Wound Care Management Market to 2018
Advanced Wound Care Modalities and an Expanding Patient Base Create Significant Growth Opportunities in Emerging Countries
GBI Research Report Guidance

- The ‘Market Characterization’ chapter provides information on market size for the historic period 2004–2011 and the forecast period 2011–2018. It also provides information related to wound care management market trends, market dynamics and competitive landscape. In the market dynamics section, comprehensive information is provided on market drivers and restraints.

- The ‘Category Analysis and Forecasts’ chapter discusses advanced wound management devices, automated suturing devices, compression therapy, Negative Pressure Wound Therapy (NPWT), ostomy drainage bags, pressure relief devices, tissue engineering, traditional wound management and wound closure devices categories and their respective segments. Market size information for the historic period 2004–2011 and the forecast period 2011–2018 are discussed for each category, along with the market dynamics and competition. Company shares for the automated suturing devices and tissue engineering categories have not been covered.

- The ‘Country Analysis and Forecasts’ chapters provides market size information for the historic period 2004–2011 and the forecast period 2011 to 2018 for the US, Canada, the UK, France, Germany, Italy, Spain, Japan, China, India, Australia and Brazil. A cross-country analysis of these countries is also discussed.

- The ‘Competitive Assessment’ chapter provides profiles of the leading wound care management devices companies, outlining the companies' products, features and benefits.

- The ‘Pipeline Product Analysis’ chapter focuses on the pipeline products for various categories. Key pipeline products are listed and discussed in detail and product approval and expected launch dates are also provided for a number of products.

- The ‘Consolidation Landscape’ chapter discusses the deals that took place in the wound care management industry during 2007–2011.
Executive Summary

The global wound care management market is forecast to grow at a CAGR of XX% during 2011-2018

The global wound care management market is expected to grow at a Compound Annual Growth Rate (CAGR) of XX% from $XX billion in 2011 to $XXX billion in 2018. Factors such as the increasing incidence of chronic wounds due to rapid lifestyle changes, the increased prevalence of diabetes and obesity, and the growing elderly population are driving the wound care management market. Technological advances are expected to increase the adoption of advanced wound care products. Emerging countries such as India and China show potential for market growth due to increasing awareness and large patient populations.

Source: GBI Research, Company Annual Reports and Interviews with Industry Experts and Key Opinion Leaders
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2 Introduction

The wound care management market is a combination of both traditional, established wound care devices categories and advanced wound care categories that continue to evolve.

The wound care management comprises advanced wound management devices, automated suturing devices, compression therapy, Negative Pressure Wound Therapy (NPWT), ostomy drainage bags, pressure relief devices, tissue engineering, traditional wound management and wound closure devices.

The increasing prevalence of lifestyle diseases such as diabetes and obesity has resulted in a growing incidence of chronic wounds. This and the increasing elderly population are fuelling the demand for effective wound care therapies. Growth in surgical procedural volumes, increased patient awareness and technological advances will further boost the growth of the wound care management market.

The advanced wound care category will witness moderate to strong growth, especially in emerging economies with large underserved markets. The growth in the diabetic populations in countries such as India will lead to a large patient pool suffering from foot ulcers. This will increase the demand for therapies, promote rapid wound healing and ensure safer patient outcomes.

Traditional wound care products are witnessing market saturation in developed countries, which is making way for scientifically advanced alternatives. The growth in the advanced wound care category can be attributed to market opportunities in developed countries, as well as the potential untapped markets of developing economies.
4.5 Global Wound Care Management Market: Market Dynamics

4.5.1 Market Drivers

4.5.1.1 Increased Prevalence of Lifestyle Disorders Resulting in a Growing Incidence of Chronic Wounds to Fuel the Demand for Wound Care Management Devices

According to the International Diabetes Federation, the global diabetic population stood at approximately XX million in 2011, a XX% increase from 2010. The diabetic population is expected to reach XX million by 2030. Diabetes poses a serious threat globally, with one in XX adults expected to suffer from the disease.

![Figure 4: Diabetes Population, Global (millions), 2011–2030](image)

Source: GBI Research, Research Articles

Nearly XX% of all diabetics are affected by foot ulcers, with amputations performed on over one million diabetics each year. Diabetic foot ulcers not only cause reduced independence, but also increase the economic burden due to long hospital stays, further treatment and rehabilitation and extended home care. The medical costs associated with the treatment of a diabetic foot ulcers was an estimated $XX in the US in 2009.

According to the International Work Group on the Diabetic Foot (IWGDF), it is estimated that one out of XX people with diabetes will be affected in developed countries, whereas the condition is believed to be more common in developing countries due to poverty and lack of proper healthcare facilities.

However, it is estimated that XX% to XX% of all amputations due to diabetic foot ulcers can be prevented with proper preventive and therapeutic measures.

Abnormalities in the cardiovascular system in diabetics can also result in the development of co-morbid conditions, most of which lead to lower extremity amputations (LEA) due to foot ulceration and infection. Conditions such as peripheral neuropathy, vascular diseases and uncontrolled hyperglycemia in diabetics make patients prone to poor circulation and impaired wound healing.
8 Global Wound Care Management: Product Pipeline Analysis

8.1 Wound Care Management – Product Pipeline Summary

The global wound care management devices market has XX products in the pipeline with most of the products in the advanced wound management category (XX products, XX% of the total pipeline). The increasing incidence of chronic wounds and the growing elderly population are increasing the demand for effective wound care devices. Wound closure devices contribute XX% of the total pipeline products. The rise in the number of surgeries and growing demand for non-invasive wound closure products are driving this category.

The use of advanced technologies such as electrical stimulation therapy and the use of bioengineered products such as skin substitutes are driving the demand for advanced wound management devices globally.

Source: GBI Research, Company Annual Reports and Interviews with Industry Experts and Key Opinion Leaders
10 Appendix

10.1 Definitions

10.1.1 Wound Care Management

The wound care management market comprises dressings, equipment and other aids to prevent, treat wounds and also quicken or promote wound healing. The wound care management market covers traditional wound management, advanced wound management, Negative Pressure Wound Therapy (NPWT), wound closure devices, ostomy drainage bags, pressure relief devices, compression therapy, tissue engineering and automated suturing devices.

10.1.1.1 Advanced Wound Management

Advanced wound care management involves the use of dressing products combined with drug formulations to provide enhanced healing properties. This gives a moist and active dressings environment for optimum healing. Active dressings are based on biomaterials like collagens. Similarly, moist dressings include materials such as hydrogels. This category includes semi-permeable films, foams, hydrofibers, hydrocolloids, hydrogels, alginates and collagens and excludes combination dressing, paste and gels.

Alginates

This dressing includes alginates produced from the naturally occurring calcium and sodium salt of alginic acid, which is found in a family of brown seaweed. Alginate dressings fall into groups: those containing 100% calcium alginate or those that contain a combination of calcium with sodium alginate, usually in a ratio of 80:20. Alginate dressings form a moist gel in the presence of wound exudates.

Antimicrobial Alginate Dressings

The alginate dressing impregnated with an agent which inhibits microbial growth.

Non Antimicrobial Alginate Dressings

This is a dressing using alginates without any antimicrobial agent.

Collagens

This segment includes dressings that are typically made up of a combination of animal collagen and any other formulation (such as cellulose or alginates) for structural integrity and sodium or calcium ions. Collagens have high absorbent properties that absorb moisture such as wound fluid by forming a soft, conformable moist gel sheet at the wound surface and maintain a moist environment.

Antimicrobial Collagen Dressings

The collagen dressing is impregnated with an agent that inhibits microbial growth.

Non Antimicrobial Collagen Dressings

This collagen based dressing is without any antimicrobial agent.

Foams

Foam dressings are made up of either a hydrophilic polyurethane or silicon foam matrix for moisture control in wounds. Polyurethane foams consist of two or three layers, including a hydrophilic wound contact surface and a hydrophobic backing, making them highly absorbent. One unit refers to a pack of 10 foam dressings.

Antimicrobial Foam Dressings

Foams impregnated with an agent that inhibits microbial growth.

Non Antimicrobial Foam Dressings

This is a dressing using foams without any antimicrobial agent. One unit refers to a pack of 10 foam dressings.

Hydrocolloids
A flat, waterproof, occlusive dressing that consists of a mixture of pectins, gelatins, sodium carboxymethylcellulose, and elastomers. This dressing forms a gel on the wound surface, promoting moist wound healing.

**Antimicrobial Hydrocolloid Dressings**
The hydrocolloid dressing is impregnated with an agent that inhibits microbial growth.

**Non Antimicrobial Hydrocolloid Dressings**
This hydrocolloid dressing does not contain any antimicrobial agents.

**Hydrofibers**
A hydrofiber is a hydrophilic, non-woven sheet or ribbon dressing composed of sodium carboxymethylcellulose (CMC). On contact with exudates, fibers are converted from a dry dressing to a soft coherent gel sheet, making them suitable for wounds with large amounts of exudates.

**Antimicrobial Hydrofiber Dressings**
The hydrofiber dressing is impregnated with an agent that inhibits microbial growth.

**Non Antimicrobial Hydrofiber Dressings**
These hydrofibers do not contain any antimicrobial agents.

**Hydrogels**
Hydrogels consist of a matrix of insoluble polymers with up to 96% water content, enabling them to donate water molecules to the wound surface and to maintain a moist environment at the wound bed. Hydrogels promote wound debridement by rehydration of non-viable tissue, facilitating the process of natural autolysis.

**Antimicrobial Hydrogel Dressings**
The hydrogel dressing is impregnated with an agent that inhibits microbial growth.

**Non Antimicrobial Hydrogel Dressings**
These hydrogels dressings do not involve any antimicrobial agent.

**Semi-Permeable Films**
Semi-Permeable films are sterile plastic sheets of polyurethane coated with hypoallergenic acrylic adhesive and are used to protect shallow, minor wounds from dirt, fluid and bacteria.

**Antimicrobial Film Dressings**
The semi-permeable film dressings are impregnated with an agent that inhibits microbial growth.

**Non Antimicrobial Film Dressings**
These semi-permeable films do not contain any antimicrobial agents.

10.1.1.2 **Automated Suturing Devices**
An automated suturing device automatically stitches the adjoining tissue layer edges by repeatedly passing a needle and attached thread without the need of manual intervention.

10.1.1.3 **Compression Therapy**
Compression therapy involves compression devices, such as compression bandages and compression pumps, to treat vascular diseases such as venous ulcers.

**Dynamic Compression Therapy**
Dynamic compression is a mechanical compression applied by a mechanical pumping device. The pressure is applied from the foot proceeding towards the lower leg and ending just below the knee.
Intermittent Pumps
Intermittent pumps provide compression therapy by compressing and decompressing the leg. The pump inflates and deflates the sleeve in one motion and with uniform pressure along the sleeve.

Segmental Pumps
Segmental pumps provide compression therapy by compressing and decompressing the leg. The pressure applied on the segments of the sleeves is uniform but the segments are deflated and inflated individually. These pumps use a multi-chambered pneumatic sleeve to exert compressive force to the limb.

Static Compression Therapy
Static compression therapy involves the application of graduated pressure from the ankle, up the lower leg and ending below the knee. The distal portion of the bandage applies greater pressure and the pressure decreases gradually towards the proximal portion of the bandage. The pressure generally averages between 30 mmHg and 40 mmHg. The exact pressure varies according to the type of garments or stockings used. Static compression therapy devices are segmented into ready-to-wear leg wear, anti-embolism stockings, diabetic shoes and compression bandages.

Anti-Embolism Stockings
Anti-embolism stockings are designed for patients that are confined to bed to help prevent blood from pooling in the veins of the leg, causing blood clots. These stockings are used for a short duration during hospitalization to deliver gradient compression. These stockings can deliver compression to the ankle at 12–20 mmHg.

Compression Bandages
Compression implies the deliberate application of pressure and is most commonly employed to control edema and reduce swelling during the treatment of venous disorders of the lower limb. Compression bandages are categorized as: light, moderate, high and extra-high performance based on their ability to produce predetermined levels of compression.

Diabetic Shoes
Diabetic shoes are specifically designed therapeutic shoes that are wider and deeper than a regular shoe. These reduce the risk of foot injuries or skin breakdown for patients suffering from diabetes.

Ready-to-Wear Leg wear
Ready-to-wear leg wear provide low-to-medium levels of compression to help blood flow continuously throughout the veins. They are typically prescribed for use after the patient is discharged from hospital or an extended care facility and can be worn comfortably for a long period of time.

10.1.1.4 Negative Pressure Wound Therapy (NPWT)
Negative Pressure Wound Therapy (NPWT) is the use of sub-atmospheric pressure to promote or assist wound healing, or to remove exudates from a wound.

Negative Pressure Wound Therapy Disposables
NPWT disposables are consumables used with NPWT equipment. This includes devices such as canisters, dressings and tubing.

Negative Pressure Wound Therapy Equipment
This is a non-invasive therapy system that creates negative pressure, also known as sub-atmospheric pressure, at the wound site to promote effective wound healing. A tube decompresses a foam dressing continuously or intermittently to remove exudates from a wound.

10.1.1.5 Ostomy Drainage Bags
An ostomy is a surgical procedure that creates an artificial opening for the elimination of waste fluids from the stomach. Devices such as ostomy pouches and related accessories are included under this category.
Colostomy

After a Colostomy procedure, a part of the colon is attached to the anterior abdominal wall, leaving a stoma in its place. A colostomy bag/pouch is then attached to the stoma to rid the body of fecal matter. There are various types of pouches: open-ended, close-ended or one-piece (in which the skin adhesive is attached and the pouch with the skin adhesive is considered a unit).

Ileostomy

Ileostomy bags are used for the disposal of body matter from a stoma in the abdomen. These bags are usually located above the groin on the right hand side of the midsection. This can be either a temporary or permanent measure. Ileostomy bags and pouches are included in this category.

Urostomy

Urostomy bags are used to collect urine after a urostomy procedure. Most urostomy bags/pouches are made with an anti-reflux valve to stop back-flow into the system. This can be either a temporary or permanent measure.

10.1.1.6 Pressure Relief Devices

Pressure relief devices provide a conforming support surface and distribute body weight over a large area. Specialty beds, mattresses replacements made of foam, air, gel and fluid; and mattress overlays made of foam, gel and air are included under this category.

Mattress Overlays

An additional support surface designed to be placed directly on an existing mattress. Mattress overlays constructed of air, foam and gel are included.

Mattresses

Mattress replacements are a support surface that totally replaces the standard mattress for pressure ulcer management. Standard foam mattresses, alternative foam mattresses, gel-filled mattresses, air-filled mattresses and fluid-filled mattresses are covered under this segment.

Specialty Beds

This includes motor-driven turning or tilting beds that aid in the manual repositioning of the patient based on medical conditions.

10.1.1.7 Tissue Engineering

Tissue engineering for wound care management is the use of the mechanical and chemical processing of materials to manufacture products that may substitute or replace all or some components that make up normal skin (ex epidermis and/or dermis, cells and matrix). They can be bi-layered, acellular or cellular, synthetic or biological and may consist of a synthetic epidermis and a collagen-based dermis to encourage the formation of new tissue. In products that have a synthetic epidermis, this may act as a temporary wound covering. Allografts and xenografts are included in this category.

Bio-engineered Allografts

Bio-engineered allografts are transplanted cells or tissues sourced from a genetically non-identical member of the same species. They undergo various processes to remove the cells and deactivate or destroy pathogens. They are typically available in the form of surgical grafts or a matrix. Allografts for both permanent and temporary applications are included.

Bio-engineered Xenografts

Bio-engineered xenografts are derived from animal sources. The tissue material is processed to remove the cells. The products derived may consist of a tissue scaffold or may be combined with synthetic material to create a composite product. Both biological and biosynthetic xenografts are tracked under this segment. Xenografts for both permanent and temporary applications are considered.

10.1.1.8 Traditional Wound Management

Traditional wound management comprises devices such as gauzes, sponges and bandages.
Appendix

Bandages
A bandage is a portion of material that provides body support. It also sometimes supports a medical device such as a dressing or splint. It differs from compression bandages.

Gauzes
Gauzes are thin, translucent pieces of cotton with a loose open weave. Many modern medical types of gauze are covered with a plastic porous film such as Telfa or a polyblend, which prevents direct contact and further minimizes wound adhesion.

Sponges
Sponges are used for absorbing body fluids and provide protection from dirt and bacteria. ABD pads, non-adherent dressings, gauze fluff rolls and self adhering foam are also included here. Both sterile and non sterile sponges are included.

10.1.1.9 Wound Closure Devices
Wound closure devices are used to close wounds that occur due to injuries or surgical procedures. They include hemostats, tissue sealants, mechanical stapling devices, ligating clips and wound closure strips.

Hemostats
Hemostats are used to improve hemostasis and promote wound healing after surgical procedures. They contain fibrinogen, thrombin and other plasma proteins, which helps promote clotting, and the formation and cross-linking of fibrin.

Collagen-Based Hemostats
Collagen based hemostats are composed of resorbable microfibrillar collagen. It attracts platelets and allows for the formation of a blood clot when it comes into contact with blood. Matrix and gauze-based hemostats are included.

Oxidized Regenerated Cellulose-Based Hemostats
Oxidized regenerated cellulose based hemostats are poly-anions – the functional unit of which is polyanhydroglucuronic acid. It aids platelets to commence the adhesion and aggregation process leading to coagulation.

Thrombin-Based Hemostats
Thrombin based hemostats transform fibrinogen into fibrin, activate factor XIII and promote the stabilization of the clot formed by fibrin and other proteins. Only hemostats in the form of a matrix and gauze are included.

Ligating Clips
Ligating clips are made up of titanium and are conventionally used for clamping tissues as needed during various procedures.

Mechanical Stapling Devices
A hand-held wound closure device used to fix the staples after surgery. This includes stapling equipment and staples. These devices may either be disposable or reusable.

Skin Closure Devices
Skin closure devices are used in closing a circuitous opening in the skin of a patient, such as a wound or an incision. Skin closure devices include staplers, strips and clips.

Tissue Sealants
Tissue sealants are a type of surgical tissue adhesive used during surgery to control bleeding. This segment includes internal sealants and external sealants.

External Sealants
External sealants are synthetic sealants that bind covalently to tissue surface proteins. External sealants consist of cyanoacrylate glue and polyethylene glycol hydrogels.
**Internal Sealants**

Internal sealants are tissue adhesives that assist in the process of coagulation by delivering fibrinogen to the affected area. Internal sealants consist of fibrin and protein sealants.

**Wound Closure Strips**

Wound closure strips are adhesive strip-like bandages for application to skin wounds for sealing the wound without the need for surface stitches or staples.

### 10.2 Sources

- Centers for Medicare & Medicaid Services (2009), Evaluation of Healthcare Common Procedure Coding System Coding for Negative Pressure Wound Therapy Devices

### 10.3 Acronyms

- **ASAPS**: American Society for Aesthetic Plastic Surgery
- **AAGL**: American Association of Gynecologic Laparoscopists
- **AC**: Alternative Current
- **AHRQ**: Agency for Healthcare Research and Quality
- **BRIC**: Brazil, Russia, India and China
- **CAGR**: Compound Annual Growth Rate
- **CMS**: Centers for Medicare & Medicaid Services
- **CVI**: Chronic Venous Insufficiency
- **CEA**: Cultured Epidermal Autograft
- **HVPC**: High Voltage Pulsed Current
- **ECM**: Extracellular Matrix
- **E-stim**: Electrical stimulation
Appendix

GAGs: Glycosaminoglycans
FDA: Food and Drug Administration
HBO2: Hyperbaric Oxygen
HBOT: Hyperbaric Oxygen Therapy
HCPCS: Healthcare Common Procedure Coding System
IWGDF: International Work Group on the Diabetic Foot
LSEs: Living Skin Equivalents
LEA: Lower Extremity Amputations
LIDC: Low Intensity Direct Current
KCI: Kinetic Concepts, Inc
MIS: Minimally Invasive Surgeries
MIPPA: Medicare Improvements for Patients and Providers Act
NICE: National Institute of Clinical Excellence
NHANES: National Health and Examination Survey
NPTP: Negative Pressure Technology Platform
NPWT: Negative Wound Pressure Therapy
NPUAP: National Pressure Ulcers Advisory Panel
NO: Nitric Oxide
OR: Operation Room
OIG: Office of Inspector General
OTC: Over-The-Counter
PDGF: Platelet Derived Growth Factors
PPS: Prospective Payment Systems
R&D: Research and Development
RCT: Randomized Controlled Trials
SSI: Surgical Site Infections
SIGN: Scottish Intercollegiate Guidelines Network
SHI: Statutory Health Insurance
TA: Technology Assessment
TAM: Traditional African Medicine
TCM: Traditional Chinese Medicine
WHO: World Health Organization
10.4 Research Methodology

GBI Research’s dedicated research and analysis teams consist of experienced professionals in marketing and market research with consulting backgrounds in the medical devices industry and advanced statistical expertise.

GBI Research adheres to the codes of practice of the Market Research Society (www.mrs.org.uk) and the Strategic and Competitive Intelligence Professionals (www.scip.org).

All GBI Research databases are continuously updated and revised. The following research methodology is followed for all databases and reports.

10.4.1 Secondary Research

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and SEC filings.
- Industry trade journals, scientific journals and other technical literature.
- Internal and external proprietary databases.
- Relevant patent and regulatory databases.
- National government documents, statistical databases and market reports.
- Procedure registries.
- News articles, press releases and web-casts specific to the companies operating in the market.

10.4.2 Primary Research

GBI Research conducts hundreds of primary interviews a year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive landscape and future outlook.
- It helps in validating and strengthening the secondary research findings.
- It further develops the analysis team’s expertise and market understanding.

Primary research involves email correspondence, telephone interviews and face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers.
- Hospital stores, laboratories, pharmacies, distributors and paramedics.
- Outside experts: investment bankers, valuation experts, research analysts specializing in specific medical equipment markets.
- Key opinion leaders: physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of medical equipment.
10.4.3 Models

Where no hard data is available GBI Research uses modeling and estimates in order to produce comprehensive data sets. The following rigorous methodology is adopted:

Available hard data is cross referenced with the following data types to produce estimates:

- Demographic data: population, split by segment.
- Macro-economic indicators: Gross Domestic Product, Inflation rate.
- Healthcare Indicators: health expenditure, physician’s base, healthcare infrastructure and facilities.
- Selected epidemiological and procedure statistics.

Data is then cross-checked by the expert panel.

All data and assumptions relating to modeling are stored and are available to clients on request.

10.4.4 Forecasts

GBI Research uses proprietary forecast models. The following four factors are utilized in the forecast models:

- Historic growth rates.
- Macro indicators such as population trends and healthcare spending.
- Forecast epidemiological data.
- Qualitative trend information and assumptions.

Data is then cross-checked by the expert panel.

All data and assumptions relating to modeling are stored and are available to clients on request.

10.4.5 Expert Panels

GBI Research uses a panel of experts to cross verify its databases and forecasts.

GBI Research’s expert panel comprises marketing managers, product specialists, international sales managers from medical device companies; academics from research universities, KOLs from hospitals, consultants from venture capital funds and distributors/suppliers of medical equipment and supplies.

Historic data and forecasts are relayed to GBI Research’s expert panel for feedback and adjusted in accordance with this feedback.
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