

Instructions for Use: VGK-X & VGK-XS



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Introduction

Intended purpose

The VGK-X/VGK-XS is tended to be solely used in lower extremity prosthetic limbs as a prosthetic knee joint to assist ambulation and activities of daily living. The product can be used for uni- or bilateral amputation. *The VGK-X/VGK-XS is currently not intended for use with osseointegration.*

Recommended user profile

The VGK-X/VGK-XS is recommended for independent prosthetic users typically of mobility classes 1-4**. The VGK-X/VGK-XS is suited for users with transfemoral amputation, knee disarticulation, or hip disarticulation. The user's body weight can be up to 80 kg for VGK-X, and up to 60 kg for VGK-XS.

** Users with significant comorbidity must be carefully monitored in the rehabilitation period to ascertain the suitability of the device for their needs.

Installation and adjustments

The VGK-X/VGK-XS must be installed by a Certified Prosthetic/Orthotist (CP or CPO) to make sure the alignment and control settings are adjusted safely. The user may adjust the controls under the guidance of their CPO. The CPO must assess whether the user is able to adjust the knee joint safely.

Compatibility

The VGK-X/VGK-XS is always supplied with an adaptor to be used at the proximal connection of the knee joint. The proximal adaptor for VGK-X/VGK-XS must be supplied by Orthomobility. Once the proximal adaptor has been installed on VGK-X/VGK-XS, the knee is compatible with the full complement of prosthetic components, energy-storing feet, hydraulic ankles, hip components, shock absorbers.

Lifetime of the device

In compliance with the EU Medical Device Regulations, Orthomobility has defined a maximum usage period of **5 Years + 3 months for VGK-X/VGK-XS**. The rate at which the device is used will vary between patients, but this limit puts a practical, manageable, and measurable limit on its use. The additional "3 months" have been added to allow time for replacement limb fitting.

VGK-X/VGK-XS must not be used after the maximum usage period. The **usage period starts on the date of shipment by the distributor** and this date appears on the product label. Please contact the distributor if the start date is not available.

Identification of the device

A VGK-X/VGK-XS unit may be identified with the serial number that is engraved on the product.

Normal use (note stairs)

The VGK-X/VGK-XS has been developed for ambulation and ordinary mobility use: walking, sitting, kneeling, and occasional wetting by rain or tap water. The use of handrails or banisters is recommended when descending downstairs. Normal use also includes cycling if the product has been ordered with a cycling function. NOTE: to set up the knee for cycling requires a special procedure to be followed .

Expectation management

Please advise the user that this device is designed to offer a service compatible with a high level of safety. The high level of safety is likely to elevate their expectations of their ability, and consequently your patient may find limits in the performance of the device. When such an event happens, they are asked to record the circumstances and report the event back to their CPO.

Irregular and extreme use

Irregular and extreme use may occasionally be required and this should be agreed with the manufacturer beforehand. Such use may involve water and dirt, mechanical shock and forceful use. Whereas these may be considered as part of intended use, it will be required that written permission is sought from the manufacturer so that such irregular use can be risk assessed, supported, or denied on grounds of risk. A considered permission/denial/support programme will be discussed on request. Use of the product in a Sauna is excluded. Avoid sand entering the knee.

Extreme temperature

The VGK-X/VGK-XS has been designed for a stable performance over a range of temperatures. The use in very low temperatures (sub-zero) may cause some stiffening in the yield action of the joint, which in hands-free slope and stairs descent could cause an imbalance. In this instance, it is advised to first try using it close to a handrail. In elevated temperatures (40 degrees plus), the VGK-X/VGK-XS maintains its performance fairly well.

Extreme device settings

The VGK-X/VGK-XS permits a high level of resistance in yield. The device has been designed to contain hydraulic pressures that arise during normal use, including leg-over-leg stair descent. However, when significant weight is placed on the leg, the device *is not intended* to be loaded in flexion in a 'locked' mode.

Body weight and additional load

The VGK-X has been designed to allow for a patient body weight of 80 kg and these persons, at this maximum body weight, to carry not more than 15 kg of additional load on a daily basis. VGK-XS is limited to 60 kg body weight and these users must not carry more than 10 kg on a daily basis.

Prevention of overheating

Do not use in the sauna because the heat may damage the metal surfaces. When used intensively, allow heat to escape via the frame by avoiding use of cosmetic foam covers.

Wear and tear

As any mechanical device, mechanical wear and tear will eventually occur, and the user and CPO are required to see that regular inspections and maintenance are carried out. Fair wear and tear includes the formation of corrosion due to lack of cleaning. Fair wear and tear falls outside the standard scope of warranty.

Storage

The VGK-X/VGK-XS must be stored in an extended position.

Alignment

General alignment

The alignment of the knee joint must follow the straight hip-knee-ankle line. The 'Ankle' refers to where the natural ankle would be, that is between $\frac{1}{4}$ and $\frac{1}{3}$ of the foot length. Ideally the knee axis should be 10 mm behind the hip-ankle line.

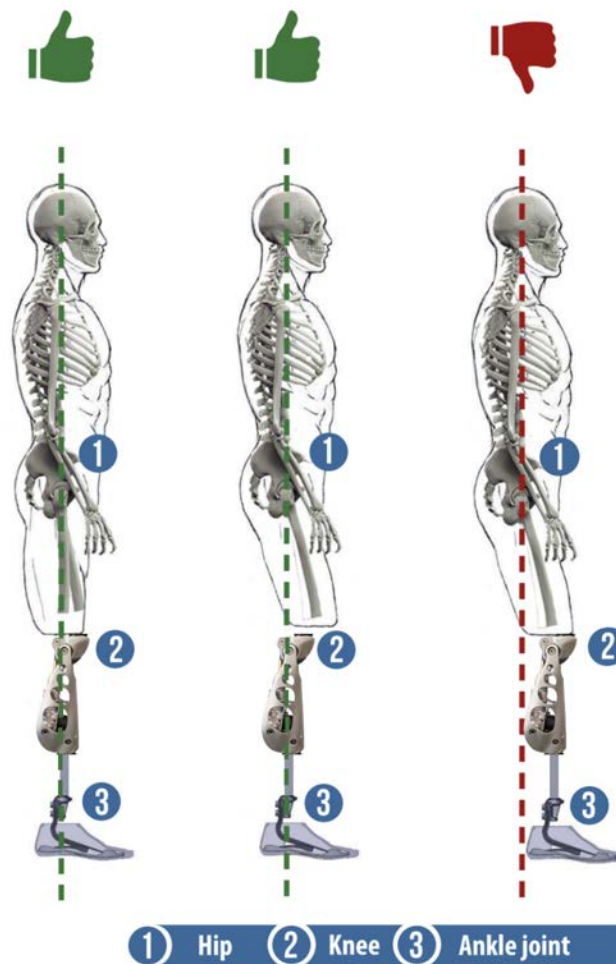


Fig 1: A vertical hip-knee-ankle line is the preferred alignment. A posteriorly placed hip/greater trochanter is liable to make swing release more difficult.

Socket flexion

A vertical hip-knee-ankle line must be maintained as well as possible, even if initial hip flexion is required in the socket. This may be achieved by moving the socket and foot forward relative to the knee joint, and letting the user exercise a small amount of hip extension to maintain extension of the knee (see **Fig 1**).

If the knee is incorrectly aligned such that there is effective initial knee flexion, there are two potential problems. The first problem is that heel strike with a flexed knee may cause the knee to suddenly shoot into extension during mid-stance, a 'double-action'. This can be uncomfortable for the user. The second problem is that initial knee flexion puts the knee axis *in front of the* hip-ankle line, and this reduces the user's ability to produce an adequate knee extension force that is necessary for swing release.

Foot alignment

The VGK-X/VGK-XS requires a toe load in late stance to release into swing. Too much dorsiflexion of the foot may make it difficult to release the knee into swing if there is insufficient forefoot loading. Equally, an unusually high heel on the shoe will reduce the effective length of the foot and therefore may cause difficulty for swing release.



Fig 2: There are two rubber parts that support safe and comfortable kneeling, the Turtle and the Kneecap.



Fig 3: Ensuring safe contact with the socket, tube, or adaptors.

Kneeling

Maximum knee flexion may cause the socket (or tube) to touch the frame of the knee, or the hydraulic unit inside. The socket is allowed to rest on the frame. The hydraulic has been designed to take the forces of kneeling or squatting provided that the contact is made in the correct region. The following rules **MUST BE** followed to ensure safe kneeling on the hydraulic:

1. It is permissible to kneel on the hydraulic provided the socket/tube comes into contact with the green regions, as indicated in **Fig 3**.
2. If the socket/tube rests on the red regions in **Fig 3**, the Turtle (see **Fig 2**) **MUST** be attached onto the hydraulic at all times. The Turtle ensures that the socket/tube rests on the green region.

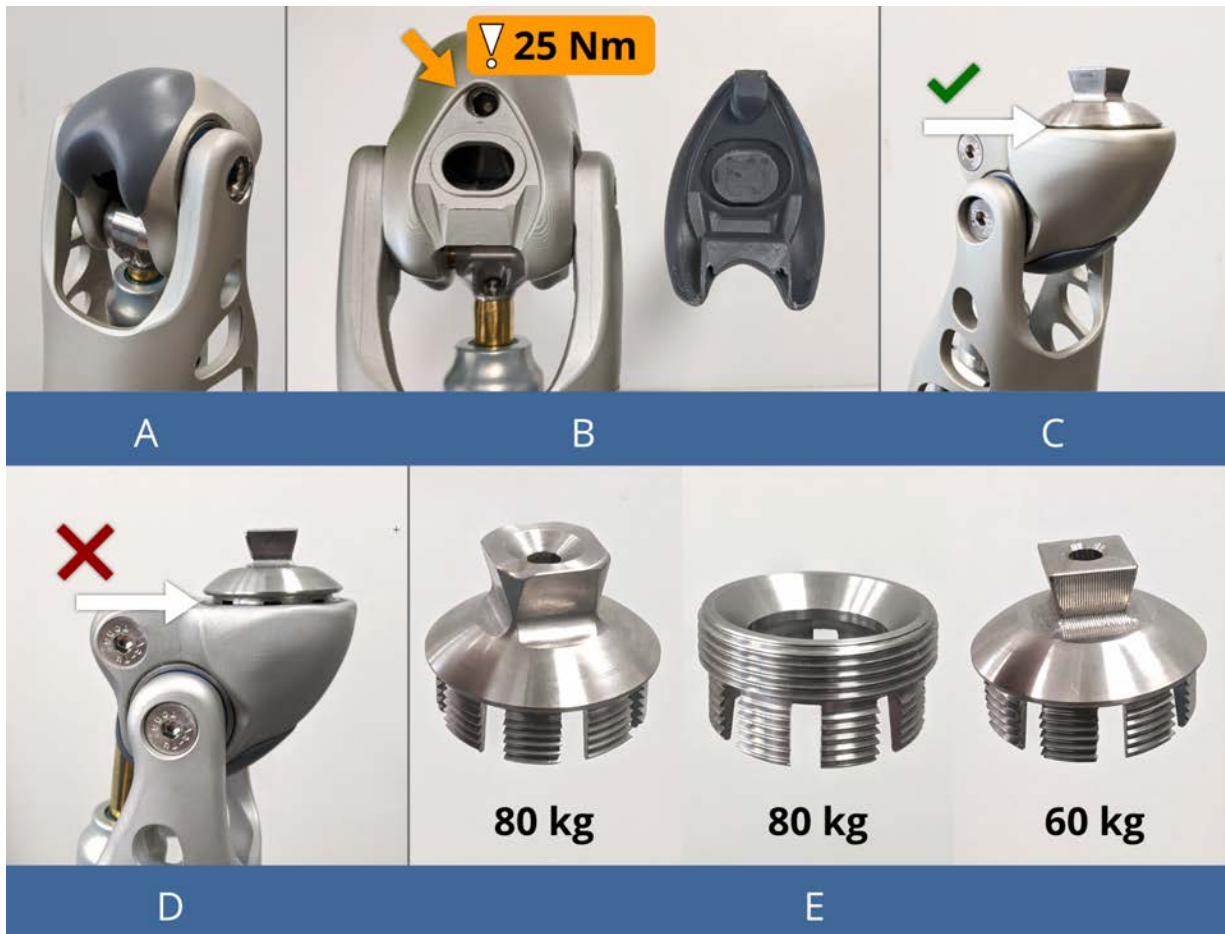


Fig 4: (A) The Kneecap is removed by putting the knee in full flexion, so that it can be unhooked from the back (B) Removing the Kneecap exposes the screw, operated by a 5 mm Hex. (C) The proximal adaptor is screwed on the top of the VGK-X/VGK-XS, such that the gap is less than 1 mm. (D) The proximal adaptor must not display a gap of more than 1 mm. (E) The proximal adaptors for the 80 kg and the 60 kg systems.

Installing the proximal adaptor

The VGK-X/VGK-XS must have a proximal adaptor installed on top to act as an interface for other prosthetic components (see [Fig 4\(C\)](#)). The proximal adaptor must be provided by Orthomobility and be compatible with VGK-X/VGK-XS. There are two proximal adaptors for the 80 kg VGK-X system, and a proximal adaptor for the 60 kg VGK-XS system (see [Fig 4\(E\)](#)).

The connection between VGK-X/VGK-XS and the adaptor is two threads that have been clamped together by means of expanding the thread on the adaptor. This is an adhesive-free solution so that rotational alignment of the adaptor is possible. Therefore, please refrain from putting Loctite or other adhesive substances on the threads.

The proximal adaptor is ONLY intended for adjusting the rotational alignment of the knee joint. Ensure that the gap between the top of the VGK-X/VGK-XS and the proximal adaptor does not exceed 1 mm (see **Fig 4(D)**).

Install the proximal adaptor as follows:

1. Remove the Kneecap (see **Fig 2**) from VGK-X/VGK-XS by unhooking it at the back.
2. With the Kneecap removed, a 5 mm HEX screw should be visible on the underside of the Kneecap (see **Fig 4(B)**). Unwind this screw.
3. Screw the proximal adaptor fully into the top of VGK-X/VGK-XS. For the first fitting of VGK-X/VGK-XS, align the adaptor straight. Tighten the screw lightly for first careful assessment ONLY.
4. When the alignment appears suitable, ENSURE that the gap between the proximal adaptor and the VGK-X/XS is less than 1 mm. Then, DO torque the screw to **25 Nm** USING A TORQUE WRENCH.
5. Replace the Kneecap.

Rotational alignment of proximal adaptor

The proximal adaptor has been designed to allow rotational (re-)alignment. Use the markings on the adaptor to take a record of the rotational alignment, if required. To change the rotational alignment, the threads of the adaptor and VGK-X/VGK-XS must be loosened. Follow these steps:

1. Remove the Kneecap (see **Fig 2**) from VGK-X/VGK-XS by unhooking it at the back.
2. With the Kneecap removed, a 5 mm HEX screw should be visible on the underside of the Kneecap (see **Fig 4(B)**). Unwind this torqued-up screw to free the adaptor.
3. Rotate the adaptor as required, ensuring that the gap between the proximal adaptor and the VGK-X/XS stays less than 1 mm.
4. Tighten the screw with a 5 mm HEX and torque it to 25 Nm.
5. Replace the Kneecap.

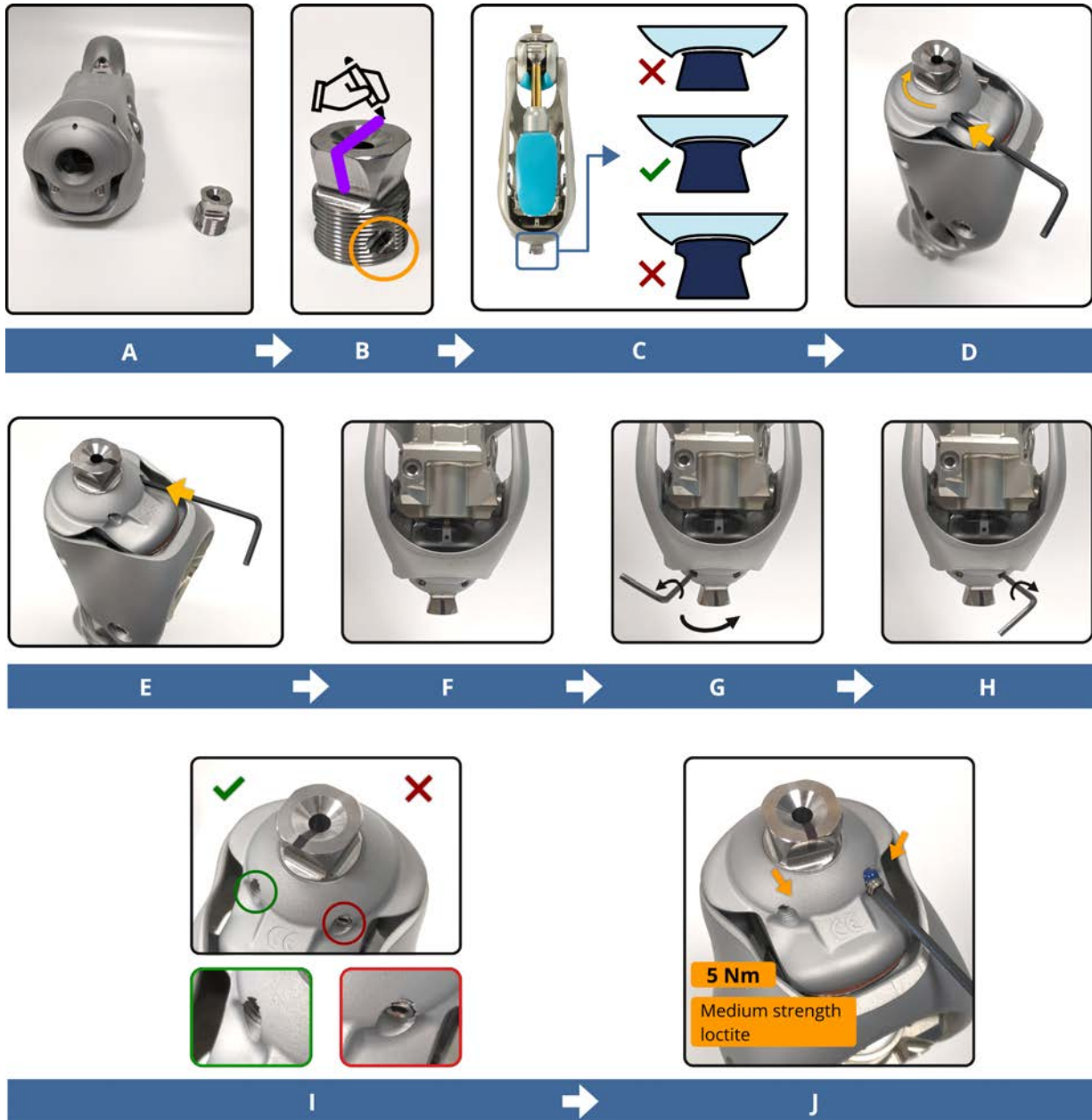


Fig 5: (A)-(J) Instructions for installing and adjusting the distal adaptor. See Sections “Installing the distal pyramid” and “Rotational alignment of distal pyramid” for further explanation.

Installing the distal pyramid

The VGK-X/VGK-XS must have a distal adaptor installed on the bottom to act as an interface for other prosthetic components. The distal adaptor must be provided by Orthomobility and be compatible with VGK-X/VGK-XS.

The instructions make reference to the steps shown in **Fig 5**.

Initial installation

Step 1	Fig 5 (A)	The VGK-X/XS is provided with a distal pyramid. There is a distal adaptor for the 80 kg VGK-X system, distinguishable by a flat pyramid top. There is also a distal adaptor for the 60 kg VGK-XS system, distinguishable by a rounded pyramid top.
Step 2	Fig 5 (B)	The distal pyramid has 4 slots on the screw thread. To help align the pyramid correctly, draw a marking on the pyramid such that the marking is on the same side as the <i>flat faces</i> of the slot.
Step 3	Fig 5 (C)	<p>Wind the distal pyramid onto the bottom of the VGK-X/XS until the pyramid is about flush with the bottom of the VGK-X/XS. Allow a step of less than 0.5 mm between the pyramid and the bottom of the VGK-X/XS.</p> <p>Now rotate the pyramid so that it is square with the VGK-X/XS and that the marking (made in step 2) faces either towards the front or the back of the VGK-X/XS. This will ensure that the two screws at the bottom of the VGK-X/XS can press on these flat faces to set the rotational alignment.</p> <p>It is very important to install the distal pyramid in the correct orientation to avoid damaging the product.</p>
Step 4	Fig 5 (D)	Wind in one screw as shown in the image. Note that at some point, winding in the screw rotates the distal pyramid. Adjust the screw until the distal pyramid is square with the frame.
Step 5	Fig 5 (E)	<p>Secure the initial rotational alignment by winding in the other screw, as shown in the image. Notice that with both screws dialed in, the pyramid can no longer rotate.</p> <p>If the alignment of the distal pyramid is already satisfactory at this stage, follow the instructions in Section “<i>Securing the rotational alignment</i>” to finish.</p>

Rotational alignment of distal pyramid

The distal pyramid has been designed to allow rotational (re-)alignment, when rotation of other components is not possible. There are two screws at the back of the distal pyramid that work together to set the rotation. Follow these steps to change the rotation:

Step 1		Loosen two adjacent pyramid set screws of the external component that is attached to the distal end of the VGK-X/XS (e.g. the foot or a tube).
Step 2	Fig 5 (F-H)	<p>For <i>external</i> rotation of the pyramid, dial out the <i>lateral screw first</i> and then dial in the medial screw.</p> <p>For <i>internal</i> rotation of the pyramid, dial out the <i>medial screw first</i> and then dial in the lateral screw.</p>
Step 3	Fig 5 (I)	<p><i>Before reattaching the external components</i>, check that the rotational alignment screws sit underneath the surface. With more extreme rotations of the distal pyramid, one of the rotational alignment screws may stick out as shown in the image.</p> <p>To avoid one of the rotational alignment screws sticking out, replace the screw with a shorter version, provided with the product.</p>

Securing the rotational alignment

See **Fig 5 (J)**. **One screw at a time**, unwind the screw and put a drop of medium strength thread sealant (such as Loctite 243) on the screw. Torque the screw to **5 Nm**.

Controls

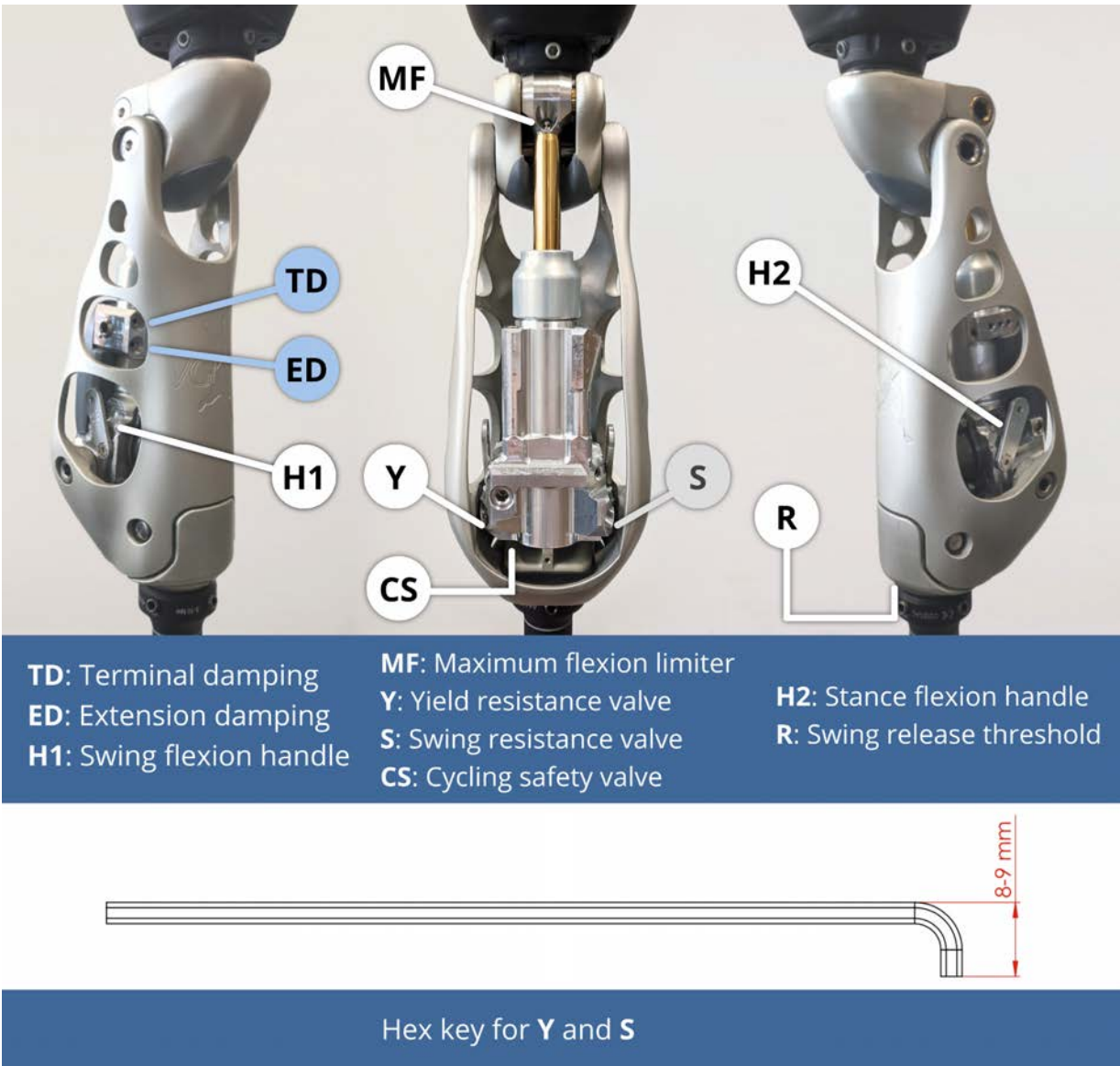


Fig 6: Locations of controls for clinical adjustments

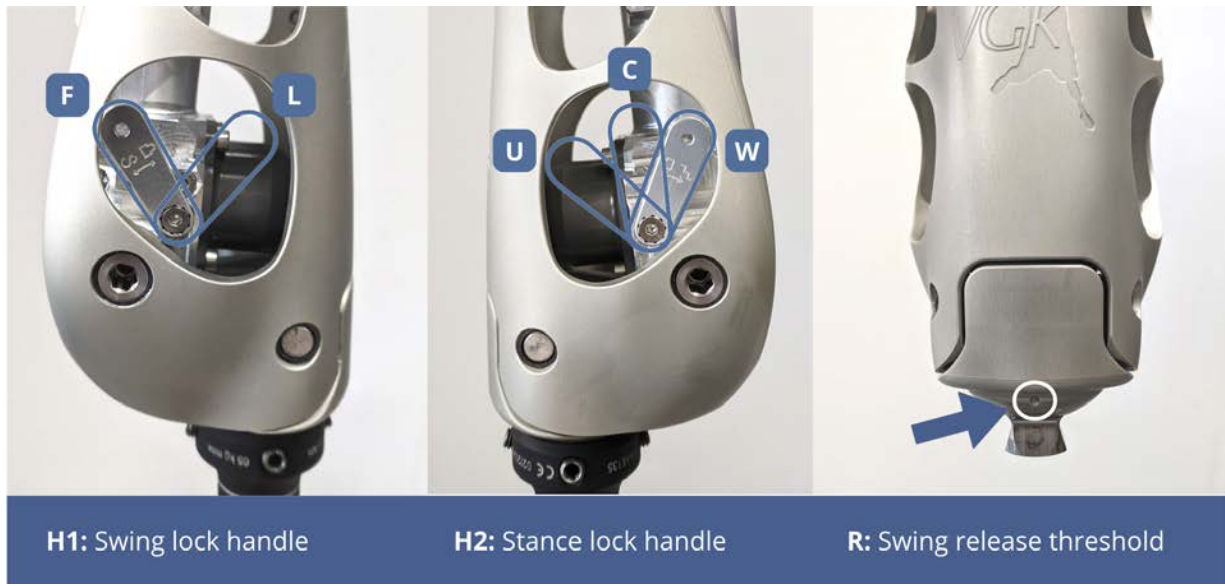


Fig 7: Positions for handle H1, positions for handle H2, and location of swing release adjustment, R

Swing release

Setting swing release threshold

The VGK-X/VGK-XS relies on the presence of knee extension and toe-load for swing-phase release. This condition is natural in terminal stance. For most users this switching behaviour is set to be as light as possible. For bilateral amputees, the transition may need to be more deliberate to secure standing balance. If the threshold for switching to swing-phase must be increased, the Swing Release Threshold, **R** in [Fig 6](#), is turned clockwise.

The VGK-X/VGK-XS senses toe load by a slight swivelling action of the distal knee section. There is a spring system in the distal knee, which for safety allows the distal knee to be biased to the stance-phase position. When weight is placed on the forefoot, the distal knee can overcome the spring tension and swivel into the swing-initiation position. Therefore the more the spring is preloaded (by clockwise turning **R** in [Fig 6](#)), the higher the toe-load must be to cross the threshold for swing initiation. There is only a limited range of adding pre-load!

Conditions for swing release

The knee joint will release into the swing phase when there is a hyperextension moment, immediately followed by a high knee flexion moment. Using the knee joint in a forceful way can, in exceptional circumstances, lead to an unintended release into the swing phase. An example of such non-recommended use is attempting to land hard on the mid-foot onto a curb or step. This user-induced failmode is unlikely to happen in ordinary walking. User confidence in the

VGK-X/VGK-XS should not be lost, provided the usual behaviour continues after such an incident or event of exceptional use.

Stance Flexion Handle

The use of yield resistance (stance resistance) is set using the stance flexion handle, **H2** in **Fig 6**. See **Fig 7** for possible positions of handle **H2**. With the handle in position **W**, the stance resistance is compatible with ordinary walking. With the handle in position **U**, there is ultra high stance resistance. If the VGK-X/VGK-XS has been ordered with a cycling function, the middle position **C** selects the cycle mode. The cycle mode (not currently available) is a free mode, with a safety catch for when the piston exceeds a threshold speed.

Swing Flexion Handle

See **Fig 7** for possible positions of handle **H1** of the swing flexion handle, **H1** in **Fig 6**. The handle provides a swing flexion lock with the handle in position **L**. With the handle in position **F** the swing-phase is free, which is compatible with ordinary walking.

Adjustments

Adjusting the stairs mode

See **Fig 6** and **Fig 7**. The stairs mode is selected by positioning the stance flexion handle (**H2**) in position **W**. The rate of knee flexion in stance can be adjusted with the Yield Resistance Valve, **Y**. Use a shortened 2 mm hex key to turn the valve clockwise for faster knee flexion, or anticlockwise for slower knee flexion. For convenience, a shortened 2 mm hex key is provided with the product. The dimensions in **Fig 6** show how far to grind back a standard hex key in case the key provided is lost.

To get the right setting for the user, allow them to descend from the last step of a stairs and adjust the valve until it is comfortable. Then adjust the valve further as required to accommodate more steps being taken in sequence.

DO take note that the resistance in stumble recovery = the resistance in stance mode. Therefore it is recommended to keep the stance mode resistance as high as is comfortable.

Ultra high resistance mode

See **Fig 6** and **Fig 7**. The ultra high resistance mode is selected by positioning the stance flexion handle (**H2**) in position **U**. This mode effectively blocks the yielding, but allows free swing (as long as the walking speed is not too high). For this reason, this mode is NOT A FULL LOCK. The user can still release the knee into the swing phase.

Adjusting the cycle mode

See **Fig 6** and **Fig 7**. The cycle mode is selected by positioning the stance flexion handle (**H2**) in position **C**. In this mode, there is a safety catch that kicks in when the knee flexion speed crosses a threshold.

The factory setting of the cycling function is ultra-safe! In this factory setting, the cycling function may not work for the user. Use the Cycling Safety Valve (**CS** in **Fig 6**) to lower the safety threshold, therefore permitting higher cycling speeds.

Bench testing cycle mode

Bench test the prosthesis to become familiar with the cycling settings. Turn the stance flexion handle to cycling mode and observe that in the factory setting, the knee does not bend easily. This is because the safety valve activates almost immediately. To turn the safety valve off, dial in the Cycling Safety Valve (**CS** in **Fig 6**) fully. Now the safety valve is effectively off and the knee should bend very easily irrespective of the flexion speed. By incrementally winding the Cycling Safety Valve screw anticlockwise again, a setting can be found where slow flexion movement is easy but fast movement incurs resistance. This is the basis for the VGK-X/VGK-XS to differentiate between the slow cycling movement that is to be permitted, and fast movement that may occur if the patient tries to walk on the knee and it has accidentally been left in the “cycling mode”.

Clinical set up of cycle mode

For clinical set-up, first select the cycling mode and turn off the safety valve (by dialling in the Cycling Safety Valve, **CS** in **Fig 6**, fully). Now, let the user cycle and incrementally dial out the safety valve until the safety feature applies itself during cycling. Agree with the user how much to reduce the sensitivity of the safety feature, where if they simulated a collapse, they would still feel confident afterwards walking on it. Naturally, if faster cycling is required, there is less safety available in walking!

Swing phase adjustments

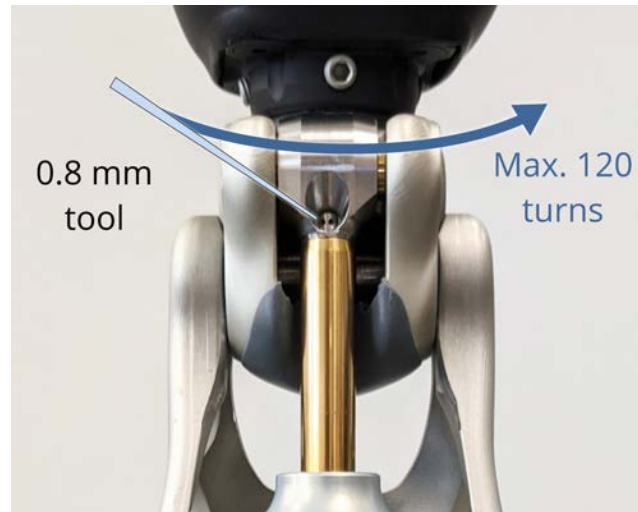


Fig 8: Adjustment of the maximum knee flexion

Maximum knee flexion

Reducing the maximum permissible knee flexion creates more forward drive of the knee. This is the MAIN control for swing phase adjustments.

The Knee Flexion Limiter (**MF** in *Fig 6*) is operated with a 0.8 mm diameter tool. The valve is factory set with minimal knee flexion limitation. To provide more knee flexion limitation the valve is turned as in *Fig 8*. This valve may require up to 120 turns across its full range. The total range between maximum and minimum is 120 swivel turns. DO RESPECT THE VALVE LIMITS. It is essential that you count the number of swivel turns in order to get a reproducible setting. Default factory setting is turned fully left.

The adjustment is quite slow, so it is recommended to first turn the valve 40 strokes and assess the changes with the patient. Then repeat with another 40 strokes and re-asses. This way an optimum can be point.

Note: Unfortunately there is currently no other indication of the current setting than counting, making the adjustment process a bit tricky. However, any other technical implementation of this setting would require more weight and/or volume to the VGK-X/VGK-XS.

Nominal swing phase resistance

If there is insufficient forward drive of the shin, even after adjusting the maximum knee flexion, the swing resistance can be increased. The Swing Resistance Valve (**S** in **Fig 6**) is operable using a shortened 2 mm hex key (see **Fig 6** for dimensions) through the access port.

Terminal impact damping

The damping characteristics at terminal swing are adjustable with the two damping adjustment valves (**TD** and **ED** in **Fig 6**). The factory setting leaves both valves fully open and they can be closed to increase the damping (i.e. more extension resistance). If more damping is required, always start with closing **ED** first before adjusting valve **TD**. This is because valve **ED** acts before valve **TD**, allowing the knee joint to slow its movement sooner.

Finishing check points

Essential movement in mechanism

An essential part of the VGK-X/VGK-XS mechanism is the slight swivelling motion in the distal knee section. The small gap between the distal knee section and the main frame must remain free of cosmeses, glue, dust particles, wedges, or anything else that could inhibit the movement. Warn the user against ingress of objects between moving parts and recommend a quarterly visual inspection. In case of doubt, a planned inspection by the clinician is recommended.

Cosmetic cover

A flexible cover can be ordered with VGK-X/VGK-XS that wraps around the main frame of the knee. The cover protects the knee against scratches and dents. When using the cover, regularly inspect the knee in case anything has fallen into the knee, to prevent damage between moving parts.

Care and maintenance

Regular inspection of the knee is recommended to prevent damage from accidental ingress of dirt and other foreign objects. Cleaning is mandatory if the prosthetic device is exposed to salt water. In this case, thoroughly hose down the knee joint with tap water and leave to dry.

If the knee joint starts to malfunction, do not use it. The user must inform their CPO of suspected device malfunction.

There is a risk of finger trapping between moving parts. Keep hands away from moving parts when bending the knee.

Please refer to www.orthomobility.com for more specific maintenance instructions

Product Disposal

Product disposal is covered on the website: <https://www.orthomobility.com/disposal/>

Warranty

Orthomobility Ltd. provides a time-based warranty against defects in materials and workmanship in accordance with terms and conditions of sale, and only when bought from approved suppliers. Defects arising from irregular and extreme use, and fair wear and tear are subject to the manufacturer's discretion. REGULAR/PLANNED WET ENVIRONMENT USE requires the manufacturer's AGREEMENT. As the use of a prosthetic device includes inherent risks, the manufacturer limits the liability arising from the use of the VGK-X/VGK-XS to that liability directly arising from a malfunction of the device, due to faulty materials and/or workmanship and excludes any other special, incidental or consequential damages. There is no implied warranty for corrosion-related breakdown following salt water use, where this has not been mitigated by thorough cleaning. For full details see Terms and Conditions on invoice.

Liability

The manufacturer liability for the use of the VGK-X/VGK-XS is limited to faults that occur from a malfunction of the device, caused by faulty materials and/or workmanship and exclude incidental damage due to misuse. For full details please refer to the Terms and Conditions provided on the invoice.

Reporting of a serious incident

VGK-X/VGK-XS is a low-risk, Class I medical device. In the unlikely event of a serious incident in relation to the device, the incident should be reported to the manufacturer (Orthomobility Ltd.) and the competent authority of the Member State in which the user and/or patient is established. According to the EU Medical Device Regulations, a serious incident is defined as *“any incident that directly or indirectly led, might have led or might lead to any of the following:*

- (a) the death of a patient, user or other person,*
- (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,*
- (c) a serious public health threat;”*

Declaration of conformity

The VGK-X/VGK-XS and its variations made by Orthomobility Ltd, Reg 5143375 conform to the Medical Device Regulation 2017/745. See www.orthomobility.com for the full declaration of conformity.

Manufacturer details

Orthomobility Ltd.
Unit E1.29 Culham Science Center
Abingdon
United Kingdom
OX14 3DB