

All-Terrain KneeTM Collection



Instructions for Use



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PRODUCT DIAGRAMS



Fig. 1 All-Terrain Knee Anterior Overview

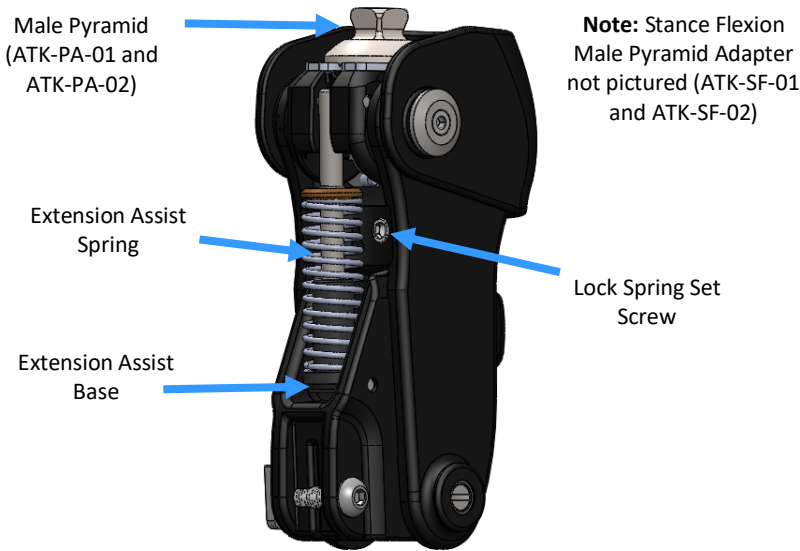


Fig. 2 All-Terrain Knee Posterior Overview

DESCRIPTION AND PURPOSE

Date of last update: 2018-05-17

- Please read this document carefully.
- The safety instructions are to be followed by both the prosthetist and the user.

Product Codes:

This instructional manual covers all current versions of the All-Terrain Knee:


Product Name	Product Code
All-Terrain Knee	ATK-PA-01
All-Terrain Knee with Stance Flexion	ATK-SF-01
All-Terrain Knee Premium	ATK-PA-02
All-Terrain Knee Premium with Stance Flexion	ATK-SF-02

The Primary components and adjustments are identical across all knee versions. Specific differences in components, features and adjustments are indicated within the document by notation of the relevant Product Code.

Intended Use:

These instructions are for use by the prosthetist fitting and/or maintaining the device.

- All device models are intended for single person use.
- All device models are to be used exclusively as part of an external lower-limb prosthesis.
- All device models are developed for everyday use and must not be used for unusual activities, such as extreme sports.
- *ATK-PA-01* and *ATK-PA-02* are designed exclusively for Knee Disarticulation or Transfemoral amputees.
- *ATK-SF-01* and *ATK-SF-02* are designed exclusively for Transfemoral amputees.

 Ensure that both the prosthetist and the user have read and understood the Instructions for Use, especially safety information. If the user experiences any problems with her device, she should immediately contact her prosthetist. If the prosthetist experiences any problems, immediately contact LegWorks.

Scope of Delivery:

- All-Terrain Knee Device
- All-Terrain Knee Device Cover
- Instructions for Use (IFU)
- Quick Reference Card (QRC)
- Short User Guide
- Extension Assist Springs: Medium stiffness (preinstalled), Strong stiffness
- *ATK-SF-01* and *ATK-SF-02* only: Posterior Stance Flexion Bumpers: Firm, Medium (preinstalled), and Soft stiffness

Function:

- Stance-Phase Control: AutoLock Technology
- Swing-Phase Control: Adjustable variable friction resistance (Variable Cadence Controller) and spring extension assist
- Design:
 - *ATK-PA-01* and *ATK-SF-01*: Waterproof in freshwater (e.g. shower, lake)
 - *ATK-PA-02* and *ATK-SF-02*: Waterproof and corrosion resistant in both freshwater and saltwater (e.g. shower, pool, ocean)
- Activity Level: Suitable for all activity levels

Indications:

- Transfemoral (all device models), Knee Disarticulation (*ATK-PA-01* and *ATK-PA-02* only)
- K1-K4 mobility level (primary prosthesis)
- Secondary prosthesis (bath or water leg)

Weight Limit:

- *ATK-PA-01* and *ATK-SF-01* have been tested and passed to the 125kg (275 lb) P6 ISO 10328:2006 standard
- *ATK-PA-02* and *ATK-SF-02* have been tested and passed to the 150kg (330 lb) P8 ISO 10328:2006 standard

PRODUCT SPECIFICATIONS

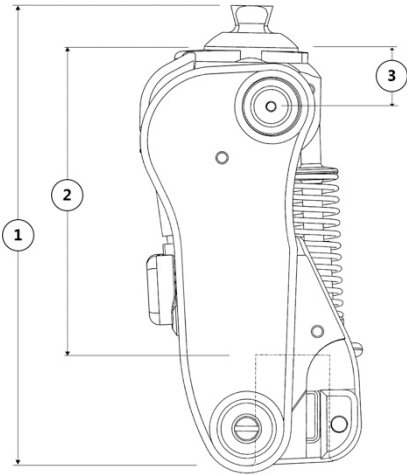


Fig. 3 All-Terrain Knee ATK-PA-01 Build Height Diagram

Product	All-Terrain Knee
Part #	ATK-PA-01
Amputation level	Transfemoral, Knee Disarticulation
Activity Level	K1-K4
Material	Advanced Fiber-Reinforced Composites, Stainless Steel
Maximum body weight	125kg/275 lb
Total fitted height (1)	186mm
Effective fitted height (2)	125mm
Fitted height (3)	24mm
Attachment point to first axis offset	9mm posterior offset
Product weight	1,040g/2.29 lb
Ground clearance	11mm
Proximal connection	Pyramid Adaptor
Swing phase control	Variable Cadence Controller (Patent Pending)
Stance phase control	AutoLock Technology (Patented)
Axes	Four axes
Flexion angle (minus socket)	150 degrees
Distal connection	30mm tube clamp

Fig. 4 ATK-PA-01 Technical Specifications

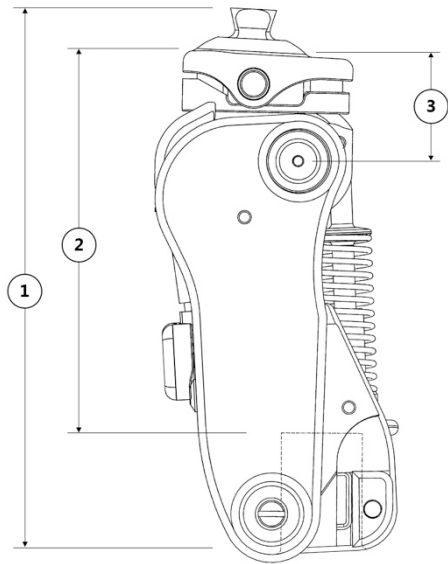


Fig. 5 All-Terrain Knee with Stance Flexion ATK-SF-01 Build Height Diagram

Product	All-Terrain Knee with Stance Flexion
Part #	ATK-SF-01
Amputation level	Transfemoral
Activity Level	K1-K4
Material	Advanced Fiber-Reinforced Composites, Stainless Steel
Maximum body weight	125kg/275 lb
Total fitted height (1)	201mm
Effective fitted height (2)	141mm
Fitted height (3)	40mm
Attachment point to first axis offset	19mm posterior offset
Product weight	1,230g/2.71 lb
Ground clearance	11mm
Proximal connection	Pyramid Adaptor
Swing phase control	Variable Cadence Controller (Patent Pending)
Stance phase control	AutoLock Technology (Patented)
Axes	Four axes with adjustable stance flexion
Flexion angle (minus socket)	150 degrees
Distal connection	30mm tube clamp

Fig. 6 ATK-SF-01 Technical Specifications

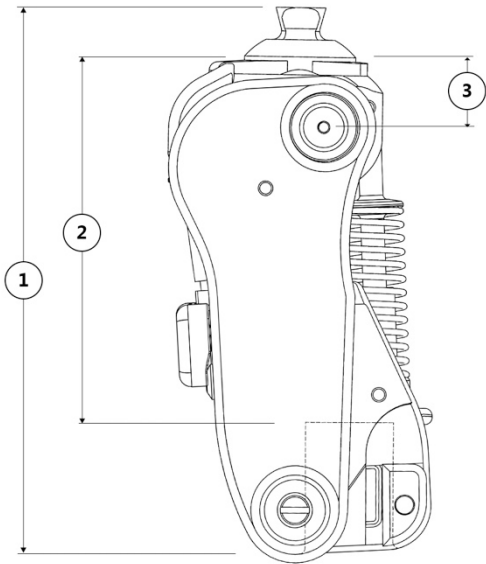


Fig. 7 All-Terrain Knee Premium ATK-PA-02 Build Height Diagram

Product	All-Terrain Knee Premium
Part #	ATK-PA-02
Amputation level	Transfemoral, Knee Disarticulation
Activity Level	K1-K4
Material	Advanced Fiber-Reinforced Composites, Stainless Steel, Titanium
Maximum body weight	150kg/330 lb
Total fitted height (1)	186mm
Effective fitted height (2)	125mm
Fitted height (3)	24mm
Attachment point to first axis offset	9mm posterior offset
Product weight	1,044g/2.30 lb
Ground clearance	11mm
Proximal connection	Pyramid Adaptor
Swing phase control	Variable Cadence Controller (Patent Pending)
Stance phase control	AutoLock Technology (Patented)
Axes	Four axes
Flexion angle (minus socket)	150 degrees
Distal connection	30mm tube clamp

Fig. 8 ATK-PA-02 Technical Specifications

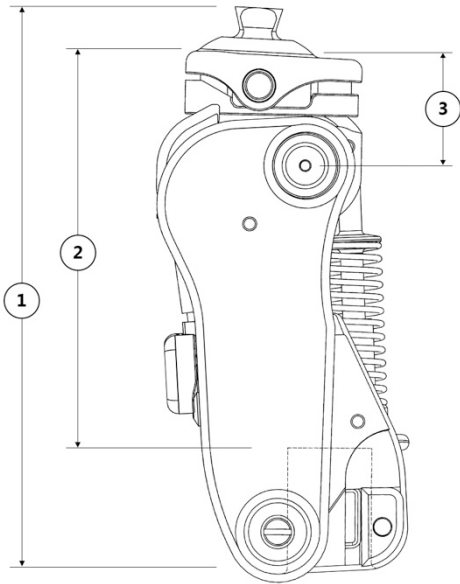


Fig. 9 All-Terrain Knee Premium with Stance Flexion ATK-SF-02 Build Height Diagram

Product	All-Terrain Knee Premium with Stance Flexion
Part #	ATK-SF-02
Amputation level	Transfemoral
Activity Level	K1-K4
Material	Advanced Fiber-Reinforced Composites, Stainless Steel, Titanium
Maximum body weight	150kg/330 lb
Total fitted height (1)	201mm
Effective fitted height (2)	141mm
Fitted height (3)	40mm
Attachment point to first axis offset	19mm posterior offset
Product weight	1,234g/2.72 lb
Ground clearance	11mm
Proximal connection	Pyramid Adaptor
Swing phase control	Variable Cadence Controller (Patent Pending)
Stance phase control	AutoLock Technology (Patented)
Axes	Four axes with adjustable stance flexion
Flexion angle (minus socket)	150 degrees
Distal connection	30mm tube clamp

Fig. 10 ATK-SF-02 Technical Specifications

OUR TECHNOLOGY

The All-Terrain Knee utilizes a proprietary stance-phase control mechanism (the AutoLock) and swing-phase control mechanism (Variable Cadence Controller or VCC). The mechanisms comprise a 4-linkage (4 bar) kinematic chain. The AutoLock technology is based on a knee lock that is automatically engaged in late-swing-phase for extra safety. The knee remains securely locked until mid-to-late stance-phase when it is disengaged for an effortless swing-phase initiation. The VCC utilizes a variable friction system with an optimized extension assist spring for efficient gait at multiple walking speeds. The 4 bar kinematic arrangement of the All-Terrain Knee mechanism results in swing-phase foot-clearance comparable to 4 and 6 bar polycentric knee mechanisms.

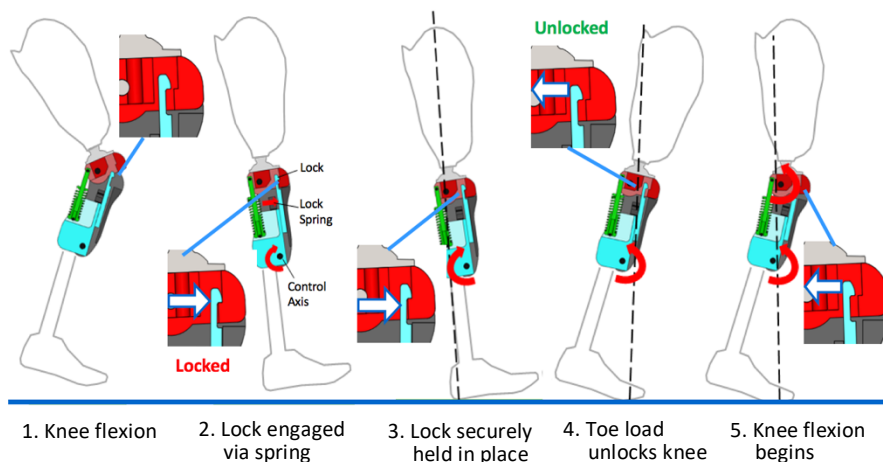



Fig. 11 Stance Phase Function

The All-Terrain Knee is suitable for users in mobility classes 1-2, due to its 2-in-1 function. It can either be used as a manual locking knee joint, or as a mechanical knee joint that allows for a natural gait as the user becomes more confident in their stability and safety. This allows new amputees to transition from early rehabilitation into more confident household and limited community ambulation.

As the user's mobility continues to improve, the friction mechanism can be adjusted to ensure that excessive heel-rise and terminal impact are prevented. The All-Terrain Knee continues to be suitable for users in mobility classes 3 and 4, for both everyday use and recreational use, due to the Variable Cadence

Controller, which allows amputees to walk at multiple speeds, while still benefiting from the stability and natural walking motion of the AutoLock Technology.

SAFETY

 All device models of the All-Terrain Knee should only be fit by a qualified professional.

In the final stage of quality control, all All-Terrain Knee Collection units undergo functional testing to ensure optimal performance standards are met. As a result, the product may ship with visible indentation marks on the pyramid.

If there are any visible changes, wear and tear, or functional limitations, replace the part, or contact the manufacturer for a replacement part, or servicing request. Please make sure the user is competent in handling of his prosthesis before leaving the premises. Failure to observe this warning may cause the user to fall.

 Please be aware of finger traps in the knee joint at all times.

The user should immediately report any changes, i.e. excessive movement in the knee during stance-phase, inconsistent locking, etc. to their prosthetist.

Always use a handrail when descending stairs and on downward slopes if available.

Any excessive changes in heel height may adversely affect the stability of the knee. Care should be taken while carrying heavy loads.

USER INSTRUCTIONS

Do not adjust your knee or change your alignment. Alert your prosthetist immediately to any suspicious sounds from the knee (clicking, crackling, etc.). Inspect your prosthesis often, clean with a towel. Do not tamper with any screws on the knee.

Observe all the above points, otherwise the warranty becomes null and void.

SETUP AND OPERATION

CONNECTIONS

The proximal connection consists of a M10 bolt that is attached directly to a male pyramid adaptor (**Fig. 13**).

ATK-SF-01 and *ATK-SF-02* ONLY - ADJUSTABLE STANCE FLEXION ADAPTER

The All-Terrain Knee versions with Stance Flexion feature a proximal articulating pyramid adaptor with anterior and posterior bumpers that compress upon loading, providing up to 12 degrees of total movement throughout stance phase.

ATK-SF-01 and *ATK-SF-02* are shipped with the adapter pre-installed with the medium grade posterior bumper inserted.

Bumper Options:

Anterior or Posterior	Bumper Color	Hardness
Anterior	Blue	Medium (preinstalled)
Posterior	Black	Soft
Posterior	Blue	Medium (preinstalled)
Posterior	Gray	Firm

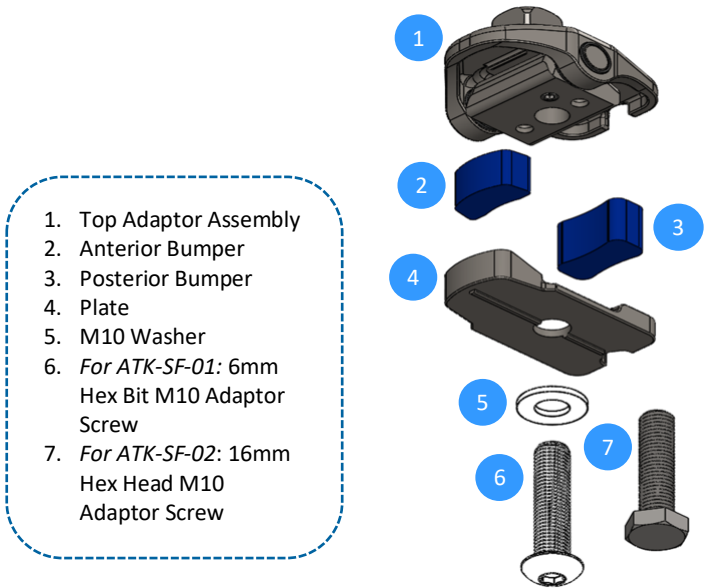




Fig. 12 Adjustable Stance Flexion Adaptor Assembly

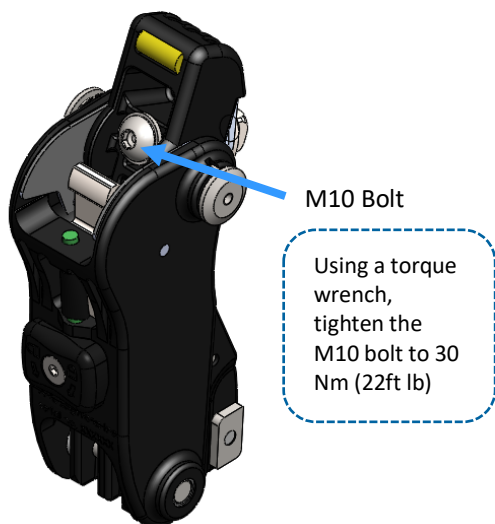
Bumper Selection Guidelines:

If patient experiences excessive motion or a sensation of instability with the preinstalled bumper: Select the firm posterior bumper (gray).

If patient experiences heel strike as too rigid: Select the soft posterior bumper (black).

Bumper Adjustment Instructions:

1. Turn M10 bolt  to remove proximal assembly
2. Select the desired posterior bumper and insert into channel as shown.
3. Ensure that the anterior bumper is properly seated into channel as shown.
4. Install combined assembly onto knee using M10 bolt with washer while ensuring that bumpers remain properly aligned and housed within the adapter while tightening the bolt.
5. Torque M10 bolt  to 30Nm / 22 ft lb
6. Check prosthetic alignment (see section 3)



For the distal connection, ensure the 30mm pylon is fully inserted. **Tighten pylon clamp screw to 12Nm (9 ft lb)** by turning the bolt with a 5mm hex bit (For ATK-PA-02 and ATK-SF-02: use 6mm hex bit) using a torque wrench.

If a loud creaking sound occurs at heel strike, apply a small amount of multi-purpose oil or silicone spray to the surface area of the pylon that rests within the knee's tube clamp.

Fig. 13 Proximal Connection

FLEXION STOP

⚠ A flexion stop must be provided between the socket and the distal posterior portion of the knee to prevent hyper flexing of the knee and damage to internal mechanisms of knee.

In maximum flexion, it is vital that a flexion stop is in effect and contacts the All-Terrain Knee in the proper location. See examples below:



Fig. 14 Absence of Flexion Stop

Incorrect: No contact point exists between socket and lower body of knee in maximum flexion. Damage to knee may occur.



Fig. 15 Malpositioned Flexion Stop

Incorrect: Socket is in direct contact with extension assist spring assembly in maximum flexion. Damage to knee may occur.



Fig. 16 Appropriate Flexion Stop

Correct: Socket naturally contacts the body of knee below the spring assembly. A flexion stop (e.g. crepe) may need to be affixed to socket to achieve this.

Alternatively, a flexion stop may need to be affixed to the knee's pylon adaptor and the sidewalls surrounding the extension assist spring.

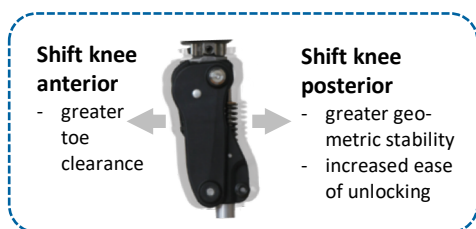
SAGITTAL PLANE ALIGNMENT

Position the knee's first axis 20mm posterior to the plumb line bisecting proximal aspect of socket (baseline recommendation)

To increase ease of unlocking, increase toe load:

- Shift knee posterior
- Plantarflex foot
- Increase socket flexion

Tighten pylon clamp of knee to 12Nm (9 ft lb)



Alignment Reference Line
(descends from proximal socket bisection point)

Socket Flexion:
3-5° initial flexion

20mm Posterior Offset Line
(extends vertically through first axis)

Foot (as per manufacturer's suggestion)

Fig. 17 Sagittal Plane Alignment

AUTOLOCK MECHANISM



Posterior View

Lock Spring Set Screw (5mm hex)

The Lock Spring Set Screw applies force to the lock spring to ensure proper performance locking upon full extension) of the AutoLock Mechanism.

Factory Setting:

¼ turn protrusion from surface

With user in parallel bars adjust as follows:

If lock fails to engage



Turn ↻ 1/4 turn

If there is a loud click at full extension



Turn ↻ 1/8 turn

Fig. 18 AutoLock Sensitivity Adjustment

FRICTION MECHANISM

Minimum Friction Setting (MFS): failure to achieve MFS causes mechanism to loosen and fall off with use.

Ensure the friction mechanism caps and disc springs are not loose i.e. able to rattle or make noise when tapped with a finger.

If user requires a more free-swinging knee, the friction mechanism assembly (**Fig. 20**) can be removed and stored for later use; this does not affect the integrity of the knee's assembly.

With user in parallel bars, adjust as follows:

If knee does not reach full extension → by 1/4 turn increments

If excessive terminal impact → by 1/4 turn increments



Fig. 19 Friction Mechanism

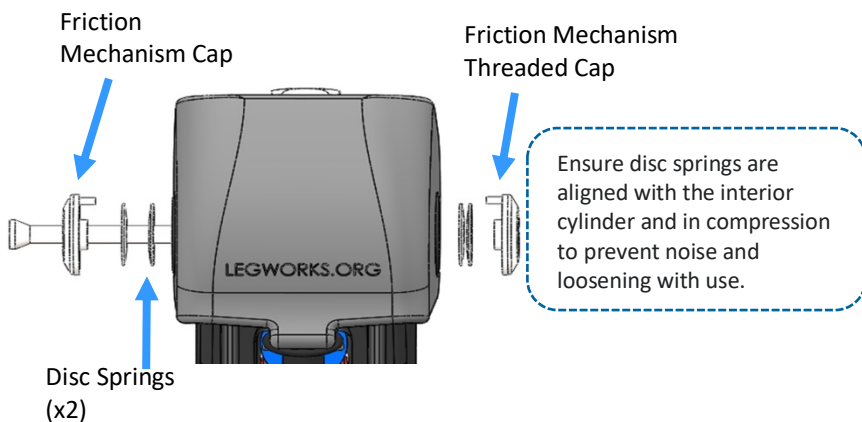


Fig. 20 Friction Mechanism Cap and Disc Springs

⚠ Over-tightening the friction mechanism may keep the knee from reaching full extension, preventing the AutoLock Technology from locking.

ADJUSTABLE EXTENSION ASSIST

The knee joint is shipped with medium stiffness extension assist spring (white) pre-installed (**Fig. 21**).

Extension Assist Bias Options



Weak	Med.	Strong
Blue	White	Red

Blue available upon request

Spring Assembly

insert spring base into chosen spring



Watch out for finger traps when compressing the spring.



Posterior View

Removal:

Insert flathead screw-driver below the spring base and above horizontal shaft. Compress spring up-ward and pull outward.

Installation:

Align horizontal groove of extension assist base with horizontal shaft prior to closing spring assembly.



Posterior View

Fig. 21 Adjustable Extension Assist

COVER

The cover protects the All-Terrain Knee, as well the user's clothes. The All-Terrain Knee can be operated without the cover. Should the cover be broken, it can be easily ordered and replaced.

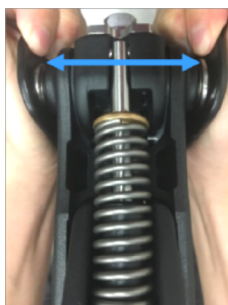


Fig. 22 All-Terrain Knee Cover Removal

The cover has an o-ring to minimize noise. Ensure the o-ring is present.

Bridge of Cover should be connected into the opening of the main body of the knee.

The cover can be used to manually unlock the knee when the knee is in the AutoLock mode.

Simply hold the cover and push down on it to unlock and flex the knee (**Fig. 23**)

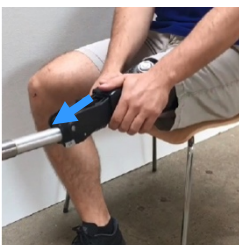



Fig. 23 All-Terrain Knee Cover Release

 When setting up the prosthesis, ensure the top of the cover does not come in contact with the socket and that a gap exists when the knee is fully extended. In case a gap does not exist, modify the socket or grind down the cover until a gap is evident. Ensure that there is no possibility of cosmetic coverings or clothes getting caught between the cover and socket, otherwise the knee will not properly lock. This could lead to fall and injury.

MANUAL LOCK

Turning the manual lock knob clockwise to the vertical position securely engages the knee lock when knee is fully extended. Turning it to the horizontal position allows for AutoLock operation. The manual lock can be engaged with knee flexed or fully extended. Activating manual lock when knee is slightly flexed is difficult and should be avoided.

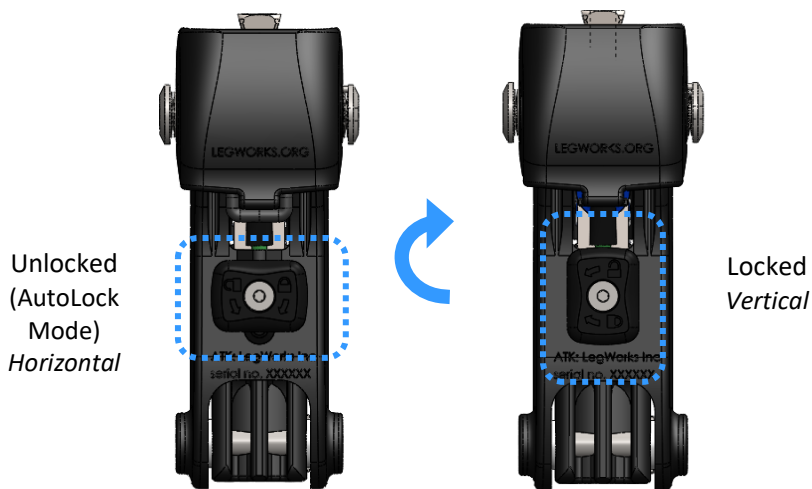


Fig. 24 Manual Lock

The manual lock screw is factory set. DO NOT adjust unless MANUAL LOCK disengages when in use. To adjust, use a 4mm hex key at the front and 10mm socket wrench from the rear of the knee after removing the extension assist spring (Fig. 24). While the knee is fully extended and locked, tighten using hex key in $\frac{1}{4}$ turn (clockwise) increments and re-test the performance. Repeat as needed. If manual lock knob becomes too tight to turn or if clicking occurs, loosen by $\frac{1}{8}$ turn.

MAINTENANCE

USER

The knee collection is designed to be used in harsh environments, including water and dirty conditions. If subjected to these environments, the knee should be cleaned immediately to prevent premature wear and tear. To clean the knee, submerge it in clean warm water or place knee under warm running water. Dry after.

The All-Terrain Knee (ATK-PA-01) and All-Terrain Knee with Stance Flexion (ATK-SF-01) should only be used in freshwater. Exposure to non-freshwater will result in corrosion and should be avoided. If any incidental contact with non-freshwater occurs, the knee should be immediately rinsed with warm clean freshwater.

The All-Terrain Knee Premium (ATK-PA-02) and the All-Terrain Knee Premium with Stance Flexion (ATK-SF-02) can be used in freshwater and saltwater, including swimming pools. If the knee is exposed to non-freshwater, rinse thoroughly in warm water immediately after exposure to dissolve salts and limit unnecessary exposure to chemicals.

Light corrosion will not affect function. In the event of heavy corrosion, contact your prosthetist as it could affect function or safety.

PROSTHETIST

Maintenance: The joint must be inspected, and repaired if necessary, at least every 6 months. Inspect: alignment, screw connections, suitability of user (weight, degree of mobility), loss of lubricant, for damage, for soiling of the bushings, extension stop, visual inspection of proximal adaptor, other damage.

Maintenance must be carried out by prosthetist. Visual inspection annually is recommended. Check for visual defects that may affect proper function.

Maintenance instructions: do not disassemble the knee joint. If there is an issue with the product, send the knee joint in for service. LegWorks recommends readjusting the knee joint's settings once the user has gotten used to the prosthesis.

CARE: clean with soft cloth and warm freshwater. Don't use aggressive cleaning agents, or compressed air.

Light corrosion will not affect function. In the event of heavy corrosion, contact LegWorks as it could affect function or safety.


WARRANTY

All device models of the All-Terrain Knee are covered by a 2-year warranty, no changes or modifications are allowed.

General Conditions: If it is being used by more than one user, product liability pursuant to the Medical Devices Directive 93/42/EEC becomes null and void.

LegWorks warrants that all device models of the All-Terrain Knee and component parts thereof will be free from defects in workmanship and materials for a period of two years from the date of purchase by a prosthetist or distributor of prosthetic products involved in the business of resale or distribution.

LegWorks does not warrant products to consumers directly, only through prosthetists.

 The All-Terrain Knee (ATK-PA-01) and the All-Terrain Knee with Stance Flexion (ATK-SF-01) may be used in freshwater. The All-Terrain Knee Premium (ATK-PA-02) and the All-Terrain Knee Premium with Stance Flexion (ATK-SF-02) may be used in freshwater and saltwater. Regular care and maintenance of all device models is needed to avoid corrosion (as described above). Maintenance must be completed the same day as exposure and is recommended as soon after exposure as possible. Failure to comply with this required maintenance for water exposure will void any warranty coverage for corrosion.

Procedure for obtaining warranty service: Contact LegWorks customer service at warranty@legworks.com to obtain a return authorization number.

All units in need of repair should be shipped by the purchaser to LegWorks. It is the responsibility of the purchaser to prepay and insure units shipped to LegWorks. LegWorks will not accept units shipped directly from the end user. For any warranty-related service LegWorks will provide a loaner unit for the length of time required to repair the unit at no charge. Units that are not under warranty or are excluded from the warranty will not receive a free loaner, however a loaner may be rented for a nominal fee and deposit. Loaner units will be invoiced for their full value and a credit issued upon their return. Any units returned under warranty for repair will carry a six-month warranty on those repairs subject to exclusions. Loaner units must be returned free from damage caused by abuse, neglect, or alteration, otherwise repair charges will be billed to the purchaser. LegWorks reserves the right to determine how units will be repaired including the option of reconditioned, or new parts.

EXCLUSIONS

This warranty does not apply to units used other than in normal use. Units that are altered or damaged as a result of an accident, negligence, or improper care are also excluded. The following items are not covered: damage to knee cap for other than normal wear.

Additionally, any unit with corrosion as a result of improper use or maintenance, evidence of contact with abnormal corrosive substances, and/or damage as a result of improper service or maintenance will not be warranted.

This warranty implied, or expressed does not cover the cost of shipping, insurance, ancillary damage to, or loss of the use of, the artificial leg in which the unit has been installed, or any economic or physical loss to purchaser or end user.

LegWorks products are guaranteed to be compatible with modular components from other manufacturers, if the following points are observed:

Use only with other components that are in compliance with their intended purpose, weight limit of weakest component applies, the use of tested individual components with the CE mark does not release the prosthetist from his obligation to check, to the best of his capabilities, the prosthesis for its sustainability, correct assembly and safety. If the prosthesis has been exposed to an unusually high stress e.g. a fall, it must be inspected immediately for possible damage. Safety relevant regulations for individual fittings must be observed.

LIABILITY

In case of damage: LegWorks can only consider complaints accompanied by a copy of the delivery note or the LegWorks invoice together with a detailed description of the reasons for returning the product. A manufacturer can only be held liable for the failure of its own components. The manufacturer can only be held liable beyond this, if it can be proved that its modular components were causally responsible for the damage to or loss of function of modular components from other manufacturers.

LegWorks recommends using the device only under the specified conditions for the intended purposes. All device models of the All-Terrain Knee Collection must be maintained as according to the instructions.

DISPOSAL

Dispose of per local, state, and federal regulations.

CE Conformity

The All-Terrain Knee (ATK-PA-01) and the All-Terrain Knee with Stance Flexion (ATK-SF-01) have been tested and passed to the 125kg P6 ISO 10328:2006 standard, and the All-Terrain Knee Premium (ATK-PA-02) and the All-Terrain Knee Premium with Stance Flexion (ATK-SF-02) have been tested and passed to the 150kg P8 ISO 10328:2006 standard.

All device models by LegWorks meet the conformity standards of the CE Mark, as outlined in Medical Device Directive 93/42/EEC. All device models of the All-Terrain Knee have been classified as a Class 1, Rule 1 medical device per the rules found in Annex IX. LegWorks has completed the essential requirements of Annex I, the clinical evaluation of X, and self-declared using Annex VII.

ORDERING AND CONTACT INFO

For Sales inquiries, or a request for more information regarding the All-Terrain Knee Collection, please email sales@legworks.com, or call +1 (408) 692-5633. For Warranty requests, customer complaints, or servicing requests, please email warranty@legworks.com, or call +1 (408) 692-5633.

LegWorks 

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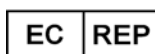
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