Department of Labor and Industries  
Office of the Medical Director  
Health Technology Assessment Brief  
Otto Bock Harmony Vacuum Assisted Socket System (VASS)

**Company:** Otto Bock/TEC

**Product:** The Harmony Socket Enhancement System includes a total surface bearing socket, Urethane interface/liner, sealing sleeves and a Harmony vacuum pump/shock absorber.

**Purpose:** Uses vacuum technology to:
1) maintain a balanced volume in an amputee’s residual limb
2) minimize limb movement in the socket
3) facilitate perspiration evaporation within the socket
4) reduce friction between the limb, liner, and socket

**FDA Status:** Exempt because prosthetic devices are excluded.

**Comparison:** None. New technology.

**Costs:** $4000
HCPCS Code L5781 “Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system.”

**Insurers:** Medicare reimburses $3150.08.
Aetna does not cover VASS.

**LNI Cases:** In 2002, 28 people underwent traumatic leg amputations, and 230 lower limb amputees received follow-up care.
Evidence: Funding for the two published studies came from TEC Interface, the manufacturer of the device.


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<td>Subject randomly began with normal or vacuum assisted condition and alternated until completed 3 trials of each condition. Subjects walked 20 m. Measurements taken after 5 steps to avoid acceleration. Measurements of residual limb to calculate leg geometry.</td>
<td>Measured average and peak pressure between skin and liner during stance. Measured average and peak air pressure during swing phase. Leg geometry.</td>
<td>Regular use of urethane liner and total surface weight bearing socket. Vascular complications.</td>
<td>9 patients with mean age 46 years, mean limb maturity 18 years.</td>
<td>Peak pressure during stance were significantly lower with vacuum device. Average and peak pressure during swing were significantly greater with vacuum device.</td>
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<td>Comparison between normal and vacuum socket. Volume measurements taken before and after 30 minute walk on a treadmill. Subjects asked to normalize diet and activity levels.</td>
<td>Stump volume before and after 30-minute walk. Transtibial amputee. No alcohol, caffeine, or exercise 24 hours before test.</td>
<td>Not reported. No</td>
<td>10 unilateral, transtibial amputees, mean age 45 years, body mass 83 kg, height 1.67 m.</td>
<td>With the vacuum, stump volume increased significantly an average of 3.7%. In the normal condition, stump volume decreased 6.5%.</td>
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