

Instructions for 1321 AP / AL Polycentric 4 Bar Knee



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1. Description and purpose

Prosthetist instructions.

- L1321 AP / AL knee is for lower limb prosthesis
- Recommended for K1 up to K2 activity level
- Weight limit for a user is up to 125kg / 275lbs

Contra-indications

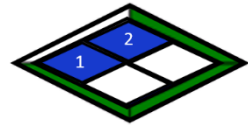
- Residual muscular weakness, contractures or proprioceptive dysfunction including poor balance
- Contra lateral joint instabilities or pathology
- Complicated conditions involving multiple disabilities

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

Product Code

- 1321 AP / AL

Polycentric 4-Bar Knee (Aluminum)

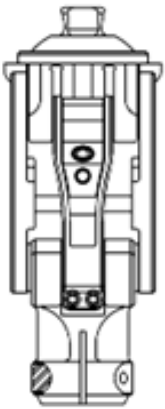


122 Kg
275 lb

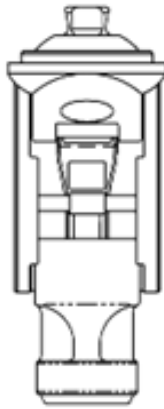
2. Construction

Principal Parts

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



(a)



(b)



(c)

Fig. 1 (a) Posterior View

(b) Anterior View

c) Lateral View

Exploded View

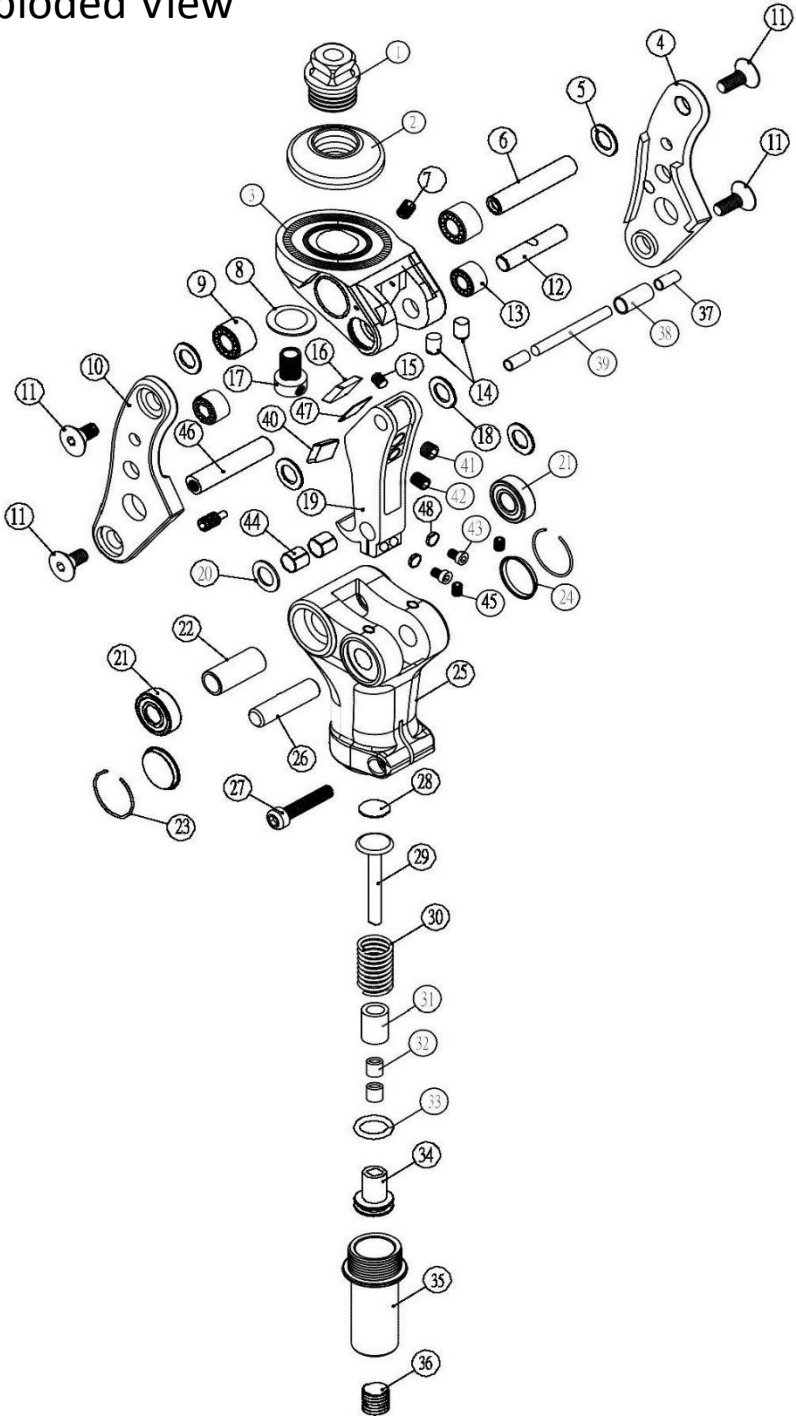



Fig. 2


3 Function


- Pyramid and Knee Disarticulation mounting options
- Tube clamp distal mount
- 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. 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 brake function is satisfactory 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 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 brake mechanism as this will void the warranty and render the brake mechanism non-functional.
- 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: between temperatures of -10°C to 50°C [14°F and 122°F]

Do not submerge or use in wet environment.

Avoid dusty environments.



7. Alignment and Set-Up

 Users be aware of potential finger trap hazard

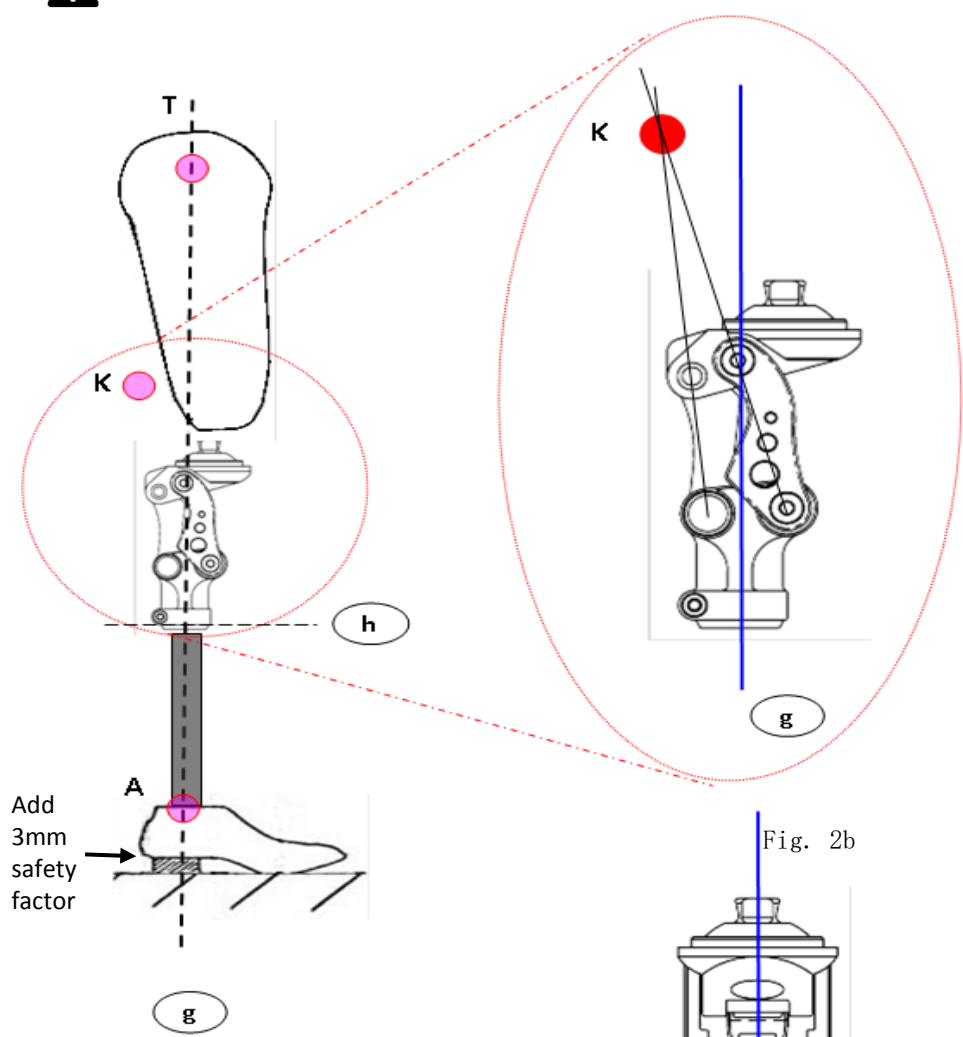


Fig. 2a

Fig. 2b

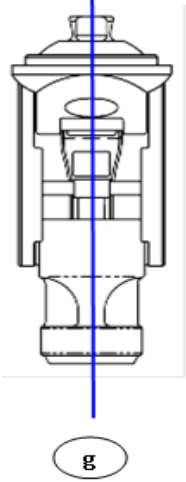


Fig. 2c

7.1 BENCH ALIGNMENT:

Note: 4-bar knees inherently are very stable due to the 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 behind the traditional TKA line that we will reference. (Fig. 2,3) Tg line in Fig. 3 is ideal placement, but in certain instances, it may be necessary to accommodate placement anteriorly (up to 3mm). The Tg line is referencing a moving A/P weight bearing line, so it could be slightly anterior or neutral.

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

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. In some cases, it may be necessary to slightly adjust the Knee Angle Tilt Adjustment screw Clockwise for a total of 1-3 degrees only. **⚠ DO NOT OVERLY ADJUST THIS SETTING** – Clockwise adjustment will reduce the K point or IKC making the knee more unstable. Some adjustment is acceptable, but take into account all aspects of patient ability, length of limb, and foot when going to this adjustment. It is advised to follow up in 1-2 weeks to reassess the alignment. Excessive adjustment from factory setting will prematurely wear out the extension stop bumper. (Refer to Section 8.2)



It is not recommended to have alignment posterior to the reference line, as it could cause knee instability!

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)

8 Knee Adjustment

8.1 Knee Extension Assist Adjustment



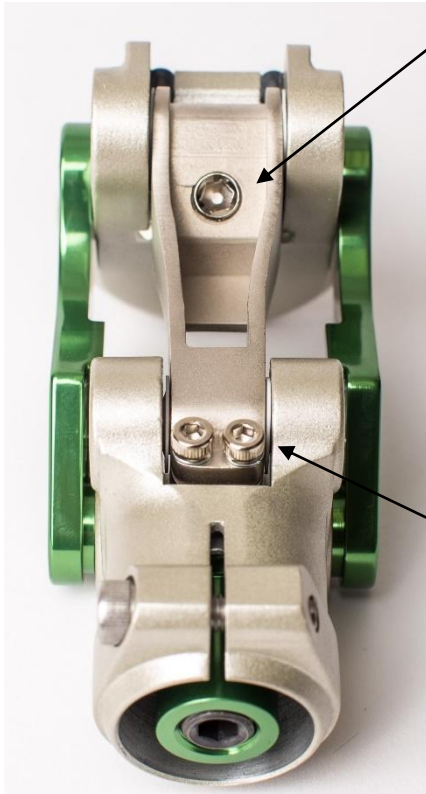
Using a 6mm hex wrench turn screw:

- clockwise to increase extension assist
- anti-clockwise to reduce the extension assist



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

8.2 Knee Head Level Adjustment



- Using a 5mm hex wrench turn the screw:
- clockwise to reduce geometric stability of the knee (high front/low rear) – will make knee easier to flex
 - anti-clockwise to increase geometric stability of the knee (low front/high rear) – will make knee more difficult to flex



Level or slight up-sloping tilt of 1-2 degrees (clockwise adjustment) is most common. Adjustment from factory setting will cause decrease in bumper life span due to excessive compression forces.

8.3 Knee Friction Adjustment

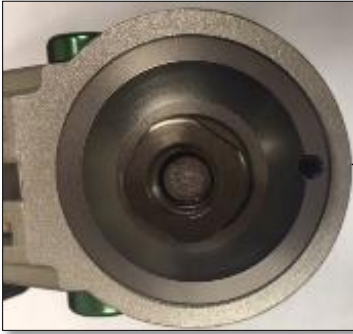
Using a 3mm hex wrench to turn both screws on base of linkage:

- clockwise to increase friction
- anti-clockwise to decrease friction.



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

8.3 Pyramid Head Position Adjusting



Loosen screw with a 2.5mm hex wrench.



Note: Mark/indicate pyramid orientation.

Loosen bolt pyramid bolt with an 8mm hex wrench



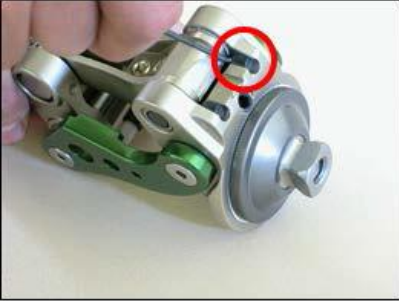
Rotate to desired orientation
Tighten bolt with 8mm hex wrench.



Remove pyramid bolt, apply thread locker, and torque bolt to 18Nm. Tighten set screw to help prevent rotation.

9 Maintenance of Knee Unit

9.1 Servicing Extension and Flexion Stop Bumpers



Use a small screw driver to pick out the rubber bumpers on the back of knee head. Apply glue to new ones and insert back into knee head.

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

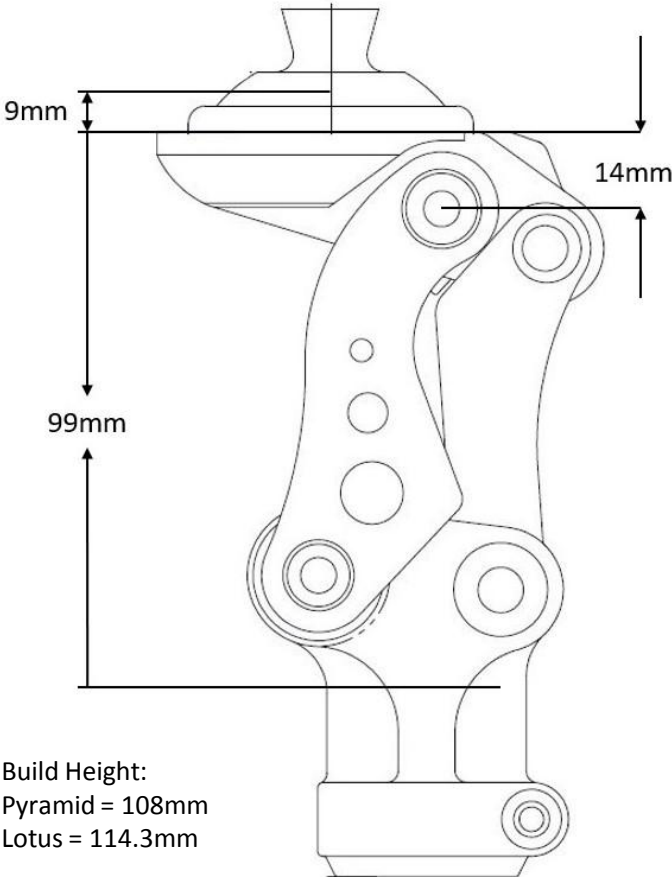


10 Technical Specification

- Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)
- Weight: 766 g (1lb 11oz)
- Recommended Activity: K2
- Maximum User Weight: 125kg (275lbs)
- Maximum flexion angle: 135 degrees
- Proximal Alignment attachment: Male Pyramid Lotus Adapter
- Distal Alignment attachment: Tube Clamp
- Tube clamp torque setting: 12Nm
- Pyramid Center Bolt: 18Nm
- Build Height: Pyramid / Lotus 108 mm / 114.3

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

Maximum flexion angle: 135 degrees



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 (MDR) 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.

1321 IFU REV. D (07-17-23)