Instructions for 1315S/1315T
Mechanical 4 Bar Knee
with manual lock

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1 Description and purpose

Prosthetist instructions.

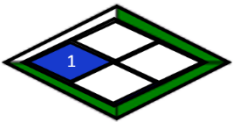
- 1315S/1315T knee is for lower limb prosthesis.
- Recommended for K1.
- Designed for low impact activity patient.
- Weight limit for a user is up to 100kg/220lbs
- Ability to get knee in full extension as part of rehabilitation process.
- High need for safety.
- Knee Disarticulation Level

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



100Kg/
220kg

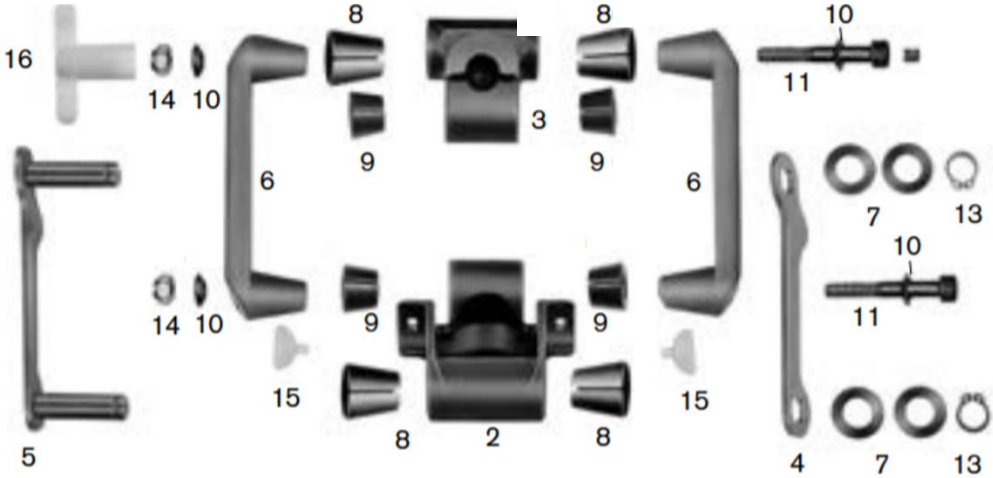
1315S/1315T

Mechanical 4 Bar Knee with manual lock

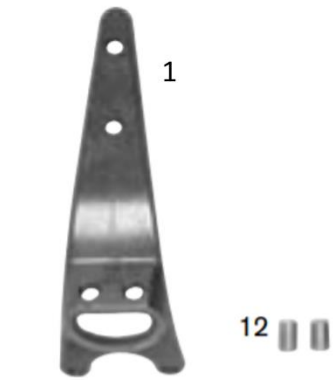
2. Construction

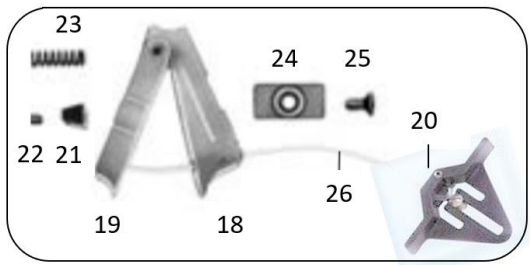
Principal Parts 1315S
1315T

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



No.	P/N	Description
1	1315-RP001	Lamination Anchor
2	1315-RP002	Lower Joint Section
3	1315-RP003	Upper Joint Section
4	1315-RP004	Axle Bracket
5	1315-RP005	Axle Bracket
6	1315-RP006	Linkage Bar
7	1315-RP007	Belleville Spring Washer
8	1315-RP008	Axle Bushing
9	1315-RP009	Slotted Bushing
10	1315-RP010	Spherical Washer
11	1315-RP011	M6x40 Socket Head Cap Screw
12	1315-RP012	M8x12 Set Screw
13	1315-RP013	Lock Ring
14	1315-RP014	M6 Lock Nut
15	1315-RP015	Stop
16	1315-RP016	Wrench
17	1315-RP019	Lock, Complete
18	1315-RP020	Posterior Lock Body
19	1315-RP021	Anterior Lock Body
20	1315-RP022	Lock Handle, Complete
21	1315-RP023	Bushing
21	1315-RP024	Nut
23	1315-RP025	Compression Spring
24	1315-RP026	Washer
25	1315-RP027	Bolt
26	1315-RP028	Perlon Cord





3 Function

- The 1315S / 1315T is a mechanical 4 Bar knee with manual lock
- Knee Disarticulation proximal mounting option
- Pyramid distal mounting option

Knee is not be walked unlocked as a free knee joint. This will lead to patient falling and is unsafe.

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 for lock to cycle, 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:

- Inability to cycle the lock of the knee
- 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.

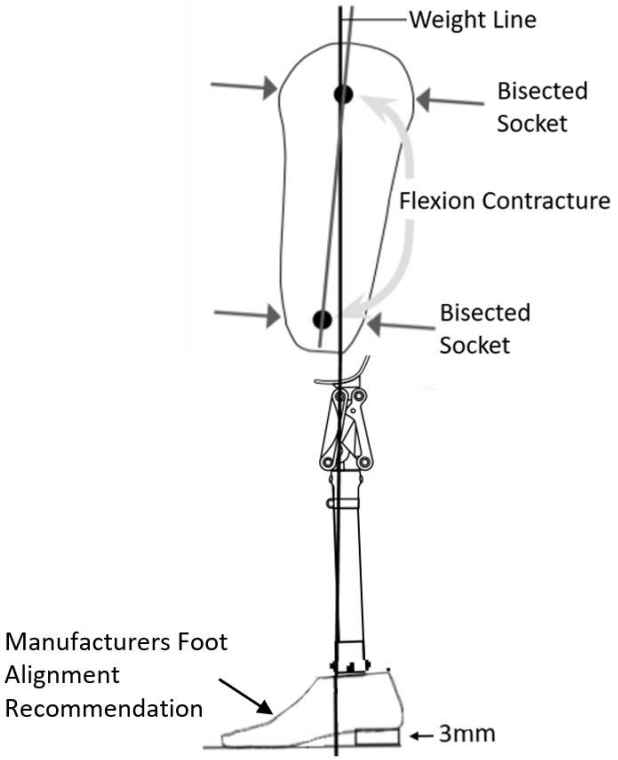
Environment:

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 1315S/1315T 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.

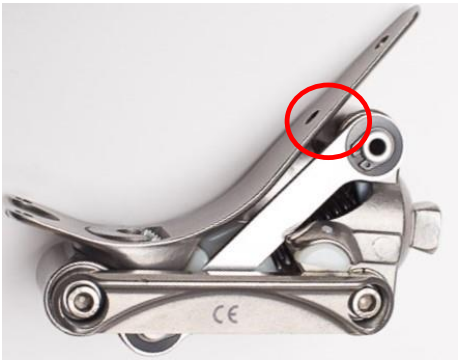
b) Foot placement versus the knee will be determined by the foot alignment requirements. The knee should not tilt excessively more than 4 degrees anterior. It is advised to follow up in 1-2 weeks to reassess the alignment.

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!

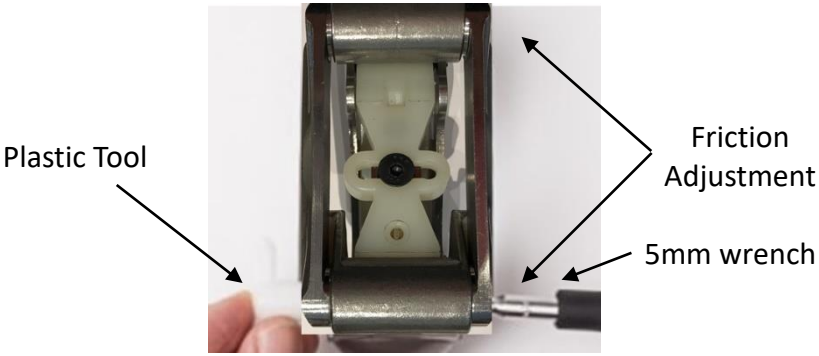


8 Knee Adjustments

8.1 Friction Adjustment

NOTE: Friction adjustment for 1315S and 1315T .

1315S / 1315T have friction adjustment located at both anterior pivot axis locations.



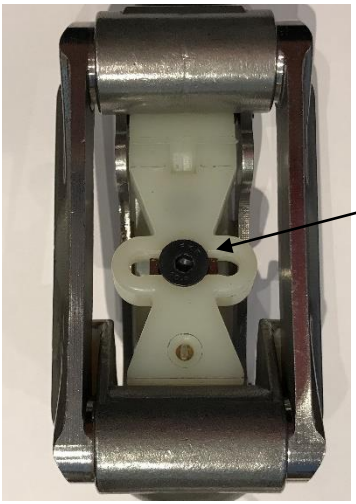
For friction adjustment:
Turn hex head cap screw using 5mm wrench while holding the nut on the opposite side using the enclosed plastic tool. Turn the screw:
clockwise to increase friction
anti-clockwise to decrease friction.

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

Manual Lock Adjustment:

Manual lock has adjustabilitiy for sensitivity and to take up slack for wear.

IMPORTANT: Do not over tighten the adjustment screw, as the lock will take a lot of effort to lock or may interfere with full engagement!



Manual Lock Adjustment Screw. Use 4mm hex wrench

Manual Lock adjustment:
Turn hex head cap screw using 4mm hex wrench.
Turn the screw:
Clockwise to increase friction
Anti-clockwise to decrease friction.

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

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 3.3mm 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 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!

Once the location is set, drill a corresponding hole the same size as the Star Nut.

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 a copper rivet that has petroleum jelly on the tip and inserted through the hole and the Star Nut placed onto it.

This will aid in locating the Star Nut when bonding it in place – Be sure to cover the nut entirely with enough to have a flush inner surface!

Apply Masking tape over the whole area to enable a smooth and relatively flat blended in surface – if the rivet 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 may vary depending on knee model used!

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!

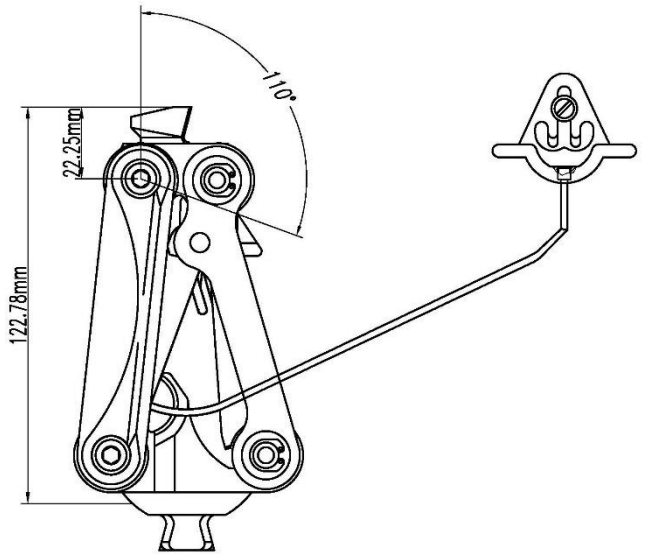
NOTE: Be sure knee lock can cycle adequately before delivering to your patient.

9 Technical Specification (1315S/1315T)

•Operating & Storage Temperature Range:	-10˚C to 50˚C (14˚F to 122˚F)
•Weight:	671g/916g
•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:	118mm

•**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

EC REP

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