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Ottobock Vacuum Solutions

Reimbursement Guide

Ottobock Vacuum Solutions Product Information

Elevated Vacuum

Elevated vacuum suspension has been commercially available in the U.S. since 1999 when Total Environmental Control (TEC) introduced the Vacuum Assisted Socket System (VASS). Today, the VASS is manufactured by Ottobock and marketed as the Harmony.

FDA Status

Under FDA's regulations, the Ottobock's Vacuum Solutions products are Class I devices, exempt from the premarket notification [510(k)] requirements. They have met all applicable general control requirements which include Establishment Registration (21 CFR part 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21 CFR part 820), Labeling (21 CFR part 801), and Medical Device Reporting (21 CFR Part 803).

Product	Product Code	Listing Number	Registration Number
Harmony Pumps	ISP	E227226	1721652
3R60 VC	ISY	E253231	9616494
Triton Harmony	ISH	E253230	1721652
DVS	ISS	E229918	9616494
EMS Socket	ISS	E229218	9616494

Health Canada Compliance

Ottobock Vacuum Solution products meet the requirements of the Medical Device Regulations (SOR/98-282). They have been classified as a class I medical device according to the classification criteria outlined in schedule 1 of the Medical Device Regulations.

Warranty

Harmony P4 and Harmony P4 HD have a 36 month manufacturer limited warranty. Other Harmony pumps and the DVS Dynamic Vacuum Pump have a 24 month manufacturer limited warranty. While under warranty, repair costs are covered except for those associated with damages resulting from improper use.

Who Can Provide Ottobock Vacuum Solutions?

Ottobock Vacuum products are prescribed by a physician and may only be provided by a qualified Prosthetist who 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 Services for the more challenging fittings, which includes on-site assistance with the fitting in conjunction with product qualification training for the practitioner.

Ottobock Vacuum Solutions Product Information

Coding (U.S. only)

The Healthcare Common Procedure Coding System (HCPCS) for prosthetics is an add-on code system. Primary codes for vacuum pumps were issued in 2003. Since then, additional features have been added to some of the Harmony pumps. Depending on which model is ordered, functions, such as shock absorption, torsion, or rotation may be provided in addition to vacuum, which are described by add-on codes.

The following HCPCS[1,2] codes are applicable to Ottobock vacuum products:

Harmony P4 (4r180) **Harmony P3** (4R147)	L5781* vacuum pump + L5988** vertical shock pylon + L5984*** axial rotation
Harmony P4 HD-330 lbs. (4R181)	L5782* vacuum pump HD + L5988** vertical shock pylon L5984*** axial rotation
Harmony E2 (4R152) **DVS** (4R220) **DVS** (4R220-1)	L5781* vacuum pumps
3R60 Vacuum (3R60=VC)	L5781* vacuum pump L5814 **polycentric, hydraulic swing phase knee L5848** stance extension damping L5845 stance flexion
Triton Harmony (1C62)	L5781* vacuum pump L5987** shank foot system L5986 multiaxial rotation
EMS Socket (6S400)	L5645 BK flex inner socket OR L5651 AK flex inner socket OR L5653 KD expandable wall socket

*Medicare K-Level 2+
**Medicare K-Level 3+
***L5984 may not be used for Triton Harmony

Other items that may be coded on a claim related to Harmony (not all inclusive):

- Base Code – L5301, L5312 or L5321
- Replacement socket – L5700 or L5701
- Test Sockets, L5618 – L5628
- UL Material L5940 or L5950
- Acrylic L5629 or L5631
- Cushion Socket – L5646 or L5648
- Flexible Inner Socket-External Frame L5645, L5651
- Expandable Wall Socket L5653
- Supracondylar Suspension - L5670
- Custom Socket Inserts (liners), L5681 or L5683 (initial insert), L5679 (additional insert)
- Prefabricated Socket Inserts (liners) L5679
- Sheaths L8400, L8410
- Sealing Sleeves L5685
- Socks L8420 , L8430, L8470, L8480

[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 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 alphanumeric system changes. [2] K-Level Restrictions may apply to coding.

Elevated Vacuum Features and Benefits

Reduced Shear Forces and Volume Fluctuations

Vacuum-assisted socket systems are known to provide excellent suspension and prosthesis control by eliminating relative movements and shear forces between the residual limb and the socket (1-4,8), and to prevent volume fluctuations of the residual limb that may result in loose socket fit (2,4-7) that needs to be compensated for by putting on several pairs of socks in the course of the day.

Elevated vacuum suspension systems manage limb volume fluctuation, a problem that people with limb loss are challenged with. Over time and on a daily basis, these volume changes can affect how the socket fits. When the limb volume increases, the socket becomes tighter, exerting pressure, restricting blood flow, and allowing for accumulated cell waste. When limb volume decreases, the socket is loose-fitting often causing pressure to bony prominences, which may result in pain and/or injury to the limb (6).

References

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Elevated Vacuum compared to Suction Suspension

Board (2001) conducted a randomized trial comparing suction suspension to vacuum-assisted suspension; evaluating changes in volume, tibia and liner pistoning, and stance phase and step length symmetry. Volume: Residual limb volume (n=10) measurements were taken before and after patients walked 30-minutes on a treadmill. Results demonstrated a significant volume increase of 3.7% or 30 ml (p=0.007) when using vacuum as compared to a significant volume decrease of 6.5% or 52 ml when using suction. Pistoning: Pistoning of the tibia and liner (n=11) were measured using X-ray and extraction force and a significant decrease (p=0.000)

Elevated Vacuum Features and Benefits

in both tibia and liner pistoning was found in favor of the vacuum system. Symmetry: Gait symmetry (n=10) was assessed with video and found significant improvements in both stance phase symmetry (p=0.037) and step length symmetry (p=0.000). Conclusion: The authors concluded that while suction suspension fits well, it also causes volume loss due to the pressure that it exerts, which in turn worsens the fit, subjecting the skin to higher stresses and "shear forces" with potential for ulcers. Vacuum suspension, such as the Harmony®, retains correct fit, averts volume loss, and lessons pistoning in the socket; maintaining skin integrity, symmetry, and comfort (1).

Beil (2002) also compared vacuum suspension to suction suspension (using total surface weight-bearing sockets) by measuring impulse and peak pressures during ambulation (n=9). Results: Findings were favorable for vacuum, both during stance phase (impulse p=0.00, peak p=0.003) and during swing phase (impulse p=0.000, average p=0.000, and peak 0.001). It is believed that elevated vacuum prevents loss of volume due to less fluid being pushed out in stance phase more fluid being pushed into the residual limb during swing phase (2).

References

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Elevated Vacuum Compared to Pin Suspension

Ferraro (2011) conducted an outcomes study (n=13) comparing pin suspension to electronic vacuum suspension. All subjects used each suspension system for at least 30 days (1). A validated measurement tool called the Activity-specific Balance Confidence (ABC) scale was used to evaluate the subject's confidence when performing certain activities (n=16) with regard to balance. Subjects taking the survey rated their confidence in performing each activity on a scale from 0 (no confidence) to 100 (completely confident) (2). A score below 67 indicates a risk for falling (3).

Results: Four surveys were excluded from the final analysis; (survey not complete, subject did not use both suspension systems, vacuum system was not electronic, and incorrect amputation level). The ABC scores for the remaining 9 surveys were: Vacuum Suspension (80±10) and Pin Suspension (65±20), resulting in a confidence level of 95% (p=0.0359) in favor of vacuum. Subjects (n=13) were also surveyed on a variety of related problems experienced with suspension systems. Results for pistoning, blisters, volume change, difficulty knee bending, redness, falls, and walking time, all favored vacuum suspension over pin suspension; however the results were not significant, possibly due to small sample size (4).

An earlier study by Beil (2004) compared pin suspension to suction suspension (n=9) by measuring impulse and peak pressures in the socket during ambulation. Results: During stance phase there was no difference between the two suspension methods (p=0.076); however, during swing phase, differences were significant (positive pressure impulses p=0.008, average positive pressure

Elevated Vacuum Features and Benefits

p=0.004, distal negative impulse p=0.053 and peak pressure p=0.026) demonstrating that pin suspension exerts an occlusive pressure on the proximal tissues of the residual limb, while at the same time generating considerable suction at the distal end of the socket, and that these pressures are likely causing both the persistent and the day-to-day skin issues witnessed with pin suspension users (5).

References

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Unhealed Wounds or Distal Pain

Until recently, standard practice was to delay the prosthetic fitting until the residual limb was in good condition and could withstand the forces generated by the prosthesis. In his research, Van Velzen (2005) found that ideally, the surgical wound from the amputation must be healed, the stump matured and conically shaped, and there should be no remaining edema when the prosthesis is fit (1,2,3).

Persons with transtibial limb loss have (4X) greater likelihood of successful prosthetic use than persons with higher-level amputations (3). However, they are also more likely to experience skin complications on the residual limb (4,5). Presence of ulcers or unhealed surgical wounds may delay prosthetic rehabilitation and increase the need for medical treatment (3,6). As a result, it has been suggested that there are benefits to accelerating the initiation of rehabilitation after amputation surgery (7,8).

Both conditions (unhealed wounds and distal pain) are usually caused by relative movements and the resulting shear forces between the residual limb and regular (including suction) below-knee sockets. This problem can be further deteriorated by residual limb volume fluctuations: The volume of the residual limb usually shrinks over the day due to the high pressure acting on it in each and every step, resulting in an increasingly loose fit of the socket that, in turn, aggravates the relative movements and resulting shear forces. The standard treatment of residual limb wounds includes that the patient discontinues the use of the prosthesis to unload the wound from pressure and shear forces to allow for healing. As a result, the patient then has to use a wheelchair or two crutches to walk until substantial wound healing is achieved, which can take weeks or sometimes even months. This is not an option for [patient name]. One randomized prospective clinical trial (4) and two case studies (1,9) have meanwhile shown that a vacuum-assisted socket (Harmony® VASS, Ottobock) allow for using the prosthesis in spite of residual limb wounds without interfering

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with wound healing or causing pain or discomfort. In the randomized prospective clinical trial (4), residual limb wounds healed equally fast while continuously using the prosthesis with a vacuum-assisted socket as in the control group that had discontinued prosthesis use. As a result, the intervention group using the vacuum-assisted socket was able to stay active and walking and demonstrate better mobility and increased prosthesis use over several months after the start of the study/wound treatment. The authors of the clinical trial (4) and the case studies (1,9) assume that the reduction/elimination of relative movements and the resulting shear forces between the residual limb and the socket is the reason why vacuum-assisted socket systems neither interfere with wound healing nor cause considerable pain or discomfort while wearing these sockets in the presence of residual limb wounds.

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Amputation Due to Dysvascular Causes

Dysvascular transtibial amputees, especially those with MFCL-3 mobility grade, benefit from the improved suspension of vacuum-assisted socket systems by reducing their risk of falling, improving their balance and overall walking capabilities. A clinical study by Samitier (2014) has demonstrated that, after 4 weeks of use of a vacuum-assisted socket (Harmony® VASS, Ottobock), dysvascular below-knee amputees with MFCL-3 mobility presented statistically significant improvements in the four square step test (FSST, p=.01) and timed up

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and go test (TUG, p=.01) as validated indicators of the risk of falling, the Berg Balance scale (BBS, p=.03) as a validated outcome measure of balance, and the 6-minute walk test (6MWT, p=01) and the Locomotor Capabilities Index (LCI-5, p=.04) as validated outcome measures of the overall walking capabilities. The authors conclude that these improvements in safety and function can be explained by the dramatically better suspension between the residual limb and the socket, resulting in improved proprioception and motor control of the prosthesis (1).

References

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Reduced Moisture Build-up

The Harmony pulls air from the sealed socket creating an even pressure total contact environment reducing the likelihood of sweating. The Harmony can also be configured for direct evacuation of moisture from the socket system thus greatly reducing moisture buildup.

Heightened Proprioception

The Harmony's elevated vacuum leads to heightened proprioception (1,2), which increases the awareness a user has of her or his leg during walking. As a result, users may experience increased balance, stability and control over the prosthesis (1-4).

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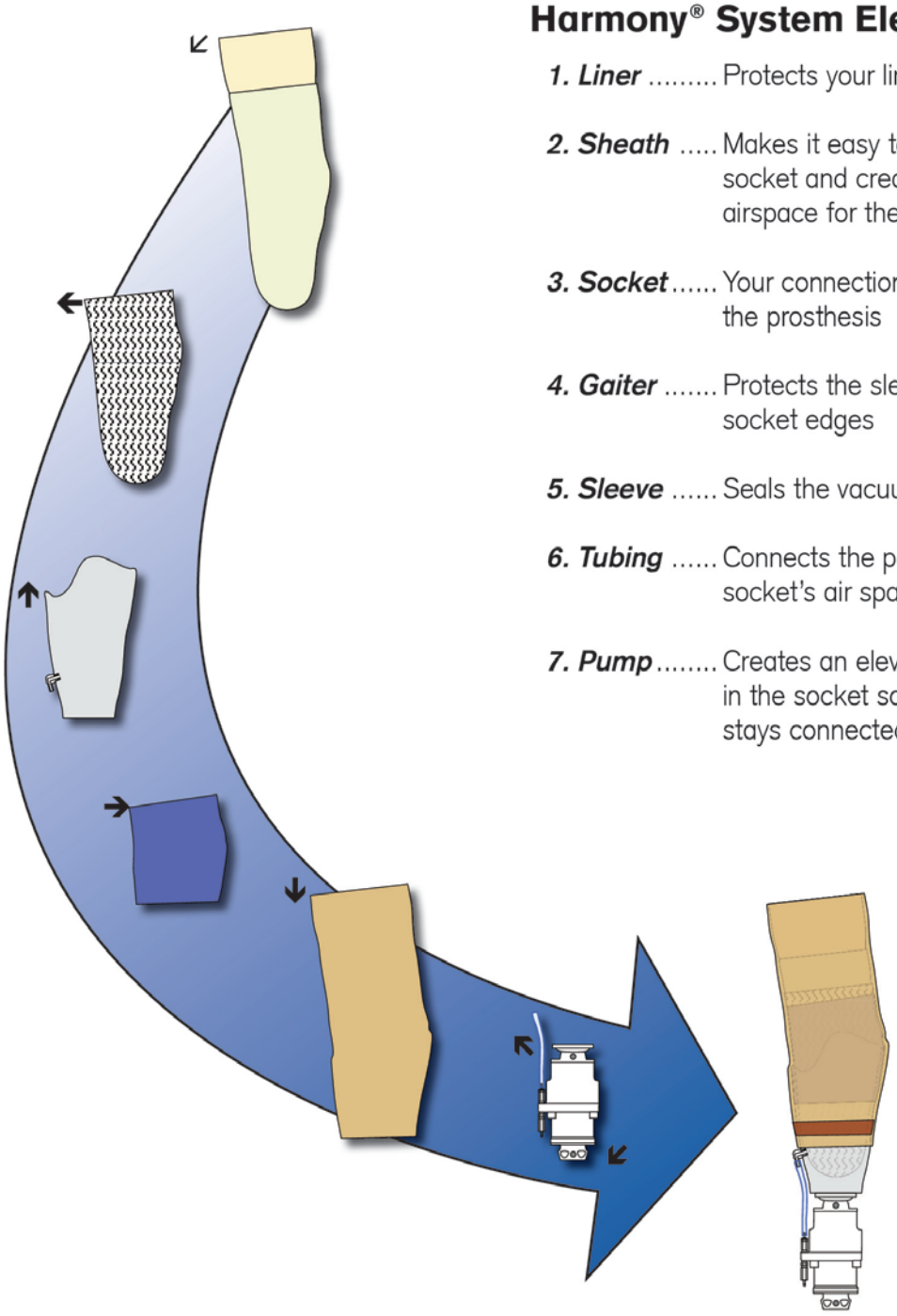
Shock Absorber and Torsion Adapter

Harmony mechanical pumps P3 and P4 models have integrated, adjustable shock absorbers and torsion adapters, which work together to increase walking comfort and relieve strain on joints and spine. These features may also contribute to a more natural gait pattern.



Harmony® System Elements

1. ***Liner*** ..... Protects your limb
2. ***Sheath*** ..... Makes it easy to slide into socket and creates an airspace for the vacuum
3. ***Socket*** ..... Your connection to the prosthesis
4. ***Gaiter*** ..... Protects the sleeve from the socket edges
5. ***Sleeve*** ..... Seals the vacuum air space
6. ***Tubing*** ..... Connects the pump to the socket's air space
7. ***Pump*** ..... Creates an elevated vacuum in the socket so your limb stays connected

Elevated Vacuum Clinical Studies

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Ottobock Reimbursement North America

P 800 328 4058 | F 800 962 2549

professionals.ottobockus.com | professionals.ottobock.ca

reimbursement911@ottobock.com