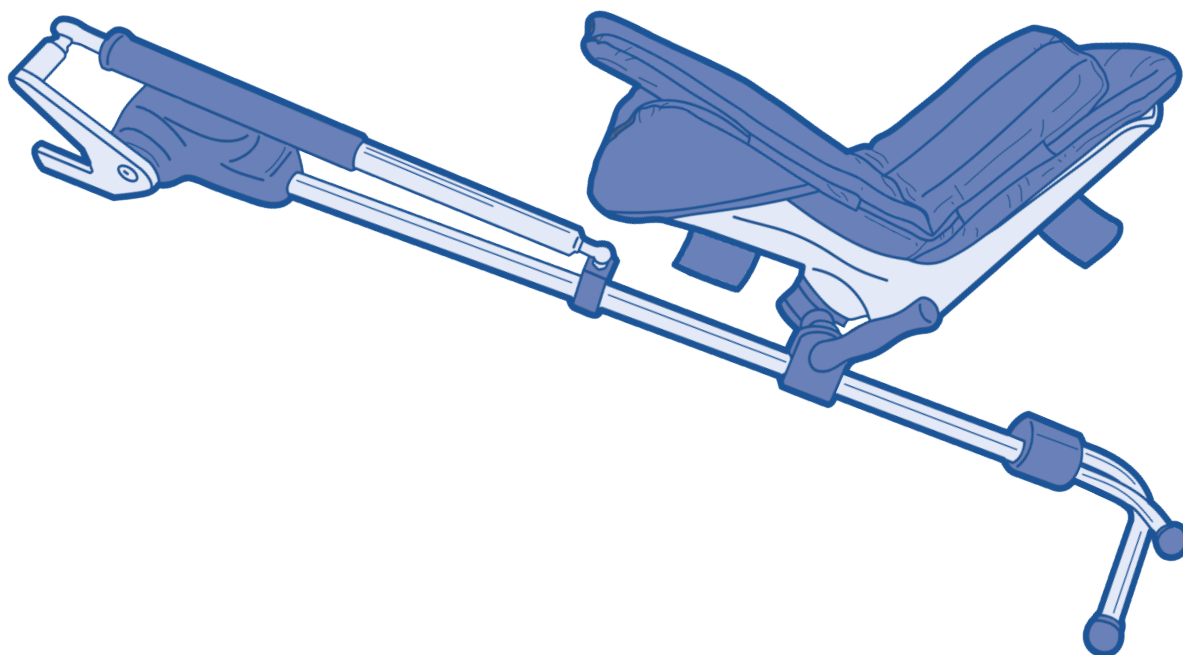




## **INSTRUCTIONS FOR USE**

### **CS FlexiFinless™ Stirrups - Hook & Loop\***

**CSM3058**

**Ref: CSM3058 – IFU (Rev.02) 03/2026**

**CSM3058 CS FlexiFinless™ Stirrup - Hook & Loop Contains:**

CSM3081 CS FlexiFinless™ Stirrup - Hook & Loop- Left (Stirrup Only),  
CSM3082 CS FlexiFinless™ Stirrup - Hook & Loop - Right (Stirrup Only)  
CSM3059 CS FlexiFinless™ - Hook & Loop - Stirrup Pads (Pair)



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Before using this or other medical devices on a patient, you should read the instructions for use and familiarise yourself with the product.

Before using the product on a patient, read and understand all warnings in these instructions for use and on the product itself.

This  symbol draws the user's attention to important procedures or safety instructions in connection with the use of this product.

The  symbol on the labels is designed to highlight when the instructions for use should be consulted.

The techniques described in this manual are only suggestions from the manufacturer. The final responsibility for patient care in connection with this device lies with the attending physician.

The functionality of the product should be checked before each use.

This product may only be operated by trained personnel.

All repairs, modifications or upgrades must be carried out by an authorised specialist.

Any severe incident related to the product should be reported to the manufacturer and the competent national authority of the user's location.



**NEVER EXCEED THE MAX PATIENT WEIGHT AND LOAD DISTRIBUTION OF THE OPERATING TABLE**



## **1 Instructions for Use**

### **1.1 Indication for Use**

These stirrup leg holders are used in a variety of surgical procedures, but are particularly suitable for gynaecological, urological, laparoscopic, colorectal, general and/or robotic surgery. The different weight capacities\* allow them to be used on a wide range of patients, subject to prior assessment by specialised staff. \*Please see 3.2 for respective patient weight capacities.

### **1.2 Intended Use**

The stirrup leg holders are intended for positioning and supporting the patient's legs during a wide range of surgical procedures including, but not restricted to, gynaecology, urology, laparoscopy, general and robotic surgery. They are intended for use by healthcare professionals in the operating theatre.

### **1.3 Authorised User and Patients**

Authorised User: Surgeons, nurses, doctors, medical practitioners and/or healthcare professionals involved in the planned procedure in which the product is used. Not intended for non-professionals.

Patients: These products are designed for use with patients who do not exceed the weight specified in the product specification in section 3.2 within the safe max patient weight.

### **1.4 Remaining Risk**

This product meets the relevant performance and safety standards. Nevertheless, damage to the product due to misuse, defects to the product, function or mechanical hazards cannot be completely ruled out. The user is responsible for ensuring that the appliance is securely fastened and operates safely.

## **2 Safety Considerations**

### **2.1 Safety hazard symbols**



DO NOT USE IF THERE IS VISIBLE DAMAGE ON THE PRODUCT



## 2.2 Misuse of the Equipment

Do not use the device if the original package is defective or has been mistakenly opened before use.

Any repairs, changes or upgrades must be made by an authorised specialist.

## 2.3 Non-hazardous Disposal

Customers should adhere to all federal, state and/or local laws and requirements regarding the non-hazardous disposal of medical equipment and accessories.

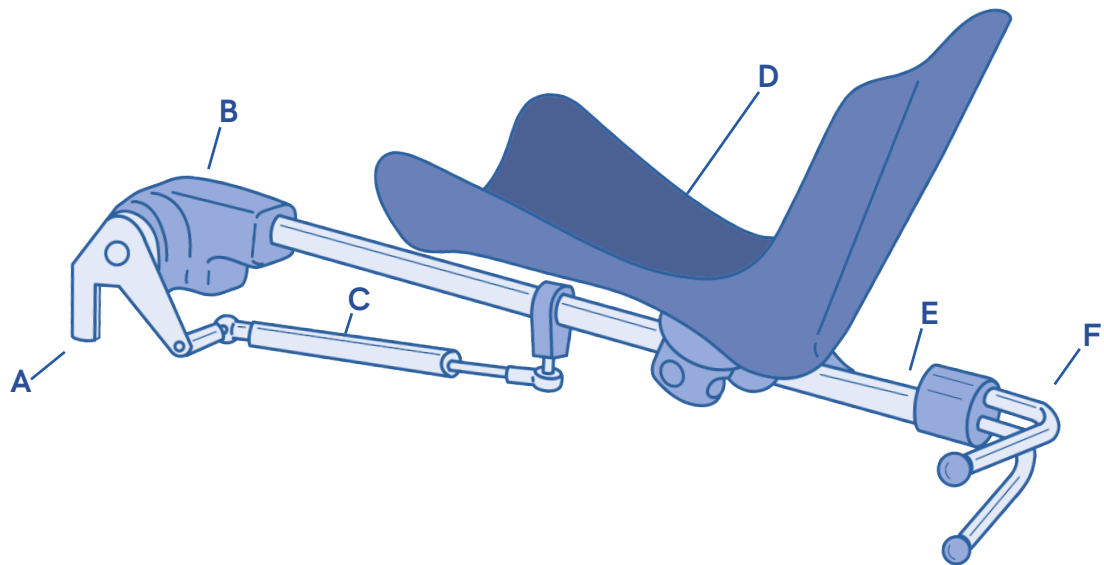
If in any doubt, the user of the product should first contact Care Surgical Ltd/LLC Technical Support for instructions on non-hazardous disposal.

| Icons Used                                                                          | Description                                                                                                                      | Reference                     |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
|    | Indicates a medical device                                                                                                       | MDR 2017/745                  |
|    | Indicates the manufacturer of the medical device                                                                                 | EN ISO 15223-1                |
|   | Indicates the serial number of the manufacturer                                                                                  | EN ISO 15223-1                |
|  | Indicates the Global Trade Item Number of the medical device                                                                     | 21 CFR 830<br>MDR<br>2017/745 |
|  | Indicates the lot number of the medical device                                                                                   | EN ISO 15223-1                |
|  | Indicates the date of manufacture of the medical device                                                                          | EN ISO 15223-1                |
|  | Indicates the manufacturers product code                                                                                         | EN ISO 15223-1                |
|  | Indicates the need for the user to consult the user manual for important cautionary information such as warnings and precautions | EN ISO 15223-1                |
|  | Indicates the device does not contain natural rubber latex                                                                       | EN ISO 15223-1                |
|  | Indicates the manufacturers authorised EU representative                                                                         | EN ISO 15223-1                |
|  | Indicates the Medical Device complies to REGULATION UK MDR 2002                                                                  | UK MDR 2002                   |
|  | Indicates the Medical Device complies to REGULATION (EU) 2017/745                                                                | MDR 2017/745                  |
|  | Indicates a Warning                                                                                                              | IEC 60601-1                   |
|  | Indicates the need for the user to consult the user manual                                                                       | EN ISO 15223-1                |

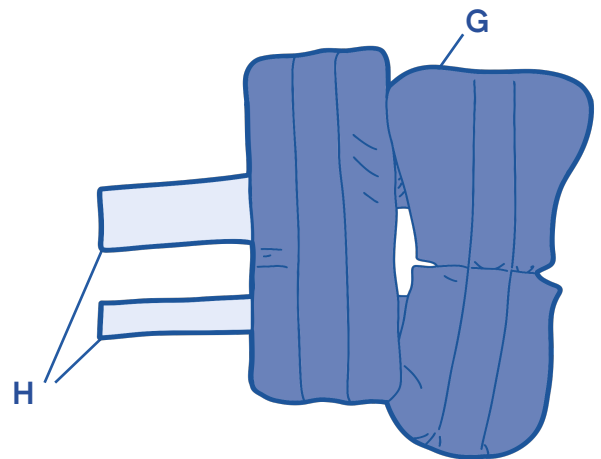


### 3 Stirrup

#### 3.1 Components

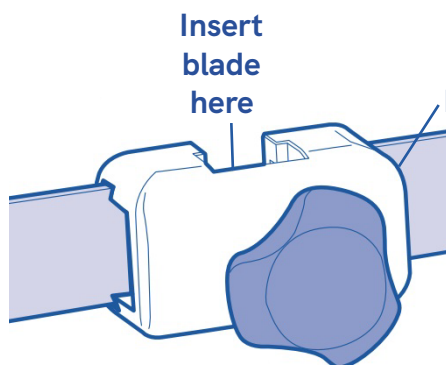


- A. Blade to place into the clamp
- B. Ball Joint
- C. Gas Shock
- D. Flexible Boot
- E. Boot Adjustment Handle
- F. Lithotomy Handle



- G. Boot Pad
- H. Fixation Straps

- I. Blade Clamp





### 3.2 Product Specification

| Mechanical Specifications                     | Description                                                                                                                                                                                                                          |
|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Dimensions                            | <b>CS FlexiFinless™ Stirrups - Hook &amp; Loop</b><br>1000 x 200 x 400mm - based on one stirrup.                                                                                                                                     |
| Material                                      | <b>CS FlexiFinless™ Stirrup - Hook &amp; Loop Left &amp; Right</b><br>Aluminium alloy, Stainless Steel, ABS<br><b>CS FlexiFinless™ Stirrup Pads - Hook and Loop (Pair)</b><br>PU foam, PU Cover, Hook&Loop straps                    |
| Maximum patient weight                        | <b>CS FlexiFinless™ Stirrups - Hook &amp; Loop</b><br>Max Patient weight - 227kg/500lbs.                                                                                                                                             |
| Overall Weight of Device                      | <b>CS FlexiFinless™ Stirrups - Hook &amp; Loop</b><br>13kg (based on one stirrup inc. Pad)                                                                                                                                           |
| Storage Specifications                        | Description                                                                                                                                                                                                                          |
| Storage and Operating Temperature             | -30°C - 40°C and -22°F - 104°F                                                                                                                                                                                                       |
| Storage and Operating Relative Humidity Range | 40%-80%                                                                                                                                                                                                                              |
| Compatibility Specifications                  | Description                                                                                                                                                                                                                          |
| Compatible with:                              | Clamps:<br>CSM2761 CS Blade Clamp UK/EU<br>CSM2762 CS Blade Clamp Plus - US<br>CSM2767 CS Blade Clamp Plus EU<br>Compatible with US, UK and EU rails<br><br>Pads with Velcro straps:<br>CSM3059 CS FlexiFinless™ Stirrup Pads (Pair) |
| Operating Table Compatibility                 | Compatible with the following din rail styles: US, UK, EU.                                                                                                                                                                           |



### **3.3 Setup and Use**

1. The patient should be examined and checked for any pre-existing conditions (e.g. artificial hip joints) that may prevent safe use of the lithotomy equipment before the stirrups are attached to the table.
2. To attach the stirrups to the table the CS Blade Clamps or similar blade clamps can be used.
3. The blade clamp should be positioned next to the patient's hip. Tighten the clamp by clockwise rotation of the knob.
4. The ball joint of the stirrup should be aligned with the head of the femur.
5. **ATTENTION:** Once the stirrup is in the required position, the blade clamps should be tightened. It is important that the clamps are firmly tightened and checked for security.
6. Loosen the boot adjustment clamp to slide the boot along the support bar until the calf area of the boot is close to the patient's calf. Tighten the boot adjustment clamp firmly on the boot so that the boot cannot move. Repeat the process for the stirrup on the opposite side.
7. Position the stirrups so that they are level with the table by squeezing the handle as you move the stirrups into position.

### **3.4 Patient's position**

Position the patient on the operating table according to the surgeon's requirements and the hospital's protocol.

1. Pre-position the stirrups as explained in 3.3. Ensure that the boot clamp mechanism is secure and the boot is positioned correctly. Ensure that the blade clamp is firmly attached to the din rail.
2. At least two staff members are required for safe positioning of the patient. Each staff member places the patient's legs in a stirrup at the same time to protect the patient from harm. Grasp the patient's heel with one hand and place the other hand under the patient's calf (do not reach directly into the hollow of the knee). Bend the patient's knee slightly towards the patient by pushing the heel cranially while supporting the leg with both hands. Each clinician should simultaneously place one leg into the stirrup boot.
3. Ensure that the patient's heels are sitting completely in the heel section of the boot and the leg is securely fixed. Close the boot pad using the straps. Ensure that the straps are fixed and the patient's leg is secured.
4. Finally, check that the patient's heels are properly seated in the heels of the boot and that there is no pressure on the calf to avoid a compartment syndrome during procedure.

The leg must be positioned centrally in the boot to avoid pressure on the peroneal nerve and fibula. The patient's knee should be bent 10 degrees.



5. The following safety guidelines apply for correct initial leg flexion.  
In the low lithotomy position, the leg must not be overstretched in order to achieve the desired abduction. For medium or high lithotomy, you should only perform minimal flexion/abduction of the legs initially, as this will increase as the positioning of the legs increases.
6. Ensure that the toes/ankles, the knee and the opposite shoulder are aligned during positioning. The foot and thigh are usually abducted at the same degree. Use the alignment marks on the bar to ensure symmetry.
7. To adjust the position of the boot and change the flexion angle, the boot should be held in one arm and with the other hand or with the assistance from a second person, the boot adjustment clamp should be loosened by turning the handle on the boot clamping mechanism until the boot can be returned to the correct position. Tighten the boot adjustment clamp firmly on the bar again.
8. To bring the patient's legs into the high or low lithotomy position, squeeze the handles at the distal end of the stirrup bar and raise or lower both legs at the same time. Let go of the handle to lock the stirrups in the desired position.
9. The boot is self adjusting to protect the calf when raising or lowering the legs. It is free floating and moves with the patient's leg as required.

### 3.5 Removing the product

1. Adjust the position of the stirrups by squeezing the handles and move the stirrups slowly to a level position at the same time
2. Carefully remove patient's legs from the stirrups. Grip under the heel and under the calf (not in the sensitive area of the hollow of the knee), move/bend the leg cranially towards the patient again and then lower it back onto the operating table.
3. Raise the stirrups into a vertical position. Release the clamps and remove stirrups.

**\*For pad removal/reinstallation, see page 10**

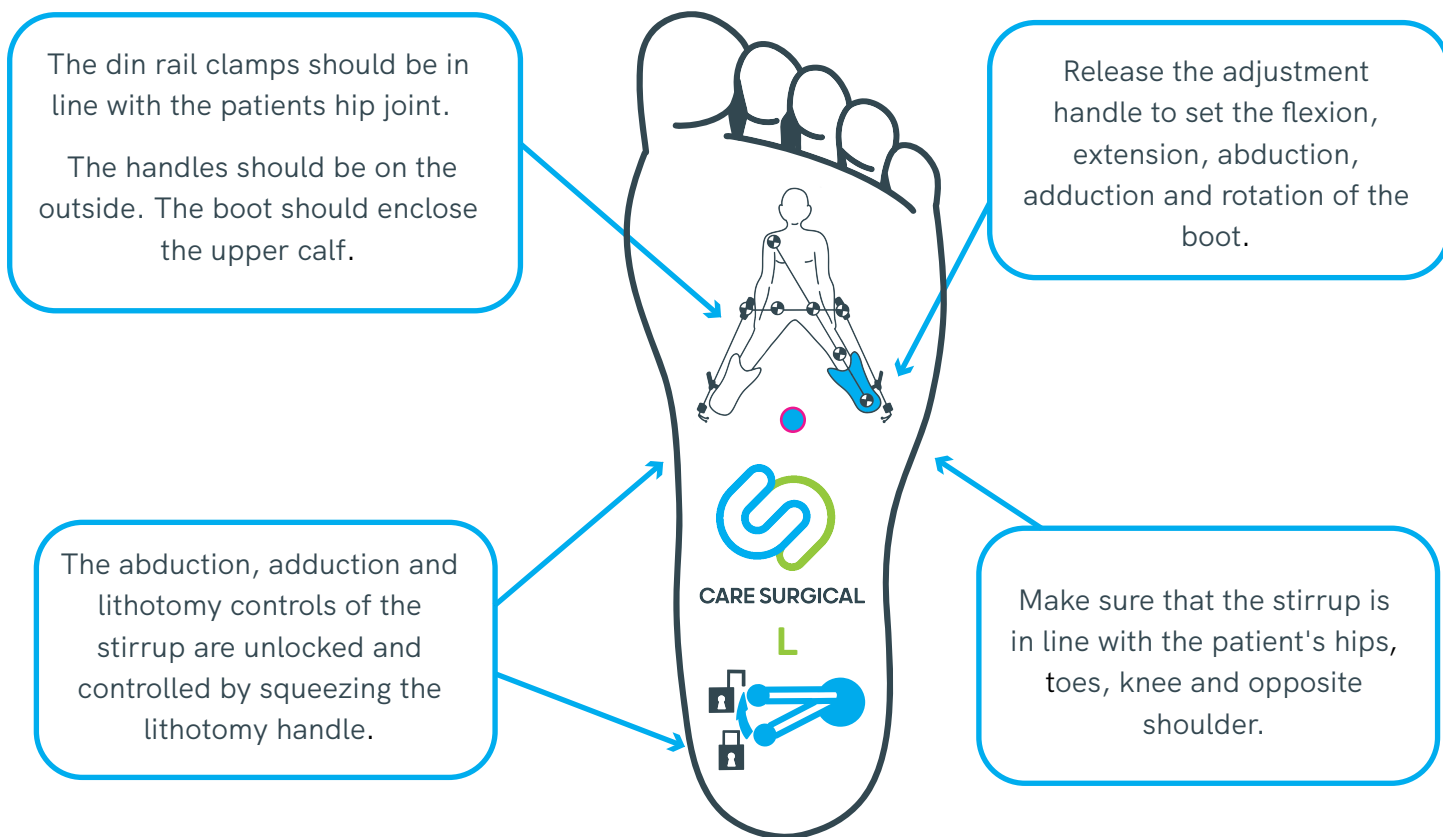


**WARNING:** When using the stirrup in Trendelenburg or reverse Trendelenburg, additional positioning products should be used.



## 3.6 Appliance controls and displays

This Illustration Represents the Patient's left foot



## 3.7 Maintenance of the product

Ensure that all labels are attached and legible. If labels need to be replaced, make a photo of the current label and send it to us before removing it by using a plastic scraper and alcohol wipe to remove any adhesive residue.

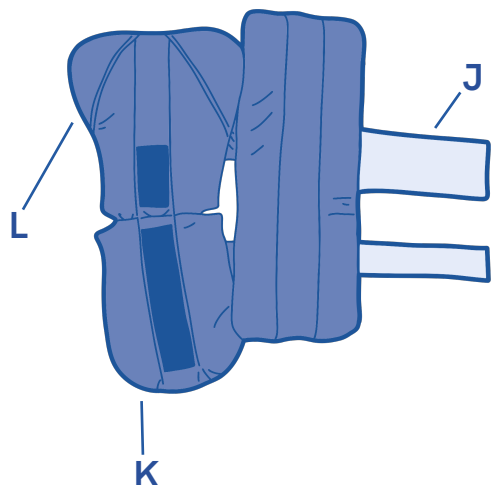
If you need labels to be replaced contact us (Care Surgical Ltd / LLC) by using the information from the contact details section.

## 3.8 Cleaning and Disinfection



### ATTENTION:

- Clean the product after each use as specified in these instructions for use.
- Do not immerse the device in liquids. This may damage the device.
- Take care in areas where liquid can get into the mechanism.
- Do not use bleach or products containing bleach to clean the product. You could injure yourself or damage the device.
- After cleaning - Wipe the product with a clean, dry cloth.
- Ensure that the product is completely dry before storing it or using it again



- 1 Position the patient's leg and foot in the stirrup, ensure that the patient's heels are fully seated in the heel section of the boot
- 2 Close the stirrup boot pad by placing the loop strap as precisely as possible over the hook part on the boot. Ensure the straps are fixed and the patient's leg is secured without too much tension on the strap or too much pressure on the back of the patient's foot.
- 3 In the event of heavy contamination, the pad can be removed for better cleaning. Make sure that all hook&loop fasteners (J) are loose and the hook & loop on the back of the pad (K) is carefully separated to prevent damage to the cover before removing the pad from the boot.
- 4 After cleaning (the pad should be completely dry), put the pad back in the boot so that the hook & loop straps on the back of the pad (K) and in the boot are on top of each other and pull the lip of the cover (L) over the edge of the boot.



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**SAFE DISPOSAL:** customers should adhere to any local laws and regulations to the safe disposal of medical devices.  
**DO NOT USE** products that appear to be damaged or worn.  
In an event of product damage or patient injury, please contact Care Surgical.



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Ref: CSM3059 - IFU (Rev.01) 09/2025

**CAUTION:** The product may be damaged if it is cleaned with corrosive chemicals or harsh abrasives.

**ATTENTION:** If any Care Surgical product is damaged, defective or broken discontinue use and contact Care Surgical Customer Service at 01704 336 671.

#### 4 Compliance with Medical Device Regulations:

This product is a non-invasive, Class I Medical Device which is in accordance with the following applicable regulatory requirements:

- UK Medical Device Regulations 2002
- Medical Device Regulation (EU) 2017/745
- FDA - Code of Federal Regulations - Title 21