1 Very Good Knee Short Transfemoral, in short: VGK-S

1.1 Introduction

The VGK-S shown in action in Figure 1, is a new type of knee joint that is unique in approach. The dynamic fluidic controlled knee joint is designed for transfemoral amputees with short transfemoral amputation (S-TF).

The VGK-S by design and construction reduces some medical problems normally associated by shortness of stump. Theory about this is discussed first. This theory must be read and understood to safely install the VGK-S.

The adjustment options of the valves and selectors are detailed in section 6, to be followed by effects of alignment, including knee centre build height.

Further, the typical small print is presented, to include a range of aspects of inherent Risk in association with fitting S-TF amputation stumps.

Finally, a short test is available on the [http://www.orthomobility.com/vgk-s-assessment/](http://www.orthomobility.com/vgk-s-assessment/)

This assessment must be completed by each CPO prior to first fitting of a VGK-S. A certification number will then be returned and must on demand be used with warranty- or support claims or -request.

It is the responsibility of the limb-fitting prosthetist to have read and understood this manual.

1.2 Terminology

From “A Manual for Above-Knee Amputees”: “In recent years, there has arisen an aversion to the use of the word "stump" in referring to that part of the limb that is left after amputation, and attempts have been made to find another term that could be used. This has proven to a difficult, if not impossible task, because there is no synonym in the English language for "stump." The terms "residual limb" and simply "limb" which have been suggested are ambiguous at best, and since nothing better seems available, the word "stump" has been retained by the International Standards Organization and is used here to avoid confusion”. The word ‘stump’ holds vital clues towards the understanding of the phenomenon. The thigh has been severed at the given anatomical level, and any musculature with retained insertions will be functional, whereas others may be fixed by myodesis, and have compromised function and relative balance. Therefore the one S-TF stump may be unlike the next shorter S-TF stump.
1.3 VGK-S, theoretical background

1.3.1 Incidence

The incidence of Short Transfemoral Amputation (S-TF) is not well reported, and estimations may need to be made on records such as in:

<table>
<thead>
<tr>
<th>n</th>
<th>S-TF/ALL</th>
<th>ref</th>
</tr>
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<tbody>
<tr>
<td>24</td>
<td>9/24</td>
<td><a href="http://jbjs.org/content/95/5/408">http://jbjs.org/content/95/5/408</a></td>
</tr>
<tr>
<td>26</td>
<td>10/26</td>
<td><a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4160504/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4160504/</a></td>
</tr>
<tr>
<td>21</td>
<td>7/21</td>
<td>Knee Joints with controlled flexion damping for Transfemoral Amputees Clinical Cross Over Study: C-leg, Rheo knee, VGK, Orion.</td>
</tr>
<tr>
<td>80</td>
<td>30/80 &gt; 30% OVERALL</td>
<td></td>
</tr>
</tbody>
</table>

These reports do not necessarily report random selection of stump length and depending on the study S-TF may well be excluded due to negative impact on product performance. Biedermann writes: “In closing, the question arises whether the fitting of short above-knee stumps still represents a problem today. In general the question must be answered in the affirmative, since each case is different. Each case presents a considerable degree of difficulty and in each it is necessary to analyse the individual conditions of the stump to make the best of what is left. We do not always achieve the desired success, but even partial successes are on the positive side. In our profession, in particular, and in this age of mass production, the supply of prostheses to difficult or even “hopeless” cases is a rewarding task. We are indebted to the past greatness of our profession for solutions to such difficult problems”.

S-TF amputation is believed to affect younger people more, due to trauma and tumours being main causes for S-TF amputation.

Note: for the purposes of this manual, a S-TF amputation is any stump length that provides clearance of 200mm or more to fit the VGK-S, rather than a percentage of femoral length.
1.3.2 Basic State-of-the-Art Functions

Modern knee joints, fluidic and electronic, show that the provision of secure stance and swing functions can significantly transform amputee-disability to good post-amputation mobility (compare: a low functionality knee joint can cause functional disability).

The basic functions that a state of the art knee joint must provide can be shown as in Figure 2: a hierarchy of needs, wherein the need of low inertia becomes (in terms of reaction forces in the soft tissues) inverse proportionally more significant to the S-TF with stump length.

There are two major theoretical aspects to VGK-S that needs to be understood to fully employ the advantages of VGK-S over knee joints with centre of mass distal to the knee axis:

- Impact of Low Second Moment of Inertia.
- Interruptible swing phase by hip extension.

Whereas it is obvious that a knee joint in a prosthesis must perform essential functions such as stability in stance and flexibility in swing, such function adds to the functional mass of the knee joint.

Uniquely, the VGK-S allows the choice of a knee joint with the function mass close to the body.

Before the full value of this arrangement can be fully appreciated a discussion of the Second Moment of Inertia of the prosthesis must be made.
1.3.3 Understanding the impact of Inertia (i.e. Second Moment of Inertia)

Transfemoral amputees need a knee joint in their prosthesis to provide the basics of stance phase (high resistance to support body-weight bearing,) and the basics of swing phase (low resistance to facilitate swing through). In walking, the amputee needs to control the prosthesis with the residual femur and the controlling muscles. Short stump causes reduced contact area within the socket causing elevated contact pressures. It goes without saying that the shorter the amputation stump, the less muscle volume there is to control the prosthesis. Muscle volume is a measure of energy production. From basic mechanical considerations it can be reasoned that the net energy that is required to kick a prosthesis forward in swing, and to reabsorb this energy in terminal swing is roughly the same for those with short and long transfemoral amputation stumps (for a given walking speed). Let this be called Net Swing Energy. The gross energy required to move a prosthesis, is believed to increase with diminishing stump length due to increase in compensatory movements for which the human body is not optimised.

From these considerations, any reduction in mass of the prosthesis will reduce the Net Swing Energy required to move the prosthesis through swing, as will reduction of walking speed. When prosthetic movement is not well attuned to the overall balance of the body, more complicated compensatory movements are required. “Mental functions which have been formed under normal conditions function optimally in similar conditions. Should the conditions change, the precision of the functions could be impaired, which may lead to increased uncertainty in the processes and thereby also increased energy consumption.” This we can call neurological energy that is expended fast when there is stress or discomfort. This neurological energy is naturally not easily detected in oximetric methods, because the caloric energy conversion in the brain is negligible, and indeed may rather be determined as exhaustion of neurotransmitters. Any reduction in mental fatigue could be a strong indication of ‘patient preference’ for a given prosthetic component.

Further, any reduction in the Second Moment of Inertia of the prosthesis will reduce the forces on the amputation stump when swinging the limb through.

‘Second Moment of Inertia’ can be explained as that for ANY given bit of MASS that is moved at a DISTANCE (e.g. a foot at its distance from the hip joint, say 85 cm), the force required is proportional to the SQUARE of the distance of that given mass. Please refer to Figure 3, a Centre of Mass is at a distance from a pivoting point, about which this mass is moved into swing. In the figure the ‘pivot’ point is chosen to be mid depth of the socket, to take into account that the femur-socket interface is
effectively a joint. Taking the Greater Trochanter as the reference point for discussing the effects of inertia would be similarly valid, as that is the point about which the muscles act.

In other words, if the distance of the foot to the hip were halved (i.e. \( \frac{1}{2} \)), the force required to move it the same step length would be \( \frac{1}{4} \), this, naturally is not possible.

However, the location of the centre of mass of the knee joint can be redesigned.

To bring the same theory alive, you can imagine the difference in feel of holding a heavy hammer close to its head Figure 4 vs at the end of its handle.

### 1.3.4 Different demands of Spine vs Stump

The mass of the prosthesis, and especially the inertial properties of the prosthesis are deemed to affect gait in two, opposing ways Figure 5. The spine and its musculature need a prosthesis that feels like the contralateral limb. This means similarities in mass, damping and energy production and absorption.

However the stump must move the prosthesis, and that places limitations on the amount of force that can be delivered. The stump requires to the contrary, a light, low-inertia limb.

Whereas this may sound contradictory, it makes sense from the ‘perspective of the hip joint’. The natural leg feels light during toe-off, (because the calf muscles fire the shin into movement, without involving the hip muscles too much moving this inertia), whereas prior to heel strike, the powerful Glutei decelerate the impulse in the leg, and work against the full inertia of the limb. The user of a prosthesis has lost the push off power of the calf muscles, and therefore the hip must assume both roles, hence the apparent contradictory requirements.

In the S-TF amputee the low inertia is of overbearing importance. Low-inertia of the prosthesis means an improved relationship between stump position and limb position, since the reactive forces are diminished, and passive tissue deformation (see also Figure 3) against a backdrop of unavoidable tissue compliance will be reduced.

Gain of proprioceptive awareness contributes to safety and wellbeing.

### 1.3.5 Second Moment of Inertia as a worked example.

Why a worked example? This gives some ideas how user feedback relates to your prosthesis design / prescription.

The prosthesis can be thought of as consisting of the foot, the knee and the socket. Here the adapters and tubes are ignored for brevity. Each of these components has a location.
To move all elements through swing requires force, and there are means to make estimations of those forces, and gain understanding of the influence of the different parts of the prosthesis on the overall experience of the prosthesis in relation to stump length.

The following reflection uses some theory from mechanics, where it is postulated that the moving of an object with mass $m$ around distance $d$ to a point, requires a force (strictly speaking a moment) $M$. The relationship between these is $M = m \times d^2$. This is the situation of the hip joint moving a distant ($=d$) prosthesis ($=m$) through swing ($=around a point, e.g. the hip$). It is worth following the simple calculations below to appreciate the relative contributions of the foot, knee, and socket. Figure 6 shows two artistic renderings of an artificial limb, with a Traditional location of mass of knee joint on the left side, and a State-of-the-Art location of mass of knee joint on the right side, that is above the knee axis.

![Figure 6](image)

refinement of theory will indicate that the delay in swing movement of the foot will cause a smoothening out of acceleration and diminish the inertial effect a little. However and whatever the inertial effect is, it is a relatively fixed given value for that walking speed, for any kind of better knee joint. Other than diminishing mass of foot and shoe, there is little that can be done with the foot to reduce the SMI of the foot. Estimate the $SMI_{foot}$ at $50\% \times 0.6 \times 0.9^2 = 0.27 \times kgm^2$, where the estimated $50\%$ accounts for the smoothening out of the acceleration of the foot due to double pendulum action.

The user specific- socket with an estimated mass $m_s$ of say 1000 gr is surrounding the stump and its close proximity to the stump $d_s = 0.1$ m from hip makes it SMI very small indeed. Estimate the $SMI_{socket}$ at $1 \times 0.1^2 = 0.01 kgm^2$. With some simple estimating calculations, a picture can be gathered about the impact of shifting the centre of mass $m_k$ of the knee joint. (The figures are made up for the purposes of the worked example, and some lesser second order rotation effects are ignored).

The foot with an estimated mass $m_f$ of say 600 gr, can only be located far away at fixed, user specific, distance $d_f=0.9$ m from the hip joint (greater trochanter as reference) to accommodate the full limb length. There is no possible alternative to its location. The distance of this mass contributes to the Second Moment of Inertia (SMI) of the prosthesis in squared proportion to its mass. A
The functional (but here imaginary-) knee with an estimated mass \( m_k \) of say 1350 gr can be located traditionally at (e.g.) 0.46 m from the hip makes an estimated SMI\(_{\text{traditional\_knee}}\) at 1.35 x \(.46^2 = .28\) kgm\(^2\). Traditional means in this case, ‘distal to the knee centre’. A VGK-S with an estimated mass \( m_k \) of 1000 gr can be equivalently located at \( d_k = 0.34 \) mm from the hip, making an estimated SMI\(_{\text{VGK-S\_knee}}\) at \( 1 \times .34^2 = .12 \) kgm\(^2\).

<table>
<thead>
<tr>
<th>(use Greater Trochanter as reference)</th>
<th>Traditional prosthesis</th>
<th>VGK-S prosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot</td>
<td>.19</td>
<td>.19</td>
</tr>
<tr>
<td>Knee</td>
<td>.28</td>
<td>.12</td>
</tr>
<tr>
<td>Socket</td>
<td>.01</td>
<td>.01</td>
</tr>
<tr>
<td>Total</td>
<td>.48</td>
<td>.32 - &gt; a saving of 40%</td>
</tr>
</tbody>
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This is, despite any margins of error in estimations, a strong indication that the experience of a lighter limb has a basis in engineering prediction.

### 1.3.6 The meaning of Inertia vs Forces in and on the Skin

The femur is moved by the muscles around it about the hip joint. The innervation in the joint capsules and muscle fibres and skin about the amputation stump provide what is called proprioceptive feedback.

After donning a socket, the skin in contact with the socket is relatively fixed (unless it rubs or slides), and the skin just outside the socket needs to stretch more than normal to allow socket movement relative to the pelvis. Naturally, the socket does not move exactly the same as the femur, due to resistance of skin stretch, and soft compliance of muscle and fat tissue between socket wall and femur. With small movements and low restriction of socket movement the relationship, that is the Femur-Socket Coupling will be good, but if the socket is restrained then the femur moves and the socket does not, and then the Femur-Socket Coupling is badly affected.

During the swing phase of the prosthesis, the SMI acts as in restraining the socket, and therefore deteriorates the Femur-Socket Coupling. It follows naturally that a lower SMI improves the Femur-Socket Coupling.

The brain is able ‘to feel’ in the distance through objects connected or held by the body, e.g. use of cutlery, walking sticks, spades, and even sockets.
and prosthesis. As the next paragraph will consider, the ability to accurately interpret distant reality (moving shin and foot in swing) through objects (like the socket) is dependent on the force levels involved.

Figure 7 illustrates the bulging of the flesh over the socket edge. The bulging betrays a ‘Pressure Edge’, and when the socket is fixed to a mass with an inertia, the Pressure Edges become dynamic: the shorter the stump, the more forceful and dynamic these Pressure Edges become, and decrease the proprioceptive awareness of the prosthesis.

### 1.3.7 Proprioceptive awareness in relation to skin stimulus

![Figure 8: Compliance of skin overlying muscle and fat tissues in rat.](image)

When inertial forces, from moving a prosthesis, cause skin displacement, (such as the bulges in Figure 7), a relationship between force and deformation is highly non-linear, and such a relationship can be illustrated from experimental results. A study, see also Figure 8, into the compliance of skin overlying muscle and fat tissues in rat shows that with low forces the displacement of skin is disproportional to the force applied, whereas at higher forces the displacement of skin is less than proportional to the force applied. The ‘Deformed mesh’ of the finite element model (see Figure 9) illustrates the ideas of skin tension about a socket edge (black).

![Figure 9: Finite element model of skin deformation.](image)

Within the skin there are Ruffini nerve endings as shown in Figure 10 that are Encapsulated Collagen type, sense Touch & Skin Stretch and signal Direction & Force. ‘The Ruffini corpuscle, which is located in the connective tissue of the dermis, is a relatively large spindle shaped structure tied into the local collagen matrix. It is, in this way, similar to the Golgi tendon organ in muscle. Its association with connective tissue makes it selectively sensitive to skin stretch’.

![Figure 10: Ruffini corpuscles and nerve endings.](image)

The neural response to mechanical response can be illustrated as per Figure 11, where it shows that the **best discrimination of the nerve cells is in the low stimulus region.** When combined with the earlier information of skin deformation vs force, the ability to feel best is when the skin is close to neutral in deformation, and when force levels are low. To the contrary, and in case of high force, the skin is taut, becomes rigid against further deformation, and the neural response also flattens out.

![Figure 11: Neural response vs stimulus strength.](image)

These are indicators that reduction in the SMI of the prosthesis supports improved proprioceptive awareness by reducing the range of tissue deformation throughout swing (when inertia dominates the forces), and thereby improving the relationship between neural response to skin stretch, and hence improve sensation of ‘direction and force’, which by reason and experience supports proprioceptive awareness.
This means that for the S-TF amputee, low SMI has an *objective medical impact*, as opposed to a possible perceived limited scope such as ‘subjective’ improved comfort.

### 1.3.8 Influence of actual Wrapped Femoral Length

Whereas the VGK-S allows the significant lowering of the SMI of the prosthesis, relative to the hip joint, the results may not be the same for the even shorter S-TF amputation stumps. The Femur-Socket-coupling becomes inversely proportionally poor with further shortening of bone length. A new useful measure would be to maximise the length of femoral bone wrapped by the socket. Let this measure be ‘wrapped femoral length’ (WFL).

Figure 12 shows the positive influence a good socket design can have on the Wrapped Femoral Length, but also how poor the relationship can be between Wrapped Femoral Length and socket diameter. As per the x-ray photo, the reaction forces in the 6 cm WFL will be double of those in a 12 cm Wrapped Femoral Length, in other words, available bone length to be contained in the socket is critical for resulting force levels. By walking slower, the amputee can reduce the Inertial forces and in that sense control comfort and proprioceptive awareness.

Working with amputees with S-TF will remain a challenge, in terms of suspension, comfort in sitting, and overall comfort in walking.

### 2 VGK-S vs. Mechanisms of Stumble Recovery

#### 2.1 Crossed Extensor Reflexes in Stumble recovery

The stumble is a brief moment of interrupted swing phase, and is poorly understood in terms of general perception. For improving amputee care it is helpful to review this event.

The ‘stumble’ is the situation when the prosthetic foot during swing extension hits the ground. The prosthetic foot cannot move and the forward momentum in the trunk cannot be immediately stopped, as so well emotionally expressed in Figure 13 where the policeman is stumbled by immobilisation of his foot. The sculpture is however not realistic but rather, depicts the popular imagination of stumbling or tripping.
The forward momentum of the foot and shin is split between an impact force to the ground and an impact force that travels to the socket into the amputation stump. More realistic movements are caricatured in Figure 14B. It appears, the arms are pulled back to pass momentum to her left leg being pushed forward. Figure 14C is in a final stage, ‘if the body figures out’ that the stumble is non recoverable, then the arms stretch out to break a fall to protect the head.

Whilst the body reflexes act, the stumbling foot and limb is the limb that must take the body weight, and here the crossed extensor reflex is understood to be triggered. Normally this reflex is explained from as a withdrawal reflex, such as when stepping on a painful stimulus. However, in case of the stumble the situation is more complex because of the momentum involved in walking. The crossed extensor reflex works the other way round: the stumbling limb with its forward momentum causes a knee flexion and a knee extensor stretch, not dissimilar to the hammer the doctor uses to test for knee tendon reflex. The knee extensors trigger, and so do the hip extensors, and by crossed extensor reflex the hip flexors and knee flexors in the contralateral limb (that is in stance phase!), initiate a rapid swing mode, that in concert with arm movements and forward bending of the trunk allow a rapid forward movement of the contralateral limb to prepare for weight acceptance, so that the tripping limb can be brought out of hazard zone.

2.2 Crossed Extensor Reflex, in the Stumble-Recovering Amputee

For the amputee, the tripping prosthesis itself cannot fire off a knee extensor reflex, and that is where a default stance knee joint normally adds so much safety to the amputee: the knee is ready to give high resistance, as if there were a knee extensor reflex.

Yet, observing a stumble recovery as in Figure 16 there appears to be a pattern like a Crossed Extensor Reflex whilst using the default stance VGK-Go!. In Figure 17 a similar pattern of lifting the
arms can be seen in this case with Stumble Recovery Support in VGK-S. The conditions were poor, as in walking in long grass, but the discontinuation of the forward swing of the foot was followed by a stumble recovery, *self-reported* by the user prior to play-back of the film. It would appear that

the spinal cord sensed the discontinuity of intended movement. By reflex action, the hip extended to press down on the prosthesis (thereby triggering high resistance mode), the arms pulled back to throw the contralateral limb forward in the Stumble Recovery Strategy.

In the event of a stumble, the presence of similar sequences of body postures, is seen in:

- the person with two biological legs
- the amputee with a default stance knee joint,
- the amputee with the VGK-S,

suggests that a Crossed Extensor Reflex is at work, and the time to consciously produce those movements is simply too short. Any failed attempted stumble recovery is associated with real reflexes of self-protection: hand stretching out to protect, as shown in Figure 15.

**2.3 Stumble Recovery by Interrupting Swing Mode**

The presence of spinal reflexes described above form the basis of an expectation of stumble recovery support in the VGK-S. The hip extension forces the VGK-S to adopt high resistance to knee flexion.

Figure 21 details 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’.

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.

If the hip is extended as applying hip extension moment $M_H$ as in Figure 18, and the foot is restrained one way or another (and returns a Ground Reaction Force $GRF$ as in the same figure, ), the same Gap will close with a closing movement $C$ in Figure 18 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 as in Figure 21 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.

3 Controls on the VGK-S

3.1 Fluidic Control Technology

The VGK-S is a fluidic processor control, weight activated knee joint, with stumble recovery support.

This information processing acts to take in information from knee angle, speed, and temperature, then generates an adaptive resistance to movement as output. This is achieved by coanda effects, irrotational vortex diodes, bi-stable valves and motion feedback loops.

This is a novel and unique combination. To date, weight activated knee joints (whether electronic or not) use the force patterns entering the foot to determine the stance or swing of the joint. The VGK-S uses the force patterns emanating from the hip to control stance or swing mode. There is no need for residual weight to be applied on to the forefoot to facilitate swing release, but such residual weight is permissible. The control of this novel, hip activated stance, allows highly versatile user control, even when the user is tired, and reacts fast to spinal reflex hip extension during stumble recovery.

The fluidic information processor evaluates continuously the progression of the swing phase and responds to changes in cadence with immediacy.

Stance phase is also fluidic control, securing a highly controlled rate of knee flexion under weight-bearing (yielding), such as in stairs and slope descent.

3.2 Switching and controlling VGK-S functions

3.2.1 Switching modes

The VGK-S is a default swing knee, which means that the user must activate a stance mode by one or both of two ways:

- Hip extension
- Application of body weight on an extended prosthesis

These actions will close a valve to support high resistance, and the high resistance self-sustains, which is the stance mode.

3.2.2 Stance mode
Once in the stance mode, there are manual options of blocking the movement (i.e. ‘locking’) using the Stance Switch, or control the rate of yielding movement to support the descent off stairs and slopes. Naturally the vortex metering technology is also used in VGK-S to control for viscosity changes due to temperature changes during use and environment.

The same stance mode is triggered during a reflex hip extension action in case of a stumble. This mechanism is detailed under a separate heading. A manual switch allows the stance mode to be blocked.

3.2.3 Swing mode
The swing mode is the default mode in VGK-S, meaning that no special effort is required to swing the limb whilst suspended from the body. This mode is also manually switchable to ‘locked’ or ‘elevated resistance’, for use like for wading through water. The Stance Switch influences the result from the operation of the Flexion Switch as per table below.

<table>
<thead>
<tr>
<th>Swing flexion resistance</th>
<th>Flexion Switch L₁ on ‘Lock’</th>
<th>Flexion Switch L₁ on ‘Swing’</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stance Switch L₃ on ‘Lock’</td>
<td>‘Locked’</td>
<td>‘Free’</td>
</tr>
<tr>
<td>Stance Switch L₃ on ‘Stairs Mode’</td>
<td>‘Elevated resistance’</td>
<td>‘Free’</td>
</tr>
</tbody>
</table>

The swing mode is controlled by four adjustments:

The general resistance to knee flexion can be set using valve F2. This valve restricts the overall flow during knee flexion. For light operation of the VGK-S, this valve is best left fully open.

The dynamic resistance that precisely control maximum knee flexion is set through Valve F₁ located in the trunion. This valve is rather insensitive and needs MANY swivel turns to adjust. To traverse the full range approximately 140 swivel turns are required. The valve is adjusted using a household needle or a special tool. This valve has a very special property in that the adjustment programs the maximum knee flexion, and after your programming of the maximum knee flexion angle, the fluidic control valve inside will adjust its dynamic resistance to produce the desired result over a wide range of walking speeds.

The extension resistance has a valve E₁ that regulates the generic resistance to extension.

For terminal impact dampening there is valve E₂ that regulates the resistance for terminal impact dampening.
It is recommended that these valves are fully open to begin with. When the terminal impact needs softening, the \( E_2 \) valve is carefully closed. When the general extension is too fast, valve \( E_1 \) can be partially closed to increase resistance. Since these valves act in parallel, adjusting the one affects the other to some degree, and a balance may need to be struck: if the general extension resistance is increased, there will be less impact energy and the terminal impact valve \( E_2 \) can be opened a little if it had been closed before.

### 3.2.4 Bicycling Mode

The VGK-S has no dedicated bicycling mode. If complete freedom is required in bicycling, the resistance will be minimised when the stump lifts the socket in an active fashion. In practice this may not be feasible.

### 3.2.5 User-centred operation

The VGK-S is intended to be understood by users, and gain permission from the CPO to adjust the settings AFTER instruction. This permission is naturally subject to local rules and regulations. The minimum set of User adjustable functionality is the operation of the selector switches, which must be taught to the user. The adjustments to the dials are for Advanced users only, and subject to CPO teaching and approval. Users should understand that CPO’s will support user adjustment in accordance to their treatment plan.

### 3.2.6 Users’ Instructions

The VGK-S is provided to you by your prosthetist who has made sure to fully understand the product and its limitations.

The VGK-S has certain valves that affect its operation, and if you want to adjust these by yourself, do so, subject to agreement with your prosthetist / local regulations, who will then guide you through the settings as laid out in this manual.

You must understand that the VGK-S, whilst compatible with expected stumble recovery, such is dependent on the efficiency of the available bone length in the stump, the socket fitting, the set-up of the leg etc. It is recommended that you experiment between parallel bars to explore the feeling of engaging stumble recovery mode by placing the leg underneath you, hip flexed, rest on the toe, and press down to engage the stance resistance as set and experience the nature of the response. Bear in mind that the resistance to stumble recovery is the same as the resistance used for downstairs walking.

You are expected to have read this whole manual to undertake responsibly any adjustments to the settings. In case of doubt consult your prosthetist.

Avoid clothing (/ high boots) that fold into thick layers in the hollow of the knee when fully flexing the knee, such as to put pressure onto the piston rod, and cause damage.
4 Set-up of Knee Axis Height

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

4.2 Arguments in favour of 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 proximal VGK-S as close as possible to the amputation stump. Raising the knee centre increases safety as in maximising femoral control over the switching of modes. It also further supports possibilities of leg over leg stairs ascent.

4.3 Arguments against raising the knee centre height
Naturally, a raised knee centre creates a longer pendulum time of the pendant foot. To provide good swing characteristics better and stronger tuning of the hydraulics is required. 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 in sitting. Sensitive negotiation with the user should allow establishing an optimised knee centre height.

4.4 Arguments in relation to lowering the knee centre height
There is no good theoretical argument for lowering the knee centre height; there may be necessity in the form of ‘long’ S-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 in Figure 19. Because of the complex needs of the S-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.
5 Alignment

5.1 Q-line

The VGK-S uses the principle of a 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 affects the switching behaviour of the VGK-S.

When a line is drawn through the proximal posterior axis (Q-axis, see Figure 21) and the main knee axis, this line (the Q-line) will intersect the foot between ankle and forefoot, indicated as Q_m in Figure 20, 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 21) and the high resistance mode is immediately activated, so that this bending occurs under high resistance. Would 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 will be diminished. NB: 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 relative 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.

By alignment the Q-line can be made to intersect the sole of the foot at different locations. When this intersect is more posterior as location Q_m as drawn in Figure 20 (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 intersect is placed more anteriorly to location Q_m as drawn in Figure 20, 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 in 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.

5.2 **Socket flexion**

The placement of the socket may involve a required flexion contracture accommodation. This needs to be done at time of bench alignment of fitting or during check socket fitting, and not afterwards. *Pay dedicated\ attention to this feature.* Naturally the more pre-flexion of amputation stump, the more loss of stability in stairs and slope descent. Orthomobility recommend to seek a socket alignment with minimal as possible, pre-flexion, as to maximise femoral grip in the socket in stairs and slope descent.

5.3 **AP-Socket position**

Once the needful or absent 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 10mm anterior to the knee centre with the knee in full extension.

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.

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

5.3.1 **Double action / unwanted mid stance flexion**

It is possible that the user experiences a double action, or unwanted mid-stance flexion. This is mostly caused by the weight line passing posterior to the knee axis. This can be caused by either of the following:

- 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.

5.4 The controls
From the front Figure 22, are visible the ports that give access to the Stance Yield valve $S$, which is operable with a 2mm hex key, and the swing flexion resistance $F_2$. Valve $S$ sets the initial resistance to stance yield resistance, and supports a comfortable rate of knee flexion during stairs and slope descent. Naturally the well-established vortex fluidic control, that is the hallmark of the VGK range, operates also in the VGK-S to secure a stable knee flexion across a wide range of temperatures.

Valve $F_2$ is operable using a 2mm hex key through the access port, and is intended to be fully open for most users. However, some users may prefer more resistance to knee flexion and may prefer the valve to be partially closed.

From the back in Figure 23, are visible the valves $E_1$, $E_2$, $F_1$, each operable with a 2mm hex key. $E_1$ and $E_2$ operate together to provide extension resistance, but $E_1$ is closed off first during terminal extension, leaving $E_2$ to control the final terminal impact damping.

To optimise extension damping, $E_2$ is left fully open, and $E_1$ may be closed to enhance terminal impact damping. In case the foot and footwear have too much mass, and causes too much terminal impact force, $E_1$ may be partially closed to pre-decelerate the foot and reduce terminal impact force. The extension resistance is optimised as a balance between these two valves.

Turning $E_1$ clockwise increases terminal impact dampening, thus slowing down forward movement of the shin for the last 6° prior to full extension. Turning $E_1$ anti-clockwise reduces resistance, thus enabling the shin to come to full extension at a higher speed, and thereby enabling a more dynamic gait style. The total range from minimum to maximum setting, is about 2 total turns.

A low resistance, i.e. low terminal impact dampening could also benefit amputees who have been used to a prosthetic knee where a ‘hard return’ gave them the confidence to put weight on the leg.

Flexion resistance is primarily set by valve $F_1$, which is operated by a .8mm diameter tool. This valve may require up to 120 turns across its full range. The valve is factory set with minimal knee flexion resistance. To provide more knee flexion limitation, and hence more forward drive, the valve is turned as in Figure 24. The adjustment is slow due to design restrictions. Recommended is to turn the valve at first 40 strokes and assess with the patient the changes. Then repeat with another 40 strokes, and re-assess. This way the optimum can be found.

Turning to the left, reduces the maximum knee flexion angle, thus providing more heel rise. Turning to the right, provides less heel rise. The total range between the minimum and maximum setting is 140 swivel turns. It is essential that you count the number of swivel turns from either the left-most (most heel rise) or right-most (least heel rise) setting in order to get a reproducible setting. Default factory setting is fully turned right. Unfortunately there is 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 have required more weight and/or volume to the VGK-S, which
on purpose is optimized for low weight and high centre of gravity, requiring some compromise from the ease of setting for the technician.

A knee flexion lock provision Lf has been made by lever Lf, as in Figure 25, which in its ‘down’ position provides free swing, and in its ‘up’ position, a restriction to the natural swing resistance. The swing resistance will be equal to the stance resistance.

The stance resistance is set using valve S, as in Figure 21, which sets the rate of resistance, or using the lever Ls, as in Figure 26, which in the ‘down’ position, allows knee flexion under weight-bearing, or provides in the ‘up’ position a blocked stance flexion.

Depending on setting of lever Lf, locking the stance mode may lock off the swing mode too.

NB: ‘Locking’ means very high resistance as opposed to a ‘mechanical lock’!

5.5 Torqueing
The set screws in the female adapter are to be loctited / tread locked and torqued to 10 Nm.

5.6 Cosmetic Finish
Any cosmetic finish must allow free movement between the main frame and the top to ensure safe operation of the knee. See also paragraph 6.2.

6 Check points

6.1 Maximum Knee flexion
The VGK-S assumes a tube adapter that is chosen as to avoid interference with the piston and cylinder in fully developed knee flexion. The rubber posterior bar is the knee flexion stop against which the tube of the shin is to contact in full knee flexion, if the foot is not touching the socket first.

Under no circumstance is the tube adapter allowed to rest against any part of the hydraulic, and a minimum clearance space must be available of 10mm to allow for bunched up items of clothing.

Users 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.

6.2 Essential movement in mechanism
The top ‘thigh plate’ can move relative to the frame about the Q-axis, and this is not only normal, it is essential that it can do so. The range movement is small indeed, and is required to operate stance control.

This movement must remain free and uninhibited by cosmesis, glue, dust, particles, wedges, or anything else to cause inhibition of this free movement. Inform the user that this movement must be free. To demonstrate the effect of inhibition, a piece of thin cardboard may be inserted to
demonstrate how the unit will no longer enter into stance mode. On removal of the ‘offending’ cardboard, normal mode switching function is restored. A quarterly visual inspection of this movement is recommended, just in case of ingress of dust or dirt.

Do inform the user that ingress of sand, dog hair, and other foreign items must be prevented, or accidental ingress must be removed. In case of doubt, a planned inspection by the clinician is recommended.

6.3 Temperature
The VGK-S has been designed to operate optimally at 20 Celcius, but does have a wide range of operating temperatures (0-40°C) at which the unit works well: the knee joint compensates for fluctuations in the properties of the operating fluid in relation to temperature.

6.4 Compatibility
The VGK-S is understood to be compatible with the usual range of prosthetic components available on the market: feet, torque absorbers, adapters, rotators, socket locks, the use of foam cosmetics. It may be tempting to use the gains from proximal mass of the knee joint for insertion of other high mass components, that may soon undo the gains made.

There will be real benefit in raising the mass of any rotators/torque absorber as proximal as possible, and a calculation may be of benefit to assess whether an additional part is better placed at the location of the ankle, or at the expense of some additional adapters more proximal or if space permits, right on top of the shin tube.

Also, the choice of foot is best chosen to be light weight, in line with the needs of the S-TF amputee.

6.5 Use with Hip Joint
Experience to date has been with 7E7 hip joint, with hip extension assist set to maximum. This hip extension assist supports the engagement of the stance control of VGK-S when VGK-S attempts to inadvertently buckle. It is Important to ensure that the Q-axis is posterior to the hip axis and Knee axis.

Figure 27 shows the posterior placement of the Q-axis to the hip-knee line. The extension assist in the 7E7 (or equivalent action) operates the
Beware of tilting the VGK-S forward to align the VGK-S 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.

6.6 Essential Verification of Correct Installation
The VGK-S must feature the following as a minimum to ascertain a correct installation:

6.6.1 Certification of the Installer
The installer / CPO has obtained a Certificate from Orthomobility as evidence of minimal competency.

6.6.2 Stance Control Engagement
When body weight is applied to the heel of the foot when the limb is extended, the device gives high resistance to bending, or shows the function of the manual locked mode. 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) triggers the SAME high resistance mode. User has been encouraged to explore the sensitivity of this feature.

6.6.3 Swing Control Release
The knee reverts to swing phase on toe-off in normal gait, or reverts 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 Qm point, due to foot construction / shoe construction / alignment of Q line).

6.6.4 Posterior clearance
On full kneeling, no clothing nor clamps or other interfering material/ clothing places pressure onto the hydraulic mechanism. In Osseo Integration the shin-tube does ideally 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.

6.6.5 Comfort
Verify the user is comfortable with the swing phase settings with regards to a range of walking speeds, verify that the rate of yielding for use on slopes and stairs matches their sense of balance, check that manual locking handles are understood by the user.

6.6.6 In-Use monitoring
The User is to be instructed that in case of altered performance they contact the installer for advice. A first time installer is advised to monitor by means of review the first few installations to gain experience that is specific to their users.
7  VGK-S the Small Print

7.1  Identification of the Device
The VGK-S is manufactured by Orthomobility Ltd, UK, and the device can be identified by the engraved logo.

Its serial number is marked on the inside edge of the main frame.

7.2  Intended Purpose
The VGK-S is intended for use in the presence of short transfemoral amputation, where ‘short’ means the presence of available space / i.e. clearance to the distal amputation stump.

The VGK-S is also intended for use in hip disarticulation prostheses, provided the hip joint used has a hip flexion limiter or hip flexion limiting bias. (Do seek manufacturer assistance to verify latest experience and recommendations).

VGK-S can be used for Osseo integration, subject to users tolerating the fine free movement in the switching mechanism that could be felt in use.

7.3  Normal Use
The VGK has been developed for ordinary mobility use: walking, sitting, kneeling, cycling and occasional wetting by rain or tap water.

7.4  Recommended User Profile
The VGK joint is recommended for independent prosthetic users, typically of mobility classes K2, K3, K4 (as in endurance activity). The patient 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.

7.5  Managing Maximum body weight limitation on VGK-S
The VGK-S has been constructed to be as lightweight as possible and highly functional. That means, the design construction has focused on the use of a minimum amount of light-weight materials. This has been made further possible, by limiting the maximum body weight allowable on the prosthesis. Body weight is predominantly formed by bone, muscle and fat. Excess body weight is predominantly caused by excess fat. Fat is a body tissue that contributes very poorly to socket comfort and the
ability to wear a prosthesis, and the S-TF amputee would make a good choice in maintaining a body weight under 100 kg. The question is how to deal with S-TF amputees who despite limb loss are over 100 kg, and need to be mobile to lose weight, and need a VGK-S to do so. In order to deal with this situation, a health care plan must be made with the appropriate parties and funders. On approval of a plan, Orthomobility can approve of a limited time use of a VGK-S, to allow loss of weight to happen, and then after the permitted period is over, and the amputee has lost the agreed weight, then the VGK-S needs to be replaced by a new one, and depending on the progress the VGK-S needs replacing until the body weight is under 100 kg.

7.6 Non-ordinary and Extreme Use
Non-ordinary and extreme use may from time to time be required and known prior to the occasion. Here, a special reference to body weight must be made. The VGK-S has been designed to provide a lightweight as possible device, and therefore body mass is strictly limited to 100 kg. When users gain weight after being supplied with the VGK-S, such weight gain will be cause of exceeding the permitted body mass, and must trigger the ‘Managing Maximum body weight limitation on VGK-S’ process as described above, unless the user reduces weight below the limit within 30 days. Other extreme use may involve water and dirt, or shock and forceful use. Whereas these may be considered as part of intended use, in anticipation of such planned extreme use, it will be required that written permission is sought from the manufacturer so that such non-ordinary use can be risk assessed, supported, or on grounds of risk, be denied. A considered permission/denial/support program will be discussed on request.

7.7 Expectation Management
Advise your patient that this device, whereas designed to offer a service compatible with a high level of safety, the same high level of safety is liable to increase their expectations of their ability, and consequently your patient may ultimately find limits of performance of the device. When such an event happens, they are asked to remember the circumstances and report any event back to their CPO.

7.8 Extreme Device Settings
Whereas the VGK-S permits a high level of resistance in yield, this function is not intended to effectively lock the joint at certain knee angles over 30 degrees when significant weight is placed upon the leg: the hydraulic pressures could damage the device. This warning does not apply to ordinary ‘leg over leg’ use.

7.9 Extreme Temperatures
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 yield action of the joint, which in hands-free slope and stairs descent could cause an imbalance. In such a case it is advised to first try to walk down close to a handrail. In elevated temperatures (40 degrees plus) the VGK maintains its performance fairly well. Best practice is to make use of handrails wherever possible.

7.10 Prevention of Overheating
Prolonged walking down slope and downstairs will heat up the joint due to energy dissipation. The frame acts as a cooling fin, and using an open structure cosmesis will optimise the temperature of the VGK-S.
7.11 Wear And Tear
As with 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.

7.12 Dirt and Water
In the event of ingress of water and dirt, the VGK-S can be washed with water and if so required, with soap. Contact with salt water requires cleaning with tap water. It is important to make sure that no sand or stones are trapped between moving parts, as this may lead to system damage. In case of use in environments with loose particles, the use of a protective (fabric) cover is recommended.

7.13 Stairs
The use of handrails or banisters is recommended when descending downstairs.

7.14 Storage
The VGK-S must be stored in a fully extended position.

7.15 Warranty
Orthomobility Ltd. offers a limited two year warranty against defects in materials and workmanship in accordance with terms and conditions of sale. Defects arising from non-ordinary and extreme use, and fair wear and tear are subject to the manufacturer’s discretion. Warranty is subject to the certification obtained by the practitioner by passing the online test at time or prior to fitting the VGK-S.

7.16 Care and Maintenance
Due to fair wear and tear, the solid bearings may show wear and may need replacing from time to time. Please refer to www.orthomobility.com for more specific maintenance instructions.

7.17 Liability
As the use of a prosthetic device includes a necessary risk, the manufacturer limits the liability arising from the use of the VGK to that liability directly arising from a malfunction of the device due to faulty materials and/or workmanship and exclude any other special, incidental or consequential damages. For full details see Terms and Conditions on invoice. The practitioner must have passed the online test at time or prior to fitting the VGK-S to avoid liability arising from ignorance, and to be allowed to fit the product.

7.18 Training and Education
Orthomobility Ltd. continuously add new material of shared experience on their website, and clinicians are expected to check for new information to ensure continuous best practice with VGK.

For extended information visit: www.orthomobility.com
7.19 Declaration of Conformity
The VGK-S made by Orthomobility Ltd, Reg 5143375 conforms to the MDD Directive 2007/47/EC and 93/42/EEC and ISO 10328:2006. The use of VGK-S in conjunction with any osseo-integrated implant is understood to maintain the Class I status of the VGK-S, since the combination is a Custom-Made Device, subject to responsibilities of the assembler of the Custom-Made Device.

7.20 Ordering Numbers
VGK100S, with standard proximal pyramid receiver.

8 Short Transfemoral Amputation (S-TF) and Risk Assessment
For the benefit of supporting a balanced risk analysis in planning the VGK-S into the limb prescription, the following considerations can be made.

8.1 Reduced proprioception.
The amputee with S-TF has inherently poor control over the prosthesis due to poor connectivity between stump and socket, and compromised functional musculature within the amputation stump. This calls for a high functional knee joint to minimise risks. The higher the second moment of inertia (SMI), the higher the reactive forces and soft tissue displacement and skin shear stress, leading to either, discomfort and loss of proprioception and/or preference for use of low function knee components (typically less mass), or ultimately, low compliance with limb wear, use of crutches and consecutive damage to shoulders and palmar nerves, or wheelchair use. In other words, loss of proprioception induces error in foot placement and increases guesswork, and emotional fatigue in using the prosthesis, leading to lower levels of limb use compliance.

The VGK-S combines high functionality with low second moment of inertia, and reduces this risk.

8.2 Loss of suspension.
S-TF is a risk factor with regards to suction loss. Any contribution to false movement between socket and femur is associated with loss of suspension. Loss of suspension in suction sockets through influx of air can occur due to loss of skin contact with the socket wall. Loss of suspension increases the need for auxiliary suspension such as unwanted straps and belts, or the need to lower the activity level such that movements will not cause such loss of suction.

The low SMI of the VGK-S helps minimise unwanted separation of skin from socket wall.

8.3 Risk arising from Knee Operating Mechanism
Every knee has a mechanism to switch between Stance and Swing vice versa. One of these modes will be the default, and the other mode the activated mode.

Whereas default stance knee joints are very safe in use, the operating mechanisms often require residual bodyweight at toe off to operate the swing release whilst at the same time causing a resistive knee extension moment. This leads to fatigue and discomfort.
This contradiction is not present in default swing knee joints. However, these are mostly not compatible with stumble recovery because the body weight applied to the tripping toe does not normally trigger the stance mode. This leads to reduced safety.

The VGK-S is the only knee joint that features weight activated stance control and supports interruptible swing phase mode in case of a stumble. The swing mode can be overridden by hip extension, even in mid-swing. This leads to increased stumble recovery support.

However, with ultra-short S-TF amputation the effectiveness of reflex stumble recovery may be diminished, and the clinician is recommended to work with the user to estimate the level of stumble recovery that is potentially achieved given the actual (femoral) stump length at hand.

It has been found that in the case of hip disarticulation prosthesis the hip flexion limiting factors built into prosthetic hip joints can support the VGK-S stumble recovery support functionality.

### 8.4 Risk arising from over-estimating Stumble Recovery

The VGK-S relies on a simple, effective body of knowledge that nevertheless must be understood by both clinicians and users to gain a realistic expectation what the device can and cannot do. This knowledge base is detailed in the earlier parts of this manual. This knowledge base supports sensible anticipations of use modes in different environments. Good connectivity between socket and femur is naturally compromised by the short femur in S-TF amputation, bone lengths of 8cm from IT have been found compatible with stumble recovery, and this makes basis for suggesting the presence of Stumble Recovery Support. The CPO must study the theory as provided to minimise risk of undue expectation.

### 8.5 Femur being too short/soft tissue too bulky

Naturally attempts will be made to apply the VGK-S to yet shorter femoral lengths, and some fittings will yield intended result and others not, with respect to Stumble Recovery Support. One of the variables to bear in mind is the amount of soft tissue surrounding the residual femur, and naturally an abundance of soft tissue will further compromise bone length to socket width ratio, and effective femoral control over the socket. For this reason the Maximum weight limit of the VGK-S has been set to 100 kg. Management of over 100 kg weight users will be discussed elsewhere in this document.

In case of very short femur, the knee centre is best brought close to the socket as possible when compatible with user agreement.

### 8.6 Excess distal tissue

Some S-TF amputation stumps feature short femur and long soft tissue. Short femoral bone length may support choice of VGK-S, but long soft tissue may compromise the full effective operation as the VGK-S cannot be brought close enough to the hip joint. The user must decide with the clinician if the benefits of ‘low weight’ of the VGK-S outweigh the potential of less effective stumble recovery, and this cannot be made generic in this document.

### 8.7 Weak musculature and Stumble Recovery

Short amputation stumps may feature flexion contractures and associated loss of muscular control over the residual femur. This may affect Stumble Recovery Support. The user must decide with the
clinician if the benefits of ‘low weight’ of the VGK-S outweigh the potential of less effective stumble recovery, and this cannot be made generic in this document.

8.8 Risk from disregarding environmental factors
The VGK-S uses a small amount of free movement just distal to the socket, and this movement must remain free and is subject to occasional inspection and maintenance. There is a possibility that dust and dirt builds up over time in the operating gap, and regular inspection will help identify such a case. In such cases, a simple means such as using some compressed air to remove any build-up of dust and support a continuous normal function of the knee joint.

Similarly, ingress of sand must be prevented, and in case of beach activity be guarded for, and in case of doubt inspected for.

8.9 Risk from use in conjunction with other components
The VGK-S is understood to be compatible with a wide choice of other components such as feet, torque absorbers, socket technologies. If there is risk, it is likely to arise from conflict in alignment instructions, and in this case the instructions for alignment for VGK-S must take precedence.

8.10 Risk from operating temperature
The VGK-S has been designed to function normally with operating temperatures between 0 and 50°C. The thin walled aluminium frame acts like a large heat sink cooling fin, and is recommended to remain exposed as possible in the more dynamic user. Modest domestic use is unlikely to build up excess heat.

8.11 Lifetime Use
The VGK-S has been designed to operate without scheduled maintenance programs, and may need servicing as needs arise. There is a requirement that the VGK-S be stored in full extension.

8.12 Use with Osseo-Integration
Use in conjunction with an Osseo integrated implant constitutes a Custom-Made device. The implant itself is a Class III medical device. In order to assist the prescriber of the Custom-made device, the following considerations may be of assistance.

8.12.1 Osseo-Perception
The small amount of movement necessary to operate the Stance activation may cause irritation due to the known Osseo-Perception. Over time this may be become known and addressable.
8.12.2 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 flexing restriction. This assessment will then confirm that risks of bone fractures due to knee flexion stop mechanisms within the VGK-S are excluded.