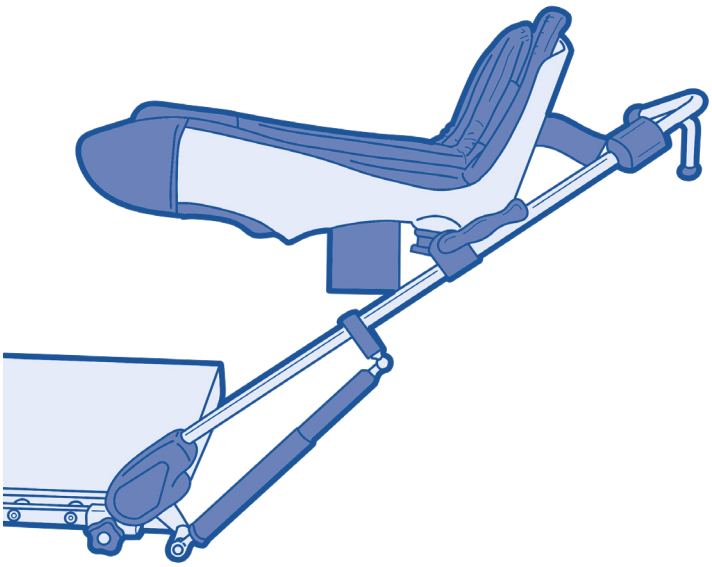


INSTRUCTIONS FOR USE

CS FlexiFin™ Stirrups* Hook & Loop

CSM2755

CS FlexiFin™ Stirrups Max** Hook & Loop

CSM2756

Rev.02 12/2025

CSM2755 CS FlexiFin™ Stirrup Contains:
CSM3025 CS FlexiFin™ Stirrup- Left (Stirrup Only),
CSM3026 CS FlexiFin™ Stirrup - Right (Stirrup Only)
CSM2997 CS FlexiFin™ Max Stirrup Pads (Pair)

CSM2756 CS FlexiFin™ Max Stirrup Contains:
CSM3027 CS FlexiFin™ Stirrup- Left (Stirrup Only),
CSM3028 CS FlexiFin™ Stirrup - Right (Stirrup Only)
CSM2995 CS FlexiFin™ Stirrup Pads (Pair)

UK: Care Surgical Ltd
Unit 6 Ringtail Road
Burscough, L40 8JY
Tel: 01704 336671

USA: Care Surgical LLC
43 Broad Street
Suite B106, Hudson,
MA 01749, USA
Tel: 866-243-4107

EU REP

Care Surgical Supplies Limited, Office 2, 12a Lower Main Street, Lucan Co. Dublin, K78 X5P8 Ireland

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 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

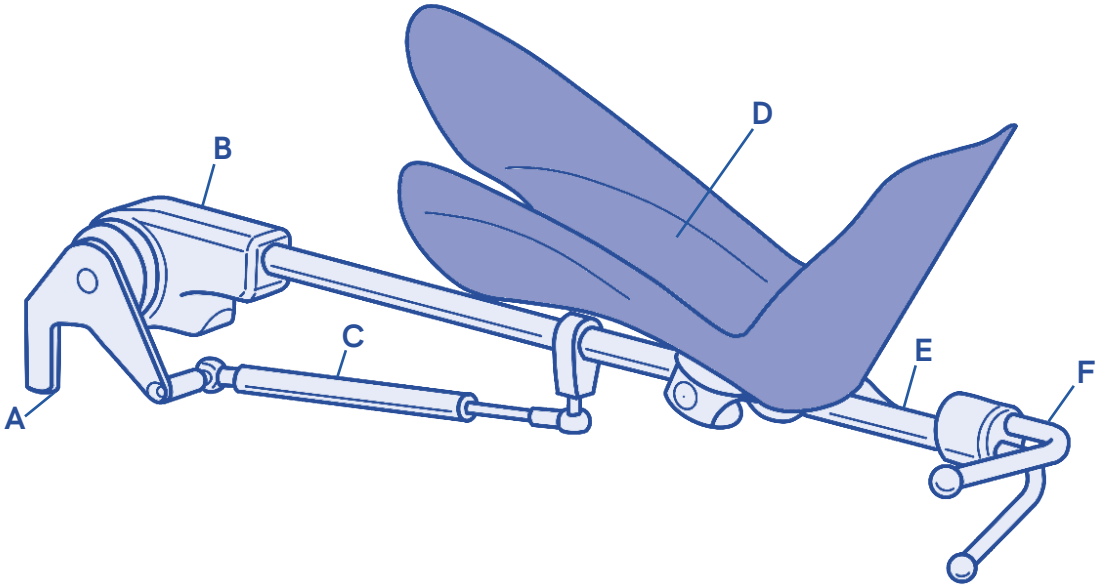
Customers should adhere to all federal, state and/or local laws and requirements regarding the non-hazardous disposal of medical equipment and accessories.

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
MD	Indicates a medical device	MDR 2017/745
	Indicates the manufacturer of the medical device	EN ISO 15223-1
SN	Indicates the serial number of the manufacturer	EN ISO 15223-1
GTIN	Indicates the Global Trade Item Number of the medical device	21 CFR 830 MDR 2017/745
LOT	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
REF	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
LATEX	Indicates the device does not contain natural rubber latex	EN ISO 15223-1
EC REP	Indicates the manufacturers authorised EU representative	EN ISO 15223-1
UK CA	Indicates the Medical Device complies to REGULATION UK MDR 2002	UK MDR 2002
CE	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

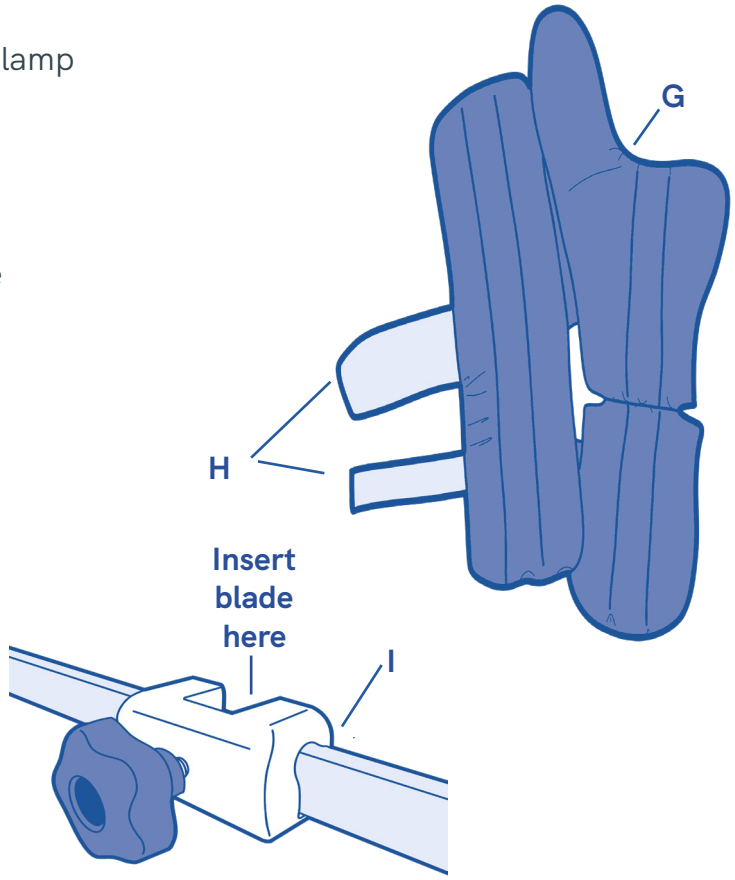
3.1 Components



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	**CS FlexiFin™ Stirrups** 1000x680x560mm **CS FlexiFin™ Max Stirrups** 1000x720x560mm
Material	**CS FlexiFin™/ FlexiFin™ Max Stirrup Left & Right** Aluminium alloy, Stainless Steel, ABS **CS FlexiFin™/ FlexiFin™ Max Stirrup Pads** PU foam, PU Cover, Hook&Loop straps
Max Patient Weight	**CS FlexiFin™ Stirrups** Max Patient weight – 227kg/500lbs. **CS FlexiFin™ Stirrups Max** Max Patient Weight – 360kg/790lbs.
Overall Weight of Device	**CS FlexiFin™ Stirrups** Weight of stirrup – 11kg/24lbs. **CS FlexiFin™ Stirrups Max** Weight of stirrup – 13.4kg/29.5lbs
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: CSM2761 CS Blade Clamp UK/EU CSM2762 CS Blade Clamp Plus - US CSM2767 CS Blade Clamp Plus EU Compatible with US, UK and EU rails
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. The shorter fin of the boots should be next to the patient's legs, the longer fin facing away from the operating table. Insert the blade of the stirrup fully into the blade clamp. 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

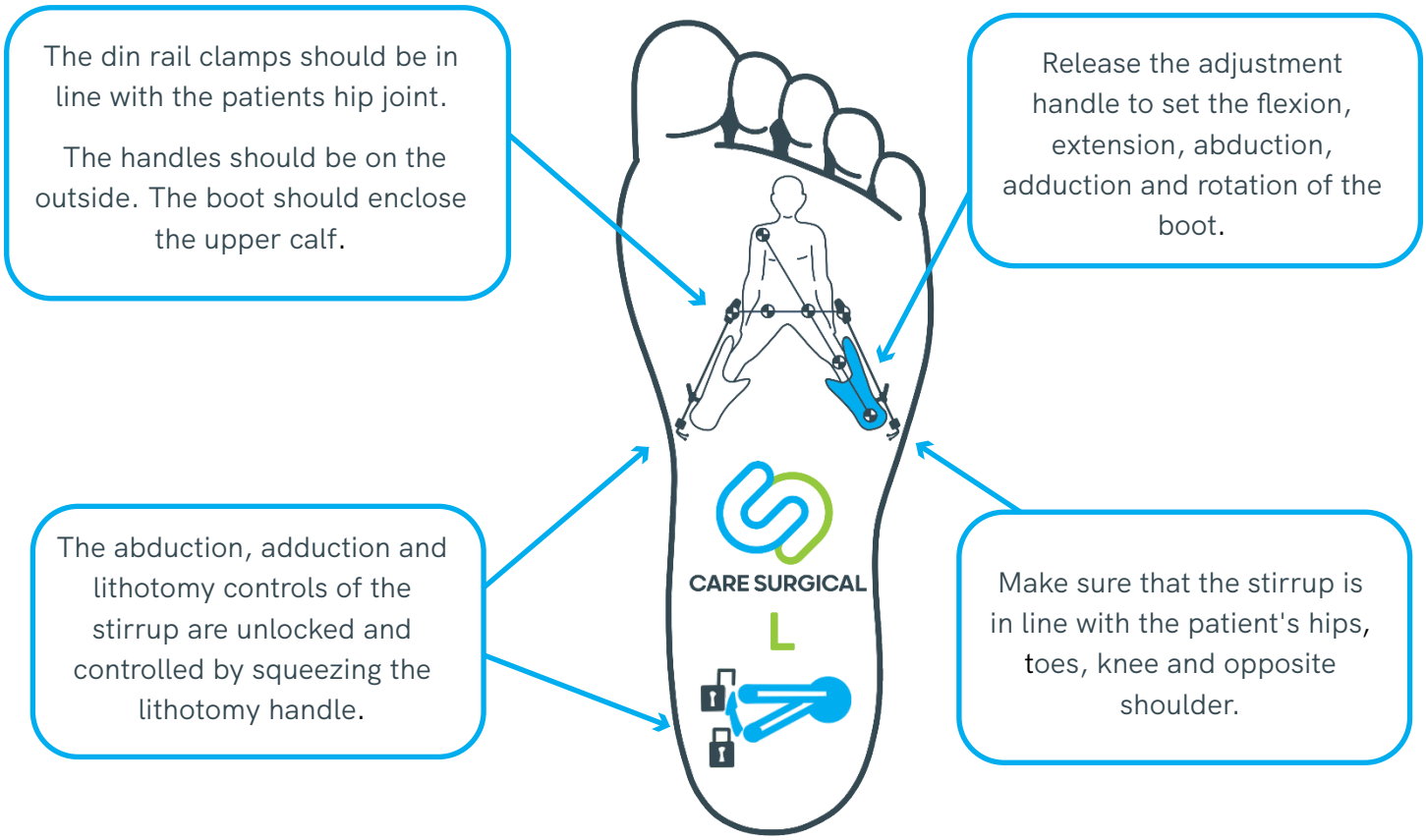
1. Adjust the position of the stirrups by squeezing the handles and move the stirrups slowly to a level position at the same time.
2. Carefully remove patient’s legs from the stirrups. Grip under the heel and under the calf (not in the sensitive area of the hollow of the knee), move/bend the leg cranially 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

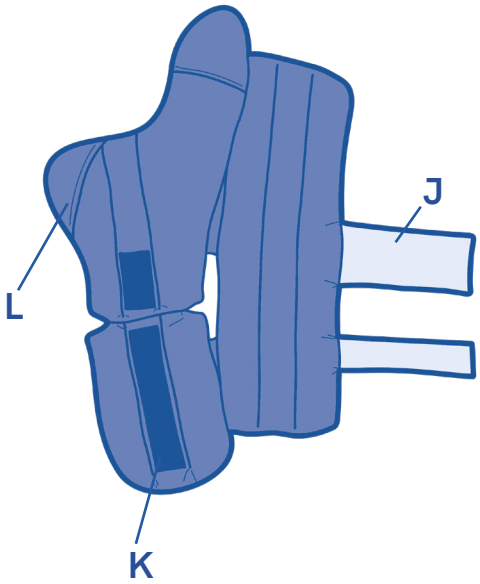
ATTENTION:

- 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

CARE SURGICAL

CS FlexiFin™ Stirrups - Hook & Loop pad

Product code: CSM2997



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 fins.

UK: Care Surgical Ltd
Unit 6 Ringtail Road
Burscough, L40 8JY
Tel: 01704 336671

USA: Care Surgical LLC
43 Broad Street
Suite B106, Hudson,
MA 01749, USA
Tel: 866-243-4107

www.care-surgical.com

EU REP Care Surgical Supplies Limited, Office 2, 12a Lower Main Street, Lucan Co. Dublin, K78 X5P8 Ireland

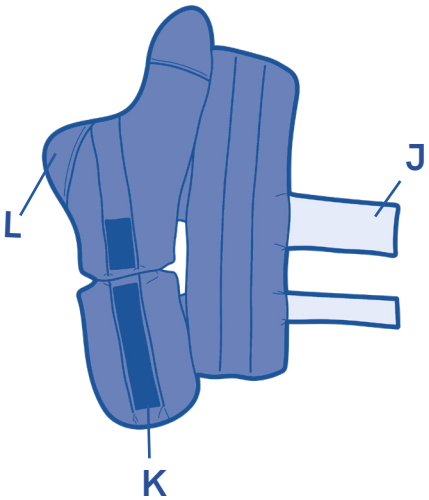
MD UK CA 2 CE LATEX NON STERILE

Ref: CSM2997 - IFU (Rev.03) 04/2025

CARE SURGICAL

FlexiFin™ Max Stirrups - Hook & Loop pad

Product code: CSM2995



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 fins.

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MD UK CA 2 CE LATEX NON STERILE

Ref: CSM2995 - IFU (Rev.03) 04/2025

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

Tick if Applicable

CSM2756
CS FlexiFin™ Max Stirrups (Pair)

CSM2756 CS FlexiFin™ Max Stirrup Contains:
CSM3027 CS FlexiFin™ Stirrup- Left (Stirrup Only),
CSM3028 CS FlexiFin™ Stirrup - Right (Stirrup Only)
CSM2995 CS FlexiFin™ Stirrup Pads (Pair)

MD Medical Device | UK CA UK Conformity Assessed | 2 Reuse | CE Mark | LATEX Latex Free | NON STERILE Non Sterile

LOT

5 060624 127564

Tick if Applicable

CSM2755
CS FlexiFin™ Stirrups (Pair)

CSM2755 CS FlexiFin™ Stirrup Contains:
CSM3025 CS FlexiFin™ Stirrup- Left (Stirrup Only),
CSM3026 CS FlexiFin™ Stirrup - Right (Stirrup Only)
CSM2997 CS FlexiFin™ Stirrup Pads (Pair)

MD Medical Device | UK CA UK Conformity Assessed | 2 Reuse | CE Mark | LATEX Latex Free | NON STERILE Non Sterile

LOT

5 060624 127557