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Composite nonwovens in medical applications

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Abstract: This chapter reviews the role of composite nonwovens in medical applications. It covers surgical gowns, clinical wearable products, wipes, wound dressings, pads, swabs, scaffolds for tissue engineering, hernia meshes, filtration materials, and incontinence products. Commercially available, innovatively designed composite nonwovens for various medical applications are improving the quality of life of many people. Specific research needs have been highlighted to further improve the effectiveness of these products. The chapter ends with some perspectives for the use of composite nonwovens in medical applications in the future.

Key words: composite nonwoven, fibre, cell, wound, scaffold.

9.1 Introduction

Composite nonwovens are fibrous materials, in which several layers of different fibres are either bonded together or combined with other textile components, while their felt characteristics remain predominant. Composite nonwovens are generally prepared by combining multiple fibrous layers of different types of polymers, fibres or textile components. Integration of multiple fibrous layers can be achieved by passing them through a set of hot rollers, needle-punching, stitch-bonding, ultrasound treatment or high-frequency welding. Such nonwoven products can be tailored to meet the requirements of the following specific clinical applications:

- personal healthcare/hygiene products, such as surgical gowns, masks, wipes, surgical drapes and bedding;
- non-implantable medical dressings, including wound dressings and bandages;
- implantable medical products, including scaffolds for tissue regeneration and orthopaedic structures.

Nanofibrous nonwoven matrices, made by using the electrospinning technique, are beyond the scope of this article. However, extensive research work is being conducted in the development of electrospun matrices made up of composite nanofibres for medical applications (Soliman *et al.* 2011; Zhang *et al.* 2009; Kai *et al.* 2013).

9.2 Surgical gowns

The main function of a surgical gown is to provide an appropriate level of hygiene, comfort and protection for surgeons and healthcare workers from blood-borne pathogens. The recent prevalence of infectious diseases such as AIDS, hepatitis, and severe acute respiratory syndrome (SARS) demonstrates the critical need to develop efficient surgical gowns, gloves and masks to ensure the highest level of protection.

A critical performance factor in protective surgical apparel relates to the ability to provide a barrier to microbial transfer from a non-sterile to a sterile side of the fabric. Microbes and pathogens can pass through the fabric, carried by dust particles or liquids such as body fluids (blood, perspiration, etc.). According to the definition of the Centers for Disease Control and Prevention (CDC, USA), liquid-resistant apparel allows minimal amounts of liquid to penetrate when pressure is applied. Liquid-proof apparel does not allow any liquid to penetrate at all (Mangram *et al.* 1999).

There is great demand for cheap disposable gowns in the cost-conscious healthcare sector. Over the last few years various strategies for developing single-use fabrics have evolved, using spunbonded-meltblown-spunbonded (SMS), spunlace hydroentangled, triplex or bicomponent fibrous webs, with or without chemical finishes to resist liquid penetration. Disposable SMS fabric can be formed by sandwiching an inner thermoplastic meltblown microfibrous web between two outer nonwoven webs of substantially continuous thermoplastic spunbonded filament, where the spunbond layer provides strength and dimensional stability while the meltblown layer provides the barrier property. The microfibrous nonwoven meltblown layers provide a barrier impervious to pathogens in the composite nonwoven fabric. However, various surgical procedures entail an extent of splashing, liquid strike-through, aerosol generation, or applied pressure, and can be of long duration. Care should therefore be taken in selecting single- or multiple-use gowns during specific procedures.

Leonas and Jinkins (1997) compared eight commercially available surgical gowns, among which five were disposable nonwovens and three were reusable woven fabrics. Four of the five nonwoven fabrics investigated were made from polypropylene-based SMS nonwoven fabrics and hydroentangled wood pulp and polyester of spun-lace fabrics. SMS nonwovens showed better efficiency in preventing the transmission of *S. aureus* and *E. coli* in a saline solution, as compared to woven fabrics. Lankester *et al.* (2002) studied the extent of bacterial penetration through disposable gowns made of spun-bonded polyester and wood pulp, as compared to reusable woven polyester gowns; the results clearly showed a comparatively inferior barrier property for reusable woven polyester fabrics. Taken together, as a very generalized conclusion (McCullough and Schoenberger 1991), polypropylene-based gowns (for example, 97–100% polypropylene, SMS laminates) provided the greatest protection against blood strike-through and

microbial penetration. Gowns composed of a single layer of nonwoven fabric provided the next highest level of effectiveness. Reusable gowns composed of 100% woven cotton provided a minimal level of protection.

9.3 Surgical facemasks and other clinical wearable products

Other than surgical gowns, several other wearable products are currently demanding attention from researchers, such as shoe covers, caps, facemasks to be worn by surgeons during surgery, facemasks for patients or caregivers, facemasks for health workers handling outbreaks of airborne diseases (SARS virus, H1N1 flu, bird flu, etc.), and masks for sanitation workers working in dusty environments. Previously, all such reusable hospital garments were made using conventional textiles (cotton, cotton-polyester, etc.), but these have now been linked to increases in so-called 'Hospital Acquired Infections'. Pathogenic bacteria present on the scalp and skin are reported to have caused epidemics (Dineen and Drusin 1973); it is therefore highly important that efficient coverings are available during surgery. All over the world, major care is being taken to reduce patient-to-patient transmission of resistant pathogens such as methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant *Enterococcus*. Nonwoven products remain the most common choice for protection, sometimes with an additional active coating.

Surgical facemasks are usually composed of three layers of an SMS nonwoven fabric, where the meltblown material acts as a filter. The design of most surgical masks includes three pleats/folds to allow the user to expand the mask to cover the area under the nose and under the chin. This design may be sufficient to protect the wearer in dusty environments, but these products are not particularly effective in offering protection from airborne pandemic diseases or in environments full of aerosols.

Several new designs of respirator mask that use advanced strategies are currently coming in the healthcare markets. For example, the multiple-use respirator mask introduced by Carey International Ltd, Westerly, RI, USA, consists of a needle-punched, four-ply nonwoven fabric in which two outer layers contain silver/copper zeolite compounds permanently embedded onto the fibres, and two inner filtration layers are designed to prevent microbial or particulate penetration (complying with the National Institute of Occupational Safety and Health standards N95 and N99). The outer layers have been demonstrated to kill *Streptococcus pyogenes* and methicillin-resistant *Staphylococcus aureus* and deactivate strains of H1N1 and H5N1, as well as common flu and other viruses. The N95 masks offer 95% or higher particle filtration efficiency.

The main limitation in the performance of shoe covers for clinicians and healthcare professionals is frequent rupturing during use (Carter 1990; Jones and Jakeways 1998). Blood easily soaks through many commercially available shoe covers, and better bacterial and liquid barrier properties are needed.

Although all these products have been commonly used for many years (Eisen 2011), there is scope for innovation in their design. For example, facemasks for health workers involved in flu pandemics must remain effective for at least a few weeks, but the standard single-use masks currently available remain effective for only a few hours. Efficient pathogen monitoring and detection mechanisms should be available for these masks.

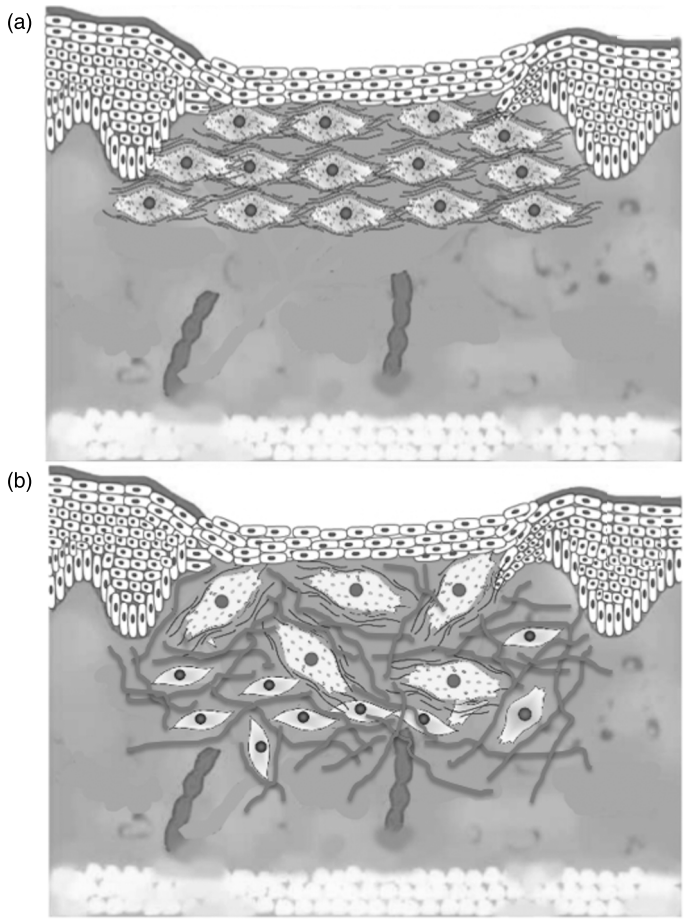
9.4 Wipes

The wipes market is experiencing massive growth, and there has been a constant stream of new nonwoven products across a number of categories, which have been innovatively applied. Examples include Procter & Gamble's 'Swiffer' household floor wipes and L'Oreal's make-up removal wipes 'Revitalift'. An extensive review of wipes is given in Chapter 6 of this book.

9.5 Wound dressings, pads and swabs

Mammalian embryos and some amphibians can spontaneously regenerate their tissues after severe injury. Adult mammals typically recover from such injuries by a 'repair' process, eventually developing scars. At the price of wound closure, severe wound contraction and scar tissue formation often cause serious clinical complications and life-long disfigurement for the survivor. During healing of skin wounds, a group of contractile cells (myofibroblasts) migrate in the wound bed. These cells express cytoplasmic bundles of microfilaments (stress fibres), using which they apply contractile forces to shrink the injured site. Eventually the wound site is filled by an irregular dense collagen fibrous matrix (Tomasek *et al.* 2002). When a nonwoven matrix is implanted within the wound bed, those contractile cells migrate randomly, following the randomly oriented fibrous architecture of the nonwoven matrix. This can result in disorientation of major axes of contractile cells and the disruption of organized cell contraction at the edges of the wound. Thus, randomization of individual force vectors of contractile cells will reduce rapid contraction of wound edges (Fig. 9.1). A significant reduction in the number of contractile cells has also been reported when the wound is treated with a nonwoven scaffold during dermis regeneration (Murphy *et al.* 1990). Despite detailed understanding of wound healing mechanisms, scarless healing in adult humans still remains a utopian concept, but extensive research is ongoing to develop bioresponsive fibrous material, such as collagen-glycosaminoglycan bicomponent fibrous web, which will be able to inhibit scar formation and cause controlled contraction (Yannas 2013).

Many basic composite nonwoven dressings are commercially available and are regularly used. These are relatively inexpensive, readily available, and versatile enough to treat several types of wounds. The simplest form is as a single nonwoven layer with a transparent waterproof backing (generally polyurethane film), which



9.1 (a) Skin wounds without nonwoven myofibroblasts get oriented to form scar tissue; (b) in the presence of nonwoven fabric, random scattering of myofibroblasts inhibit scar tissue formation.

forms an attachment to the skin to keep the dressing in place while the nonwoven absorbent layer contains medication to promote healing.

Strategies to induce fast clotting are critically needed for wound dressing materials to achieve minimum blood loss and absorption of exudates. Numerous commercial wound dressing products use composite nonwoven adhesive tape (usually polyester) as an absorbent pad/wound contact layer. In some dressings, these absorbent pads are placed continuously edge-to-edge, whereas in some products they are located as an island in the central region of the dressing. Such dressings can handle low-to-moderate exudate. In some dressings, such as Kendall's Viasorb, super-absorbent polymers may be added for handling moderately- to heavily-exuding wounds.

9.6 Scaffolds for tissue engineering

Tissue engineering is a rapidly developing multidisciplinary field and holds great promise for the repair and reconstruction of tissues and organs damaged by disease, accidents, congenital abnormality and defects. There are numerous methods of scaffold fabrication, but porous sponge-like scaffolds made using porogen-leaching techniques and nonwoven-based structures are the two most common. These offer much in terms of high surface area, porosity and pore size distribution, ease of preparation, and fibrous randomness, as per anatomical requirement. High porosity and pore interconnectivity are needed for cell attachment, migration and uniform distribution throughout the scaffold.

In the early stages of embrogenesis, trophoblast cells form an outer layer of blastocyst to provide nutrients to the embryo. Culturing human trophoblast cells on needle-punched nonwoven polyethylene terephthalate fabric has shown that metabolic activities and proliferation rate are dependent on the porosity of the nonwoven scaffold. However, a higher extent of cellular differentiation has been observed with high-porosity mesh than with low-porosity mesh, as evidenced by the expression of specific biomarkers (Ma *et al.* 2000). These findings are important, as a critical balance between cell proliferation and differentiation can govern tissue development.

Human embryonic stem cells have the potential to differentiate into all three germ layers and develop into any tissue types found in our body. These cells can proliferate in long-term culture *in vitro*. However, until recently, undifferentiated embryonic stem cells needed culture on a layer of feeder cells, such as mouse embryonic fibroblasts. Feeder cells produce some important soluble factors, such as the cytokine Leukemia Inhibitory Factor (LIF), which are critically needed for embryonic stem cells to maintain their undifferentiated, pluripotent phenotype. Cetinkaya *et al.* (2007) generated carboxylic acid groups on poly(ethylene terephthalate) fibrous nonwoven material by hydrolysis reaction, which helped in immobilizing LIF via ionic interaction with amino groups. LIF-immobilized scaffold supported the growth of embryonic stem cells, but undifferentiated morphology was not retained as anticipated.

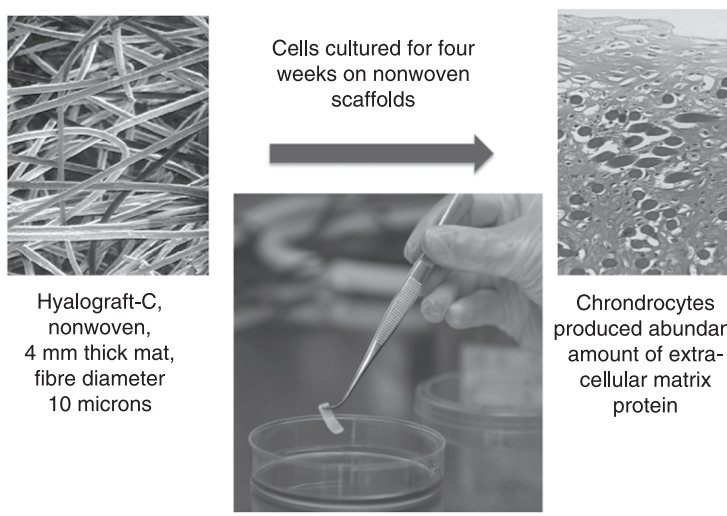
First-generation tissue engineering experiments targeted cartilage regeneration using poly lactic acid/poly glycolic acid (PLA/PGA)-based nonwoven matrices. For example, Shieh *et al.* (2004) used PGA nonwoven fibrous scaffolds, where fibres were treated with poly-L-lactide (PLLA)-chloroform solution; a human ear-shaped architecture was developed using a negative mould. Sheep chondrocytes were then cultured to develop tissue-engineered auricular cartilage.

Hyaluronic acid is an important molecule in the maintenance of the physicochemical characteristics of the cartilage extracellular matrix. Sodium hyaluronate salt is water-soluble, so sodium hyaluronate is esterified in order to impart water insolubility. Esterified hyaluronic acid fibres show easy processability and enhanced residence time *in vivo*. Esterified hyaluronic acid-based nonwovens

(e.g., Hyaff-11, Fidia Advanced Biopolymers, Italy) have been extensively used for knee-joint cartilage tissue engineering (Moretti *et al.* 2005) and nose reconstruction (Farhadi *et al.* 2006). Statistically, chondrocytes produced a significantly higher amount of glycosaminoglycan and collagen in the nonwoven scaffold (Fig. 9.2) as compared to porogen-leached poly ethelene glycol terephthalate/poly butylene terephthalate (PEGT/PBT) scaffolds (Miot *et al.* 2006). Nonwoven porous polymer tubes fabricated from nonwoven meshes of polyglycolic acid fibres have been seeded with rat hepatocytes and the constructs successfully implanted in small intestinal submucosa (Kim and Mooney 1998).

Spinal cord damage can cause paraplegia or quadriplegia. Attempts have been made to fill gaps in the spinal cord by seeding adult rat spinal cord-derived cells in a polyglycolic acid nonwoven mesh (Albany International, Albany, NY, USA); in these experiments, the construct was implanted into a 3–4 mm-long gap. Cells gradually differentiated into neurons, astrocytes, and oligodendrocytes and contributed to the restoration of function to the lower limbs. After six months, coordinated gait in hind limbs and motor control of the tail were noticed. This work demonstrated the fascinating promise for spinal cord repair by incorporating undifferentiated neural progenitor cells into implants to fill gaps in the damaged spinal cord (Vacanti *et al.* 2001).

Wakita and colleagues developed siloxane-poly(lactic acid)-calcium carbonate composite fibrous structures so that mineral components are agglomerated within the PLA fibre matrix. Such nonwoven scaffolds release calcium and silicate ions, and have potential for bone regeneration (Wakita *et al.* 2011). However, most



9.2 Cartilage tissue engineering using nonwoven scaffold.

nonwoven scaffolds reported so far have poor compressive strength and are hence unsuitable for bone tissue engineering. For the purpose of bone regeneration, attempts have been made to develop fibre-reinforced polymer foam. The reinforcing effect of fibres within a matrix becomes effective when fibres are uniformly distributed throughout the matrix, the degree of fibre-polymer contact is maximized and fibre–fibre contact is kept at a minimum. Generally, this type of scaffold is made using a solvent-casting technique. Mandal *et al.* (2012) attempted to develop a silk-fibre-reinforced scaffold to simulate the compressive modulus of bone. Interfacial bonding between the silk fibre and the silk matrix resulted in an compressive modulus of 10 MPa in hydrated conditions. Such matrix stiffness and surface roughness support osteogenic differentiation of mesenchymal stem cells to prepare bone-like tissue (Mandal *et al.* 2012).

There is no successful clinical option available for patients suffering from end-stage liver disease. Bioartificial liver support systems based on hollow fibre technology have undergone clinical trials and have been demonstrated to be promising (Watanabe *et al.* 1997). In this system, hepatocytes are placed inside a chambered cartridge. When patients' blood is passed through, cells process toxins from the blood and synthesize proteins and metabolites. This plasma is then returned to the patient's body. In such systems, oxygenated plasma flows through the fibre capillary, but hepatocytes are attached in extracapillary spaces. As a result, the oxygen supply to the hepatocytes is inadequate because the oxygen-binding ability of plasma is less than one-tenth of that of whole blood. This limited oxygen supply leads to insufficient function of hepatocytes.

Li *et al.* (2006) used a roller pump in which polysulfone hollow fibres were spirally wound with polytetrafluoroethylene nonwoven fabric. Nonwoven fabric allowed attachment and aggregation of hepatocytes, and semipermeable membranes of hollow fibres served as gas exchangers and immuno-protective barriers. Whole blood passed through the intra-luminal space of the hollow fibres and was exposed to the hepatocytes for effective oxygen supply, CO_2 removal and exchange of metabolic waste and nutrients. Hence, the diffusion distance was reduced and mass exchange took place akin to that in the sinusoids of the liver parenchyma.

9.7 Hernia meshes

A hernia is a protrusion of a tissue through the wall of the cavity in which it is normally contained. Nonwoven meshes should be easy to use in both laparoscopic and open hernia repair. Fibrous capsule formation, cellular attachment and mesh contraction result in the recurrence of hernias in most patients. Woven polypropylene meshes frequently form adhesion and fistula when transplanted intra-peritoneally. Polypropylene nonwoven fabric has been demonstrated to overcome such complications due to its microporous structure giving a high capacity for tissue in-growth and integration (Langenbach *et al.* 2003).

Raptis *et al.* (2011) implanted woven as well as nonwoven polypropylene fabrics into 12 pigs to compare ease of incorporation and removal by histology and adhesion formation 90 days after implantation. Intraperitoneally, woven polypropylene fabric became fully peritonealized, but generated thick and abundant adhesions. Interestingly, polypropylene nonwoven fabric became fully peritonealized and generated only very thin adhesions, and to a strikingly lesser extent. Woven meshes formed comparatively dense adhesions that could only be detached with greater difficulty than with nonwoven meshes (Raptis *et al.* 2011).

Weyhe *et al.* (2006) and Dubova *et al.* (2007) investigated the inflammatory response in rats during abdominal wall reconstruction using polypropylene fabrics, at different time points after surgery. One group of rats received heavy woven polypropylene meshes with macro-dimensional pores, and the other group of rats received light nonwoven fabrics with micro-dimensional pores. A more severe inflammatory reaction was noticed in the group which received nonwoven fabrics. Interestingly, however, Dubova *et al.* (2007) noticed less intense fibrosis in the nonwoven fabric, with uniform tissue growth after 28 days, while Weyhe *et al.* (2006) reported a decline in the concentration of inflammatory cells over time in both groups. Fibrous tissue formation took place in both types of hernia mesh after 45 days, with no statistical difference between the groups.

9.8 Filtration materials for medical applications

Red blood cell concentrates and platelet concentrates are commonly transfused to patients. It has been observed that the presence of white blood cells (leukocytes) in blood during transfusion may cause several adverse reactions, including recurrent febrile nonhemolytic transfusion reaction with high fever and vomiting, platelet refractoriness, graft versus host disease, and transmission of viruses (e.g. cytomegalovirus and HIV). The preferred method is therefore to reduce leukocyte-counts before storage of peripheral blood at the blood bank.

Kim *et al.* (2009) developed meltblown poly(butylene terephthalate) nonwoven and graft-polymerized acrylic acid onto it by oxygen plasma glow discharge treatment. They then immersed the nonwoven fabric in an aqueous solution containing high concentrations of phosphate and calcium ions to produce a thin layer of hydroxyapatite. This composite nonwoven was found to successfully remove 98.5% of leukocytes and recovered 99.5% of erythrocytes. This strategy seems promising compared to the standard procedure of removing cell populations by centrifugation.

Bone marrow-derived mesenchymal stem cells are regularly used for regenerative medicine strategies. Isolation of these stem cells from total marrow is usually conducted using a sucrose-based density gradient column, which is a time-consuming process. After screening 200 biomaterials, Ito *et al.* (2010) selected rayon–polyethylene nonwoven fabric for the development of a filter for the collection of mesenchymal stem cells from bone marrow hematopoietic

mononuclear cells. Mesenchymal stem cells adhered tightly to highly hydrophilic and rough surfaces as compared to hydrophobic and smooth surfaces, resulting in a rapid and efficient method of cell isolation filtration.

9.9 Incontinence products

Healthcare and hygiene products for incontinence tend to basically consist of an absorbent pad and skin contact layer and a transparent (waterproof) film adhesive tape. Composite nonwoven based incontinence and hygiene products can be classified as follows:

- Babycare products: baby nappies and baby wipes (dry or moisturized).
- Feminine hygiene products: sanitary napkins, panty shields and liners.
- Adult incontinence: adult nappies, nursing pads, disposable underwear, bladder control pads.

These products are discussed in detail in Chapter 5 of this book.

9.10 Conclusion and future trends

Advances in the development of composite nonwovens for various medical applications are significantly changing the lives of many people. However, the emergence of drug-resistant microbial strains demands more efficient detection mechanisms for surgical drapings and masks and better anti-viral, anti-microbial strategies. The detection, prevention and killing of viruses and bacteria such as methicillin-resistant *Staphylococcus aureus*, hepatitis, SARS or H1N1, remain permanent challenges in the development of protection for healthcare workers.

Although significant progress has already been made in research on nonwovens, structure–function relationships still need to be elucidated. Moreover, in order to face up to such challenging problems, researchers should not be afraid of blurring the boundaries of traditional textile technology. A multi-disciplinary approach is required to develop the next generation of products – for example, electronics-embedded nonwovens for efficient detection of viral particles on a facemask – to improve understanding of the interaction of the nonwoven matrix with cells and the related cellular signalling process to induce organ regeneration. As boundaries between disciplines blur, multi-disciplinary research will become the norm rather than the exception, stimulating further growth in the nonwovens sector.

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9.12 Appendix: recent patents based on composite nonwovens for medical applications

Table 9.1

Serial no.	Patent no.	Name of patent	Invention	Date of patent	Inventor name
1.	US8341768 B2	Surgical garment with means for affixing a glove thereto	Surgical garment was developed with a front portion, back portion and two sleeves, with each sleeve having at least one adhesive region for affixing a donned surgical glove thereto	1 January 2013	MoInlycke Health Care ABNewsRx.com
2.	US8361913	Nonwoven composite containing an apertured elastic film	Composite nonwoven material were used for diapers, absorbent underpants, incontinence articles, feminine hygiene products, baby wipes, medical absorbent articles, underpads, bedpads, bandages, absorbent drapes, and medical wipes	29 January 2013	Kimberly-Clark Worldwide, Inc.
3.	US8283029	Multilayer microporous films and composites for barrier protective materials, and methods	A breathable composite non-woven multilayer microporous film was designed with controlled pore size which provided adequate barriers to blood and blood-borne pathogens (viruses)	9 October 2012	Clopay Plastic Products Company, Inc.
4.	WO2011078442 A1	Medical nonwoven fabric, and preparation method thereof	Medical nonwoven fabric was developed, with improved dimensional stability and adhesion barrier. This invention was further used for anti-adhesion, anti-air injection shield	30 June 2011	Korea Institute of Industrial Technology
5.	WO2009081421 A1	Composite material made of non-woven fabric with a high absorbing capacity	The composite non-woven fabric was used for medical products and hygiene products, including napkins	2 July 2009	Achille Costamagna, Sogetec S.P.A

(*Continued*)

Table 9.1 Continued

Serial no.	Patent no.	Name of patent	Invention	Date of patent	Inventor name
6.	US6723892	Personal care products having reduced leakage	The products to be used in absorbent articles for personal care (diapers, bandages, feminine hygiene) or wound care to promote rapid absorption and retention of fluids with comfort to the user and optimum dryness	20 April 2004	Kimberly-Clark Worldwide, Inc.
7.	US6774069 B2	Hot-melt adhesive for non-woven elastic composite bonding	Composite non-woven material used as medical garment, feminine care product, adult incontinence garment and diaper	10 August 2004	Kimberly-Clark Worldwide, Inc.
8.	US6610163 B1	Enhanced barrier film and laminate and method for producing same	Composite nonwoven material developed for use as surgical drapes and gowns having soft outer cover and breathable properties	26 August 2003	Kimberly-Clark Worldwide, Inc., Michael P. Mathis
9.	EP 1364773 A1	Composite nonwoven fabric for protective clothing and production method thereof	Composite nonwoven fabric used for protective clothing such as medical underwear and gowns due to excellent water vapour permeability, water resistance and strength	26 November 2003	Chori Co., Ltd, Kuraray Co., Ltd
10.	US6410464 B1	Hand-tearable tape	Pressure sensitive adhesives developed for constructing medical tapes which are physically and biologically compatible with human skin	25 Jun 2002	Robert H. Menzies, Robert J. Maki
11.	WO2001015898 A1	Breathable multilayer films with breakable skin layers	Breathable multilayer films for use in absorbent articles, medical garments	8 March 2001	Kimberly-Clark Worldwide, Inc.