

Instructions for L1321 AP / AL Polycentric 4 Bar Mechanical Manual Locking Knee



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1. Description and purpose

Prosthetist instructions.

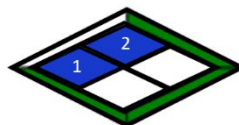
- L1321 AP / AL knee is for lower limb prosthesis.
- Recommended for K1, K2.
- Weight limit for a user is up to 125kg / 275lbs
- Ability to lock knee in full extension as part of rehabilitation process.
- Can progress from locking to full-time unlocked knee.
- Only ST&G Pylons are recommended with ST&G 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



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



125kg
275lb

Product Code

•L1321 AP / AL

Polycentric 4-Bar Mechanical Manual Locking Knee

2 Construction

Principal Parts:

- Frame Aluminum Alloy, Brass, Stainless Steel, Steel
- Knee head Aluminum Alloy, Stainless Steel
- Knee control Various materials principally Aluminum Alloy, Stainless Steel, Poly Urethane, Copper

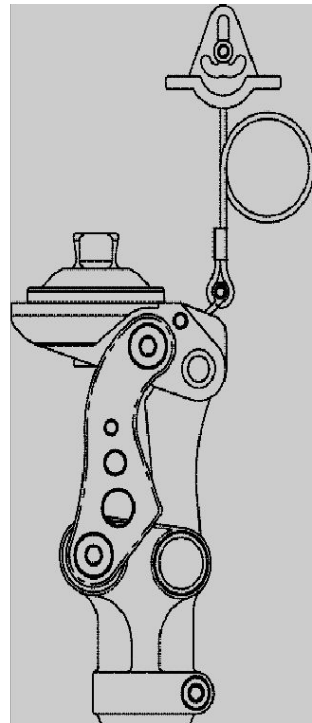
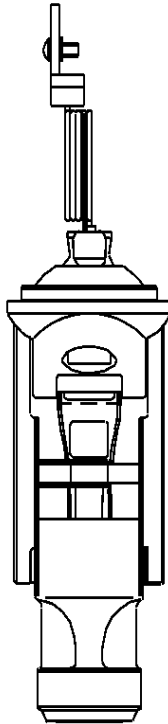
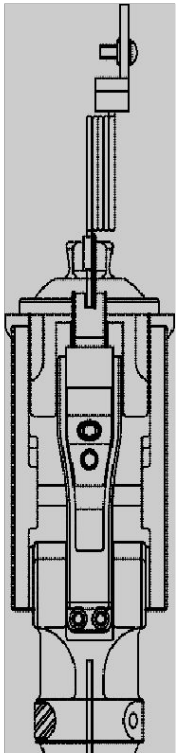
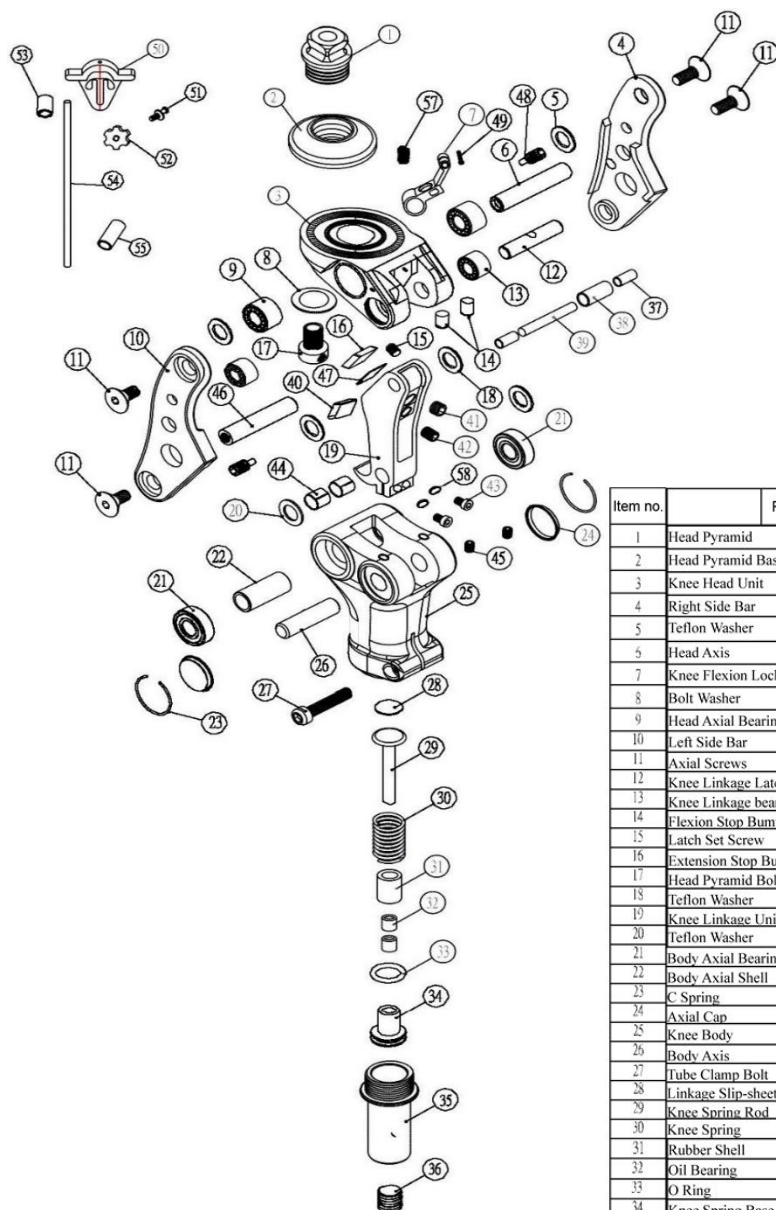


Fig. 1 (a) Posterior View, (b) Anterior View, (c) Lateral View of Knee Unit

Exploded View



Item no.	Parts name	Qty
1	Head Pyramid	1
2	Head Pyramid Base	1
3	Knee Head Unit	1
4	Right Side Bar	1
5	Teflon Washer	2
6	Head Axis	1
7	Knee Flexion Lock Screw	1
8	Bolt Washer	1
9	Head Axial Bearing	2
10	Left Side Bar	1
11	Axial Screws	4
12	Knee Linkage Latch	1
13	Knee Linkage bearing	2
14	Flexion Stop Bumper	2
15	Latch Set Screw	1
16	Extension Stop Bumper	1
17	Head Pyramid Bolt	1
18	Teflon Washer	2
19	Knee Linkage Unit	1
20	Teflon Washer	2
21	Body Axial Bearing	2
22	Body Axial Shell	1
23	C Spring	2
24	Axial Cap	2
25	Knee Body	1
26	Body Axis	1
27	Tube Clamp Bolt	1
28	Linkage Slip-sheet	1
29	Knee Spring Rod	1
30	Knee Spring	1
31	Rubber Shell	1
32	Oil Bearing	2
33	O Ring	1
34	Knee Spring Base	1
35	Spring Base Housing	1
36	Asjusting Screw	1
37	Flexion I/II Stop Support	2
38	Flexion I/II Stop Shell	1
39	Flexion I/II Stop Bar	1
40	Flexion I/II Bumper	1
41	Head Level Adj. Screw	1
42	Flexion I/II Force Adj. Screw	1
43	Flex./Ext. Resistance Adj. Screw	2
44	Linkage Oil Bearing	2
45	Axial Set Screw	2
46	Body Axis	1

3 Function

- Pyramid and Knee Disarticulation mounting options
 - 30mm Tube Clamp distal mount
 - Adjustable spring extension assist
 - Adjustable friction
 - Manual lock can be disabled
-

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. instability or lag in transition from full stance flexion moment to full knee extension moment in the knee should be immediately reported to the Clinician / Practitioner



Always use a hand rail when descending stairs and at any other time if available.



Any excessive changes in heel height may adversely affect the stability of 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 lock and 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 lock during weight activation
- 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 or lock mechanism 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.

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:

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, sand

Unallowable environmental conditions

Storage/transportation: high vibrations, impacts

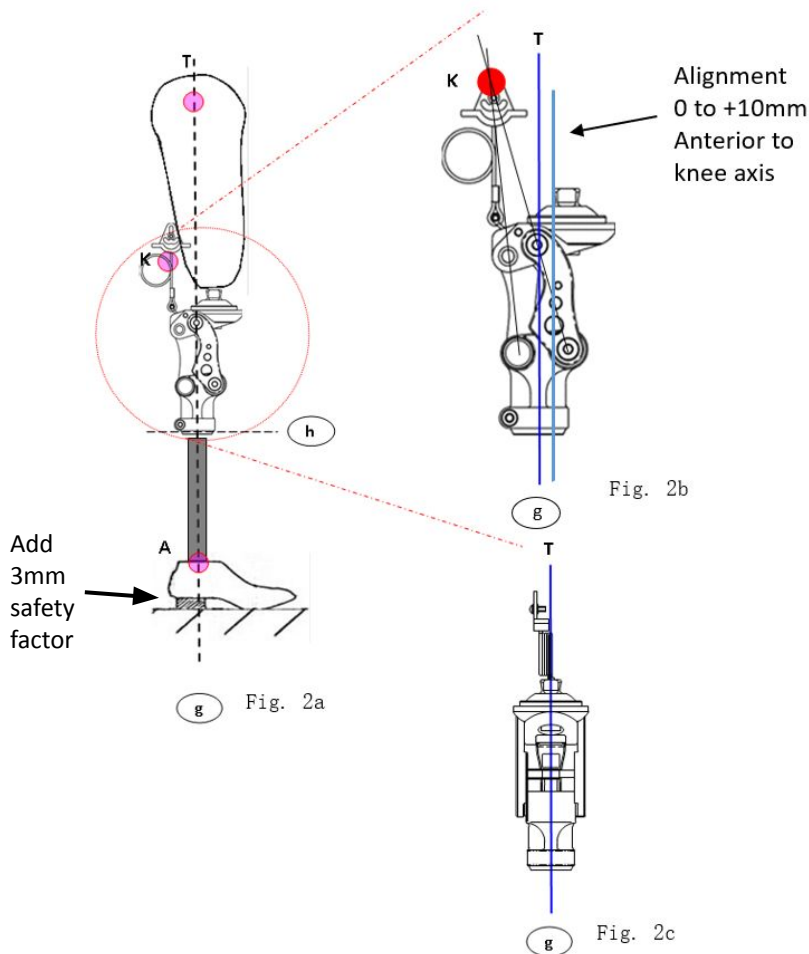
Cleaning agents containing solvents



7. Alignment and Set-Up



Users be aware of potential finger trap hazard



Note: 4-bar knees inherently are very stable due geometry built into each design. This is commonly referred to as the Instant Knee Center (IKC). The IKC point when doing bench alignment, will fall posterior and anterior to the traditional TKA line that we will reference as Tg (Fig. 2a/b). Tg line in Fig. 2a is ideal placement, but in certain instances, it may be necessary to accommodate placement anteriorly (up to 10mm). The Tg line is referencing a moving A/P weight bearing line, so it could be slightly anterior or neutral.

7.1 BENCH ALIGNMENT:

a) With prosthesis assembled, taking into account hip flexion contractures, abduction, Line Of Progression, and toe out (Fig.2a), the TKA plumb line should pass through the knee center (center of proximal/anterior pivot Fig.2a, 2b) and in front of the IKC (red dot).

! NOTE: Take into account shoe heel height, and add 3mm safety factor.

b) Ideally, the pylon connecting the knee and foot should end up vertical. There may be a variance due to the foot alignment recommendations. In this case, the maximum anterior tilt of the pylon should not to exceed 3-4 degrees, and it may be necessary to utilize 1222T offset tube clamp adapter. It is advised to follow up in 1-2 weeks to reassess the alignment.

c) With prosthesis donned, the weight line should pass through the centerline of the knee in the Coronal or M/L plane (Fig. 2c). Excessive outset or inset will put undue stress on the knee joint.

d) With prosthesis donned, the weight line for Sagittal or A/P plane should have the plumb line passing ideally through the knee center (proximal anterior pivot), and be perpendicular to the ground. (Fig. 2a, 2b)

! It is not recommended to adjust the head tilt feature of this knee, as it will interfere with the lock mechanism. Adjustment can lead to lock not engaging, or to lock damage which will void the warranty!

8 Knee Adjustment

8.1 Knee Extension Assist Adjustment



Use 6mm hex wrench and turn:
Clockwise to increase extension assist.
Anti-clockwise to reduce extension assist.

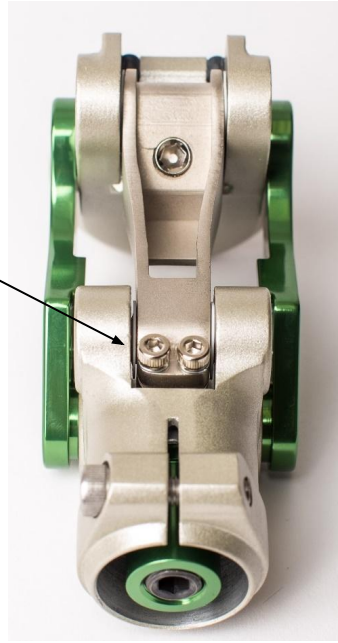
! After inserting pylon, apply thread locker to the 5mm pinch bolt and torque 12Nm

8.2 Knee Friction Adjustment

Use 3mm driver to turn both screws
on base of linkage:
Clockwise to increase friction.
Anti-clockwise to reduce friction.

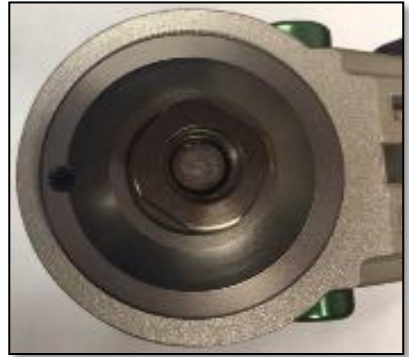


Turn screws equally so friction is
distributed evenly on linkage
bearing.

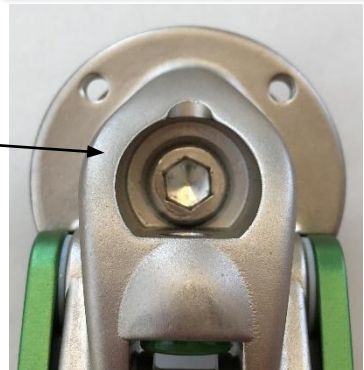


8.3 Pyramid Head Position Adjusting

Adjust screw with 2.5mm hex wrench,
torque to 2-3Nm.



With a 8mm Hex wrench,
Loosen pyramid bolt.
Rotate/slide to desired orientation
Then apply thread locker and torque bolt
to 30Nm.



Note: Mark / indicate pyramid orientation. Remove pyramid bolt, apply
thread locker, reposition bolt and torque to 30Nm.

8.4 Lock Disable Mechanism

Set lock lever in the “Unlock” position, with a 2.5mm hex wrench, screw in both symmetrically to disable the lock function. Uneven tightening can induce knee noise, or inhibit knee function

Lock Lever



lock disable set screw
(Note: Total of 2 set screws)

For more info, refer to
STNGCorporation on youtube for
relevant video material

Lock cable retainer screw can be removed to eliminate lock cable.

For Unlocked gait Deviations

GAIT DEVIATIONS AND ADJUSTMENTS:

Excessive Heel Rise:

For excessive heel rise during walking, first try adjusting the knee friction adjustment by turning it up to slow knee flexion initiation during swing. It might be necessary to very slightly increase knee extension assist spring tension by 1/8 turn increments. Increasing extension assist spring tension alone, will not reduce excessive heel rise tendencies. (Refer to Section 8.3)

Terminal Impact:

Terminal Impact can be reduced by increasing knee friction through the two knee friction adjustment screws. Be sure to adjust both screws symmetrically. Also, it may be necessary to reduce the extension assist spring tension. (Refer to Section 8.3, 8.1)

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.



9 Maintenance of Knee Unit

9.1 Servicing Extension Stop Bumper

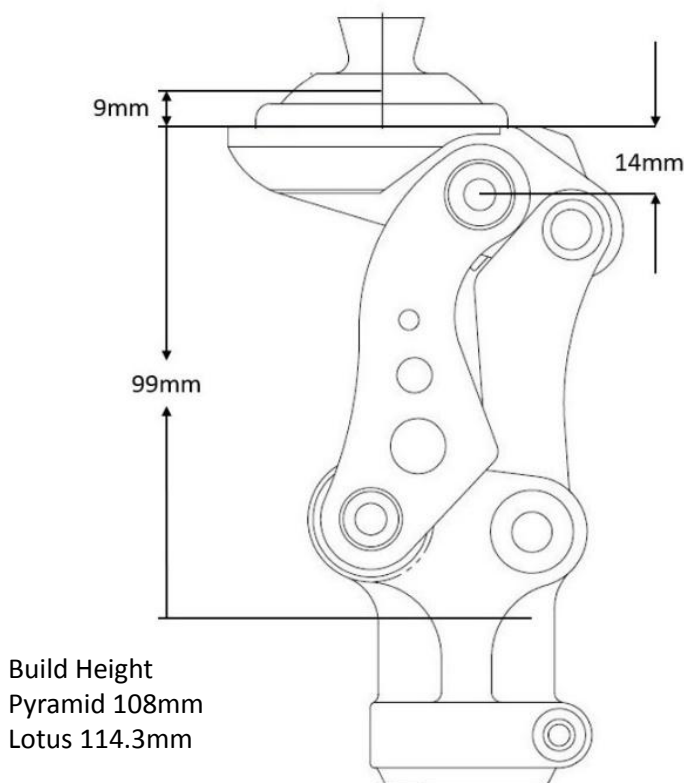
Use a small screw driver to pick out the extension stop rubber bumper on knee level adjusting screw. Insert new one into slot.



10 Technical Specification

- Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)
- Weight (Pyramid / Lotus): 766 g (1lb 11oz)
- Recommended Activity: K1, K2
- Maximum User Weight: 125kg (275lbs)
- Maximum flexion angle: 135 degrees
- Proximal Alignment attachment: Rotatable Male Pyramid,
Lotus Adapter
- Distal Alignment attachment: Tube Clamp
- Tube clamp torque setting: **12Nm**
- Pyramid Center Bolt: **30Nm**
- Build Height (Pyramid / Lotus): 108mm / 114.3mm

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



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.

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 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.

L1321 IFU REV G (6-18-26)

Specifications subject to change