly clean this accessory prior to disposal!

Regulatory issues

Device classification

The devices described in these instructions for use are accessories for class I medical devices when combined with the approved accessory parts in accordance with Annex VIII of Medical Device Regulation 2017/745/EU.

Harmonised standards such as IEC 60601-1:2005 + amendment:2006 + amendment:2007 + A1:2012 and other relevant standards as well as the corresponding special parts have been demonstrably applied.

The devices thus satisfy the basic safety and performance requirements in accordance with Annex I of EU Regulation 2017/745/EU.

Intended use

Only uses listed in this “Intended use” chapter are deemed to be intended for the purposes of IEC 60601-1:2005 + amendment:2006 + amendment:2007 + A1:2012. Any other use will result in an exclusion of liability.

The UniLeg leg support is intended only for the purposes of human medicine in combination with the approved accessories.

The UniLeg leg support should only be used for the following purposes:

- for positioning the patient’s legs during surgery and the anaesthetic and recovery stages on operating tables,
- for positioning the patient’s legs during examination and treatment on gynaecological chairs.

It may only be used to hold patients up to a maximum body weight of 182 kg.

This accessory is designed to be used together with operating tables or examination chairs by SCHMITZ u. Söhne GmbH & Co. KG. Compatibility and appropriate use with devices by other manufacturers must be confirmed by checking the respective instructions for use.

The device may only be used as described in the instructions for use. Permitted user groups for this accessory are:

- trained medical personnel (physician/nurse),
- hospital technicians,
- trained cleaning staff.

The device is only approved for use in Group 0, 1 and 2 medical areas as per IEC 60364-7-710:2002, modified / HD 60364-7-710:2012.

An essential performance of this accessory is as follows: no unintentional movement in the event of a “single fault condition” or combinations of faults. A definition of these terms can be found in the glossary of these instructions for use.

Description

Diagram

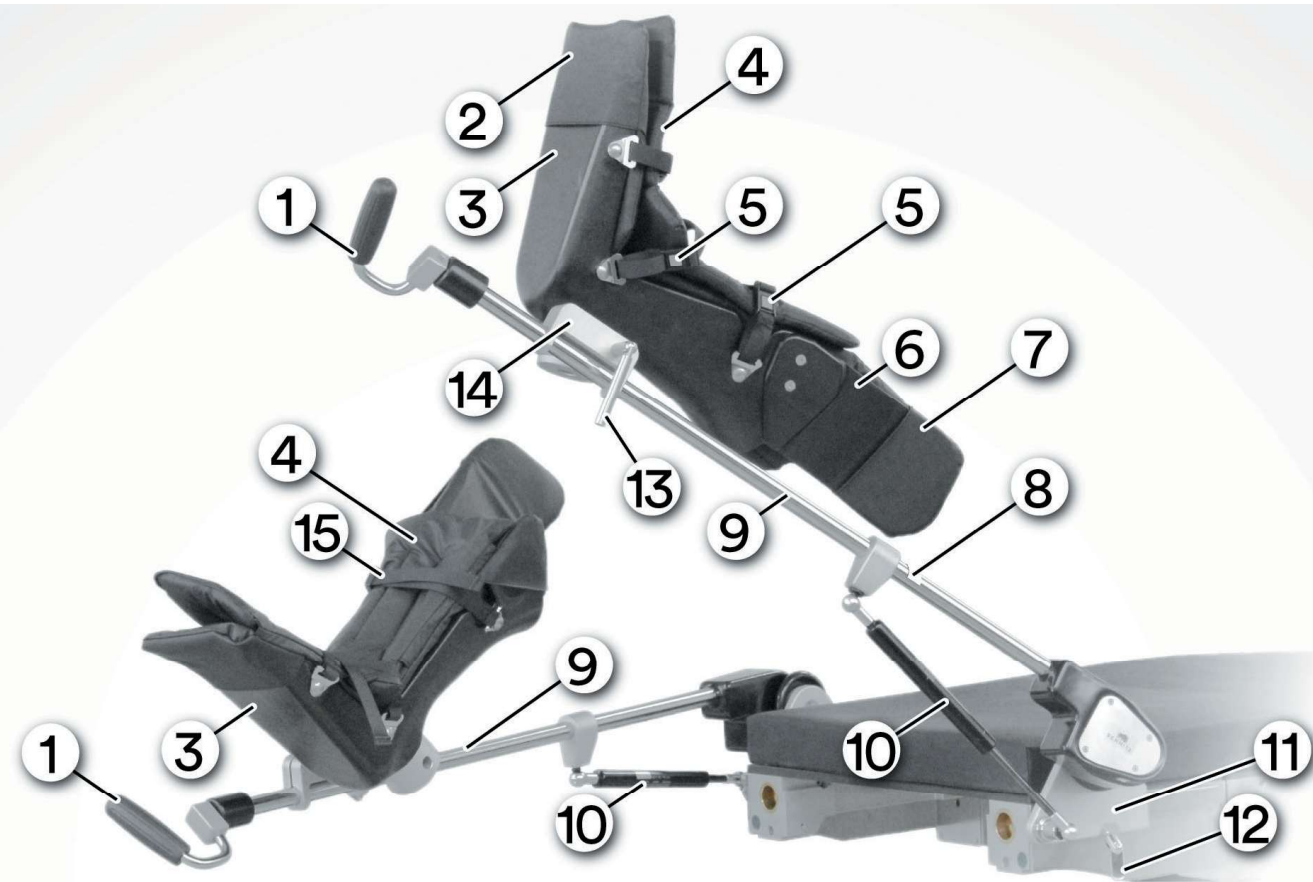


Fig. 1
UniLeg leg support (pictured here with side fin, illustration may vary)

① Release handle	② Front sleeve	③ Support boot
④ Padded cover 7.4.4.4 p	⑤ Quick-release buckle	⑥ Side fin
⑦ Back sleeve	⑧ Identification plate	⑨ Slide tube
⑩ Gas spring	⑪ Side rail adapter	⑫ Clamping screw with locking mechanism
⑬ Clamping lever 7.4.4.1 p	⑭ Carriage	⑮ Strap

Tab. 2
Position numbers for the illustration above

Features

The UniLeg leg support consists of a support boot which can be moved along a slide tube. The support boot can rotate and tilt. You can adjust the slide tubes vertically and horizontally by turning the release handles.

The side rail adapter is used to attach the leg support to the operating table/examination chair. The padding of the support boot is black and electroconductive.




Delivery

SCHMITZ u. Söhne GmbH & Co. KG and/or its distribution partners are usually responsible for storing this accessory prior to shipping and transport to the end customer and unpacking the delivered accessory at the place of use.

This chapter is intended for those who handle storage of the accessory prior to shipping and transport of the accessory to the end customer's premises and unpacking of the supplied accessory at the place of use.

Storage

During transport to the place of destination and during storage, specific requirements apply for the ambient conditions. These requirements may deviate from the ambient conditions required during operation. The admissible ambient conditions during transport to the destination and during storage are indicated by symbols on the packaging. For the ambient conditions permitted for storage and transportation, please see Tab. 3.

Parameters	Limits	Symbol
Temperature	-20°C - +50°C	
Relative humidity	10% - 95%	
Air pressure	500 - 1,060 hPa	

Tab. 3
Ambient conditions permitted during storage and transport

Mounting

Safety information

⚠ DANGER

Risk of serious injury!

If you use accessories that are

- 1) insufficiently secured
- 2) worn or
- 3) damaged

they can unexpectedly come loose during use and cause life-threatening injury to patients (for example during surgery).

For this reason, when mounting accessories always ensure that they are properly attached, and review the condition of the accessory!

Side rail adapter

Attaching the side rail adapter

- ▶ Undo the clamping screw with locking mechanism on the side rail adapter.
- ▶ Slide the side rail adapter all the way onto the side rail.

⚠ WARNING Risk of injury!

If you do not attach the side rail adapter to the side rail so that it fully clasps the side rail, you will put patients and bystanders at risk!

Incorrectly attached side rail adapters can slip off the side rail. This can cause the attached accessories to suddenly swivel and fall, which in turn could injure patients and bystanders! Therefore, when attaching the side rail adapter, make sure that the side rail protrudes out of the side rail adapter on the left and right!

- ▶ Tighten the clamping screw with locking mechanism.

Removing the side rail adapter

- ▶ Undo the clamping screw with locking mechanism on the side rail adapter.
- ▶ Lift the side rail adapter off the side rail.

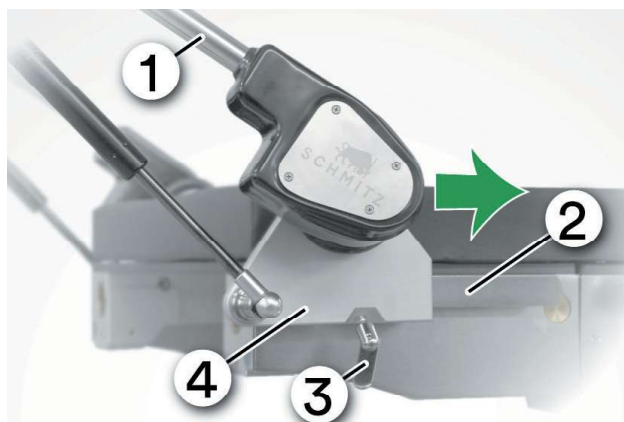


Fig. 2

Attachment

1) Slide tube 2) Side rail 3) Clamping screw with locking mechanism 4) Side rail adapter

Pad

Inserting the pad

- Set the three straps on the support boot Fig. 3 aside.



Fig. 3
Support boot without pad
1) Side fin



Fig. 4
support boot with attached pad

① Padded cover 7.4.4.5 p.	② Front sleeve	③ Buckle connector
④ Strap	⑤ Quick-release buckle	⑥ Back sleeve

Tab. 4
Position numbers for the illustration above

- Place the padding in the support boot as shown in Fig. 4.
- If the leg support features a side fin, the sleeve of the padding goes onto the side fin. Otherwise, the sleeve of the padding goes onto the back of the support boot.
- Guide the padding in such a way that the side fin/back of the support boot goes into the back sleeve.
- Guide the padding in such a way that the front of the support boot goes into the front sleeve.

Removing the pad

- Remove the sleeve of the padding from the front of the support boot.
- Remove the sleeve of the padding from the side fin/back of the support boot.
- Remove the pad.

Preparation

Cover the pads!

- Cover the pads with a suitable sterile underlay.

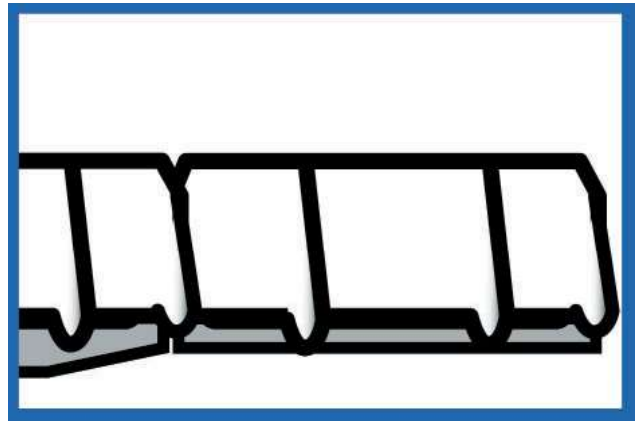


Fig. 5
Cover the pads!

Operation

Safety information

DANGER

Risk of serious injury!
Overloading accessories can cause life-threatening injury to patients!
Each accessory has a dedicated safe working load. (The safe working load can be found in chapter “Technical data” on page 39.)
Overloading can cause parts of the patient’s body to suddenly fall off the chair. This could prove life-threatening, especially during an operation!
Therefore, do not place loads greater than the safe working load on this accessory!

DANGER

Risk of serious injury!
The use of HF surgical devices or defibrillator devices can easily result in serious accidents! Without appropriate safety precautions, HF surgical devices and defibrillator devices can cause severe electric shocks to patients and bystanders on the operating table! These can cause life-threatening injuries to patients!
Place an electrically insulated underlay on the lying surface before putting the patient on the operating table!
Make sure that the patient does not come into contact with electroconductive parts, especially when changing the patient’s position.
Observe the instructions for use in the user manual for the high-frequency surgical device/defibrillator device!

WARNING

Risk of injury!
Using the leg support when the locking elements are not fully tightened puts patients at risk!
Locking elements (side rail adapter, carriage, etc.) that are not correctly tightened can come loose. As a result, the patient’s leg can move suddenly, for example during surgery, and cause serious injury to the patient!
Therefore, securely tighten the locking elements before using them! Make sure that the locking mechanism cannot move!

WARNING

Risk of injury!
You can undo the locking elements and move this accessory while it is in contact with the patient.
If you do not support or secure the patient in this situation by other means, you will put people at risk. When you undo the locking elements, the accessory will no longer support or secure the patient. As a result, body parts could unexpectedly move. This could injure patients!
Therefore, support or secure the patient’s relevant body parts by other means before undoing the locking elements!

NOTE

Risk of damage!
Using this accessory when it is not working correctly can result in damage to property. Therefore, make sure that this accessory is working properly before using it!

Ambient conditions

During operation there are specific limits that apply with regard to the ambient conditions. To view the list of ambient conditions permitted for operation, please see Tab. 5.

Ambient condition	Value
Ambient temperature	+10°C - +40°C
Relative humidity	10% - 95%, non-condensing
Permitted operating height	Maximum 4000 m above sea level

Tab. 5
Permissible ambient conditions during operation

Securing the lower leg / Removing it from the support boot

Fixing the lower leg in position

- ▶ Undo the quick-release buckles (if not already undone).
 - ▷ Press the sides of the quick-release buckle together.
 - The quick-release buckle will release.
- ▶ Fold the padded cover to the side.
- ▶ Place the patient's foot in the padded support boot as shown in Fig. 6.
- ▶ Wrap the padded cover around the foot.
- ▶ Secure the padded cover to the support boot with the three straps.
 - ▷ Insert the buckle connector into the buckle.
 - You will hear a click.
 - ▷ Tighten the strap.



Fig. 6
Wrap the padded cover around the foot

Removing the lower leg from the support boot

- ▶ Undo the quick-release buckles.
 - ▷ Press the sides of the quick-release buckle together.
 - The quick-release buckle will release.
- ▶ Fold the padded cover to the side.
- ▶ Take the patient's foot out of the support boot.



Fig. 7
Undo the quick-release buckles
1) Quick-release buckle

Adjusting the leg support

You can set the following parameters when the release handle is released:

- height of the support boot and
- distance between the support boots.

7.4.2 p.

You can set the angle vertically between -35° and $+60^{\circ}$.

You can set the angle horizontally between -21° and $+21^{\circ}$.

7.4.3 p.



Fig. 8
Horizontal adjustment (top view, not to scale)

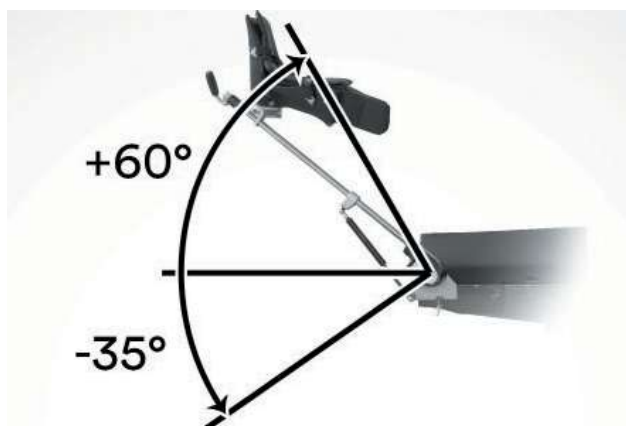


Fig. 9
Vertical adjustment (side view)



Fig. 10
Turn release handle (top arrows), adjust slide tubes (bottom arrows)
1) Release handle 2) Slide tube

- ▶ Turn the release handles as shown in Fig. 10.
- ▶ Move the slide tubes to the required position.
- ▶ Let go of the release handles.

Move the support boot

You can set the following parameters when the clamping lever is released:

- the rotation angle of the support boot around the slide tube,
- the rotation angle around the mounting axle,
- the distance of the support boot from the operating table/examination chair and
- the tilt of the support boot.

- Release the clamping lever as shown in Fig. 11.



Fig. 11
Releasing the clamping lever
1) Clamping lever

- Rotate the support boot around the slide tube to the required rotation angle as shown in Figure 13.

⚠ CAUTION Risk of injury!

Holding the leg support by the carriage can result in injury!

Limbs can get caught both on the carriage and between the cradle and locking element. You could get crushed as a result.

Therefore, do not hold the leg support by the carriage!



Fig. 12
Rotate the support boot around the slide tube

- Rotate the support boot around the mounting axle to the required rotation angle.



Fig. 13
Rotate the support boot around the mounting axle
1) Clamping lever

- ▶ Move the support boot along the slide tube until it is the required distance from the operating table/examination chair as shown in Fig. 14.
 - ▷ Hold the bottom of the support boot.
 - ▷ Raise the support boot slightly.
 - There is slightly less weight on the carriage.
 - ▷ Move the support boot and carriage to the required position.



Fig. 14
Move the support boot

- ▶ Rotate the support boot to the required tilt angle as shown in Fig. 15.
- ▶ Tighten the clamping lever.

You can change the tilt angle even when the clamping lever is tightened. This requires more effort than when the clamping lever is released.



Fig. 15
Tilt the support boot

Cleaning and disinfecting

This chapter describes the rules that have to be observed when cleaning and disinfecting this device.

In addition, in-house rules for cleaning and disinfecting that result from the operational duties of your hospital / your clinic / your surgery apply. Furthermore, the instructions of the cleaning and disinfectant manufacturers must be observed.

Accessories by manufacturers other than SCHMITZ u. Söhne GmbH & Co. KG have their

own cleaning information which can be found in the instructions for use for the respective accessory.

Observe the regulations in effect in your country and at your organisation for the cleaning and disinfection of medical devices! Observe the safety and operating information of the cleaning and disinfectant manufacturer, the applicable hygiene rules as well as the occupational health and safety rules!

NOTE

Risk of damage!

Using unsuitable disinfectants will damage the surface of the device! Therefore, only use disinfectants with the following active ingredient combinations:

- aldehyde (e.g. formaldehyde)
- quaternary ammonium compounds ('Quats')
- guanidine derivatives

Do not use the following for cleaning and disinfection:

- abrasives or solvents, in particular organic solvents such as benzene, benzol or acetone
- products containing alcohol (e.g. skin disinfectant)
- solutions that contain or split off halides (e.g. fluorine, chlorine, iodine or bromine)
- abrasive cleaning agents (e.g. wire brushes, steel wool)
- water containing ferrous particles
- cleaning sponges containing iron
- products containing hydrochloric acid
- saline or isotonic solutions
- machine cleaning procedure
- moist heat procedure
- Sprays
- High-pressure cleaner



Fig. 16
Use the correct disinfectant!
Do not use solutions containing alcohol!

NOTE

Risk of damage!

If you spray or splash cleaning or disinfectant fluids on a device, you could irreparably damage the device. Sprayed and splashed liquids can get into mechanical and electronic parts. As a result these parts will rust and be damaged.

Therefore only ever apply cleaning and disinfection fluids by wiping the device with a cloth soaked in the cleaning or disinfection fluid!

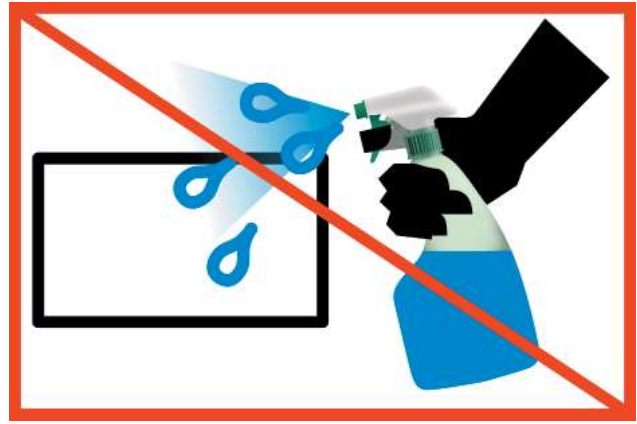


Fig. 17
Do not spray!

Clean and disinfect devices by SCHMITZ u. Söhne GmbH & Co. KG immediately after use! This also applies to newly delivered devices. Devices by SCHMITZ u. Söhne GmbH & Co. KG are not delivered sterile. Unless expressly stated otherwise in the corresponding instructions for use, the devices are not suitable for sterilisation.

- ▶ Remove the pad from the supporting surface if this is possible.
- ▶ Clean the device. For best results use “Cleaner 500” (cleaning set with brush: art. no. 2026973). Alternatively, you can also use a mild alkaline cleaner, e.g. mild cleaning agent or soap and water. Follow the instructions of the cleaning agent.
- ▶ Remove any cleaning agent residue.

- ▶ After cleaning the device, dry it with an absorbent lint-free cloth.
- ▶ Disinfect with a suitable surface disinfectant. An up-to-date list of suitable surface disinfectants and the recommended concentrations can be obtained from the Technical Service of SCHMITZ u. Söhne GmbH & Co. KG (contact details: see next chapter “Technical Service”).
- ▶ Allow the disinfectant solution to air dry. Do not wipe off the solution. Wiping transfers new germs to the disinfected surface.
- ▶ Check the device after cleaning/disinfection for freedom of movement, corrosion, damaged surfaces, chipping and any remaining dirt.
- ▶ Replace damaged devices.

Stainless steel parts

NOTE

Risk of damage!

If you do not handle items with stainless steel surfaces correctly, they may rust prematurely. Care must be taken to prevent the stainless steel surface from being damaged by scratches, the use of unsuitable cleaning agents, or prolonged contact with chlorides, acids, humidity, iron, or similar! Always observe the following directive for the cleaning, storage and use of stainless steel parts!

Cleaning

Always keep stainless steel parts clean and dry!

On a daily basis, remove harmful substances such as

- dried blood
- skin disinfectant
- limescale
- grease
- starch and
- protein layers!

RECOMMENDATION

If such harmful substances should come into contact with the stainless steel surfaces, remove these substances as quickly as possible!

Do not allow the stainless steel products to come into contact with iron or steel (shavings from wires, ferrous water) or with other metals!

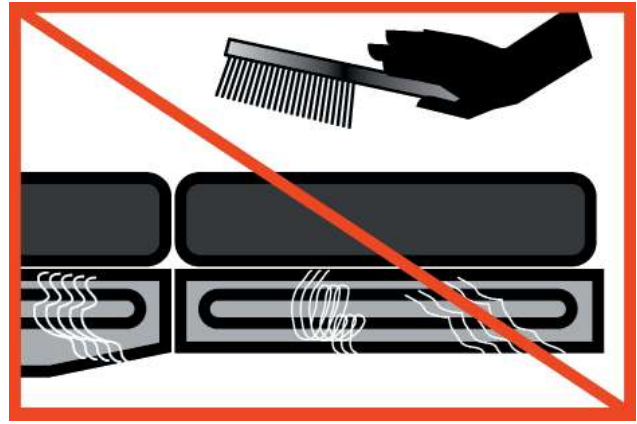


Fig. 18
Do not scratch stainless steel parts!

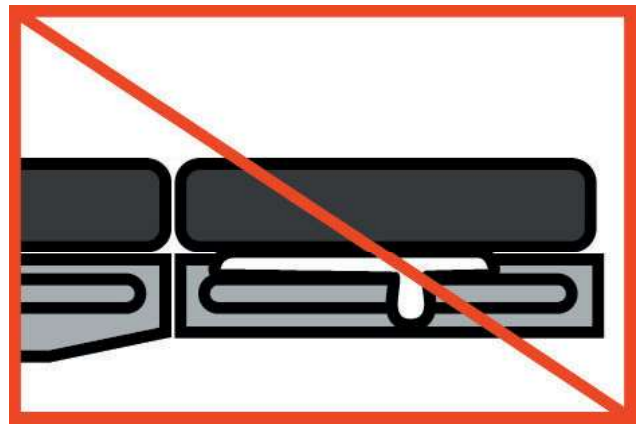


Fig. 19
Remove any skin disinfectant residue from stainless steel parts!

- ▶ Remove liquids, signs of corrosion, dried blood, etc. from stainless steel parts.
 - ▷ Only clean using standard cleaning agents for stainless steel products! Refer to the list of prohibited substances and procedures on Page 25. This must be observed stringently for stainless steel surfaces and harmful substances like concentrated acids, acid fumes, salts, chloride, etc.
 - ▷ For mechanical cleaning, only use brushes with natural or plastic bristles!
 - ▷ Do not use steel wool or steel brushes for mechanical cleaning!
 - ▷ Do not damage the surface of stainless steel products through scratching, scraping, etc.!
- ▶ After each cleaning, always remove all cleaning agent residues by wiping the surface thoroughly with fresh water!
- ▶ Carefully dry the surface!

Retaining

- Always remove cleaning fluid residues prior to storage!
- Always store stainless steel products carefully so that they are accessible to air.

Pads

⚠ WARNING

Danger of infection!

Using damaged pads can infect patients and third parties with pathogens.

Damaged pads (e.g. slit or torn) often contain stubborn pathogens from normal use. They cannot be completely removed even by means of thorough disinfection. Upon contact with injuries or open skin areas, these pathogens can be transferred to the bloodstream of the patient and third parties.

Therefore, always replace damaged pads immediately!

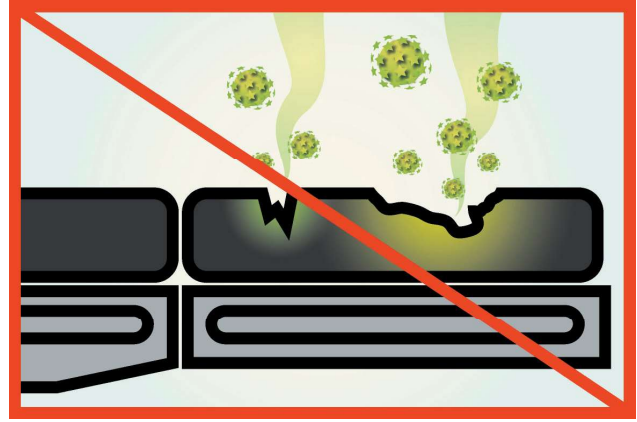


Fig. 20
Never use damaged pads!

⚠ CAUTION

Danger of infection!

Rinsing or pouring water over the pads puts the health of patients and users at risk!

The pads absorb water if they are in water for a long time. The absorbed water could multiply germs. This could infect patients and users! Contact with a damp cloth, however, is quite safe.

Therefore, do not rinse the pads! Do not pour water over the pads! Clean the pads by wiping them down with a damp cloth!

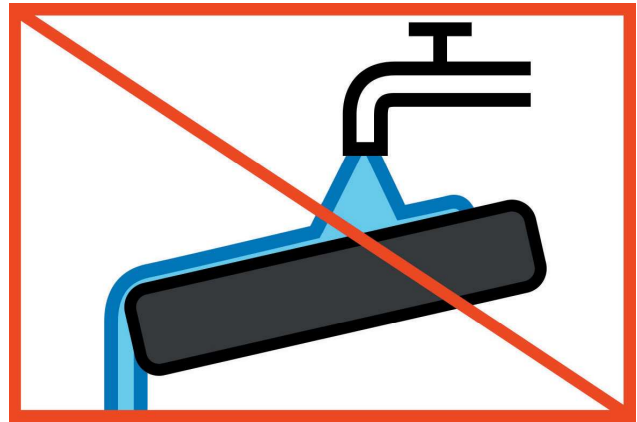


Fig. 21
Do not douse the padding with water!

NOTE

Risk of damage!

Exposing the pads to high temperatures can damage the pads. High temperatures will deform the pads and make them hard. It also reduces the adhesive strength of the adhesive gel strips.

For this reason, when cleaning and disinfecting the pad, do not employ any method with temperatures over 80°C.

NOTE

Risk of damage!

Skin disinfectants or wound and mucous membrane disinfectants that come into contact with the pads could react with the pad surface. The pad surface will disintegrate and be damaged beyond repair.

Therefore, remove all disinfectant residue from the pad surface by using a clean cloth to wipe over the area several times where the disinfectant was spilled on the pad.

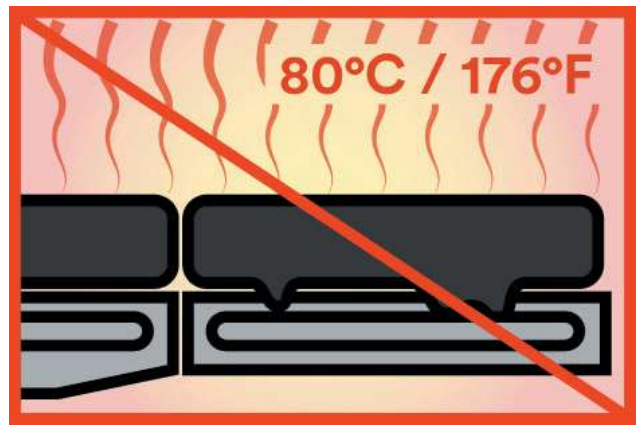


Fig. 22

Do not heat to over 80°C!

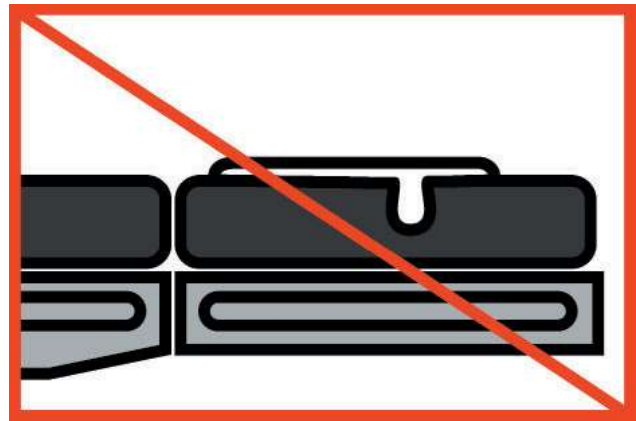


Fig. 23

Remove disinfectant residue immediately

Padded surfaces

- ▶ Dirty pads must be cleaned and disinfected immediately!
- ▷ For best results use “Cleaner 500” (cleaning set with brush: art. no. 2026973). Alternatively, you can also use a mild alkaline cleaner, e.g. mild cleaning agent or soap and water. Follow the instructions of the cleaning agent.

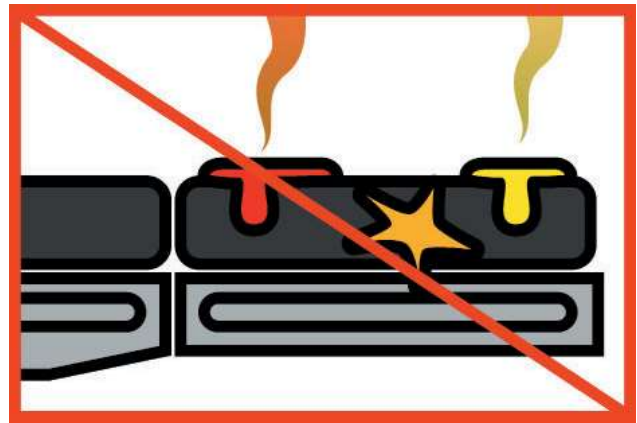


Fig. 24
Clean and disinfect dirty pads immediately!

- ▷ Disinfect with a suitable surface disinfectant. An up-to-date list of suitable surface disinfectants and the recommended concentrations can be obtained from the Technical Service of SCHMITZ u. Söhne GmbH & Co. KG (contact details: see next chapter “Technical Service”).
- ▷ Allow the disinfectant solution to air dry. Do not wipe off the solution. Wiping transfers new germs to the disinfected surface.
- ▷ Regularly remove any organic salt residue from the disinfectant solution (approx. every three months)! In addition, use a cleaner with non-ionogenic tensides or “Cleaner 500”.

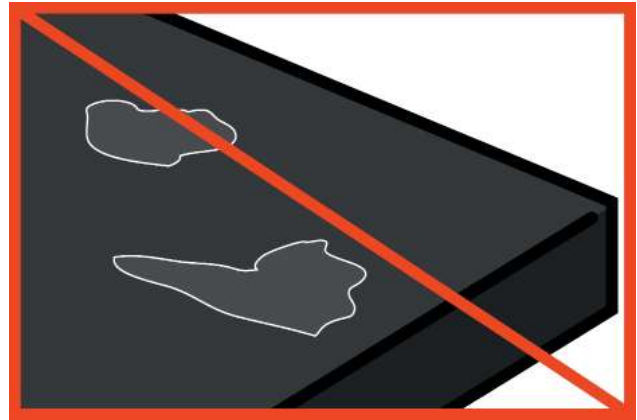


Fig. 25
Regularly remove organic salt residue!

Technical Service

When asking service questions, always state the following numbers, which appear on the identification plate of your device:

- the model number (on the identification plate after “REF”) and
- the ID number (on the identification plate after “LOT”).

See the “Identification plate” chapter for the location of the identification plate. If the identification plate is damaged, please contact Technical Service at SCHMITZ u. Söhne GmbH & Co. KG.

Technical service contact details

Telephone: +49 (0) 2377 84 549
Fax: +49 (0) 2377 84 210
Email: service@schmitz-soehne.de

Replacement parts

Replacement parts can be ordered from your authorised dealer or directly from Technical Service at SCHMITZ u. Söhne GmbH & Co. KG.

Wear parts

SCHMITZ u. Söhne GmbH & Co. KG devices contain components subject to wear as a result of their design, function or chemical composition, or which may wear due to improper use. These wear parts include pneumatic springs, batteries and pads.

Faults and repairs

In the event of malfunctions, please contact your dealer, or call Technical Service at SCHMITZ u. Söhne GmbH & Co. KG directly. Only personnel authorised by the manufacturer may carry out repairs on SCHMITZ u. Söhne GmbH & Co. KG devices. Unauthorised intervention with your device voids the warranty.

DANGER Risk of infection!

Repairing dirty accessories can spread infection. During its use, the accessory comes into contact with materials that carry pathogens or harmful substances (e.g. bodily fluids). During repair works, minor injuries in particular can result in the transmission of these pathogens. Therefore, first thoroughly clean and disinfect the accessory before having it repaired!

WARNING Risk of injury!

Carrying out technical work to an accessory while a patient is on it can cause accidents. This could result in personal injury. Therefore, do not carry out technical work while the accessory is in use.

Under the General Terms and Conditions, these wear parts are not covered by the two-year warranty period. For these wear parts, SCHMITZ u. Söhne GmbH & Co. KG provides a one-year warranty.

Servicing

SCHMITZ devices represent the highest quality, durability and reliability. You can significantly extend the service life with regular and professional prevention in the form of inspection and maintenance. A longer life cycle means greater economic efficiency for you.

What does servicing involve?

Servicing includes the following:

- an inspection (including a safety check of electrical devices in accordance with EN-IEC 62353:2014) and
- maintenance, if necessary.

(The visual and functional check as per the checklist in this chapter is not considered servicing.)

How often is servicing required?

Servicing takes place at set intervals. This device should be serviced every two years, and every year from the fifth year. There may be a service label on your device. This states when the next service is due.

Who can perform servicing?

Servicing may only be performed by:

- the SCHMITZ u. Söhne GmbH & Co. KG Service Team or
- authorised service partners of SCHMITZ u. Söhne GmbH & Co. KG.

Call the Service Team hotline to find out which organisation is responsible for your country (telephone number and email address: see previous page).

What are the advantages of the Service Agreement?

We recommend taking out a Service Agreement with the Service Team of SCHMITZ u. Söhne GmbH & Co. KG.

- Your individual Service Agreement offers very attractive terms compared to the standard list prices.
- SCHMITZ will let you know when your next service is due. This allows you to plan the service in advance when it suits you.
- Predictable costs with maximum service life thanks to preventive maintenance by certified professional service staff.

Visual and functional checks

For proper operation, visual and functional checks must be performed by a trained inspector prior to every use.

The results of the visual and functional checks are to be documented with the date and signature of the tester. The following table can be used as a template.

Checklist

1. Has this accessory been cleaned and disinfected in accordance with the hygiene guidelines in effect at your hospital/clinic?

- | | | | |
|--------------------------|--|--------------------------|--|
| <input type="checkbox"/> | ► No actions are required for this item. | <input type="checkbox"/> | ► Stop using the accessory for the time being. |
| Yes | | No | ► Clean and disinfect the accessory. |

2. Do the pads show signs of cracking or damage?

- | | | | |
|--------------------------|--|--------------------------|------------------------|
| <input type="checkbox"/> | ► No actions are required for this item. | <input type="checkbox"/> | ► Stop using the pads. |
| Yes | | No | |

3. Is there any external damage visible on the accessory?

- | | | | |
|--------------------------|--|--------------------------|--|
| <input type="checkbox"/> | ► Stop using the accessory for the time being. | <input type="checkbox"/> | ► No actions are required for this item. |
| Yes | ► Notify Technical Service. | No | |

4. Are all of the locking elements (carriage, side rail adapter) working?

- | | | | |
|--------------------------|--|--------------------------|--|
| <input type="checkbox"/> | ► No actions are required for this item. | <input type="checkbox"/> | ► Stop using the accessory for the time being. |
| Yes | | No | ► Notify Technical Service. |

5. Can the device's adjustment functions be moved to the end positions?

- | | | | |
|--------------------------|--|--------------------------|--|
| <input type="checkbox"/> | ► No actions are required for this item. | <input type="checkbox"/> | ► Stop using the accessory for the time being. |
| Yes | | No | ► Notify Technical Service. |

6. Are the strap and quick-release buckle intact?

- | | | | |
|--------------------------|--|--------------------------|--|
| <input type="checkbox"/> | ► No actions are required for this item. | <input type="checkbox"/> | ► Stop using the accessory for the time being. |
| Yes | | No | ► Notify Technical Service. |

Date

Signature of the inspector

--	--

Tab. 6
Checklist for visual and functional checks

Disposal

DANGER

Danger of infection!

Disposing of dirty accessories can spread infection. During its use, the accessory comes into contact with materials that carry pathogens or harmful substances (e.g. bodily fluids). During disposal, minor injuries in particular can result in the transmission of these pathogens.

For this reason, thoroughly clean and disinfect accessories prior to disposal!

Dispose of the components of this accessory (e.g. metal parts, electronic components, foam (e.g. pads), PVC parts (e.g. bellows), hydraulic oil etc.) according to the applicable national regulations.

To dispose of this accessory, please contact the Technical Service of SCHMITZ u. Söhne GmbH & Co. KG. In EU member states, Directive 2012/19/EU must be observed for electrical equipment (e.g. no disposal via municipal collection points, obligation to notify of proper disposal in the event of transfer to commercial third parties).

Device identification

Identification plate



Fig. 27
Identification plate (sample)

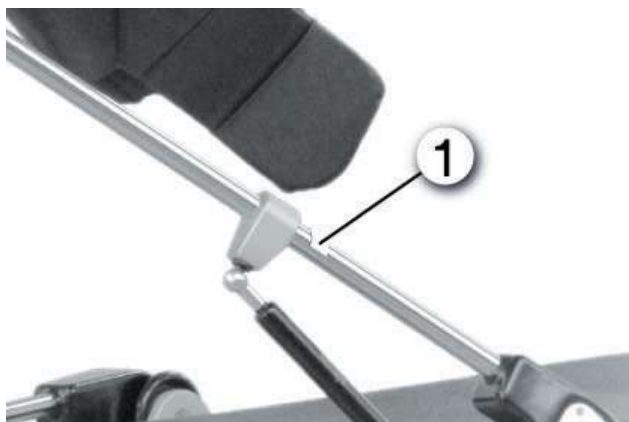














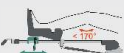

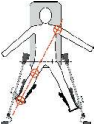
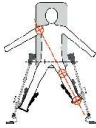

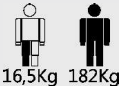






Fig. 28
Position of the identification plate on the
UniLeg leg support
1) Identification plate

Symbols used

Tab. 7 explains pursuant to IEC 60601-1:2005 + amendment:2006 + amendment:2007 + A1:2012, chap. 7.6, the symbols used in the lettering on the accessory. This also includes symbols on labels, on the identification plate and on the packaging.

Symbol	Meaning	Symbol	Meaning
	Name and address of the manufacturer		Date of manufacture
	Centre of gravity		Permitted temperature range for transport and storage
	Permitted air humidity range for transport and storage		Permitted air pressure range for transport and storage
	Top		Fragile, handle with care
	Protect against moisture		Applied part, Type B
	Weight of the accessory		Always use the device in accordance with the instructions for use.
	Press the release handle down to adjust the leg support		Press the release handle down to adjust the leg support
	Positioning tip: do not fully extend the patient's leg when it is in position!		Positioning tip: do not fully extend the patient's leg when it is in position!
	Positioning tip: do not spread the patient's legs too far apart! The imaginary line running through the ankle joint/knee joint and extending to the head should pass <i>between</i> the two shoulder joints.		
			
	Always use the device in accordance with the instructions for use.		The safe working load per leg support is 16.5 kg. This is equivalent to a patient weight of 182 kg.
	Attention! Risk of crushing!		Indicates a medical device
	Packaging is recycled in Germany under the RESY system		This device satisfies the requirements of EU Regulation 2017/745/EU, Annex I.

Tab. 7
Symbols used and what they mean

Approved accessories

There are no approved accessories for this device.

Technical data

Subject to design and dimensional changes.
Minor deviations from the values set out in these instructions for use are caused by design factors and do not represent defects.

Parameters	Value
Total length	7.4.1 p. 1,140 mm
Total width	270 mm (per unit)
Total height	420 mm
Net weight	7 kg (per unit)
Adjustment range	Vertical: -35° to 60° Horizontal: -21° to +21° Along the slide tube: 480 mm to 880 mm
Safe working load (see “Glossary” on page 42)	16.5 kg
Maximum patient weight	7.4.4.2 p. 182 kg
Expected service life (see “Glossary” on page 42)	10 years
Pads	electrically conductive, black, smooth

Tab. 8
Technical data of this accessory

Declaration of conformity



EU-Konformitätserklärung für Medizinprodukte

Declaration of EU-Conformity for Medical Devices

Hersteller SCHMITZ u. Söhne GmbH & Co. KG

Manufacturer

Hauptfirmensitz Zum Ostenfeld 29
Place of Business D-58739 Wickede (Ruhr)

Wir erklären in alleiniger Verantwortung, dass das Produkt:

Declares under sole responsibility that the product:

Beinhalter UniLeg – für Operationstische und Untersuchungsstühle, allgemein

UniLeg leg supports for operating tables and examination chairs, general

Basis-UDI-DI:	4049199UNILEG4H
----------------------	-----------------

Modellbezeichnung / Designation	Katalog Nr. / Catalogue No.	UDI-DI
Beinhalter UniLeg (Paar) mit Peroneusschutz / UniLeg leg supports (pair) with peroneal nerve protection	101.0369.0	4049199009223
Beinhalter UniLeg (Paar) / UniLeg leg supports (pair)	101.0678.0	4049199009513

Verwendete UDI-PI: (10) LOT / Verkaufsauftragsnummer und (21) Seriennummer

Produkt-Code gemäß Nomenklatur UMDNS: 12-315

Product Code from nomenclature UMDNS:

Zweckbestimmung

Intended Purpose

Die Beinhalter dienen der Lagerung der Beine des Patienten vor, während und nach einer Operation, bzw. der Untersuchung und der Behandlung.

The leg supports are used to support the patient's legs before, during and after an operation, or for examination and treatment.

Risiko-Klassifizierung

Risk Class

Klasse I

gemäß der Klassifizierungsregel 1 des Anhanges VIII der Konsolidierte Version der Verordnung (EU) 2017/745 über Medizinprodukte (MDR) in der letztgültigen Fassung.

Class I

According to the Classification rule 1 of Annex VIII of the Consolidated version of the regulation (EU) 2017/745 on medical devices (MDR) as last amended.

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Zum Ostenfeld 29
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Deutschland
T +49 (0)2377 84 0
zentrale@schmitz-soehne.de

Single Registration Number (SRN)

DIMI-Di-Herstellercode
DE/0000009918

Seite 1 von 2

Geschäftsführer
Bernhard Schmitz, Ludolf Schmitz,
Friedrich Schmitz, Matthias Schmitz

Steuer-Nr.
343/5795/0019

Amtsgericht Arnsberg HRA 4554
Persönlich haftende Gesellschafterin:
SCHMITZ u. Söhne GmbH
Amtsgericht Arnsberg HRB 4087
USt-IdNr. DE 126635552
WEEE DE 90062386
Gläubiger-ID
n266511540000007888

Fig. 29
Declaration of Conformity, Part 1



In Verbindung mit den in Anhang 1 aufgeführten Zubehör und den einschlägigen Bestimmungen der konsolidierten Version der Verordnung (EU) 2017/745 über Medizinprodukte (MDR) in der letztgültigen Fassung entspricht. Die Konformität gemäß MDR (EU) 2017/745 Artikel 19 nach Erstellung der technischen Dokumentation gemäß Anhang I, II und III wurde erstmals erklärt am:

In conjunction with the accessories listed in Appendix 1 and the relevant provisions of the consolidated version of the Ordinance (EU) 2017/745 on Medical Devices (MDR) as last amended. The conformity according to MDR (EU) 2017/745 Article 19 after preparation of the technical documentation according to Annex I, II and III was first declared on:

08.04.2021

Gemeinsame Spezifikationen sind für dieses Produkt nicht anwendbar. Diese Konformitätserklärung ist gültig bis zum 05.07.2024.

Common specifications are not applicable to this product. This Declaration of Conformity is valid until 2024/07/05.

Ausstellungsort und -datum: Wickede (Ruhr), 19.05.2021

Place and date of issue:

Matthias Schmitz

Geschäftsführung / CEO

Verantwortliche Person für Regulierungsvorschriften

Person responsible for regulatory compliance

Thomas Krüger

Leitung Qualitätsmanagement

Head of Quality Management

Ausstellungsdatum: 19.05.2021

Date of issue:

Firmensitz / Kontakt
SCHMITZ u. Söhne GmbH & Co. KG
Zum Ostenfeld 29
58739 Wickede (Ruhr)

Single Registration Number (SRN)

DIMDI-Herstellercode

Seite 2 von 2

Geschäftsführer
Bernhard Schmitz, Ludolf Schmitz,
Friedrich Schmitz, Matthias Schmitz

Amtsgericht Arnsberg HRA 4554
Persönlich haftende Gesellschafterin:
SCHMITZ u. Söhne GmbH
Amtsgericht Arnsberg HRB 4067

Fig. 30
Declaration of Conformity, Part 2

Glossary

The following terms are defined in standards. They are explained in more detail below.

Term	Source	Meaning
Safe working load	IEC 60601-1:2005 + amendment:2006 + amendment:2007 + A1:2012	Maximum weight (specified in kilograms), which may be placed on the device or accessory. The value includes the weight of any attached accessories. Therefore, to determine the weight load actually permitted, the weight of any attached accessories must be subtracted from the safe working load. The standard stipulates that manufacturers state this information.
Expected service life	IEC 60601-1:2005 + amendment:2006 + amendment:2007 + A1:2012	For how long (at minimum) the manufacturer believes the device can be safely used after delivery and in compliance with the prescribed maintenance intervals. The standard stipulates that manufacturers state this information.
Intended use	IEC 60601-1:2005 + amendment:2006 + amendment:2007 + A1:2012	Use for which the device is intended according to the specifications, instructions and information provided by the manufacturer. The standard stipulates that manufacturers state this information.
Intended purpose	IEC 60601-1:2005 + amendment:2006 + amendment:2007 + A1:2012	Use of a machine in compliance with the information provided in the user information. Using this device in a way that does not comply with the intended purpose will lead to exclusion of liability.
Patient leakage current	IEC 60601-1:2005 + amendment:2006 + amendment:2007 + A1:2012, Table 3	Maximum permitted current allowed to flow through or along the patient which is not necessary for functioning. If the value stipulated in the standard is exceeded, the operator of the device must earth the device, e.g. using a potential equalisation.
Essential performance	IEC 60601-2-46:2016	Clinical function of the medical device which 1) is essential during use and 2) is fully preserved even in the event of a "single fault condition" - provided the user is using the medical device as intended.
Single fault condition	IEC 60601-2-46:2016	Failure of an individual safeguard on the device. – A device or accessory is "single fault safe" if it can continue to be safely operated when a single fault condition occurs. "Single fault safe" is an essential performance feature.

Tab. 9
Glossary



**SCHMITZ u. Söhne
GmbH & Co. KG**

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on our website.



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