Instructions for 1324 AP / AL
Stance Flexion 5 Bar
Mechanical Knee

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1 Description and purpose

These instructions are for use by the practitioner.

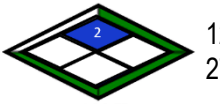
- The 1324 AP/AL knee is to be used exclusively as part of a lower limb prosthesis
- Recommended for amputees with K2 activity level
- Weight limit for a user is up to 125 kg / 275 lbs

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



125Kg
275lbs

1324 AP / AL

Polycentric Mechanical Knee Unit (Aluminum) with Stance Flexion Control

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

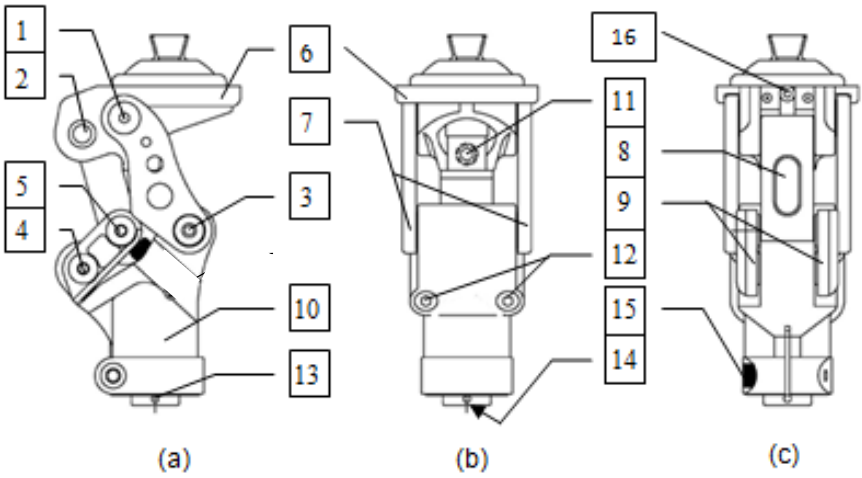


Fig. 1 (a) Lateral View (b) Anterior View (c) Posterior View

1) The First Axis
2) The Second Axis
3) The Third Axis
4) The Fifth Axis
5) The Fourth Axis
6) Knee Head
7) Side Bars
8) Back Linkage
9) Fifth Axial Bars
10) Knee Body
11) Knee Head Level Adjusting Screw
12) Flexion Control Adjusting Screw
13) Lock Screw for Extension Assist Adjusting Screw
14) Extension Assist Adjusting Screw
15) Tube Clamp Screw
16) Friction Swing Resistance Adjustment Screw

3 Function

- The flexion control angle up to 12 degree for mimicking normal knee flexion from heel strike to foot flat of a gait cycle
- Pyramid and Knee Disarticulation mounting options
- 30mm Distal Tube Clamp
- Adjustable spring extension assist
- Adjustable knee head level angle
- Adjustable friction
- The most light weight in the present market

Important:
DO NOT adjust out stance flexion to 0° - must maintain minimum of 5° stance flexion up to 12°, 0° stance flexion can potentially lead to knee failure.

NOTE: Stance Flexion set screws have been eliminated. The threaded holes remain, but will not contain a screw.

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

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/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 (2 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 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 and 122˚F]

7 Alignment and Set-Up

Users be aware of potential finger trap hazard

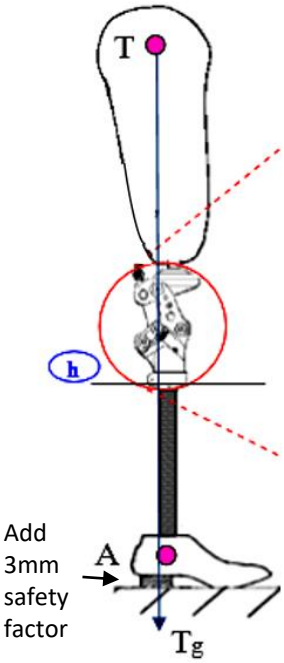


Fig. 2

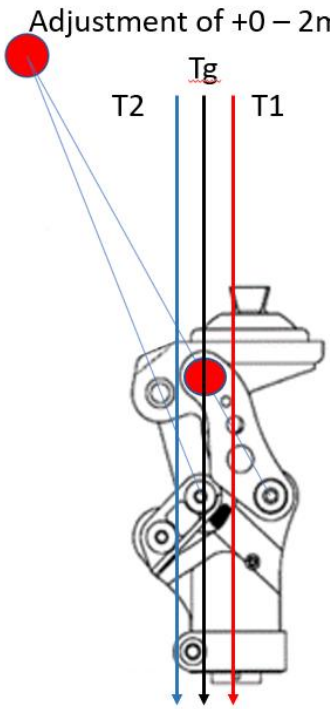


Fig. 3

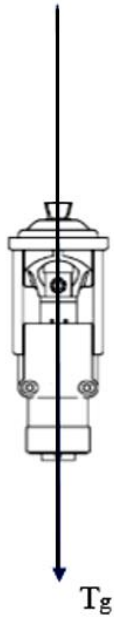


Fig. 4

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 (into the T1 zone up to 2mm), or posteriorly (into the T2 zone up to 2mm). The Tg line is referencing a moving weight bearing line, so it could be in T1, neutral, or in T2 zones.

BENCH ALIGNMENT:

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 (at the proximal/anterior pivot – red dot pivot Fig.3) and in front of the K point (IKC). Take into account shoe heel height, and add 3mm safety factor.

Set the bench alignment taking into account the heel height of associated footwear plus 3mm safety factor!

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

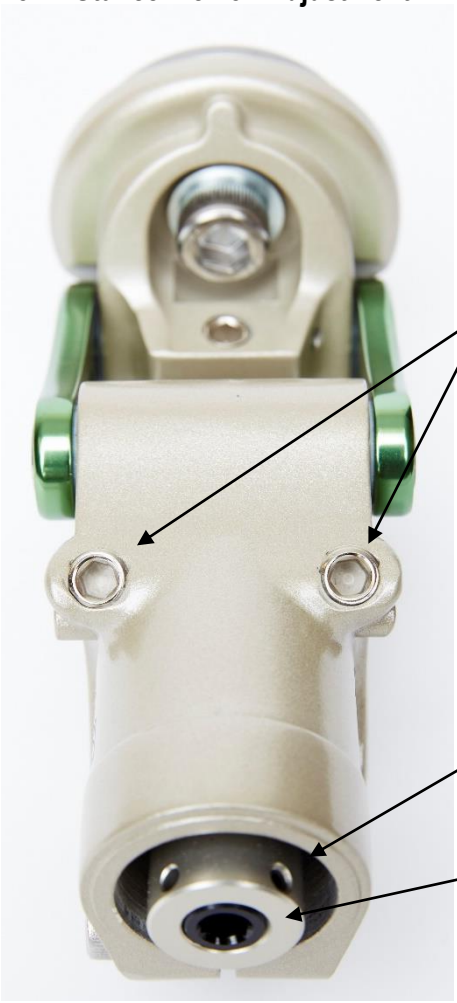
b) Ideally, the pylon connecting the knee and foot should end up vertical. Of course, there may be a variance due to the foot alignment recommendations. In this case, the maximum
anterior tilt of the pylon should not to exceed 4 degrees, and it may be necessary to utilize offset adapters like the 1222T off set tube clamp
c) The weight line should pass through the centerline of the knee in the Coronal or M/L plane (Fig. 4). Excessive outset or inset will put undue stress on the knee joint.
d) The weight line for Sagittal or A/P plane should have the plumb line passing through T (Tg) line. Ideally, Tg line should pass through the knee center (red colored pivot) and be perpendicular to the ground. (Fig. 3)
e) **When to use ZONE 1 option** - For the higher weight spectrum patients, Tg line should pass slightly into the "Zone I" area (up to 2mm), which is indicated as up to "T1" (Fig. 3) so that it will reduce stance flexion moment forces of the 5th bar. It is recommended to have controlled stance flexion action of the 5th bar, and not to lock it out or have excessively long duration of it. Excessive stance flexion moment and/or duration can be adjusted through tightening the "Flexion Control Adjusting Screw" in, and/or adjusting alignment (of socket and/or foot) into the T1 zone (up to 2mm). The goal is to have smooth transition from stance flexion to neutral mid-stance motion, and not excessive stance flexion duration.
f) **When to use ZONE 2 option** - For the lighter weight spectrum patients, such as women and children, Tg line should pass slightly into the "Zone II" area (up to 2mm), which is indicated as up to "T2" (Fig.3) so that it will increase stance flexion moment forces of the 5th bar linkage. It is recommended to have controlled stance flexion action of the 5th bar, and not excessively short duration, or abrupt motion of it. Excessive short stance flexion moment and/or duration can be adjusted through loosening the "Flexion Control Adjusting Screw" out, and/or adjusting alignment (of socket and/or foot) into the T2 zone (up to 2mm). The goal is to have smooth transition from stance flexion to neutral mid-stance motion, and not abrupt motion or excessively short stance flexion duration.

CAUTION: Please pay extra caution on Tg line passing towards the maximum (up to 2mm) or past Zone I because it will cause excessive knee head extension force, which will generate excessive leverage pressure on "back linkage" and "fifth axial bar" and could result in knee breakage as shown in Fig. 5.
It is highly recommended that Tg line should ONLY pass through the "Red Dot". (Fig. 3)

Fig. 5 An exaggerated schematic diagram to show affect on 5-bar linkage with excessive anterior alignment

8 Knee Adjustment

8.1 Stance Flexion Adjustment



NOTE: Stance Flexion set screws have been eliminated. The threaded holes remain, but will not contain a screw.

Stance flexion adjustment screws are located on the anterior body of the knee. With 5mm hex wrench, turning both screws clockwise decreases the 5th axis motion, reducing the stance flexion angle. Anti-clockwise will increase 5th axis motion, increasing the stance flexion angle. Adjustments need to be symmetrical!

Important! adjustments to Stance Flexion Bumper screws need to be symmetrical! Apply thread locker to screws one at a time to prevent screw backing out.

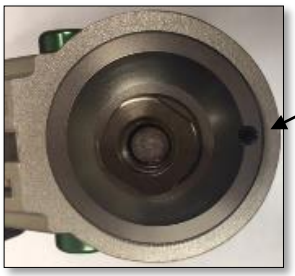
8.2 Extension Assist Adjustment

Note: Loosen set screw prior to adjusting.

Use 6mm hex wrench to turn screw clockwise to increase extension assist, and anti-clockwise to reduce extension assist.

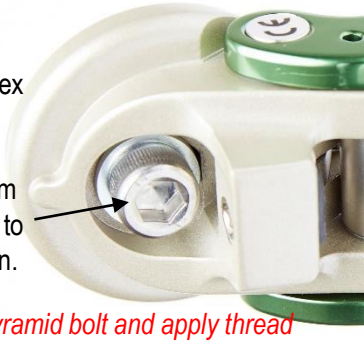
Note: Tighten set screws after adjusting.

8.3 Pyramid Head Position Adjusting



Loosen screw with 2.5mm hex wrench.

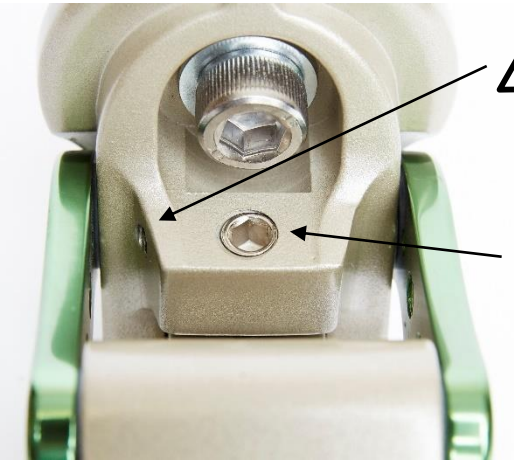
Loosen Pyramid bolt with 8mm hex wrench and rotate to desired orientation and tighten.



Note: Mark/indicate pyramid orientation. Remove pyramid bolt and apply thread locker, and torque bolt 18Nm. Tighten set screw to help prevent rotation.

8.4 Knee Head Tilting Adjusting

IMPORTANT! Head Tilt Feature is for fine tuning knee flexion initiation only!
It is not for increasing flexion or extension range for alignment. It is possible to decrease knee stability by incorrectly adjusting this feature, which could lead to your patient falling!



Loosen the set screw prior to adjusting. After adjusting, tighten set screw.

Use 5mm driver and turn the screw clockwise to reduce geometric stability of the knee (high front/low rear) which makes knee flexion initiation easier. Anti-clockwise will increase geometric stability of the knee (low front/high rear) which can make knee flexion initiation more difficult.

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

8.6 Knee Friction Adjustment

Using a 3mm hex wrench, turn screw:

Clockwise to increase resistance.
Anti-Clockwise to reduce resistance.

GAIT DEVIATIONS AND ADJUSTMENTS:

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.

Alignment of this knee is influenced by weight line of socket, and interaction of foot (stance flexion is reactive by these 2 factors). In most cases, Stance Flexion might not be visibly noticeable, but the effect can be felt by the wearer. 5 degrees of Stance Flexion will make a big difference. In some cases, 12 degrees may be too excessive. Again, check your alignment with the patient standing to see where the TA line falls versus the knee joint reference point – the anterior proximal knee pivot.

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)

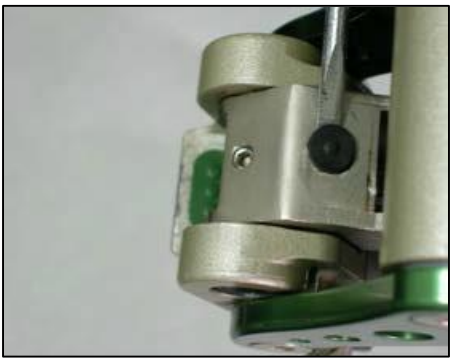
9. Knee Maintenance

9.1 Changing Various bumpers:

For the knee head leveling bumper, use 2mm hex wrench to loosen the bumper set screw by turning anti-clockwise.

Note: Indicate position of the screw prior to removal. Push out the bumper by turning the screw with 5mm hex wrench clockwise.

Place new bumper back into the slot same as previous one.
For the round shape bumper, use a small standard screwdriver to pry out the old bumper.
Insert with a new one.



9.2.2 Changing Stance Flexion Bumper

Use 4mm hex wrench to loosen the screws of fourth and fifth axes to take out the side bars of stance flexion unit.

Please refer to the picture below

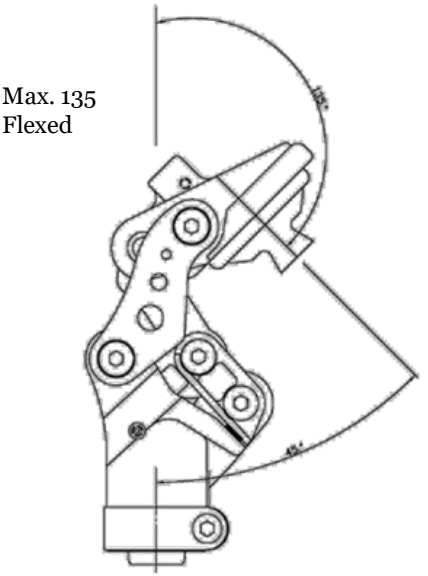
Pull out opposite side bar along with fourth and fifth axes. Stance flexion bumpers should be accessible for servicing.

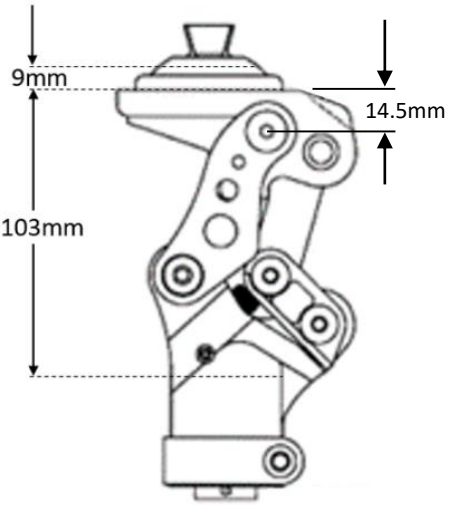
9 Technical Specification

•Operating & Storage Temperature Range:	-10˚C to 50˚C (14˚F to 122˚F)
•Weight (Pyramid/Lotus):	766g / 781g
•Recommended Activity:	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:	18Nm
•Build Height (Pyramid/Lotus):	112mm / 118.3mm

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

Key Dimensions:





Build Height:
Pyramid = 112mm
Lotus = 118.3mm

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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