

Instructions for 1313A-N Manual Locking Knee



ST&G USA Corp.
2691 Saturn St.
Brea, CA 92821

Phone: (714) 524-0663
Fax: (714) 364-8113
www.stngco.com

Description and purpose

Prosthetist instructions.

- 1313A-N knee is for lower limb prosthesis.
- Recommended for K1.
- Designed for new or low activity elderly patient.
- Weight limit for a user is up to 100kg / 220lbs
- Ability to lock knee in full extension as part of rehabilitation process.
- Only ST&G Pylons are recommended with ST&G Knees due to tolerance variability among different manufacturers

Contra-indications

- Residual muscular weakness, contractures or proprioceptive dysfunction including poor balance.
- Contra lateral joint instabilities or pathology
- Complicated conditions involving multiple disabilities
- Lack of cognitive ability to cycle manual lock feature



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

Product Code

1313A-N

Manual Locking Knee



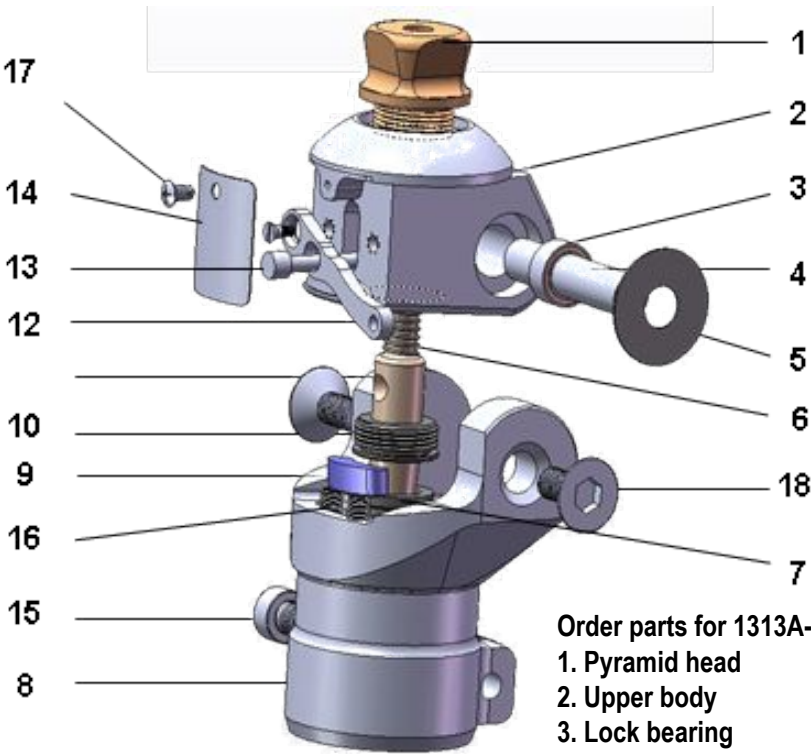
100Kg
220lbs

Construction

Principal Parts

Frame Aluminum Alloy, Brass, Stainless Steel, Steel

Knee head Aluminum Alloy, Stainless Steel



- Order parts for 1313A-N:
- 1. Pyramid head
 - 2. Upper body
 - 3. Lock bearing
 - 4. Main axis
 - 5. Washers x2
 - 6. Lock spring
 - 7. Lock house
 - 8. Lower body
 - 9. Bumper
 - 10. Lock cover
 - 11. Lock pin
 - 12. Lock arm
 - 13. Lock axis
 - 14. Knee cap
 - 15. Clamp screw
 - 16. Bumper adjustment screws x2
 - 17. Knee cap screw
 - 18. Main axis screws x2

Function

- The 1313A-N 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

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.

Maintenance

- Maintenance must be carried out by qualified personnel.
- Bi-Annual inspection to be sure knee function is satisfactory.
- 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 into a locked or unlocked position.
- 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 and could attract excessive dust or aggregate which can accelerate wear and tear on the component.
- If the limb/knee comes into contact with salt or chlorinated water, it should be rinsed with fresh water and dried.

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. Always provide at least a 9Kg / 20lb. Buffer to account for any spiking activities, such as stepping down obstacles.

Environment:

Store at room temperature, and avoid extremely hot, cold, or moist storage environments Storage Temperature Range: between temperatures of -10°C to 50°C [14°F and 122°F]

Do not store in wet or very hot environment.



Allowable environmental conditions

Use – relative humidity: 0 % to 90 %, non-condensing

Storage/transportation – relative humidity: 20 % to 90 %, non-condensing

Splash - Fresh water, rain, salt water, urine, dust, sand, particles of foam cosmetics

cleaning required after contact with salt-laden air, salt water, chlorinated water, urine, and sand

Unallowable environmental conditions

Storage/transportation: high vibrations, impacts

Cleaning agents containing solvents



Alignment and Set-Up



Users be aware of potential finger trap hazard

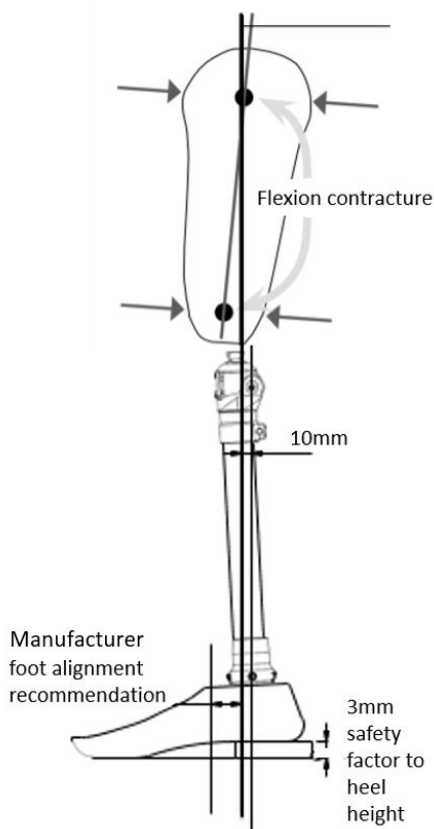


Fig. 1

M/L weight
line should
be centered

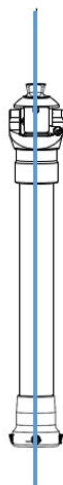


Fig. 2

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

BENCH ALIGNMENT:

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. Take into account shoe heel height, and add 3mm safety factor (Fig.1).

b) Foot placement should reflect recommended foot alignment. 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 (Fig. 2). 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!

Knee Adjustment



Users be aware of potential finger trap hazard



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

BENCH ALIGNMENT:

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. Take into account shoe heel height, and add 3mm safety factor (Fig.1).

b) Foot placement should reflect recommended foot alignment. 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 (Fig. 2). 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!

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

! NOTE: 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.

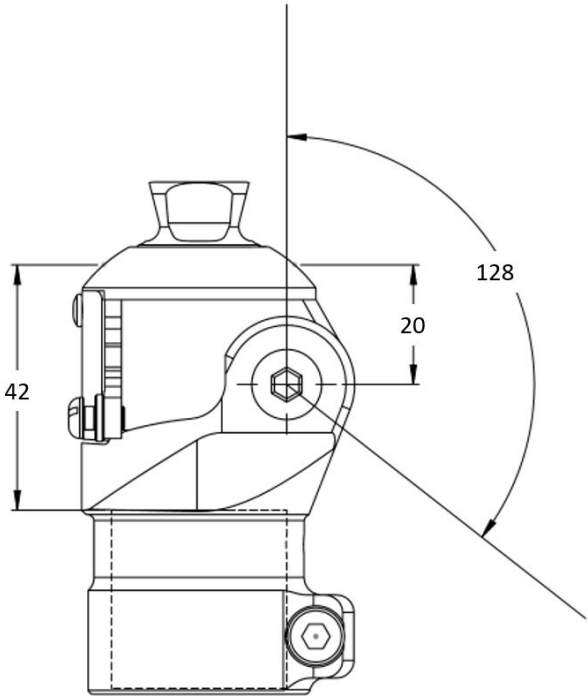


Technical Specification

- Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)
- Weight: 281g (lbs oz)
- Recommended Activity: K1
- Maximum User Weight: 100kg (220lbs)
- Maximum flexion angle: degrees
- Proximal Alignment attachment: Male Pyramid
- Distal Alignment attachment: Tube Clamp
- Tube clamp torque setting: 12Nm
- Build Height: 43.5mm

•Materials: Aluminum Alloy

Key Dimensions:



10 Warranty

Warranted for 2 years from the date of invoice by ST&G.

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

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 Council EU 2017/745 (EU) 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.

Useful Life

Service life of the product is covered by the warranty period.

Disposal

The device and its packaging must be disposed of in accordance with respective national/local environmental regulations.

1313A-N IFU REV. G (07-10-26)

Specifications subject to change