Wound treatment
Bioresorbable dressing containing growth factor proteins


The fabric is designed to accelerate tissue regeneration and wound-healing processes. It is especially suited to facilitate the treatment of burns, skin lesions, skin injuries and skin grafts, diabetic wounds and diabetic ulcers, such as diabetic foot ulcers, explains the company of Heidelberg, Germany. The nonwoven fabric is made from fibres of a raw material comprising bioresorbable polymers, with the...
(GDF5)-related protein, distributed in the fibres. Optionally, additional GDF5-related protein may be present on the fibres. The inventors surprisingly found that GDF5-related proteins, despite their relatively high hydrophobicity, can be incorporated inside the fibres, which increases the stability of the protein.

Suitable raw materials for the fibres include natural polymers, for example polypeptides such as collagen, gelatin, fibrin and casein, or polysaccharides such as dextran, cellulose, starch, chitin, chitosan, hyaluronic acid and alginate, as well as synthetic polymers such as polylactide, polyglycolide and polycaprolactone.

Biopharm says some of the fibres can be nanofibres, which makes the nonwoven fabric particularly light and thin.

Further, the nonwoven fabric can have an open-pore structure having an air permeability of 0.01–100 l.min⁻¹.cm⁻² (according to DIN 9237). Such a fabric is particularly suitable as a dressing material as it enables the skin to release moisture and to breathe.

See also: US Patent 9 278 156, Bioreposable wound dressing.

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Silicone gel-coated dressing

A wound dressing that features a silicone-coated substrate has been developed by KCI USA.

According to the company of San Antonio, Texas, USA, the dressing material featured in US Patent 9 295 749 is characterized by tacky upper (4) and lower (5) silicone coatings on the substrate (2), with each coating having a different tackiness; the coating is a hydrophobic, tacky, cross-linked silicone gel.

The substrate is porous and permeable. It can be, for instance, a mesh, web or fabric formed from a woven, nonwoven or knitted textile or a moulded mesh.
In particular, the substrate is a fabric such as a cellulose acetate gauze or a mesh containing a series of apertures, preferably with a diameter of 0.5–2.0 mm, that ensure the material can be adequately coated with silicone gel without becoming occluded.

The substrate is formed from any medically acceptable material, such as cellulose, polyolefins, polyesters (PESs) or polyamides (PAs). A particularly suitable material is cellulose acetate gauze. Most preferably, the substrate has a weight of 50–150 g.m⁻².

The silicone-coated substrate retains open apertures to allow the passage of wound fluid. The open area of the coated substrate can be, for instance, 10–50%.

Identical release-coated cover sheets (7, 8) are applied to the upper and lower silicone-coated surfaces. In use, the lower release sheet (8) is removed first to expose the less tacky lower surface of the dressing material.

KCI says it is relatively easy to remove the lower release sheet because of the lower adherency of this sheet to the material compared with the upper release sheet (7).

The lower surface may then be applied to a wound surface, followed by removal of the upper release sheet and application of secondary dressing elements, such as an absorbent layer.

See also: US Patent 9,295,749, Silicone gel-coated wound dressing.

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Combined compression and absorption dressing


According to the company of Centurion, South Africa, the wound dressing includes:

- a short stretch compression bandage;
- an absorptive wound dressing that is integral with the compression bandage.

Shown in Figure 3 as a three-layer rectangular laminate pad, the dressing (10) comprises first (12) and second (14) absorbent layers of a nonwoven fabric comprising by volume 70% viscose fibres and 30% polyester (PES) fibres. The first absorbent layers are in the form of a fibre batt or mat.

The viscose and PES fibres have a length of 3–10 mm and a fineness of 2.0–2.5 denier. Further, each of the absorbent layers has a weight per unit area of around 100 g.m⁻².

The inner layer (16) is a 100% PES short-stretch weft-knitted scrim with a yarn count of 40 and a weight of 70 g.m⁻².

The wound dressing thus has a total weight per unit area of around 270 g.m⁻² and a total thickness of 1.5–2.5 mm.

The three layers are bonded together by means of a needle-punching process that produces 300–500 punches per square centimetre.

Further, the outer layers (18, 22) of the absorbent layers are subjected to heat treatment, such that the
dressing is provided with smooth and non-adherent outer faces.

Importantly, the inner layer is a short-stretch compression bandage. The bandage can stretch in the direction of arrows 26 (i.e. lengthwise), but not in the direction of arrow 28 (i.e. widthwise).

The compression dressing/bandage can be supplied in lengths of 2–4 m and widths of 75–100 mm.

The outer layers of the absorbent layers are present along the first 1.3 m of the dressing/bandage, after which a length of 1.5–2.0 m defines a normal-stretch bandage.

The dressing described in the Patent can be used to dress a wide range of wounds to limbs and combines the effects of a wound dressing and a compression bandage.

The absorbent layers, being stretchable in unison with the short-stretch bandage, provide a comfortable fit and permit long-term treatment of wounds, says IWMT.

The viscose fibres have high moisture-absorbing properties and are air-permeable, while the PES fibres are relatively strong and have high abrasion-resistance; further, after heat treatment PES fibres have the ability to retain a smoothened or flattened profile.

Owing to the viscose fibres the dressing is relatively soft and thus resists discomfort to a patient. It not only absorbs exudate from wounds, but also, because of capillary action resulting from the construction of the dressing, directs absorbed exudates and bacteria away from a wound.

The dressing further serves to improve blood and lymph circulation in the region of the wound, which is of particular importance where wounds are related to associated circulatory conditions, such as lymphoedema, and other wounds, such as ulcers and burns, the company states.

See also: US Patent 9 271 877, Combined compression and absorption dressing/bandage.


Water-insoluble absorbent materials for advanced wound care

Absorbent materials useful in the manufacture of absorbent articles, in particular dressings for the advanced wound care market, have been developed by Speciality Fibres & Materials (SFM).

The absorbent materials described in US Patent 9 221 963 are sulphonated polysaccharides, particularly water-insoluble cellulose alkyl sulphonates in which the cellulose is substituted by one type of alkyl sulphonate group.

The company of Coventry, UK, explains that the preferred cellulose alkyl sulphonate is cellulose ethyl sulphonate, where ethyl sulphonate or one of its salts is attached via one or more of the hydroxyl groups on the anhydroglucose units of the cellulose.

Reinforcing fibres and/or antimicrobial agents can be optionally applied to the cellulose alkyl sulphonate.

Fibrous cellulosics with a high degree of crystallinity that are particularly suitable include cotton or regenerated cellulose fibres, such as lyocell.
SFM notes that cellulose fibre can be modified by sulphonation, for example, by substitution with an alkyl sulphonate at one or more of the hydroxyl groups on the anhydroglucose monomers that make up the cellulose backbone, forming ether linkages. Such cellulose derivatives are known as cellulose alkyl sulphonates.

Previous water-insoluble cellulose alkyl sulphonates that have been developed for use as absorbent materials have required substitution of the cellulose with at least two different groups.

However, the method disclosed in the Patent requires the substitution of cellulose with just one type of alkyl sulfonate, which avoids the use of additional reactants and processing steps, reduces the cost of manufacture and does not impair the biodegradability of the fibre.

The modified polysaccharides for use as absorbent materials in wound dressings are said to exhibit excellent absorption and retention of fluid while maintaining their integrity sufficiently to be removed from the wound site in one piece, without irrigation, and with minimum pain and shedding.

As with carboxymethyl cellulose, absorption of fluid is virtually instantaneous since ionic exchange is not required for the fibres to become gellable.

However, the water-soluble polysaccharide alkyl sulphonates disclosed in the Patent are said to have advantages over carboxymethyl cellulose because the absorptive capacity may be affected to a lesser extent by changes in pH. Wound dressings containing these materials continue to absorb to a good level at low pH, SFM says.

Further, fibres of the cellulose alkyl sulphonates have an absorbency (of 0.9% saline solution) most preferably of at least 10 g·g⁻¹.

The resulting absorbent materials made with these fibres exhibit:

- instant gelling in aqueous media;
- good absorbency;
- good retention of absorbency in an acidic environment.

The company says this makes them ideal for use as an absorbent wound dressing. They are particularly useful for wounds with moderate-to-high levels of exudates, and for flat or cavity wounds of this type; typical examples include pressure sores and leg ulcers.

Beyond wound care products, their absorbent properties, biodegradability and the fact that cellulose is a renewable material mean that these cellulose alkyl sulphonates are also applicable for use in the personal care sector, particularly for disposable sanitary articles, such as disposable diapers and training pants, feminine care products (e.g. tampons, sanitary towels or napkins and panty liners) and incontinence products.

See also: US Patent 9 221 963, Absorbent material.

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Compression therapy

Compression sleeve for treating lymphoedema of the legs

A compression garment configured to treat deep vein thrombosis of a limb, particularly a leg, has been developed by Compression Kinetics.

The active compression sleeve disclosed in US Patent 9 271 890 is designed to aid circulation of the lower legs by contracting and actively squeezing fluid from the legs back to the thoracic cavity. It can, therefore, be used to treat lymphoedema and helps reduce swelling, such as of feet and ankles, according to the company of Memphis, Tennessee, USA.

The compression can be achieved with the use of shape memory alloy, such as Flexinol, which is woven into a sleeve fabric that, upon application of a current, will compress in a cyclical fashion, thereby encouraging fluid flow.

Such artificial pumping that propagates up the leg more closely resembles natural circulation via the constriction...
of veins, says Compression Kinetics. Further, with the use of monitoring systems the active compression sleeve can be programmed to compress at different rates and time determined by the user’s heart rate.

The compression garment apparatus includes a flexible backing for contacting the body part. This backing can be a woven or knitted stretchable fabric or an expandable nonwoven fabric; it can also include an optional liner for insulation.

The backing can be attached to the limb by means of fastening straps, such as Velcro or elastic straps.

The incorporation of the shape memory alloy wire into the fabric creates a mechanical load that allows distinct compression and relaxation of the compression sleeve. The different wires in the fabric function independently of each other to produce a propagating wave, which can be controlled through a control unit, such as a microcontroller.

Figure 4 shows the compression garment apparatus that is divided into a number of segmented flex frames (20a, 20b, 20c, 20f). A shape memory alloy (40) is positioned in an X-pattern (80) on each of these flex frames, which are connected to a flexible backing (13).

A controller (50) is used to provide current to the shape metal alloy. In addition, a sensor (90) is shown positioned over a spring link of the segmented flex frame and connected to the controller, which provides the timing of power as well as the power to the shape metal alloy.

In particular, the device described in the Patent will enable diabetic people to treat their legs to daily massages to improve blood flow to both prevent and help treat diabetic foot ulcers, says Compression Kinetics.

**See also:** US Patent 9 271 890, Compression garment apparatus.

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### Prostheses

**US law firm calls for ban on Boston Scientific surgical mesh**

A Houston, Texas, USA-based law firm has petitioned the US Food and Drug Administration (FDA) to recall Boston Scientific’s surgical mesh products that are allegedly made of defective, counterfeit material from China.

The request, filed by Mostyn Law on behalf of a woman from West Virginia, USA, who suffered health problems from a Boston Scientific pelvic mesh implant, accuses the company of smuggling more than 15 tonnes of unverified synthetic resin from China to make the mesh.

The petition cites internal Boston Scientific emails that say the company bought the stock in 2011 and 2012 from a suspected counterfeiter in China without fully testing it or getting FDA approval for its use as a vaginal implant. Mostyn Law alleges that Boston Scientific ran out of FDA-approved supplies and “started using counterfeit resin from China with no history as to when it was made, how it was made, who made it, no title, and was smuggled out” in a
series of transactions “mimicking an international drug deal”.

The petition also includes a recent letter from Boston Scientific to customers acknowledging that the plastic resin being used to make the surgical mesh is not the FDA-approved brand, but is still being made into vaginal inserts.

The FDA said it is aware of the allegations that Boston Scientific’s urogynecologic surgical mesh may contain counterfeit raw material, adding that it is examining these allegations to determine any necessary and appropriate next steps.

However, the agency says it is “not currently aware that the alleged counterfeit raw material contributes to adverse events associated with these products”.

Boston Scientific is to conduct additional testing relevant to the safety and effectiveness of the finished product. This should be sufficient for the FDA to determine whether or not the urogynecologic surgical mesh manufactured from the alleged counterfeit raw material is equivalent to that manufactured from the original raw material supplier. It is expected that this additional testing will take several months to complete.

However, following the FDA’s safety alert, Mostyn Law called on the agency to take this “dangerous product off the market immediately”.

“The FDA’s watered-down warning of the risk posed by Boston Scientific’s surgical mesh falls far short of what is needed to protect women’s health,” said attorney Amber Mostyn. “We are talking about a counterfeit version of a product that the original US manufacturer has repeatedly said should not be used in the human body.”

Earlier this year, the FDA deemed vaginal surgical mesh procedures as “high risk”, possibly resulting in “severe pelvic pain and organ perforation”.

Mostyn Law says implant manufacturers are facing thousands of lawsuits from women who say they have suffered discomfort, bleeding, infections, painful intercourse, urinary problems and other complications from the implants.

About 55,000 women receive Boston Scientific’s pelvic mesh each year.

The Marlborough, Massachusetts, USA-based company makes US$120 million in revenue annually from the mesh products, according to Mostyn Law.

See also: Medical Textiles, July 2015, Jury finds Boston Scientific liable for defective trans-vaginal mesh devices, page 5.


Coating and laminating
Buoyant industry meeting in Prague

The drive to find alternatives to fluorocarbons for repellent coatings was a key issue discussed at the latest International Conference on Textile Coating and Laminating (TCL2016) held in March in Prague, Czech Republic.

Alternatives mentioned included carbon-6 technologies and fluorocarbon-free chemistries, including a radically new technology – hyperbaric dry finishing from Green Theme Technologies.

The company of Albuquerque, New Mexico, USA, revealed that new investment was behind a plant now being built in Taiwan to commercialize the technology and hinted at further developments that will allow three-dimensional (3D) coating, presenting an increased surface area for the functional surface.

Also during the two-day conference Vetex of Ingelmunster, Belgium, confirmed its commitment to develop solvent-free technologies regardless of the existing regulations.

Organized by International Newsletters of Droitwich, UK, the TCL2016 event attracted a record number of delegates.
A CD-ROM of the proceedings is available for pre-order.

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Hygiene
Absorbent structure with discrete acquisition cells

An absorbent structure (10) that includes a composite absorbent laminate (30) is disclosed in US Patent 9 238 089 by Attends Healthcare Products. The structure is suitable for use in disposable absorbent products, such as for infant or incontinence care.

The device provides a means to generate free volume in an ultra-thin absorbent core, on demand, for rapid absorption of liquid in response to wetting, says the company of Greenville, North Carolina, USA.

The composite absorbent laminate is positioned in a liquid-transfer relationship between the acquisition layer (22) and the absorbent core (20).

The laminate comprises a substrate in the form of first and second nonwoven layers (32) with a matrix of filamentary or fibrous adhesive and discrete acquisition cells (DACs) positioned between the nonwoven layers. The DACs can comprise particles or fragments of cellulose absorbent material, such as compressed cellulosic sponge particles, compressed cross-linked wood pulp fibres, creped tissue and paper, or shredded paper; DACs of non-cellulosic material can comprise, for instance, particles or fragments of compressed, synthetic fibres, such as crimped polyester (PES) fibres cut from a continuous fibre tow.

The filamentary adhesive of the composite laminate acts to stabilize the DACs in the laminate, while simultaneously adhering and integrating the nonwoven layers.

The absorbent structure further comprises particulate superabsorbent polymer that can either be blended with the particulate DACs in the absorbent laminate or provided in a separate absorbent layer of the structure.

The DACs generate free volume for rapid capillary absorption in an ultra-thin absorbent structure.

To produce the composite absorbent laminate, hot-melt adhesive is used to laminate a continuous layer of particles between two layers of nonwoven substrates to form a sandwich structure.

Preferably, the laminate is made by forming the adhesive into microfibres or filaments using meltblown processes available from such hot-melt equipment manufacturers as Nordson or ITW Dynatec.

This produces a random curtain of hot-melt-adhesive microfibres, which are then mixed with DAC particles, and optionally with superabsorbent polymer particles.

This mixture is deposited onto a moving nonwoven substrate and then another nonwoven substrate is placed on top of the tacky mixture to form a sandwich structure, Attends Healthcare Products explains.

See also: US Patent 9 238 089, Absorbent structure with discrete acquisition cells.

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Reduced furfural content in cross-linked cellulose fibres

Absorbent articles comprising bleached polyacrylic acid cross-linked cellulose fibres with reduced furfural...
content are disclosed by Procter & Gamble in US Patent 9 205 405.

The company of Cincinnati, Ohio, USA, explains that polycarboxylic acids are used to cross-link cellulose fibres to enhance their wet bulk by imparting stiffness, twist and curl to the fibres: the fibre structure’s wet bulk determines the liquid-holding capacity.

Reducing the furfural content of bleached polyacrylic acid cross-linked cellulose fibres can be achieved by treatment with hydrogen peroxide, in an amount of 0.045–9.07 kg per air-dried metric tonne (ADMT) of fibre, in the absence of sodium hydroxide or other bleaching agent.

The treatment is carried out following curing of the polyacrylic acid cross-linked cellulose fibres.

The polyacrylic acid cross-linked cellulose fibres had a furfural content lower than 1.3 ppm (and in some cases less than 0.4 ppm) up to 21 days after treatment. Further, the reduction of furfural content of the treated cross-linked fibres was at least 55% (and in some cases at least 75%), as measured up to 21 days after the treatment, compared with the untreated fibres.

It was unexpectedly found that a reduction in furfural levels was accompanied by a strong reduction of the “burnt” malodour associated with such fibres.

Procter & Gamble speculates that furfural is the main odoriferous volatile organic compound causing the malodour, and that treatment with hydrogen peroxide replaces the compound with reaction products that impart a clean, fresh odour.

Hemicellulose, which accompanies the cellulose fibres obtained from wood during the pulping process, is the main source of furfural generation during thermal treatment (e.g. curing) of the cellulose fibres.

See also: US Patent 9 205 405, Reduced furfural content in polycrylic acid crosslinked cellulose fibers used in absorbent articles.


Absorbent article containing a bacterial composition

An absorbent article, such as a sanitary napkin, panty liner, tampon, diaper, pant diaper or adult incontinence guard, that contains a bacterial composition has been developed by SCA Hygiene Products. The bacterial composition, which comprises a lactic acid-producing bacterial strain, is in a lipid phase.

The company of Gothenburg, Sweden, notes that lactic acid-producing bacteria belonging to the genus *Lactobacillus* are important for retaining a healthy microbial flora in the female urogenital areas and act as probiotic bacteria with an antagonistic effect against pathogenic microbial species.

They inhibit growth and colonization by other microorganisms by occupying suitable niches for colonization, by forming biofilms and competing for available nutrients, thereby excluding colonization by harmful microorganisms.

In addition, the production of hydrogen peroxide, specific inhibiting substances, such as bacteriocines and organic acids (including lactic acid and acetic acid) that lower the pH, inhibit colonization by other microorganisms.

US Patent 9 248 213 discloses an absorbent article that:
- delivers lactic acid-producing bacteria to the urogenital area;
- is convenient to use;
- results in the efficient transfer of the bacteria to the area where they are applied;
- can be stored for long time periods without loss of viability of the bacterial cells.

Figure 6 shows an exemplary sanitary napkin that contains a probiotic preparation comprising a dried
bacterial composition (8) that is mixed with a lipid phase (9), which is a wax and/or an oil, such as petrolatum.

The hydrophobic character of the lipid phase decreases the amount of air humidity that reaches the bacterial cells dispersed in the lipid phase, thereby increasing the survival time for the bacteria in the bacterial composition.

SCA Hygiene Products says dispersing the lactic acid-producing bacteria in a lipid phase has the additional advantage that transfer of the bacteria to the skin and/or urogenital area is enhanced.

When the product is used, the lipid phase softens when exposed to body heat and the bacterial composition is transferred to the skin.

When the bacteria come in contact with moisture after delivery to the skin, they are reactivated, start to grow and perform their probiotic action, the company explains.

The probiotic preparation comprising the lipid phase containing the bacterial composition is applied on a carrier member (10) located on a wearer-facing side of the absorbent structure (4) and on top of the topsheet (2).

The carrier member is of a material, such as a polymer film, metal foil or laminate, that is impermeable to the lipid phase, which prevents any significant transfer of the lipid phase into the absorbent structure.

One or more pockets or wells (11) with a depth of 5–8 mm can be formed in the flat carrier member to contain the probiotic preparation.

Before use of the article, these pockets are covered by a material (12) that is impermeable to the lipid phase. This cover material can be water-soluble so that it is readily dissolved when contacted with body fluid or, alternatively, can be of a material that melts when exerted to body temperature and thus exposes the probiotic preparation.

See also: US Patent 9 248 213, Absorbent article.

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Business news
Duvaltex acquires True Textiles

Duvaltex, a Québec, Canada-based textile holding company that owns North American textile manufacturer Victor Textiles, has acquired all of the True Textiles business units, including True, Guilford of Maine and Teknit.

As a result of the acquisition, Duvaltex has become one of the largest manufacturers of commercial and contract interior fabrics in the USA and Canada, serving the office furniture, institutional, healthcare and hospitality industries.

Both Victor Textiles and True Textiles will continue to operate as independent business units.

Vertically integrated True Textiles manufactures high-performance fabrics for such applications as panel, upholstery, acoustic and privacy curtains for the
corporate, healthcare, education and hospitality markets. Based in Grand Rapids, Michigan, USA, it has expertise in fabric design, yarn production, weaving, weft knitting, finishing and performance enhancements.

Victor Textiles of Saint-Georges, Québec, Canada, specializes in fabrics for the corporate, healthcare, apparel and specialty markets.

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Uniquetex to open first US facility

Uniquetex, a manufacturer of nonwoven fabrics for medical and healthcare providers, is to open its first US production facility in Cleveland County, North Carolina, USA. The US$31.6-million production facility will employ 150 people over the next five years.

The company is a joint venture between Foshan Nanhai Beautiful Nonwoven, one of China’s largest nonwoven textile businesses, and Wenzhou Chaolong Textile Machinery, a Zhejiang, China-based developer of equipment and technologies for nonwoven textile manufacturing.

The project was made possible in part by a performance-based grant of up to $800,000 from the One North Carolina Fund, which provides financial assistance, through local governments, to attract business projects that will stimulate economic activity and create new jobs in the state.

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Markets

Spunlaid nonwovens market to grow to US$22.5 billion by 2021

Spunlaid is now the most prevalent process used to produce nonwovens, accounting for almost half of global consumption in 2016.

A new report* from Smithers Pira predicts that the global spunlaid nonwovens market will grow from 4.6 million tonnes or 136.9 billion m$^2$ valued at US$15.6 billion in 2016 to 6.7 million tonnes or 206.5 billion m$^2$ valued at $22.5 billion by 2021.

Spunlaid is a web-forming process in which the polymers are molten, extruded and laid down to form webs. Spunlaid nonwovens include spunbond, flash-spun, meltblown, spunbond-meltblown-spunbond (SMS) and electrospun products.

Spunlaid nonwovens are used in every major nonwovens market and in disposable and durable end-uses. In particular, they dominate the largest market segment – disposables, which includes hygiene products, wipes and medical items, says Phillip Mango, author of the report.

The study notes that consumption of spunlaid nonwovens continues to grow in Asia, while North America and Europe are slowing. The Asian market is expected to achieve a global market share of 50% with consumption reaching 3.4 million tonnes by 2021, says Smithers Pira.


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http://www.technical-textiles.net
Surgical

Suture comprising a drug-loaded biodegradable polymer layer

A suture, the surface of which is wound with a film including a drug-loaded biodegradable polymer layer, or coated with such a layer, has been developed by researchers from Seoul National University of Seoul, South Korea.

Described in US Patent 9 295 462, the biodegradable material, which can be loaded with a range of drugs, such as anti-cancer agents, anti-inflammatory drugs and antibiotics, ensures topical transfer of the drug, thereby improving therapeutic effects.

The suture enables the delivery of a drug without lowering its mechanical strength by preparing a film including a drug-loaded biodegradable polymer layer, then winding it around the surface of the suture, or by directly coating the surface of the suture with a drug-loaded biodegradable polymer layer in a non-wet manner.

The researchers suggest that the biodegradable polymer can comprise a wide range of materials, including polyester (PES)-based biodegradable polymers, chitosan, starch, guar gum, gelatin and collagen.

The film including the polymer layer can be formed, for instance, using electrospinning or solution casting.

See also: US Patent 9 295 462, Suture comprising drug-loaded polymer layer and method of manufacturing the same.

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Figure 7:
The process of winding the drug carrier around the surface of a suture developed by Seoul National University.