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## Lower Limb Prosthesis Documentation Packet

## Lower Limb Prosthesis Documentation Packet

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### If you need help:

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#### Contact the Ottobock Reimbursement Team

- Call 800-328-4058 and ask for reimbursement, or
- Email your request to [Reimbursement911@Ottobock.com](mailto:Reimbursement911@Ottobock.com)

Ottobock Reimbursement North America

P 800 328 4058 F 800 962 2549

[professionals.ottobockus.com](http://professionals.ottobockus.com)

[professionals.ottobock.ca](http://professionals.ottobock.ca)

[reimbursement911@ottobock.com](mailto:reimbursement911@ottobock.com)

## Documentation Checklist

Patient Name: \_\_\_\_\_

Date: \_\_\_\_\_

Completed by: \_\_\_\_\_

### FROM THE PHYSICIAN

#### History of Amputation

- ☐ Date and Cause of amputation(s)
- ☐ Affected side(s)
- ☐ Clinical course, interventions & results, prognosis

#### Physical Examination

- ☐ Height, weight, recent loss/gain
- ☐ Cognitive ability to use & care for new prosthesis
- ☐ Condition of residual limb
- ☐ Cardiopulmonary, Musculoskeletal, Neurological
- ☐ Strength, ROM, gait, balance, coordination

#### Functional Limitations

- ☐ Limitations caused by current condition/comorbidities
- ☐ Diagnoses causing the symptoms.

#### Ambulatory assistance

- ☐ Used currently/prior to amputation
- ☐ Situational/temporary?
- ☐ Plan to be free of assistive devices (if applicable).

#### Functional Level

- ☐ Patient's activities prior to amputation
- ☐ Patient's current activities & impact of the limitations identified above.
- ☐ Desired & potential activities using new prosthesis

#### Prosthetic Use

- ☐ Past: components tried & result
- ☐ Current: History and condition of each component
- ☐ Reason for replacement

#### For Repair, Replacement, or Refill

- ☐ Patient continues to use a prosthesis
- ☐ The prosthesis is medically necessary

#### Desire and Motivation

- ☐ To ambulate and use new prosthesis

#### Functional State

- ☐ K-Level (based on prior activities, current condition, and motivation to ambulate).
- ☐ Recommendation for new prosthetic components
- ☐ For potential K-level, include explanation & plan to reach desired K-Level & approx. how long it will take

### DISPENSING ORDER (RX)

Effective 1/1/20 not required for Medicare

- ☐ Patient's name
- ☐ Date of order (prescription date/date of call)
- ☐ Description of item being dispensed
- ☐ Printed name and signature of physician or person who took the call.
- ☐ Meets your state's requirement for orders

### STANDARD WRITTEN ORDER (SWO) –supplier generated

Effective 01/01/2020 – replaces DWO

- ☐ Date of Order: **on/prior to the delivery date**
- ☐ Narrative description, HCPCS code, HCPCS code narrative, or Brand Name/Model Number.
- ☐ Physician demographics/**NPI ok for Medicare**
- ☐ Physician's hand written signature, date
- ☐ Quantity & RT/LT
- ☐ Meets your state's requirement for orders
- ☐ Patient name on each page/**MBI ok for Medicare**

### PROSTHETIST'S DOCUMENTATION

#### Functional Level – should match physician's determination

- ☐ Testing
- ☐ Activities prior to amputation
- ☐ Current Activities
- ☐ Future activities
- ☐ For potential K-Level: explanation for the difference

#### History of Prosthetic Use Over Time

- ☐ Brand, how long used, result

#### History of Current Components

- ☐ History of components being replaced (age, condition, result)
- ☐ Description of Labor (casting, modification, time, tools, materials & where applied)
- ☐ Reason for Replacement

#### Recommendation for Type and Brand of Prosthesis

- ☐ Based on physician's recommendation
- ☐ Medical Necessity and Justification for each component

#### Desire and Motivation

- ☐ To ambulate and use new prosthesis

#### Additional

- ☐ Chart note for each visit
- ☐ Signature of signee

#### For Refills (liners, socks, etc)

- ☐ Continued Need: MD note within 12 mo. (or substitute new verbal/written order).
- ☐ Continued Use: Document the refill request and condition of the item being replaced.

### PROOF OF DELIVERY

- ☐ Delivery Date
- ☐ Patient's Name
- ☐ Delivery Address
- ☐ Narrative description, HCPCS code, HCPCS code narrative, or Brand Name/Model Number.
- ☐ Signature and Printed name of signee
- ☐ Relationship to patient and reason why patient cannot sign
- ☐ Signature time, if signed on same day as SWO obtained.

#### ☐ BENEFICIARY AUTHORIZATION

#### ☐ ABN IF REQUIRED

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Following is Medicare's criteria for coverage of LL Prosthetics, which also can be found in other medical coverage policies.

## Medical Necessity

Medical necessity for prosthetic components or additions to the prosthesis is based on:

1. The patient's past history [activities],
2. The patient's current condition [residual limb and any medical conditions that might affect patient's ability to use the new prosthesis], and
3. Desire to ambulate. [desire to use the new prosthesis and get back to those previous activities]

A lower limb prosthesis is covered when:

4. Prescribed by a physician
5. The member will reach or maintain a defined functional state ( Potential K-Level) within a reasonable period of time, and
6. The member is motivated to ambulate

Note: For Medicare all 6 criteria must be documented.

- ➔ All documents that support medical necessity must be signed and dated prior to the delivery date.

## Item 1: Physician Documentation

Recent physical evaluation (focus should be on the amputation, the prosthesis, and ambulatory difficulties). Elements that should be included:

### a. History of the Amputation

- Diagnosis/etiology of amputation(s)
- Date and affected side (s)
- Clinical course
- Therapeutic interventions and results
- Prognosis

### b. Physical Examination Relevant to Functional Limitations

- Height, weight, recent loss/gain
- Cognitive ability to use & care for new prosthesis
- Description of the residual limb (e.g. local and/or phantom pain; wound healing issues; skin irritation, breakdown, infection; limb volume changes or swelling; weight fluctuations; muscle atrophy or contractures; osteoarthritis, or other arthritic conditions of the residual limb joints).
- Cardiopulmonary, musculoskeletal, neurological, arm and leg strength, ROM, gait, balance, coordination

### c. Functional Limitations

Describe the nature and extent of any functional limitations whether from current condition or comorbidities.

- ➔ You should have on file chart notes reflecting the need for the care (e.g. evaluation, treatment plan, history and physical, etc.) from the patient's medical records charted contemporaneously, in other words, when the patient is present.
- ➔ To be on the safe side, it is recommended that this information be collected up-front to be sure the physician's documentation supports the claim.

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## Examples:

- **Cardiopulmonary** conditions that might limit the patient's capacity [e.g. congestive heart failure (CHF), coronary heart disease (CHD), endocarditis, myocarditis, arrhythmias, peripheral arterial (occlusive) disease (PAD/PAOD), chronic venous insufficiency (CVI) with recurring ulcers, lymphedema].
- **Musculoskeletal** conditions (e.g. osteoarthritis sound side leg joints, spinal stenosis, severe low back pain, etc.).
- **Neurological** conditions that cause impairments in gait, balance or coordination (e.g. MS, stroke, SCI, Parkinson's, peripheral nerve lesions, lumbar disc herniation with motor paresis, dementia/Alzheimer's disease, depression, psychiatric disorders/diseases).
- **Other comorbidities** (e.g. chronic kidney failure, chronic liver failure, cancer with chemotherapy/radiation, general deconditioning).

d. **Ambulatory Assistance** prior to the amputation and/or currently used (e.g. cane, walker, wheelchair, caregiver).

- For non-routine/occasional use, describe the situation when the patient uses the assistive device.
- If this is a temporary situation state in your opinion how long it will take the patient to be back to functioning at the desired level (free of the assistive device).

## e. Define Patient's Functional State:

Describe patient's functional capabilities in K-Level terms, as they relate to the patient's activities. These should be **real activities**, such as "walking the dog" and related K-level functions that patient encounters (e.g. long-distance ambulation, obstacles, types of terrain, slopes, stairs, ramps, crowds, public transportation).

### Functional Levels (K-Levels)

**Level 0:** Does not have the ability or potential to ambulate (or transfer safely) with or without assistance and a prosthesis does not enhance their quality of life or mobility [*i.e. patient likely will not be able to ambulate at all*].

**Level 1:** Has the ability or potential to use prosthesis for transfers or ambulation on level surfaces at fixed cadence [*i.e. patient likely will be able to use the prosthesis within his/her dwelling only*].

**Level 2:** Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces [*i.e. patient will likely be able to use prosthesis within his/her dwelling and a limited radius in the community*].

**Level 3:** Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion. [*i.e. patient will likely have a prosthetic ability comparable with that of a non-amputated person with no mobility restrictions*].

**Level 4:** Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

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## Following is what must be in the record:

- **Patient's activities prior to amputation.**  
Identify prior activities in the patient's potential K-Level category.
- **Patient's current activities.** Include the impact of the limitations identified above. Is the patient more limited by his/her medical conditions or by the function of the prosthesis?
- **Activities that patient desires to get back to** (and has the potential for) using the new prosthesis.

**Note:** If patient was a community ambulator (K3/K4) earlier in life, but not prior to the amputation due to a medical condition (e.g. neuropathy, ulcers, and neuropathic pain) or if patient was never a community ambulator (K3/K4) and now has demonstrated capacity to be one, include why you believe the patient will be a community ambulator with the new prosthesis (e.g. sound limb is asymptomatic, achievements during rehabilitation/physical therapy, diseased limb was the primary cause of the mobility restrictions, etc.).

## f. Document the Current Prosthesis:

- **Condition of each component** (e.g. socket, knee, pylon, ankle, foot) should be documented.
- **Reasons for replacement** One of the following reasons should be documented for each component being replaced.

*Reasons allowed by most payers:*

- Patient's functional needs have changed

- Due to physical changes the component no longer fits
- Device is irreparably worn

*Additional reasons allowed by Medicare*

- Device is lost or damaged beyond repair
- Cost to repair will be greater than 60% of the cost (Medicare allowable) to purchase a new device.

- **If the patient's condition has changed,** describe why the current prosthesis is no longer appropriate. (e.g. weight gain/loss, decreased stability, etc.)
- **If the device was damaged or lost,** describe the incident.

## g. Previous Prostheses:

- Document patient's past experience with prosthetic components (what has been tried, and the result).

## h. For a Repair, Replacement or Refill

- Document that patient continues to use prosthesis.
- And prosthesis is medically necessary.

## i. Desire and Motivation:

- Document patient's desire to use the new prosthesis.
- Document patient's motivation to ambulate.

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- j. **Recommendation for the type of new Prosthesis/ Component(s)** and the medical reason for your decision.
- The recommendation should be based on patient's prior activities, current condition, and desire to ambulate (used to determine the K-Level).
  - The Brand name of the prosthetic components is not required.
  - **Important:** If the patient has the potential to reach a higher K-level designation in the future, an explanation for the difference is required. Include a treatment plan that will achieve this increase in functional level, and what it will take to get there (e.g. physical therapy, gait training, etc.). For Medicare, the plan should specify in your opinion approximately how long \_\_\_\_\_ it will take the patient to be functioning at the potential K-Level.

## Item 2: Initial Order (Prescription)

- **Effective January 1, 2020:** For Medicare the initial order is no longer required for orthotics and prosthetics; however, a signed Standard Written Order (SWO) must be obtained prior to billing.
- If an initial order is required by the insurance payer, state, or credentialing agency, the initial order can either be verbal and documented in the patient's chart OR written by the ordering physician.
- It is the supplier's responsibility to ensure compliance with pertinent insurance criteria, credentialing, and state laws.

### Elements included on a typical initial order/ prescription when required (best practice):

- a. **Patient's name**
- b. **Date of order**
  - For written order: use the date of the prescription
  - For verbal order: use the date the call was received
- c. **Description of item(s)**
- d. **Signature**
  - For written order: Physician's signature and date , printed name and credential
  - For verbal order: Printed name of person taking order, signature, date, time.

## New Item 3: Standard Written Order (SWO)

- The SWO replaces the DWO
- The provider may write the SWO; however, the physician must review and sign it.
- An initial order can be used as a SWO if it contains all elements required below.
- The SWO must meet state prescribing, credentialing and/or other applicable laws.

### Minimum elements that must be included on a "supplier generated" SWO: **Effective Jan. 1, 2020**

- a. **Order date** **New:** The SWO must be dated on/prior to the date of delivery
- b. **Describe what is being ordered** (list all items, options or additional features that will be separately billed or require an upgraded code).



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You may use **one** of the following methods:

- **Narrative description** (AK polycentric knee w/friction)
- **HCPCS code** (L5613),
- **HCPCS code narrative** (Addition to lower extremity, endoskeletal system, above knee, knee disarticulation, 4-bar linkage, with friction swing phase control)
- **Brand name/model number** (4R36 Titan polycentric knee joint)

To avoid confusion, we recommend including brand name and model number for items with multiple HCPCS codes.

- c. **Physician's Demographics** printed name, credential, address, phone, NPI  
**Effective January 1, 2020:** only the physician's name/National Provider Identifier (NPI) number is required for Medicare.
- d. **Quantity** to be dispensed
- e. **RT/LT** (recommended)
- f. **Physician's signature**
- g. **Patient's name** on each page (**Effective January 1, 2020:** The Medicare Beneficiary Identifier (MBI) may be used in place of patient's name for Medicare)

## Item 4: Liners, Socks, Other Non-Consumable Items

- These are treated as a refill and covered under the original order.
- Note: keep in mind that Medicare and other large payers have medically unlikely edits established for liners and socks. Look up your code [here](#).

- Replace only when item is no longer functional and document condition with sufficient detail.
- For documentation requirements, see Item 5.f.

**The following items must be included in a liner, sock, or other non-consumable order** (information may be included on the SWO).

- a. **Patient's name** (**Effective January 1, 2020:** MBI is allowed in place of name for Medicare)
- b. **Order date**
- c. **Description of item(s)** being ordered
- d. **Quantity** to be dispensed
- e. **RT/LT** (recommended)
- f. **Patient continues to use the orthosis**
- g. **Physician demographics** printed name, credential, address, phone, NPI (**Effective January 1, 2020:** only physician's name or NPI required for Medicare)
- h. **Physician's signature**

## Item 5: Prosthetist's Documentation

- Medical records must support that the device is still medically necessary.
  - Medicare expects that a lost/damaged item would be reported to some authority (e.g. police, homeowners insurance, etc.) and requires that a copy of that report be available. If patient did not report the accident/loss, you will need a signed statement from the patient describing the incident.
- a. **Functional Evaluation** (K-level should match physician's evaluation -see Physician Documentation section )
  - b.



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- **Activities prior to amputation**
  - Activities that patient did in the past and would like to get back to using a new device (e.g. home, work, therapeutic, exercise).
- **Current activities.**
  - Focus on activities that the new prosthesis will allow that the current prosthesis does not.
  - Describe difficulties, such as falls, stumbles, not making it across street before light changes, inability to change speed when needed, etc.
  - How will patient be able to do it better with the new prosthesis?
- **Potential future activities.**
  - If these vary from prior activities, an explanation will be required)

## c. History of Prosthetic Use

- Your records should have a history of each prosthesis patient has used/trialed in the past.
  - Brand of component
  - How long did patient use it?
  - What was the result?

## d. Current Prosthesis

- **History of each component being replaced** (age, condition, how did it work out?)
- **Description of the labor involved** (e.g. casting, modification, time, tools used, materials used, where was material applied, etc.)
- **Reason for replacement** (e.g. change in patient's condition, device no longer fits, device does not meet functional needs, item is worn and cannot be repaired. Medicare and some payers also allow replacement

when the cost to repair is greater than 60% of the Medicare allowable for a new device or item is lost or damaged beyond repair).

## e. Recommendation for the type and brand of the new prosthesis:

- Must be based on physician's recommendation
- Include rationale for your decision
- Include medical necessity and justification for each code that will be billed.

## f. Patient's motivation and desire to use the new prosthesis (and to ambulate for lower extremity)

## g. Document Refill Requests (e.g. liners, socks, other non-consumable items). This can be a written request from the patient or telephone contact between supplier and patient.

The following elements should be included on the refill request:

- **Patient's name** (or authorized representative and relationship)
  - **Date of request** (must be no sooner than 14 calendar days prior to delivery/shipping)
  - **Description** of each item requested
  - **RT/LT**
  - **Quantity and functional condition** of items being replaced
- Note:** Shipment/delivery may not occur sooner than 10 calendar days prior to current supply exhausting.

## h. Chart note for each visit with patient with printed name, credential, signature and date on each note.

## i. Patient's name on each page.

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## Item 6: Proof of Delivery (POD)

- ☞ A signature date is no longer required; however, if there is one on the form, it must be the date of service on your claim.

Elements to be included on the POD when device is delivered direct to the patient:

- a. **Delivery Date**
- b. **Patient's name**
- c. **Address** where item is delivered (your office, patient's home, SNF, etc.)
- d. **Quantity** delivered for each item
- e. **Amputation side** for each item, LT/RT
- f. Describe what will be delivered. You may use **one** of the following methods:
  - **Narrative description** (AK polycentric knee w/friction)
  - **HCPCS code** (L5613)
  - **HCPCS code narrative** (Addition to lower extremity, endoskeletal system, above knee, knee disarticulation, 4-bar linkage, with friction swing phase control)
  - **Brand name/model number** (4R36 Titan polycentric knee joint)
  - **Note:** To avoid confusion, we recommend including brand name and model number for items with multiple HCPCS codes.
- g. **Signature and printed name** of the patient or designee

Note: If designee signs, include the designee's relationship to the patient and the reason why patient could not sign. This person cannot have any financial connection to the provider.

## Item 7: Beneficiary Authorization

- A new authorization is required anytime a new prosthesis/component(s) is provided. In other words, a new authorization is required anytime a new HCPCS code is billed.
- This authorization should give you:
  - Permission to submit claims on behalf of beneficiary.
  - Permission to pay you directly (assigns the benefits to the provider).
  - Release to authorize the provider to obtain confidential medical information about the beneficiary in order to process the claim.

### Example of an Authorization:

- Name of Beneficiary:
- HICN:
- I authorize (supplier)\_\_\_\_\_ to submit claims to Medicare on my behalf. I request that payment of authorized Medicare benefits be made either to me or on my behalf to (supplier)\_\_\_\_\_ for any services furnished me by that supplier.
- I authorize any holder of medical information about me to release to (supplier)\_\_\_\_\_ and/or the Centers for Medicare & Medicaid Services and its agents any information needed to determine these benefits or the benefits payable for related services.
- 
- Signature\_\_\_\_\_
- Date\_\_\_\_\_

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## Item 8. Advanced Beneficiary Notice (ABN) if required

- NOTE: Medicare does not allow “blanket” ABN’s to be issued. In other words, one cannot give an ABN to every patient, in anticipation that Medicare might deny. ABNs are to be used on a case-by-case basis when there is a clear indication that the device will be denied as not medically necessary/not reasonable and necessary. The most common situation would be when a patient does not meet the criteria for coverage.
- **Examples of when an ABN might be used:**
  - Patient does not meet criteria for coverage as stated in LCD
  - Physician clearly has not provided sufficient documentation to meet Medicare’s documentation requirements and there is a high probability that the claim will be denied as not medically necessary.



**References:** Joint DME MAC Local Coverage Policy L33686 and Policy Articles: A55426 and A52457 effective January 1, 2020; CGS & Noridian Supplier Manuals.

Fax to:		Fax from:	
Company:		Company:	
Phone:	Fax:	Phone:	Fax:
Patient Name:		Date of Birth:	No. Pages:

**FAX: Documentation Request for a Lower Limb Prosthesis**

This is a request for medical records on the above patient relative to his/her prosthesis.

- **History of Amputation:** Cause, date & side of amputation(s); clinical course, therapeutic interventions & results, prognosis
- **Physical Examination**
  1. Weight, Height, Weight Loss/Gain.
  2. Cognitive ability to use the use and care for the new prosthesis
  3. Condition of residual limb
  4. Cardiopulmonary, musculoskeletal, neurological, strength, ROM, gait, balance, coordination
- **Functional Limitations** Describe nature and extent of any functional limitations, whether from current prosthesis, current condition, or comorbidities (e.g., decreased pulmonary reserve, disabling cardiovascular, neuromuscular, peripheral vascular or musculoskeletal conditions).
- **Ambulatory Assistance Used** prior to the amputation and/or current. Is it routine, situational, temporary? Explain
- **Document Medical Necessity in K-Level Terms:** (see descriptions below)
  1. Patient's activities prior to amputation
  2. Patient's current activities along with any functional limitations as identified above
  3. Activities that patient desires to get back to (and has the potential for) using the new prosthesis.
  4. Describe patient's desire and motivation to ambulate with the new prosthesis
- **Document the condition/status of current prosthesis and reason for replacement of each component.** If worn/broken, describe the condition of each component that needs to be replaced. If patient's physical condition or functional needs have changed, describe why prosthesis/component no longer meets his/her needs.
- **Describe Past Experience with Prostheses/Components** Describe what has been tried in the past and the results.
- **For continuing care (e.g. replacement, repair, or refill)** Document continued medical necessity and continued use.
- **Recommendation for the new components.** Include medical reason for your decision.
- **K-Level.** If the patient has potential to reach a higher K-level designation in the future, include an explanation and treatment plan that will achieve this increase in functional level, and what it will take to get there (e.g. physical therapy, gait training, etc.). The plan should specify in your opinion approximately how long \_\_\_\_\_ it will take the patient to be functioning at the potential K-Level and address use of the mobility aid if pertinent.
- **Functional Capabilities for Lower Extremity [K-Levels]**
  - Level K-0:** Does not have the ability/potential to ambulate or transfer safely with/without assistance
  - Level K-1:** Home Ambulator with ability/potential for transfers or ambulation on level surfaces at fixed cadence.
  - Level K-2:** Limited Community Ambulator with ability/potential for ambulation and to traverse low level environmental barriers
  - Level K-3:** Full Community Ambulator with ability/potential for ambulation with variable cadence and to traverse higher level barriers
  - Level K-4:** Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

**Please FAX the signed and dated Medical Necessity documents to:**

\_\_\_\_\_ at (\_\_\_\_\_)\_\_\_\_\_

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# Documentation Tips

## Justifying Functional Level

Following is Medicare's coverage criteria for a lower limb prosthesis, which is also found in many private insurance policies. For Medicare **all** criteria must be documented!

### COVERAGE

A lower limb prosthesis is covered when the beneficiary:

1. Will reach or maintain a defined functional state within a reasonable period of time; and
2. Is motivated to ambulate.

### FUNCTIONAL LEVELS:

A determination of the medical necessity for certain components/additions to the prosthesis is based on the beneficiary's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to:

- The beneficiary's past history (including prior prosthetic use if applicable); and
- The beneficiary's current condition including the status of the residual limb and the nature of other medical problems; and
- The beneficiary's desire to ambulate.

### CLASSIFICATION LEVELS:

Clinical assessments of beneficiary rehabilitation potential must be based on the following classification levels:

**Level 0:** Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility

**Level 1:** Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.

**Level 2:** Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.

**Level 3:** Has the ability or potential for ambulation with variable cadence. Typical of the community ambulatory who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

**Level 4:** Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

The records must document the beneficiary's current functional capabilities and his/her expected functional potential, including an explanation for the difference, if that is the case. It is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications. However, the records must still document the beneficiary's past history, current condition, and expected functional potential.

# Documentation Tips

## Justifying Functional Level

### For devices with K3 criteria requirements:

Use “K-Level” language in your documentation. Include “real life” daily activities that require ambulation with variable cadence, and describe with great detail the terrain encountered. Include vocational, therapeutic, and exercise activities that demand prosthetic utilization beyond simple (K2 level) locomotion. Describe why patient has the potential or ability to perform each activity and what is involved, such as how far will the patient walk, when will he/she need to change cadence, and types of barriers encountered. If the patient has other functional limitations (e.g. vascular/ cardiovascular disease, cognitive issues, osteoarthritis, etc.), explain why these issues will not limit the patient’s ability to use the device to perform the activities.

Per the Medicare LCD for LL Prosthetics, the following codes are covered for K3 and above:

<b>Feet</b>			
L5973	MP Controlled ankle foot system, dorsiflex and/or plantarflex control	L5976	Energy storing foot (Seattle Carbon Copy II or equal)
L5979	Dynamic response foot with multi-axial ankle	L5980	Flex foot system
L5981	Flex-walk system or equal	L5987	Shank foot system with vertical loading pylon
<b>Knees (Endoskeletal Knee Shin System)</b>			
L5610	Hydracadence system	L5613	Knee disarticulation, 4-bar linkage with hyd swing phase control
L5814	Polycentric, hydraulic swing phase control, mechanical stance phase lock.	L5822	Pneumatic swing, friction stance phase control
L5824	Fluid swing phase control	L5826	Hydraulic swing phase control, with miniature high activity knee frame
L5828	Fluid swing and stance phase control	L5830	Pneumatic/swing phase control
L5840	4-bar linkage or multiaxial, pneumatic swing phase control	L5848	Fluid stance extension, dampening feature
L5856	MP control feature, swing and stance phase	L5857	MP control feature, swing phase only
L5858	MP control feature, stance phase only	L5859	Powered programmable flexion/extension assist control (see LCD for additional criteria)
<b>Hips</b>			
L5961	Polycentric hip joint, pneumatic/hydraulic control, rotation control w/w out flexion and/or extension		

# Documentation Tips

## Justifying Functional Level

### For devices with K2 criteria requirements:

Use “K-Level” language in your documentation. Describe “real life” daily activities detailing the terrain encountered, including low-level environmental barriers that the patient encounters, such as a curb, minimal stairs, or slightly uneven surface. Describe why patient has potential or ability to perform these activities. If patient has other functional limitations (e.g. vascular/cardiovascular disease, cognitive issues, osteoarthritis, etc.), explain why these issues will not limit the patient’s ability to use the new prosthesis to perform the activities.

Per the Medicare LCD for LL Prosthetics, the following codes are covered for K2 and above:

Feet			
L5972	Flexible keel Foot	L5878	Multi-axial ankle/foot
Axial Rotation			
L5984	Axial rotation unit, w/ without adjustability	L5985	Dynamic prosthetic pylon
L5986	Multi-axial rotation unit (MCP or equal)		

### Example – Changing from a Mechanical knee to a C-Leg

Daily Activities	Current Prosthesis/ Component	Replacement Prosthesis/ Component
List daily activities in great detail, including those that require traversing environmental barriers, changes in gait speed, and prosthetic utilization beyond simple locomotion when applicable.	Describe current prosthesis (e.g. technologic design & features).	Describe replacement prosthesis (E.g. technologic design & features).
Activities (e.g. home, work, therapeutic, exercise, and recreational). <ul style="list-style-type: none"> <li>Describe setting</li> <li>Current Responsibilities</li> <li>Problems with prosthesis</li> <li>Goals</li> </ul>	How does the current prosthesis work for this activity? <ul style="list-style-type: none"> <li>Can patient successfully execute the activity?</li> <li>Any falls or stumbles?</li> <li>Strain to sound side?</li> <li>Other issues?</li> </ul>	How will the replacement prosthesis solve the problem? <ul style="list-style-type: none"> <li>What feature will allow patient to execute the activity?</li> <li>Or do it better?</li> <li>Explain why</li> </ul>



# Medicare Rules for Replacement of Prosthesis or Components

## Documentation Requirements

January 2020

**Correct Prosthesis:** The supplier (prosthetist) is responsible to provide the correct prosthesis for the patient. If an incorrect prosthesis is supplied the supplier is obligated to make the situation right (take back the incorrect prosthesis, provide the correct one, and adjust the billing). There is no time limit for this.

**Repairs and Adjustments:** Repairs and adjustments are covered when necessary to make the prosthesis functional. Repairs and adjustments are covered under the initial order. Manufacturer-Required Maintenance is covered as a repair.

**What about the 5-year Useful Lifetime Rule?** This rule does not apply to prosthetics. The Social Security Act was amended in 2001 to exclude Prosthetics from the Useful Lifetime Rule, so amputees could get replacements when needed.

**What is a Replacement?** A replacement is the provision of an identical or nearly identical item. If the prosthesis is different, it is considered a new device and no longer covered under the original order.

## Rules for Replacement

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1. **Replacement** is covered if the treating physician orders a replacement of the entire prosthesis or a major component (e.g. socket, knee, or foot) and the replacement falls under one of the following **Reasons for Replacement** (documented on the order or in the referring physician's notes).
  - a) There is a change in the physiological condition of the beneficiary; or
  - b) There is irreparable wear of the prosthesis/component; or
  - c) The condition of the prosthesis/component requires repairs, and the cost of such repairs [list price of parts + labor] is greater than 60% of the cost [Medicare allowable] of the replacement prosthesis/component.
2. **Loss or Irreparable damage** without a physician's order
3. **Socket Replacements** are considered for payment if reasonable and necessary due to:
  - a) changes in the residual limb; or
  - b) functional need changes; or
  - c) wear/tear due to excessive patient weight; or
  - d) wear/tear due to prosthetic demands of very active amputees; or

# Medicare Rules for Replacement of Prosthesis or Components

## Documentation Requirements

January 2020

### Tips

- 1) Take care when describing the current prosthesis in the medical record, so it does not sound like an incorrect prosthesis was provided.
- 2) Choose one reason (see examples below) for replacing the prosthesis and carefully build a case to support this in the patient's medical record. Explain in great detail why the prosthesis is being replaced. While it is required that the status of the current prosthesis be documented, if the patient's functional need or physiological condition has changed and a different prosthesis is needed, this should be the focus of the documentation.

## Documentation Requirements

Reason for Replacement	Documentation Requirement
<b>CHANGE IN PATIENT'S CONDITION</b> <b>PHYSIOLOGICAL OR FUNCTIONAL</b> Replace with Identical or Nearly Identical Device  <i>Note: If device is not identical or nearly identical, it is considered a new prosthesis/component. See Documentation Guide in this packet.</i>	Physician:  New Standard Written Order (SWO) is required. The reason for replacement can be on the order (SWO) or in the physician's medical record. The reason for replacement in this case would be the change that has occurred in the patient's physiological condition or a change in the patient's functional need.  Prosthetist:  Document condition of components being replaced, orders, reason for replacement, description of labor involved, and proof of delivery.
<b>IRREPARABLE WEAR/TEAR OF THE DEVICE.</b> Replace with Identical or Nearly Identical Device  <i>Note: If device is not identical or nearly identical, it is considered a new prosthesis/component. See Documentation Guide in this packet.</i>	Physician:  New Standard Written Order (SWO) is required. The reason for replacement must be on the order (SWO) or in the physician's medical record. The reason for the replacement would be "due to wear/tear (e.g. device cannot be repaired)"  Prosthetist:  Document condition of components being replaced, orders, reason for replacement, description of labor involved, and proof of delivery.

# Medicare Rules for Replacement of Prosthesis or Components

## Documentation Requirements

January 2020

Reason for Replacement	Documentation Requirement
<p><b>WEAR/TEAR OF THE DEVICE OR COMPONENT; WHEN COST OF REPAIR IS GREATER THAN 60% OF THE COST OF A REPLACEMENT.</b></p> <p>Replace with Identical or Nearly Identical Device</p> <p><i>Note: If device is not identical or nearly identical, it is considered a new prosthesis/component. See Documentation Guide in this packet.</i></p>	<p>Physician:</p> <p>New Standard Written Order (SWO) is required. The reason for replacement must be on the order (SWO) or in the physician's medical record. The reason for the replacement would be "the cost of repair is greater than 60% of the cost of replacement and the reason for wear/tear (device cannot be repaired.)"</p> <p>Prosthetist:</p> <p>Document condition of the components being replaced, reason for replacement, a description of labor involved, orders, and proof of delivery.</p> <p>If replacing an MPK, we suggest having on file a quotation demonstrating repair cost will exceed 60% of replacement cost (i.e. 60% of the total allowable for the new codes being billed).</p>
<p><b>IRREPARABLE DAMAGE DUE TO SPECIFIC ACCIDENT OR NATURAL DISASTER (E.G. FIRE OR FLOOD)</b></p> <p><b>OR</b></p> <p><b>DEVICE IS LOST OR STOLEN</b></p> <p>Replace with exact same device as originally ordered.</p>	<p>Physician:</p> <p>May be replaced under the original order.</p> <p>Prosthetist:</p> <p>Proof of loss or damage through documentation such as a police report, picture, or corroborating statement should be submitted with the claim.</p> <p>Describe in medical record that the prosthesis, as originally ordered, still meets the beneficiary's medical needs.</p> <p>Retain documentation of components being replaced, reason for replacement, description of labor involved, original orders, and proof of delivery.</p>
<p><b>SOCKET REPLACEMENTS DUE TO:</b></p> <ul style="list-style-type: none"> <li>• Changes in residual limb,</li> <li>• Functional need changes, or</li> <li>• Irreparable damage/wear and tear due to excessive beneficiary weight or prosthetic demands of a very active amputee.</li> </ul>	<p>Physician:</p> <p>May be replaced under original order.</p> <p>Prosthetist:</p> <p>Reason for replacement, condition of components, original orders, description of labor and proof of delivery.</p> <p>Describe in medical record that the prosthesis, as originally ordered, still meets the beneficiary's medical needs.</p>

**Reference:** LCA. Standard Documentation for All Claims Submitted to the DME MACs (A55426).  
[Revised January 1, 2020]

# Signature Requirements for Documentation

## What is Allowed?

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Handwritten, Electronic, and Stamped (only if the signee cannot sign due to a disability)

## Handwritten Signatures

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- A handwritten signature is a mark or sign for services provided/ordered.
- An illegible signature should be accompanied by a signature log or attestation statement.
- Documentation (other than orders) that lack a signature, require an attestation.
- Orders (e.g. authorizations for tests, plans of care, and procedures) must be validated with a timely signature. Without a signature, they will not be considered.
- It is not allowed to add late signatures to a medical record (beyond the short delay that occurs during the transcription process).

## Signature Dates

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Signatures do not need to be dated if there is enough information to determine the date when the service was performed or ordered. Example: entries immediately above or below the signature.

## Signature Log/Key

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- A signature log accompanies one set of medical records.
- Lists the printed name (and credentials) associated with initials or an illegible signature.
- The signature log can be a separate document (or it can be on the actual page where the initials or illegible signature are used).
- A signature log may be created at any time.
- This may include yourself and/or your office staff.

Example:

Name	Signature	Initial	Date of Signature
John Doe, MD	<i>John Doe, MD</i>	<i>JD</i>	8/31/2019
A. Prosthetist, CPO	<i>A. Prosthetist, CPO</i>	<i>AP</i>	8/31/2019
I.M. Manager	<i>I.M. Manager, Office Manager</i>	<i>IMM</i>	8/31/2019

# Signature Requirements for Documentation

## Signature Attestation Statement Example

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Patient Name: I.M. Patient  
 Medicare Number: 555555555A

I, John Doe, hereby attest that the medical record entry for July 1, 2019 accurately reflects signatures/notations that I made in my capacity as MD when I treated/diagnosed the above listed Medicare beneficiary. I do hereby attest that this information is true, accurate, and complete to the best of my knowledge and I understand that any falsification, omission or concealment of material fact may subject me to administrative, civil, or criminal liability.

John Doe, MD  
 Signature

08/12/2019  
 Date

*Note: In order to be a valid attestation, it must be signed by the person who authored the medical record entry. It cannot be a partner in the same group practice or other staff member.*

## Electronic Signature

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Examples of electronic signature notations (not all inclusive):

Electronically signed by	Finalized by
Authenticated by	Signed by
Approved by	Validated by
Completed by	Sealed by

### References

DME MAC Joint Publication. Medicare Record Authentications – Tips for Physicians. July 2011  
 CMS Pub. 100-08, Medicare Program Integrity Manual, Chap. 3-Section 3.3.2.4 (Rev. 751; Issued: 10-20-17; Effective 11-20-17; Implementation 11-20-17)  
 Medicare Learning Network. Complying with Medicare Signature Requirements. ICN 905364. May 2018

# Changes to the Medical Record

## Amendments, Corrections and Delayed/Late Entries

The CMS Program Integrity Manual, instructs the Medicare Auditors to consider all properly written amendments, corrections and late/delayed entries in patient medical records. This means that the physician can add clarification to the medical record after-the-fact if something was missed when the patient was there; however, there are specific record keeping principles that need to be followed.

“All services provided to beneficiaries are expected to be documented in the medical record at the time they are rendered. Occasionally, certain entries related to services provided are not properly documented. In this event, the documentation will need to be amended, corrected, or entered after rendering the service. When making review determinations the MACs, CERT, Recovery Auditors, SMRC, and ZPICs shall consider all submitted entries that comply with the widely accepted Recordkeeping Principles.” (CMS Program Integrity Manual)

### What are Recordkeeping Principles?

“Regardless of whether a documentation submission originates from a paper record or an electronic health record, documents submitted to MA, CERT, Recovery Auditors, and UPICs containing amendments, corrections or addenda must:

- Clearly and permanently identify any amendment, correction or delayed entry as such, and
- Clearly indicate the date and author of any amendment, correction or delayed entry, and
- Clearly identify all original content, without deletion” (CGS JC)

### Specific Rules for Amendments, Corrections and Late Entries

#### Late Entries

“A late entry supplies additional information that was omitted from the original entry. The late entry bears the current date, is added as soon as possible, is written only if the person documenting has total recall of the omitted information and signs the late entry.” (Noridian JE)

#### Addendums:

“An addendum is used to provide information that was not available at the time of the original entry. The addendum should also be timely and bear the current date and reason for the addition or clarification of information being added to the medical record and be signed by the person making the addendum.” (Noridian JE)

*[An example would be a lab test not yet available at the time of the exam.]*

# Changes to the Medical Record

## Amendments, Corrections and Delayed/Late Entries

### Corrections:

#### “Paper Medical Record

- Use a single line strike through so the original content is still readable, and
- The author of the alteration must sign and date the revision.

#### Electronic Health Records (EHR):

- Distinctly identify any amendment, correction or delayed entry, and
- Provide a reliable means to clearly identify the original content, the modified content, and the date and authorship of each modification of the record.” (CGS JC)

### What is Considered Falsified Documentation?

“Examples of falsifying records include:

- Creation of new records when records are requested
- Back-dating entries
- Post-dating entries
- Pre-dating entries
- Writing over, or
- Adding to existing documentation (except as described in late entries, addendums and corrections)” (Noridian JE)

#### References

CMS Program Integrity Manual. 3.3.2.5 Amendments, Corrections and Delayed Entries in Medical Documentation. (Rev. 732; Issued: 07-21-17; Effective: 08-22-17; Implementation: 08-22-17)

CGS Jurisdiction C. Entries in Medical Records: Amendments, Corrections, and Delayed Entries. (January 19, 2016 – revised 03.21.19)

Noridian JE Part B Medical Review. Documentation Guidelines for Amended Medical Records: Amended Medical Records. (Last Updated Aug 14, 2018)

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# Meridium Reimbursement Guide



# Meridium Reimbursement Guide

## Product Information

Effective: October 1, 2018

### Meridium

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 (14.5 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 <sup>1, 2</sup>

Effective October 1, 2018, the HCPCS code for Meridium is L5973

### 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 part 820), 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.

### Warranty

Meridium microprocessor ankle foot comes with a three-year manufacturer warranty. During the warranty period, repair costs are covered except for those associated with damages resulting from improper use. Extended warranties are available for purchase

### 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.

<sup>1</sup> 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 are based on reasonable judgment and are not recommended to replace the Supplier's judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

<sup>2</sup> The manufacturer's 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).



# Meridium Reimbursement Guide

## Functions and Benefits

### Real-time Adaptation over full Range of Motion

- Separate control of dorsiflexion (14.5°) and plantarflexion (22°).

### 4 – Axis Kinematics

- Meridium's 4-axis design allows movement of ankle, foot and separate toe section resulting in excellent adaptability, more similar to 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 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

### 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.



# Meridium Reimbursement Guide

## Functions and Benefits

### 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.



### 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.

### 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.

### 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 leg room, such as public transportation, or theaters, and cinemas.



## Microprocessor Feet Clinical Studies

Agrawal V, Gailey RS, Gaunaud IA, O'Toole C, Finnieston AA. Agrawal V, Gailey RS, Gaunaud IA, O'Toole C, Finnieston AA. Comparison between microprocessor-controlled ankle/foot and conventional prosthetic feet during stair negotiation in people with unilateral transtibial amputation. J Rehabil Res Dev. 2013; 50 (7): 941–950.

[Abstract](#)

Agrawal V, Gailey RS, Gaunaud IA, O'Toole C, Finnieston AA, Tolchin R. Comparison of four different categories of prosthetic feet during ramp ambulation in unilateral transtibial amputees. Prosthet Orthot Int. 2014 Jun 12. pii: 0309364614536762. [Epub ahead of print]. [Abstract](#)

Agrawal V, Gailey RS, O'Toole C, Gaunaud IA, Dowell T. Symmetry in External Work (SEW): A novel method of quantifying gait differences between prosthetic feet. Prosthet Orthot Int. 2009 June; 33(2): 148–156. [Abstract](#)

Alimusaj M, Fradet L, Braatz F, Gerner HJ, Wolf SI. Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of transtibial amputees. Gait & Posture 30 (2009) 356–363. [Abstract](#)

Fradet L, Alimusaj M, Braatz F, Wolf SI. Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. Gait & Posture 32 (2010) 191–198. [Abstract](#)

Hahn A, Sreckovic I, Reiter S, Mileusnic M. First results concerning the safety, walking, and satisfaction with an innovative, microprocessor- controlled four-axes prosthetic foot. Prosthet Orthot Int. 2018 Jun;42(3):350-356.

[Abstract](#)

Wolf SI, Alimusaj M, Fradet L, Siegel J, Braatz F. Pressure characteristics at the stump/socket interface in transtibial amputees using an adaptive prosthetic foot. Clinical Biomechanics 24 (2009) 860–865. [Abstract](#)

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