

Instructions for L1311A

Weight Activated Brake Knee with Manual Lock



1 Description and purpose

Prosthetist instructions.

- L1311A knee is for lower limb prosthesis.
- Recommended for K1 up to K2.
- Weight limit for a user is up to 125kg / 275lbs
- Ability to lock knee in full extension as part of rehabilitation process.
- Can progress from locking to full-time unlocked weight activated brake knee.

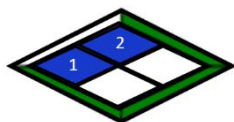
Contra-indications

- Residual muscular weakness, contractures or proprioceptive dysfunction including poor balance.
- Inability to comprehend instructions
- Contra lateral joint instabilities or pathology
- Complicated conditions involving multiple disabilities



Ensure the end user has understood any Instructions for use, especially to the safety information.

Product Code



125Kg
275lbs

L1311A

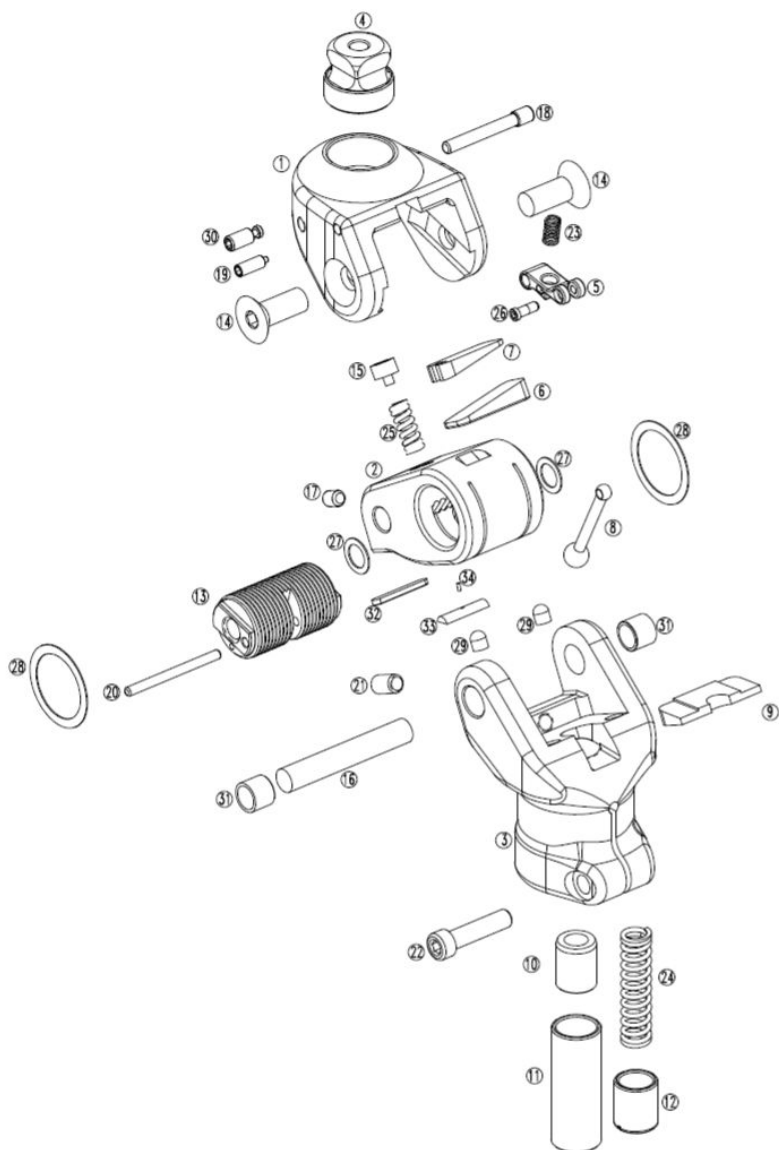
Mechanical Single Axis Knee Joint with Brake Function and Optional Manual Lock

2. Construction

Principal Parts

Frame Aluminum Alloy

Knee control Various materials principally Aluminum Alloy, Brass, Stainless Steel, Polyurethane



3 Function

- Pyramid proximal mount
- 30mm distal tube clamp mount
- Adjustable integrated spring extension assist
- Adjustable weight activated brake sensitivity
- Adjustable swing friction
- Dual function manual lock lanyard handle
- Manual lock can be disabled
- Enables easy switching between locked knee and free weight activated brake knee

Overview

Due to unique construction, the L1311A knee joint can be used both as a locking joint with manual release, and as a weight activated brake knee joint as the user's mobility progresses. The L1311A is particularly suitable for above-knee amputees with a high need for safety as the innovative brake mechanism increases the safety of the knee which can help compensate for some reduced muscle activity of the hip.

4 Safety Information

 **The Caution symbol highlights safety information which must be followed carefully.**



Be aware of finger trap hazard at all times



Any changes in performance of the knee e.g. inability to engage manual lock mechanism, instability or lag in transition from flexion moment to full knee extension moment in the knee, or unusual noise should be immediately reported to the Clinician / Practitioner



Any excessive changes in heel height may adversely affect the stability of the knee.



The user should be advised to contact their Clinician / Practitioner if their condition changes.

5 Maintenance

- Maintenance must be carried out by qualified personnel.
- Bi-Annual inspection to be sure brake function is satisfactory is recommended.
- Check for visual defects that may affect proper function.
- A loaner system is available should servicing be required.

The wearer should be advised:

Any changes in performance of this device must be reported to the Clinician / Practitioner.

Changes in performance may include:

- Inability to activate friction brake during weight activation
- Inability to cycle locking mechanism
- Inability to smoothly flex during swing
- Any unusual noises

Cleaning:

- Use a damp cloth and mild soap to clean the outside surfaces.
- DO NOT use aggressive cleaning agents.
- DO NOT use any petroleum lubrication on pivots or friction brake mechanism as this will void the warranty and render the friction brake mechanism non-functional, and could attract excessive dust or aggregate which can accelerate wear and tear on the component.
- If the limb/knee comes into contact with salt or chlorinated water, it should be rinsed with fresh water and dried.

6 Limitations on use

Intended Life:

- Service life of the product is covered by the warranty period (1 year)
- This product is recommended for use with other ST&G Products.

Lifting Loads:

Amputee weight and activity is governed by the stated limits.

Combined amputee, and carrying load, should not be at, or exceed stated weight limit. Always provide at least a 9Kg / 20lb. Buffer to account for any spiking activities, such as stepping down obstacles.

Environment:

Store at room temperature, and avoid extremely hot, cold, or moist storage environments Storage Temperature Range: between temperatures of -10°C to 50°C [14°F and 122°F]

Do not store in wet or very hot environment.



Allowable environmental conditions

Use – relative humidity: 0 % to 90 %, non-condensing

Storage/transportation – relative humidity: 20 % to 90 %, non-condensing

Splash - Fresh water, rain, salt water, urine, dust, sand, particles of foam cosmetics

cleaning required after contact with salt-laden air, salt water, chlorinated water, urine, sand

Unallowable environmental conditions

Storage/transportation: high vibrations, impacts

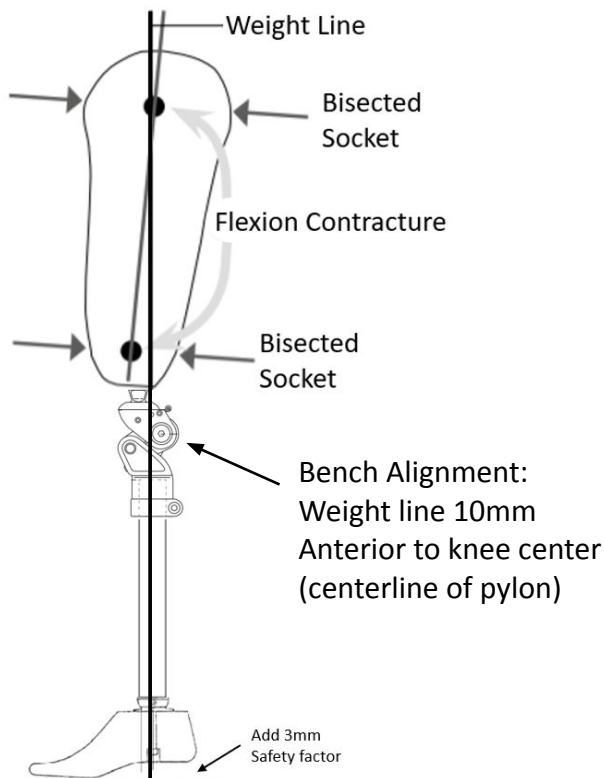
Cleaning agents containing solvents



7 Alignment and Set-Up



Users be aware of potential finger trap hazard



Alignment for the L1311A should be adhered to so as to enable a stable and safe functioning prosthesis for the wearer. The recommended alignment is 10mm anterior to the Knee Center which will have the weight line on the centerline along the length of the pylon. Weight line should also be along the centerline of the pylon in the sagittal plane so as to not promote undue stress on the knee joint axis.

Important: If the weight line is too close to the knee center, there is possibility of inadvertent knee instability. Adhere to allowance for safety factor of at least 3mm for initial fitting, and to reassess knee alignment and function on a regular basis initially (especially for new amputees) so as to gauge their progression and ability with the need for fine tuning knee function!



Set the bench alignment taking into account the heel height of associated footwear plus 3mm safety factor!



It is not recommended to have alignment too close to the knee center, as it could cause knee instability or inconsistent weight activation of brake!



Do not insert any tube spacers into tube clamp section – This can lead to potential failure. Only the intended pylon should be fully inserted to the tube clamp bottom.

8 Knee Adjustment

The L1311A is supplied by the factory in the basic setting.

Carefully assess the brake function with the wearer during the dynamic initial fitting to see if the basic setting is optimal.

If adjustment is necessary, it is best to start with the Stance Phase adjustment and then go to Swing Phase adjustments.

⚠ NOTE: There is a fine balance to adjusting this so as to ensure that the wearer will have a smooth transition to swing. Overly adjusting will cause the knee to not release during swing initiation!

8.1 STANCE PHASE - Brake Sensitivity Stance Adjustment

The brake sensitivity adjustment is to fine tune the amount of load required during stance phase to activate the brake mechanism.

To access the adjustment screw, be sure the knee is unlocked and flex to fully expose the adjustment screw on the brake mechanism face (fig. 1)

Using a 4 mm hex wrench turn adjustment screw:

Clockwise = more weight needed to initiate the brake function

Counter-Clockwise = less weight needed to initiate the brake function

⚠ NOTE: Adjust in $\frac{1}{4}$ or $\frac{1}{2}$ turn increments

Resetting Brake sensitivity to factory setting: Turn screw all the way till you feel soft stop. Then adjust out in $\frac{1}{4}$ turn increments till the patient can easily walk over the knee and it flexes without “sticking.”

⚠ IMPORTANT: The Friction adjustment should also be adjusted accordingly when resetting to factory setting!

- 1) Adjust Brake Sensitivity all the way in and then $\frac{1}{4}$ turn out.
- 2) Adjust Friction screw out till no pressure on the screw is felt, then turn till there is some resistance on the screw, and then turn $\frac{1}{4}$ turn in. This is factory setting for the Friction adjustment. Then proceed to adjust the Brake sensitivity adjustment screw out $\frac{1}{4}$ turn at a time to where the knee can release and swing without “sticking” and then can fine tune from there.

⚠ If there is no friction resistance at all, the brake will not function even at its highest sensitivity level. So make sure the friction screw is adjusted to a minimum of 1/4 turn after feeling the soft stop. Further adjustment may be needed!

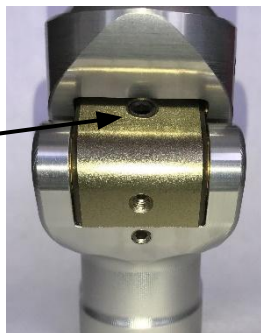


Fig. 1
Note that knee is flexed to expose screw

8.2 SWING PHASE - Friction Adjustment

The Knee Friction Adjustment screw is located on the bottom anterior face. Adjust with a 3mm hex. (fig. 2)

Knee friction adjustment is sensitive, so 1/8 turn will provide a notable difference!

The knee friction effect may occur during initial swing (prosthesis sticks) depending on the user's weight or walking habit.

In this case, adjust knee friction screw with a 3mm hex wrench. Reassess knee function during walking and adjust accordingly.

⚠ Important: flexion and extension must be possible at all settings!

⚠ To reset, Turn Brake Sensitivity screw in till you feel a soft stop, then back out the screw ½ turn before adjusting the Friction adjustment screw.

Adjust Friction screw out till no pressure on the screw is felt, then turn in till there is some resistance on the screw, then turn ¼ turn in. This is factory setting for the Friction adjustment. Proceed to adjust the Brake sensitivity adjustment screw out ¼ turn at a time to where the knee can release and swing without “sticking” and then can fine tune from there.

If there is no friction resistance at all, the brake will not function even at its highest sensitivity level. So make sure the friction screw is adjusted to a minimum of 1/4 turn after feeling the soft stop. Further adjustment may be needed!

8.3 SWING PHASE – Spring Extension Assist

The Knee Spring Extension Adjustment screw is located within the tube clamp portion of the knee joint, and is adjusted with a flat blade screwdriver. (fig. 3)

Using a flat blade screwdriver, the spring extension assist adjustment screw can be turned:

Clockwise for increased extension assist.

Anti-Clockwise for reduced extension assist.

⚠ Important: Knee action should be smooth. This knee is a low activity knee, so do not expect for very rapid extension assist to occur. Excessive spring tension could possibly affect knee friction tension.

Be sure that the 5mm Hex Wrench Tube Clamp Pinch Bolt torque is set to 16Nm.

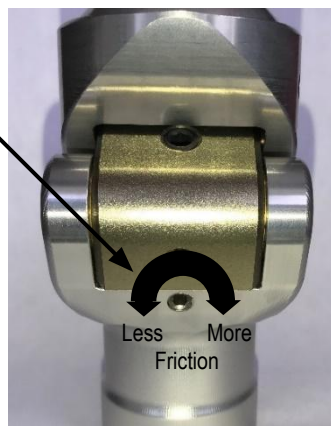


Fig. 2
Clockwise = increased friction
Anti-Clockwise = reduced friction

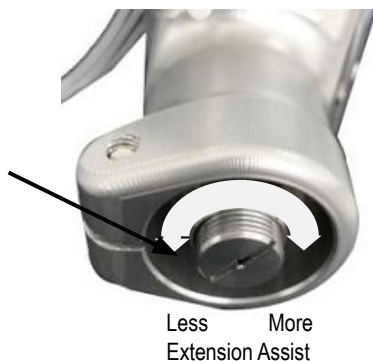


Fig. 3
Note that the screw is inside the tube clamp. (Screw accessed by removing pylon from knee unit tube clamp)

8 Knee Adjustment

8.4 Unlocked Knee Mode - Manual Lock Disable Procedure

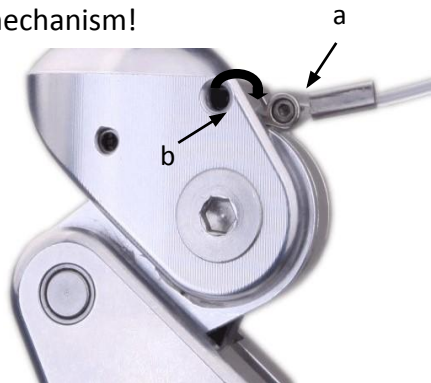


Note: Lock should only be disabled by the prosthetist when patient has been released to have the ability to control the prosthesis without the need for the manual lock mechanism!

Manual Lock Disable:

Lock mechanism-

- Push the locking lever (a) upwards and hold it in this position (fig. 7)
- Lanyard can be removed by removing the retainer screw with 2.5mm hex wrench.
- Secure locking lever (a) in this position by turning the set screw (b) with a 2.5 mm hex wrench clockwise. Apply thread locker!



IMPORTANT: Set screw (b) should be tightened to a torque of 5 Nm and secured with thread locker when finishing the prosthesis. Do not over tighten! Use a torque wrench!



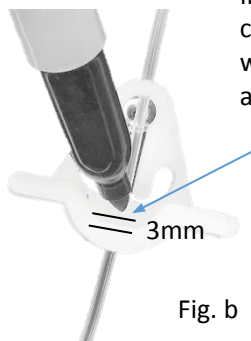
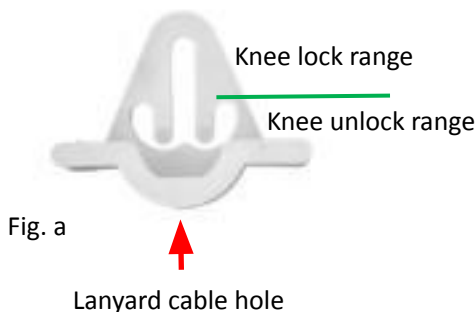
Note: Failure to adequately secure the set screw (b) when disabling the locking lever (a), can result in loss of function of the knee and / or makes it impossible to move the knee freely.



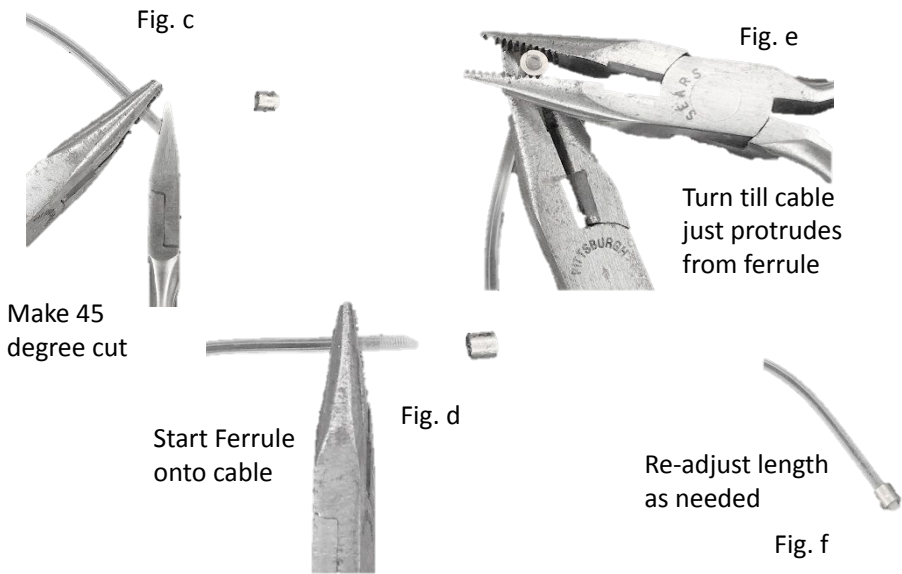
Note: If being used with the locking function, the disable set screw (b) must not impede the function of the locking lever (a) and must be secured with Loctite to rule out inadvertent loosening and inadvertent function.

8.5 Lock Lanyard

The Lanyard should move unrestricted by cosmesis, and should be able to unlock the knee, and lock the knee when the handle is not held.



Indicate where to cut the lanyard with a line 3mm above the handle



Setting the Lanyard Handle on the Cable:

Once the retainer screw is mounted with the star nut on the socket (refer to “Attachment of Lanyard Handle Star Nut” Section):

Setting the length:

- set the length by pulling the slack out of the cable from the lock lever and lanyard handle with the lanyard handle set in the “knee lock range” side of the handle making sure that the lock is pushed down in the locked position.

⚠ NOTE: We want to be sure that the lock will release by simply pulling up on the lanyard handle, and that the knee will again lock by releasing the lanyard handle.

- Set the lanyard length by having knee in locked position, and handle in the locked position.
- Take out unwanted slack in the lanyard cable by pushing excess length out of the handle, and remove ferrule by unscrewing but do not remove handle.
- Mark cable as indicated. (fig. b)
- Cut cable at a 45 degree angle as indicated. (fig. c)
- Screw ferrule onto cable. (fig. d, e)
- Confirm lock function by cycling the lanyard handle to assess that the knee locks, and unlocks. Adjust length as needed by screwing ferrule more onto the cable and cut excess. (fig. f)
- If used with the locking function, the locking lever or lanyard cable must not be impeded by the cosmesis. The cable must run freely.

⚠ IMPORTANT! Secure the cable so that it cannot catch in grinding tools when modifications are required to socket! Hazard potential!

Attachment of Lanyard Handle Star Nut:

The Star Nut needs to be laminated into the socket. Depending on the nut supplied, the hole should be burnished through, and then:

If the Star Nut is not threaded, drill out with 3mm drill bit and tap with 4mm tap.

If the Star Nut is threaded, chase threaded nut to clean thread with 4mm tap.

If for some reason, the Star Nut is not laminated into the socket, a relief can be sanded into the interior of the socket so that the Star Nut sits completely into the relief and does not protrude into the socket – The location and amount the Star Nut needs to be flush is to be determined by the Prosthetist.



Drill a corresponding hole the same size as the star nut hole into the determined location that the Lanyard Handle will be.

After relief is achieved, the Star Nut must be bonded into position.

The Star Nut will need to be completely covered over with bonding agent, and the bonded area can be covered with Masking Tape till the bond is totally cured.

Once cured, the hole should be burnished and chased with a tap, or drilled and tapped.



The following is not the preferred method, but should the situation arise, this technique could be utilized as a temporary method!

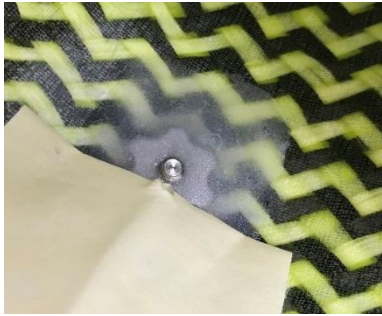


Fig. a



Fig. b

- Once the location is set, drill a corresponding hole the same size as the Star Nut (3mm bit).
- Sand down the inside of the socket enough to have the Star Nut lay flush with the socket surface.
- You can locate the Star Nut with the associated screw (if threaded, otherwise utilize a rivet) that has petroleum jelly on the threads and inserted through the hole and the Star Nut very slightly screwed onto it (fig a).
- Be sure to cover the nut entirely with enough bonding agent to have a flush inner surface! (fig. b)
- Slightly tighten the screw to draw in the Star Nut to the socket wall before the bonding agent cures. This will help to clean out the threaded area as well.



Apply Masking tape over the whole area to enable a smooth and relatively flat blended in surface – if the screw sticks through the tape, that is ok. You want to be sure that the Star Nut is completely covered so it stays in place when the hole is either chased, or drilled and tapped.

After Star Nut bonding has cured:

If Star Nut is threaded, burnish a through hole, and chase the threads with a 4mm metric tap.

If not threaded, burnish a through hole, re-drill a clean hole, and tap with a 4mm metric tap.

Apply thread locker to the stud threads, and screw the stud into the hole and into the Star Nut.

After determining the length needed for the cable, run through the lanyard handle.

NOTE: Cable can be run through a housing.

NOTE: Lanyard handle can hold knee unlocked when pulled past the retainer screw into side channel.

After the length is established, insert the handle so the pull tabs are on the distal aspect when inserted onto the stud.

NOTE: Do not tighten set screw completely in case length needs to be adjusted!

Once length is established, the set screw(s) can be tightened down. (Lock handle will vary depending on the knee!)

NOTE: Be sure to leave some extra cable in case some length adjustment may need to be done at a later time!

NOTE: Be sure knee lock can cycle adequately before delivering to your patient.

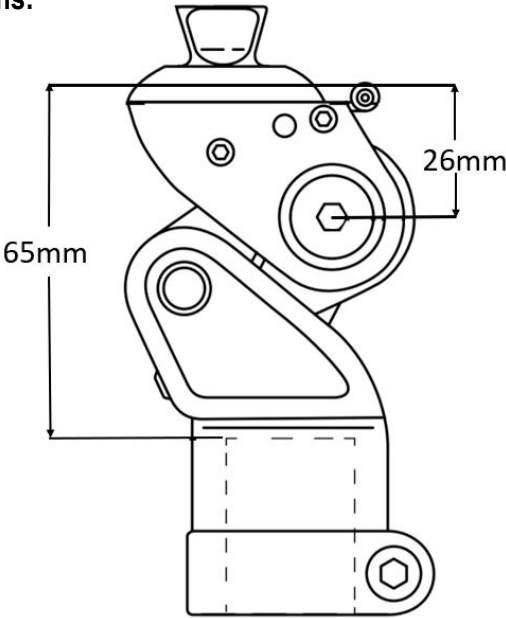


9 Technical Specification

- Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)
- Weight: 495g
- Recommended Activity: K1, K2
- Maximum User Weight: 125kg (275lbs)
- Maximum flexion angle (without socket): 145 degrees
- Proximal Alignment attachment: Pyramid
- Distal Alignment attachment: 30mm Tube Clamp
- Tube clamp torque setting: 16Nm
- Build Height: 65mm
- Swing Phase: Integrated Extension Spring
- Stance Phase: Optional lock or weight activated Brake Mechanism

•Materials: Aluminum Alloy, Stainless Steel, Steel, Urethane

Key Dimensions:



Build Height:
Component = 65mm
Knee Center to mid ball = 26mm

10 Warranty

Warranted for 2 years from the date of invoice by ST&G.

The user should be aware that changes or modifications not approved will void the warranty.

11 Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use supplied with the device. The manufacturer is not liable for damage caused by the component combinations that were not authorized by the manufacturer.



CE Conformity

This product meets the requirements of Council EU 2017/745 (EU) for medical products. This product has been classified as a class I product according to the classification criteria outlined in appendix IX of the guidelines. Please keep this manual in safe place for future use.

L1311A IFU REV H (07-09-26)

Specifications subject to change