

# Ankle CCD Lever Kit

## Assembly & Instructions for use





## ► GENERAL DETAILS

- ★ **Manufacturer's part number:** 3L7076
- ★ **Product name:** Ankle CCD Lever Kit
- ★ **Pack content:** x2 sets of parts
- ★ **Description:** Lever hardware accessory kit for a customised ankle contracture correction device as prescribed for patient use by a professional Clinician.
- ★ **Intended use:** For assembly by professional Orthotists, Orthotic Technicians & Orthopaedic Clinicians.
- ★ **UK MDR classification:** Class I accessory (low risk).

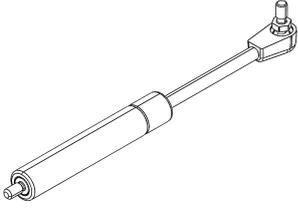
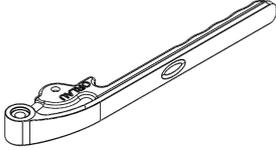
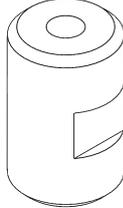
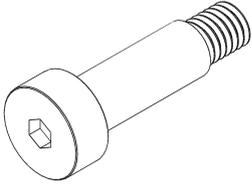
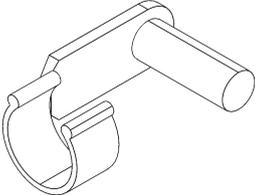
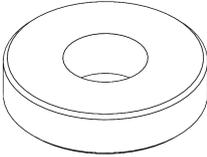
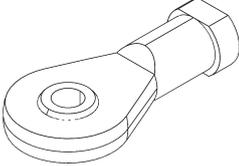
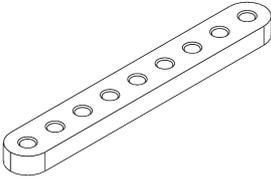
► SAFETY INFORMATION

	<p><b>Warning:</b> Contains high pressure nitrogen gas springs.</p>	 <p><b>THIS WAY UP</b></p>	
	<p>Do not pierce gas spring. Do not heat gas spring.</p>	<p>Pay attention to storage orientation of boxed kit. The gas spring should be stored in the rod-down position.</p>	
<p>Gas Springs are filled with Nitrogen gas at VERY high pressures, and under no circumstances should they be opened or tampered with or subjected to excessive heat or tension.</p>		 <p><b>50°C</b> <b>Upper limit of storage temperature</b></p>	<p>Storage maximum temperature for Gas strut specifically. Note that the operation range is -30°C to +100°C.</p>
			

► PRODUCT LABELLING

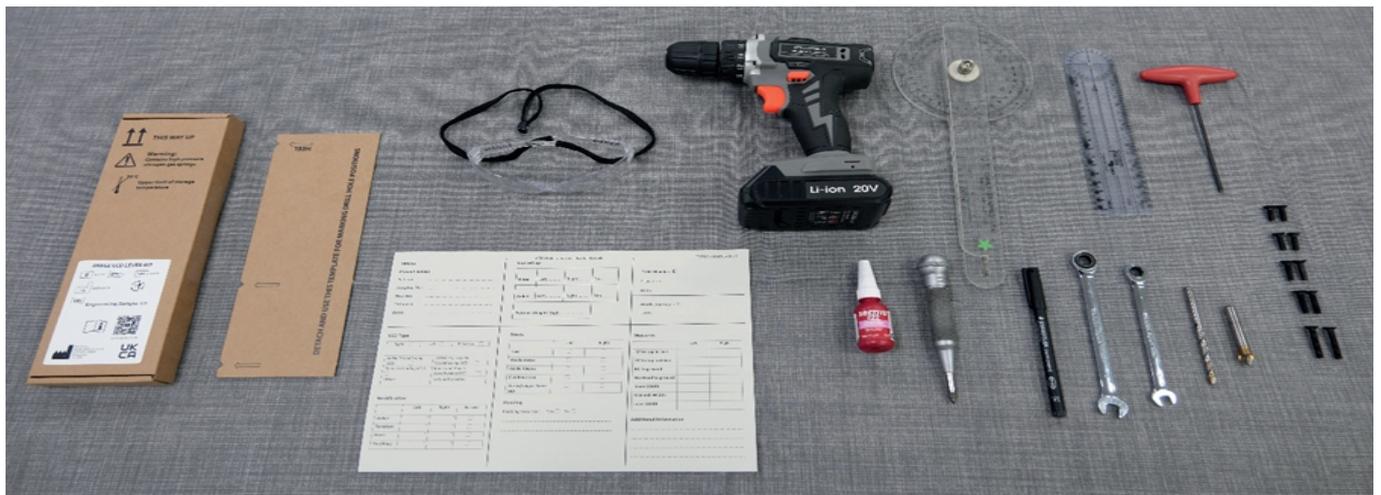
	<p>Symbol for: MANUFACTURER'S PRODUCT CODE</p>		<p>Symbol for: UNIQUE DEVICE IDENTIFICATION NUMBER</p>		<p>Symbol for: SINGLE PATIENT MULTIPLE USE</p>
	<p>Symbol for: QUANTITY PER BOX</p>		<p>Symbol for: MANUFACTURE DATE (WITH COUNTRY OF ORIGIN)</p>		<p>Symbol for: INSTRUCTIONS FOR USE</p>
	<p>Symbol for: LOT NUMBER (TRACEABILITY)</p>		<p>Symbol for: MANUFACTURER</p>		<p>Symbol for: UK CONFORMITY ASSESSED</p>

► **KIT CONTENTS (EACH BOX CONTAINS TWO KITS)**

 GAS SPRING x1	 LEVER x1	 GAS SPRING BOSS x1
 SHOULDER SCREW x1	 SPRING-LOADED CLIP x1	 TEMPLATE (one per box - to be reused)
 WASHER x3	 ROD END x1	 BRACKET x1
 WARNING DECAL x1		

► **TOOLS REQUIRED**

- ★ 8mm Spanner
- ★ 10mm Spanner
- ★ 3mm Allen Key
- ★ Goniometer
- ★ Marker Pen
- ★ Drilling Position Template
- ★ Safety Glasses
- ★ Automatic Centre Punch
- ★ Cordless Drill
- ★ 5.5mm Drill Bit
- ★ Counter Sink Drill Bit



► **ADDITIONAL ITEMS REQUIRED (not supplied)**

- ★ 1 x Unique Patient CCD Order Information, showing contracture angle in degrees and patient weight.
- ★ 1 x CCD Shell (responsibility of the Clinician).
- ★ Threadlocking adhesive, low strength (Loctite® 222).
- ★ Selection of M5 Counter Sink Screws to suit (approx. 12mm - 25mm as a guide).

## ► INTRODUCTION

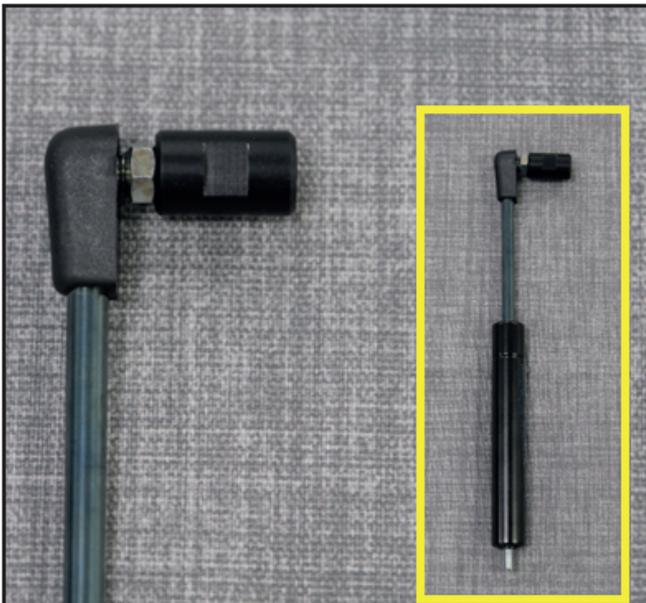
This kit is applicable to a wide range of adolescent and adult patients. As such, the Orthotic Technician (i.e. the assembler) of the kit will need to be in receipt of key information such as the angle of the fixed contracture, without this information, the drilling of the shell should not take place.

The kit of parts has been developed to be attached to a bespoke hinged Ankle Foot Orthosis (AFO) Shell. This shell requires a freely rotating ankle hinge (such as the Otto Bock's Active Contour Ankle Joint). Also, an additional polypropylene strengthening rib from the back of the heel to the top of the calf section which should be moulded in, during AFO manufacture. This strengthening rib is essential to ensure the torque is transmitted appropriately and that the kit of parts can be securely attached. The rib should be at least 25mm wide and of the same material as the base AFO.

## ► ASSEMBLY INSTRUCTIONS

Instructional video is available on RICOH 3D website (link displayed at the end of this document)

### ▷ STEP 1 - Assemble the CCD Lever Kit



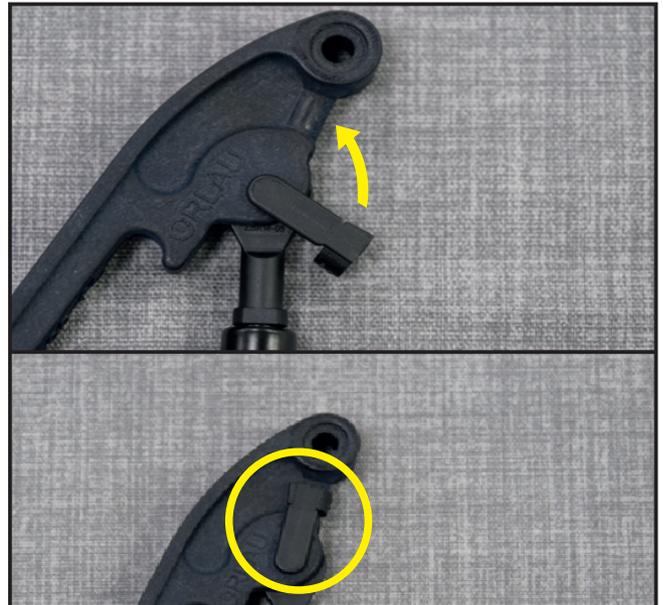
**1.1** Attach the **Gas Spring Boss** to the **Gas Spring** nipple. Tighten securely using the 8mm and 10mm Spanners.



**1.2** Attach the **Rod End** to the **Gas Spring** and tighten securely using the 10mm Spanner.



**1.3** Fit the **Rod End** into the **Lever** slot and align holes. It is advised that the **Lever** is placed on the LHS at this stage. The **Lever** position on the CCD Shell is set later.



**1.4** Fit the **Spring-Loaded Clip** through the **Lever** and **Rod End**, rotate anti-clockwise and engage the **Spring-Loaded Clip** onto the **Lever**. NOTE: Do not fit the **Spring-Loaded Clip** to the **Rod End**. It must be fitted to the **Lever**.



**RIGHT-HAND MOUNTED**

**1.5** Decide which side the **Lever** is to be placed on the CCD Shell and rotate accordingly. Fit the **Lever** to the **Bracket** with the **Shoulder Screw**. Fit to the 3rd hole from the top of the **Bracket** with the 3mm Allen Key.



**LEFT-HAND MOUNTED**

**1.6** Note, configuration is slightly different when left-hand mounting is required.

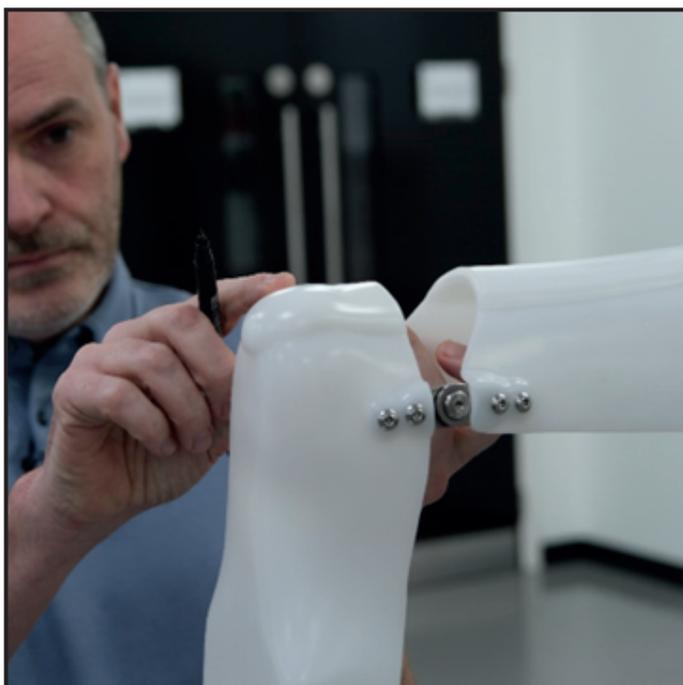
## ▷ STEP 2 - Preparing the CCD Shell



**2.1** Referring to the Unique Patient CCD Order Information, set the required angle of the CCD Shell to that of the patient's contracture angle, using the Goniometer.



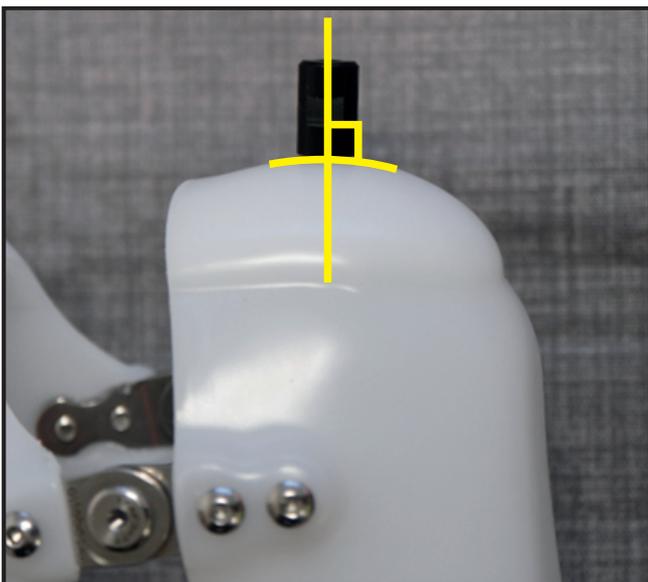
**2.2** The key information here is the angle of the contracture, without this, you cannot successfully assemble the CCD Lever Kit to the CCD Shell.



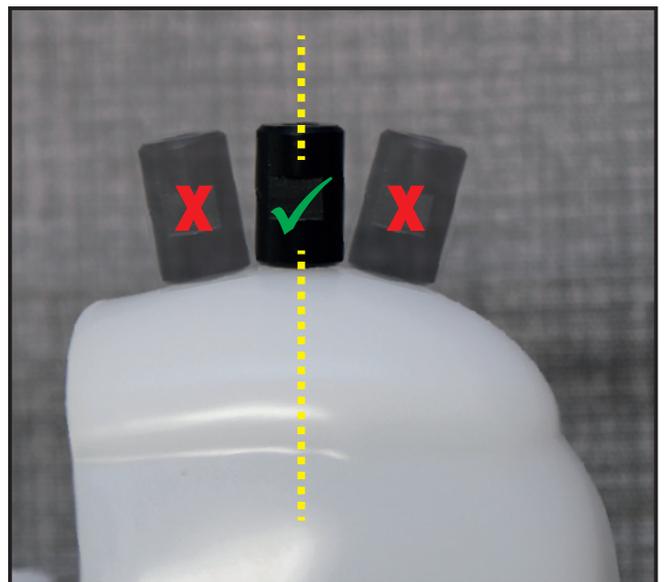
**2.3** Find and mark the centre line of the CCD shell. Locate and mark a 'cross hair' on the apex of the heel region of the CCD shell.



**2.3 (continued)** The marking should be in-line with the CCD shell strengthening rib. This will be the first hole position and sets the location of the **Gas Spring Boss**.  
NOTE: For this step, be careful not to adjust the angle of the CCD shell that was set in Step 2.1



**2.4** The correct position for the **Gas Spring Boss** is perpendicular to the apex of the heel with the CCD shell matching the position of the contracture. This ensures the CCD Shell can extend into a donning position and also close beyond the stretching position.



**2.5** Incorrect setting of the **Gas Spring Boss** can result in it popping off the nipple, during normal use. As well as the correct position, the image above shows 2 incorrect positions where the **Gas Spring Boss** has been set too far from the heel apex.



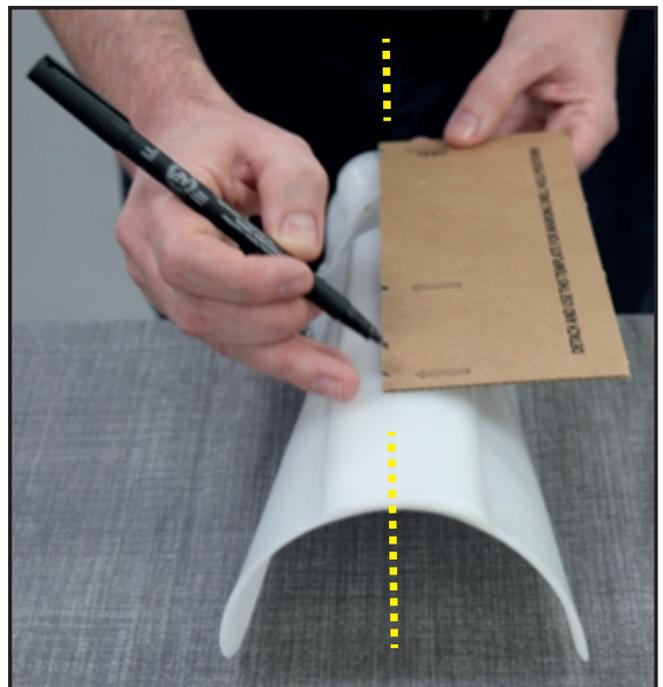
**2.6** After marking the CCD Shell check the angle set in 2.1 has been unaltered using the Goniometer.



**2.7** Place the CCD on a work surface with the foot section over hanging the edge of the working area (being careful not to move the ankle joint angle set in Step 2.1). Detach the template for marking drill hole positions from the kit box and align the bottom v-cut (marked "HEEL") with the cross-hair previously drawn on the CCD heel apex.



**2.8** While holding the drill position template aligned at the heel position, mark the remaining x2 positions in the v-cuts also indicated by arrows on the template.



**2.9** While marking the remaining drill hole positions, ensure the template is aligned with the centre of the back of the CCD shell from the heel mark. Be careful not to adjust the angle of the CCD shell set earlier.



**2.10** Use the Centre Punch to indent the x3 confirmed hole positions on the CCD Shell.



**2.11** Use the Hand Drill and 5.5mm Drill Bit to drill the x3 marked hole positions.



Caution: Wear Safety Glasses when drilling.



**2.11 (continued)**

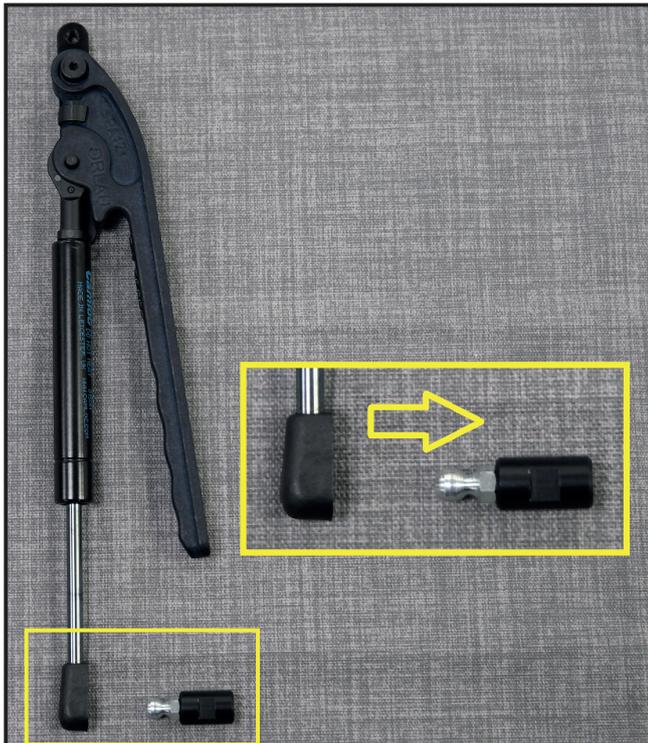


Caution: Wear Safety Glasses when drilling.



**2.12** Use the Counter Sink Bit and Hand Drill to remove any burrs from both sides of the drilled holes. Apply a 3mm Countersink to the inside face of the CCD Shell to all 3 holes.

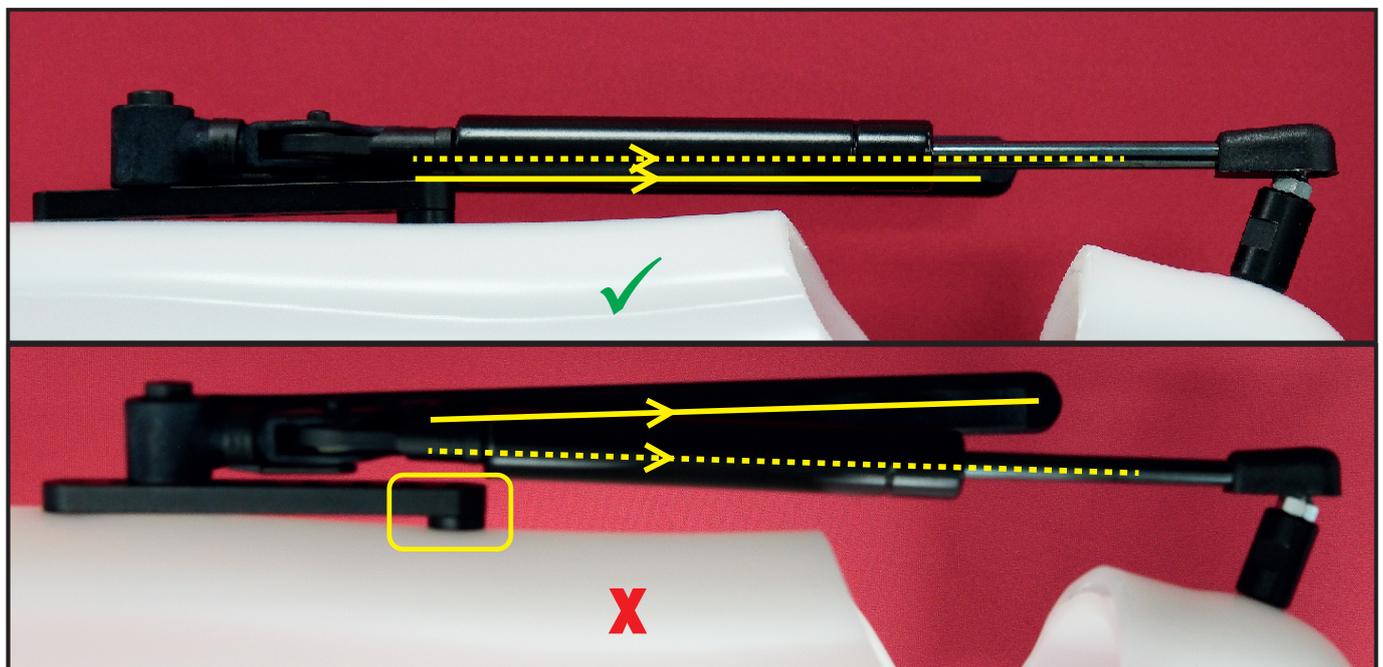
▷ **STEP 3 - Assemble the CCD Lever Kit to the CCD Shell**



**3.1** Remove the **Gas Spring Boss** and Gas Spring Nipple from the **Gas Spring**.



**3.2** Attach the **Gas Spring Boss** to the Heel. Use the 3mm Allen Key and 10mm spanner to tighten securely. Use one of the M5 Counter Sinks Screws to fix.



**3.3** Decide which side the **Lever** is to be placed on the Orthotic and rotate accordingly. Fit the **Bracket** to the CCD Shell. Use the **Washers** as required to set the gap between the CCD Shell and the **Bracket** keeping the **Lever** parallel with the **Gas Spring**. Use the selection of M5 Counter Sink Screws to secure the **Bracket** via the inside of the CCD Shell. Ensure that the Screw thread does not protrude the **Bracket**.  
NOTE: It is not necessary to use all of the **Washers**. The set-up is dependent on the patient and shape of the CCD Shell. It is suggested that the Screws are first fitted loosely and are tightened securely after confirmation of set-up.



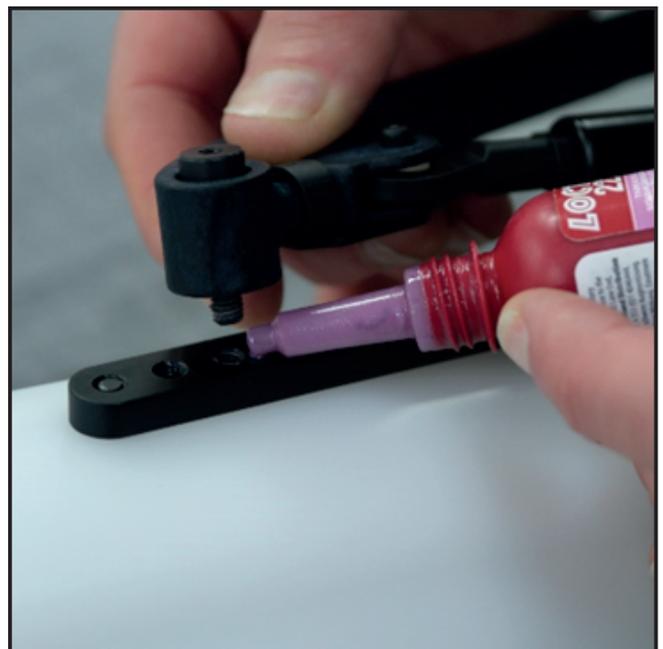
**3.4** Re-attach the **Gas Spring** to the Gas Spring Nipple. It is advised to place the CCD Lever Kit onto a hard surface (table or workbench) and press the **Gas Spring Boss** and Nipple which is attached to the CCD Shell into the **Gas Spring**.



**3.5** Attach the 'Trap Point' **Warning Decal** onto the CCD Shell. Locate on the opposite side to the **Lever** near to the potential trapping point (which is where the **Rod End** contacts with the **Lever**).



**3.5 (continued)** Note, the orientation of the **Warning Decal** is set for viewing from the patient's point of view when wearing the Orthotic (appears upside down in the image above).



**3.6** Remove the **Shoulder Screw** and apply a very small drop of Threadlocker to the thread to prevent the **Shoulder Screw** from working loose during use. Allow 24 hours to fully cure.

The images in these instructions show an Orthotic Shell without the relevant straps attached. Your finished product should contain a shin strap, ankle strap and top strap where relevant. This should be discussed and agreed with your Orthotic Technician.

▷ **This completes the assembly process.**

## ► PATIENT CHECKS

When checking the fit on the patient, ensure the straps are working fully and that their heel is positioned into the shell completely.

Before releasing the finished CCD to the patient, ensure correct use has been explained, the device fits and is comfortable.

The health care professional **MUST** give a physical copy of the **Patient's Instructions For Use** document to the patient, recording their name & Hospital Number on it. This can be downloaded here:

<https://rapidfab.ricoh-europe.com/industries/medical-manufacturing/orlau-ankle-ccd-lever-kit/>

## ► GENERAL NOTES

Life Expectancy:

As the nature of a gas spring is to lose its force over a long period of time, it is advisable to periodically check its ability to operate as initially intended. Check and replace when necessary.

Disposal:

For safe disposal of the gas spring as a pressurised item, it is recommended that the guidelines for safe disposal are followed at the end of their useful life. Further information can be found by following the website link above.

## ► CONTACT & SUPPORT

For clinical assistance:  Keith Miller Rehabilitation Engineer ORLAU Orthotic Research & Locomotor Assessment Unit RJA Orthopaedic Hospital NHS Foundation Trust Oswestry Shropshire SY10 7AG  t: +44 (0)1691 404351 e: kmiller10@nhs.net	For parts kit assistance: (kit manufacturer & distributor)  RICOH 3D Ricoh UK Products Ltd Priorslee Telford Shropshire TF2 9NS  t: +44 (0)800 3047196 e: 3denquiries@ricoh-rpl.com
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