1335 4-Bar Pneumatic Knee (Pyramid or Threaded KD)

Instructions For Use

The 1335 4-Bar Pneumatic Knee promotes stance control a 4-Bar axis design, yet has smooth swing phase control. The pneumatic Flexion and Extension adjustments are located on the posterior of the knee to fine tune knee function.

- 4-Bar Stance Stability Design
- Independent Swing Flexion and Swing Extension Adjustment
- Pyramid mount with distal 30mm tube clamp
- Pneumatic Flexion and Extension Swing Phase Control

KD adapter
Bolt Torque 16Nm

INTENDED USE

1335 4-Bar Pneumatic Knee is intended to be used in the construction of a lower limb prosthesis. The 4-Bar design promotes for stance phase control, but allows for easy transition to swing phase. The Extension and Flexion adjustments are located on the posterior of the knee.

Suitability of the device for the prosthesis and the patient must be evaluated by a healthcare professional.

The device must be fitted and adjusted by a healthcare professional. Intended for single device use only, not to be reused on another device.

The device is intended for K2 and K3 use.

The 1335 is rated for 125Kg/275lb max weight. (assume a buffer factor to the weight limit for activities of daily living. I.E. stairs, stepping off curbs, any activity that will spike the loading of the prosthesis).

INDICATIONS FOR USE

- Lower limb loss, amputation, or deficiency
- Moderate activity to high activity (not for running, or jogging)

GENERAL SAFETY INSTRUCTIONS

The healthcare professional should inform the patient about everything in this document that is required for safe use of this device.

Ensure that the user has understood any IFU (Instructions For Use), drawing particular attention to the safety information.

Warning: If there is a change or loss in device functionality, or if the device shows signs of damage or wear hindering its normal functions, the patient should stop using the device and contact a healthcare professional.

The device is for single patient use.

Notify patient to avoid finger trap posturing about the knee joint to prevent injury.

Bench Alignment

- Assemble prosthesis, and be sure that the Greater Trochanter is set to the proximal knee axis.
- Be sure to align with a 6mm safety factor under the heel for initial alignment prior to weight bearing in parallel bars. This will provide the most stable alignment possible.

Part Number	1335AP	1335KD
Build Height	191mm / 7.5in	183.5mm / 7.38in
Knee Center to Tube Clamp	163mm / 6.4in	163mm / 6.4in
Build Height to Knee Center	16mm / 0.63in	15.5mm / 0.6in
Part Weight	898g / 31.7oz	852g / 30oz
Weight Limit	125kg / 275lb	125kg / 275lb
Clamp Torque	12Nm	12Nm
Max Flexion	150°	150°
Material	Aluminum Alloy	Aluminum Alloy
K Level	2 , 3	2 , 3

Initial Preparation

1. Cut the pylon to length with a clean cut (use a sharp tube cutter, or cut off saw). If using a rolling tube cutter, sand off the mushroomed end and prepare the sanded area so there are no burrs or rough surfaces on the pylon, as this could gall the knee frame and cause it to wedge into the tube clamp.
2. Be sure to no overly torque the clamp bolt beyond 12Nm, and only apply Blue thread locker. Never apply Red thread locker.

Static Alignment

- With the patient standing in the parallel bars, set the Weight Balance Line to be 35mm anterior to Proximal Knee axis. • The alignment should be verified with the patient quietly standing in the parallel bars with even pressure on the prosthesis, and the foot/shoe. This can be verified by checking that there is even pressure on the heel and ball of the shoe, and with

the patient in a good upright relaxed standing posture.

Dynamic Trial Fitting

Adjusting the Settings

Fall precautions should be observed due • The alignment should be verified with the patient quietly standing in the parallel bars with even pressure on the prosthesis, and the foot/shoe. This can be verified by checking that there is even pressure on the heel and ball of the to incorrect or unfamiliar settings

► Only adapt the settings to the patient gradually.

► Explain the effects of the adjustments on the use of the prosthesis to the patient.

During dynamic trial fitting, the alignment and settings of the prosthesis are checked and adapted for optimum walking according to the needs and abilities of the patient.

The patient has to learn the safe use of the prosthesis through intensive training.

The following subsections describe the adjustment possibilities for adapting the product to the patient.

The list below provides an overview of the sequence for working through the subsections:

• Checking the Factory Settings

• Setting Flexion Damping

• Setting Extension Damping

Checking the Factory Settings

Using a 3mm Hex driver:

Function	Means of adjustment	Factory setting	Meaning
Flexion damping	Adjustment valve "F"	From the left-hand stop, turned to the right (number of turns: 2.5)	Valve slightly closed – low damping as the starting point for adjustment to the patient
Extension damping	Adjustment valve "E"	Turned all the way to the left	Valve fully open – minimal damping as the starting point for adaptation to the patient (safety setting)

1) Check whether the settings match the factory settings.

2) In case of deviations, restore the factory settings using the adjustment wrench.

Setting Flexion Damping

Function	Means of adjustment	Setting	Meaning
Flexion damping	Adjustment valve "F"	Rotation to the right	Increase damping
		Rotation to the left	Reduce damping

► CAUTION! The prosthetic foot should swing through with good timing for initial contact!

Adjust flexion damping using the adjustment wrench so that the prosthetic foot swings through sufficiently according to the needs of the patient.

Setting Extension Damping

Function	Means of adjustment	Setting	Meaning
Extension damping	Adjustment valve "E"	Rotation to the right	Increase damping
		Rotation to the left	Reduce damping

► CAUTION! The prosthetic knee joint has to reach full extension, even at slow walking speeds.

Using the adjustment wrench, adjust extension damping so that the prosthetic knee joint does not swing too hard against the extension stop.

► IMPORTANT! ALWAYS make adjustments to both the Extension AND Flexion valve screws to balance out the knee function, not just one or the other.

There has to be balanced air flow within the pneumatic cylinder to allow for proper function.

WARNING:

• Avoid exposing any ST&G knee to corrosives such as salt water, chlorinated water, ammonia, highly acidic, or highly alkaline agents. In case of exposure, rinse with fresh water and allow to thoroughly dry.

• Do not allow moisture to accumulate or dwell inside the knee.

• Never modify or try to repair any ST&G Knee or components. If any repair is necessary, call ST&G to arrange for a loaner and how to proceed for repair. Any knee sent to ST&G that has been modified, had an attempted repair, or signs of abuse will be deemed out of warranty, and subject to either disposal or return to customer at their expense

Any modifications to an adapter will void the warranty and can lead to failure.
• Final application of fastener tightening torque must be done within 2 hours of initial application of blue Loctite 243 thread retaining compound.
• DO NOT use high-strength forms of thread retaining compound (example: Red or Green Loctite formulations). • Insufficient fastener torque will lead to fatigue failure of any modular adapter.
• Excessive fastener torque can strip threads.
• Be sure to verify screw hole depth to screw length before assembly, and especially before applying torque to the screws.
• When adjusting alignment or re-assembling components that had been previously assembled with thread locker, the threads of the fasteners and threaded holes should be cleaned and free of any retaining compound residue to ensure a smooth fit.
• Torque settings should be checked periodically. A loose fastener may lead to component failure, or a fall of the patient.
• Never reuse old bolts.
• Do not contaminate fasteners with any type of paint, glue, or cement, except for the recommended thread locker. For all fasteners, ensure a free-running thread fit prior to applying final tightening torque.
• Failure to follow the installation and use procedures set forth above may lead to structural failure of the components subjecting the user to a risk of serious personal injury.

Environmental Conditions and Maintenance

There are no identified restrictions on the temperature of storage and use.
The knee can tolerate occasional contact with: Clean water, perspiration, and mild soaps, but must be cleaned immediately or will void warranty if corrosion is present.
Clean with fresh water after exposure to other liquids, chemicals, sand, dust, or dirt and dry with a cloth.
Avoid submerging the knee in water as there are bearings which can rust due to water exposure, and will void the warranty.

REPORT OF SERIOUS INCIDENT

Any serious incident in relation to the device must be reported to the manufacturer and relevant authorities.

DISPOSAL

The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

Environment:

Avoid abrasive, wet, or very dusty environments such as those containing sand, and water submersion, for example as these may promote premature wear. Avoid contact with talcum powder or harsh chemicals.
Operating and Storage Temperature Range: between temperatures of -10˚C to 50˚C [14˚F and 122˚F]
Do not submerge or use in wet environment.
Avoid dusty environments.

WARRANTY

Warranty: 24 months against manufacturing defect only.
This warranty will not apply if the PRODUCT has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that the PRODUCT has been modified/repaired by unauthorized persons Damage from misuse, exposure to non-allowed conditions will void the warranty.

LIABILITY

ST&G USA Corporation does not assume liability for the following:
• Device not maintained as instructed by the instructions for use.
• Device assembled with components from other manufacturers.
• Device used outside of recommended use condition, application, or environment.
ST&G products are manufactured and tested for a particular weight and activity impact level. Use by another user for whom it was not originally manufactured may cause injury and voids any written or implied warranty or liability. The liability shall fall upon those that resale/provide the product to anyone other than the original user delivered to. Not to be resold by private party.

Useful Life

Service life of the product is covered by the warranty period.

MD

Disposal

The device and its packaging must be disposed of in accordance with respective national/local environmental regulations.

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.

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