Instructions for Use: VGK-S

VGK by Orthomobility

1. Introduction

1.1. Intended purpose

The VGK-S is intended 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-S is compatible with osseointegration, however, permission MUST be obtained from the manufacturer prior to use with osseointegration. Permission for use with osseointegration is considered on a case-by-case basis.

1.2. Technology

The VGK-S is a **Fluidic Processor Knee (FPK)**, which uses fluidic sensors to respond to changes in gait in real-time, by adjusting motion resistance within a single step.

1.3. Recommended user profile

The VGK-S is recommended for independent prosthetic users typically of mobility classes 1-4**. The VGK-S is suited for users with short transfemoral amputation or hip disarticulation. The user's body weight can be up to 100 kg.

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

1.4. Installation and adjustments

The VGK-S must be installed by a Certified Prosthetic/Orthotist (CP or CPO) to make sure the alignment and control settings are adjusted safely. The installer must also have obtained a certificate from Orthomobility as evidence of VGK-S training.

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.

1.5. Compatibility

The VGK-S is compatible with the full complement of prosthetic components, energy-storing feet, hydraulic ankles, hip components, shock absorbers. However, there are special compatibility considerations with hip joints.

It may be tempting to use the gains from the proximal mass of the knee joint in order to insert other high mass components, which may soon undo the gains made. Orthomobility recommends placing

the mass of any rotators/torque absorber as close to the stump as possible, to reduce the moment of inertia of the mass during swing.

Orthomobility recommends the use of a lightweight foot, in line with the needs of the short transfemoral amputee.

1.5.1. Compatibility with hip joints

Only the VGK100H model is compatible with hip joints. This VGK-S model features **elevated extension assist** and **stance-bias**. The alignment principles in **Section 3** (and in particular **Section 3.3**) must be followed. Prior to installation, consult the manufacturer (or the manufacturer's representative) for advice on specific hip joints and socket considerations.

1.6. 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-S**. 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-S 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.

1.7. Identification of the device

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

1.8. Normal use (note stairs)

The VGK-S 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 bannisters is recommended when descending downstairs. Normal use also includes cycling if the product has been ordered with a cycling function.

1.9. 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.

1.10. 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.

1.10.1. Extreme temperature

The VGK-S 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 swing and 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-S maintains its performance fairly well.

1.10.2. Extreme device settings

The VGK-S 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.

1.11. Body weight and additional load

The VGK-S has been designed to allow for a patient body weight of 100 kg and these persons, at this maximum body weight, to carry not more than 15 kg of additional load on a daily basis.

1.12. Prevention of overheating

Do not use VGK-S 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.

1.13. Wear and tear

As any device with mechanical elements, 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.

1.14. Storage

The VGK-S must be stored in an extended position.

2. The stumble recovery mechanism

2.1. Defining the ‘stumble’

The stumble is a brief moment of interrupted swing phase. The stumble happens in the situation when the prosthetic foot hits the ground (or an object) during swing extension. During a stumble the prosthetic foot cannot move and the forward momentum in the trunk cannot be immediately stopped.

2.2. Interruptible swing phase

Hip extension is the trigger for the VGK-S to adopt high resistance to knee flexion, as well as hip flexion resistance under a flexing knee. The spinal reflexes create a hip extension moment during a stumble, which forms the basis of an expectation of stumble recovery support in the VGK-S. Further background information on the spinal reflexes during stumble recovery is available on the website, www.orthomobility.com.

Figure 2.1(a) shows the presence of a ‘gap’ that allows a small movement about the Q-axis, which controls a valve that can block the swing mode. When the prosthesis is in swing mode, and is pulled forward, the Gap is maximum, and the swing valve is ‘opened’.

A more detailed explanation: When weight or hip extension is applied onto the prosthesis, the socket and bodyweight press down on the Gap, and it closes, such as to block the swing mode. When the limb is lifted off by weight relief and hip flexion, this Gap opens as far as possible, and permits the swing mode. This is the basic mode of operation. The movement of this Gap must not be blocked.

If the hip is extended, like the application of hip extension moment M_H in **Figure 2.1(b)**, and the foot is restrained one way or another (and returns a Ground Reaction Force GRF in **Figure 2.1(b)**), the same Gap will close with a closing movement C in and engages the Yield Function Y, which is the high resistance. You may notice that upon the initiation of the high resistance to bending Y, the socket will now ‘fall off’ about the Q-axis, and cause a reversal of movement C, and should disengage the yielding resistance Y. This is however not the case, because an internal memory retains the state of high resistance despite the removal of the resistance-triggering movement C. In this way, the combination of the hip extensor reflex in the presence of an interrupted swing switching the VGK-S to high resistance mode, and the internal memory systems maintaining this state of high resistance, makes Stumble Recovery Support a reality.

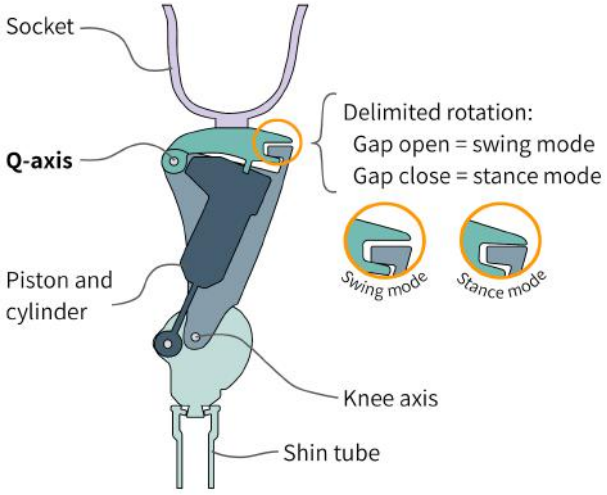

Figure 2.1(a): VGK-S stumble recovery concept

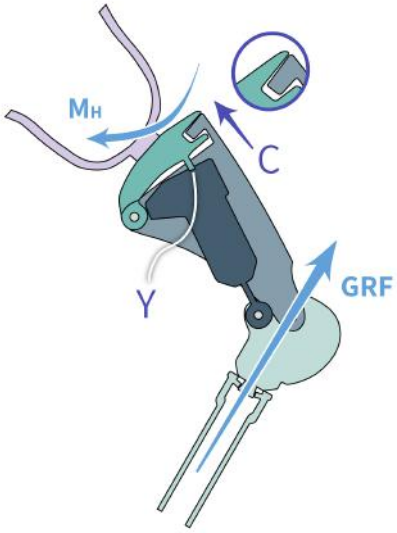

Figure 2.1(b): The engagement of stumble recovery mode

3. Alignment

3.1. Location of the knee centre

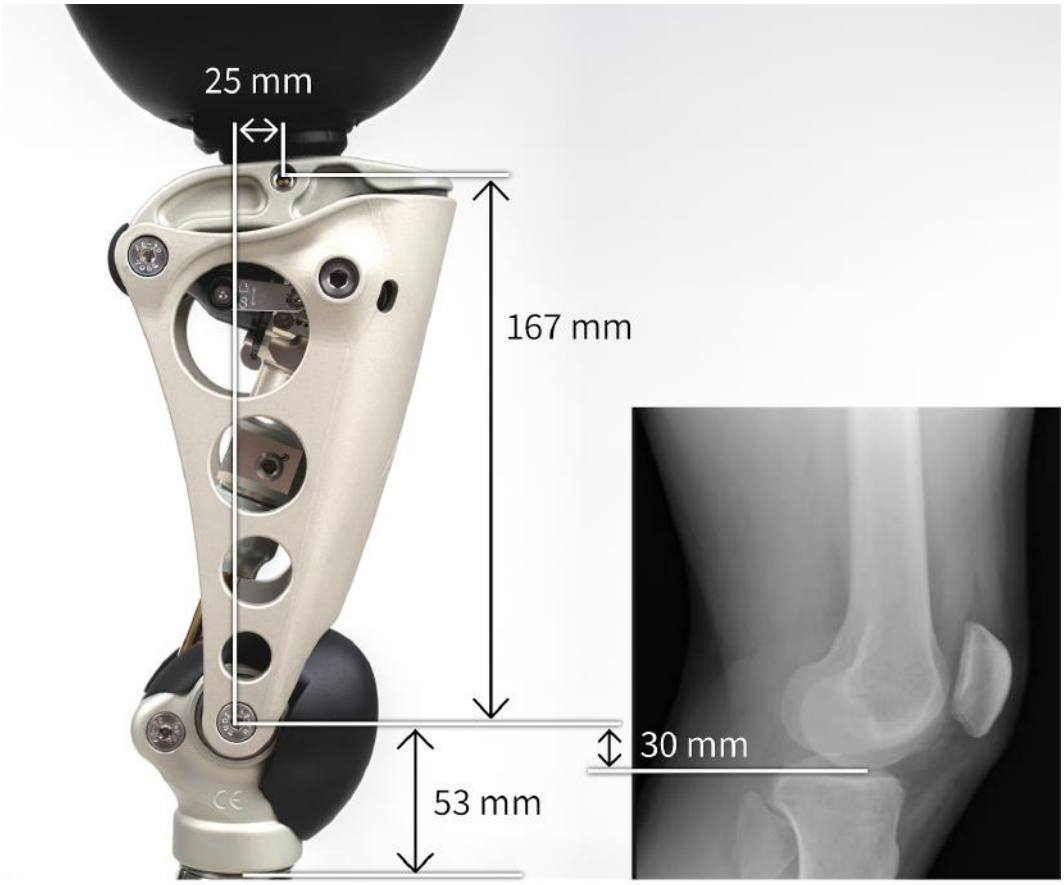

***Figure 3.1**: Location of the VGK-S knee centre*

The VGK-S has been designed with the knee axis to be ideally **30 mm proximal to the tibial plateau** of the contralateral limb. The length of the VGK-S will take most of the space between the knee axis and the end of the socket. In the case of the *very* short transfemoral amputation stump there will be residual space, and for those instances the following suggestions apply.

3.1.1. Arguments for and against raising the knee centre height

When there is residual space between end of stump and proximal VGK-S, there is a good argument to further lift the location of the knee axis, such as to bring the mode-switching-apparatus of the VGK-S as close as possible to the amputation stump. Raising the knee centre increases safety by **maximising femoral control over the switching of modes**. It also further supports possibilities of leg over leg stairs ascent.

However, a raised knee centre naturally creates a longer pendulum time of the pendant foot. Better and stronger tuning of the hydraulics is required to still provide good swing characteristics. The longer pendant shin will marginally reduce toe clearance. The cosmetic aspect will be affected: the thigh will be short, and the knee is raised while sitting. Sensitive negotiation with the user should allow establishing an optimised knee centre height.

3.1.2. Arguments in relation to lowering the knee centre height

There is no good theoretical argument for lowering the knee centre height; it may be necessary in case of a 'longer' short-TF amputation stump, or the requirement of additional components such as socket locking systems or turntables. In principle the socket should be constructed in such a way, and whenever possible, to maintain the recommended knee centre height. Orthomobility strongly recommends the knee centre to stay above tibial plateau height in all instances.

The choice of height of knee centre also affects the ability to achieve a good kneeling balance as seen adjacent. Because of the complex needs of the Short-TF amputee, the CPO needs to decide with the user, what the optimum is between the different arguments in favour of raising or lowering the height of the knee axis.

***Figure 3.2**: Kneeling height*

3.2. General alignment

3.2.1. The Q-line

The VGK-S uses the principle of a hip-knee-ankle (HKA) alignment system, where the knee centre is ideally a minimum of **10 mm posterior to the Hip Ankle line**. There are known cases where the user wants a more dynamic set-up, and that is permissible in agreement with the CPO. The VGK-S has a proximal pyramid receiver and a distal male pyramid. This allows for some mechanical alignment changes that affect the switching behaviour of the VGK-S.

When a line is drawn through the proximal posterior axis (the 'Q-axis' in **Figure 3.3**) and the main knee axis, this line (the Q-line) will intersect the foot between ankle and forefoot, indicated as Q_m in **Figure 3.3**, with 'm' referring to 'midfoot'. This location determines that any ground reaction vector entering the foot posterior to Q_m has the possibility to pass posterior to the knee axis, causing a knee flexion moment. This will cause the knee to bend. If this ground reaction force passes anterior to the Q-axis, the gap anterior to the Q-axis closes (see **Figure 2.1(a)**) and the high resistance mode is immediately activated, so that this bending occurs under high resistance. Should the ground reaction force pass posterior to the Q-axis as well, then no high resistance will initially be activated and the socket will flex about both the knee and the hip. Because the socket is wrapped around the residual limb, this socket flexion about the hip is resisted by the residual limb and this resistance will belatedly trigger the high resistance function, and a high resistance flexion is expected.

If the residual femur is extremely short, then the effectiveness of this *belated control* (interruptible swing) will be diminished. Note: Such *belated control is impossible in conventional weight activated knee joints.*

When a GRF passes anterior to the knee axis, the knee is naturally stable.

When a GRF passes **posterior to the knee axis AND posterior to the Q-axis**, the knee is forced into flexion, and, due to the relatively minor displacement of the top pyramid receiving thigh plate moving away from the main frame, the hydraulic unit is in low flexion resistance to support swing.

The Q-line can be made to intersect the sole of the foot at different locations through changes in alignment. When this intersection is more posterior than location Q_m in **Figure 3.3** (this is achieved by the knee leaning forward over the shin), then the safety (in relation to accidental or intended midfoot-strike) is reduced, and requires more corrective hip effort.

When this intersection is placed more anteriorly to location Q_m in **Figure 3.3**, the safety increases (knee tilting back over the shin), but at a potential cost of making swing release more deliberate, since there will be less forefoot area available to functionally transmit the GRF. This set-up can be used with those users who lift their limb prior to swing initiation and want maximum safety.

A proximal VGK-S perpendicular to the shin tube delivers normally the best results (the top flat of the VGK-S being horizontal).

In planning for the safety and ease of operation, the Q-line must be set-up first.

For specific alignment case studies, see the website www.orthomobility.com.

***Figure 3.3**: The Q-line in the VGK-S alignment*

3.3. Use with a hip joint

It is important to ensure that the Q-axis is posterior to the hip-knee line (see **Figure 3.4**).

Beware of tilting the VGK-S forward if the knee is aligned to the forward tilting thigh tube, as this will alter the Q-line alignment. Rather use a well tilted set of adapters to create the static alignment in 'Canadian hip-disarticulation' style set-up. When the weight line passes posterior to the knee axis in static alignment, the knee will bend under weight-bearing! It is highly recommended to set the knee centre 10 millimetres posterior to the 'greater trochanter' - ankle line.

***Figure 3.4**: Hip knee alignment*

3.4. 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.

3.5. Anterior-posterior socket position

Once the planned socket flexion is determined, the centre of the greater trochanter is taken as the Hip for the purposes of alignment. The line through Hip and Ankle should normally pass **10 mm anterior to the knee centre with the knee in full extension**.

The CPO is to make the final judgement decision on optimising socket position.

- Further anterior shift will make the knee naturally more stable, and this stability will, in the presence of residual body weight over the forefoot, to some degree hinder the ease of swing initiation.
- A posterior shift does the reverse: there will be less inherent stability with increased demand on the hip extensors to maintain a straight knee at heel strike and in mid stance.

Make sure the alignment is satisfactory prior to completing the socket: repositioning the socket by tilting the knee about the knee axis affects the operation of the knee in an unplanned, and therefore adverse way.

3.6. Double action / unwanted mid stance flexion

The user may experience a double action, or unwanted mid-stance flexion. This is mostly caused by the weight line passing posterior to the knee axis, possible due to one of the following reasons:

- an unsuitable HKA line- foot too dorsiflexed
- long / hard heel of shoe
- posterior tilt of socket relative to knee axis
- insufficient hip extension from the user during early stance.

3.7. Kneeling

The rubber posterior bar is the knee flexion stop against which the tube of the shin (or foot) is to contact in full knee flexion. *Under no circumstance* is the tube adapter allowed to rest against any part of the hydraulic during maximum knee flexion, and a minimum clearance space must be available of 10 mm to allow for bunched up items of clothing. Users must be warned that excess fabric bunched up in full knee flexion under force of bodyweight (kneeling down), can potentially cause damage to the knee mechanism.

For use with osseointegration, the shin-tube ideally does not touch the knee at all in full knee flexion, or agreement is made that the knee flexion is acceptable and compatible with the intended safety of the patient in the unlikely event of knee joint collapse.

4. Controls

Figure 4.1: Locations of controls for clinical adjustments

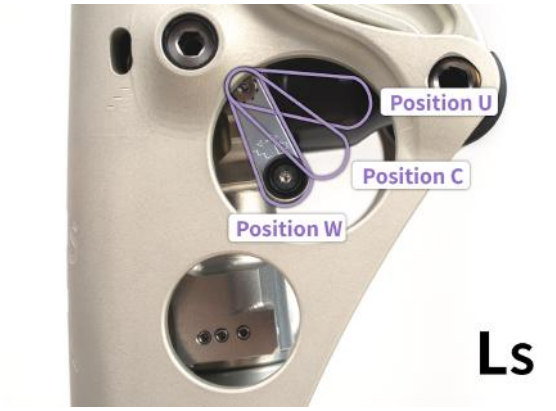

Figure 4.2(a): Positions of Stance Flexion Handle, L_s

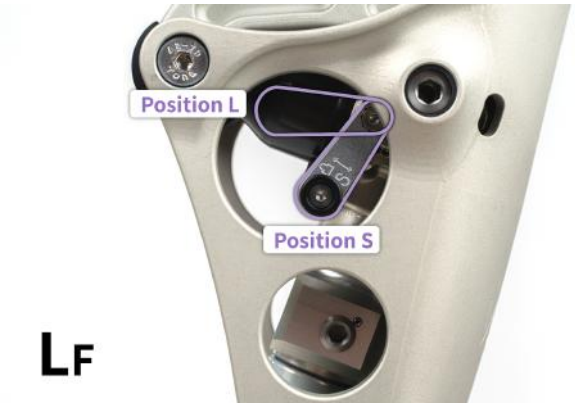

Figure 4.2(b): Positions of Swing Flexion Handle, L_f

4.1. Stance Flexion Handle

The yield resistance (stance resistance) is set using the stance flexion handle, $\mathbf{L_s}$ in **Figure 4.1**. See **Figure 4.2(a)** for possible positions of handle $\mathbf{L_s}$. 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-S 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.

4.2. Swing Flexion Handle

See **Figure 4.2(b)** for possible positions of handle $\mathbf{L_f}$ of the swing flexion handle, $\mathbf{L_f}$ in **Figure 4.1**. 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.

5. Adjustments

5.1. Adjusting the stairs mode

See **Figure 4.2(a)**. The stairs mode is selected by positioning the stance flexion handle (**L_s**) in **position W** (compatible with normal walking). The rate of knee flexion in stance can be adjusted with the Stance Resistance Valve, **S**. The valve is accessible through a port in the frame. Use a 2 mm hex key to turn the valve clockwise for faster knee flexion, or anticlockwise for slower knee flexion.

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.

5.2. Ultra high resistance mode

See **Figure 4.2(a)**. The ultra high resistance mode is selected by positioning the stance flexion handle (**L_s**) 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.

5.3. Cycle mode

See **Figure 4.2(a)**. The cycle mode is selected by positioning the stance flexion handle (**L_s**) in **position C**. Note that in the cycling mode, the knee bends freely irrespective of the knee flexion speed. This means that there is **no stumble recovery or safety catch in the cycling mode**.

5.4. Swing phase adjustments

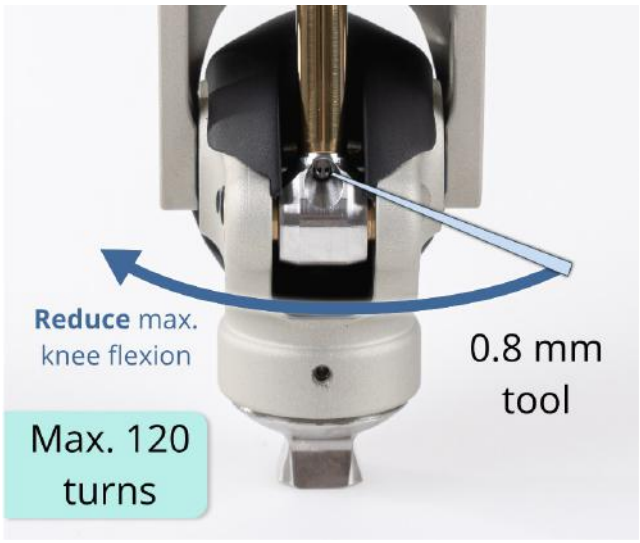

***Figure 5.1**: Adjustment of the maximum knee flexion*

5.4.1. 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 (**F1** in **Figure 4.1**) is operated with a 0.8 mm diameter tool. The valve is factory set with maximum knee flexion. To reduce the maximum permitted knee flexion, the valve is turned as in **Figure 5.1**. This valve may require up to 120 swivel-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 right, which is the minimum knee flexion limitation.

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-S.

5.4.2. 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 (**F2** in **Figure 4.1**) is operable using a 2 mm hex key through the access port.

5.4.3. Terminal impact damping

The damping characteristics at terminal swing are adjustable with the two damping adjustment valves (**E1** and **E2** in **Figure 4.1**). 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, experiment with adjustments of the **E1** and **E2** valves. Understand that the ***E1*** *valve acts before* ***E2*** during extension.

6. Finishing check points

6.1. Essential movement in mechanism

An essential part of the VGK-S mechanism is the slight swivelling motion in the top knee section, the 'thigh plate'. The thigh plate swivels about the Q-axis (see **Figure 2.1(a)**). This movement must remain uninhibited by 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.

6.2. Verify stance control engagement

When body weight is applied to the heel of the foot when the limb is extended, the device must give high resistance to bending. When the toe is placed under the body whilst the knee is flexed, the extension of the hip (effort from femur or force from artificial hip) must trigger the SAME high resistance mode. The user should be encouraged to explore the sensitivity of this feature.

6.3. Verify swing control release

The knee should revert to swing phase on toe-off in normal gait, or it should revert to swing phase on hip-hiking. (Hint: If the swing phase does not release, this may be due to the ground reaction force arising too close to the Q_m point in **Figure 3.3**, due to foot construction / shoe construction / alignment of Q-line, see **Figure 3.3**).

6.4. Torqueing

The set screws in the female adapter are to be loctited / tread locked with medium strength thread locker, and torqued to 10 Nm. The thread locker helps prevent water ingress in the treads and protects the screws.

6.5. Cosmetic cover

Any cosmetic finish must allow free movement between the main frame and the top to ensure safe operation of the knee.

7. Use with osseointegration

7.1. Osseo-perception

It is worth noting that the slight swivelling movement at the top of the VGK-S may cause irritation for a user with osseointegration. This movement is essential to the operation of the VGK-S and therefore cannot be avoided.

7.2. Safety considerations in case of collapse

To assess safety for any non-controlled fall, confirm that the prosthesis foot will hit the pelvis before the VGK-S contacts any knee flexion restriction. This assessment will then confirm that risks of bone fractures due to knee flexion stop mechanisms within the VGK-S are excluded.

7.3. Cycling mode

Within the cycling mode, the VGK-S does not have stumble recovery or a safety catch. The VGK-S model with cycling mode is therefore not recommended unless the risks and opportunities have been weighed by both clinician and patient, and that this assessment has been documented in the medical notes.

The risk assessment must include the following consideration:

- The benefit is: low resistance whilst cycling.
- The risk is: lack of stance mode resistance when stepping off the bicycle prior to switching the stance mode back to either Yield or Lock. This could lead to a fall.

8. 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

9. Product Disposal

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

10. 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-S 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.

11. Liability

The manufacturer liability for the use of the VGK-S 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.

12. Reporting of a serious incident

VGK-S 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;"

13. Declaration of conformity

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

The VGK-S and its variations made by Orthomobility Ltd, Reg 5143375 conform to the UK Medical Devices Regulations 2002. See www.orthomobility.com for the full declarations of conformity.

14. Manufacturer details

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