

INFINITE™ **SOCKET**

2018 Service Guide to
Value Based Service and
Socket Technology - 10.11.2018

STEP 1: MATCH PATIENT NEEDS TO SOLUTION

How patient's clinical issues are addressed:

CLINICAL ISSUE	INFINITE SOCKET® SYSTEM SOLUTION
Limb volume fluctuation	<p>The radial slide and angular pivot features of the custom formed carbon struts on the Infinite TF accommodate ongoing changes in volume and shape of the residual limb.</p> <p>The thermoplastic carbon fiber struts can be re-contoured in response to changes in volume or anatomy.</p> <p>The adjustable features allow for tension adjustments in response to daily fluctuation and activity levels.</p>
Neuroma pain	<p>Height adjustments on the ischial seat and medial brim on the Infinite TF reduce weight bearing on painful distal end neuromas.</p> <p>Air bladders and soft goods from the Infinite TT-S conform around the limb to provide support and offload sensitive areas of the residual limb.</p>
Hip flexion contractures and force indications	<p>Interchangeable base plates accommodate a range of hip flexion positions for the Infinite TF.</p>
Documented fall history	<p>Modular socket components and adjustability ensure ongoing, real time fit optimization. Fall risk is thereby minimized with improved comfort, suspension, and function.</p>
General fatigue and limited walking range	<p>The natural mechanical compliance of the custom molded carbon struts promote greater comfort along weight bearing areas of the residual limb. This allows greater mobility and comfort for improved endurance.</p>
Skin ulcerations and heterotopic ossification	<p>Ability to re-contour struts provides relief from bony anatomy, neuromas, wounds, and ulcerations.</p>
Sitting comfort	<p>Ability to loosen the flexible textile brim in the Infinite TF provides sitting comfort for soft tissues. Then, tightening the brim when walking achieves socket stability against skeletal tissue.</p> <p>Height adjustments in the posterior popliteal area of the Infinite TT-S allows from knee flexion and comfort while sitting.</p>

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STEP 2: REQUIRED PHYSICIAN DOCUMENTATION

Work with the patient's physician by providing them with the following:

1. Letter of Medical Necessity (LMN)
2. To provide complete medical justification, be sure to:
 - Clearly outline clinical observations
 - Cite Functional Outcome Measures (FOMs)
 - Pair the patient's functional needs with Infinite Socket features and benefits
 - Summarize treatment plan recommendations
3. Detailed written order/prescription
4. Cover letter to accompany foregoing items
5. Physician's corroborating clinical notes

Physician Documentation Checklist:

- Patient's functional level pre- and post-amputation, ex. patient's desire and motivation to ambulate.
- Potential functional level versus the current functional level, and a discussion of the difference if applicable.
- Medical history as it relates to the need for a replacement socket.
- A list of any symptoms and their respective diagnosis, leading to ambulatory limitations.
- A list of comorbidities relating to ambulatory problems.
- Documentation of the use of assistive devices (cane, walker, wheelchair, caregiver).
- A description of daily activities and any limitations to achieving them.
- Documentation of a physical examination to assess functional deficits.
- Documentation of weight and height, including any weight fluctuations.
- Description of leg strength and range of motion.
- Diagnosis, side of amputation, date of amputation.
- Patient identified on each page of the physician's records.

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STEP 3: RECOMMENDED L-CODES : INFINITE SOCKET™ TF

- = Code is indicated for this Infinite Socket™ suspension configuration.
- = Only include code for optional feature.

	Code	Description	Pin Lock	Lanyard	Seal In
Base Code Select only ONE.	L5321	Above knee, molded socket, open end, SACH foot, endoskeletal system, single axis knee	●	●	●
	L5701	Replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model	●	●	●
	L5590	Preparatory, above knee/knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, SACH foot, laminated socket, molded to patient model	●	●	●
Add-On Codes	L5631	Addition to lower extremity, above knee or knee disarticulation, acrylic socket	●	●	●
	L5649	Addition to lower extremity, ischial containment/narrow M-L socket	●	●	●
	L5650	Addition to lower extremity, total contact, above knee or knee disarticulation socket	●	●	●
	L5651	Addition to lower extremity, above knee, flexible inner socket, external frame	●	●	●
	L5652	Addition to lower extremity, suction suspension, above knee or knee disarticulation socket			●
	L5671	Addition to lower extremity, below knee/above knee suspension locking mechanism (shuttle, lanyard or equal), excludes socket insert	●	●	
	L5920	Addition, endoskeletal system, above knee or hip disarticulation, alignable system	●	●	●
	L5950	Addition, endoskeletal system, above knee, ultralight material (titanium, carbon fiber or equal)	●	●	●

The product/device “Supplier” (defined as an O&P practitioner, O&P patient care facility, or DME Supplier that renders clinical care who submits claim for reimbursement) assumes full responsibility for accurate billing of LIM Innovations 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. LIM Innovations 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.

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RECOMMENDED L-CODES : INFINITE SOCKET™ TT-S

- = Code is indicated for this Infinite Socket™ suspension configuration.
- = Only include code for optional feature.

	Code	Description	Pin Lock	Suction	Elevated Vacuum	Seal In
Base Code Select only ONE.	L5301	Below knee, molded socket, shin, SACH foot, endoskeletal system	●	●	●	●
	L5700	Replacement, socket, below knee, molded to patient model	●	●	●	●
	L5540	Preparatory, below knee PTB type socket, non-alignable system, pylon, no cover, SACH foot, laminated socket, molded to patient model	●	●	●	●
Add-On Codes	L5670	Addition to lower extremity, below knee, molded supracondylar suspension ('pts' or similar)	●	●	●	●
	L5637	Addition to lower extremity, below knee, total contact	●			
	L5645	Addition to lower extremity, below knee, flexible inner socket, external frame	●	●	●	●
	L5647	Addition to lower extremity, below knee, suction socket		●		●
	L5671	Addition to lower extremity, below knee/above knee suspension locking mechanism (shuttle, lanyard or equal), excludes socket insert	●	●	●	●
	L5910	Addition, endoskeletal system, below knee, alignable system	●	●	●	●
	L5781	Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system			●	
	L5940	Addition, endoskeletal system, below knee, ultralight material (titanium, carbon fiber or equal)	●	●	●	●

* L5647 - Only for use with one way valve. Do not use with L5781 or L5540

* L5910 - Do not bill with L5700

* L5670 - Only for use with high trim lines

* L5781 - Bill only with vacuum pump. LIM will not provide the elevated vacuum, but will modify the socket to accommodate

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STEP 4: DOCUMENT MEDICAL NECESSITY AND PROSTHETIC RECOMMENDATION

EXHIBIT A

Example Letter Of Medical Necessity

It's a good idea to include a detailed letter of medical necessity when writing to a physician requesting a prescription for an Infinite Socket™. Describe in detail the functional characteristics of the Infinite Socket and how those features will help the patient.

Dear [Dr. Name]:

I am the prosthetist treating our mutual patient, [Patient Name] . I examined [Mr./Mrs./Miss Name] on [Date]. Based upon my findings cited below, [Mr./Mrs./Miss Name] requires a new prosthetic socket. Below, you'll find detailed sections within this letter of medical necessity to facilitate the request for prescription:

1. [Mr./Mrs./Miss Name] Clinical History
2. Clinical Findings
3. [Mr./Mrs./Miss Name] Medical Needs
4. Requested Prescription

Clinical History

[Title] Mr./Ms./Sgt./Prof./etc. [Patient Name] is a [Age] year-old [Man/Woman] with a [Left/Right] 1. [Patient Name] 's Clinical History [Transfemoral /Transtibial/ Knee Disarticulation] amputation secondary to [Cause].

[Patient Name] is a 55 year-old above-the-knee amputee. He lost his right leg above the knee 6 years ago as a result of diabetes. I have treated [Patient Name] since his amputation, and he has demonstrated a consistent ability and desire to successfully utilize a prosthesis and be a fully functional, contributing member of society.

[Patient Name] returned to his career as a warehouse manager after the loss of his leg, an occupation that he has held since graduating high school. He works for a manufacturing company that makes safety equipment. He currently works 3-4 days a week, spending 8-10 hours a day operating various tasks including driving a forklift and carrying boxes. His physically demanding job includes the need to traverse the warehouse, drive equipment and maintain physical endurance.

When not working, [Patient Name] often helps care for his two young grandchildren while his son and daughter in-law work. On average, he watches the children 2 days a week from 8:30 in the morning until 5:30 at night. In this role, he has to regularly walk the children to and from the park and other activities up and down stairs, as well as walk across uneven park/playground terrain.

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EXHIBIT B

Medical Needs

[Patient Name] has multiple complaints arising out of the inadequacy of his current prosthetic socket; pain, instability, escalating residual limb, knee and lower-back pain. None of these symptoms can be addressed by repairing or replacing his existing prosthetic socket design. In order for him to function painlessly, safely and reduce chronic stress on his sound limb and back he requires a custom-molded, dynamic, modular, adjustable prosthetic socket - LIM Innovations' Infinite Socket®.

This prosthetic socket system allows modular component changes and dynamic fitting adjustments. [Patient Name] would be able to adjust his socket daily, at any time, to accommodate changes in residual limb volume, activity, or environmental conditions. Clinically, this concentrates my office visit time with [Patient Name]. Accommodating typical volume fluctuation, adjusting localized socket pressure points, modifying socket tensions, and aligning components are adjustments that can be completed immediately and easily during one visit. Increasing the direct time spent on [Patient Name]'s prosthetic care will improve the efficacy of his prosthetic system *CITE, expedite his return to mobility, and continue his growing activity level.

[Reference several Infinite Socket features, and describe how they resolve an existing issue for the patient that cannot be rectified with the current socket. Examples below]

1. The radial slide and angular pivot feature of the custom-formed carbon struts addresses [Patient Name] 's chronic volume fluctuation. By securing his limb's daily volume changes, [Patient Name] demonstrates more symmetrical step length/time, reduced circumduction, and less frequent back pain.
2. The adjustable ratchet tensioner allows [Patient Name] to quickly tighten and loosen his proximal brim fit, essential when driving a forklift for extended times as work. Loosening the socket while seated will eliminate irritation of [Patient Name] 's skin and tissue, thereby reducing the risk of ulceration.
3. The adjustable ischial seat base varies the amount of distal end weight bearing while standing for his job as a warehouse manager. Optimal weight distribution proximally has minimized [Patient Name] 's neuroma pain. He and his surgeon have delayed their neurological revision at this time.

[Patient Name] 's current conventional socket design has been repaired/adjusted/modified/replaced /re-fabricated: State which, then document:

1. Problem and resolution (example: daily volume fluctuation of 5-7 sock ply, socket fabricated for 7-ply fit)
2. Time and frequency of adjustment (example: second test socket or laminated socket manufactured)
3. Functional outcome (example: although building in adjustable socket ply fit accommodated [Patient Name]'s volume changes, he continues to experience back pain and adverse socket pressures)
4. Functional measures.

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EXHIBIT C

Example Detailed Written Order (DWO)

It is not necessary that a physician complete the DWO (i.e., a prosthetist may do this). However, the treating physician must review the DWO and personally sign and date the order to indicate agreement. Note: Most O&P softwares offer similar DWO templates.

DETAILED WRITTEN ORDER: INFINITE SOCKET® SYSTEM

Date: _____

Patient Name: _____

Address: _____

Phone #: _____ DOB: _____ Email: _____

Code: _____ Insurance #: _____

[Your clinic name]

[Your address street address]

[Your city, state, zip code]

[Your phone number]

Federal Tax #: _____ NPI: _____ Diagnosis (ICD-10): _____

Check here if additional items are listed on attached pages

Physician Attestation _____

Physician's Name, Address & Telephone _____

UPIN #: _____

NPI: _____

I certify that I am the physician identified above. I have received this detailed written order, including a full narrative description with HCPCS code and pricing. I certify that the diagnosis information shown above is to the best of my knowledge true and accurate and justifies the medical necessity of the item(s) shown.

PHYSICIAN'S SIGNATURE _____

DATE _____

Check here if additional items are listed on attached pages

Physician Attestation _____

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EXHIBIT D

Example Cover Letter

Dear [Doctor name]:

I am the prosthetist who treats [Patient Name]. The insurance provider has recently set forth specific requirements regarding physician documentation for prosthetic devices. Without that documentation, I am not able to deliver medically necessary care and treatment to our mutual patient, [Patient Name]. This letter is intended to provide a quick summary of insurance provider's latest requirements so that we can together work for the benefit of [Patient Name].

Generally speaking, insurance providers want to see that your medical records corroborate my findings/recommendations. Your records can be in the form of previous chart notes and/or a full, current patient physical evaluation. At a minimum, insurance providers require that the physician notes contain documentation supporting the following information:

1. [Patient Name]'s functional abilities, including your specific findings regarding whether [Patient Name] has the potential to ambulate with variable cadence and has a lifestyle that demands more than simple locomotion
2. [Patient Name] past history, including prior prosthetic use and other assistive device use (if applicable)
3. [Patient Name] current condition, including the status of [his/her] residual limb
4. The nature of any other medical problems [Patient Name]
5. [Patient Name] desire to ambulate
6. Your signature and the date of that signature on the attached Detailed Written Order
7. If you deem it appropriate or necessary, [Patient Name] can be referred to a PM&R specialist and/or a physical therapist for a full evaluation and report. Once a report from either of those specialists is sent to you, reviewed, acknowledged by you in the form of your signature on the report, and placed in the medical records, it constitutes appropriate documentation based upon insurance provider's guidance

If I can answer any questions you may have about insurance provider's documentation requirements for prosthetic care, please do not hesitate to contact me directly. Otherwise, thank you in advance for providing the insurance provider-required documentation that will permit me to deliver [Patient Name] the medically necessary prosthetic care and treatment [he/she] requires in a timely fashion.

Regards,

[Prosthetist Name]
[Prosthetist Certification]
[Certification Number]

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STEP 5: FINAL REVIEW CHECKLIST

You are now ready to proceed to delivery and filing the claim for reimbursement. Verify your patient delivery sheet contains all of the required information.

Final Review Checklist

- The patient's or patient's designee's name?
- The delivery address?
- The item(s) being delivered (brand name, serial number, or narrative description)?
- The number of item(s) being delivered?
- The delivery date?
- The patient's or patient's designee's signature?
- The date of signature (must be the date the patient/designee received the item(s))?
- The prescribing physician is listed in PECOS?
- You've included the prescribing physician's NPI.
- Listed the appropriate diagnosis code.
- Included the correct date of service for every L code.
- Selected the appropriate place of service for this patient.
- Included the "L" and/or "R" modifier for every L code.
- Listed the patient's K level for every L code.
- Billed using the appropriate codes for the Infinite Socket.

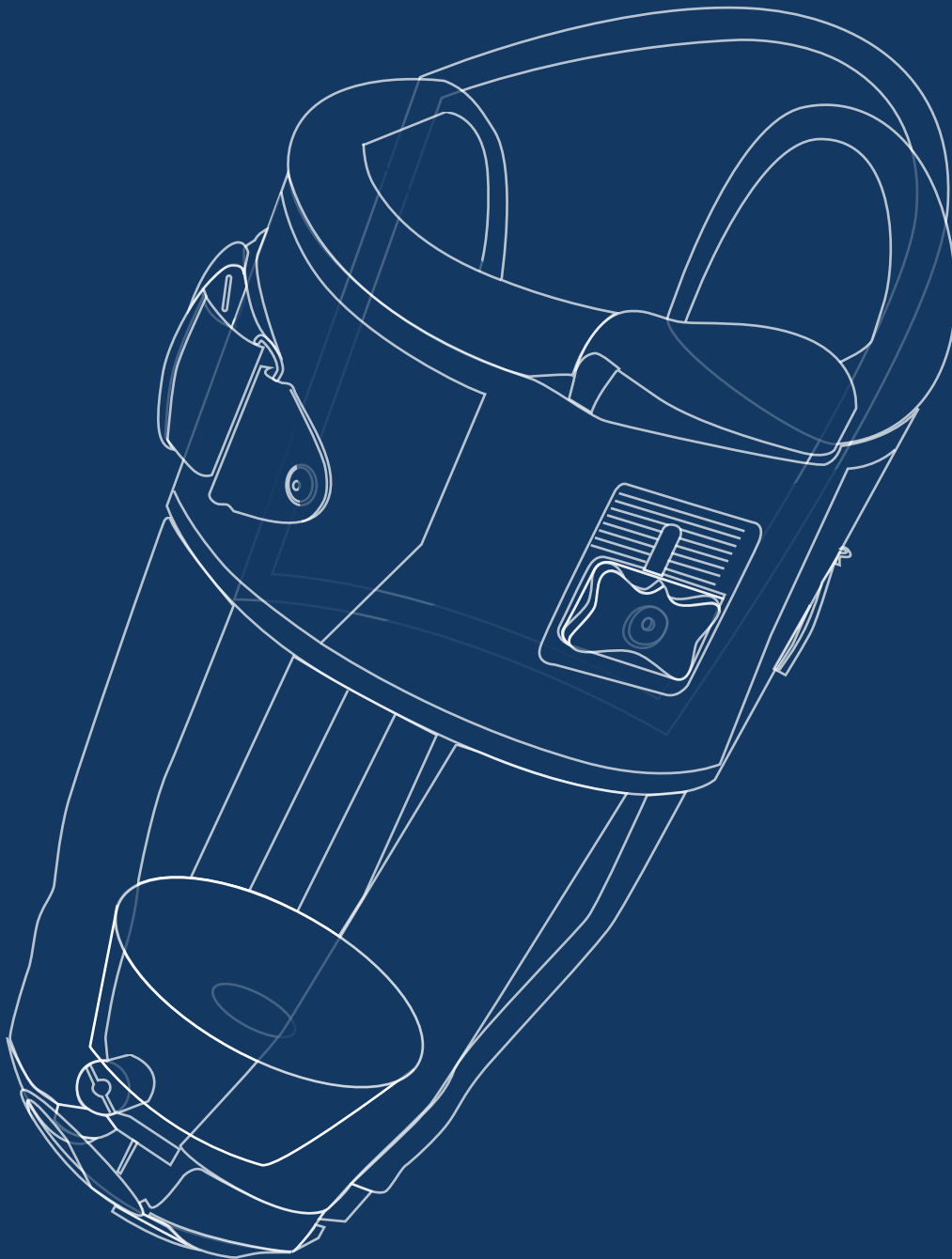
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REPLACEMENT PARTS

To place an order, please contact your regional Clinical Support Specialist or call Customer Support at (855) 658-0711.

Item	Description	Category	Suggested L Codes
Hardware Kit Complete	Hardware necessary to complete the socket (bolts, screws, etc)	Hardware	
Capture Tool Set	Length gauge and trochanteric tool	Measuring Tools	
Distal Base Plate	4-hole base plate	Plates	L5910
Ischial Seat Kit Complete	Ischial seat base, 70 mm seat/ 90 mm seat, locking plate and hardware	Seats	
Brim Kit Medium 3.1.8/ Std. Tensioner	Medial brim with lateral paddle and preferred tensioning system	Soft Goods	
Ratchet Tensioner	Dacron tensioning system with ratchet	Soft Goods	
Velcro Tensioner	Dacron tensioning system with velcro™	Soft Goods	
Strut Sleeves (x4)	Cushioned covers for carbon struts	Soft Goods	
Ischial Seat Cover	Anti-microbial protective thin cover	Soft Goods	
Strut-7ply-Complete	One buffed thermoplastic carbon fiber strut complete with metal cladding (unformed)	Struts	
Distal Cup Kit Complete (Elevated Vacuum)	Thermoplastic cup with Unity valve	Suspension	L5651 or L5658+L5652
Distal Cup Kit Complete (Expulsion & Lyn Valves)	Thermoplastic cup with appropriate valve	Suspension	L5651 or L5658+L5652
Lanyard Kit (Complete w/ Strap and Chafe)	Lanyard base, 3D printed pad, lanyard strap with proximal chafe and necessary hardware	Suspension	L5671

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