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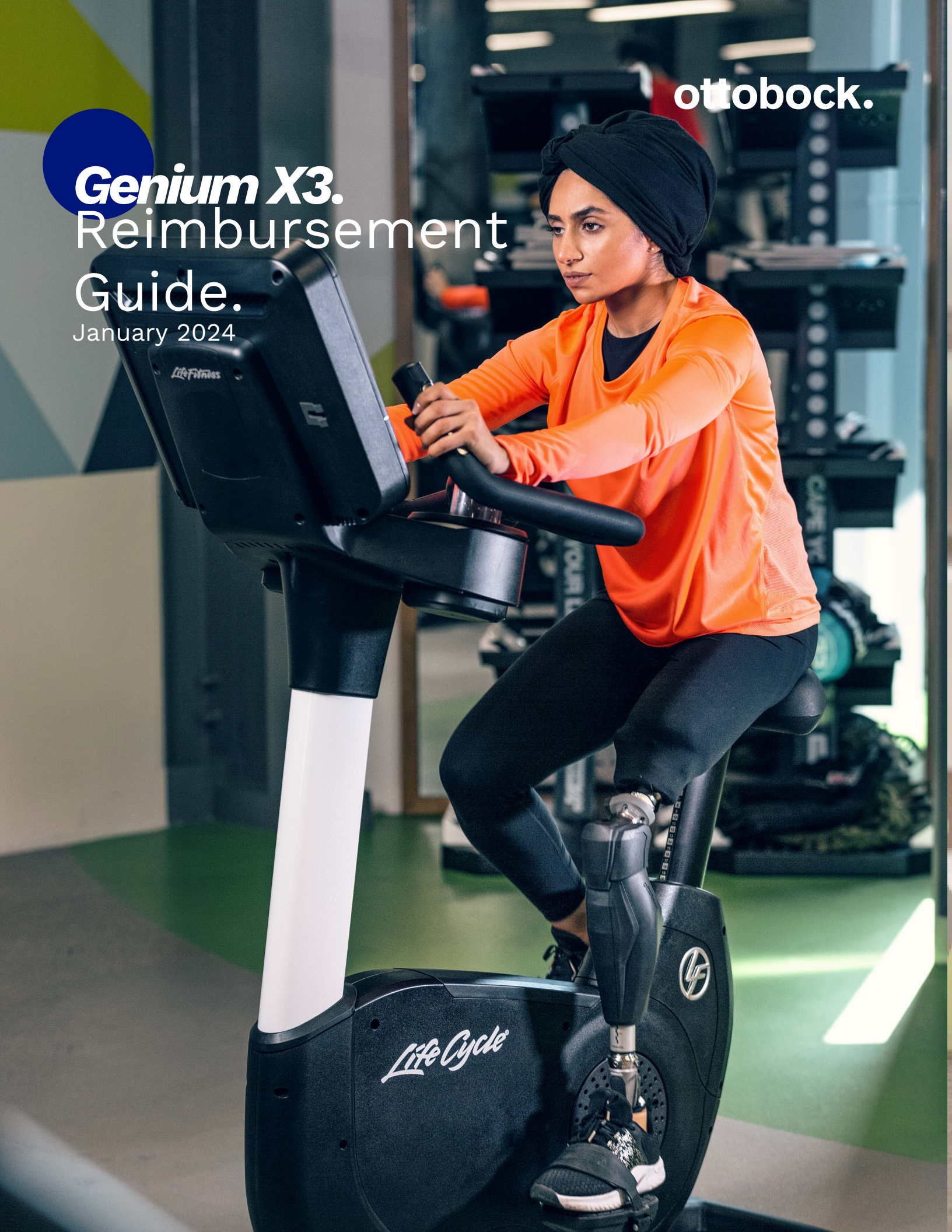
Genium X3. Reimbursement Guide.

January 2024



Genium X3.
Product Information.

The 3B5-3 *Genium X3* utilizes a complex sensory system including inertial motion unit (IMU) control with gyroscope and accelerometer, paired with optimized physiologic gait technology. The appropriate resistances are calculated using multi-modal proprioceptive inputs (including knee angle, knee angular velocity, ankle angular velocity, and ground reaction force components). As a result, the *Genium X3* is able to monitor the user's motion possibilities at any given time. Additionally, the *Genium X3* is rated for both IP68 (waterproof and completely submersible) and IP66 (protected from powerful water jets), is corrosion resistant and has running functionality.

FDA Status.

Under FDA's regulations, the *Genium X3* Microprocessor-Controlled Prosthetic Knee is a Class I device, exempt from the premarket notification [510(k)] requirements. The *Genium X3* prosthetic knee has met all applicable general control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21CFR part820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). The *Genium X3* prosthetic knee is listed under JOINT, KNEE, EXTERNAL LIMB COMPONENT; Listing Number is E253231, and Manufacturer Registration Number is 3005190268.

Health Canada Compliance.

This device meets the requirements of the Medical Device Regulations (SOR/98-282). It has been classified as a class I medical device according to the classification criteria outlined in schedule 1 of the Medical Device Regulations.

Warranty.

Genium X3 comes with a three-year manufacturer warranty (extendable to six years) which includes:

- Repair costs*
- Service inspection in months 12 and 24
- Service unit during the repair and service inspections

* Superficial damage and damage resulting from improper use, intent, negligence or force majeure are not covered. See *Genium X3* Warranty for details.

Who Can Provide a *Genium X3*?

The *Genium X3* is prescribed by a physician and may only be provided by a qualified Prosthetist that has received specific product training. Ottobock employs a team of orthotists and prosthetists to educate practitioners on fabricating and fitting our products. This includes in-person and online training, webinars, and technical bulletins. We also provide Cooperative Care Service**s** for the more challenging fittings, which includes on-site assistance with the fitting in conjunction with product qualification training for the practitioner.

Billing for the *Genium X3* (U.S.only).

[1] Coding

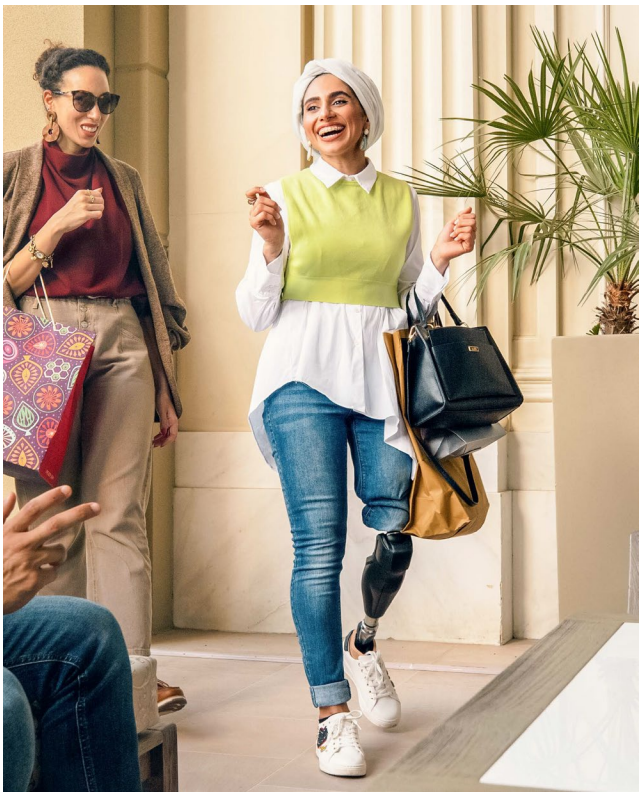
Currently, there is not an existing Healthcare Common Procedure Coding System (HCPCS) code to fully describe the *Genium X3* and miscellaneous code L5999 is available to use. We do not recommend billing *Genium X3* to Medicare until specific coding is secured.

[1] L5999 Addition to lower extremity endoskeletal system, Ottobock 3B5-3 *Genium X3* adaptive microprocessor-controlled swing and stance phase knee, with stance flexion; stance extension damping; simulated-physiologic rule sets, predicted by multi-modal proprioceptive input; loading flexed knee to traverse obstacles and stairs; dynamic stability control for all transitional gait (i.e. safe multidirectional movement in confined spaces, stance release on ramps, transition to running, weight compensation for stance release); inertial motion control unit feature for intuitive standing and backwards walking, IP 68 submersible, IP 66 waterjets, Running mode, plus 5 additional programmable modes, includes battery and charger.

[1] Short narrative description of L5999 for *Genium X3* for use on a claim:

[1] L5999 Addition to LL prosthesis Ottobock 3B5-3 *Genium X3* prosthetic knee, MSRP $_____

[2] Manufacturer Suggested Retail Price (MSRP) $138,000



[1] The product/device “Supplier” (defined as an O&P practitioner, O&P patient care facility, or DME supplier) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier’s responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier’s contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides do not replace the Supplier’s judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

[2] The manufacturer suggested retail pricing (MSRP) is a suggested retail price only. Ottobock has provided the suggested MSRP in the event that third party and/or federal healthcare payers request it for reimbursement purposes. The practitioner and/or patient care facility is neither obligated nor required to charge the MSRP when submitting billing claims for third party reimbursement for the product (s).

Genium X3.

Justification for L5999.

Hydraulic Swing and Stance Phase Knee.

Hydraulic swing phase control allows patients to vary cadence. The hydraulic fluid flows through narrow channels, providing a frictional resistance, which increases with the speed of compression; a faster gait speed allows quicker knee extension. The hydraulic also provides swing extension dampening to prevent a hard impact at terminal swing that may cause vibrations in the prosthesis and, as a consequence, an unsafe feeling in the patient.

Hydraulic stance phase control allows for knee flexion during weightbearing. This is necessary for walking with physiologic stance flexion on level ground, and natural step-over-step slope and stair descent and negotiation of uneven terrain. The hydraulic also provides sufficient knee flexion resistance for full weightbearing for "stumble recovery" during tripping.

Optimized Prosthetic Gait (OPG) with Pre-Flex.

Physiologic Rule Sets: The 3B5-3 *Genium X3* uses simulated physiologic rule sets with multi-modal proprioceptive input (six separate sensors) run by a state-of-the-art microprocessor. It significantly improves overall prosthetic function, especially ambulation, utility, social burden and well-being as well as the perceived difficulty and safety of many activities of daily living .

Unlike all other microprocessor-controlled knees that have to be (unphysiologically) fully extended at heel strike, the 3B5-3 *Genium X3*'s simulated physiologic rule sets allow optimized prosthetic gait (OPG) with a nearly physiologic pre-flexion of the knee at heel strike.

Pre-flexion allows for easier "riding into the knee" with a reduction of braking forces during walking (reduction of the feeling to have to "climb over the prosthesis") and easier use of physiologic knee stance flexion for shock absorption.

Foot-Flat: Pre-flexion facilitates earlier foot-flat and increased prosthetic weight bearing resulting in improved safety and more physiologic step-over-step gait pattern during slope descent.

Step-Over-Step: Pre-flexion supports easier and more physiologic step-over-step slope ascent by reducing the need to "climb up over the limb."

Pre-flexion facilitates a consistent positioning of the foot for step-over-step stair descent, resulting in more confidence and prosthetic side weight bearing.

Incline to Decline: The improvements in safety and gait patterns in slope ambulation also facilitate the negotiation of uneven terrain that is basically a permanent switchover between inclines and declines.

Obstacles and Stairs Function.

Obstacles: The 3B5-3 *Genium X3* allows for nearly normal stepping over bigger obstacles with the prosthetic leg first – the knee can be normally flexed, and the prosthesis be moved over the obstacle like taking a long step. *Genium X3* is safe while loaded bent past the obstacle. All other MPK´s require that the patient has to move the extended/stiff prosthetic leg around obstacle using circumduction, which is associated with a high risk of catching the toes, stumbling and falling.

The 3B5-3 *Genium X3* also enables nearly normal stepping over bigger obstacles with the sound leg first. Using this function of *Genium X3*, the trailing prosthetic leg can be normally bent and moved over the obstacle. All other MPK´s require that the patient moves the trailing extended/stiff prosthetic leg around the obstacle using circumduction or to hop forward on the sound leg and drag the stiff prosthetic leg over the obstacle. Both ways are associated with a substantial risk of catching toes, stumbling, and falling.

Stair Ascension: The 3B5-3 *Genium X3* allows for ascending stairs in the natural step-over-step manner with a prosthetic knee that bends to maximize clearance of the stair with each step. In the walk upstairs mode, the bent prosthetic knee produces enough flexion resistance that the patient can use the prosthesis as a counter bearing to lift his/her body up to the next step using his/her hip and residual limb muscles. The conventional method for ascending stairs with a prosthetic knee is to take two steps at a time with the sound-side limb and ascend stairs with a straight knee on the prosthetic side, which results in a significant strain to the sound limb joints and muscles.

Dynamic Stability Control.

Multi-Directional Walking: The *Genium X3* allows for safe multi-directional motion and transitional gait by controlling the switch from stance to swing. Thus, it significantly improves overall prosthetic function, especially ambulation and utility as well as the perceived difficulty and safety of many activities of daily living.

Crowds and Confined Areas: The *Genium X3* also provides stability in crowds and confined areas, because of its ability to reliably transition from stance into swing phase while taking small and shuffling steps.

Walking Speed: The *Genium X3* also offers an optimized swing phase control with a nearly physiologic swing knee flexion angle of 64° independent of walking speed. This provides improved toe clearance in slower walking speeds as well as timely shank swing in higher walking speeds – that patient doesn´t have to wait for a lagging shank to swing forward.

Slopes: The optimized swing phase control also results in increased knee flexion and thus toe clearance and safety when ascending and descending slopes.

Walk2Run feature: The *Genium X3*'s knee joint is able to detect transition from walking to running automatically while in basic mode and reacts accordingly, by switching into a larger swing phase angle suited for running (higher swing flexion angle, decreased swing extension resistance, with no Preflex behavior). This innovative Walk2Run mode is ideal for running short distances and start-and-stop running such as across a street, down the hall or to catch a bus.

Inertial Motion Unit (IMU)

The Inertial Motion Unit (IMU) consists of a separate microprocessor that processes the information of a 3D-gyrosocope and a 3D-accelerometer to calculate the position and movement directions of the prosthesis to feed it into the main microprocessor board of *Genium X3*.

Intuitive Stance: This patented technology allows the patient to intuitively stand on a flexed and stable knee on level, uneven, or inclined surfaces (ramps or hills). The user does not need to activate or deactivate the stance function; both occur intuitively. Stance function is ended with a simple step (prosthesis side or sound side). With traditional prosthetic knees it is imperative that the user cognitively ensure at all times that the center of mass stays ahead of the knee axis in order to prevent unexpected flexing of the prosthetic knee, which can cause the knee to collapse. In this situation, the user will uncomfortably stand with the hip extended in order to attempt to stabilize the knee.

Backwards Walking: This IMU also provides stability when taking steps backwards. Traditional microprocessor knees do not accommodate backward walking, because the knee is programmed to go into swing when the toe is loaded, causing the knee to collapse when stepping backward.

Stumble Recovery Feature.

The *Genium X3* provides resistance if the toe catches during midswing. As soon as the knee stops flexing and maximum heel rise is achieved, this feature is immediately activated; thus, if at any point the toe catches a supporting resistance is available. This allows patients enough time to bring their contralateral side through to catch themselves, thus preventing a fall and keeping it at controlled "stumble." This resistance is angle dependent, meaning it will provide additional resistance compared to normal stance phase resistance. The further the knee bends (or the further the patient is into the fall) the higher the resistance that will be provided.

Stance Flexion Yielding.

More Natural Gait Pattern: When the prosthesis initially contacts the ground, this feature allows the patient to mimic the natural gait pattern by loading the knee in a flexed position. Benefits include **shock absorption**, reducing the modulation of the center of gravity throughout the gait cycle, **energy efficiency** (less energy spent on "pulling back" on hamstrings to lock a fully extended knee), and an overall more natural gait pattern. Hip and lower back stress will also be minimized.

This feature also allows patients to "ride" the knee (the knee supports patients' weight on flexed knee without buckling and lowers them into desired position) when sitting into a chair, kneeling, and when descending stairs and slopes.

Stance Extension Damping.

After the knee is flexed during stance phase (stance flexion), it needs to extend again to advance the body forward through mid- and terminal stance. This feature provides increased resistance to this extension. Without this dampening the patient will feel a pronounced "snap back" or "jerk" at the knee that may cause a feeling of insecurity, and will also present with an unnatural looking gait pattern. Energy is conserved by having this feature, as the patient will not have to attempt to use hamstrings to control this motion.

Running Mode.

The *Genium X3* has a Running Mode in addition to the Walk-to-Run function provided by the Dynamic Stability Control feature. The Running Mode is selected via the Cockpit App and will stay in running mode until deselected, which is preferred for longer distances. In this case appropriate running feet (e.g. 1E90 Sprinter) or feet with axial compression (e.g. 1C61 Triton Vertical Shock) are required.

Swimming and Showering.

The 3B5-3 *Genium X3* is ideal for patients working in or near water and allows unprecedented contact with water including showering, swimming, boating, fishing and more.

Submergible: The 3B5-3 *Genium X3* has undergone stringent testing and is water and corrosion resistant (IP 68), which allows the prosthesis to be submerged.

Waterjets: The 3B5-3 *Genium X3* can be exposed to stronger jets of water as well (IP66). As a result, the *Genium X3* can be thoroughly rinsed after spending time in chlorinated or salt water.

Corrosion Resistant: The 3B5-3 *Genium X3* is constructed with corrosion resistant materials (titanium, hard anodized aluminum, stainless steel, coatings).

Rugged Protection.

The **Rubber Protector** on the 3B5-3 *Genium X3* was designed in cooperation with users at Walter Reed and Brook Army Medical Centers and protects the joint against impacts and scratches. The *X3* protector can be replaced by the user if worn out.

Additional Features.

Supported Ramp Descent: Stance flexion on the 3B5-3 *Genium X3* increases resistance as the knee angle increases. This causes a slower and more controlled walking down ramps and stairs

Deliberate Stance Function: When enhanced stability is needed (e.g. bilateral, hip disarticulation, etc.), the 3B5-3 *Genium X3* has a deliberate stance function feature that can be programmed by the prosthetist. Deliberate stance function is initiated by simply holding the prosthesis still for just 125 milliseconds. This stance function is ended when the user takes the weight off the prosthesis or extends it slightly.

Supported Sitting Function: Flexion resistance on the 3B5-3 *Genium X3* can be set to be increasing or constant depending on the patient's need.

Activity Report: The provider can track and document the user's progress towards rehabilitation goals. The tracking system can also be used to satisfy reimbursement requirements or optimize service of the device.

Patient App: The 3B5-3 *Genium X3* has a Cockpit app compatible with both Android and iOS phones. With this app the user can switch between activities. The Cockpit app also allows the user to check battery life and view step counts.

Genium/ *Genium X3* microprocessor knee.
Evidence Summary.

	Mobility need or deficit of the patient	Evidence for benefits of the *Genium* compared to an MPK billed with L5856
Activities of daily living (ADL)	Restrictions to performing activities of daily living	*Genium* significantly improves overall performance in activities of daily living; difference to able-bodied subjects was no longer statistically significant.
Level walking	Restrictions to walking longer distances	*Genium*'s pre-flex function reduces the perception of having to "climb over the prosthesis" at loading response, reduces braking forces during level walking making it easier to "ride into the knee" and use stance flexion for shock absorption. Improved swing control provides more consistent knee swing flexion (=toe clearance) across all walking speeds.
Walking with heavy footwear	Patients has to walk with heavy footwear (e.g. hard-toed shoes or boots) on a regular basis	*Genium*'s swing control is able to compensate for additional distal weight and provide sufficient knee swing flexion (=toe clearance).
Multi-directional ambulation and walking with small steps	Patient has to ambulate in confined areas and/or with small steps on a regular basis	*Genium* provides more reliable swing release and swing knee flexion (=toe clearance) in small steps. Greater self-reported ease of walking with small steps and executing ADLs with multi-directional movements.
Slope ambulation / uneven terrain	Difficulties to negotiate slopes / uneven terrain and/or considerable compensatory movements when walking on slopes / uneven terrain (uneven terrain = permanent switch between inclines and declines)	*Genium* improves self-selected walking speed and quality of slope descent (decreased reliance on handrail use) and provides increased knee flexion at initial contact and in swing phase (=toe clearance) during slope ascent and descent. Its pre-flex function also supports more physiologic and symmetric slope descent with higher prosthetic side weight bearing and step length. Greater self-reported ease of slope ascent and descent.
Stair negotiation	Difficulties to negotiate stairs and/or considerable compensatory movements when walking on stairs	More consistent positioning of the foot on the stair and increased prosthetic side weight-bearing during stair descent. Ability to walk upstairs step over step with unloading of the sound knee and more natural appearance. Greater self-reported ease of stair ascent and descent. The walk-upstairs function can also be used for stepping over bigger obstacles without cumbersome and dangerous compensatory movements.
	Mobility need or deficit of the patient	**Evidence for benefits of the *Genium* compared to an MPK billed with L5856**
Gait symmetry and unloading of the sound limb and spine	Patient suffers from pain in the joints of the sound limb and/or low back pain	*Genium* allows for a more natural gait, greater gait symmetry, and makes it easier to ride into the knee and use knee stance flexion for shock absorption. Increased symmetry of gait is an indicator of more even load distribution and may thus reduce short- and long-term comorbidities of the sound limb and spine.

Standing	Patient needs to stand for extended periods of time on a regular basis and has difficulties to do so	*Genium* has an intuitive standing function that automatically locks for standing and allows for significantly higher prosthetic side weight-bearing and thus more relaxed standing.
Walking backwards	Patient needs to walk backwards on a regular basis and has fallen repeatedly or has to use compensatory movements for safe backwards walking	*Genium* recognizes the direction of movement and prevents the knee from collapsing when walking backwards.

Activities of daily living (ADL) and overall mobility.

- Pre-flexion, intuitive stance function, obstacle and stairs function, and safe walking backwards provide the basis for improving the overall performance in 10 ADLs with *Genium* measured by the validated Physical Functional Performance assessment (PFP-10; p=.03) (2, 16).
- *Genium* significantly improved the Upper Body Function (p=.01), Balance (p=.03) and Endurance (p=.02) subscores of the PFP-10 compared to *C-Leg* (2, 16).
- The PFP-10 total score and its Upper Body Function, Upper Body Strength, Lower Body Strength and Balance subscores were no longer significantly lower with *Genium* compared to those of able-bodied individuals. Only the Endurance subscore was significantly lower in *Genium* users compared to able-bodied subjects (2, 16).
- *Genium* significantly improved the functional performance as measured by the Amputee Mobility predictor (AMP, p≤.001) (1, 16).
- *Genium* significantly improved the step-activity-derived functional level (SAD-FL, p=.01) (1, 16).
- Based on the significant improvements in ADL performance balanced with the difference in cost between *Genium* and *C-Leg,* the *Genium* was found to be a cost-effective prosthetic intervention (1, 16).

Walking longer distances.

- Pre-flexion allows for easier “riding into the knee” with easier use of physiologic knee stance flexion for shock absorption (5, 6, 9, 16) and a reduction of braking forces during walking (reduction of the feeling to have to “climb over the prosthesis”). Research has shown that mean knee stance flexion for shock absorption is 2-4° higher with *Genium* than with *C-Leg* over all walking velocities (5, 6, 9), reaching statistical significance for slow (p=.01) and normal walking speed (p=.02) (5). Mean vertical and horizontal ground reaction (braking) forces are reduced for medium and fast walking speed (6, 9, 16). The reduction of braking forces makes it easier to walk longer distances.
- The *Genium* offers an optimized swing phase control with a nearly physiologic swing knee flexion angle of 64° independent of walking speed. This provides improved toe clearance in slower walking speeds as well as timely shank swing in higher walking speeds – that patient doesn´t have to wait for a lagging shank to swing forward (6, 9, 16). The improved swing control also supports to walk longer distances.

Improved and consistent toe clearance across all walking speeds and with heavy footwear.

- The *Genium* offers an optimized swing phase control with a nearly physiologic swing knee flexion angle of 64° independent of walking speed. This provides improved toe clearance in slower walking speeds as well as timely shank swing in higher walking speeds – that patient doesn´t have to wait for a lagging shank to swing forward (6, 9, 16). It is also able to compensate for an additional 500 g (16.6 Oz) weight simulating heavy shoes or boots. Peak knee swing flexion increases by a significant 3-6° ($p \leq .02$) for all walking speeds, ensuring adequate toe clearance (5, 16).

Improved negotiation of slopes and uneven terrain.

- Pre-flexion improves self-selected walking speed ($p = .041$) and quality of slope descent ($p = .026$), mainly due to reduced reliance on handrail use (4, 16).

- Pre-flexion facilitates significantly increased prosthetic leg weight-bearing during slope descent, represented by a significant 12% increase in the knee stance flexion moment ($p < .05$) (4, 6, 9, 16) and a significant 3-4° increase in knee flexion peaks with *Genium* as compared to *C-Leg* (5). This results in a more physiologic and symmetric step-over-step gait pattern with unloading of the sound limb (3, 5, 6, 9) and improved perceived ease ($p = .002$ and $p < .03$, respectively) (7, 8) and safety of slope descent (8, 16).

- Pre-flexion also supports easier and more physiologic and symmetric step-over-step slope ascent by increased prosthetic knee stance flexion and weight-bearing (3, 5), reducing the need to “climb up over the limb” (3, 5-9). Consequently, ascending slopes and hills was rated significantly easier ($p < .001$ and $p < .02$, respectively) and considerably safer with *Genium* as compared to *C-Leg* (7, 8, 16).

- The optimized swing phase control results in increased knee flexion and thus toe clearance and safety when ascending and descending slopes (4-9). Compared to *C-Leg*, knee swing flexion during slope ambulation with *Genium* is significantly increased by 8-9° ($p < .01$) in slope descent and 3-8° ($p < .01$) in slope ascent (4, 5, 6, 9), thus ensuring improved toe clearance and longer prosthetic side step length (4, 16).

- The improvements in safety and gait patterns in slope ambulation also facilitate the negotiation of uneven terrain that is basically a permanent switchover between inclines and declines. Thus, patients rated walking on uneven and unknown terrain considerably easier and safer with the *Genium* as compared to using a *C-Leg* (8, 16).

Improved negotiation of stairs and bigger obstacles.

- Pre-flexion facilitates a consistent positioning of the foot for step-over-step stair descent, resulting in more confidence and prosthetic side weight-bearing, represented by a significant 15% increase ($p < .05$) in the prosthetic side knee flexion moment (6, 9). Consequently, patients rated the ease of descending stairs significantly greater with *Genium* than with *C-Leg* ($p = .019$ and $p < .03$, respectively) (7, 8).

- *Genium* allows for ascending stairs in the natural step-over-step manner with a prosthetic knee that bends to maximize clearance of the stair with each step (1, 6, 8, 9-12). In the walk upstairs mode, the bent prosthetic knee produces enough flexion resistance that the patient can use the prosthesis as a counter bearing to lift his/her body up to the next step using his/her hip and residual limb muscles (6, 8, 9-12, 16). The conventional method for ascending stairs with a prosthetic knee is to take two steps at a time with the sound limb and drag the prosthetic leg up (“skip-step”), which results in a significant strain to the sound limb joints and muscles (9-12). Research has shown that most above-knee amputees are able to walk upstairs

step overstep with the *Genium*, resulting in a movement pattern that clearly approximates that of non-amputated subjects (6, 9-12). With the conventional prosthetic knees, including *C-Leg* (10 out 14 patients), the median score on the Stair Assessment Index (SAI) was 5, representing step-to-step pattern (one step with the sound limb at a time) without handrail use. With the *Genium*, the median SAI score improved significantly to 11 (p=.005), representing a step-over-step pattern with handrail use (1, 10). Participants were also more symmetrical while using the *Genium* to include more similar peak knee and hip flexion during swing and peak hip power generation during push-up when comparing between the prosthetic and the sound limb (10). The extent of movements of the knee and hip of both legs while ascending stairs with the *Genium* was very similar to that of healthy subjects after only 1 day (9, 11) and further improved and became more consistent after accommodation of 3 months (6). When compared to the conventional skip-step method, the loading of the sound knee, demonstrated by the maximum knee extension power, was significantly reduced by 12% (p<.05). The mean maximum residual limb extension power during step-over-step stair ascent with *Genium* was comparable with the leg extension power in sound subjects (9, 11). Consequently, patients rated the ease of walking upstairs significantly greater (p=.04) with *Genium* than with a *C-Leg* (8, 16).

- The *Genium* allows for nearly normal stepping over large obstacles (8) with the prosthetic leg first – the knee can be normally flexed, and the prosthesis be moved over the obstacle like taking a long step. Using this function, *Genium* is safe in a loaded and bent position when landing past the obstacle (6, 9-12, 16). All other MPK´s require that the patient move the extended/stiff prosthetic leg around obstacle using circumduction, which is associated with a high risk of catching the toes, stumbling and falling.

- The *Genium* also enables nearly normal stepping over large obstacles (8) with the sound leg first. Using this function of *Genium*, the trailing prosthetic leg can be normally bent and moved over the obstacle (6, 9-12, 16). All other MPK´s require that the patient move the trailing extended/stiff prosthetic leg around the obstacle using circumduction or to hop forward on the sound leg and drag the stiff prosthetic leg over the obstacle. Both ways are associated with a substantial risk of catching toes, stumbling, and falling.

- The benefit of the obstacle function is reflected by a significant improvement in the completion time of the Four Square Step Test (FSST), a validated outcome measure for the risk of falling in higher functioning amputees (p=.04) (1, 16). The test requires stepping over crutches on the ground with both the sound and prosthetic leg first.

Improved multi-directional ambulation walking with small steps.

- *Genium* allows for safe multi-directional motion and transitional gait by controlling the switch from stance to swing. Thus, it significantly improves overall prosthetic function, especially utility (7) as well as the perceived ease and safety of many activities of daily living (8, 16).

- *Genium* provides a considerably more reliable swing initiation for improved toe clearance in small and shuffling steps, as needed for ambulation in crowds and confined spaces (5, 9). The mean maximum knee swing flexion angle in small steps with *Genium* is a significant 5.4° greater (p<.05) than with *C-leg* (6, 9), thus ensuring greater toe clearance. Consequently, walking with small steps and in close spaces is rated significantly easier (p=.025) and considerably safer with *Genium* than with a *C-leg* (7, 8, 16).

More natural gait, improved gait symmetry, unloading of the sound limb and spine.

- Unlike all other microprocessor controlled knees that have to be (unphysiologically) fully extended at heel strike, these simulated physiologic rule sets allow *Genium* for optimized prosthetic gait (OPG) with a nearly physiologic pre-flexion of the knee at heel strike (5, 6, 9). Compared to the *C-Leg,* this results in increased symmetry of gait (step length) at all walking velocities, reaching statistical significance ($p<.05$) for very slow, slow, and medium walking speeds (5, 6, 9, 16). Increased symmetry of gait is an indicator of more even load distribution between the prosthetic and sound limbs and may thus reduce long-term comorbidities of the sound limb and spine (13, 16).

- Pre-flexion allows for easier "riding into the knee" with easier use of physiologic knee stance flexion for shock absorption (5, 6, 9) and a reduction of braking forces during walking (reduction of the feeling to have to "climb over the prosthesis"). Research has shown that mean knee stance flexion for shock absorption is 2-4° higher with *Genium* than with *C-Leg* over all walking velocities (5, 6, 9), reaching statistical significance for slow ($p=.01$) and normal walking speed ($p=.02$) (5). Mean vertical and horizontal ground reaction (braking) forces are reduced for medium and fast walking speed (6, 9, 16).

- *Genium* significantly improves overall prosthetic function, especially utility, social burden, perceived response and well-being (8) as well as the perceived ease and safety of many activities of daily living (7, 8, 16).

- Compared to individuals with transfemoral amputation who used mechanical knee joints or *C-Leg*, users of the *Genium* demonstrated the best correction of kinematic and kinetic gait deviations and compensatory mechanisms (15).

Improved ability to stand still for longer periods of time.

Genium allows the patient to intuitively stand on a flexed and stable knee on level, uneven, or inclined surfaces (ramps or hills) (7-9). The user does not need to activate or deactivate the stance function; both occur intuitively. Stance function is ended with a simple step (prosthesis side or sound side) (7). With traditional prosthetic knees it is imperative that the user cognitively ensure at all times that the center of mass stays ahead of the knee axis in order to prevent unexpected flexing of the prosthetic knee, which can cause the knee to collapse. In a study, prosthetic leg weight-bearing and mean sagittal knee flexion moment while standing on a 10° slope with *Genium* were significantly increased by 85% or 92%, respectively ($p<.05$ each), while the prosthetic side mean hip moment was reduced by 69% compared to standing with a *C-Leg*. Also, prosthetic side postural sway was significantly reduced ($p<.01$) when standing on the *Genium* as compared to a *C-Leg* (9). This means that the user is able to stand longer periods of time in a more relaxed manner with *Genium*, by loading the prosthesis with significantly more weight while requiring much less hip force to stabilize the prosthesis and being able to unload the sound limb at the same time (9). These objective findings have been supported by self-reported outcomes in the corresponding items of the Prosthesis Evaluation Questionnaire (PEQ) and an Activity of Daily Living Questionnaire, confirming the significantly increased perceived ease of standing still for longer periods of time (7, 8, 16).

Safe walking backwards.

- *Genium* provides stability when taking steps backwards. Traditional microprocessor knees do not accommodate backward walking, because the knee is programmed to go into swing when the toe is loaded, which may cause the knee to collapse when stepping backwards. Being that the *Genium* reliably detects the direction in which the prosthesis is moving in real time, there is no danger of the knee collapsing while walking backwards. This was confirmed in a study surveying patients and the perceived ease and safety of activities of daily living. Walking backwards was rated significantly easier (p=.04) and considerably safer when using the *Genium* as compared to the *C-Leg* (8, 16).

Results of 899 trial fittings with *Genium* in Germany.

- Based on the prosthetists' assessment, more than 85% of patients benefit from *Genium* in the domains of safety, ability to vary walking speed, ability for divided attention during walking, unloading of the sound limb, necessary effort to walk, and gait symmetry compared to previous *C-Leg* use (14).

- Based on the patients' self-assessment, they benefit from *Genium* in walking up and down stairs, clearing larger obstacles, walking up and down slopes, standing for longer periods of time on level surface or slopes, varying walking speed, walking with small steps, walking backwards, carrying heavy loads, and in activities in confined spaces such as in the bathroom, compared to previous use of the *C-Leg* (14).

- It turned out to be impossible to predict success (additional benefits) or failure (no additional benefits) of *Genium* fitting compared to *C-Leg* use. A multitude of patient characteristics including but not limited to age, mobility grade, amputation etiology, time since amputation, comorbidities, and many others (26 in total) failed to demonstrate any predictive value whether or not a patient would benefit from *Genium* as compared to *C-Leg* (14).

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