Instructions for 1326 AP / AL
4 Bar Knee for AK & KD

ST&G USA CORPORATION

ST&G USA Corp.
2691 Saturn St.
Brea, CA 92821

Phone: (714) 524-0663
Fax: (714) 364-8113
www.stngco.com

1. Description and purpose

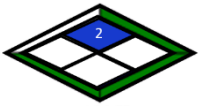
These instructions are for use by the practitioner.

- The 1326 AP / AL knee is for lower limb prosthesis.
- Recommended for amputees with K2 activity level.
- Weight limit for a user is up to 100kg / 220lbs

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.



100Kg
220lbs

Product Code

1326 AP / AL

4 Bar Knee for AK & KD (Aluminum)

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

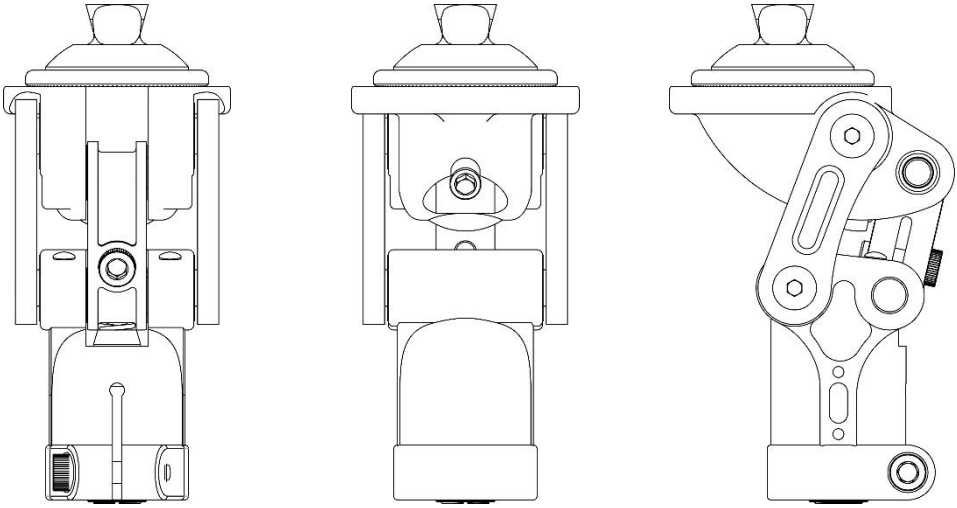


Fig. 1 (a) Posterior View (b) Anterior View c) Lateral View

Exploded View

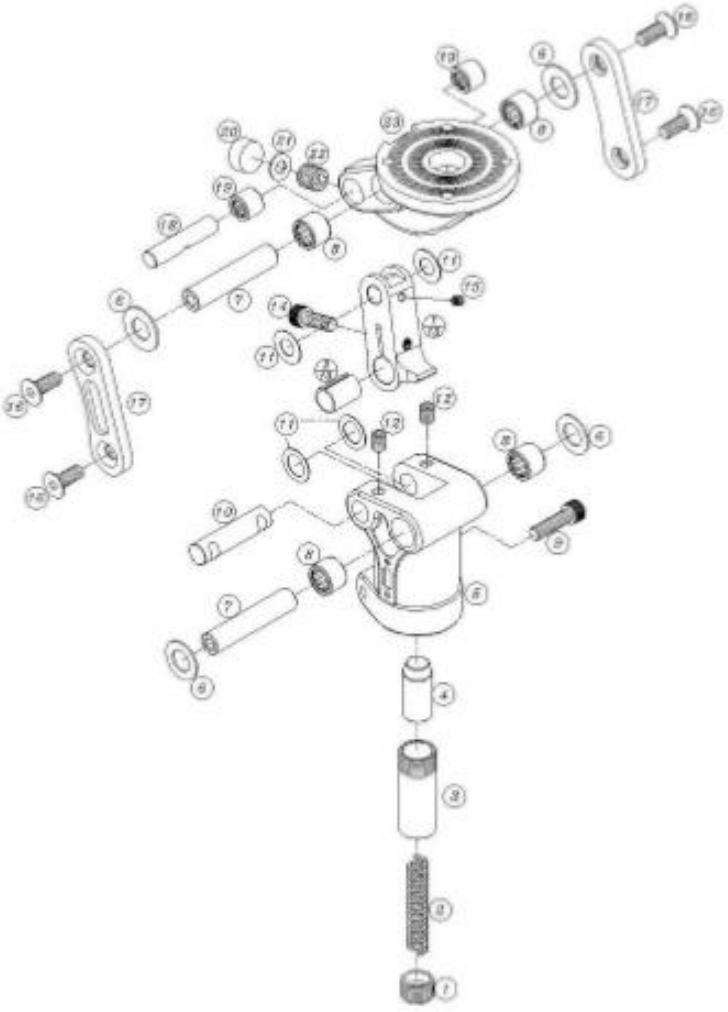


Fig. 2

3 Function

- Pyramid and Knee Disarticulation mounting options
- Distal tube clamp
- 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 flexion moment to full knee extension moment in the knee should be immediately reported to the Clinician / Practitioner

Always use a hand rail when encountering obstacles.

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

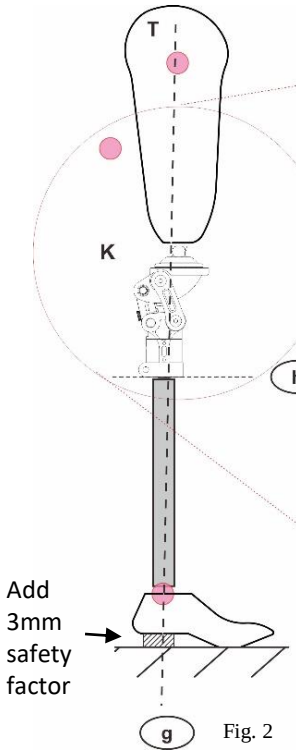


Fig. 2

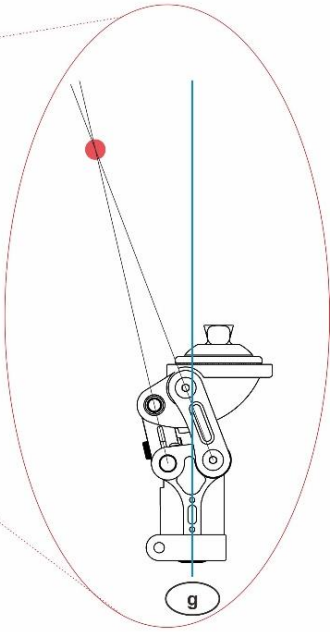


Fig. 3

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 2mm), or posteriorly (up to 2mm). The Tg line is referencing a moving weight bearing line.

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!

7.1 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 just anterior to the knee center (the proximal - anterior 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 anterior tilt of the pylon should not to exceed 3 degrees, and it may be necessary to utilize adapters like the 1222T off set tube clamp. In some cases, it may be necessary to slightly adjust the knee pyramid platform angle (1-3 degrees only) adjustment 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.

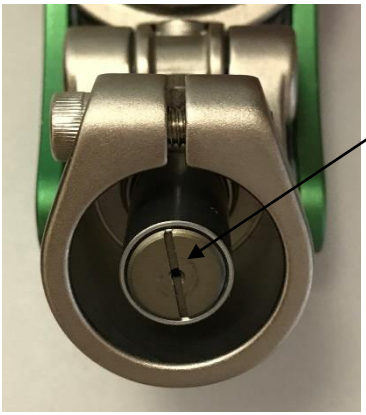
IMPORTANT: FOR HEAD TILT ADJUSTMENTS, REFER TO SECTION 8.4 FOR DETAILED INSTRUCTION!

c) The weight line should pass through the centerline of the knee in the Coronal or M/L plane. 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 just anterior to the knee center and be perpendicular to the ground. (Fig. 3)

8 Knee Adjustment

8.1 Extension Assist Adjustment



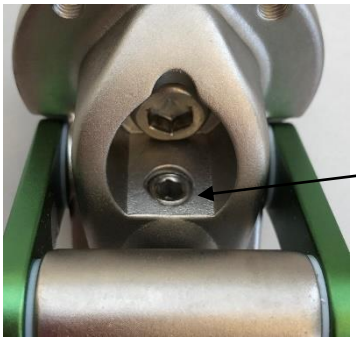
Adjust slotted screw Clockwise to increase extension assist, and Anti-Clockwise to reduce extension assist.

8.2 Knee Friction Adjustment

With a 5mm Hex wrench, turn screw:
Clockwise to increase resistance.
Anti-Clockwise to reduce resistance.

8.3 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!

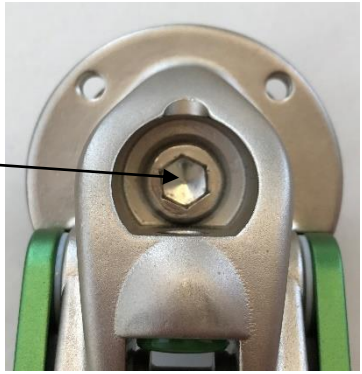


Use 5mm driver and turn the screw clockwise to reduce geometric stability of the knee (high front/low rear) which makes knee flexion initiation easier. Anti-clockwise will increase geometric stability of the knee (low front/high rear) which can make knee flexion initiation more difficult.

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.

8.4 Pyramid/Lotus Head Position Adjusting

With a 8mm Hex wrench,
Loosen pyramid bolt.
Rotate/slide to desired orientation
Then apply thread locker and torque bolt to 18Nm.



Note: Mark / indicate pyramid orientation. Remove pyramid bolt, apply thread locker, reposition bolt and torque to 18Nm.

8.5 Tube Clamp Pinch Bolt Torque

With a 5mm hex wrench, tube clamp pinch bolt is recommended to be torqued to 12Nm.

For gait Deviations

GAIT DEVIATIONS AND ADJUSTMENTS:

Excessive Heel Rise:
During walking, first try adjusting the knee friction adjustment by turning it Clockwise to slow knee flexion initiation during swing. It might be necessary to very slightly increase (Clockwise) 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. 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 knee friction adjustment screw. Also, it may be necessary to reduce the extension assist spring tension (Anti-Clockwise). (Refer to Section 8.2, 8.1)

9 Maintenance of Knee Unit

The 1326 4 bar knee is a simple and very low maintenance knee.

It is best to check the prosthesis bi-annually when your patient returns for follow up.

Check all connector screws for proper torque.

It may be necessary to check knee function (friction and extension assist tension) as they walk. Readjust as needed.

Keeping the knee clean is recommended, especially if bodily fluids are noted to accumulate in the socket or on the cover. In this case, be sure to expose the knee during follow up visits to visually and mechanically check the condition of the knee joints and function.

Do not lubricate any joint associated with the knee friction adjustment, as it will reduce the effectiveness of that adjustment.

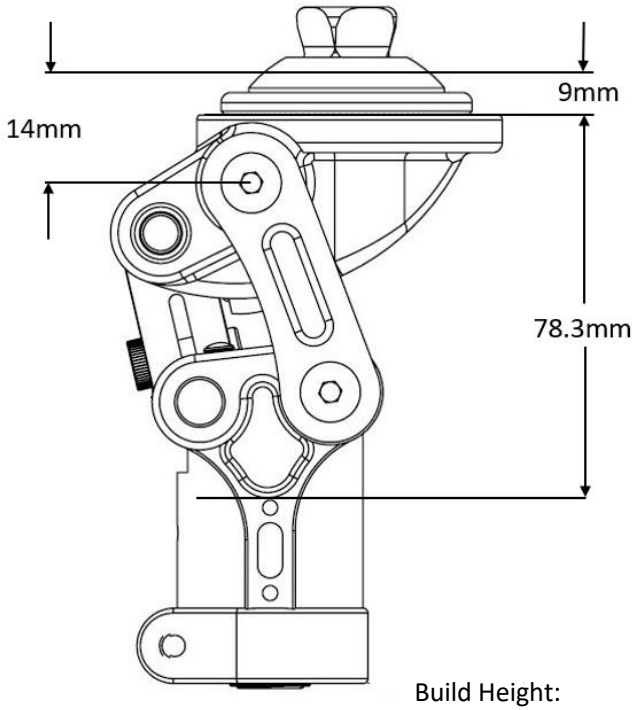
Periodic lubrication of the extension assist spring may be necessary should some noise from the spring be apparent. This can be accomplished by removing the extension assist spring adjustment screw (Section 8.1), remove and lubricate the spring with a quality synthetic grease and reassemble – you will need to reassess the effectiveness of the spring extension assist after this procedure.

10 Technical Specification

•Operating & Storage Temperature Range:	-10˚C to 50˚C (14˚F to 122˚F)
•Weight (pyramid/lotus):	532g/547g
•Recommended Activity:	K2
•Build Height (pyramid/Lotus):	87.3mm/93.6mm
•Tube Depth:	33.7mm
•Maximum User Weight:	100kg (220lbs)
•Maximum flexion angle:	135 degrees
•Proximal Alignment attachment:	Rotatable Male Pyramid or Lotus Adapter
•Distal Alignment attachment:	Tube Clamp
•Tube clamp torque setting:	12Nm
•Pyramid Center Bolt:	18Nm

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

Key Dimensions:



Build Height:
Pyramid = 87.3mm
Lotus = 93.6mm

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

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

ST&G USA Corporation
www.stngco.com e-mail: info@stngco.com

2691 Saturn Street, Brea, CA 92821, USA
Tel: 1-714-524-0663 Fax: 1-714-364-8113