Instructions for 1312S/1312T
Mechanical 4 Bar Knee

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1 Description and purpose

Prosthetist instructions.

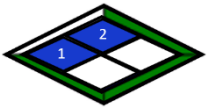
- 1312 (S/T) knee is for lower limb prosthesis.
- Recommended for K1, K2.
- Designed for low to moderate impact activity patient.
- Weight limit for a user is up to 1312S 125kg/275lbs, 1312T 125kg/275lbs
- Ability to get knee in full extension as part of rehabilitation process.
- High need for safety.

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



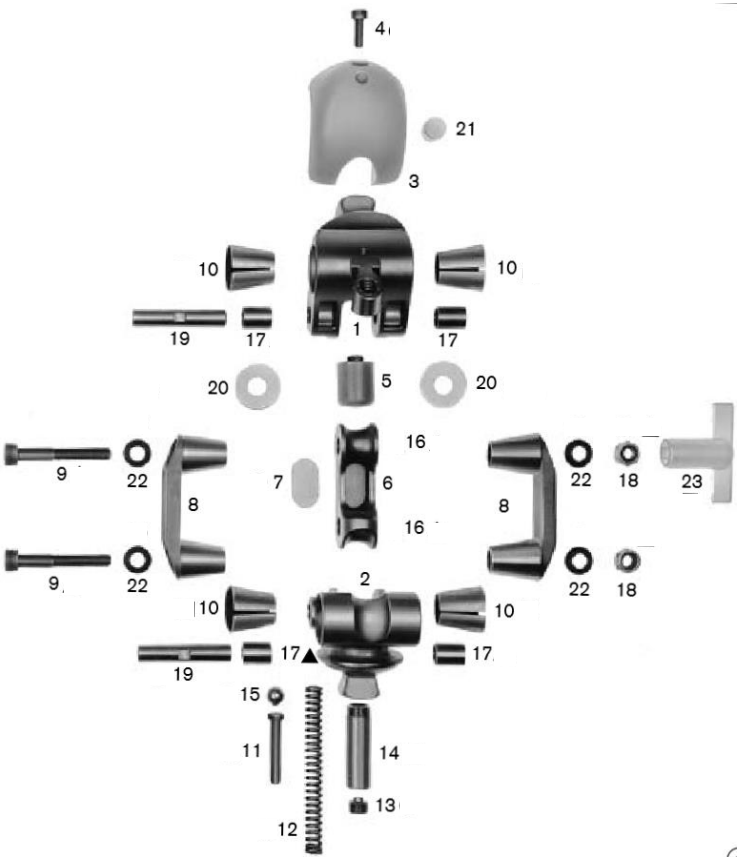
100Kg/220kg
114kg/250lbs

1312S/1312T
Mechanical 4 Bar Knee

2. Construction

Principal Parts 1312S
1312T

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



Components for 1312T/S					
No.	P/N	Description	No.	P/N	Description
1	1312-RP001	Upper Joint Section	13	1312-RP013	Adjustment Screw
2	1312-RP002	Lower Joint Section	14	1312-RP014	Spring Housing
3	1312-RP003	Plastic Knee Cap	15	1312-RP015	Bearing Ball, Stainless Steel
4	1312-RP004	M4x12 Cap Screw with Hexagon Socket	16	1312-RP016	M6x6 Set Screw with Hexagon Socket
5	1312-RP005	Extension Stop, Complete	17	1312-RP017	Bushing
6	1312-RP006	Posterior Linkage Bar	18	1312-RP018	M6 Lock Nut
7	1312-RP007	Stop Bumper	19	1312-RP019	Posterior Axis Pin
8	1312-RP008	Anterior Linkage Bar	20	1312-RP020	Brass Washer
9	1312-RP009	M6x40 Cap Screw with Hexagon Socket	21	1312-RP021	Friction Stop Bumper
10	1312-RP010	Knee Axis Bushing	22	1312-RP022	Washer
11	1312-RP011	Pin for Extension Assist	23	1312-RP023	Wrench
12	1312-RP012	Spring for Extension Assist			

3 Function

- The 1312S / 1312T is a mechanical 4 Bar knee
- Pyramid mounting option
- Adjustable Spring Extension Assist
- Adjustable Friction

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 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.

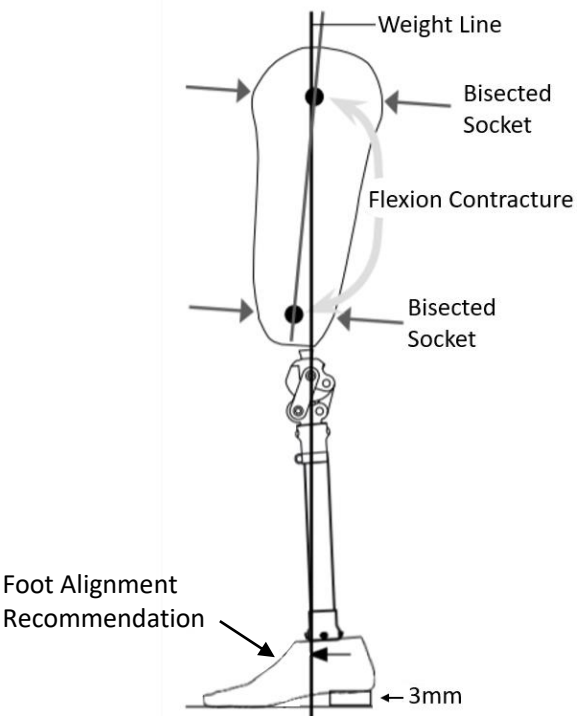
Environment:

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 1312S/1312T 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!

8 Knee Adjustments

Swing Phase Control:

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

Spring Extension Assist:
The 1312S and 1312T have an adjustable Spring Extension Assist located through the distal pyramid. The knee should be disconnected from the female pyramid receiver prior to adjustment.

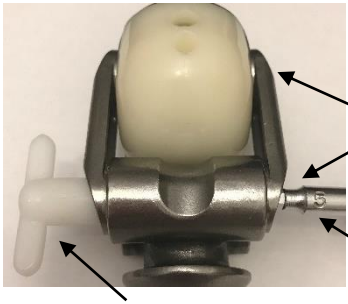
Use a 4mm driver to turn the spring extension assist screw:
clockwise for faster extension;
anti-clockwise for slower extension;

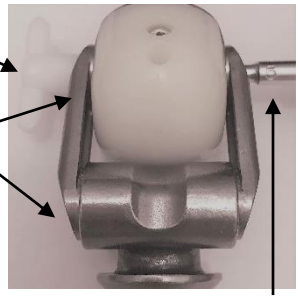
Swing Phase Control:

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

Friction Adjustment:

The 1312S and 1312T 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

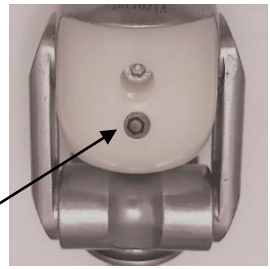
anti-clockwise to decrease friction.

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

Pyramid Head Tilt Adjustment:

It may become necessary in some circumstances to vary the position of the Instant Knee Center (IKC) more anterior or posterior according to individual needs.

Turn the adjustment screw using 4mm hex head wrench.



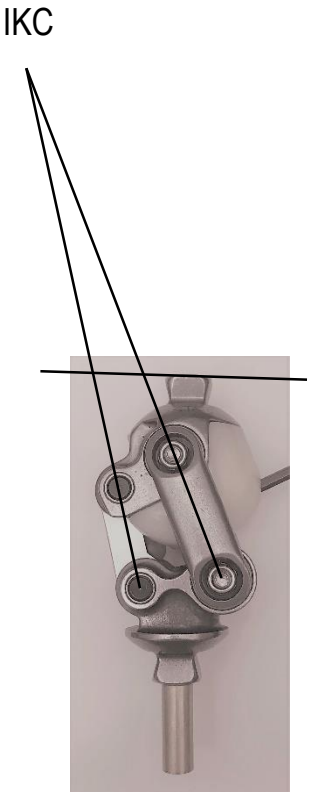
Adjusting the Pyramid Head Tilt feature can induce knee instability. This should typically be done only in very small increments, and to a very small final amount of adjustment. Typically a head tilt adjustment with an anterior tilt is more stable than an adjustment with a posterior head tile which is more unstable.

Pyramid Head Tilt Adjustment:

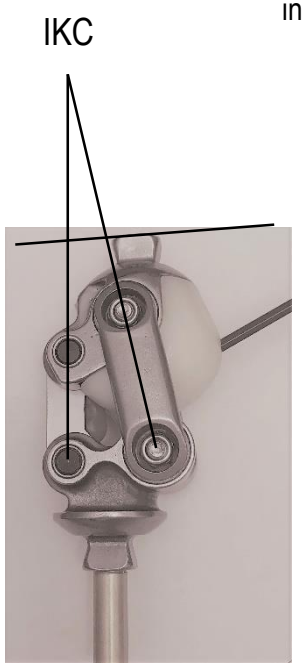
Adjusting the Head Tilt will move the IKC. If the IKC is set too anterior (less stable) and the socket weight line too far posterior, the knee will be very unstable and could lead to fall or injury. Head Tilt is to “Fine Tune” the knee and will not substitute for inadequate socket placement!

Anti-clockwise rotation will tilt the pyramid anteriorly which increases stability by adding extensión into the socket and moving the weight line anteiorly versus the ICR. (ICR is more posterior of socket making flexion initiation harder)

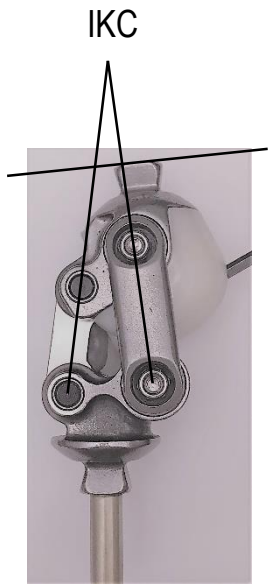
Clockwise rotation will tilt the pyramid posteriorly which decreases stability by adding flexion into the socket and moving the weight line posteriorly versus the ICR. (ICR is more anterior of socket making flexion initiation easier)



Very Stable
Harder to initiate swing



Stable
Neutral Function



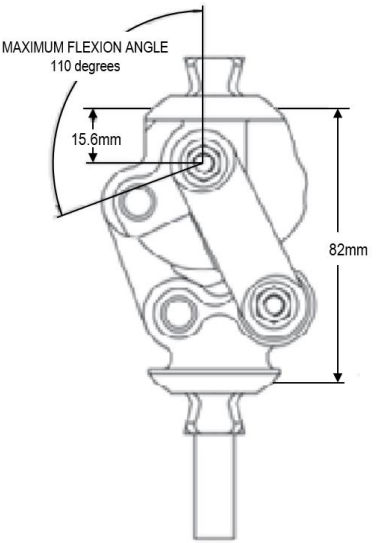
Less Stable
Easier to initiate swing

9 Technical Specification (1312S/1312T)

•Operating & Storage Temperature Range:	-10˚C to 50˚C (14˚F to 122˚F)
•Weight:	719g/481g
•Recommended Activity:	K2
•Maximum User Weight:	114kg (250lbs)/100kg (220lbs)
•Maximum flexion angle:	110 degrees
•Proximal Alignment attachment:	Male Pyramid
•Distal Alignment attachment:	Male Pyramid
•Extension Assist:	Adjustable Spring Extension Assist
•Build Height:	82mm

•**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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