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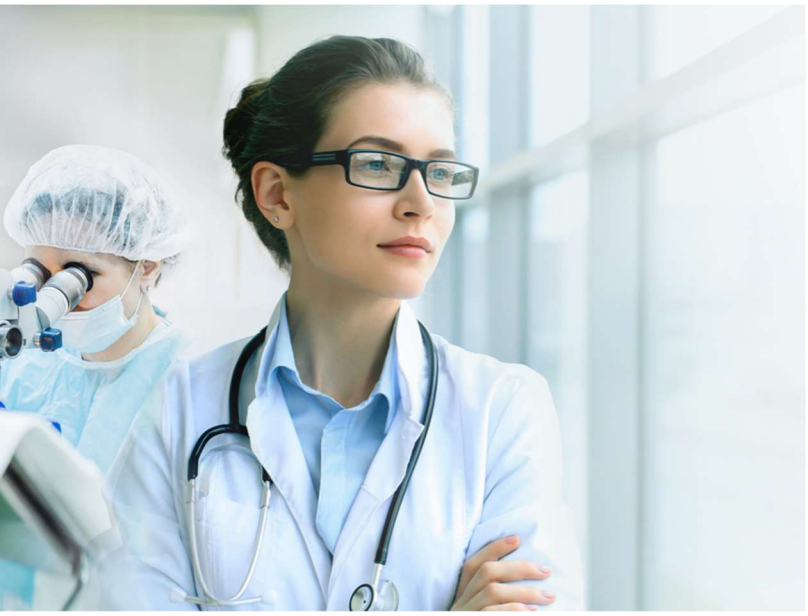


Instructions for Care and Use

GoldLine® Leg Support
100.035.019 KS

444.GA.GL-KS.EN
Stand: 14.07.2021

CE 0044

Contents

1. Introduction

1.1. About this manual

These instructions for use encompass all the information relevant to use of the Condor GoldLine® Leg Support for total knee replacement. This section contains information about the structure of the user manual as well as explanations of the signs and symbols used.

This user manual may contain inaccuracies or printing errors. The information provided here is updated periodically and changes are incorporated in later issues in the course of product modifications. Thus, changes or improvements are possible at any time without previous notification.

The latest version of these instructions for use can be found on the Condor website: www.condor-medtec.de.

Should you have further questions, please contact us directly.

These instructions for use are to be read and used by all persons who use or operate the retractor system. In addition to the instructions in this manual and any binding regulations for the prevention of accidents in the country and at the location of use, observe accepted rules for safe and professional work.

1.2. Symbols used in the text

The following signal words and/or symbols are used in this manual to indicate especially important information.

Danger!
This symbol indicates safety instructions warning of risks to personal health and safety. It indicates imminent danger of death or serious injury.

Caution!
This symbol indicates potentially dangerous situations involving a risk of light injury.

Attention!
This symbol is used with safety instructions indication a risk of damage to the device or other property.

- A dot in front of the text means: This task is mandatory.

  Indented text describes the result of your action.

– A dash in front of the text means: This is part of a list.

1.3. General safety instructions

The Condor GoldLine® Leg support is constructed according to the state of the art and complies with accepted safety rules. However, its use may present risks to the patient or third parties or risk of damage to the device or other property.

Use the GoldLine® Leg support only when in proper working condition, within the scope of the intended use, in consideration of safety and potential hazards and in compliance with this user manual. Immediately repair any defects that could possibly affect safety. The Leg support may be only used for human medicine. The Condor GoldLine® Leg support should not be used in any way that deviates from its specification. Always keep this manual readily accessible at the location of use. In addition to this manual, observe all applicable laws and other regulations on accident prevention and environmental protection.

Do not make any changes, extensions, or conversions to the Leg support without the manufacturer's permission. Spare parts must comply with the requirements stipulated by the manufacturer. Original spare parts always comply with these requirements. Ensure safe and environmentally friendly disposal of operating and auxiliary materials, as well as replacement parts!

1.4. Summary of the safety instructions

Danger!
Direct skin contact with the metal can cause burns. Ensure that there is no direct metal contact between the patient and the footrest.

Caution!
If the clamp is opened too far, it is not possible to insert the crossbar. In this case, turn the hand wheel slightly in the opposite direction.

Attention!
The Condor GoldLine® Leg support must not be used, if an MRI (magnetic resonance imaging) is used at the same time, as this can lead to malfunctions of the MRI. Only components which are approved by Condor MedTec may be used.

1.5. Graphical symbols used

Graphical symbol	Identification
	Identification in agreement with ISO 15223-1 standard. Symbol for ‘product number‘
	Identification in agreement with ISO 15223-1 standard. Symbol for ‘serial number‘
	Identification in agreement with ISO 15223-1 standard. Symbol for ‘name and address of the manufacturer ‘
	Identification in agreement with ISO 15223-1 standard. Symbol for „date of manufacture“
	Identification in agreement with ISO 15223-1 standard. Symbol for ‘observe instruction for use‘
	Identification in agreement with ISO 15223-1 standard. Symbol for ‘product not sterile‘
	Labelling of medical devices. Symbol for „Medical Device“
	Identification for a data carrier which contains the Unique Device Identifier contains. Symbol for „Unique Device Identifier“.
	Labelling of products developed and marketed in accordance with relevant European legal provisions.

2. Basic Requirements

2.1. Intended use

The Leg support is used for intraoperative positioning of the leg. The settings of the leg are hold by the Leg support and optimize precise work. The adjustment options enable an intraoperative stability test.

The Leg support may only be used in sterile state and must not come into contact with the patient's skin and must therefore be adequately padded.

The Leg support is designed exclusively for use in human medicine. It is an accessory for a medical device. The Leg support may only be used in conjunction with an operating table.

The Leg support may only be used by people who have familiarised themselves with the product using the operating instructions and who are specialist medical staff. They may only be used in complete agreement with the relevant operating instructions. Liability cannot be accepted for any product damages or personal injuries caused by third-party accessories or reciprocal elimination of the intended use.

We cannot undertake any liability for damage to persons or the product that has been caused by external accessories or subsequent deviation from the intended purpose.

The intended purpose is the use as specified. This is described completely for the operator or user on the labelling and the instructions for use. The Condor GoldLine® Leg support is only to be used in full compliance with the instructions for use.

3. Storage

The Condor GoldLine® Leg support may only be used in a sterile state. Observe the instructions for use and preparation when storing, preparing and sterilising the system.

The instruments should always be:

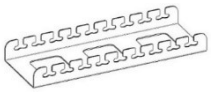
- Stored in a clean, cool and dry place.
- Protected against mechanical damage.
- Protected against falling and handled carefully.

The generally valid directives and recommendations apply for example:

- DIN EN ISO 17664:2018-04
- RKI recommendations
- AKI (Instrument Reprocessing Working Group) – Correct instruments reprocessing for storage of re-sterilisable instruments.

4. Replacement parts

The Condor GoldLine® Leg support (set number: 100.035.019 KS) includes the following components:

Main holder for Leg support	Crossbar for Leg support	Ratchet for Leg support	Foot storage for Leg support
			
100.055.060 KS	100.020.012 KS	100.390.134 KS	100.256.215 KS

Replacement parts you may need should only be acquired from Condor® MedTec GmbH. Always have the article number at hand when ordering technical descriptions or replacement parts from the manufacturer. This information is on the laser inscription of the respective product.

5. Operation

Please read the instructions for use carefully before starting to use the GoldLine® Leg support!

The QR code directs you to an application video for the knee brace. Please note that this video does not replace reading these instructions for use!

5.1. Securing the foot in the foot storage 100.256.215 KS

- Pad the foot storage with sterile material (e.g. sterile cloths, sterile cotton wool).
- There must be no skin contact between the patient and the foot storage.
- The padding must cover all skin contact points.
- Also pad the transition between the Leg support and the calf.
- Wrap the padded leg to the foot storage with a sterile gauze bandage.
- Check that the fit is sufficiently secure.
- Check that there is still no contact between skin and metal.

Figure 1 Prevent direct skin contact with the metal by using sterile material

Danger!

Direct skin contact with the metal can cause burns. Ensure that there is no direct metal contact between the patient and the foot storage.

Attention!

The Condor GoldLine® Leg support must not use, if an MRI (magnetic resonance imaging) is used at the same time, as this can lead to malfunctions of the MRI. Only components which are approved by Condor® MedTec may be used.

5.2. Positioning and attaching the ratchet and crossbar 100.390.134 KS and 100.020.012 KS

- Check the flexion of the leg and select the appropriate position of the ratchet.
- In knee endoprosthetics the ratchet should be aligned as cranially as possible.
- The crossbar with the main holder is used to fix the ratchet.
- Press the ratchet and the crossbar as firmly as possible in the direction of the leg plate. This prevents slipping when there is a soft padding.
- Please note, that the detent ratchet hole occupied by the crossbar cannot be used to engage the foot storage.

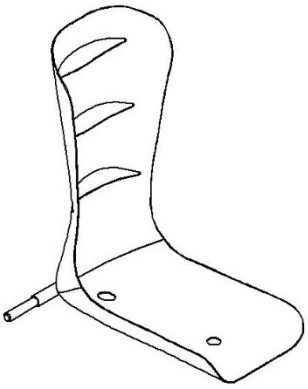


Figure 2 Foot storage for leg support I Art.-Nr.: 100.256.215 KS

The crossbar with integrated insulation provides additional protection against electric currents.

- The crossbar is inserted with its rectangular side into the main holder 100.055.060 KS.
- The round end attaches the ratchet to the operating table.

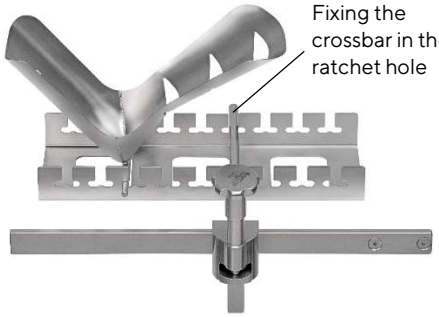


Figure 3 Fixing the crossbar in the ratchet hole

5.3. Attaching main holder to operation table 100.055.060 KS

The Condor GoldLine® Leg support can be attached to all operating tables that have a standard rail. The main holder is attached to the operating table above the sterile cover. The position of the main holder is oriented on the surgical side.

- In order to tighten the main holder, always make sure that the clamp at the bottom end of the main holder is completely open.
- Place the main holder on the standard rail. Turn the hand-heel to the right to fasten the main holder to the standard rail.

Attention!
If the clamp is opened too far, it is not possible to insert the crossbar. In this case, turn the hand wheel slightly in the opposite direction.

Main holders of the latest generation can be disassembled.

- In order to disassemble the main holder, unscrew the hand wheel in a counter-clockwise direction.
- After the hand wheel is unscrewed together with the threaded, the individual parts can be prepared.

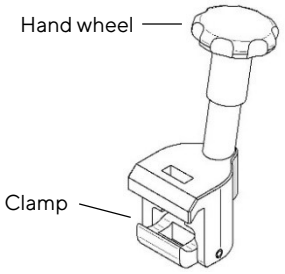


Figure 4 Main holder for leg support I Art.-Nr. 100.055.060 KS

6. Instructions for care and use Condor GoldLine® Leg support

6.1. Service Life

The Surgical Retractor System Condor GoldLine® and the Leg support are related to the product line of "re-usable surgical instruments". The end of the product service life is principally determined by wear and damages due to use. With increasing service life instruments get passive layers subject to material composition, surface condition and cleaning conditions. Passive layers on the instruments neither show quality defects nor affect the functions of the system. And from experience the corrosion risk rather decreases with an increasing passive layer.

In order to ensure long-lasting functionality and safety as well as accordance with your quality requirements, we recommend you to carry out the following steps when processing the instruments supplied unsterile and reprocessing the contaminated instruments.

6.2. Pretreatment

It is recommended to carry out reprocessing of the contaminated instruments as soon as possible after use. They should be transported in closed containers. After the use of recyclable instruments, attention should be paid to them not being damaged during transport. Prior to cleaning, the instruments have to be disassembled as far as possible.

Because of the corrosion risk and also cleaning factors, long intervals between use and treatment for reuse should be avoided, e. g. overnight or over the weekend. This applies to both "wet" and "dry disposal". The Instrument Preparation Working Group (www.a-k-i.org) recommends, wherever possible, the method of "dry disposal" to be preferred. In case of "dry disposal" intervals of over 6 hours should be avoided.

A mechanical process must be used for cleaning and disinfection. When selecting the cleaning agent to be used, attention must be paid to material compatibility, suitability and effectiveness for cleaning medical devices. The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent or detergent and disinfectant as well as the specifications for rinsing must be observed.

6.3. Cleaning

Cleaning comprises 3 steps:

1. **Precleaning**
   1.1. Manual precleaning
   1.2. Precleaning in the ultrasonic bath
2. **Automatic cleaning according to DIN EN ISO 158833-1 and -2 (in a washer-disinfector unit)**

We recommend the use of detergents that are effective against prions (please take notice of the manufacturer´s instructions for application). Current studies analysing decontamination of infectious prions show that a consecutive cleaning with an alkaline detergent (pH value > 10) and disinfection or sterilisation is the most effective method. Please carry out the cleaning steps according to the instructions of the cleaning agent manufacturer! The following points refer to the alkaline cleaner Deconex 28 Alka One from Borer Chemie, with which our products were validated.

1. Precleaning

1.1. Manual precleaning
Soak the contaminated components in cold water (at least drinking water quality) for at least 10 minutes. Please note: The instruments should not, however, lie in water and / or cleaning and disinfection agents over a longer period of time, e. g., overnight / over the weekend.

- Submerse the components and clean them with a soft brush for at least 1 min, making sure that all surfaces are treated. In case of heavy contamination, the duration of the pre-cleaning may differ from those indicated. Cannulings and blind holes should be treated specifically with a brush suited for this purpose.
- Thoroughly rinse the components in running water (at least drinking water quality). The water has to run through the cannulings; blind holes have to be filled and emptied repeatedly.

1.2 Precleaning in the ultrasonic bath
Place the pretreated components in an ultrasonic bath (frequency: 35 to 40 kHz) heated to approx. 40°C, containing cleaning agent (e.g., Deconex 28 Alka One, Borer Chemie) according to the manufacturer's instructions for use and then sonicate the instruments for 10 minutes. After cleaning in the ultrasonic bath, rinse the instruments for 1 min under cold running water (at least drinking water quality).

2. Automatic cleaning (in a washer-disinfector unit cleaning according to DIN EN ISO 158833-1 and -2)

Before you start with the machine cleaning, you should have carried out a pre-cleaning according to point 1. For the automatic cleaning the instruments have to be placed in perforated baskets suited for cleaning (avoid areas that cannot be reached by the water).

Hollow-body instruments must be connected to hollow-body rinsing systems of washer-disinfectors. An alkaline cleaner (pH > 10) should be used according to the manufacturer's instructions for use. Pay attention to the correct dosage! The products are validated for alkaline cleaning. Acidic cleaning agents and disinfectants must not be used.

Also observe the instructions of the equipment manufacturer. A typical cycle should include the following steps and should be carried out according to the instructions to the cleaning manufacturer's instructions:

Example of a cleaning cycle incl. disinfection:
(please note the specifications of the cleaning agent manufacturer)

- at least 2 minutes of pre-washing using cold water (drinking water quality and max. 45°C)
- treat with alkaline cleaning agent for the appropriate exposure time, concentration and temperature as specified by the detergent manufacturer (e.g. at least 5 min with Deconex 28 Alka One, Borer Chemie at 70°C).
- Carry out intermediate rinse(s) according to the detergent manufacturer's instructions.
  (e.g. 1 min with 40-45°C warm drinking water, then 1 min with deionised water (DI water))

- Thermal disinfection with DI water and max. 93°C – A_0 Value ≥ 3000 (e.g. 5 min at 90°C)
- drying cycle (max. 120°C)

The information given above may vary depending on loading and programme.

After the programme has finished, the instrument must be taken out of the machine immediately and cooled down to room temperature. They should not remain in the washer-disinfector after the washing process.

- After disinfection, check all components for visible contaminations (especially in the cannulings and blind holes). If necessary, repeat the cycle or clean manually.
- All parts, especially hinges must be dried with clean compressed air after disinfection.

Caution!
Insufficient drying can lead to corrosion of the instruments! Therefore, make sure that the instruments are completely dry after disinfection.

After disinfection, store the product under the following conditions: completely dry, protected from dust, in a closed container, under low-germ conditions (see section Storage).

Caution!
When storing for several days, disinfect the product again before sterilization!

The medical devices must be sterilised in the context of reprocessing after disinfection (chapter 6.4). Inspect parts for damage that may affect their functionality.

Damaged and defective instruments have to be sorted out and replaced. Instruments that are to be returned to Condor for repair must also be sterilised beforehand (individual packaging, see section Sterilisation). Please use our form for returns at the end of these instructions for use.

After the instruments have been cleaned and cooled down, areas such as joints, threads, etc. have to be treated with appropriate care products (medical white oil) according to the manufacturer's range of application.

6.4. Sterilization

The instruments can be sterilised packaged individually (in standard sterilisation bags), in dedicated container systems or all-purpose sterilisation containers. Containers should not be overloaded (please take notice of the manufacturer´s instructions).

Sterilisation should be carried out applying a validated method with steam and fractionated pre-vacuum. (e.g. steriliser according to EN 285 and validated according to DIN EN ISO 17665-1). A residence time of 5 minutes must be adhered to at a temperature of 134°C. All joints and eccentric catches must be in open position during sterilisation.

After sterilisation, store the product in sterile packaging protected from moisture, temperature fluctuations, direct sunlight and dust.

Caution!
Improper storage can lead to loss of sterility - the manufacturer accepts no liability in this respect. The manufacturer accepts no liability in this respect.

6.5. Concluding advice

The instructions given above have been validated by the Condor® GmbH as being suitable for the pretreatment of the reusable Surgical Retractor System Condor GoldLine® and the GoldLine Leg support. It is the reprocessing person's responsibility to make sure that the reprocessing actually carried out yields the desired results with the equipment, materials, and personnel used in the reprocessing

facility. Normally, the procedure has to be validated and monitored routinely for this purpose. In the same fashion, any deviation from the provided instructions by the reprocessing person has to be carefully evaluated as regards effectiveness and potential disadvantageous impacts!

We finally confirm that none of the products leave our house prior to passing an appropriate quality control procedure. Nevertheless, complaints are possible. Please examine the articles for completeness and operability and notify us immediately in case of any flaws. Please do not use any flawed articles.

Instruments returned to Condor for repair should also be sterilised before being dispatched (packaged individually, refer to item "sterilization"). For this, please use our template (form) at the end of these instructions for use.

Condor® MedTec GmbH verifies that the above instructions are suitable for the preparation of instruments for reprocessing. We would like to refer you to further literature:

- DIN Taschenbuch 100/1 „Medizinische Instrumente 1", Beuth Verlag GmbH Berlin, Wien, Zürich, ISBN-13: 978-3-410-20746-7
- DIN Taschenbuch 100/2 „Medizinische Instrumente 2", Beuth Verlag GmbH Berlin, Wien, Zürich, ISBN-13: 978-3-410-20749-8
- Recommendations of the Robert Koch Institute at www.rki.de/EN
- AKI (Instrument Preparation Working Group) – Proper Maintenance of Instruments (Red Brochure) at www.a-k-i.org

7. Maintenance

Careful use, inspections, and maintenance, guarantee functional and operational safety over many years. Inspections are for safety and minimise the risk of malfunctions. We therefore recommend that you perform maintenance / reworking at regular intervals. Maintenance work should only ever be performed by Condor. Maintenance improves reliability. It is an essential prerequisite for maintaining functional and occupational safety. We therefore recommend that you preform maintenance at regular intervals. Condor® MedTec GmbH also offers a general overhaul of your systems after expiry of your guarantee.

8. Repairs

Only have repairs carried out by the manufacturer.
In the case of malfunctions, please contact Condor® MedTec GmbH (contact details in chapter 10).
This will assign an appropriate service provider to you.

All serious incidents relating to the product must be notified to the manufacturer and the competent authority of the member state in which the user is located.

9. Disposal

9.1. Packaging

Condor® MedTec GmbH will take back the complete packaging on request. Where possible, parts of the packaging will be re-used. If you do not want to make use of this, you can dispose of the packaging via the paper and household waste. When designing the product, it was ensured that as few composite materials as possible were used. This design concept permits a high level of recycling. After the product lifespan ends, please dispose of the surgical instruments professionally or use a recycling system. For all disposal measures, observe the national directives and disposal guidelines.

10. Technical specifications

Manufacturer	Address	Contact details
	Condor® MedTec GmbH Dr.-Krismann-Str. 15 33154 Salzkotten GERMANY	Tel. +49 5258 9916-0 Fax +49 5258 9916-16 info@condor-medtec.de www.condor-medtec.de

10.1. Classification

The Leg support is a class IIa medical device according to Annex IX, Rule 7, of the Medical Device Directive 93/42 EEC. It serves as an accessory for the Condor GoldLine® Surgical Retractor System.

10.2. Applied standards

The Surgical Retractor System Condor GoldLine® and the Leg support fulfil the following standard requirements:

- EN ISO 13485: 2016 + AC: 2016
- 93/42/EEC Annex II without (4) / Reg. No. 44 232 117867
- (EU) 2017/745 (Medical Device Regulation, MDR)

After switching to Medical Device Regulation (MDR) the basic security and performance requirements from Annex I to Regulation (EU) 2017/745 apply automatically.

10.3. Certificates

- The current certificates can be downloaded from our homepage (www.condor-medtec.de/downloads).

11. Copyrights

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For reconsignment please note this!

- **Loan instruments back**
- **Instruments back for repair**

Please complete this form and enclose it to your reconsignment.

We hereby confirm the correct desinfection, cleaning and sterilisation of the (loan) instruments enclosed.

Instruments:	Certificate/label:
Hospital (address):	
Departments:	
Responsible:	
Date, Stamp, Signature:	

Stand: 12.02.19