Instructions for 1322 AP / AL
Polycentric Pneumatic 4 Bar Knee

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1. Description and purpose

These instructions are for use by the practitioner.

- The 1322 AP / AL knee is to be used exclusively as part of a lower limb prosthesis.
- Recommended for amputees k2 to K3.
- Weight limit for a user is up to 125kg / 275lbs

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Contra-indications

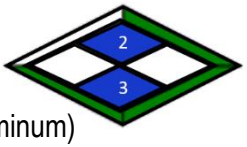
- Residual muscular weakness, contractures or proprioceptive dysfunction including poor balance.
- Contra lateral joint instabilities or pathology
- Complicated conditions involving multiple disabilities

Ensure that the user has understood any Instructions for use, drawing particular attention to the safety information.

Product Code

- **1322 AP / AL**

Polycentric Pneumatic 4-Bar Knee (Aluminum)



125kg
275lb

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, Pneumatic Cylinder

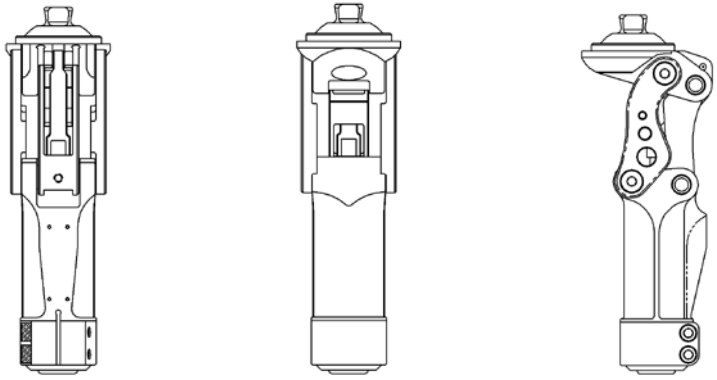
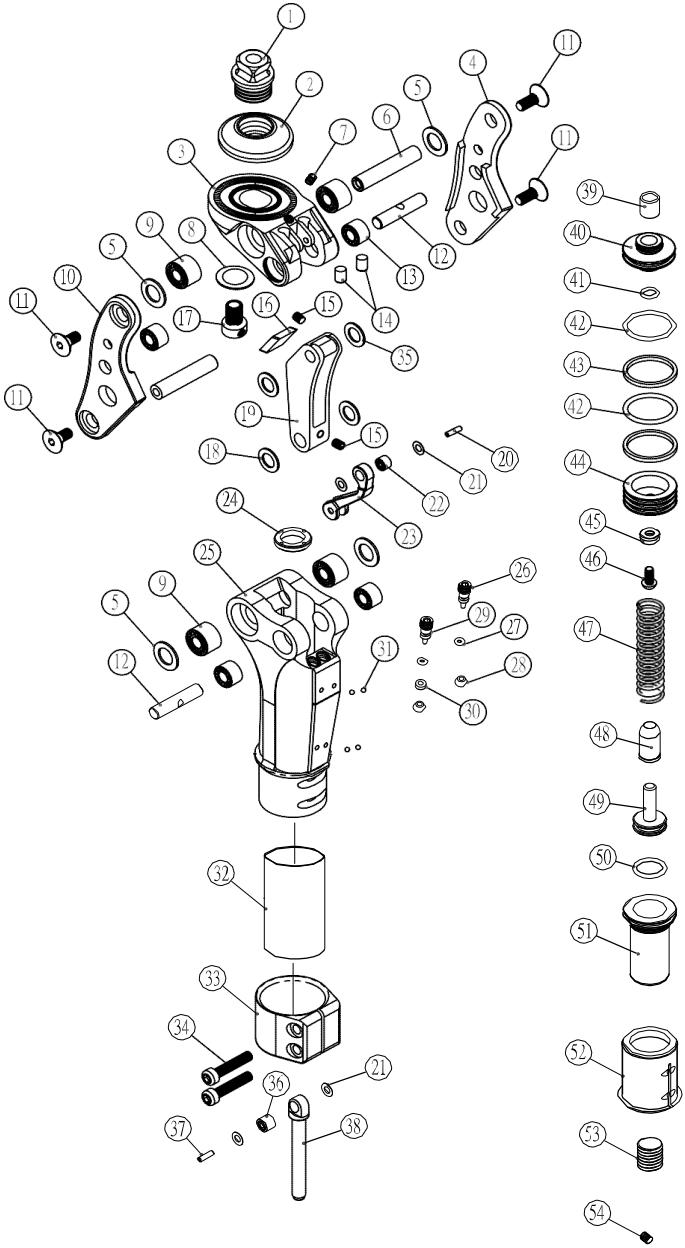


Fig. 1 (a) Posterior View (b) Anterior View c) Lateral View of Knee Unit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3. Function

- Adjustable spring extension assist
- Independently adjustable pneumatic flexion and extension resistances.
- Pyramid and Knee Disarticulation mounting options.
- Built-in bearings which allow for ultra smooth walking movement
- Frame construction made of superlight aluminum alloy
- Proximal attachment has A-P slide and rotating adjustment
- Tube clamp distal mount

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 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:
- Increase in knee stiffness
- Knee instability
- 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/prosthesis 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 (2 years)
- This product is recommended for use with other ST&G Products.
- A local risk assessment should be carried out based upon activity and usage when using as part of a hybrid limb build with other manufacturers components.

Lifting Loads:
Amputee weight and activity is governed by the stated limits.
Combined weight of amputee and carrying load, should not 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 to 122˚F]

7. Alignment and Set-Up

Users be aware of potential finger trap hazard

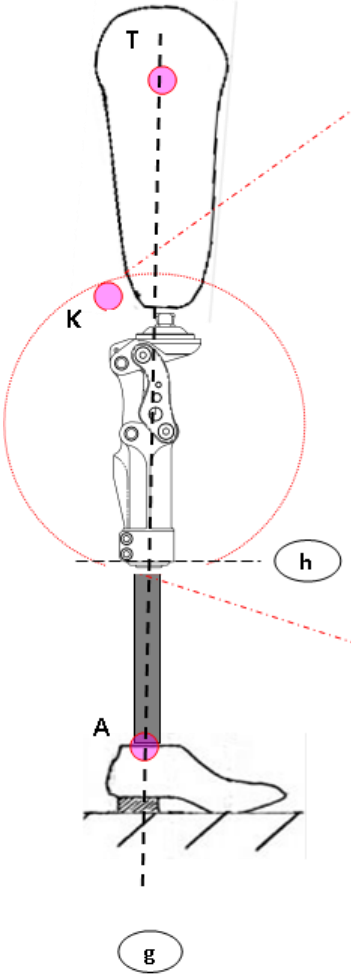


Fig. 2a

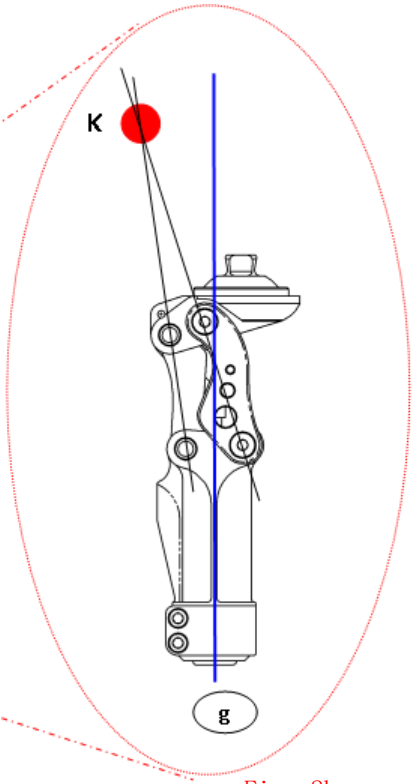


Fig. 2b

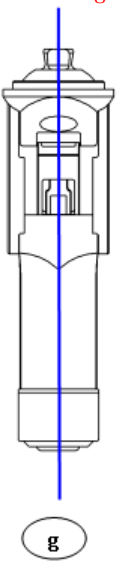


Fig. 2c

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. 2a,2b) Tg line in Fig. 3 is ideal placement, but in certain instances, it may be necessary to accommodate placement anteriorly (0 to 10mm). 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.2a), the TKA plumb line should pass through the knee center (center ot 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 exceed 3 degrees, and it may be necessary to utilize 1222T offset tube clamp adapter.

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 have alignment posterior to the reference line, as it could cause knee instability!

8 Knee Adjustment

8.1 Flexion / Extension Adjustment

Swing Phase Pneumatic setting is pre-set from the factory. Extension or flexion adjustment is only needed if the clinician finds the wearer shows a need for higher or lower walking speeds.

Swing Phase Control Adjustment: It is advisable to adjust **flexion before extension** for optimum walking symmetry. If needed, please follow directions below.

Ensure full knee extension occurs before performing extension adjustment.

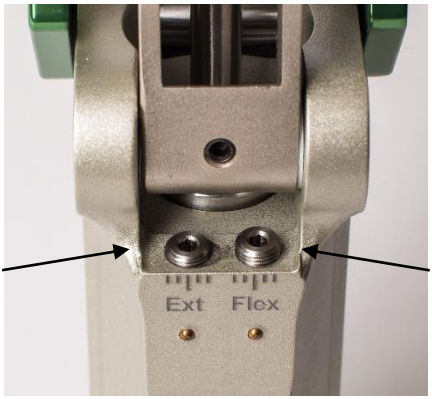
Use following procedure only if there is a need to adjust extension or flexion:

- 1) Turn extension screw anti-clockwise to lowest resistance - then
- 2) Turn the flexion screw clockwise to set to highest resistance

(Do not over tighten if screw has resistance, or bottoms out – damage may occur and void warranty!)

- Incrementally loosen (anti-clockwise) the flexion screw to adjust heel lift;
- Incrementally tighten (clockwise) the extension screw to smoothly stop extension.

Adjust Extension screw with 2.5mm hex wrench



Adjust Flexion screw with 2.5mm hex wrench

Extension Resistance Adjustment: (Figure above right)
Using a 2.5mm hex wrench, turn Extension adjustment screw:
Clockwise increases knee extension resistance.
Anti-clockwise reduces knee extension resistance.

Flexion Resistance Adjustment: (Figure above left)
Using a 2.5mm hex wrench, turn Flexion adjustment screw:
Clockwise increases knee flexion resistance.
Anti-clockwise reduces knee flexion resistance.

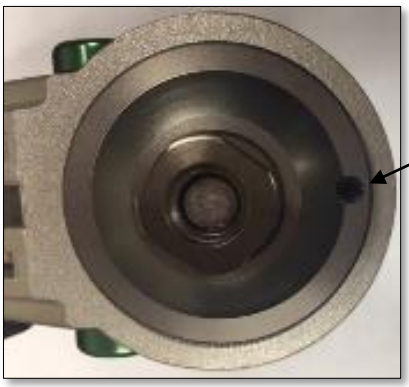
8.2 Extension Assist Adjustment

Loosen set screw prior to any adjustment to Extension Assist!
Tighten back up after adjustment is made!

Use 6mm driver and turn clockwise to increase extension assist. Turn screw anti-clockwise to reduce the extension assist.

After inserting pylon, apply Loctite 242 to pinch bolt and torque 12Nm using 5mm driver.

8.3 Pyramid Head Position Adjustment



Loosen set screw using 2.5mm driver.

Note: Mark/indicate pyramid orientation.

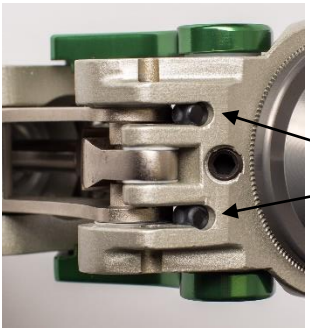
Loosen Pyramid bolt
Using 8mm driver

Establish orientation and tighten bolt.

Mark new location, remove pyramid bolt, apply LocTite, and torque 8mm bolt 18Nm. Tighten set screw to help prevent rotation.

9 Maintenance of Knee Unit

9.1 Servicing Flexion and Extension Stop Bumpers



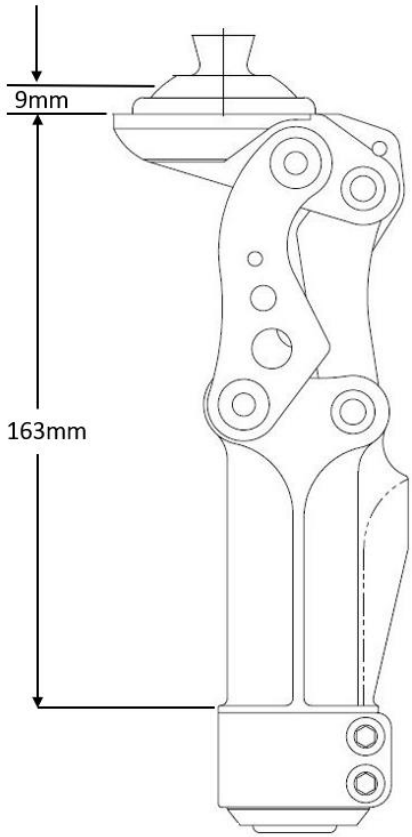
Use a small screw driver to pick out the rubber bumpers on the back of knee head. Apply glue to new ones and insert back into knee head.

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 to K3
•Maximum User Weight:	125kg (275lbs)
•Maximum flexion angle:	135 degrees
•Proximal Alignment attachment:	Male Pyramid or Lotus Adapter
•Distal Alignment attachment:	Tube Clamp
•Tube clamp torque setting:	12Nm
•Pyramid Center Bolt:	18Nm
•Build Height: Pyramid / Lotus	172mm / 178.3

•**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 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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