Instructions for 1313A
Manual Locking Knee

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1 Description and purpose

Prosthetist instructions.

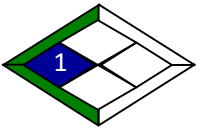
- 1313A knee is for lower limb prosthesis.
- Recommended for K1.
- Weight limit for a user is up to 90kg / 198lbs
- Ability to lock knee in full extension as part of rehabilitation process.

Contra-indications

- Residual muscular weakness, contractures or proprioceptive dysfunction including poor balance.
- Contra lateral joint instabilities or pathology
- Complicated conditions involving multiple disabilities

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

Product Code



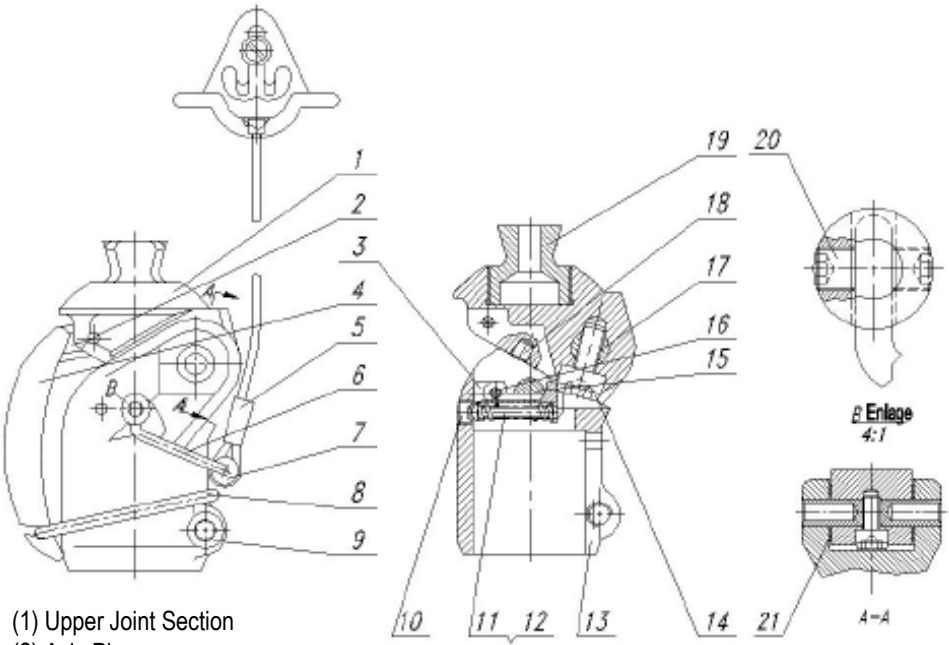
90Kg
198lbs

L1313A
Manual Locking Knee

2. Construction

Principal Parts

Frame	Aluminum Alloy, Brass, Stainless Steel, Steel
Knee head	Aluminum Alloy, Stainless Steel



(Illustration 1)

(1) Upper Joint Section
(2) Axis Pin
(3) Lock Latch
(4) Plastic Knee Cap*
(5) Cable Clamp
(6) Lock Bale
(7) Cable Guide
(8) Plastic Ring*
(9) Cap Screw M6x20
(10) Spring Screw
(11) Guide Pin
(12) Compression Spring
(13) Low Joint Section
(14) Extension Stop Screw
(15) Lock Axis
(16) Axis Pin
(17) Joint Axis
(18) Extension Stop
(19) Pyramid Section
(20) Set Screw M3x4
(21) Brass Washer

3 Function

- The 1313A is a single axis mechanical knee with lever activated manual locking feature.
- Pyramid mounting options
- Manual lock handle can be placed as needed
- Knee is not intended for walking while unlocked

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 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.
- 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 years)
- 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.

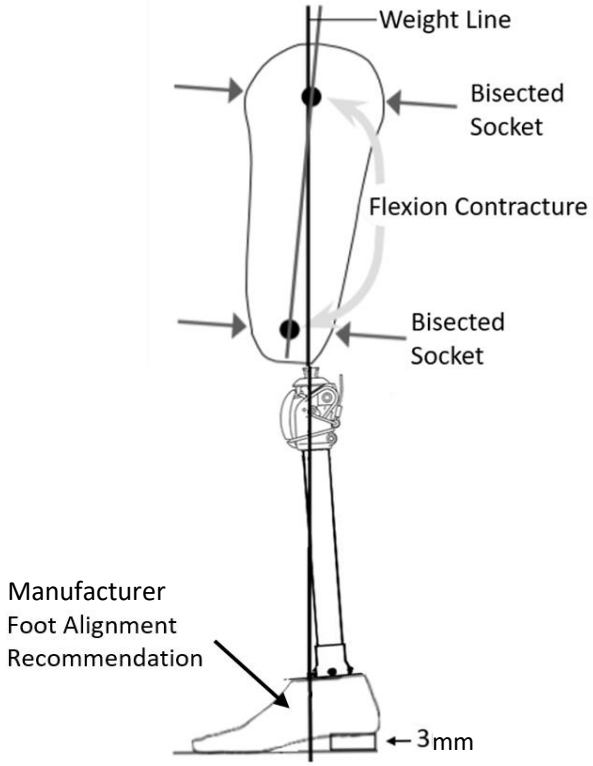
Environment:

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 1313A is a single axis knee with manual lock feature. This knee is not intended for walking without the lock engaged.

BENCH ALIGNMENT:

a) With prosthesis assembled, taking into account hip flexion contractures, abduction, Line Of Progression, and toe out (Fig.1), the TKA plumb line should pass 15mm anterior of the knee axis, about where the bail lock pivot axis is. Take into account shoe heel height, and add 3mm safety factor.

b) Align the knee according to the foot per foot recommendation. 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!

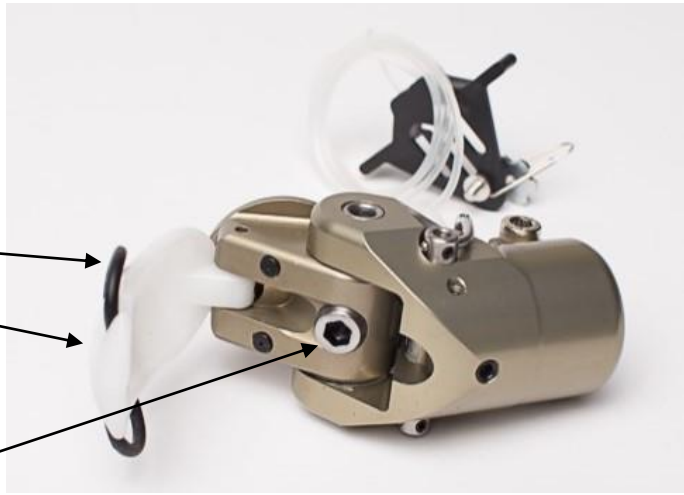
8 Knee Adjustments

Lock Mechanism Adjustment:

The 1313A Manual Locking Knee Joint has been factory inspected and set for immediate use. The extension stop screw (14) is secured with 242 Loctite. Slight clearance does not result in functional disadvantages The lock mechanism is adjustable with the stop screw (14) as follows:

- Remove rubber ring (8) from the plastic knee cap (4)
- Disengage the lock mechanism and flex the knee.
- Use a 6 mm allen wrench to adjust the "play" of the extension stop screw.
  Turn extension stop screw clockwise for more play.
  Turn extension stop screw counterclockwise for less play.

The Extension Stop Screw Adjustment should only be done if the knee lock mechanism is loose. It is not recommended to loosen the Extension Stop Screw excessively, as the lock may not function properly!



After adjustment by means of the extension stop screw (14), make sure that the lock catches and that the joint is reliably locked. Secure screw head with 242 Loctite.

To eliminate noise in the cosmetic foam cover, use Silicone Spray. Do not use talcum powder! Talcum powder reduces the lubrication of the mechanical parts, which may lead to a malfunction and thus increase the risk of falling. Apply Silicone Spray directly on the friction surfaces of the cosmetic foam cover!

Lock Mechanism Bale Lever:

It may become necessary to remove the Lock Mechanism Bale Lever. To do this, utilize the included 1.5mm allen wrench and loosen both set screws on the lock axis, then slip the lever out.

DO NOT COMPLETELY REMOVE THE SET SCREWS!
Care should be taken not to lose the set screws for the Bale Lever.
It is easier to loosen both set screws to remove the lever, otherwise the lever will not slip out from either side!

(20) Bale Set Screws

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!

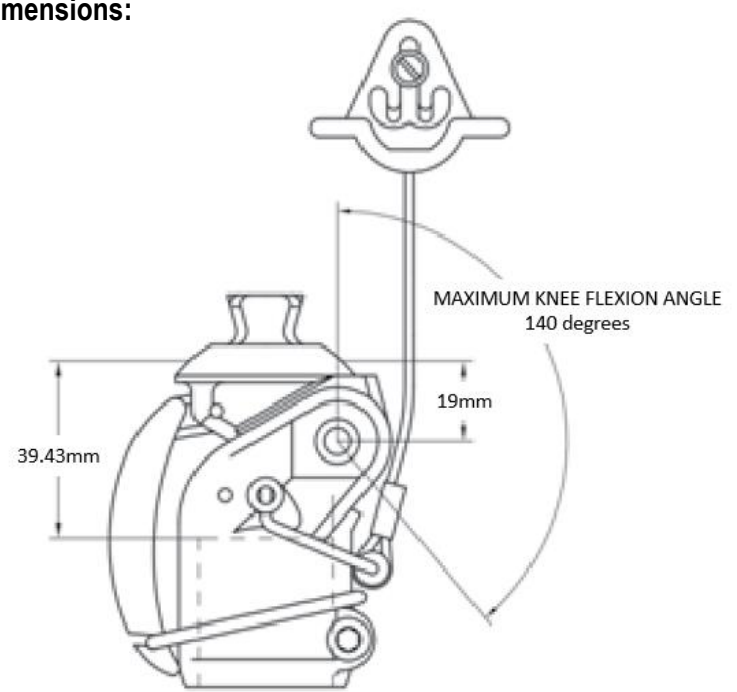
NOTE: Be sure knee lock can cycle adequately before delivering to your patient.

9 Technical Specification

•Operating & Storage Temperature Range:	-10˚C to 50˚C (14˚F to 122˚F)
•Weight:	290g (10.22 oz)
•Recommended Activity:	K1
•Maximum User Weight:	90kg (198lbs)
•Maximum flexion angle:	140 degrees
•Proximal Alignment attachment:	Male Pyramid
•Distal Alignment attachment:	Tube Clamp
•Tube clamp torque setting:	13Nm
•Build Height:	39.43mm

•**Materials: High Strength Aluminum Alloy, Stainless Steel, Steel, Rubber, 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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