ottobock.

Meridium.

Reimbursement Guide.

Product Information.

The Meridium microprocessor-controlled prosthetic foot is designed for transtibial and transfemoral prosthetic users, both limited and full community ambulators.

The Meridium utilizes a complex sensory system (including an inertial motion unit) along with sophisticated rule sets that allow for real-time adaptive adjustments to the user's walking speed and ground conditions, whether on slopes, stairs or varying terrain including an intuitive standing lock on all surfaces. This occurs over the full ROM (14 degrees dorsiflexion and 22 degrees plantarflexion). This is a big plus for the user during everyday activities, making both greater flexibility and enhanced stability possible.

HCPCS Code [1, 2] (U.S. only)

L5973

Endoskeletal ankle foot system, microprocessor-controlled feature, dorsiflexion and/or plantar flexion control, includes power source.

Warranty

Three-year manufacturer warranty (extendable to six years); Repair costs are covered except for those

associated with damages resulting from improper use. Service inspection is required within 36 months (and within 72 months for six-year warranty).

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.

Who Can Provide a Meridium?

The Meridium 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 training, online training, webinars, and technical bulletins. We also provide Cooperative Care Services for the more challenging fittings, which includes on-site assistance with the fitting in conjunction with product qualification training for the practitioner.

FDA Status

Under FDA's regulations, the Meridium is a Class I medical device and exempt from the premarket notification [510(k)] requirements. Given the low risk of Class I medical devices, FDA determined that General Controls are sufficient to provide reasonable assurance of the device's safety and effectiveness; therefore, safety and effectiveness research is not required for this device. The Meridium has met all the 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 Meridium is listed under External Limb Prosthetic Component; Product Code ISH; Listing Number E253230.

[1] The product/device "Supplier" (defined as an O&P Practitioner or O&P patient care facility) 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's suggested retail pricing (MSRP) is a suggested retail price only. Ottobock has provided the suggested MSRP if 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).

Justification.

Real-time Adaptation over full Range of Motion

Separate control of dorsiflexion (14°) and plantarflexion (22°).

4 – Axis Kinematics

The Meridium's 4-axis design allows movement of ankle, foot and separate toe section resulting in excellent adaptability, more like natural gait and reduced need for compensatory movements

Walking Speed changes

Real-time adaptation combined with Meridium's 4-axis design provides almost natural rollover, resulting in better control of walking speed.

Compare this to conventional prosthetic feet which have stiff ankles and only partially mimic the function of an ankle joint.

When the user changes walking speed, the dorsiflexion resistance automatically adjusts itself to the change in forces, allowing the user to easily vary gait speed without feeling any change in the foot's behavior.

Increased Foot clearance during swing

During the swing phase, the foot remains in the dorsiflexion position to provide greater ground clearance, which in turn requires less compensatory movements and allows better gait symmetry. This prevents the tip of the foot from getting caught and may help to reduce stumbles and falls.

Walking on Uneven Ground

The advantages of real-time adjustment are particularly evident on uneven surfaces such as cobblestones, grass, forest paths, and other similarly structured surfaces. With every step, the dorsiflexion and plantar flexion angles are fully and immediately adapted to the walking surface. The improved contact with the ground increases the user's safety.

Smaller obstacles are therefore no longer perceived as a problem, but rather as if they had been smoothed over.

Stairs

The Meridium recognizes the movement pattern when walking on stairs and adjusts both dorsiflexion and rollover angle, in real time, step by step.

This allows up to full surface contact meaning that on stairs the patient doesn´t have to roll over the edge of the step anymore which provides additional stability. Benefit to the user is enhanced safety and stability.

Expanded Full-Surface Contact with the Ground

Meridium allows for expanded, full-surface contact with the ground for improved stability and traction when walking on level ground, uneven terrain, and slopes.

Compare this to mechanical feet which have always represented a compromise between flexibility and stability.

Individually adjusted plantar flexion resistance allows the foot to lower itself according to the gait situation with every step.

Hydraulic resistance is adjusted during initial ground contact to achieve a comfortable heel leverage adapted to the user's stride length.

Walking on Hills and Slopes

Plantar flexion and rollover are adjusted in real time according to the incline and dorsiflexion resistance supports consistent rollover across the wide range of motion.

With each step, the foot moves to a full-surface (flat on the ground) position as the user walks up or down the slope.

Real-time adjustment and wide range of motion allow the user to place an equal load on both legs and enables a more uniform gait symmetry.

When descending a slope, this full-surface contact prevents undesired acceleration, providing additional safety. The user also finds it easier to control knee flexion, because less flexion moment occurs.

The dorsiflexion position also provides greater ground clearance when walking up slopes. This prevents the tip of the foot from getting caught and may help to reduce stumbles and falls.

Backwards Walking

The Meridium adapts in real-time to the movement pattern when walking backwards. Controlled lowering of heel down to the ground for full foot flat and ease of rolling over backwards.

Intuitive Stance

Meridium can differentiate between walking and standing based on the situation.

Meridium provides intuitive stance on both level ground and slopes, and the user maintains the same level of stability in either case. Dorsiflexion is locked for stable standing and immediately returns to adaptation for walking once movement is sensed.

Relief Function

This function automatically lowers the foot to the floor when a load is placed on the heel for a prolonged period and allows the foot to be flat on the floor while sitting or standing. Helpful when in areas with minimal legroom, such as public transportation, or theaters, and cinemas.

Evidence Essentials.
Microprocessor-Controlled Hydraulic Ankle-Foot.

	Mobility need or deficit of the patient	Evidence for benefits of the Meridium or other hydraulic or MP ankles compared to standard feet
Safety	Patient trips and falls repeatedly	- **Significant improvement in minimal toe clearance** (De Asha et al., 2014; Rosenblatt et al., 2014) - **Significant increase in minimal toe clearance during slope ascent** (Lamers et al., 2019) - **Reduction of the risk of tripping over an unseen obstacle of 5 mm (1/5 in) height from 1 in 166 steps to 1 in 3,169 steps** (Rosenblatt et al., 2014) - **Patient reported improved perceived safety and balance as well as 35% fewer stumbles and 23% fewer falls with Meridium** (Hahn et al., 2018)
Mobility	Patient feels limited or restricted in his/her overall mobility	- **Cross-sectional study found that users of MP controlled ankles had significantly higher overall mobility compared to users of other types of prosthetic feet** (Wurdeman et al., 2019) - **Significant increase in self-selected walking speed and walking distance in K2 patients** (Barnett et al., 2018) - **Significant improvement in overall patient-reported prosthetic function in K2 and K3 patients as measured with the PEQ** (Kaluf et al., 2020; Moore et al., 2017)
Mobility	Patient has difficulty negotiating uneven terrain	- **Significantly improved gait symmetry and reduction in kinematic and kinetic gait deviations and, thus, unloading of the locomotor system** (Bai et al., 2017; Schmalz et al., 2019) - **Patients perceived walking on uneven terrain as safer and easier** (Bai et al., 2017; Hahn et al., 2018)

Mobility	Patient feels limited or restricted in ambulating on level ground	- **Significant reduction in braking forces ("dead spot phenomenon") in level walking with consecutive significant increase in self-selected walking speed** (De Asha et al., 2013A and 2014) - **Significant reduction in kinetic compensations of the sound limb** (De Asha et al., 2013B) - **Significantly improved gait symmetry and reduction in kinematic and kinetic gait deviations in K2 and K3 as well as bilateral patients** (Moore et al., 2016) - **Significantly reduced metabolic energy consumption** (Askew et al., 2019; Delussu et al., 2013)
Mobility	Patient has difficulty ascending and descending stairs	- **Improved gait symmetry and reduction in kinematic and kinetic gait deviations during stair ascent and descent and, thus, unloading of the locomotor system** (Alimusaj et a., 2009)
Residual limb health	Patient suffers from residual limb pressure sores or ulcers due to frequent ambulation on non-level surfaces	- **Significant reduction in interface pressures between the residual limb and the socket when walking on level and uneven terrain, slopes and stairs** (Moore et al., 2018; Portnoy et al., 2012; Wolf et al., 2009) - **Significantly improved socket comfort when walking on non-level terrains** (Kaluf et al., 2020)
Mobility	Patient has difficulty standing on and/or negotiating slopes and hills	- **Significant increase in minimal toe clearance during slope ascent** (Lamers et al., 2019) - **Significant increase in self-selected walking speed during slope ascent** (Askew et al., 2019) - **Significantly slowed shank rotational velocity and, thus, improved control over walking speed during slope descent** (Struchkov et al., 2016)

- **Significantly improved gait symmetry reduction in kinematic and kinetic gait deviations and, thus, unloading of the locomotor system during slope descent**
(Darter et al., 2014; Fradet et al., 2010; McGrath et al., 2018)

- **Patients perceived slope ambulation and standing on slopes as safer and easier**
(Darter et al., 2014; Fradet et al., 2010; Hahn et al., 2018)

- **Significantly improved symmetry and reduction in kinematic and kinetic gait deviations and, thus, unloading of the locomotor system during standing on slopes**
(Ernst et al., 2017; McGrath et al., 2019; Thomas-Pohl et al., 2019)

- **Significantly reduced metabolic energy consumption for slope ascent**
(Askew et al., 2019)

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