

Instructions for 1311S

Weight Activated Brake Knee

Includes 1311-1 Extension Assist Kit and Cable for 1311



Description and purpose

Prosthetist instructions.

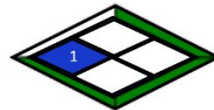
- 1311S knee is for lower limb prosthesis.
- Recommended for K1, K2.
- Designed for low activity patient.
- Weight limit for a user is up to 100kg / 220lbs
- Ability to get knee in full extension as part of rehabilitation process.
- Suitable for amputees with lower functional levels who desire to avoid using a manual locking knee.
- Not recommended for amputees with higher functional levels.
- The knee is suited for transfemoral amputees who require a high degree of stability.
- 1311-1 Extension Assist Kit and Cable included, and available as replacement

Contra-indications

- Residual muscular weakness, contractures or proprioceptive dysfunction including poor balance.
- Contra lateral joint instabilities or pathology
- Complicated conditions involving multiple disabilities
- Lack ability to adequately clear prosthetic side during swing



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



100Kg
220lbs

Product Code

1311S

Weight Activated Brake Knee

Construction

Principal Parts 1311S (Includes 1311-1 Extension Assist Kit)

Frame Stainless Steel, Steel, Brass, Plastic

No.	Description
1	Upper Joint Section with Pyramid
2	Lower Joint Section
3	Swing Block
4	Knee Axis
5	Swing Axis
6	Pressure Block
7	M6x12 Set Screw
8	Plastic Block
9	Compression Spring
10	Plastic Guide Pin
11	Stance Control Adjustment Screw
12	Extension Stop
13	Bumper
14	M4x6 Cap Screw
15	Brake Bushing
16	Busing Safety Device
17	Axis Screw
18	Brass Washer
19	External Lock Ring
20	Extension Assist Cable
21	Distal Anchor Shell
22	Adjustment Ring
23	M8x25 Adjustment Screw
24	Compression Spring
25	Flexible Plastic Cover
26	Brass Washer
27	Extension Stop
28	M6x20 Cap Screw (not illustrated)



Function

- The 1311S is a single axis mechanical knee with weight activated locking feature.
- Pyramid mounting option
- Adjustable Spring Extension Assist with mounting cable, attachment block, cover
- Knee is not intended for walking without extension assist

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. any change in how the knee functions should be immediately reported to the Clinician / Practitioner



Any excessive changes in heel height may adversely affect the ability to lock the knee, and the stability of the prosthesis



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



Clinician / Practitioner is responsible for assessing that patient is appropriate for this device.



Clinician / Practitioner is responsible for instructing patient of relevant content related to operation and safety of this device.



ST&G products are manufactured and tested for a particular weight and activity impact level. Use by another user for whom it was not originally manufactured may cause injury and voids any written or implied warranty or liability. The liability shall fall upon those that resale/provide the product to anyone other than the original user the foot was delivered to. Not to be resold by private party.

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 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.

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

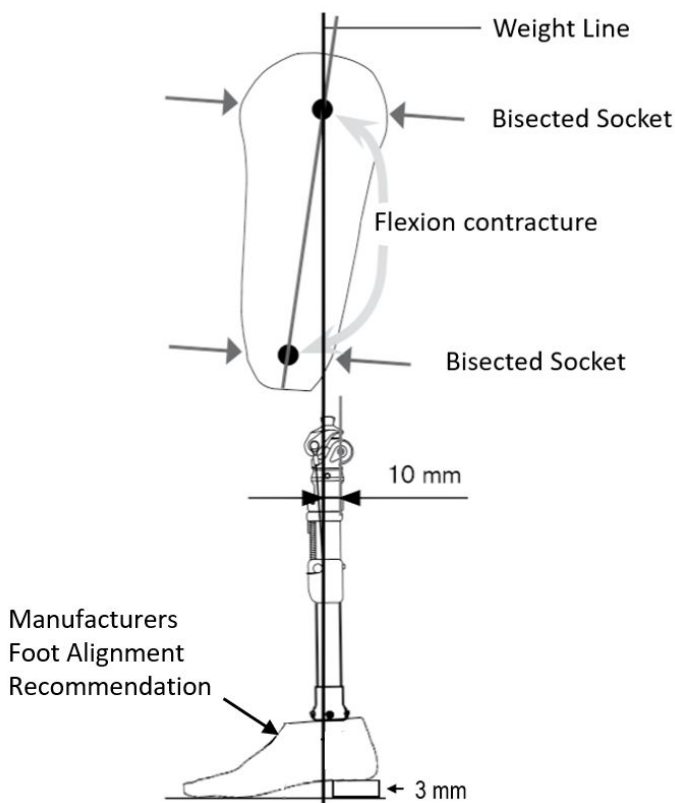
Cleaning agents containing solvents



Alignment and Set-Up



Users be aware of potential finger trap hazard



Note: The 1311 is a single axis knee with weight activated brake feature. This knee is not intended for variable cadence, high activity wearer, or without spring extension assist.

BENCH ALIGNMENT:

- With prosthesis assembled, taking into account hip flexion contractures, abduction, Line Of Progression, and toe out, the TKA plumb line should pass 10mm anterior to the knee center. Take into account shoe heel height, and add 3mm safety factor.
- It is advised to follow up in 1-2 weeks to reassess the alignment.
- The weight line should pass through the centerline of the knee in the Coronal or M/L plane. Excessive outset or inset will put undue stress on the knee joint.



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

Adjusting Swing and Stance Phase

! IMPORTANT! The knee must be adjusted to the individual needs of each patient.

NOTE: Swing Phase and Stance Phase are individually adjusted through the degree of adjustable spring extension assist force and friction (Swing) and the adjusted braking action which is dependent upon weight bearing (Stance).

1311-1 Extension Assist Assembly:

Extension assist is attached to the knee by hooking the loop of the cable to the anterior pivot axis of the knee.

(Fig. 1)



Swing Phase with Extension Assist:

Adjust the spring tension by turning the screw with a 4mm hex wrench on the adjustment ring.

Screw rotation:

Clockwise = increased spring tension

Anti-clockwise = reduced spring tension

(Applying dry graphite lubricant on the spring will prevent possible noise. Using a liquid lubricant can attract dust which can cause noise to develop)



Adjusting Swing and Stance Phase...Continued

Swing Phase Speed Friction Adjustment:
Knee movement resistance between the knee axis and the brake bushing is adjusted with the set screw in the posterior section of the knee using 3mm hex wrench. (Fig. 3)

Set Screw Rotation:

Clockwise = increase friction

Anti-clockwise = reduce friction

Adjustments as little as 15 to 20 degrees provide a perceptible change.

! IMPORTANT: If the friction setting is too loose, it will lead to play and malfunction of the knee. If the friction setting is too tight, the knee can brake even without weight bearing, or by just flexing an unweighted knee!



Stance Control/Brake Adjustment:
The responsiveness of the brake effect can be controlled by the stance control adjustment set screw using a 6mm hex wrench which is located by flexing the knee open (Fig. 4)

Screw Rotation:

Clockwise = brake is less responsive

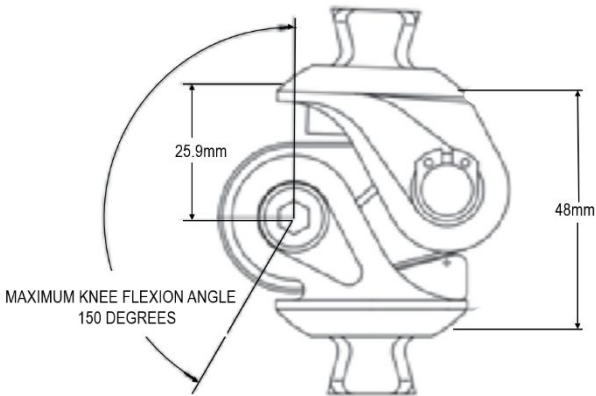
Anti-clockwise = brake is more responsive



Technical Specification

- Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)
 - Weight: 1311T/1311S 532g
 - Recommended Activity: K1, K2
 - Maximum User Weight: 120g (220lbs)
 - Maximum flexion angle: 150 degrees
 - Proximal Alignment attachment: Male Pyramid
 - Distal Alignment attachment: Male Pyramid
 - Extension Assist: Adjustable Spring Extension Assist
 - Build Height: 48mm
- Materials: Titanium, Steel, Brass, Plastic
Stainless Steel, Steel, Brass, Plastic

Key Dimensions:



Warranty

Warranted for 1 year from the date of invoice by ST&G.

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

ST&G products are manufactured and tested for a particular weight and activity impact level. Use by another user for whom it was not originally manufactured may cause injury and shall void any written or implied warranty or liability. The liability shall fall upon those that resale/provide the product to anyone other than the original user the foot was delivered to. Not to be resold by private party.

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.

Allowable environmental conditions

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

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



CE Conformity

This product meets the requirements 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.



Useful Life

Service life of the product is covered by the warranty period.

Disposal

The device and its packaging must be disposed of in accordance with respective national/local environmental regulations.

1311 IFU REV. H (07-10-26)

Specifications subject to change