

Instructions for 1314S/1314T Mechanical 4 Bar Knee



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1 Description and purpose

Prosthetist instructions.

- 1314S/1314T knee is for lower limb prosthesis.
- Recommended for K2.
- Designed for low impact activity patient.
- Weight limit for a user is up to 125kg/275lbs
- Ability to get knee in full extension as part of rehabilitation process.
- High need for safety.
- Knee Disarticulation Level

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

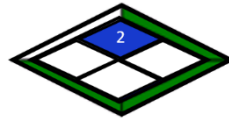


Ensure the end user has understood any Instructions for use, especially to the safety information.

Product Code

1314S/1314T

Mechanical 4 Bar Knee

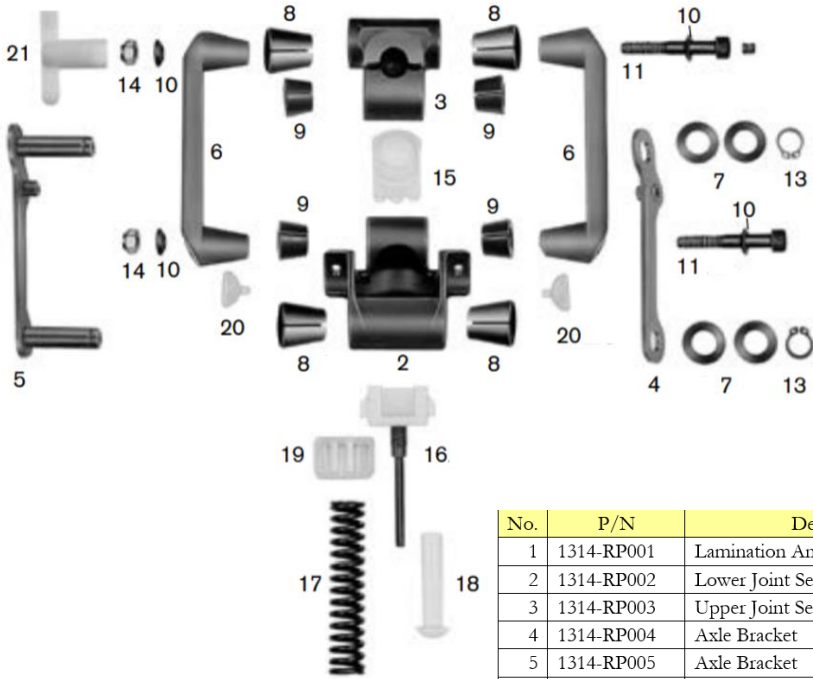


125Kg/
275kg

2. Construction

Principal Parts 1314S 1314T

Frame Stainless Steel, Steel, Brass, Plastic
Titanium, Steel, Brass, Plastic



No.	P/N	Description
1	1314-RP001	Lamination Anchor
2	1314-RP002	Lower Joint Section
3	1314-RP003	Upper Joint Section
4	1314-RP004	Axle Bracket
5	1314-RP005	Axle Bracket
6	1314-RP006	Linkage Bar
7	1314-RP007	Belleville Spring Washer
8	1314-RP008	Axle Bushing
9	1314-RP009	Slotted Bushing
10	1314-RP010	Spherical Washer
11	1314-RP011	M6x40 Socket Head Cap Screw
12	1314-RP012	M8x12 Set Screw
12a	1314-RP012a	M8x10 Set Screw
13	1314-RP013	Lock Ring
14	1314-RP014	M6 Lock Nut
15	1314-RP015	Plastic Block
16	1314-RP016	Guide for Extension Assist
17	1314-RP017	Extension Assist Spring
18	1314-RP018	Lock Control Plate-Plastic
19	1314-RP019	Knob for Extension Assist
20	1314-RP020	Stop
21	1314-RP021	Wrench
22	1314-RP022	M5x16 Truss Head Screw
23	1314-RP023	Two-Hole Nut

3 Function

- The 1314S / 1314T is a mechanical 4 Bar knee
- Knee Disarticulation Mounting Plate
- Distal Pyramid mounting option
- Adjustable Spring Extension Assist

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. 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.

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:

- Lack of smooth knee function
- Any unusual noises

Cleaning:

- Use a damp cloth and mild soap to clean the outside surfaces.
- DO NOT use aggressive cleaning agents.
- 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.

Environment:

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

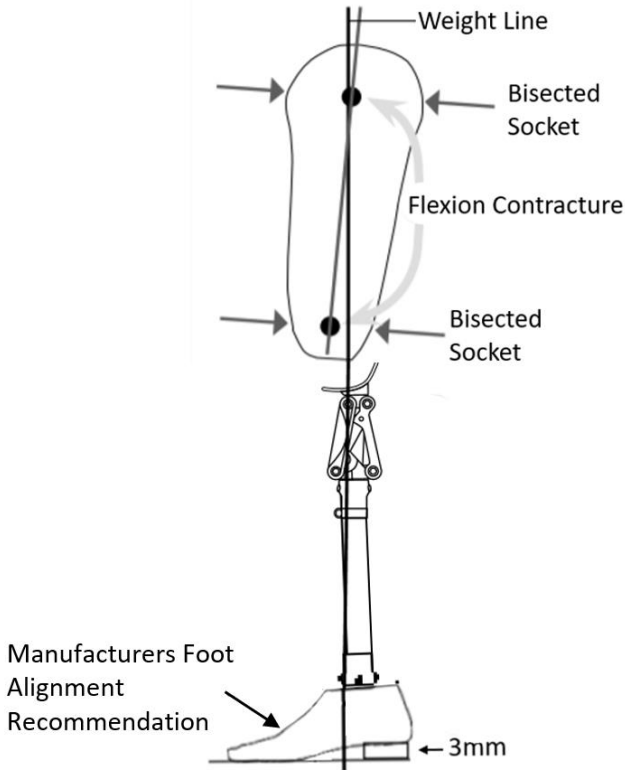
Operating and Storage Temperature Range:

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



Note: The 1314S/1314T is a mechanical 4 bar knee. 4 bar knees are inherently stable, but care needs to be taken to properly bench align the knee with the prosthesis.

BENCH ALIGNMENT:

- a) With prosthesis assembled, taking into account hip flexion contractures, abduction, Line Of Progression, and toe out, the TKA plumb line should pass through the knee center at the proximal/anterior pivot. Take into account shoe heel height, and add 3mm safety factor.
- b) Foot placement versus the knee will be determined by the foot alignment requirements. The knee should not tilt excessively more than 4 degrees anterior. It is advised to follow up in 1-2 weeks to reassess the alignment.
- c) 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!

Flexion Stop

NOTE: It is advisable to be sure that the mounting bracket portion of the socket contacts the distal knee pivot aspect of the frame, and not the posterior link! Damage could result from incorrect contact!



8 Knee Adjustments

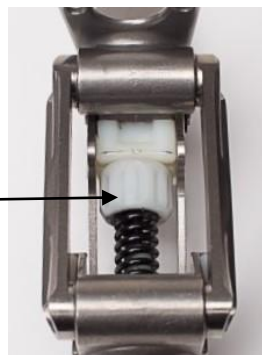
8.1 Swing Phase Control:

NOTE: It is advisable to adjust the extension spring, then the friction adjustment if needed.

Spring Extension Assist:

The 1314S / 1314T has an adjustable Spring Extension Assist knob located in between the posterior linkages of the knee.

Spring Extension Assist



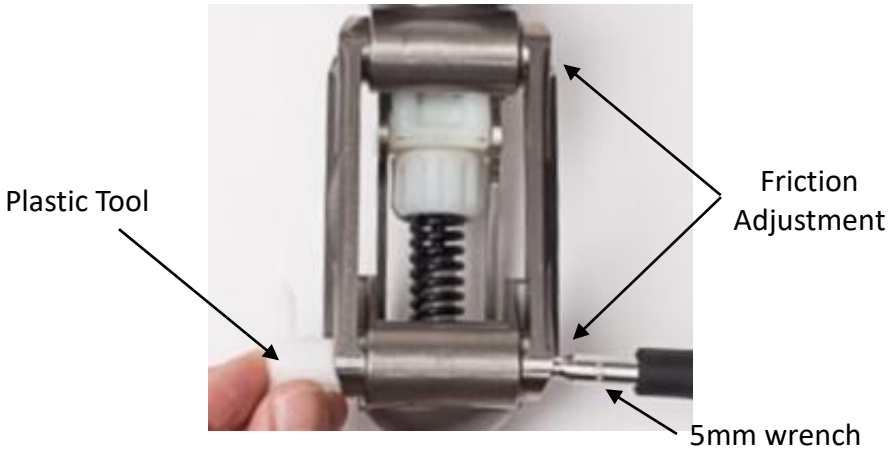
Turn the spring extension assist knob:
clockwise for increased extension assist;
anti-clockwise for reduced extension assist.

Swing Phase Control:

NOTE: It is advisable to adjust the extension spring, then the friction.

Friction Adjustment:

The 1314S and 1314T have the friction adjustment located at both anterior pivot axis locations.



For friction adjustment:

Turn hex head cap screw using 5mm wrench while holding the nut on the opposite using the enclosed plastic tool.

Turn the screw:

clockwise to increase friction

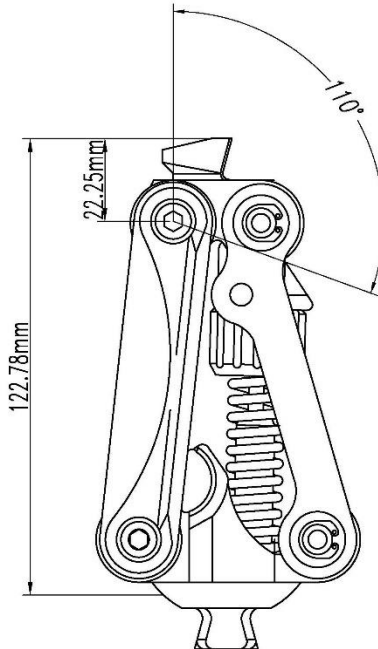
anti-clockwise to decrease friction.

NOTE: Adjustments of as little as 5 to 10 degrees provide a perceptible change.

9 Technical Specification (1314S/1314T)

- Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)
 - Weight: 671g/918g
 - Recommended Activity: K2
 - Maximum User Weight: 125kg (275lbs)
 - Maximum flexion angle: 110 degrees
 - Proximal Alignment attachment: Low Profile Knee
Disarticulation Level
 - Distal Alignment attachment: Male Pyramid
 - Extension Assist: Adjustable Spring Extension Assist
 - Build Height: 122.78mm
- Materials: Stainless Steel, Steel, Brass, Plastic / Titanium, Steel, Brass, Plastic

Key Dimensions:



10 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.

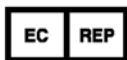
11 Liability

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



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