

Instructions for 1318T/1318S Single Axis Knee with Manual Lock



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1 Description and purpose

Prosthetist instructions.

- 1318S/1318T knee is for lower limb prosthesis.
- Recommended for K1.
- Designed for low activity patient only.
- Intended for wearers needing high stance phase stability, minimum swing phase control
- Weight limit for a user is up to 100kg / 220lbs
- Ability to get knee in full extension as part of rehabilitation process.

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

1318S / 1318T

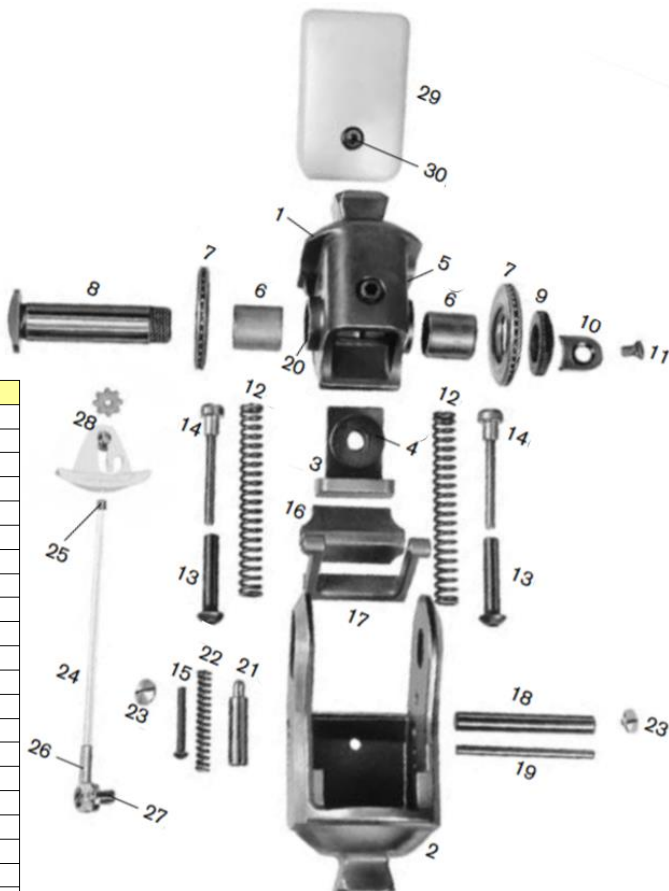
Single Axis Knee with Manual Lock

2. Construction

Principal Parts 1318S / 1318T

- Frame Stainless Steel, Steel, Plastic
Titanium, Steel, Plastic

No.	P/N	Description
1	1318-RP001	Upper Joint Section
2	1318-RP002	Lower Joint Section
3	1318-RP003	Extension Stop
4	1318-RP004	Rubber Bumper
5	1318-RP005	M8x20 Set Screw
6	1318-RP006	Joint Axis Bushing
7	1318-RP007	Thrust Bearing
8	1318-RP008	Axis
9	1318-RP009	Nut for Axis
10	1318-RP010	Safety Plate
11	1318-RP011	M4x5 Oval Head Screw
12	1318-RP012	Compression Spring
13	1318-RP013	Spring Guide Housing
14	1318-RP014	Spring Guide Pin
15	1318-RP015	Guide Pin
16	1318-RP016	Lock Cam
17	1318-RP017	Lock Lever
18	1318-RP018	Axis Pin
19	1318-RP019	Axis Pin
20	1318-RP020	Axis Pin
21	1318-RP021	Spring Guide Housing
22	1318-RP022	Compression Spring
23	1318-RP023	M3.5x8 Lock Screw
24	1318-RP024	Perlon Cord
25	1318-RP025	Threaded Fitting, Short
26	1318-RP026	Cable Clamp
27	1318-RP027	Button Head Screw, Nickel Plated
28	1318-RP028	Lock Handle, Complete
29	1318-RP029	Plastic Knee Cap
30	1318-RP030	M4x8 Cap Screw



3 Function

- The 1318S / 1318T is a single axis knee with manual lock.
- Pyramid top and bottom mounting option.
- Spring extension assist.
- Very low socket to knee center build height.
- Friction adjustment.

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 cycle the manual locking feature, or 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 stability of the prosthesis, and ability to lock 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 of satisfactory knee function 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 manual knee lock
- 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 as this will void the warranty.
- 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 weight of amputee and carrying load, should not 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.

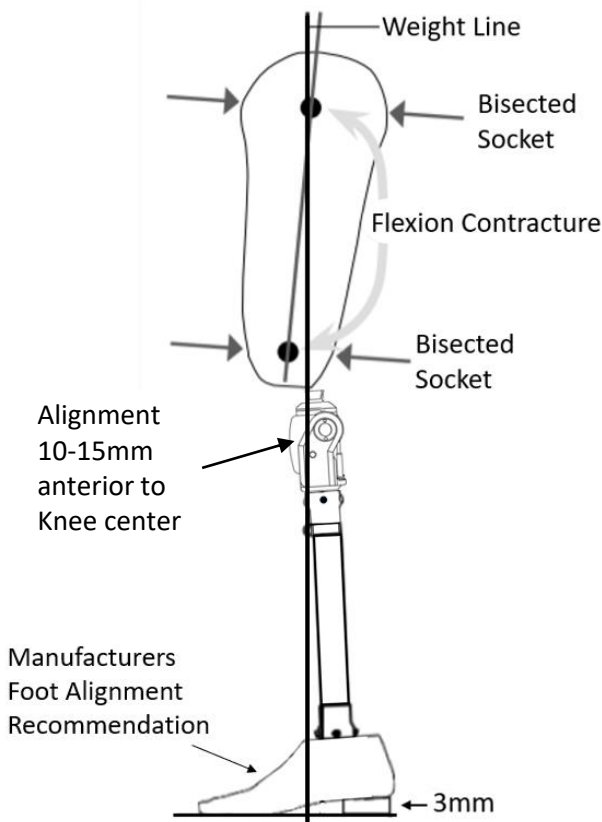
Operating and Storage Temperature Range:

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



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

Note: The 1318 is a Single Axis locking knee. This knee is not intended for unlocked activity wearer.

BENCH ALIGNMENT:

- With prosthesis assembled, taking into account hip flexion contractures, abduction, Line Of Progression, and toe out, the TKA plumb line should pass 10-15mm anterior to the knee axis. 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.

8 Knee Adjustments

8 A. Friction Adjustment

Friction of the axis can be adjusted with a 4mm hex wrench by turning the Set Screw which becomes accessible when the knee is flexed. Flex the Knee Joint until the Set Screw becomes accessible.



With 4mm hex wrench, turn screw:
Clockwise = increase friction
Anti-clockwise = reduce friction

8 B. Compensating for medial/lateral Movement

If medial/lateral joint play develops, it may be reduced by tightening the Axis Nut.



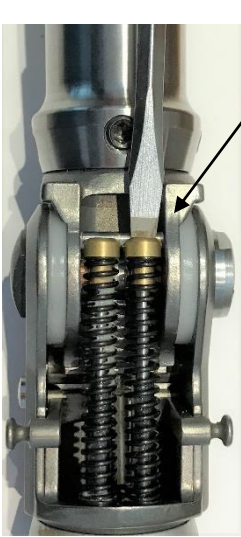
Slightly tighten the Axis Nut.

Important: Overtightening the nut will bind up the axis and restrict normal movement of the Knee Joint!

8 C. Extension Spring

(1) Removal

Using a flat blade screw driver, press the Spring Guide Pin downward until it disengages from the Axis Pin . Does not require much force.

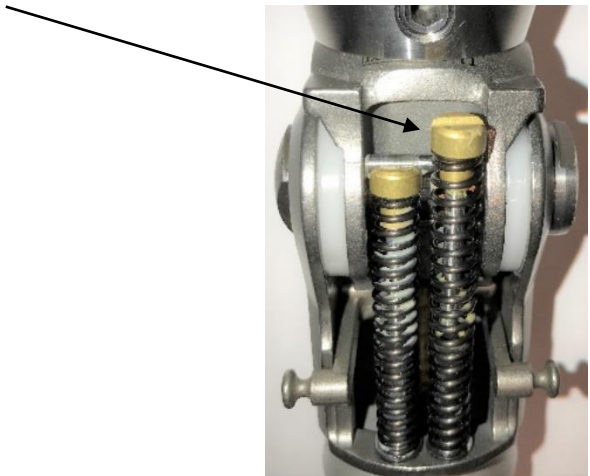


Remove spring assembly from spring seat

(2) Installation

Simultaneously place spring onto spring seat on frame, and push Spring Guide Pin into spring to compress it with flat Blade screw driver, then place Spring Guide Pin under Axis Pin. Remove screw driver and slide Spring Guide Pin notch under Axis Pin.

Spring Guide Pin notch



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!

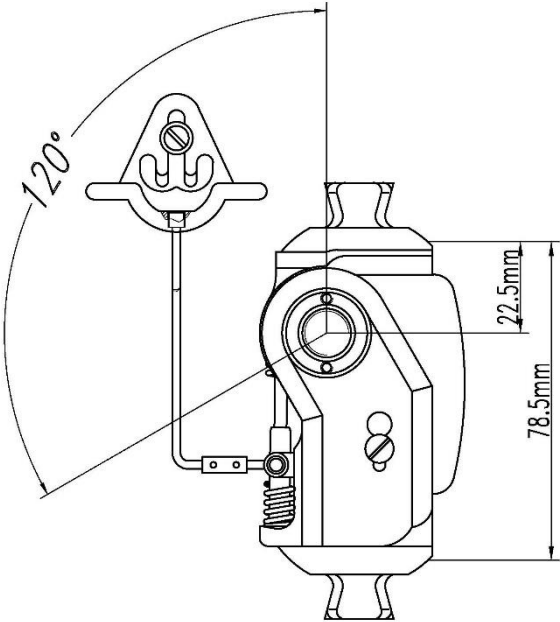
NOTE: Be sure knee lock can cycle adequately before delivering to your patient.



9 Technical Specification

•Operating & Storage Temperature Range:	-10°C to 50°C (14°F to 122°F)
•Weight: 1318S / 1318T	589g (lbs oz)/389g (lbs oz)
•Recommended Activity:	K1
•Maximum User Weight:	100g (220lbs)
•Maximum flexion angle:	120 degrees
•Proximal Alignment attachment:	Male Pyramid
•Distal Alignment attachment:	Male Pyramid
•Build Height:	78.5mm
•Knee Center to mid pyramid ball	22.5mm
•Materials: 1318S Stainless Steel, Steel, Plastic	
1318T Titanium, Steel, Plastic	

Key Dimensions:



10 Warranty

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

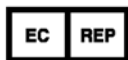
The user should be aware that changes or modifications not approved will void the warranty.

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.



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