Instructions for P313

Pediatric 4-Bar Knee – manual lock

KA31 KD Adapter

Product Code

P313AP – 4-Bar Knee Pyramid Adapter Version

P313AL – 4-Bar Knee Knee Disarticulation Version

4-Bar Mechanical Knee Unit (Aluminum) with Adjustable Extension Assist

Description and purpose

These instructions are for use by the practitioner.

- The P313 knee is to be used exclusively as part of a lower limb prosthesis
- Recommended for pediatric wearers only, not intended for small adults.
- Weight limit for a user is up to 55 kg / 121 lbs
- Use of this component limited to patients up to 145cm / 57” and foot lengths up to 21cm

Contra-indications

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

Ensure the end user has understood any Instructions for use, especially the safety information, and inspection interval every 3 months!

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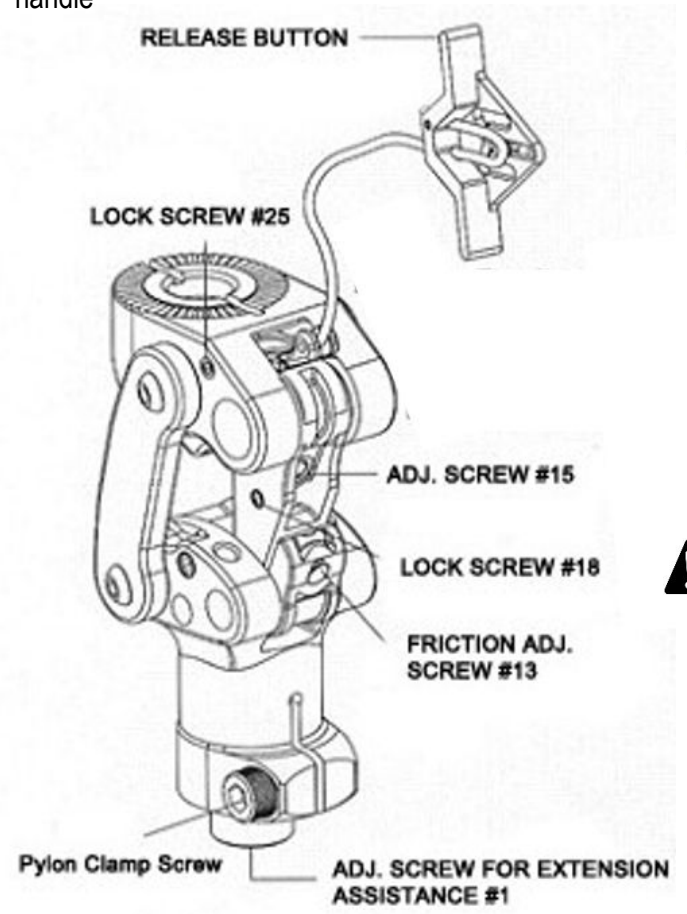
Construction

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

Knee Assembly

P313AP = Knee with a Pyramid mount, Lanyard, Lanyard handle
P313AL = Knee with a Knee Disarticulation mount (KA31), Lanyard, Lanyard handle



P313 adjustment locations

KA31 KD Adapter

PA31 Adapter

Be sure to apply Loctite and torque mounting bolt to 21.5 Nm using a torque wrench.

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.

For single user only, not to be reused for a different wearer

Maintenance

Due to the extreme stresses that children place on the components, regular inspections and servicing by the prosthetist are necessary at predetermined intervals. We recommend that the components be inspected every 3 months. Function should be tested and the tube adapters examined for any evidence of deformities or damage.

- Maintenance must be carried out by qualified personnel.
- Quarterly inspection to be sure 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 is performance of this device must be reported to the Clinician

Changes in performance may include:

- Increase in knee stiffness
- Knee instability
- Decreased knee performance
- Any unusual noises

Cleaning:

- Use a damp cloth and mild soap to clean the outside surfaces by hand.
- DO NOT use aggressive cleaning agents.
- DO NOT use any petroleum lubrication on pivots, as this will void the warranty.
- If the limb/knee comes into contact with salt or chlorinated water, it should be rinsed with fresh water and dried.

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:

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

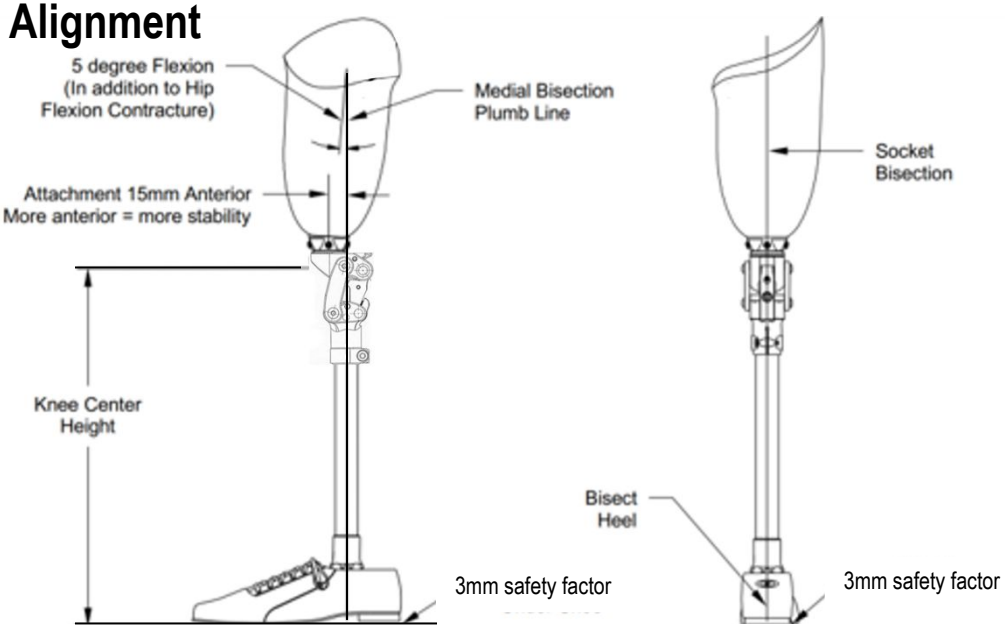
Use – relative humidity: 0 % to 90 %, non-condensing
Storage/transportation – relative humidity: 20 % to 90 %, non-condensing
Splash - Fresh water, rain, salt water, urine, dust, sand, particles of foam cosmetics
cleaning required after contact with salt-laden air, salt water, chlorinated water, urine, sand

Unallowable environmental conditions

Storage/transportation: high vibrations, impacts
Cleaning agents containing solvents

⚠To eliminate noise in the cosmetic foam cover, use Silicone Spray. Do not use talcum powder! Talcum powder reduces the lubrication of the mechanical parts, which may lead to a malfunction and thus increase the risk of falling. Using this medical product after application of talcum powder will render all claims against ST&G null and void. Apply Silicone Spray directly on the friction surfaces of the cosmetic foam cover!

Alignment



Bench Alignment:

Sagittal Alignment:

a) Preflex interface 5 degrees more than measured hip flexion contracture (if any).

b) Place 3mm airspace under heel of shoe.

c) Find Medial Bisection of interface and use plumb line to project distally.

d) Zero pyramid adjustments at ankle.

e) Medial Bisection Plumb Line should bisect ankle attachment.

f) Centerline of knee attachment should be 20mm anterior of Medial Bisection Plumb Line.

Coronal Alignment:

a) Project plumb line from socket bisection distally.

b) Bi-section of ankle should be placed to desired amount of outset.

c) Outset changes with limb length 0-65mm from Ischium.

Height Adjustment:

a) Upper link approximates Knee Center for height measurement.

b) Anatomic Knee Center is found halfway between Adductor Tubercle and MTP.

⚠ **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!**

Initial Flexion Stability Check:
a) Observe patient standing in parallel bars holding on, loading prosthesis, and assess alignment.
b) Have patient initiate knee flexion.
c) If more stability is needed, first plantarflex foot slightly.
d) If more stability is needed, shift socket more anterior.
Friction Adjustment:
a) Set Friction adjustment to have smooth symmetrical heel rise and reduced terminal impact.
b) Be sure patient is not trying to power too much through the walking cycle.

Knee Adjustment

Manual Lock Disable:

Push lock lever up, and screw in both lock screws #25 in till the lever stays up. The lock screw is located on the right and left side of the knee joint.
Remove lanyard retention screw to remove lanyard.

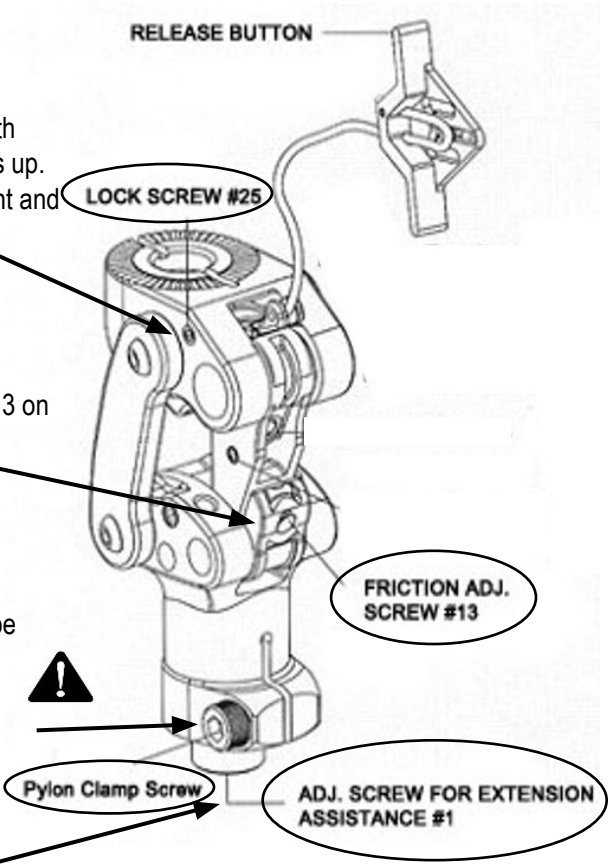
Swing Friction:

Locate Friction adjustment screw #13 on the lower part of the posterior link.
Clockwise = More friction
Counter-Clockwise = Less friction

Extension assist

NOTE: Remove pylon from knee tube clamp to access Extension Assist adjustment.
Torque clamping screw: 10 Nm

Turn to make adjustments.
Clockwise = More spring assist
Counter-Clockwise = Less spring assist



8 Technical Specification

- Operating & Storage Temperature Range: -10˚C to 50˚C (14˚F to 122˚F)
- Weight (Pyramid / KD): 422g / 488g
- Recommended Wearer: Up to 4'9" size 21cm foot
- Maximum User Weight: 55kg (121lbs)
- Maximum flexion angle: 140 degrees
- Proximal Alignment attachment: Male Pyramid / KD plate
- Distal Alignment attachment: Tube Clamp (22mm tube)
- Tube clamp torque setting: 10Nm
- Build Height (Pyramid / KD): 83mm / 82mm
- Knee Center to attachment (pyramid / KD): 20mm / 19mm

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

Warranty

Warranted for 1 year from the date of invoice by ST&G.
The user should be aware that changes or modifications not approved will void the warranty.

Disposal

In some jurisdictions it is not permissible to dispose of the product with unsorted household waste. Improper disposal can be harmful to health and the environment. Observe the information provided by the responsible authorities in your country regarding return, collection and disposal procedures.

Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregard of this document, particularly due to improper use or unauthorized modification of the product.

CE Conformity

This product meets the requirements Council EU 2017/1745 (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.

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