Instructions for L1311A

Weight Activated Brake Knee with Manual Lock

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1 Description and purpose

Prosthetist instructions.

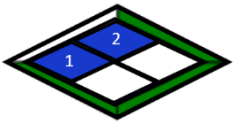
- L1311A knee is for lower limb prosthesis.
- Recommended for K1 up to K2.
- Weight limit for a user is up to 125kg / 275lbs
- Ability to lock knee in full extension as part of rehabilitation process.
- Can progress from locking to full-time unlocked weight activated brake knee.

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



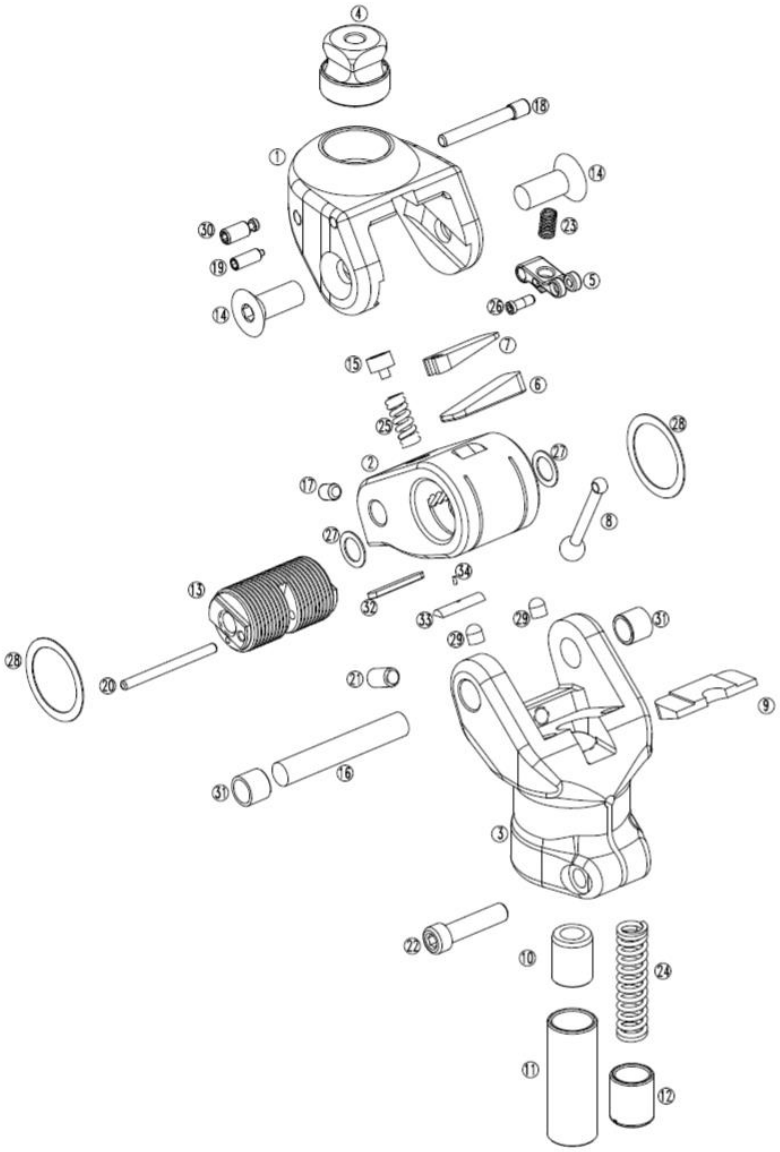
125Kg
275lbs

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, Poly Urethane



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 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:

- Increase in knee stiffness
- Inability to easily lock the knee with full extension
- Knee instability
- Any unusual noises

Cleaning:

- Use a damp cloth and mild soap to clean the outside surfaces.
- DO NOT use aggressive cleaning agents or lubricants.
- If the limb/knee comes into contact with salt or chlorinated water, or bodily fluids, 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 (2 years)
- 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.

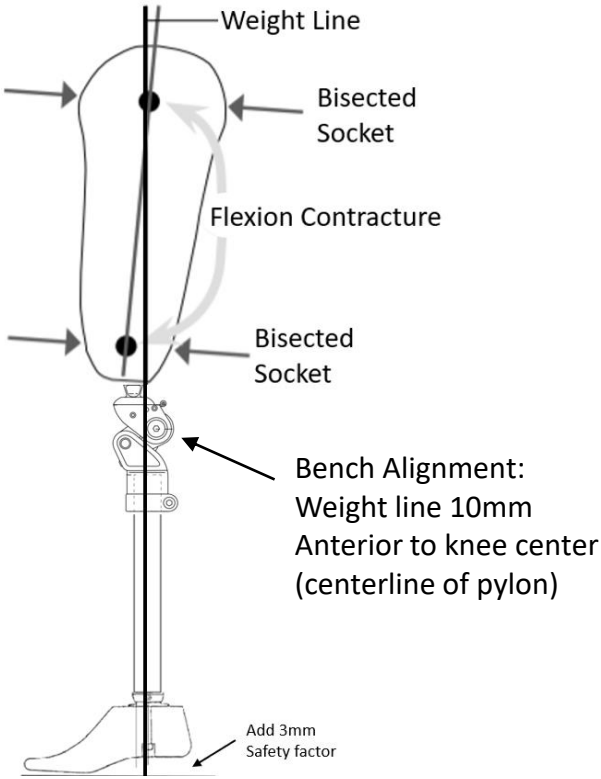
Environment:

Avoid abrasive environments such as those containing dust or sand for example as these may promote premature wear. Avoid contact with talcum powder.

Operating and Storage Temperature Range:
Exclusively for use between temperatures of -10˚C to 50˚C [14˚F and 122˚F]

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

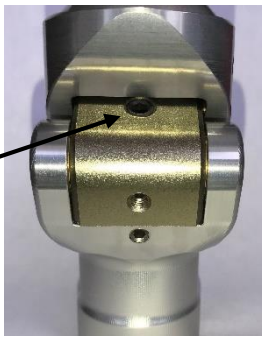
The L1311A is supplied by the factory in the basic setting.
Carefully assess the brake function with the wearer during the dynamic initial fitting to see if the basic setting is optimal.
If adjustment is necessary, it is best to start with the Stance Phase adjustment and then go to Swing Phase adjustments.

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.

Brake sensitivity adjustment screw location on L1311A



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 requires more weight needed to initiate the brake function so the brake effect is induced later (fig. 1)

Anti-Clockwise requires less weight needed to initiate the brake function so the brake effect is induced earlier (fig. 1)

Fig. 1
Note that knee is flexed to expose screw

NOTE: Adjustment as little as 5 degree turn makes a notable difference!

Resetting Brake sensitivity to factory setting: Brake sensitivity adjustment screw head should be flush with the knee brake mechanism surface.

8.2 SWING PHASE - Friction Adjustment

The Knee Friction Adjustment screw is located towards the bottom of the knee joint on the anterior and can be adjusted with a 3mm hex wrench. (fig. 2)

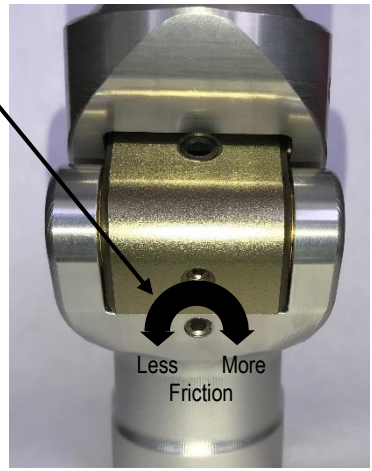


Fig. 2
Note that the screw is on the bottom.
Clockwise = increased friction
Anti-Clockwise = reduced friction
(Screw accessed above it is knee axis pin retainer screw)

Readjusting the knee friction setting.
NOTE: Minor adjustments of as little as 3 degree turn will provide a notable difference!

The knee friction effect may occur anyway during initial swing (prosthesis sticks) depending on the user's weight or walking habits which could impair the safety and the user's walking behavior.

In this case, the knee friction screw can be turned using a 3mm hex wrench:

Anti-Clockwise to reduce friction/sticking during initial swing. Reassess knee function during walking and adjust accordingly.

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

Resetting Friction to factory setting: Friction adjustment screw should be reset to be flush with knee frame surface.

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 screw driver. (fig. 3)

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

Using a flat blade screw driver, 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.

8 Knee Adjustment

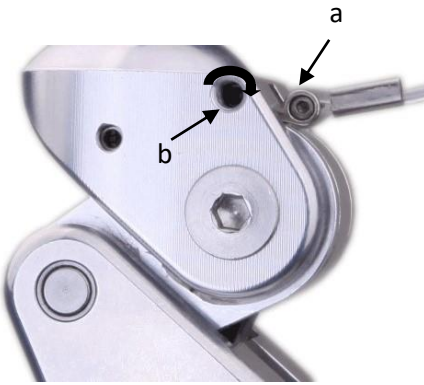
8.4 Unlocked Knee Mode - Manual Lock Disable Procedure

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!



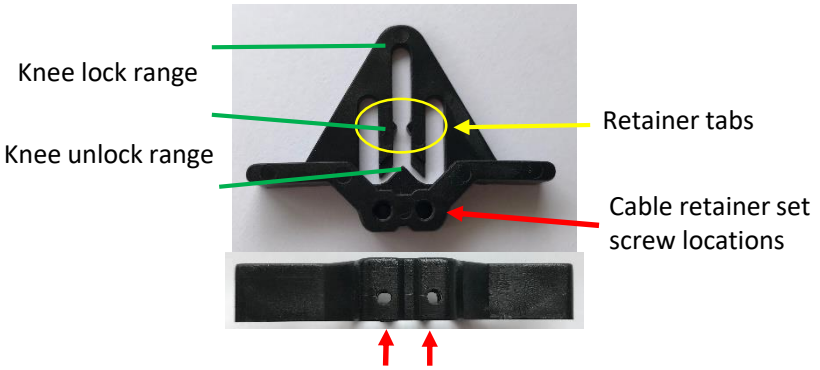
IMPORTANT: Set screw (b) should be tightened to a torque of 5 Nm and secured with thread locker when finishing the prosthesis. Do not over tighten! Use a torque wrench!

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.

The Dual Function Lanyard Handle

The Dual Function Lanyard Handle has the ability to keep the knee in either the temporary unlocked or locked position.



Setting the Dual Function Lanyard Handle on the Lanyard 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 Lanyard Cable length:

• Unlock knee and flex the prosthesis.
• 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 retainer tabs making sure that the lock is pushed down so it is not completely at the maximum open range.

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

• Set the lanyard handle cable retainer screw so it is snug, but not crushing the cable as to make further adjustment easier.
• Confirm lock mechanism function by cycling the lanyard handle to assess that the knee lock lever does lock in a completely extended position, and unlocks to allow knee flexion in the "knee lock range" of the handle.
• Confirm lock mechanism stays temporarily unlocked by having prosthesis fully extended/locked, and pull on the lanyard handle past the retainer tabs. Prosthesis should be able to flex without holding lanyard handle.
• Readjust cable as needed.
• 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 can be Bonded into position with Acrylic Sealing Resin with fiber filler, or ST&G Glu-It Urethane Adhesive.

The Star Nut will need to be completely covered over, 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 – PLEASE REFER TO Attachment of Lanyard Handle Star Nut.

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

Fig. a

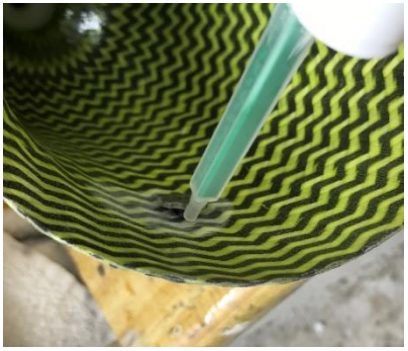


Fig. b

- 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).
- Use Urethane Adhesive, such as ST&G Glu-It, or bonding resin with filler, and be sure to cover the nut entirely with enough to have a flush inner surface! (fig. b)
- Slightly tighten the screw to draw in the Star Nut to the socket wall

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 is a dual function type that can hold knee unlocked when pulled past the retainer screw.

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.

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

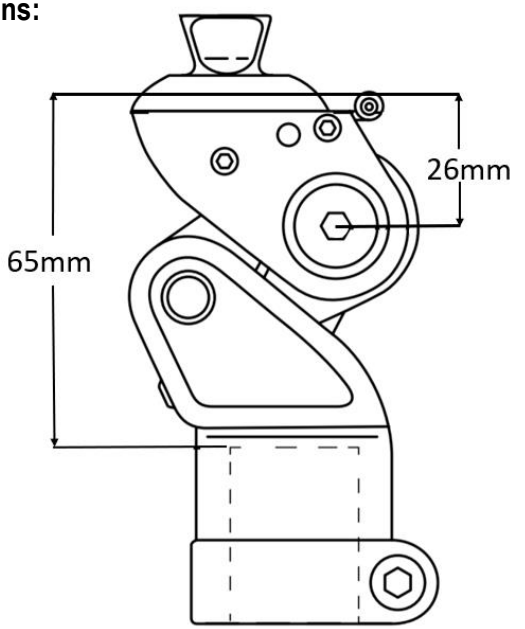
NOTE: Be sure knee lock can cycle adequately before delivering to your patient.

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 93/42/EEC guidelines 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.

CE

EC REP

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