

Instructions for 1324 AP / AL

Stance Flexion 5 Bar

Mechanical Knee



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
- 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
275lbs

Product Code

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

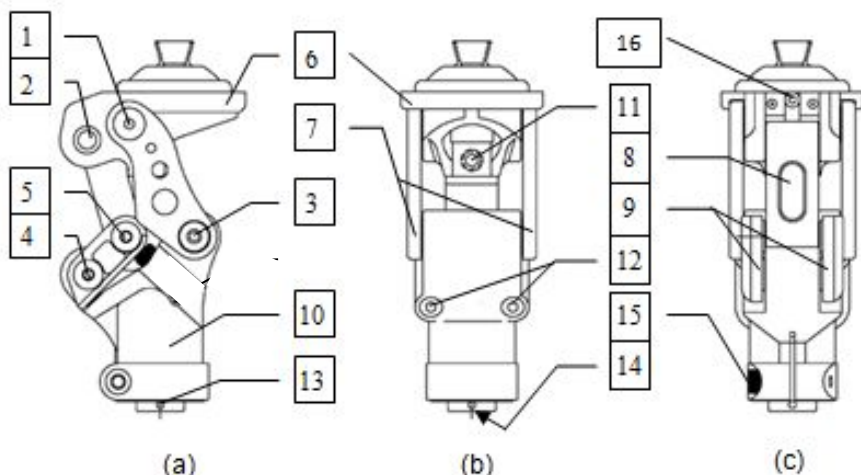


Fig. 1 (a) Lateral View

(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 stance 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
- Manual lock can be disabled



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. Excessive stance flexion can lead to unwanted noise and excessive knee stance stability which will make it difficult to initiate flexion.

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 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 fully extend during weight activation
- Inability to smoothly flex during swing
- 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 friction mechanism as this will void the warranty and render the friction mechanism non-functional, 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 height 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, 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

Adjustment of +0 – 2mm

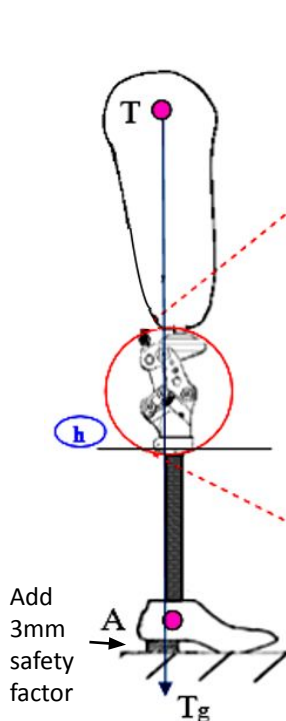


Fig. 2

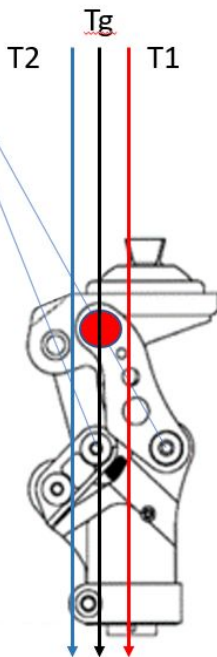


Fig. 3

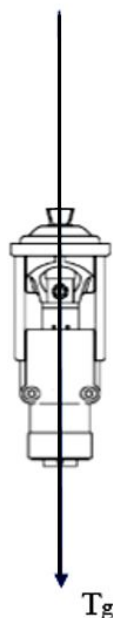


Fig. 4

! 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.

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



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!

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. In some cases, it may be necessary to slightly adjust the pyramid angle adjustment by loosening the set screw for the adjustment screw and then tuning the angle adjustment screw clockwise. **⚠ DO NOT OVERLY ADJUST THIS SETTING** – it 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.

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.

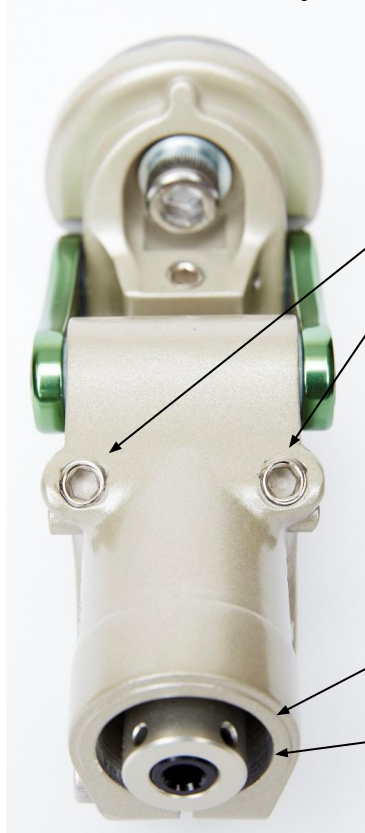
It is highly recommended that Tg line should ONLY pass through the “Red Dot”. (Fig. 3)



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



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! Adjust Stance Flexion Bumper screws **symmetrically!** Apply thread locker to screws one at a time to prevent screw backing out.

8.2 Extension Assist Adjustment



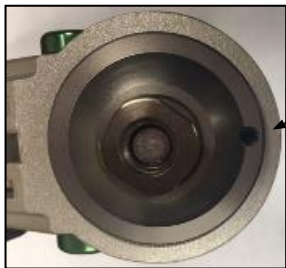
Note: Loosen set screw prior to adjusting.

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



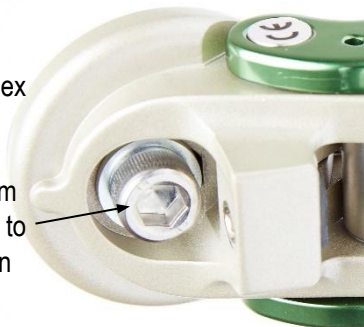
Note: Tighten set screw after adjusting.

8.3 Pyramid Head Position Adjusting



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

Loosen Pyramid bolt with 8mm hex wrench and rotate to desired orientation and tighten To **30Nm**.



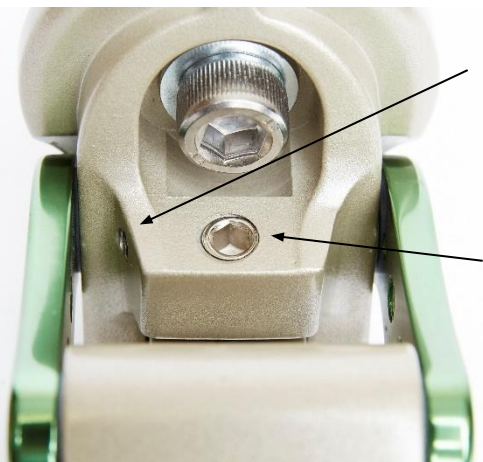
! *Note: Mark/indicate pyramid orientation. Remove pyramid bolt and apply thread locker, and torque bolt **30Nm**. Tighten set screw to help prevent rotation.*

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.



Pyramid Head Tilt Adjustment:

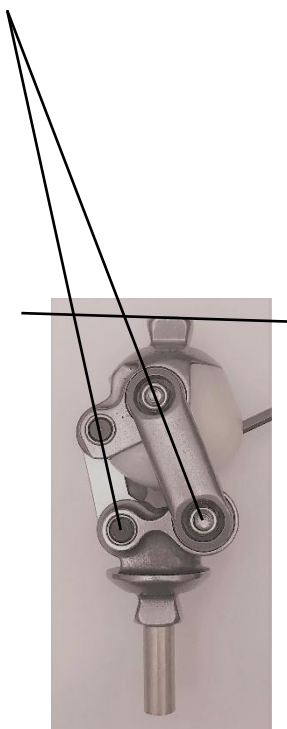


Adjusting the Head Tilt will move the IKC. If the IKC is set too anterior (less stable) and the socket weight line too far posterior, the knee will be very unstable and could lead to fall or injury. Head Tilt is to “Fine Tune” the knee and will not substitute for inadequate socket placement!

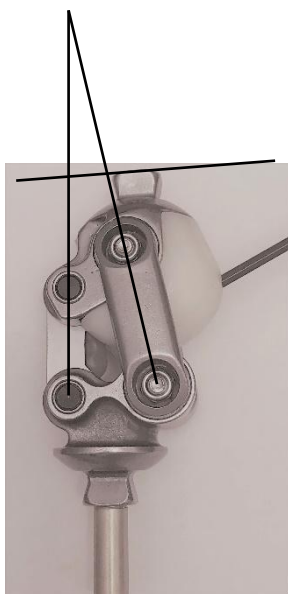
Anti-clockwise rotation will tilt the pyramid anteriorly which increases stability by adding extension into the socket and moving the weight line anteriorly versus the ICR. (ICR is more posterior of socket making flexion initiation harder)

Clockwise rotation will tilt the pyramid posteriorly which decreases stability by adding flexion into the socket and moving the weight line posteriorly versus the ICR. (ICR is more anterior of socket making flexion initiation easier)

IKC



IKC



IKC



Very Stable
Harder to initiate swing

Stable
Neutral Function

Less Stable
Easier to initiate swing

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. Fig. right



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



Place new bumper back into the slot same as previous one.

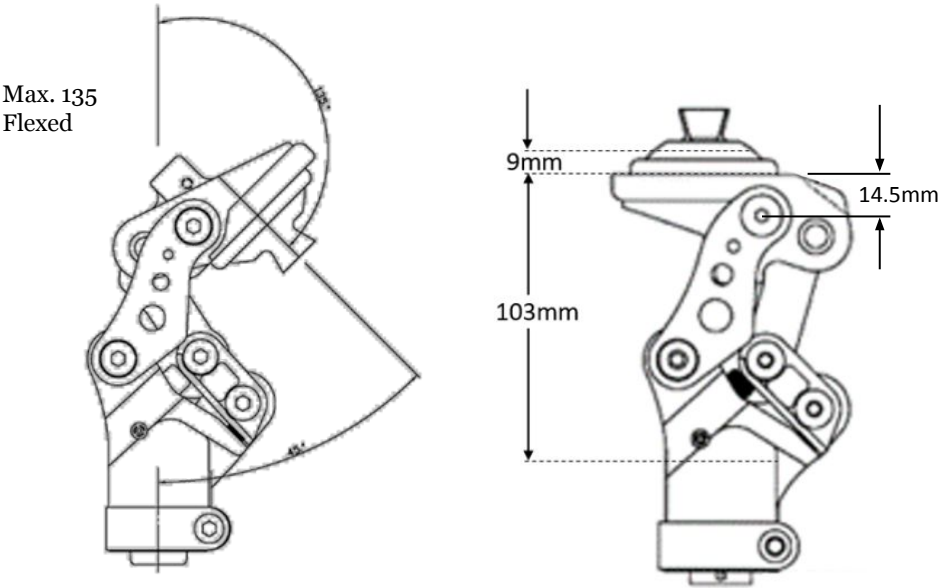
For the round shape bumper, use a small standard screwdriver to pry out the old bumper. Insert with a new one.



9 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: **30Nm**
 - 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 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.

1324 IFU REV I (6-18-26)