

ALL-TERRAIN KNEE™ INSTRUCTIONS FOR USE

ORIGINAL & PREMIUM SERIES



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QNET BV Kantstraat 19 NL-5076NP Haaren The Netherlands

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PRODUCT DIAGRAMS

All-Terrain Knee Anterior Overview





All-Terrain Knee Posterior Overview

DESCRIPTION & PURPOSE

Last updated: 2022-09-15

- 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 Collection:

Product Name	Product Code
All-Terrain Knee	ATK-PA-01
All-Terrain Knee with Threaded Top	ATK-TT-01
All-Terrain Knee with Stance Flexion	ATK-SF-01
All-Terrain Knee Premium	ATK-PA-02
All-Terrain Knee Premium with Threaded Top	ATK-TT-02
All-Terrain Knee Premium with Stance Flexion	ATK-SF-02
All-Terrain Knee Premium HD	ATK-PA-03
All-Terrain Knee Premium HD with Threaded Top	ATK-TT-03
All-Terrain Knee Premium HD with Stance Flexion	ATK-SF-03

The Basic UDI-DI for all knees in the All-Terrain Knee Collection is 0850038961ATK4K. 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 individual 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, ATK-PA-02, and ATK-PA-03 are designed exclusively for Knee Disarticulation or Transfemoral amputees.
- ATK-TT-01, ATK-TT-02, and ATK-TT-03 are designed exclusively for Knee Disarticulation or Transfemoral amputees.
- ATK-SF-01, ATK-SF-02, and ATK-SF-03 are designed exclusively for Transfemoral amputees.

Ensure that both the prosthetist and the user have read and understood the *Instructions for Use*, especially the safety information. If the user experiences any issues with the device, they should immediately contact their prosthetist. If the prosthetist experiences any issues, immediately contact LegWorks.

PACKAGE CONTENTS

- · All-Terrain Knee Device
- · All-Terrain Knee Device Cover
- Instructions for Use (IFU) manual
- Quick Reference Card (QRC)
- User Guide
- · Extension Assist Springs:
 - Medium stiffness (pre-installed)
 - Strong stiffness
- Posterior Stance Flexion Bumpers ATK-SF-01, ATK-SF-02:
 - Medium (pre-installed)
 - Firm and soft stiffness
- Posterior Stance Flexion Bumpers ATK-SF-03 only:
 - Firm (pre-installed)
 - Medium included in packaging

FUNCTION

- · Stance Phase Control
 - AutoLock Technology
- Swing Phase Control
 - Adjustable variable friction resistance (Variable Cadence Controller) and spring extension assist

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INDICATIONS

- · Transfemoral: All device models
- Knee Disarticulation: ATK-PA-01, ATK-TT-01, ATK-PA-02, ATK-TT-02, ATK-PA-03, ATK-TT-03
- Primary prosthesis: K1-K4 mobility level
- Secondary prosthesis (bathing or water leg)

WEIGHT LIMIT

- ATK-PA-01, ATK-TT-01, and ATK-SF-01: 125kg (275 lb)
- ATK-PA-02, ATK-TT-02, and ATK-SF-02: 150kg (330 lb)
- ATK-PA-03, ATK-TT-03, and ATK-SF-03: 200kg (440 lb)

CLINICAL BENEFITS

See https://legworks.com/pages/clinical-education/ for the clinical study abstracts and the clinical benefit findings of the studies on the technology in the All-Terrain Knee.

PERFORMANCE CHARACTERISTICS OF THE KNEE

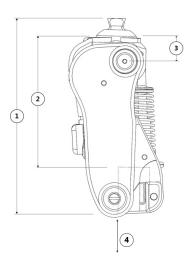
- Knee locks upon reaching full extension until a toe-load and hip-flexion moment release the knee into swing-phase.
- Secondary manual lock mode provides complete stability for the user.

RESIDUAL RISKS AND CONTRAINDICATIONS

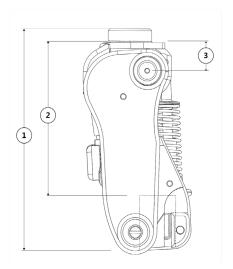
- The device must be operated per instructions in order to provide safety to the user.
- Improper usage of the device may create a fall risk.
- Contraindications include weight ratings above the specified weight limit for each device's product code and individuals who are unable to retain the method of operating the device safely.

This device is a single-use device and as such should not be refit on other individuals. All devices are ISO 10328:2016 tested for structural and fatigue strength and should be used for the period of 5-years service lifetime by one user.

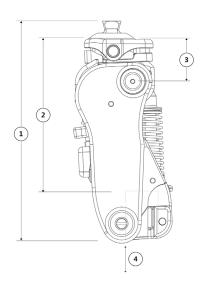
PRODUCT SPECIFICATIONS



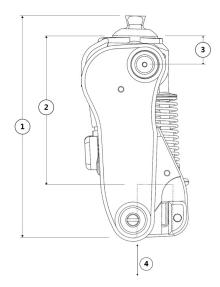
All-Terrain Knee		
Part #	ATK-PA-01	
Product Weight	1,040g (2.29 lb)	
Maximum Body Weight	125kg (275 lb)	
Material	Advanced Fiber-Reinforced Composite, Stainless Steel	
Waterproof Rating	Freshwater proof	
Activity Level	K1-K4	
Amputation Level	Transfemoral, Knee Disarticulation	
Total Fitted Height (1)	186mm (7 ⁵ / ₁₆ in)	
Effective Fitted Height (2)	125mm (4 ¹⁵ / ₁₆ in)	
Fitted Height (3)	24mm (¹⁵ / ₁₆ in)	
Tube Clamp Depth (4)	45mm (1 ³ / ₄ in)	
Attachment point to first axis offset	9mm posterior offset	
Ground Clearance	11mm (⁷ / ₁₆ in)	
Proximal Connection	Pyramid Adaptor	
Distal Connection	30mm tube clamp	
Swing Phase Control	Variable Cadence Controller (Patent Pending)	
Stance Phase Control	AutoLock Technology (Patented)	
Axes	Four axes	
Flexion angle (less socket)	150 degrees	

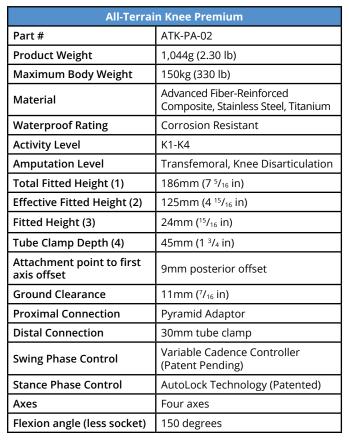


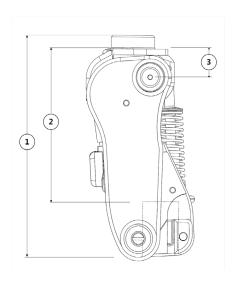




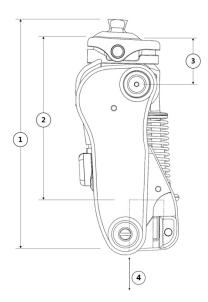
All-Terrain Knee with Stance Flexion		
Part #	ATK-SF-01	
Product Weight	1,230g (2.71 lb)	
Maximum Body Weight	125kg (275 lb)	
Material	Advanced Fiber-Reinforced Composite, Stainless Steel	
Waterproof Rating	Freshwater proof	
Activity Level	K1-K4	
Amputation Level	Transfemoral	
Total Fitted Height (1)	201mm (7 ¹⁵ / ₁₆ in)	
Effective Fitted Height (2)	141mm (5 ⁹ / ₁₆ in)	
Fitted Height (3)	40mm (1 ⁹ / ₁₆ in)	
Tube Clamp Depth (4)	45mm (1 ³ / ₄ in)	
Attachment point to first axis offset	19mm posterior offset	
Ground Clearance	11mm (⁷ / ₁₆ in)	
Proximal Connection	Pyramid Adaptor	
Distal Connection	30mm tube clamp	
Swing Phase Control	Variable Cadence Controller (Patent Pending)	
Stance Phase Control	AutoLock Technology (Patented)	
Axes	Four axes	
Flexion angle (less socket)	150 degrees	

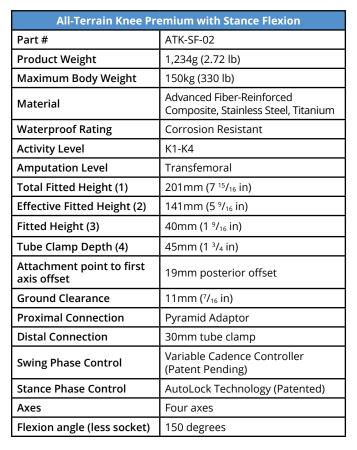


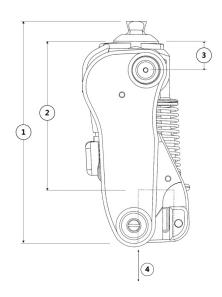




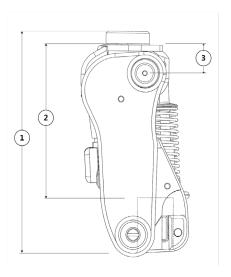
	(-TT-02	
Product Weight 1.04	40~ (2.21 lb)	
.,.	1,049g (2.31 lb)	
Maximum Body Weight 150	kg (330 lb)	
Material	vanced Fiber-Reinforced mposite, Stainless Steel, Titanium	
Waterproof Rating Cor	rosion Resistant	
Activity Level K1-	K4	
Amputation Level Tra	nsfemoral, Knee Disarticulation	
Total Fitted Height (1) 179	9mm (7 ¹ / ₁₆ in)	
Effective Fitted Height (2) 125	5mm (4 ¹⁵ / ₁₆ in)	
Fitted Height (3) 17n	nm (¹¹ / ₁₆ in)	
Tube Clamp Depth (4) 45n	nm (1 ³ / ₄ in)	
Attachment point to first axis offset	nm posterior offset	
Ground Clearance 11n	mm (⁷ / ₁₆ in)	
Proximal Connection Thr	eaded Adaptors	
Distal Connection 30n	mm tube clamp	
Swing Phase (ontrol I	iable Cadence Controller tent Pending)	
Stance Phase Control Aut	oLock Technology (Patented)	
Axes Fou	ır axes	
Flexion angle (less socket) 150) degrees	



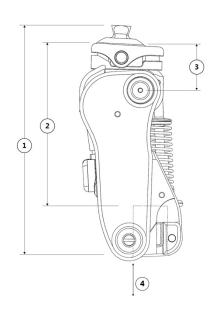




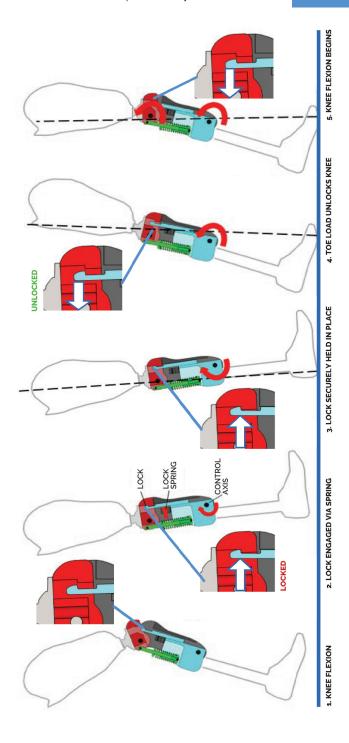
All-Terrain Knee Premium HD		
Part #	ATK-PA-03	
Product Weight	1,044g (2.30 lb)	
Maximum Body Weight	200kg (440 lb)	
Material	Advanced Fiber-Reinforced Composite, Stainless Steel, Titanium	
Waterproof Rating	Corrosion Resistant	
Activity Level	K1-K4	
Amputation Level	Transfemoral, Knee Disarticulation	
Total Fitted Height (1)	186mm (7 ⁵ / ₁₆ in)	
Effective Fitted Height (2)	125mm (4 ¹⁵ / ₁₆ in)	
Fitted Height (3)	24mm (¹⁵ / ₁₆ in)	
Tube Clamp Depth (4)	45mm (1 ³ / ₄ in)	
Attachment point to first axis offset	9mm posterior offset	
Ground Clearance	11mm (⁷ / ₁₆ in)	
Proximal Connection	Pyramid Adaptor	
Distal Connection	30mm tube clamp	
Swing Phase Control	Variable Cadence Controller (Patent Pending)	
Stance Phase Control	AutoLock Technology (Patented)	
Axes	Four axes	
Flexion angle (less socket)	150 degrees	







All-Terrain Knee Premium HD with Stance Flexion		
Part #	ATK-SF-03	
Product Weight	1,234g (2.72 lb)	
Maximum Body Weight	200kg (440 lb)	
Material	Advanced Fiber-Reinforced Composite, Stainless Steel, Titanium	
Waterproof Rating	Corrosion Resistant	
Activity Level	K1-K4	
Amputation Level	Transfemoral	
Total Fitted Height (1)	201mm (7 ¹⁵ / ₁₆ in)	
Effective Fitted Height (2)	141mm (5 ⁹ / ₁₆ in)	
Fitted Height (3)	40mm (1 ⁹ / ₁₆ in)	
Tube Clamp Depth (4)	45mm (1 ³ / ₄ in)	
Attachment point to first axis offset	19mm posterior offset	
Ground Clearance	11mm (⁷ / ₁₆ in)	
Proximal Connection	Pyramid Adaptor	
Distal Connection	30mm tube clamp	
Swing Phase Control	Variable Cadence Controller (Patent Pending)	
Stance Phase Control	AutoLock Technology (Patented)	
Axes	Four axes	
Flexion angle (less socket)	150 degrees	



Stance Phase Function

OUR TECHNOLOGY

FEATURES AND BENEFITS: AUTOLOCK TECHNOLOGY

- Positive locking upon swing phase extension heightens user confidence
- Remains securely locked until mid to late stance phase for effortless stance to swing transition.
- 4-bar kinematics, 11mm ground clearance in swing phase for added safety

FEATURES AND BENEFITS: VARIABLE CADENCE CONTROLLER

- Non fluid-based system for comfortable and efficient gait at multiple walking speeds
- Facilitates progression from single to variable cadence ambulation
- Adjustability via friction setting and choice of extension spring

ADDITIONAL FEATURES AND BENEFITS

- Highly durable, suitable for mobility classes 1-4
- Simple cable-free manual lock knob for initial or situational use
- Choice of waterproof or corrosion resistant versions expands recreational usage options

SETUP AND OPERATION

CONNECTIONS

The proximal connection consists of an M10 bolt that is attached directly to the proximal adaptor ATK-SF-01, ATK-SF-02 and ATK-SF-03 models only).

ADJUSTABLE STANCE FLEXION ADAPTER

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

The ATK-SF-01 and ATK-SF-02 are shipped with the adapter pre-installed with the medium grade posterior bumper inserted. The ATK-SF-03 is shipped with the adapter pre-installed with the stiff posterior bumper inserted and the medium grade (blue) in the packaging to swap out, if desired.

ADJUSTABLE STANCE FLEXION ADAPTOR **ASSEMBLY**



- 1. Top Adaptor Assembly
- 2. Anterior Bumper
- 3. Posterior Bumper
- 4. Plate
- 5. M10 Washer
- 6. For ATK-SF-01: 6mm Hex Bit M10 Adaptor Screw
- 7. For ATK-SF-02: 16mm Hex Head M10 Adaptor



BUMPER OPTIONS (ATK-SF-01 and ATK-SF-02 only)

Placement	Bumper Color	Hardness
Anterior	Blue	Medium (pre-installed)
Posterior	Black	Soft
Posterior	Blue	Medium (pre-installed)
Posterior	Gray	Firm

BUMPER SELECTION GUIDELINES

If patient experiences excessive motion or a sensation of instability with the pre-installed 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 **5** 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 **C** to 30Nm / 22 ft lb (35Nm/ 26 ft lbs for ATK-PA-03, ATK-TT-03, and ATK-SF-03).
- 6. Check prosthetic alignment



For the distal connection, ensure the 30mm pylon is fully inserted. Tighten pylon clamp screw to 12Nm (9 ft lb) using a 5mm hex bit (For ATK-PA-02, ATK-PA-03, ATK-TT-02, ATK-TT-03, ATK-SF-02, and ATK-SF-03: use 6mm hex bit) using a torque wrench. If a creaking sound occurs at heel strike, apply a small amount of multi-purpose oil to the surface area of the pylon that rests within the knee's tube clamp.

SAGITTAL PLANE ALIGNMENT

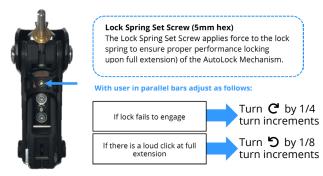
Position the knee's first axis 20mm posterior to the plumb line bisecting proximal aspect of socket (baseline recommendation).

To promote ease of unlocking, increase toe load.

· Shift knee posterior



AUTOLOCK TECHNOLOGY™ MECHANISM



Posterior View



WARNING: Loosening the lock spring setting may cause inconsistent locking function of the AutoLock Technology. The Lock Spring Set Screw ships with a factory preset setting. Do not loosen the Lock Spring setting. Only tighten the Lock Spring Set Screw as needed if there is inconsistent locking function. Tighten in 1/4 turn increments.

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:



INCORRECT:

Absence of Flexion Stop. No contact point exists between socket and lower body of knee in maximum flexion. Damage to knee may occur.



INCORRECT:

Malpositioned Flexion Stop. Socket is in direct contact with extension assist spring assembly in maximum flexion. Damage to knee may occur.



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

FRICTION MECHANISM

Minimum Friction Setting (MFS): failure to maintain MFS causes mechanism to loosen or disengage 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.

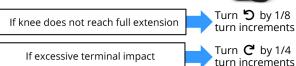


Gap present with disc springs in slight compression

If user requires a more free-swinging knee, the friction mechanism assembly 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:







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

FRICTION MECHANISM REMOVAL

If user requires a more free swinging knee, remove the friction mechanism by loosening the 4mm hex bolt until threading releases. Carefully remove and re-assemble to avoid misplacing parts.



1. Turn the 4mm hex head bolt counter clockwise while maintaining a firm grip on the friction mechanism threaded cap on the opposite side. Turn until the threading releases.



2. Pull the friction mechanism cap, the two disc springs and the threaded bolt out of the knee while maintaining pressure on the friction mechanism threaded cap on the opposite side.



Carefully gather threaded cap and two disc springs.

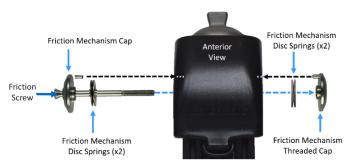
Re-assemble friction mechanism to avoid losing parts.



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FRICTION MECHANISM **INSTALLATION**

All-Terrain Knee Collection | Instructions for Use



- 1. Position friction mechanism threaded caps so that the post engages with the opening on the mating surface of the knee.
- 2. Ensure disc springs openings are centered over theopening of the interior cylinder of the knee.
- 3. Insert friction screw with friction mechanism cap and washers and tighten until threading engages with the opposite side.
- 4. Turn knee so friction mechanism threaded cap is facing up, apply Loctite 242 or similar. Allow to penetrate threading of screw.
- 5. Tighten friction unit bolt head until there is norattling or audible noise when tapping the opposite side friction mechanism cap with a finger. There should be a gap present with the disc springs in slight compression.

This is the **minimum friction setting**.



ADJUSTABLE EXTENSION ASSIST

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



SPRING ASSEMBLY

Insert spring base into chosen spring.







Beware of finger traps when compressing the spring.

REMOVAL (LEFT)

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

INSTALLATION (RIGHT)

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

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COVER

The cover protects the knee and the user's clothes. The All-Terrain Knee can be operated without the cover. Should the cover be damaged, a replacement can be ordered.



To remove cover, grasp and separate sides of cover from knee before pulling away from the anterior location of the joint. Cover should be removed when attaching the knee to a socket and/or adjusting the set screws for alignment.

COVER O-RING

Ensure o-ring is present to minimize noise. 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.



Grasp and push down on cover to unlock and flex the knee.





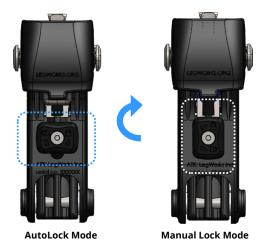


All-Terrain Knee Cover Release

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. If necessary, 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

Turn knob 1/4 turn clockwise to vertical position will activate manual lock mode upon full extension of knee (if engaged from seated position). Do not attempt to activate manual lock with knee in slight flexion.



DO NOT adjust the manual lock screw unless disengagement occurs with 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. While the knee is fully extended and locked, tighten using hex key in 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 1/8 turn.

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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 ensure the user is competent in handling of their 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.

MAINTENANCE

Ensure that the amputee is provided with the included Short User Guide and that care and maintenance guidelines are explained. The All-Terrain 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 by placing device under warm running water or by submerging

in clean warm freshwater. Dry after.

The All-Terrain Knee (ATK-PA-01), All-Terrain Knee with Threaded Top (ATK-TT-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 clean warm freshwater.

The All-Terrain Knee Premium (ATK-PA-02), All-Terrain Knee Premium HD (ATK-PA-03), All-Terrain Knee Premium with Threaded Top (ATK-TT-02), All-Terrain Knee Premium HD with Threaded Top (ATK-TT-03), All-Terrain Knee Premium with Stance Flexion (ATK-SF-02), and All-Terrain Knee Premium with Stance Flexion (ATK-SF-03) can be used in freshwater and saltwater, including swimming pools. If the knee is exposed to non-freshwater, rinse thoroughly in clean warm freshwater 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.

The joint must be inspected, and repaired if necessary, at least every 6 months. 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 acclimated to the prosthesis. Clean with soft cloth and warm freshwater. Do not 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 Regulation (EU) 2017/745 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.

Failure to follow all maintenance guidelines (pg. 28) will void the warranty.

For warranty claims or service requests, email warranty@legworks.com, or call +1 (408) 692-5633.

EXCLUSIONS

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 their obligation to check, to the best of their 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: 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), the All-Terrain Knee with Threaded Top (ATK-TT-01), and the All-Terrain Knee with Stance Flexion (ATK-SF-01) have been tested and passed to the 125kg P6 ISO 10328:2016 standard: the All-Terrain Knee Premium (ATK-PA-02), the All-Terrain Knee Premium with Threaded Top (ATK-TT-02), and the All-Terrain Knee Premium with Stance Flexion (ATK-SF-02) have been tested and passed to the 150kg P8 ISO 10328:2016 standard; and the All-Terrain Knee Premium HD (ATK-PA-03), the All-Terrain Knee Premium HD with Threaded Top (ATK-TT-03), and the All-Terrain Knee Premium HD with Stance Flexion (ATK-SF-03) have been tested and passed to the 200kg P10 ISO 10328:2016 standard. All device models by LegWorks meet the conformity standards of the CE Mark, as outlined in Medical Device Regulation (EU) 2017/745. 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 VIII.

This device is a single-use device and as such should not be refit on other individuals. All devices are ISO 10328:2016 tested for structural and fatigue strength and should be used for the period of 5-years service lifetime by one user.

ORDERING AND CONTACT INFORMATION

For sales inquiries, or to request information, email sales@legworks.com, or call +1 (408) 692-5633.

For warranty claims or service requests, email warranty@legworks.com, or call +1 (408) 692-5633.

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