

 egWorks

ATK HydraPro™



INSTRUCTIONS FOR USE

CE

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QNET BV
Kantstraat 19
NL-5076NP Haaren
The Netherlands

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PRODUCT DIAGRAMS



Fig. 1 ATK HydraPro Anterior Overview

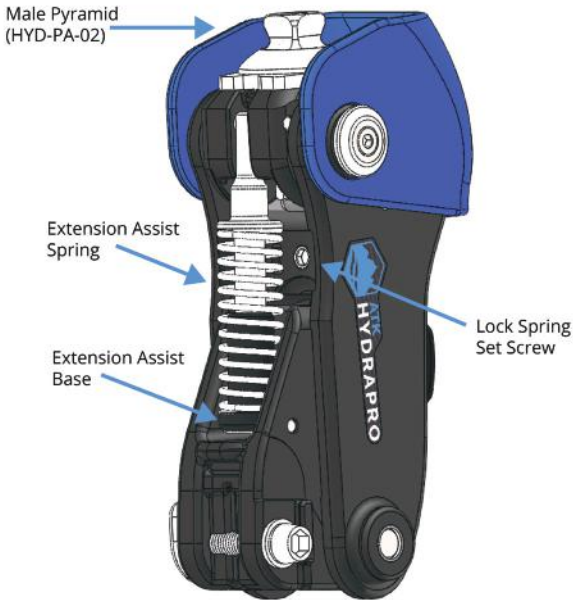


Fig. 2 ATK HydraPro Posterior Overview

DESCRIPTION & PURPOSE

Last updated: 2019-08-01

- 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 ATK HydraPro:

Product Name	Product Code
ATK HydraPro	HYD-PA-02
ATK HydraPro with Stance Flexion	HYD-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.
- Both device models are intended for single person use.
- Both device models are to be used exclusively as part of an external lower-limb prosthesis.
- Both device models are developed for everyday use and must not be used for unusual activities, such as extreme sports.
- HYD-PA-02 is designed exclusively for Knee Disarticulation or Transfemoral amputees.
- HYD-SF-02 is 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.

DESCRIPTION & PURPOSE

SCOPE OF DELIVERY

- ATK HydraPro Device
- ATK HydraPro Device Cover
- *Instructions for Use* (IFU) manual
- Quick Reference Card (QRC)
- ATK HydraPro User Guide
- Extension Assist Springs:
 - medium stiffness (pre-installed)
 - strong stiffness
 - weak stiffness
- HYD-SF-02 only: Posterior Stance Flexion Bumpers: Firm, Medium (pre-installed), and Soft stiffness

FUNCTION

- Stance Phase Control: AutoLock Technology
- Swing Phase Control: Adjustable variable friction resistance (Variable Cadence Controller) and spring extension assist
- Design:
 - HYD-PA-02 and HYD-SF-02: Waterproof and corrosion resistant in both freshwater and saltwater (e.g. shower, pool, ocean)
- Activity Level: Suitable for K3 and K4 activity levels

INDICATIONS

- Transfemoral (both device models), Knee Disarticulation (HYD-PA-02 model only)
- K3-K4 mobility level (primary prosthesis)
- Secondary prosthesis (bathing or water leg)

WEIGHT LIMIT

- HYD-PA-02 and HYD-SF-02 have been tested and passed to the 150kg (330 lb) P8 ISO 10328:2006 standard

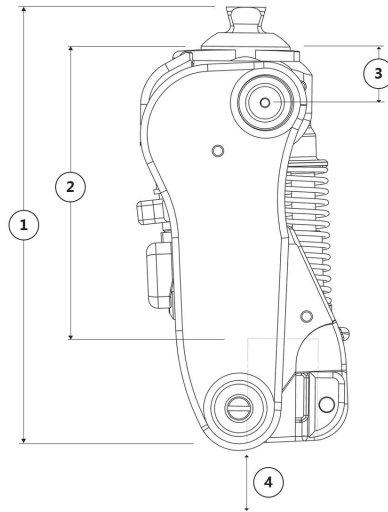


Fig. 3 ATK HydraPro HYD-PA-02 Build Height Diagram

Product	ATK HydraPro
Part #	HYD-PA-02
Amputation Level	Transfemoral, Knee Disarticulation
Activity Level	K3-K4
Material	Advanced Fiber-Reinforced Composite, Stainless Steel, Titanium
Maximum Body Weight	150kg (330 lb)
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
Product Weight	1,052g (2.32 lb)
Ground Clearance	11mm (⁷ / ₁₆ in)
Proximal Connection	Pyramid Adaptor
Swing Phase Control	Hydraulic Variable Cadence Controller
Stance Phase Control	AutoLock Technology (Patented)
Axes	Four Axes
Flexion Angle (minus socket)	150 degrees
Distal Connection	30mm Tube Clamp

Fig. 4 ATK HydraPro Premium HYD-PA-02 Technical Specifications

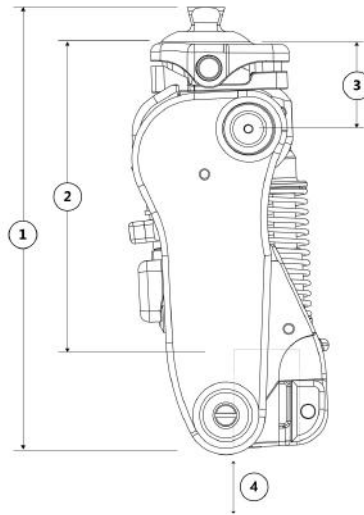


Fig. 5 ATK HydraPro HYD-SF-02 Build Height Diagram

Product	ATK HydraPro with Stance Flexion
Part #	HYD-SF-02
Amputation Level	Transfemoral
Activity Level	K3-K4
Material	Advanced Fiber-Reinforced Composite, Stainless Steel, Titanium
Maximum Body Weight	150kg (330 lb)
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
Product Weight	1,242g (2.74 lb)
Ground Clearance	11mm (⁷ / ₁₆ in)
Proximal Connection	Pyramid Adaptor
Swing Phase Control	Hydraulic Variable Cadence Controller
Stance Phase Control	AutoLock Technology (Patented)
Axes	Four Axes
Flexion Angle (minus socket)	150 Degrees
Distal Connection	30mm Tube Clamp

Fig. 6 ATK HydraPro HYD-SF-02 Technical Specifications

OUR TECHNOLOGY

The ATK HydraPro utilizes a proprietary stance-phase control mechanism (AutoLock Technology) and swing-phase control mechanism (Hydraulic Variable Cadence Controller or Hydraulic 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 Hydraulic VCC utilizes a combination of hydraulic damping, a variable friction system, and an optimized extension assist spring for efficient gait at multiple walking speeds. The 4-bar kinematic arrangement of the ATK HydraPro mechanism results in swing-phase foot clearance comparable to 4 and 6 bar polycentric knee mechanisms.

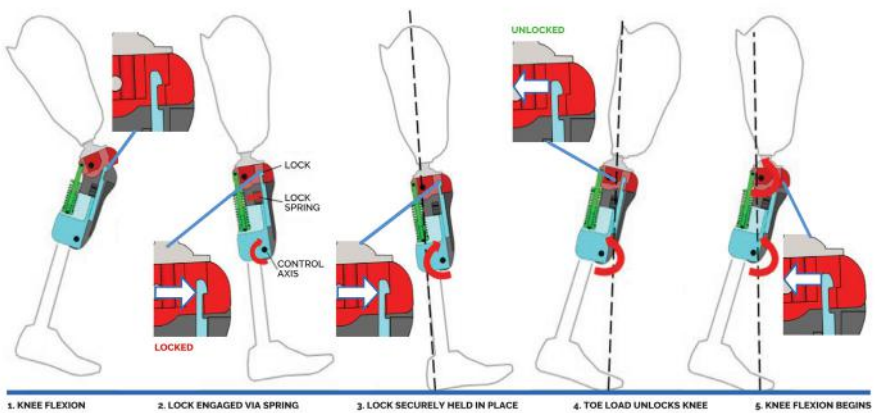



Fig. 7 Stance Phase Function

The ATK HydraPro is suitable for users in mobility classes 3-4. Adjustments can be made to the Hydraulic VCC to control heel rise and terminal impact levels, resulting in smooth and responsive swing dynamics at different walking speeds. The AutoLock Mechanism ensures optimal stability when negotiating uneven terrain. Simple conversion to manual lock mode is also possible for situational use.

SAFETY

 Both device models of the ATK HydraPro should only be fit by a qualified professional.

In the final stage of quality control, all ATK HydraPro 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 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.

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. 9).

HYD-SF-02 ONLY - ADJUSTABLE STANCE FLEXION ADAPTER

The ATK HydraPro with Stance Flexion features 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.

The HYD-SF-02 is shipped with the adapter pre-installed with the medium grade posterior bumper inserted.

BUMPER OPTIONS

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

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





Fig. 8 Adjustable Stance Flexion Adaptor Assembly

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  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 120Nm (9 ft lb) by turning the bolt with a 6mm hex bit 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.

Using a torque wrench, tighten the M10 bolt to 30 Nm (22ft lb)

Fig. 9 Proximal Connection

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. 10 Sagittal Plane Alignment

AUTOLOCK TECHNOLOGY™ 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 ↻ by 1/4 turn increments

If there is a loud click at full extension



Turn ↺ by 1/4 turn increments

Fig. 11 Lock Spring Set Screw

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 ATK HydraPro in the proper location. See examples below:



Fig. 12 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. 13 Malpositioned Flexion Stop

Incorrect:

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



Fig. 14 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.

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

FRICITION 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 can be removed (Fig. 21) and stored for later use; this does not affect the integrity of the knee's assembly.



Gap present with disc springs in slight compression

With user in parallel bars, adjust as follows:

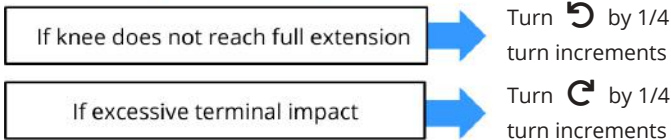


Fig. 15 Friction Mechanism

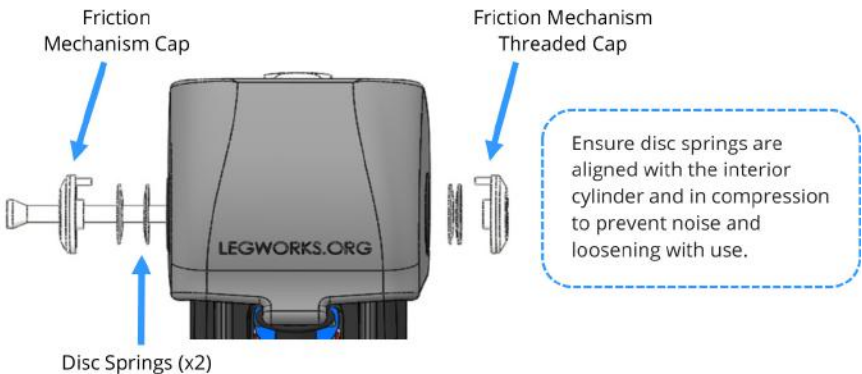


Fig. 16 Friction Mechanism Cap and Disc Springs



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

FRICITION 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.



3. Carefully gather threaded cap and two disc springs.

Fig. 17 Friction Mechanism Removal

Re-assemble friction mechanism to avoid losing parts.



FRICITION MECHANISM INSTALLATION

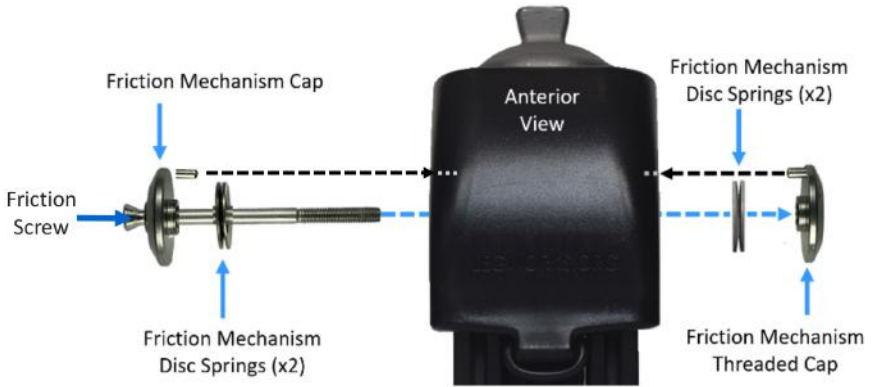
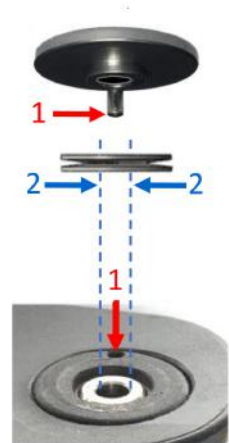


Fig. 18 Friction Mechanism Installation

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 the opening 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 no rattling 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 (Fig. 19).

EXTENSION ASSIST BIAS OPTIONS



**WEAK
BLUE**

MED.
WHITE

**STRONG
RED**

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.

Fig. 19 Adjustable Extension Assist

COVER

The cover protects the ATK HydraPro, as well the user's clothes. The ATK HydraPro can be operated without the cover. Should the cover be broken, it can be easily ordered and replaced.



To remove cover, grasp and separate sides of cover from knee before pulling away from the anterior location of the joint (Fig. 20).

Cover should be removed when attaching the knee to a socket and/or adjusting the set screws for alignment.

Fig. 20 ATK HydraPro Cover Removal

COVER O-RING

The cover has an o-ring to minimize noise. Ensure the o-ring is present. The bridge of the cover should be connected into the opening of the main body of the knee.

AUTOLOCK RELEASE

Activation of the "AutoLock Release" unlocks the knee which initiates flexion after sitting with the knee in AutoLock mode (locked and extended). Simply push the 'AutoLock Release' to either side to unlock and flex the knee.

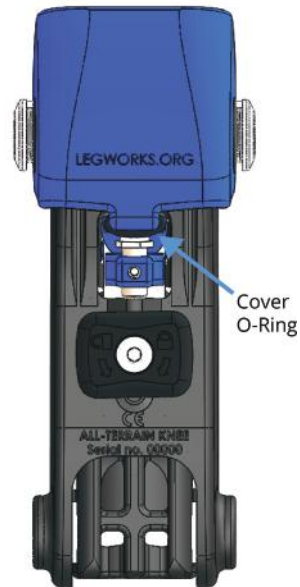


Fig. 21 ATK HydraPro AutoLock Release

! 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 in slightly flexed is difficult and should be avoided.

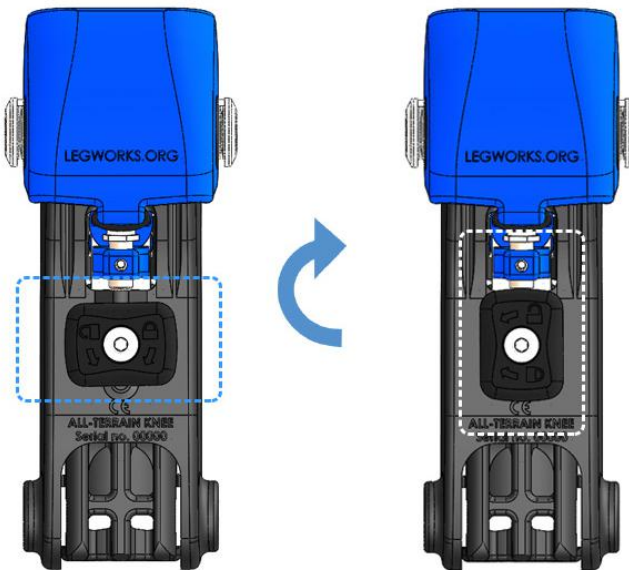


Fig. 22 Manual Lock

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. 16). 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.

MAINTENANCE

USER

The ATK HydraPro 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 freshwater or place knee under warm running water. Dry after.

The ATK HydraPro (HYD-PA-02) and the ATK HydraPro with Stance Flexion (HYD-SF-02) 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.

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. 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

Both device models of the ATK HydraPro 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 ATK HydraPro 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 ATK HydraPro Premium (ATK-PA-02) and the ATK HydraPro Premium with Stance Flexion (ATK- SF-02) may be used in freshwater and saltwater. Regular care and maintenance of both device models is needed to avoid corrosion (as described on Pg. 21). 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.

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 credits 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 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: 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. Both device models of the ATK HydraPro must be maintained as according to the instructions.

DISPOSAL

Dispose of per local, state, and federal regulations.

CE CONFORMITY

The ATK HydraPro (HYD-PA-02) and the ATK HydraPro with Stance Flexion (HYD-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, and 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 INFORMATION

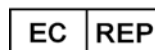
For sales inquiries, or to request information regarding the ATK HydraPro, please email sales@legworks.com, or call +1 (408) 692-5633.

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

LegWorks

77 Goodell Street
Fourth Floor
Buffalo, NY 14203
United States of America
+1 (408) 692-5633
legworks.com

Made in Germany
Manufactured for LegWorks



QNET BV
Kantstraat 19
NL-5076NP Haaren
The Netherlands