

1336 GeoLock Hydraulic Knee

Instructions For Use

The 1336 GeoLock Hydraulic Knee promotes solid stance control due to the effective mechanical geometric locking 4-Bar axis design, yet has smooth predictable swing phase transitioning. The hydraulic Flexion and Extension adjustments are located on the front of the knee for easy access to fine tune knee function.

- Geometrical Locking Mechanical Stance Stability Design
- Smooth predictable swing phase transitions
- Pyramid or Threaded KD mount with 30mm distal tube clamp
- Easy access Flexion and Extension adjustments

INTENDED USE

1336 GeoLock 4-Bar Hydraulic Knee is intended to be used in the construction of a lower limb prosthesis. The Geometric 4-Bar design promotes for very stable stance phase from initial contact, but allows for easy transition to swing during stance phase. The easy access Extension and Flexion hydraulic adjustments are readily located on the front of the knee joint.

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.

The device is intended for K2 and K3 use, e.g., slow and fast walking.

The 1336 is rated for 125Kg/275lb max weight. (You must 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).

Knee can be ordered with Pyramid or Threaded KD adapters. If adapter needs to be swapped, remove knee mount cover, and loosen bolt to swap adapters. Apply Loctite and torque to 16Nm. Reapply knee mount cover.

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 Weight Line is set within 5-13mm of the knee axis reference line, but not at the knee axis.

Be sure to align the knee as vertical as possible with the knee head parallel to the floor. This will provide the most stable alignment possible.

- Be sure to align with a 6mm safety factor under the heel for initial alignment prior to weight bearing in parallel bars.



KD adapter
Bolt Torque 16Nm



Part Number	1336AP	1336KD
Build Height	155mm / 6.1in	155.5mm / 6.12in
Knee Center to Tube Clamp	138mm / 5.43in	138mm / 5.43in
Build height to Knee Center	17mm / 0.67in	17.5mm / 0.69in
Part Weight	851g / 30oz	825g/29.1oz
Weight Limit	125kg / 275lb	125kg / 275lb
Clamp Torque	12Nm	12Nm
Max Flexion	145°	145°
Material	Magnesium Aluminum Alloy	Magnesium 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 not overly torque the clamp bolt beyond 12Nm, and only apply Blue thread locker. Never apply Red thread locker.

Dynamic Trial Fitting

CAUTION

Adjusting the Settings

Fall precautions should be observed due 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:

- Setting Extension Damping
- Setting Flexion Damping

HYDRAULIC ADJUSTMENTS:

EXTENSION

- To REDUCE Extension resistance – Rotate E Adjuster counter-clockwise when extension timing is too slow



- To INCREASE Extension resistance – Rotate E Adjuster clockwise when extension timing is too quick



FLEXION

- To REDUCE Flexion resistance – Rotate F Adjuster clockwise when heel rise is too low



- To INCREASE Flexion resistance - Rotate F Adjuster counter-clockwise when heel rise is too high



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.
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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: 36 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/repared 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.

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 2017/745 (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.

Specifications subject to change

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