Negative Pressure Wound Therapy: A Review

Background

The Center for Medicare Management at the Centers for Medicare and Medicaid Services (CMS) requested this report from The Technology Assessment Program (TAP) at the Agency for Healthcare Research and Quality (AHRQ). AHRQ assigned this report to the following Evidence-based Practice Center: ECRI Institute EPC (Contract Number: 290-2007-10063).

Section 154 (c) (3) of the Medicare Improvements for Patient and Providers Act (MIPPA) of 2008 calls for the Secretary of Health and Human Services to perform an evaluation of the Healthcare Common Procedure Coding System (HCPCS) coding decisions for Negative Pressure Wound Therapy (NPWT) devices. Specifically the evaluation of existing HCPCS codes for NPWT should:

- ensure accurate reporting and billing for items and services under such codes; and
- use an existing process for the consideration of coding changes and consider all relevant studies and information furnished pursuant to such processes.

The HCPCS Level II coding system is a comprehensive, standardized system that classifies similar products that are medical in nature into categories for the purpose of efficient claims processing. Products are classified based on similarities in function and whether the products exhibit significant therapeutic distinctions from other products. Currently, all NPWT devices are classified into the same HCPCS codes. The Healthcare Common Procedures Coding System (HCPCS) code E2402 applies to the pump (NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE) and HCPCS code A6550 applies to the dressing sets (WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES AND ACCESSORIES). HCPCS code A7000 applies to the canister that goes with the pump.

Chronic and Acute Wounds

This report specifically examined the use of NPWT for the treatment of the following wound types: diabetic foot ulcers, pressure ulcers, vascular ulcers (includes venous ulcers and arterial ulcers), burn wounds, surgical wounds (especially infected sternal wounds) and trauma-induced wounds. More than 2.8 million patients in the United States suffer from chronic wounds. The prevalence of chronic ulcers has been estimated to be 120 per 100,000 patients between the ages of 45 and 64 years; prevalence increases to more than 800 per 100,000 patients over age 75.

Chronic wounds have not completed the process of healing in the expected time frame, usually within 30 days, or have proceeded through the healing phase without establishing the expected functional result. These wounds usually do not close without interventions, and are sometimes resistant to healing interventions. Diabetic foot ulcers, pressure ulcers or "bed sores," vascular ulcers, and complications of surgically created sternal wounds commonly become chronic wounds because their etiologies impede healing and they persist without proper medical care. For the purposes of this review, we consider chronic wounds to be those wounds present for more than 30 days and acute wounds to be those present for less than 30 days. Diabetic foot ulcers, pressure ulcers, venous leg ulcers, and infected sternal wounds are the chronic wounds most often treated with NPWT. Surgical wounds, burn wounds and trauma wounds are the most common acute wounds treated with NPWT.

Diabetic Foot Ulcers

Patients with diabetes often develop foot ulcers due to atherosclerosis that impedes blood flow to the extremities and peripheral neuropathy that prevents the sensation of discomfort associated with mechanical stress on or injury to the feet. Each of these complications of diabetes increases the probability of ulcer
Diabetic foot ulcers are classified in stages according to the degree of tissue damage. Stage 1 pressure ulcers are distinguished by non-blanchable redness of intact skin, stage 2 by superficial skin loss (partial-thickness skin loss of the epidermis and dermis), stage 3 by subcutaneous tissue loss (full-thickness skin loss penetrating through the epidermis and dermis into the subcutaneous tissue), and stage 4 by tissue loss that extends into the underlying muscle, tendon, or bone. The health consequences of pressure ulcers include local infection, sepsis, osteomyelitis, and pain. Local infection of pressure wounds is common and is usually controlled by debridement and antibiotics. Osteomyelitis is a risk in pressure ulcer patients because these ulcers develop over bony prominences.

In addition to the four stages described above, the National Pressure Ulcer Advisory Panel (NPUAP) also lists "Suspected Deep Tissue Injury" and "Unstageable" as pressure ulcer stages. The Suspected Deep Tissue Injury stage is described as a "purple or maroon localized areas of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue." This new stage recognizes that some pressure ulcers begin with deep tissue damage and work their way to the surface rather than starting at the surface and working their way down. The designation "unstageable" is recommended when the base of an ulcer is covered by slough and/or eschar. However, since these new pressure ulcer stages and definitions were published in 2007, earlier clinical publications will refer only to stages 1 through 4.

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Treatment of pressure ulcers centers on the following interventions: management of tissue load (i.e., pressure, friction, shearing), nutritional support, ulcer care, and management of bacterial colonization and infection.
Standard care for pressure ulcers depends on the ulcer stage and usually includes pressure relief and skin protection to prevent progression of the ulcer to advanced stages, debridement of necrotic tissue in stage 3 and 4 ulcers, wound cleansing, and dressings that promote a moist wound environment.

**Venous Leg Ulcers**

Vascular leg ulcers are the result of chronic venous insufficiency (venous leg ulcers, 80% to 95% of vascular ulcers), or arterial insufficiency (arterial leg ulcers, 5% to 10%). Between 10% and 35% of the U.S. population has some type of venous disease, and lower extremity skin ulcers are reported in 1% to 22% of individuals over age 60. The underlying problem in venous leg ulcers is venous hypertension in the deep and superficial venous system caused by incompetent valves and the incomplete removal of blood from the venous system. The disorder may be due to a previous blood clot that destroys the valves, a comorbid medical problem (arterial disease), or a hereditary absence of the valves in the venous system. The venous hypertension dilates capillaries, increases capillary filtration causing edema followed by destruction of subcutaneous tissues and the formation of an ulcer. Due to poor blood flow in the area of the ulcer, wounds caused by venous insufficiency are hard to heal and often recur. (14)

Venous leg ulcers, if left untreated, may remain for years and lead to depression, anxiety, reduced activity, and a reduction in the patient's quality of life. (15,16) Pain may be experienced by as many as 80% of venous leg ulcer patients. (17) Edema of the leg is frequently associated with venous leg ulcers. The edema may be the result of the venous insufficiency, inflammation, compromised lymphatic system associated with the wound, or of systemic disorders such as heart failure. (18) Contact dermatitis is also common in venous leg ulcer patients, and allergic reactions to wound dressings, topical ointments, and bandage material may hinder wound healing.

Treatment of venous leg ulcers involves cleaning and protecting the wound, facilitating the healing process, and providing hemodynamic support to control the underlying disorder responsible for the ulcer. (14) Wound cleaning can be performed with sterile or nonsterile water or saline and gauze compresses to remove loose slough and eschar from the wound. When necessary, debridement can be performed with application of enzymes or sharp debridement procedures (forceps, scissors, lasers) before applying the dressing and compression bandages. Hemodynamic support is provided by compression bandages that counter the venous hypertension responsible for ulcer development. Compression bandages are a vital part of treating venous leg ulcers. Therapeutic compression stockings with compression of 30 to 40 mmHg will counteract the capillary pressure in the tissues. Restoring blood flow through the skin reduces edema, increases oxygen and carbon dioxide exchange, and increases nutrient flow into the tissues. Compression may be applied using a single-component (a stocking or single type of bandage) or a multi-component system using several layers of material. A systematic review from 2009 examined the evidence for compression treatment of venous leg ulcers. According to the authors venous ulcers heal more rapidly with compression than without and multi-component systems achieve better healing outcomes than single-component compression. (19)

**Surgical Wounds**

Most surgically created sternal wounds heal without complications. However, in some cases wound healing is delayed due to the presence of infection or wound dehiscence (partial or complete separation of the wound). (20) Most chest wound infections arise from complications of cardiac surgery through a sternotomy incision. (21) Sternal wound infections are associated with an extremely high mortality rate if recognized late or treated improperly. (22) Complications associated with sternotomy occur in about 2% to 5% of closures. Approximately 1.2% of patients undergoing sternotomy will develop deep sternal wound infections. Patients with sternal wound infections can develop mediastinitis (deep chest infection), with potential exposure of bypass grafts and rupture of the ventricle, contributing to an approximately 20% overall reported mortality. (20)

There are a variety of classification methods used to differentiate between acute and chronic, superficial or deep, and infected or non-infected sternal wounds. The Centers for Disease Control and Prevention (CDC) defines a deep surgical site infection (SSI) as one that occurs within 30 days after the operation, appears to be
related to the operation, involves the deep soft tissues of the incision, and at least one of the following: 1) purulent drainage from the deep incision but not from the organ/space component of the surgical site; 2) deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following symptoms: fever, localized pain or tenderness, unless site is culture negative; 3) an abscess or other evidence of infection involving the deep incision is found on direct observation, histopathologic, or radiological examination; and 4) diagnosis of a deep SSI by a surgeon or attending physician. (21)

Treatment of sternal wound infections usually involves aggressive surgical debridement, sternal wound drainage, management of infection, closed irrigation, periodic open packing of the wound, and delayed closure of the sternal defect. (23) Advances in plastic and reconstructive surgery have shown the importance of bringing well-vascularized tissue into the wound following debridement. (21) Debridement creates a void (a deficit or defect), which if not filled, can be a space for fluid and bacteria to accumulate. Vascularized tissue fills the space, delivers antibiotics, and heals the wound by forming connections to surrounding tissues through multiple small blood vessel connections.

Burns

Severe burns can cause significant morbidity and mortality because the resulting wounds are at a high risk of becoming seriously infected. Infection remains the leading cause of death among patients who are hospitalized for burns. Second-degree (partial thickness) and third-degree (full thickness) burns, because they destroy the epidermis and part or all of the underlying dermis, have only limited ability to heal. The risk of burn wound infection increases with the extent of the burn due to breakdown of the skin's natural barrier to pathogen invasion and generalized immune suppression. Burn wounds may be classified as wound cellulitis (in which the infection involves the unburned skin at the margin of the burn) or as an invasive wound infection (characterized by microbial invasion of viable tissue beneath the burn wound eschar). Recommendations typically call for debridement of nonviable tissue in the wound, followed by the application of silver sulfadiazine cream every 12 hours. Wounds that are colonized more heavily or those that deteriorate are often treated with mafenide acetate (Sulfamylon®). The topical creams are removed daily, and the wound is cleaned with a surgical detergent. (24)

Trauma Wounds

Soft-tissue injuries due to high energy trauma (caused by motor vehicle accidents, industrial injuries, falls, and gunshot wounds) can be difficult to treat. NPWT is being used to treat many of these wounds with the hope of reducing infection and promoting healing sufficient to allow skin grafting or flap closure. (25-27)

Phases of Normal Wound Healing

Skin wounds heal in three distinct phases: the hemostatic or inflammation phase, the proliferative phase, and the maturation or remodeling phase. (7, 28-30) The inflammatory phase begins with tissue damage that often results in the release of blood and the formation of a fibrin clot. Platelets release cytokines and growth factors that attract inflammatory cells (neutrophils, eosinophils, and monocytes) and initiate the inflammatory response. The inflammatory phase also initiates cellular and vascular responses that clear dead tissue, bacteria, and foreign material from the wound. Vasodilation and increased capillary permeability around the wound allow serum proteins and leukocytes to infiltrate the area and begin the healing process. Macrophages appear within 48 hours and aggressively remove dead tissue and bacteria. Activated macrophages secrete cytokines that attract fibroblasts to the wound. The clot forms a temporary shield over the wound and also provides a structure through which inflammatory cells, fibroblasts, and vascular endothelial cells move to form granulation tissue. The inflammatory phase lasts about 2-5 days. (30, 31)

Fibroblasts appear in the wound within two to three days and mark the beginning of the fibroblast proliferation phase. This phase may last up to 3 weeks. Fibroblasts produce and extrude collagen, which then forms into fibers that provide tensile strength to the wound. Fibroblasts also secrete a variety of growth factors that guide
the formation of the new extracellular matrix. New blood vessels advance into the wound along with the fibroblasts to satisfy the metabolic needs of collagen formation. The new blood vessels, collagen, and proteoglycan ground substance form the granulation tissue. Granulation tissue fills a deep wound during the early phases of the healing process and is composed of rapidly dividing fibroblasts, new collagen fibers produced by those fibroblasts, and new capillaries that supply oxygen and nutrients to the new tissue. Its formation is a key part of wound healing. Myofibroblasts within the granulation tissue contract, pull the wound edges together, and reduce the size of the wound. Reepithelialization occurs during the fibroblast proliferative phase as epithelial cells proliferate and migrate over the granulation tissue. The new epithelial cells provide a barrier to bacteria and prevent fluid loss. In wounds with a large surface, epithelialization is enhanced by a moist environment. Dry wounds with a large dry eschar (commonly referred to as a scab) impede epithelial cell migration.

By three weeks after injury, collagen synthesis and degradation are in homeostasis, and wound remodeling begins. Maturation of the wound takes place with increasing levels of type I collagen, compared to type III collagen, and thickening of the collagen fibers. The new tissue formed in the wound progressively increases in tensile strength. This process may continue for up to two years.\(^\text{(30,31)}\)

**Negative Pressure Wound Therapy**

### Principles of NPWT

In his book on vacuum therapy, published in 2006, Willy \(^\text{(32)}\) lists five mechanisms by which the application of negative pressure to a wound may aid in the healing process: 1) wound retraction, 2) stimulation of granulation tissue formation, 3) continuous wound cleansing after adequate primary surgical debridement, 4) continuous removal of exudate, and 5) reduction of interstitial edema. Wound retraction under negative pressure brings the edges of the wound closer together while also putting mechanical stress on the tissue. The externally applied stress is thought to create microdeformations in individual cells that induces the production of cellular messengers responsible for increasing matrix synthesis and cell proliferation within the wound.\(^\text{(33-35)}\)

Increased rates of granulation tissue formation have been noted in studies using NPWT.\(^\text{(33,35,36)}\) Continuous wound cleansing may reduce the bacterial burden present in a wound\(^\text{(33)}\) as well as remove substances that inhibit wound healing. However, some studies have noted no change or an increase in the bacterial burden during the use of NPWT that did not affect the healing process.\(^\text{(37,38)}\) Interstitial fluid (exudate) that accumulates in a wound may mechanically compress local capillaries and restrict blood flow into the wound. Removal of exudate from a wound may reduce tissue edema and promote blood flow back into the wound area.\(^\text{(33,39,40)}\)

Manufacturers of NPWT devices use different wound dressings. The two most commonly used dressings are foam and moistened cotton gauze. The manufacturer of Vacuum Assisted Closure (V.A.C.®), Kinetic Concepts, Inc. (KCI) uses open-celled reticulated foam dressing to evenly distribute the negative pressure across the wound bed. The foam is covered with a transparent film that prevents bacteria from reaching the wound and also seals the wounds to maintain the vacuum. Foams containing silver or other antibiotics are available from some manufacturers. Other NPWT systems may use moistened gauze instead of foam. Nonadherent gauze is placed next to the wound bed and then the moistened gauze is used to fill the wound. Antimicrobial gauze may also be used. Once applied, the gauze is also covered by a transparent adhesive film dressing. Manufacturers recommend initially changing the dressing at 48 hours then two to three times per week as indicated.

Once the dressing is applied, an evacuation tube runs from the wound through the dressing, drawing excess exudates away from the wound and into a canister attached at the other end. The canister is attached to a vacuum pump that provides either continuous or intermittent negative pressure, adjusted for the type of wound. Pressure is applied in the range of -5 to -125 mmHg (adjustable to higher pressures, depending on the particular device used).\(^\text{(41)}\)

This technology is primarily intended for chronic wounds that have been resistant to other forms of wound care, and for minimizing scarring on acute wounds by promoting healing through granulation tissue formation and re-
Contraindications of NPWT

Contraindications to NPWT for chronic wounds include, but may not be limited to:

- Exposed vital organs (treatment may proceed after the organ has been covered by vicryl absorbable mesh).
- Inadequately debrided wounds; granulation tissue that will not form over necrotic tissue.
- Untreated osteomyelitis or sepsis within the vicinity of the wound.
- Presence of untreated coagulopathy.
- Necrotic tissue with eschar.
- Malignancy in the wound (negative pressure therapy may lead to cellular proliferation).
- Allergy to any component required for the procedure.

NPWT should be used cautiously when there is active bleeding, when the patient is on anticoagulants, when there is difficult wound hemostasis, or when placing the dressing in proximity to blood vessels.

Negative Pressure Wound Therapy Systems

NPWT systems include a vacuum pump, drainage tubing, and a dressing set. The pump may be stationary or portable, rely on AC or battery power, allows for regulation of the suction strength, has alarms to indicate loss of suction, and has a replaceable collection canister. The dressing sets may contain either foam or gauze dressing to be placed in the wound and an adhesive film drape for sealing the wound. The drainage tubes come in a variety of configurations depending on the dressings used or wound being treated.

The Healthcare Common Procedures Coding System (HCPCS) code E2402 applies to the pump (NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE) and HCPCS code A6550 applies to the dressing sets (WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES AND ACCESSORIES). HCPCS code A7000 applies to the canister that goes with the pump.

NPWT systems are considered Class II devices by the U.S. Food and Drug Administration (FDA) and fall into one of two FDA Product Codes. Devices under product code "JCX" are described as "apparatus, suction, ward use, portable, ac-powered" and under product code "BTA" as "pump, portable, aspiration (manual or powered)." Devices that are not NPWT systems are included under product codes JCX and BTA. Both codes are under regulation number 878.4780 which describes powered suction pumps:

A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter.

Redon bottles (high-vacuum drainage bottles) were one of the early vacuum sources used for wound drainage and vacuum therapy. (32) Initially the suction strength is approximately 900 mmHg but declines as the canister is filled. The Redon set comes with a bottle and drainage tubing but no dressing set. The Redon bottle is not included in HCPCS code E2402 because it is not an electric pump. Vacuum drainage bottles are covered under HCPCS code A7043 (VACUUM DRAINAGE BOTTLE AND TUBING FOR USE WITH IMPLANTED CATHETER). The Redon set received FDA 510(k) clearance for marketing in July 2000 as "a non-powered, single patient, portable suction apparatus that consists of a manually operated plastic disposable evacuation system intended to provide vacuum for suction drainage of surgical wounds."

Vacuum therapy for wounds was developed in the 1980s and became commercially available in the 1990s. (32) Table 2 lists NPWT systems that have U.S. Food and Drug Administration 510(k) clearance for marketing in
the United States. The table contains specific indications and contraindications according to 1) information in the 510(k) clearance summary and 2) company Web sites and labeling information. Table 3 lists specific product information by manufacturer.

Table 2. Negative Pressure Wound Therapy Systems: Indications and Contraindications

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>U.S. Food and Drug Administration Indications for Use (510k database)</th>
<th>Indications Presented on Company Web site</th>
<th>Contraindications Presented on Company Web site</th>
</tr>
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<tbody>
<tr>
<td>V1STA Negative Wound Therapy (portable unit)</td>
<td>Blue Sky Medical Group /now owned by Smith &amp; Nephew, Inc.</td>
<td>The BlueSky VISTA™ Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing (K061367 / Aug 2006)</td>
<td>V1STA and EZCARE are indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing. V1STA and EZCARE are appropriate for use on the following wounds: • Pressure ulcers • Diabetic/neuropathic ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Explored fistulas • Skin flaps and grafts</td>
<td>• Untreated Osteomyelitis. Negative Pressure can be used to treat wounds with osteomyelitis in conjunction with appropriate antibiotic therapy and adequate debridement. • Presence of Necrotic Tissue with Eschar. Ideally non-viable tissue should be removed from the wound bed to maximize results. • Exposed organs or blood vessels • Malignancy in the wound bed with the exception of palliative care where negative pressure has been ordered to relieve pain and manage excessive drainage. • Unexplored fistulas</td>
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<tr>
<td>EZCARE Negative Wound Therapy (stationary unit)</td>
<td>Blue Sky Medical Group /now owned by Smith &amp; Nephew, Inc.</td>
<td>The Versatile 1 EZCare™ Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing (K061919 / Feb 2007)</td>
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</table>
| Engenex® Advanced NPWT System | Hoechst Wound Systems | The Hoechst Laboratories Suction Pump System is intended for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudate, irrigation fluids, body fluids and infectious materials (K061788 / Jul 2006) | The Engenex Advanced Negative Pressure Wound Therapy System is intended for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudate, irrigation fluids, body fluids, and infectious materials. | Do not use the Engenex Advanced Negative Pressure Wound Therapy System for application to wounds where there is evidence of:

- Exposed arteries or veins in wound
- Fistula—unexplored
- Fistula - non enteric
- Osteomyelitis, untreated
- Malignancy in the wound
- Necrotic tissue with eschar

Emergency Airway Aspiration

Pleural, mediastinal or chest tube drainage. These applications require a device that provides specific low suction levels and an underwater seal.

Surgical Suction

Do not apply the Engenex Wound Dressings directly to exposed blood vessels, organs, or nerves. |

| SVEDMAN™ Wound Treatment System | Innovative Therapies Inc. | The ANTLIA II™ Suction Pump System is indicated for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials (K070904 / Apr 2007) | The SVEDMAN™ Wound Treatment System is indicated for patients who would benefit from vacuum-assisted drainage with delivery of topical wound treatment solutions and suspensions over the wound bed. Types of wounds for which the SVEDMAN® Wound Treatment System has been indicated include chronic, acute, traumatic, subacute, and dehisced wounds, diabetic ulcers, pressure ulcers, flaps | The SVEDMAN™ Wound Treatment System is contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulas, or necrotic tissue with eschar present. Do not place the Svamp® Dressing over exposed blood vessels or organs. The Svamp® Dressings are |

<p>| SVED™ Wound Treatment System | Innovative Therapies Inc. | The SVEDMAN™ Wound Treatment System is indicated for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials (K070904 / Apr 2007) | The SVEDMAN™ Wound Treatment System is indicated for patients who would benefit from vacuum-assisted drainage with delivery of topical wound treatment solutions and suspensions over the wound bed. Types of wounds for which the SVEDMAN® Wound Treatment System has been indicated include chronic, acute, traumatic, subacute, and dehisced wounds, diabetic ulcers, pressure ulcers, flaps | The SVEDMAN™ Wound Treatment System is contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulas, or necrotic tissue with eschar present. Do not place the Svamp® Dressing over exposed blood vessels or organs. The Svamp® Dressings are |</p>
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<th>Device Name</th>
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<th>Description</th>
<th>Notes</th>
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<tr>
<td>NPD 1000 Negative Pressure Wound</td>
<td>Kalypto Medical</td>
<td>NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing (K080275 / Oct 2008)</td>
<td>Not available</td>
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<td>Therapy System</td>
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<td>Not available</td>
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<tr>
<td>InfoV.A.C.® Therapy Unit</td>
<td>KCI, USA Inc.</td>
<td>The V.A.C.® Therapy System is an integrated wound management system for use in acute, extended and home care setting. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.</td>
<td>From the V.A.C.® Therapy Safety Information Brochure: Do not place foam dressings of the V.A.C.® Therapy System directly in contact with exposed blood vessels, anastomotic sites, organs, or nerves. NOTE: Refer to Warnings section for additional information concerning Bleeding.</td>
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<tr>
<td>ActiV.A.C.® Therapy</td>
<td>KCI, USA Inc.</td>
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<td>V.A.C.® Therapy is contraindicated for patients with: Malignancy in the wound, Untreated osteomyelitis NOTE: Refer to Warnings</td>
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<tr>
<td>V.A.C.® Therapy Unit</td>
<td>KCI, USA Inc.</td>
<td>The V.A.C.® GranuFoam® Silver™ Dressing is an effective barrier to bacterial penetration and may help</td>
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<td>Products</td>
<td>Manufacturer</td>
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<tr>
<td>mini V.A.C.®, V.A.C.® Freedom™, V.A.C.® ATS™</td>
<td>KCI, USA Inc.</td>
<td>The V.A.C.® family of devices with wound site feedback control are negative pressure devices used to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. From brochure: Chronic, diabetic or pressure ulcers; acute, traumatic or dehisced wounds; flaps and grafts; partial-thickness burns. From brochure: Contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistula, or necrotic tissue with eschar present. Do not place V.A.C.® dressing over exposed blood vessels or organs. KCI dressing systems are also contraindicated for use with hydrogen peroxide and solutions that are alcohol based or contain alcohol. It is not recommended to deliver fluids to the thoracic cavity.</td>
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<tr>
<td>The V.A.C.® GranuFoam® Silver™ Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types. (Info V.A.C.® Therapy Unit: K063740 / Jun 2007) (Acti V.A.C.® Therapy Unit: K063692 / Jun 2007) (V.A.C.® Therapy System: K062227 / Oct 2006)</td>
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<td>reduce infection in the above wound types. section for Osteomyelitis information. • Non-enteric and unexplored fistulas • Necrotic tissue with eschar present NOTE: After debridement of necrotic tissue and complete removal of eschar, V.A.C.® Therapy may be used. • Sensitivity to silver (V.A.C.® GranuFoam® Silver Dressing only).</td>
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<tr>
<td>V.A.C.® (Vacuum Assisted Closure™)</td>
<td>KCI, USA Inc.</td>
<td>The V.A.C.® System is a powered suction pump system that is intended for use on patients who would benefit from a suction device, particularly as the device may promote wound healing, including patients who would benefit from vacuum-assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or alternating suction pressures. * The V.A.C.® is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, diabetic ulcers, pressure ulcers, flaps, and grafts.</td>
<td>See above</td>
</tr>
<tr>
<td>V.A.C.® Instill Device (delivery of topical solutions)</td>
<td>KCI, USA Inc.</td>
<td>The V.A.C. Instill® device is indicated for patients who would benefit from vacuum-assisted drainage and controlled delivery</td>
<td>See above</td>
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<td>The V.A.C.® Instill System is indicated for patients who could benefit from V.A.C.® Instill Therapy coupled with controlled delivery and drainage of topical wound treatment solutions and</td>
<td>From brochure: Contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistula, or necrotic tissue</td>
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</tbody>
</table>
| Invia Liberty Wound Therapy (portable) | Medela Healthcare, Medela, Inc. | The Medela® INVIA Wound Therapy is indicated to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. (K080357 / Jul 2008) | The Invia Vario 18 AC/DC c/i is intended to be used to create localized topical negative pressure when used with a wound sealing kit based on the publications and teachings of Mark Chariker, MD and Katherine Jeter, EdD, ET to promote wound healing and drainage of fluids and infected materials from the wound into a disposable or reusable canister. The types of wounds indicated are:
- Diabetic/Neuropathic ulcers
- Pressure ulcers
- Chronic and acute wounds
- Dehisced wounds
Contraindicated for patients with:
- Malignancy of the wound
- Untreated osteomyelitis
- Non-enteric and unexplored fistula
- Necrotic tissue with eschar present
Do not place Invia® Healing System dressing over exposed blood vessels or organs. |
| Invia Vario 18 c/i Wound Therapy (stationary, mobile with battery) | Medela Healthcare, Medela, Inc. | The Medela Invia Vario 18 c/i Suction Pump is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. The device is also | Of topical wound treatment solutions and suspensions over the wound bed. This includes patients who would benefit from removal of infectious material or fluids from wounds under the influence of continuous negative pressure.
*From brochure:* Chronic, diabetic or pressure ulcers; acute, traumatic or dehisced wounds; flaps and grafts; partial-thickness burns
Do not place V.A.C.® dressing over exposed blood vessels or organs. KCI dressing systems are also contraindicated for use with hydrogen peroxide and solutions that are alcohol based or contain alcohol. It is not recommended to deliver fluids to the thoracic cavity. |
<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Description</th>
<th>Web Site Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exusdex® wound drainage pump</td>
<td>MediTop BV / The Medical Company</td>
<td>The Exusdex® Wound Drainage Device is a compact, portable device indicated for patients who would benefit from the application of negative pressure to the area of a wound, for the aspiration and removal of surgical fluids, irrigation fluids, tissue (including bone), gases, bodily fluids or infectious materials either during surgery or at the patient's bedside particularly as the device may promote wound healing.</td>
<td>The company Web site does not provide this information</td>
</tr>
<tr>
<td>Prodigy™ NPWT System (PMS-800 and PMS-800V)</td>
<td>Premco Medical Systems, Inc.</td>
<td>The Prodigy™ 800V NPWT System is indicated for use in patients that would benefit from a suction device particularly as the device may promote wound healing or for aspiration and</td>
<td>The company Web site does not provide this information</td>
</tr>
</tbody>
</table>

(K0614345 / Jun 2006)  
(K082311 / Oct 2008)
removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious material from a patient's airway or respiratory support system either during surgery or at the patient's bedside.

(K082415 / Nov 2008)

<table>
<thead>
<tr>
<th>PRO-I™ (stationary)</th>
<th>Prospera</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRO-II™ (portable)</td>
<td>Prospera</td>
</tr>
</tbody>
</table>

The NovaSpine Powered Suction Pump PRO-I is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing or for the aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from a patient's airway or respiratory support system either during surgery or at the patient's bedside.

(K062456 / Oct 2006)

The PRO-I has the same configuration and construction as the SIMEX suction pumps which have a separate 510(k) clearance also granted to NovaSpine LLC.

The Prospera PRO Negative Pressure Wound Therapy pumps are indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing.

When used for wound healing, the PRO-I and PRO-II are contraindicated in the presence of:

- Necrotic Tissue
- Unexplored or non-enteric fistulas
- Untreated osteomyelitis
- Wounds containing malignant tissue
- Exposed arteries, veins, or organs

<table>
<thead>
<tr>
<th>RENASYSTM EZ</th>
<th>Smith and Nephew</th>
</tr>
</thead>
</table>

The Renasys EZ is indicated for patients who would benefit from a suction device particularly as the device may promote
Use of the Venturi™ Negative Pressure Wound Therapy system is indicated for use for patients with acute or chronic wounds that may be benefited by the application of negative pressure therapy and the potential wound healing effects of removal of fluids including wound exudates, irrigation fluids, body fluids, and infectious materials. Venturi is intended for use in acute care settings only.

The Venturi™ Negative Pressure Wound Therapy system is contraindicated in the presence of:

- Necrotic tissue
- Untreated osteomyelitis
- Fistula
- Wounds with malignant tissue
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site
- Exposed bone or tendons
- Wounds with difficult
**Table 3. Negative Pressure Wound Therapy Device Product Description (information obtained from manufacturer Web sites)**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Pump</th>
<th>Drains</th>
<th>Dressing Set</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1STA Negative Wound Therapy</td>
<td>Blue Sky Medical Group/now Smith &amp; Nephew, Inc.</td>
<td><strong>Maximum vacuum:</strong> 200 mmHg</td>
<td>Drains for small, medium, large, X-large, and fistula wounds. Drains come in flat, channel, and round. These drains are placed inside the wounds with one end leaving the wound from under the transparent film. The drain must be secured to maintain a seal.</td>
<td><strong>Non-adherent gauze:</strong> placed on the wound bed</td>
</tr>
<tr>
<td>(portable unit)</td>
<td></td>
<td><strong>Weight:</strong> 1.9kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Battery operation:</strong> Up to 12 hours</td>
<td></td>
<td><strong>Antimicrobial gauze:</strong> fills the wound space, impregnated with 0.2% polyhexamethylene biguanide</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Battery type:</strong> Nickel Metal-Hydride</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Charging:</strong> ~4 hours</td>
<td></td>
<td><strong>Transparent film:</strong> covers the entire wound and 2 inches of the periwound skin</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Alarms:</strong> Low vacuum Low battery High vacuum/release</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Mode of Operation:</strong> Constant and Intermittent</td>
<td></td>
<td><strong>Uses the Chariker-Jeter Technique</strong></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dressing is changed after 48 hrs and 2-3 times per week thereafter</td>
</tr>
<tr>
<td>EZCARE Negative Wound Therapy</td>
<td>Blue Sky Medical Group / now Smith &amp; Nephew, Inc.</td>
<td><strong>Maximum vacuum:</strong> 200 mm Hg</td>
<td></td>
<td><strong>A Foam Dressing Kit</strong> received FDA 510(k) clearance in November 2008. The foam is made of polyurethane.</td>
</tr>
<tr>
<td>(stationary unit)</td>
<td></td>
<td><strong>Weight:</strong> 3.3kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Battery operation:</strong> ~40 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Battery type:</strong> Lithium Ion</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Charging:</strong> 3 hours to 80% charge</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Alarms:</strong> Low vacuum Low battery</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Mode of Operation:</strong> Constant and Intermittent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Engenex® Advanced Wound</td>
<td>Boehringer</td>
<td>The therapy unit includes a case that</td>
<td>The <strong>Tube Attachment Device</strong></td>
<td>The wound dressing incorporates the unique</td>
</tr>
<tr>
<td>Therapy Unit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NPWT System</strong></td>
<td>Systems</td>
<td>encloses a diaphragm pump, a regulation control circuit and a rechargeable battery. The pump applies controlled suction adjustable by the user in the range of 30 mmHg to 75 mmHg. The pump operates in continuous and intermittent modes. It incorporates a proprietary detection system to monitor and display the condition of the wound dressing and the collection system. Compliance monitoring on all models allows clinicians to track the progress of therapy at the site of the wound.</td>
<td><strong>(TAD)</strong> consists of tubing joined to a moisture vapor-permeable adhesive film. The Tube Attachment Device includes a controlled filter vent. The vent works in combination with the flow detection system of the pump to provide information on system performance. The TAD is applied over the wound cover to provide the suction source for negative pressure wound therapy. TADs are provided sterile. On small wounds, the T.A.D. may be used in place of the wound cover to cover and seal the wound.</td>
<td><strong>Bio-Dome</strong> technology to promote healing. The wound dressing is comprised of non-woven polyester layers joined by a silicone elastomer. This material is arranged in three layers and comprises the packing portion of the dressing, which effectively fills the wound while permitting efficient fluid transport of exudates. <strong>Bio-Dome Easy Release:</strong> These dressings provide a smooth contact surface that may be used in all wound types and should result in less patient discomfort during dressing changes. The Bio-Dome™ Easy Release dressing is available in small, medium, large and extra large varieties. The Wound Cover is a thin film dressing that serves to cover and seal wounds. It consists of polyurethane film coated on one side with a hypoallergenic, pressure sensitive acrylate adhesive. The Engenex® Tunnel Dressing is recommended for use in wounds with tunnels or sinus tracts. The tunnel dressing is comprised of non-woven polyester layers, and are provided sterile. Tunnel dressings are tapered for ease of insertion. Tunnel dressings are used to maintain a flow passage for therapy administration until the distal portion of the tunnel has closed. Two sizes are available: small and large.</td>
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<tr>
<td><strong>SVEDMAN™ Wound Treatment System</strong></td>
<td>Innovative Therapies, Inc.</td>
<td>The SVEDMAN™ Wound Treatment System device is enclosed in an aluminum case to help prevent damage from drops and impacts. <strong>Light Weight —</strong> The therapy unit weighs</td>
<td><strong>SpeedConnect™ Tubing Set</strong> and irrigation tubing.</td>
<td>The Svedman® and Sved® Wound Treatment Systems are offered with our proprietary and patent pending <strong>Svamp® Foam Dressing</strong>. Also comes with an occlusive drape.</td>
</tr>
<tr>
<td>System</td>
<td>Manufacturer</td>
<td>Description</td>
<td></td>
<td></td>
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<tr>
<td>-----------------------------</td>
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<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SVED™ Wound Treatment System</td>
<td>Innovative Therapies, Inc.</td>
<td>Light Weight — The therapy unit weighs only 1.9 lbs. (862 g) and can be easily carried and transported. Other features same as above.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NPD 1000 Negative Pressure Wound Therapy System</td>
<td>Kalypto Medical</td>
<td>The manufacturer does not currently have a Web site that provides product information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>InfoV.A.C.® Therapy Unit (stationary unit)</td>
<td>KCI, USA Inc. (the following 5 systems are listed by KCI as currently available)</td>
<td>The InfoV.A.C.® Therapy System includes new features, like SensaT.R.A.C.® Technology, including Seal Check™, Therapy History Reports and Digital SensaT.R.A.C.® Pad - designed with patient comfort in mind. Thinner, more flexible pad material for easy application over body contours. Designed with V.A.C. GranuFoam® Dressing is a black, polyurethane foam dressing: Assists granulation tissue formation in wounds. Open pore nature (400-600 microns) provides equal distribution of negative pressure at the wound site.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ActiV.A.C.® Therapy</td>
<td>KCI, USA Inc. (the following 5 systems are listed by KCI as currently available)</td>
<td></td>
<td></td>
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<tr>
<td>---------------------</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portable system</td>
<td>KCI, USA Inc. (the following 5 systems are listed by KCI as currently available)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.4 lbs.</td>
<td>Portable system 2.4 lbs. 14 hour average battery life 300 ml canister 25-200 mmHg Continuous and Intermittent</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Enhanced fluid dynamics to help reduce tubing blocks and associated alarms. Low profile design is discreet under clothing. A hole is cut in the Tegaderm Dressing and the T.R.A.C. pad seals over the hole.

- **TRAC tubing** - patented T.R.A.C.® (Therapeutic Regulated Accurate Care) technology monitors and maintains target pressure. T.R.A.C. allows for Smart Alarms to help ensure patient safety.

- **SensaT.R.A.C.® Technology** helps monitor and maintain target pressure. Audible and visual alarms for enhanced patient safety. Alarm differentiation for easier troubleshooting. Seal Check™ to help locate and resolve leaks.

- **TRAC tubing** - patented T.R.A.C.® (Therapeutic Regulated Accurate Care) technology monitors and maintains target pressure. T.R.A.C. allows for Smart Alarms to help ensure patient safety.

- **Seal Check™** to help locate and resolve leaks.

- **Digital Wound Imaging** - Upload wound images from your digital camera. Helps calculate wound area and volume.

- **Hydrophobic, open pore structure** helps facilitate exudate removal. Available dedicated dressings for specific wound applications. This dressing is cut to size and placed in the wound.

- **V.A.C. GranuFoam® Silver®**: Micro-bonded metallic silver is uniformly distributed throughout the dressing, providing continuous delivery of silver even after sizing.

- **V.A.C. Vers-Foam®** dressing is a versatile, micro-porous, polyvinyl alcohol dressing that is used with the V.A.C.® System to help promote healing for many traumatic and chronic wounds. Non-adherent material helps promote graft take. High tensile strength makes it easy to place and remove from tunnels and undermining. Increased density for restricted in-growth of granulation tissue for a more comfortable dressing change. Helps protect delicate underlying structures in wounds, such as tendon and bone. Pre-moistened with sterile water.

- **3M™ Tegaderm™ Dressing**: Designed exclusively for use with V.A.C.® Therapy. Provides a moist wound healing environment. Barrier to outside contaminants. Applied over the wound and foam dressing.

- **Hydrophobic, open pore structure** helps facilitate exudate removal. Available dedicated dressings for specific wound applications. This dressing is cut to size and placed in the wound.

- **V.A.C. GranuFoam® Silver®**: Micro-bonded metallic silver is uniformly distributed throughout the dressing, providing continuous delivery of silver even after sizing.

- **V.A.C. Vers-Foam®** dressing is a versatile, micro-porous, polyvinyl alcohol dressing that is used with the V.A.C.® System to help promote healing for many traumatic and chronic wounds. Non-adherent material helps promote graft take. High tensile strength makes it easy to place and remove from tunnels and undermining. Increased density for restricted in-growth of granulation tissue for a more comfortable dressing change. Helps protect delicate underlying structures in wounds, such as tendon and bone. Pre-moistened with sterile water.

- **3M™ Tegaderm™ Dressing**: Designed exclusively for use with V.A.C.® Therapy. Provides a moist wound healing environment. Barrier to outside contaminants. Applied over the wound and foam dressing.

<table>
<thead>
<tr>
<th>Portable system</th>
<th>2.4 lbs. 14 hour average battery life 300 ml canister 25-200 mmHg Continuous and Intermittent</th>
</tr>
</thead>
</table>

- Enhanced fluid dynamics to help reduce tubing blocks and associated alarms. Low profile design is discreet under clothing. A hole is cut in the Tegaderm Dressing and the T.R.A.C. pad seals over the hole.

- **TRAC tubing** - patented T.R.A.C.® (Therapeutic Regulated Accurate Care) technology monitors and maintains target pressure. T.R.A.C. allows for Smart Alarms to help ensure patient safety.

- **SensaT.R.A.C.® Technology** helps monitor and maintain target pressure. Audible and visual alarms for enhanced patient safety. Alarm differentiation for easier troubleshooting. Seal Check™ to help locate and resolve leaks.

- **TRAC tubing** - patented T.R.A.C.® (Therapeutic Regulated Accurate Care) technology monitors and maintains target pressure. T.R.A.C. allows for Smart Alarms to help ensure patient safety.

- **Seal Check™** to help locate and resolve leaks.

- **Digital Wound Imaging** - Upload wound images from your digital camera. Helps calculate wound area and volume.

- **Hydrophobic, open pore structure** helps facilitate exudate removal. Available dedicated dressings for specific wound applications. This dressing is cut to size and placed in the wound.

- **V.A.C. GranuFoam® Silver®**: Micro-bonded metallic silver is uniformly distributed throughout the dressing, providing continuous delivery of silver even after sizing.

- **V.A.C. Vers-Foam®** dressing is a versatile, micro-porous, polyvinyl alcohol dressing that is used with the V.A.C.® System to help promote healing for many traumatic and chronic wounds. Non-adherent material helps promote graft take. High tensile strength makes it easy to place and remove from tunnels and undermining. Increased density for restricted in-growth of granulation tissue for a more comfortable dressing change. Helps protect delicate underlying structures in wounds, such as tendon and bone. Pre-moistened with sterile water.

- **3M™ Tegaderm™ Dressing**: Designed exclusively for use with V.A.C.® Therapy. Provides a moist wound healing environment. Barrier to outside contaminants. Applied over the wound and foam dressing.

- **Hydrophobic, open pore structure** helps facilitate exudate removal. Available dedicated dressings for specific wound applications. This dressing is cut to size and placed in the wound.

- **V.A.C. GranuFoam® Silver®**: Micro-bonded metallic silver is uniformly distributed throughout the dressing, providing continuous delivery of silver even after sizing.

- **V.A.C. Vers-Foam®** dressing is a versatile, micro-porous, polyvinyl alcohol dressing that is used with the V.A.C.® System to help promote healing for many traumatic and chronic wounds. Non-adherent material helps promote graft take. High tensile strength makes it easy to place and remove from tunnels and undermining. Increased density for restricted in-growth of granulation tissue for a more comfortable dressing change. Helps protect delicate underlying structures in wounds, such as tendon and bone. Pre-moistened with sterile water.

- **3M™ Tegaderm™ Dressing**: Designed exclusively for use with V.A.C.® Therapy. Provides a moist wound healing environment. Barrier to outside contaminants. Applied over the wound and foam dressing.
<table>
<thead>
<tr>
<th>System</th>
<th>Manufacturer</th>
<th>Description</th>
<th>Weight</th>
<th>Battery Life:</th>
</tr>
</thead>
<tbody>
<tr>
<td>V.A.C.® Freedom™</td>
<td>KCI, USA Inc.</td>
<td>Portable system</td>
<td>3.20 lbs</td>
<td>Approximately 12 hours</td>
</tr>
<tr>
<td>V.A.C.® Instill System®</td>
<td>KCI, USA Inc.</td>
<td>Designed for delivery of topical solutions as well as negative pressure therapy.</td>
<td>14.5 lbs</td>
<td>4 hrs</td>
</tr>
<tr>
<td>Invia Liberty Wound Therapy (portable)</td>
<td>Medela Healthcare, Medela Inc.</td>
<td></td>
<td>2.2 lbs</td>
<td>Wound drain: 100% silicone drain is easy to cut and flexible allowing simple placement in the wound.</td>
</tr>
<tr>
<td>Invia Vario 18 c/i Wound Therapy (stationary)</td>
<td>Medela Healthcare, Medela Inc.</td>
<td></td>
<td>c/i = constant / intermittent</td>
<td>Antimicrobial Kerlix™ gauze: Fluff into the wound bed to provide a preventative barrier reducing risk of infection.</td>
</tr>
<tr>
<td>Mobile with battery</td>
<td>Exusdex® wound drainage pump</td>
<td>Prodigy™ NPWT System (PMS-800 and PMS-800V)</td>
<td>PRO-I™ (stationary)</td>
<td>PRO-II™ (portable)</td>
</tr>
<tr>
<td>---------------------</td>
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<td>---------------------</td>
</tr>
<tr>
<td>MediTop BV</td>
<td>The company Web site does not provide this information.</td>
<td>Our PMS-800 and PMS-800V <em>(Variable)</em> differ significantly from other devices of its kind in that they are controlled by a microprocessor with fully operational touch screen interface.</td>
<td>Developed for hospital and in-home use.</td>
<td>Contoured design for patient comfort. Virtually silent operation. Discreet, disposable canister.</td>
</tr>
<tr>
<td>Uses Kerlix / Kerlix AMD gauze. The Web site does not provide any further product information.</td>
<td>The company Web site does not provide this information.</td>
<td>The company Web site does not provide this information.</td>
<td>Variety of drain sizes and shapes.</td>
<td>Uses the Chariker-Jeter technique</td>
</tr>
</tbody>
</table>

**Transparent dressing:**
Waterproof film designed to protect the integrity of the wound; easy to cut and customizable to each unique size.

**Variable Pressure Therapy (VPT):**
Pressure levels and time settings for high and low pressures are completely customizable. Recommended pressures of between 40 and 80 mmHg

**Non-contact layer:**
Reduce the risk of gauze adherence over vital structures such as bone, tendon, ligament, cartilage, muscle and vessels. (Optional step) Custom cut-to-fit the wound bed.

**AMD™ gauze:**
Reduces the microbial population and absorbs exudate. Impregnated with Polyhexamethylene Biguanide. Offers 48-72 hours microbial control. "Moisten" gauze for drier wounds. Use dry gauze for highly exuding wounds. Wrap or "sandwich" the drain between the gauze. Place into wound until level or below skin surface.

**Transparency:**
Secures the components below. Protects wound from environment. Allows moisture vapor transfer rate.
| **RENASYS™ EZ** | Smith and Nephew, Inc. | Intuitive design and quick-click connectors to help reduce the risk of medical errors. User-friendly analog pressure control (40-200 mm Hg). Simple on/off toggle switch. Multiple safety alarms with patient lock-out feature. Lightweight (7.4 lbs/3.3 kg). Up to 40-hour battery life after charging to 80% capacity in 3 hours. IV pole and bed mount. 800 cc canisters. | Variety of drain sizes and shapes. | **RENASYS™-F Foam Dressing Kit**
- Hydrophobic, open-pore foam for exudate removal.
- Integral groove.
- Available in a variety of sizes to fit a range of wound types. **RENASYS™-G Gauze Dressing Kit**
- Ideal for explored fistulae, circumferential and tunneling wounds.
- Fits most wound sizes and types.
- Simplified for quick and easy use in the O.R.
- Enhances patient comfort upon application and removal. Dressing kits are also described above for the EZCARE and VISTA. |
<table>
<thead>
<tr>
<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Venturi™ Negative Pressure Wound Therapy</strong></td>
<td>Talley Group, Ltd.</td>
<td>The Web sites provide very few details about the pump.</td>
<td>The Web sites provide very few details about the drains.</td>
<td>Range of wound sealing kits—no specifics presented on the company Web site. Demonstration used gauze dressing with the drainage tube placed within the wound.</td>
</tr>
</tbody>
</table>

**Complementary or Competing Products**

There are several requirements for proper and rapid healing of an open wound. First, either the edges of the wound must be allowed to seal back together (healing by "primary intention"), or granulation tissue must form to fill the wound bed (healing by "secondary intention"). Second, the wound must remain moist because new epidermal cells will only travel across moist surfaces. Third, bacterial infection must be prevented by not allowing contamination to reach the wound. Fourth, any fluids should be removed from the wound site and while appropriate moisture is maintained. Finally, contributing factors to wound occurrence should be eliminated, or minimized, if elimination is not possible. Bedridden patients may need special support surfaces, protein-calorie malnutrition and vitamin deficiencies should be corrected, inadequate blood flow to the site of the wound should be corrected if possible, and drugs know to impede wound healing should be adjusted.\(^{(28)}\)

**Standard Treatments**
Standard treatment for established wounds incorporates common principles that apply to the management of all wound types. These include removal of necrotic tissue through debridement (achieved through sharp debridement using forceps and scissors, autolytic debridement by endogenous enzymes present in the wound, or application of exogenous enzymes in commercially available wound care products) and moisture balance through the selection of the proper wound dressing.\(^{(28)}\)

For most chronic and acute wounds, saline-moistened cotton gauze (wet-to-moist) has been the standard treatment and most commonly used dressing. Gauze dressings are moderately absorptive, easily available, and inexpensive. Saline-moistened gauze dressings can maintain a moist wound environment provided they are kept continuously moist until the dressing is removed. Therefore, wet-to-moist gauze dressings require close maintenance and added nursing time. The removal of a wet-to-moist dressing that has been allowed to dry may reinjure the wound by removing granulation tissue and lead to delayed wound healing. The removal of dried gauze dressings also causes considerable pain, impedes healing, and increases the risk of infection. While gauze dressings are much less expensive per dressing than modern synthetic dressings, the increase in labor costs and ancillary supplies such as gloves and biohazardous waste disposal increase the total cost of care. The drawbacks to the use of saline-moistened gauze dressings have been reviewed elsewhere.\(^{(43)}\)

**Synthetic Wound Dressings**

Dressings are selected based on the characteristics of the wound at any given point during the healing process.\(^{(28)}\) Wounds which produce exudate will need an absorptive dressing (hydrocolloid, foam, alginate, hydrofiber) and dry wounds will need a dressing that provides hydration (hydrogel). The type of dressing used will change as the wound goes through the phases of wound healing. Synthetic wound dressings inhibit the loss of water vapor from the wound, thereby creating a moist environment. Moist wound environments promote epithelialization and healing. In addition to creating a moist wound environment, ideal synthetic dressings perform the following functions: remove excess exudates and toxic components; allow gaseous exchange; provide thermal insulation; and protect against secondary infection. A wide variety of synthetic wound dressings are available.\(^{(44-46)}\) Some of the unique features of each are described below. Often, these dressings are used in conjunction with silver or other topical agents intended to limit infection and speed healing.

The following dressings may be used on chronic or acute wounds depending on the nature of the wound.

- **Hydrocolloid dressings** are composed of adhesive, absorbent, and elastomeric components. Carboxymethylcellulose is the most common absorptive ingredient. They are permeable to moisture vapor, but not to water. In addition, they facilitate autolytic debridement, are self-adhesive, mold well, provide light-to-moderate exudate absorption, and can be left in place for several days, minimizing skin trauma and healing disruption. They are intended for use on light-to-moderately exuding, acute or chronic partial- or full thickness wounds, but are not intended for use on infected wounds. Upon sustained contact with wound fluid, the hydrocolloid forms a gel.

- **Foam dressings** vary widely in composition and construction. They consist of a polymer, often polyurethane, with small, open cells that are able to hold fluids. Some varieties of foam dressings have a waterproof film covering the top surface and may or may not have an adhesive coating on the wound contact side or border. Foams are permeable to water and gas, and are able to absorb light to heavy exudate. This type of dressing is frequently used under compression stockings in patients with venous leg ulcers.

- **Film dressings** consist of a single thin transparent sheet of polyurethane coated on one side with an adhesive. The sheet is permeable to gases and water vapor but impermeable to wound fluids. Film dressings retain moisture, are impermeable to bacteria and other contaminants, allow wound observation, and do not require a secondary dressing. The adhesive is inactivated by moisture and therefore will not stick to the moist wound bed or to moist skin. Excessive fluid buildup may break the adhesive seal and allow leakage. Film dressings are intended for superficial wounds with little exudate and are commonly used as a secondary dressing to attach a primary absorbent dressing. The dressing may remain in place for up to seven days if excessive fluid does not accumulate. Film dressings are generally hard to apply due to self-sticking and must be placed at least 1 to 2 cm
beyond the wound edges. Film dressings have been used extensively to treat split thickness graft donor sites.

- Alginate dressings are made from calcium or calcium-sodium salts of natural polysaccharides derived from brown seaweed. When the alginate material comes into contact with sodium-rich wound exudates, an ion exchange takes place and produces a hydrophilic gel. This hydrophilic gel is capable of absorbing up to 20 times its weight and does not adhere to the wound. This dressing sometimes emits a foul odor, but can remain in place for about seven days if enough exudate is present to prevent drying. This category of dressing is best suited for moist, moderate to heavy exuding wounds. Alginate dressings require a secondary dressing, such as a film dressing, to hold them in place and to prevent the alginate from drying out.

- Hydrofiber dressing is composed of sodium carboxymethylcellulose fibers. The fibers maintain a moist wound environment by absorbing large amounts of exudate and forming a gel. This dressing is not intended for lightly exuding wounds. A secondary dressing is required.

- Hydrogel sheets are three-dimensional networks of cross-linked hydrophilic polymers. Their high water content provides moisture to the wound, but these dressings can absorb small to large amounts of fluid, depending on their composition. These dressings are cooling and soothing, reduce pain, rehydrate dry wound beds, and are easy to apply and remove. Depending on wound exudate levels, hydrogels may require more frequent dressing changes, every one to three days, compared to other synthetic dressings. Hydrogel sheets can be used on most wound types but may not be effective on heavily exuding wounds. Amorphous hydrogels are similar in composition to hydrogel sheets but lack the cross-linking. The gel may also contain additional ingredients such as collagens, alginate, or complex carbohydrates. Amorphous hydrogels can donate moisture to a dry wound with eschar and facilitate autolytic debridement in necrotic wounds. A second dressing may be used to retain the gel in shallow wounds.

- Collagen-based dressings contain purified collagen derived from bovine, porcine, equine, or avian sources. The type and concentration of collagen varies depending on the actual dressing. Rather than just providing structural support within a wound, collagen is now believed to play a critical role in all aspects of wound healing. When a wound is first formed platelets aggregate around exposed collagen. The platelets release a variety of growth factors and cytokines that attract inflammatory cells (macrophages, neutrophils, eosinophils) to the wound. The inflammatory cells degrade collagen and other protein debris in the wound and at the same time produce factors that attract and stimulate fibroblast activity. Fibroblasts secrete matrix metalloproteinase (MMP) along with collagen and produce factors that attract additional fibroblasts as well as epithelial cells and vascular endothelial cells into the wound. These cells then produce the granulation tissue that forms the extracellular matrix. The MMPs are responsible for degrading non-viable collagen while the new matrix is forming. However, in chronic wounds fibroblasts may produce too much MMPs and too little of the factors that inhibit MMPs. When this occurs the MMPs may be destroying new viable collagen as well and preventing proper wound healing. Collagen-based dressings are believed to aid wound healing by stimulating fibroblast production, have a hydrophilic property that enhances fibroblast movement, and inhibition and deactivation of MMPs.\(^{[29]}\)

**Antimicrobial Wound Dressings**

**Infected wounds** are defined as having a bacterial population size of \(10^5\) colony forming units per gram of tissue. Most wounds are either "contaminated" or "colonized" by bacteria which are not necessarily associated with tissue invasion. The concept of "critical colonization" has been introduced in recent years to convey that bacterial growth may play a role in delayed healing of wounds in the absence of the traditional criteria for infection. Approaches to reducing the volume or "density" of bacteria in a noninfected wound include use of gentle wound irrigation with normal saline and use of occlusive dressings, or application of topical antibiotics or antiseptics designed to remain in contact with the wound surface.\(^{[28,48]}\) Chronic wound infections generally have multiple bacterial contaminants with *Staphylococcus aureus* the most common.\(^{[49]}\)

Bacteria within an infected wound are embedded in a protective polysaccharide biofilm produced by the bacteria. The biofilm allows for the exchange of water and nutrients and impedes the entry of antibiotics. The
biofilm may be responsible for increased resistance to the actions of antibiotics as well as to natural host defenses. Thus the biofilm makes wound bacteria hard to eradicate. Bacterial colonization may obstruct wound healing by impairing white cell function, increasing tissue hypoxia, reducing the number and proliferation of fibroblasts through the production of endotoxins, and prolongation of the inflammatory phase of wound healing. Infected wounds are diagnosed clinically through the following signs and symptoms: increased pain and exudate, foul odor, an excessive inflammatory response in the wound bed coupled with an unhealthy appearance to the granulation tissue. Wound debridement is a critical means of reducing bacterial burden while also removing bacterial toxins and the wound debris that is a source of nutrients to the bacteria. Appropriate systemic antibiotic therapy is also recommended for infected wounds when bacteremia, septicemia, progressive cellulitis, or intractable osteomyelitis are present.\(^{(28,49-53)}\)

Silver has been used for several centuries to treat wounds. Silver's antibacterial and antifungal properties have been used in the treatment of burn wounds, venous leg ulcers, diabetic foot ulcers, and other types of chronic wounds. Today, several brands of wound dressings incorporate silver into advanced synthetic wound dressing materials. As the dressing material accumulates fluid, silver ions are released from the dressing into the wound environment. Free silver cations are responsible for silver's antimicrobial action by blocking cellular respiration and disrupting bacterial cell membranes. Silver ions bind to tissue proteins causing lethal changes to cell structures. Silver ions also bind and denature bacterial RNA and DNA. Silver nitrate solutions were first used to treat burn wounds in the late 1960s followed by the use of silver sulfadiazine cream.\(^{(50,54)}\)

The following is a partial list of wound dressings that contain silver or other antimicrobial agents:

- Coloplast Corporation manufactures Contreet® Foam Adhesive/Non-Adhesive and Contreet® Hydrocolloid Dressing containing silver.
- Hollister Incorporated manufactures Restore Foam Dressing Silver, Restore Contact Layer Silver, and Restore Calcium Alginate Dressing Silver.
- Johnson & Johnson, Inc. manufactures Actisorb®, a line of silver-containing dressings.
- Kendall manufactures Kerlix™ AMD™ gauze that contains polyhexamethylene biguanide.\(^{(55)}\)
- Smith & Nephew, Inc manufactures Acticoat™ Moisture Control Dressing containing nanocrystalline silver.

Skin Grafts

Skin grafts are utilized in the treatment of venous leg ulcers\(^{(56)}\), diabetic foot ulcers, and burn wounds.\(^{(57)}\)

Skin grafts are believed to assist wound healing by providing dermal collagen, growth factors, and biological occlusion and protection of the wound.\(^{(57,58)}\) Skin grafts are usually taken from a portion of intact skin of the same individual (autograft), but may be obtained by human skin donors (allograft). Skin grafts may be used in later stages of wound healing after the wound has established sufficient granulation tissue to support the graft.

A variety of skin substitutes and alternatives have been developed to treat chronic wounds.\(^{(59,60)}\) Autologous tissue grafting is an invasive and painful procedure, and often the extent of damaged skin is too large to be covered by autologous tissue graft alone. Bioengineered skin substitutes are designed to replace the damaged epithelial and dermal layers of skin with a biological replacement that enhances wound healing. Many of the conditions and biological factors needed in the healing process may be provided by the substitute skin products.

Skin substitutes allow re-epithelialization to occur while permitting gas and fluid exchange, and provide mechanical coverage and protection from bacterial influx. Most biosynthetic skin substitutes are used temporarily as a specialized dressing to replace skin function until the skin repairs spontaneously or until skin replacement is possible with autograft. A small number, however, are designed to permanently incorporate into the debrided wound (e.g., by generating neodermis). Skin substitutes may be acellular or cellular. Acellular products only contain the matrix composed of collagen, hyaluronic acid, and fibronectin. The construction of the matrix allows easy access by host cells during the healing process. Cellular products contain cells such as fibroblasts and keratinocytes within a collagen or polyglactin matrix. The cells may be allogeneic or autologous.
The biological materials used to form these skin substitutes vary by product. The following is a brief description of some of the products currently available to treat burns and other skin wounds:

- **AlloDerm®** (LifeCell Corporation, Branchburg, NJ, USA)—acellular, de-epithelialized cadaver dermis.
- **Apligraf®** (Organogenesis, Inc., Canton, MA, USA)—neonatal keratinocytes and collagen seeded with neonatal fibroblasts.
- **Biobrane®** (UDL Laboratories, Inc., Rockford, IL, USA)—silicone, nylon mesh, and collagen.
- **Dermagraft®** (Advanced BioHealing, Inc., Westport, CT, USA)—polyglycolic acid or polyglactin-910 seeded with neonatal fibroblasts.
- **Epicel®** (Genzyme Biosurgery, Cambridge, MA)—autologous cultured keratinocytes.
- **Integra® Dermal Regeneration Template** (Integra LifeSciences Holding Corp., South Plainsboro, NJ, USA)—silicone, collagen, and glycosaminoglycan.
- **Oasis®** (Healthpoint Ltd., Fort Worth, TX, USA)—derived from porcine small intestinal submucosa.
- **OrCel®** (Forticell Bioscience, Inc., New York, NY, USA) - normal human allogeneic skin cells (epidermal keratinocytes and dermal fibroblasts) are cultured in two separate layers into a Type I bovine collagen sponge.
- **Promogran®** (Systagenix Wound Management, London, UK; formerly marketed by the professional wound care business of Ethicon Inc, a Johnson & Johnson company)—bovine collagen and oxidized regenerated cellulose.
- **Suprathel®** (Polymedics Innovations GMbH, Denkendorf, Germany)—lacto-capromer, polylactic acid.