

# 1. LIGASANO®: History and Mode of Action

## 1.1. The Development of LIGASANO®

LIGASANO® white and LIGASANO® green are polyurethane foams of the newest generation.

The origins of polyurethane date from the middle of the past century. The basic chemical reaction was developed by the chemist Würtz already in 1848. But the importance of this chemical process was recognised considerably later and taken up in 1937 by Otto Bayer in Leverkusen/Germany. Because of his single-minded research it was possible to launch first the polyester rigid foam, later the polyester soft foam and after 20 years of work the polyether foam. These plastics obtained the collective name polyurethane (PUR) and were developed to the most universal material at all.

Source: Association of the polyurethane soft foam industry

In cooperation with Prof. Dr. med. Gerhard Weber (MD), at that time head physician of the dermal department of the Clinical Centre Nürnberg/Germany, a polyurethane foam for the medical application was created and named LIGASANO®. This term without further supplement refers to the product that is known today by the term "LIGASANO® white". The additional expression "white" refers to the colour of the product and became necessary because another polyurethane material, further named "Green Climate Grid®" is now available by the term "LIGASANO® green". The impulse of developing LIGASANO® green came, just as in the case of LIGASANO® white, from the medical and nursing practice. To produce a complete healing of pressure ulcers it is absolutely essential to effect a release of pressure in the wound, apart from the local wound treatment. As described in an article of the specialists periodical "Deutsches Ärzteblatt" from 1980 (page 1621-1625) by Gerhard Weber and Karl-Heinz Galli, LIGASANO® white as well accomplishes this task with excellent results.

### Citation of the article:

The longtime clinical application and resultant experiences show that LIGASANO® white is superior to all conventional materials for the prophylaxis of pressure ulcers, for the treatment of infected ulcers and wounds, for the postoperative wound or transplant treatment as well as for mechanical debridement in the case of burns. The details of the clinical use are discussed.

For more than 15 years LIGASANO® has proved itself in our hospital in various medical fields of application in an excellent way. During the period of application we have applied LIGASANO® with a thickness of either 1 or 2 centimeters and a volumetric weight of 20 kg/m<sup>3</sup>. The material is porous, permeable to air and water and for this reason it does not cause accumulation of heat, contrary to foam.

The application is quite easy, the price low. Basically we have identified three principles of action:

#### 1. Mechanical effect at the wound:

The surface structure of LIGASANO® results from cutting through the vesicular material. A very fine honeycomb structure is then obtained. Depending upon the requirements, pads of LIGASANO® cut into flat 1 or 2 cm thick sheets that can be trimmed to any desired shape, are placed directly on the wound. Owing to the elasticity of the material, relatively uniform contact is achieved between the wound and the material. Through the action of the body's own weight - for example in the case of decubitus ulcers - or the pressure of an elastic bandage applied to it, the wound surface is constantly stimulated by the structure of LIGASANO®. This mechanical action itself is augmented by slight movements that

additionally exert tangential tensile or thrust forces. Within days of application, this results in a visible increase in wound secretion, which is accompanied by the sloughing of fibrin and necrotic material.

**The result is a cleansing of the wound without the need for manual or medicinal measures.**

#### 2. Absorptive effect:

The sponge-like internal structure of LIGASANO® exerts an appreciable absorptive effect. In consequence, the material absorbs wound secretion, thus preventing its accumulation and reducing the number of bacteria.

#### 3. Pressure relief by pressure distribution:

The relief of pressure is of particular importance in the case of bed-ridden, inactive patients. In such cases, where the subcutaneous tissue available is insufficient to distribute the pressure of the surface of the body, areas of very high pressure occur which, as is well known, lead to ischaemic necrosis, in particular in the sacral area and at the heels. Here the foam reduces the local maximum pressure, since, because of its elasticity, it takes over the pressure distributing function of the absent subcutaneous

tissue. The mechanism behind this effect is, conceivably, that tiny blood vessels are less strongly compressed, with the result that the oxygen supply to the tissues is improved. This effect is of considerable importance both for prophylaxis and therapy.



Fig. 1a: Roentgen ulcer, after prolonged treatment by conventional means



Fig. 1b: Healing induced solely by the application of LIGASANO®



Fig. 2a: Arterial ulcer

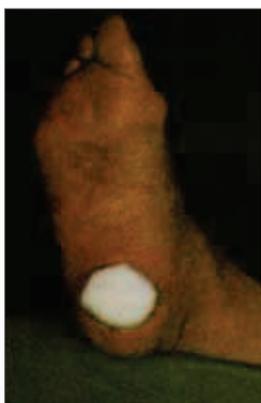


Fig. 2b: LIGASANO® applied to the defect



Fig. 2c: Healed defect

## INDICATIONS:

### Prophylaxis and therapy of bed sores

The indication for the application of foam arises from the above mentioned modes of action. Probably, the most common application is in the prophylaxis and treatment of bedsores. Squares of LIGASANO®, measuring 50 x 50 cm and 2 or 4 cm in thickness (depending on the patient's weight) serve as a pad beneath the sacral area. While, as it is well known, conventional support can lead to areas of high pressure and subsequent ischaemia, the use of flexible foam results in the uniform distribution of pressure due, on the one hand to the elasticity of the material and, on the other hand, to slight movements of the patient's body, for example during breathing. In addition, the constant compression and decompression of LIGASANO® reduces the accumulation of moisture on the skin and thus the maceration usually seen in such cases. The foam pads need to be tailored to the degree of immobility and the weight of the patient, and the use of cubical, cylindrical or wedge-shaped pieces of foam has been found to be necessary for prophylaxis in patients with transverse lesions of the spinal cord. These measures do not, however, obviate the need to change the position of the patient at the usual regular intervals. In the case of heels or other frequently moved parts of the body, the foam is fixed in position with the aid of a bandage. If decubitus ulcers have already developed, the defect can be filled with sheets, wedges or sheres of foam, cut to the appropriate size, and the patient is bedded on a large foam sheet. In the case of ulcers of the heel, the foam sheet is held in position with an elastic bandage.

With both forms of application, considerable secretion is being observed within a matter of days, even in the case of otherwise dry ulcers. This is accompanied by the sloughing of detrius and the formation of fresh granulation tissue, which is subsequently followed by epithelization. If marked secondary infection of the ulcers occur, the short-term application of antiseptic solutions is indicated to accelerate cleansing, as a supportive measure.

### Ulcus cruris

When treating venous and arterial ulcers of the leg with LIGASANO®, consideration must also be given to the underlying vascular insufficiency. Here, too, a foam sheet cut to match the configuration of the ulcer defect is applied. Since the use of foam is associated with an increase of secretion, the skin adjacent to the ulceration must be covered with zinc lotion to prevent maceration. Here, ointments or creams are not recommended. A firm elastic bandage applied starting at the forefoot, augments the mechanical effect of the LIGASANO® pad on the venous ulcer, while also improving venous return.

In the case of arterial ulcers, however, this additional bandage must be avoided. Here, the foam dressing should be held in place under moderate pressure using, for example, strips of plaster or a gauze bandage.

In the case of extensive ulcers, as soon as the cleansing effect has been achieved and fresh granulation tissue has formed, a split-skin graft is employed to accelerate healing. Under the conditions described, such grafting is more likely to succeed even in the case of arterial ulcers.

### Post-operative wound dressing and graft covering:

At our department, this foam was originally used as a post-operative wound dressing. The foam dressing does not have the disadvantages of the conventional gauze bandage - accumulation of secretion and body moisture, adhesion to the wound with the associated risk of secondary infection and inadequate elastic padding. Its advantages are particularly important for the covering of skin grafts. If the graft bed is below the level of the surrounding skin, a sterile piece of LIGASANO® foam cut to match the shape and size of the graft is placed over it and fixed in position with strips of plaster. This pad is covered by a larger sheet of foam and held in place with an elastic bandage under slight pressure. If, however, the wound is at skin-level, a single sheet of LIGASANO®, larger than the graft suffices to cover it. To avoid adhesion in the case of excessive secretion by the

wound, a piece of gauze expediently containing an antibiotic, is placed between the graft and the foam. Covering the graft with LIGASANO® has two advantages:

1. Wound secretion and blood are absorbed
2. Thanks to the elasticity of the foam, traction and compression forces associated with small movements are cushioned, so that a constant and uniform pressure is applied to the graft.

In an analogous manner, LIGASANO® can also be employed as a "dosed pressure bandage" to cover a sliding flap. At our department, deep excisions that cannot be closed primarily, are treated with skin grafting at a later date, when the defect has filled with granulation tissue. In such cases, foam, cut to the appropriate shape and size, is applied in order to accelerate the growth of granulation tissue, and to keep the wound clean.



Fig. 3a: Wound dehiscence after amputation



Fig. 3b: Overlapping graft, fixed in place



Fig. 3c: Dressing 1. gauze, 2. LIGASANO® pad, 3. covering of LIGASANO®



Fig. 3d: Healing graft

## Burns

For the treatment of burns, we have been using the polyester foam LIGASANO® for about ten years now, mainly for mechanical debridement of the wound surfaces, in particular on areas of the body in contact with the mattress. The following procedure has proved expedient: The mattress is first protected by a waterproof plastic sheet. Over this sheet, a layer of Moltex or similar material is placed, and over this a disposable absorbent sheet to prevent displacement of the underlying layers. Upon the sheet is

placed a sheet of LIGASANO® with the same dimensions as the mattress and a thickness of 2 to 4 cm, on which the patient is then bedded. The LIGASANO® sheet is changed daily. Secondary infection is additionally treated by daily spraying the wound with antiseptic solutions, or by the application of an antibiotic-containing ointment to the foam. When the foam is changed, its cleansing action is impressively revealed. It bears a complete imprint of the burn wound comprising infected secretion and necrotic

material, while the wound itself is progressively cleansed. Here, too, the uniform distribution of pressure and promotion of secretion exercise a positive influence.

### Literature:

Seiler, W. O., Stäblein, H. B.:  
Zur Verhütung und Therapie von Dekubitalulzera, Fortschr. Med. 675-677 (1979) 97



Fig. 4: Burn patient bedded on LIGASANO®



Fig. 5a: Third-degree burn, mechanical debridement of necrotic material

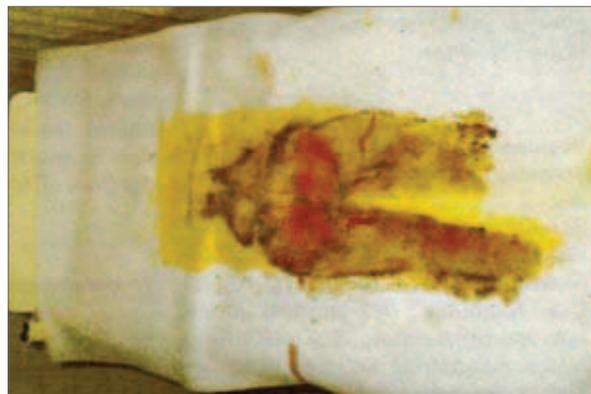


Fig. 5a: Impression of the burn wound

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**In the original paper the authors had spoken of “foam” or “polyester foam”, because the trade name for this special foam - LIGASANO® - does not exist at that time. To prevent misapprehensions and to distinguish from other polyurethane foams (which are indeed partly similar, but have other properties than LIGASANO®), we replaced in the just cited article the old terms with the trade name LIGASANO®.**

Until the development of LIGASANO® green, the climatization of skin was a defile at decompressing positioning. LIGASANO® green is a polyurethane foam as well. Its pores are relatively large (multiple larger than those of LIGASANO® white), and by this oppose a capillary effect. In addition the material is submitted to a reticulation process, where the membranes between the cell ligaments are almost completely removed. LIGASANO® green has no appreciable properties in temperature insulation. It has scarcely circulatory resistance at gaseous and liquid substances. This is a great advantage for several medical indications.

About the efficiency of the suggested methods of wound treatment there are reports of practical experience and they show how even seemingly therapy-resisting wounds often respond very well and heal completely. If desired we will send you the corresponding literature.



**LIGASANO® white and LIGASANO® green are classified in class IIb according to EC rule 93/42/EEC.**

Therapeutically effective for wound healing and prevention. Products of this class are predominantly used at wounds whose dermis is cut through and can be cured only by secondary wound healing.

## What does this mean?

High-class medical and nursing service needs high-class tools. As your patients trust you, you should have faith in the used products.

### **Hygiene and product safety:**

We solely produce high quality medical products. The production facility, the modern machinery, the trained and motivated employees, the whole operating schedule is in line with thoroughgoing quality and hygiene. We supervise the quality of compartment air, retraceability without interruption, non-interdependent double controls of every production step. These are only some of our safety measures. The outcome: product safety at the best, often beyond the legal requirements. LIGAMED® medical Produkte GmbH keeps a quality assurance system for medical devices.

### **Application security:**

Quality of treatment requires the appropriate use of the preparations. The application of our products is easy and clearly described with many meaningful illustrations and photo documentations. With practical courses and workshops we communicate every year expert knowledge about the LIGASANO® therapy to thousands of users. And if desired we help on location at individual problems. This service gives you the certainty to do the right and deserves your confidence.

### **Cost effectiveness:**

The cost effectiveness of LIGASANO® white at wound treatment results from efficiency and safety in use about a wide case spectrum, quick change of dressing, hardly side costs for additional preparations and a low priced product. At a couple of wounds there are nearly no expedient alternatives, if you consider the chance of therapy success with the costs. According to reports of users, even apparently therapy resistant wounds have good curative chances in existence, some plastic-surgical interventions are avoidable.

### **Guaranteed future:**

The close contact to practical users is a never dwindling source by experiences and ideas. No year has passed by without realising one or more suggestions to helpful new products, pharmaceutical forms or improvements. For us the orientation of ourselves to the users is no catchword but programme.

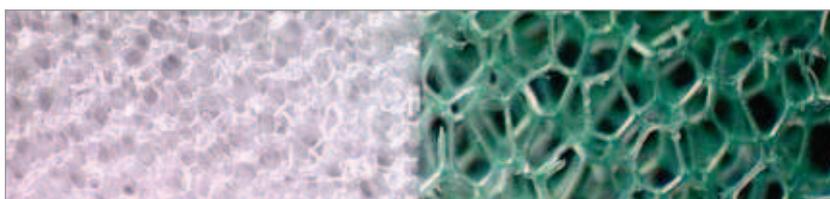
## 1.2. Technical Informationen

**Sterilisation:** LIGASANO® white and LIGASANO® green are available in both sterile and non-sterile forms. You can sterilise LIGASANO® white and LIGASANO® green with steam, 4 minutes at 134° C (273° F). According to the report of validation sterility is guaranteed. A longer time of sterilisation (up to 20 minutes at 134 °C) has no influence on the material properties of LIGASANO®. If required please ask for our technical information "sterilisation".

**Disposal / Environmental relevance:** Apart from quality we document environmental awareness, too. LIGAMED® is approved according to the European Community Eco-Management and Audit-Scheme (**EMAS II**) and is a participant in the Bavarian Environmental Understanding (**Umweltpakt Bayern**). LIGASANO® white and LIGASANO® green are single-substance materials made of polyurethane, consist of approx. 97-98% air and can be disposed of with the regular household waste. Disposal of the packaging is regulated differently internationally, in Germany via Vfw-Remedica. For further information please contact our quality and environmental management (QM/UM).

**Storage / Fire behavior pattern:** LIGASANO® white and LIGASANO® green are highly flammable and sensitive to UV radiation. Therefore protect against fire, embers, heat, UV radiation and humidity/moisture. In its original packaging a confined protection exists against humidity and UV radiation by the special plastic film (it filters out a great part of the ultraviolet rays) we use. The storage is only permitted in the original packaging. You must complain immediately to the vendor if LIGASANO® is delivered in damaged packaging or refuse to accept the goods if collecting them by yourself. If it is delivered, record the damage on the delivery note. Please follow our information for storage on the packages.

Permissible storage conditions for sterile products: +10°C to +30°C at 30-65% r.h.  
for unsterile products: -20°C to +60°C



Technic information	LIGASANO® white	LIGASANO® green
Basis of material	Polyurethane expanded	Polyurethane expanded
Cell structure	Mixed-pored, cell type 750	Completely open-pored, cell type 1500
Absorptivity	Controlled absorptive on skin-deep wounds up to 30 volume per cent (= 1500 weight per cent); in deep wounds and cavities up to 90 volume per cent (= 4500 weight per cent)	Permeable to water like a sieve
Breathing activity	Active with breathing	Nearly completely permeable to air
Permeability to steam	Very high permeability <small>(The permeability to steam of both products is high to such a degree that the usual methods of measuring, e.g. according to DIN 53122, ISO 11092, DIN 31092 are unfit for ascertainment.)</small>	Almost unhindered permeability
Pressure tension	Rapidly falling, ca. 40 % after 20 minutes	Less falling
Adaption to shapes	Adapts to shapes with low pressure	Permanent elastic, low decrease in pressure
Mechanical stimulus, stimulation of blood flow	Effective stimulation of blood flow, thereby scarcely a risk for normal and sensitive skin; at the beginning formication, after 15-20 minutes neutral.	Great mechanical stimulus, risk of lesion at direct contact with very sensitive skin; the mechanical stimulus is used only in special cases.
Allergies	Neutral to allergies	Neutral to allergies
Durability	The mechanical stimulus is lost after three days of application, the material deforms durably.	Depending on the load, up to several weeks.

**Side effects:** with the correct application of LIGASANO® white and LIGASANO® green there are no known undesirable side effects, incompatibility or interactions with medicine. Typical and desirable is reddening of the skin in contact, initial „itching“, a more intense wound, return of sensivity (in the case of wounds also pain) as a result of stimulation of the blood circulation.

**Please notify us immediately of any other side effects and recognised or assumed risks!**

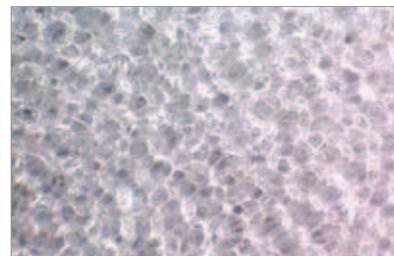
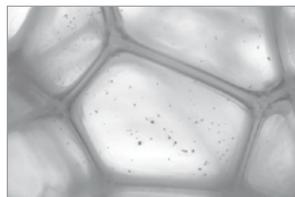
## 1.3. Mode of Action of LIGASANO® white and LIGASANO® green

### a) LIGASANO® white

LIGASANO® white is a therapeutically effective polyurethane foam material with a wide range of application for wound care and prevention. It must always be applied by a physician or medically trained personnel.

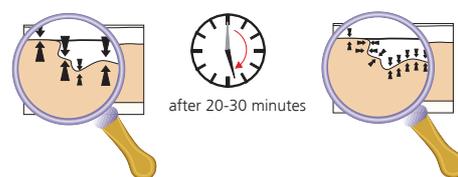
The therapeutic use is based essentially on three underlying principles:

- rapidly falling pressure tension
- mechanical stimulus
- controlled absorption effect



#### Rapidly falling pressure tension:

Low pressure adaption to contours and even minimized pressure on wound and body. The pressure of the body of bed-ridden, inactive patients is evenly distributed by LIGASANO® white as it adapts well to the contours of the body. The low pressure tension and compression of LIGASANO® white effectively prevents pressure ulcers.



#### LIGASANO® white for the prevention of pressure ulcers:

The patient must be placed directly onto LIGASANO® white. The contact of the foam with the skin stimulates the blood supply on the affected areas, prevents formation of heat, absorbs body perspiration and relieves pressure in affected areas by redistribution of the patients body weight.



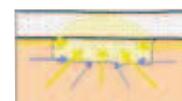
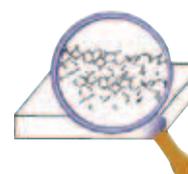
#### LIGASANO® white for the positioning of paralysed patients by a transverse lesion of the cord and by spastic paralysis:

The bedding onto LIGASANO® white is approved in many years of clinical experience and meanwhile international in practice. Pressure ulcers and mycotic infections can be prevented by pressure compensation without folds, promotion of blood flow and absorption of sweat.

#### Mechanical stimulus:

Stimulates local blood circulation in the wound and where there is skin contact, thereby improving the supply of nutrients and oxygen in the wound area (activation of the wound) and acts as a preventative on skin which is still intact. Stimulates normal bodily functions at local level, especially in the case of inactive patients or where these functions are reduced. The mechanical stimulus lasts up to three days by which time LIGASANO® white should then have been changed. Even without conscious movements, the surface structure of LIGASANO® white develops a mechanical stimulus. Due to contact with the skin the blood flow is stimulated, secretions increase, germs slough and dry necrotic material is removed thereby achieving a self-action cleansing of the wound, that may assist manually, if required.

Micro and macro motions of the patient cause an intermittent negative pressure and this promotes a mechanical stimulus on wound and skin.





#### LIGASANO® white for local treatment of large burns:

The patient must be placed directly onto LIGASANO® white. Burns in the dorsal area or in the folds of the legs will be cleaned mechanically, secretions and necrotic tissue will be absorbed.

#### LIGASANO® white for the treatment of pressure ulcers, fistulae and skin pockets:

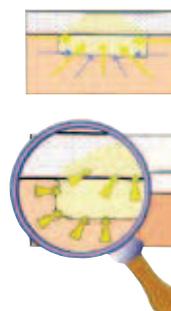
Fill the wounds completely with LIGASANO® white. For wounds with narrow opening and fistulas, LIGASANO® white wound strip is splendid qualified for this application. You have to tender the surrounding wound area always extensively. By placing the patient directly onto LIGASANO® white, wound cleaning, stimulation of granulation and epithelisation is improved.

#### LIGASANO® white for the treatment of leg ulcers and foot lesions:

LIGASANO® white must be cut to size, placed directly into the wound, with a further piece of LIGASANO® white covering the entire wound. In the case of venous leg ulcers fix with a pressure bandage. When an arterial leg ulcer is treated, no pressure should be placed on the area, however a LIGASANO® white bandage should be taken from the foot to the thigh to improve arterial circulation. An increase in the secretion of the wound is desirable for wound healing and granulation.

#### Controlled absorption effect:

Absorbs exudate without a drying-out effect. Creates a moist and warm wound environment, is antiseptic, cleans the wound with no sticking to the wound. Averts skin maceration and is skin-friendly. High absorption volume without change of dimensions, no hardening. LIGASANO® white has a high absorptive effect due to its honeycomb inner structure. Excess wound secretions from the body are absorbed, thus preventing maceration of tissue surrounding the wound. The risk of bacterial flora is decreased.



#### LIGASANO® white for covering skin transplants, surgical wounds and for drainage of weeping interdigital areas:

LIGASANO® white is trimmed accordingly to the size of the transplant, held with adhesive gauze. A bandage adapting to the form and the extension of the wound prevents congestion of secretions and adhesion in the wound area.

At eczema, mycotics, diabetic and arterial sclerosis and gangrene in the toe area LIGASANO® white is cut in strips and placed into or between the toe shaft to absorb secretions and to drain the wound area. The „clean“ wound offers air-borne germs hardly culture medium. Surplus secretion is absorbed, the wound is nearly clean. The risk of a secondary infection by air-borne germs is reduced.



LIGASANO® white significantly reduces the risk of wound creation as a result of poor blood circulation. Wound healing disorders due to poor blood circulation are reduced or removed and contaminated or local infected wounds are cleaned, largely without the need for any further action. It stimulates granulation and epithelisation and the desired results usually occur surprisingly quickly and clearly. LIGASANO® white is not an implant, and therefore must not remain permanently in wounds. After a maximum of three days the LIGASANO® white padding on the wound surface and/or padding inserted into the wound must be changed.

Please keep in mind that an adequate nutrition is of important meaning for the successful healing of chronic wounds. Patients with chronic wounds have a higher need of energy, proteins, zinc, vitamins and liquid.

For further information use our calculation sheet on page 54 or make use of our download-offer at [www.ligasano.com](http://www.ligasano.com).

Here a short review in table form of the significant modes of action of LIGASANO® white:

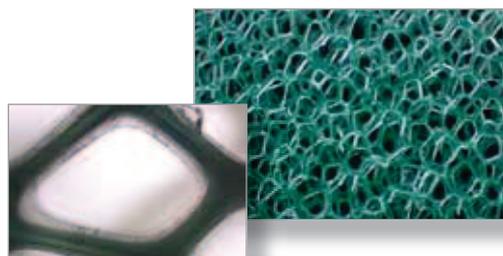
	Wound treatment	Prevention
<b>Rapidly falling pressure tension</b>	Reduction of pressure, promotion of granulation, reduced counter pressure to the new regenerated granulation tissue.	Anatomic adaption to body contours.
<b>Mechanical stimulus</b>	Because of its surface structure (the structure of the material is perceived by the tissue) LIGASANO® white promotes the perfusion and activates the self-cleaning („hydrogel, produced naturally in the body“). The intermittent negative pressure, which is caused by the pumping effect in connection with conscious and unconscious body movements, produces a mechanical stimulus, too.	Because of its surface structure (the structure of the material is perceived by the tissue) LIGASANO® white promotes the perfusion, non-vital dermal skin cells are removed automatically (peeling).
<b>Controlled absorption effect</b>	Since only surplus exudate is absorbed, LIGASANO® white does not dry out the wound. Depending on the thickness of the material, an intermittent negative pressure occurs.	Works effectively against maceration of the skin.
<b>Permeability to steam</b>	In the case of hardly exuding wounds LIGASANO® white may adhere by drying up exudate. At burns this is sometimes desired (mechanical debridement).	Works effectively against maceration of the skin.
<b>Please note:</b>	For wound treatment the thickness of LIGASANO® white has to be always at least two centimetre (measured from the wound ground), to reduce the permeability to steam and to assure enough temperature insulation. You get the required thickness by putting LIGASANO® white one upon the other.	

## b) LIGASANO® green

LIGASANO® green is an elastic, expanded polyurethane (PUR), which is almost always pervious to air and liquids (e.g. water) - imagine a three-dimensional sieve. It has a coarse texture and rough surface.

LIGASANO® green is used for wound treatment and care, if a strength and elastic material with high permeability to air and liquid is required.

- 1. Sterile** on or in wounds, if the dermis is cut through and may only be healed by secondary wound healing.  
**Sterile or unsterile** for nursing care and concomittant wound treatment without direct contact to wound, but with direct contact to skin.
- 2. Sterile or unsterile** for pressure relief and hygiene without direct contact to the skin.



### What is important to remember in all applications:

The surface of LIGASANO® green is relatively rough. If it is used in wounds or on skin lesions may occur, especially by friction.

**It must always be applied by medic or medically trained personnel.**

### What kind of products are there:

LIGASANO® green is available in different sizes (e.g. sheets, rests for operating tables, compresses, wound strip), and depending on application is available in sterile or unsterile forms. Please see the available sizes in the particular current product list.

### The use of LIGASANO® green for wound treatment and contact to skin:

- ▶ With LIGASANO® green you can cover or fill wounds. It countervails a collapse of wounds by effect of external pressure or suction, e.g. during an active wound drainage.
- ▶ By the special properties of its surface a mechanical stimulus is caused on the area of contact, favouring the blood flow, and hence stimulates at contaminated or infected wounds the normal body reaction "wound cleaning by secretion". Moreover the transportation of substances should be stimulated hereby in the wound and so effects a promotion of granulation. This active principle is known and approved since decades by LIGASANO® white.
- ▶ You can apply LIGASANO® green also on skin, especially in the wound area. Thus you can utilise the above described mechanical stimulus on a greater area to stimulate the wound healing.

- ▶ By the described open structure of LIGASANO® green wound irrigations are possible despite the filled wound.
- ▶ A drainage of exudate, irrigation etc., following the gravitation down out of the wound is made possible.
- ▶ In some cases of application LIGASANO® green can be combined with LIGASANO® white.
- ▶ A combination makes sense if e.g. a considerable quantity of exudate has to be subdued, which exceeds the absorption capacity of LIGASANO® white.
- ▶ At urinary incontinence an urinary outflow should be made possible within the usual incontinent care with a common underlay or trousers, down, away from the skin, so that the skin is protected against this duress.
- ▶ The decision about the particular kind of application of LIGASANO® green is determined by medic or medically trained personnel and is adapted and appropriated in every single case.



## Risks and Adverse Effects - Contraindications

### LIGASANO® green

- ▶ Is in its sterile form qualified only for single use. The sterility of the sterile forms is ensured only at intact package.
- ▶ Must not be used anymore after the expiration date.
- ▶ Is not allowed for reconditioning / re-sterilisation if you use it for wound treatment.
- ▶ Must not remain in the wound or on the body in perpetuity. Recommendation: 1 – 4 days, depending on the indication.
- ▶ Must not have any contact to the mucosa.
- ▶ Must not have any direct contact to organs.
- ▶ Due to the rough surface the medic has to decide in every single case, whether contact to skin or to wound is allowed.
- ▶ Applications in contact, connection or combination with additional preparations, drugs, solutions, ointments etc., are not checked by us.
- ▶ Applications in combination with additional mechanical, electrical or electronical apparatus and aids are not checked by us.
- ▶ Because of its cell structure a vascularisation e.g. of granulation tissue into the material is possible. You can prevent this by a change in time of LIGASANO® green.
- ▶ During application and change of the dressing you have to avoid as much as possible a friction of wound, wound-ground or skin, for no respectively no additional lesions, which might cause.
- ▶ Especially at the application on or in hitherto passive wounds or on parts of the body, which are as yet badly supplied with blood, it can come to considerable pain sensations. This circumstance appears, if by the mechanical stimulus of the material the blood circulation is stimulated so far, that previously reduced or lapsed (and therefore unaccustomed) sensation of pain returns. But this is initially felt often for abnormal intense. Usually this sensation is regularised after some hours or not later than after a few days. If this effect is not desired, you should renounce this application.
- ▶ In case of an "open wound care" without additional cover you have to take into consideration that there exists barely protection against the ambient atmosphere.
- ▶ Too heavy pressure by initial tension of the material, extraneous cause or suction may lead to compression of vessels and therefore to pressure ulcers.

### Consideration of risks:

**LIGASANO® green is a very simple product, the effect of which results in its structure. It contains no agents and does not emit such either. The effect respectively the aspired effect is little complex - contrariwise quite easy and with general knowledge well comprehensible.**

At intended use the risks are marginal. A mechanical overstraining in the contact area of wound or skin is well predictable with the naked eye, and due to the anyway required medical care, the preparation may be removed in time, if necessary, before any injury occurs. The effect is pure physical and stops virtually promptly after removal of the preparation.

The unavoidable residual risks are marginal compared to clinical advantage and seem acceptable.

## The use of LIGASANO® green for pressure relief and hygiene without contact to skin:

LIGASANO® green has cushion qualities, as known from elastic foams, but without their property of thermal insulation, which is unfavourable in nursing care. The special properties of LIGASANO® green mean that parts of the body can breathe, where dampness or suppuration would otherwise accumulate as a result of contact with other objects (e.g. flat bed surfaces, seats or back-rests etc.). As a result of gravity, large amounts of fluid can run downwards, and dampness (e.g. sweat) can evaporate. Skin maceration can be effectively prevented with this product.

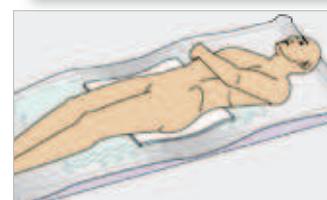
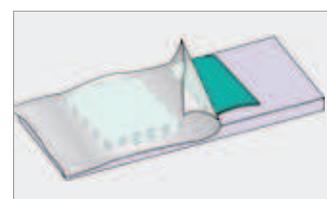
▶ At this application of LIGASANO® green the contact with the skin is avoided, because the rough surface of the material is mostly felt as unpleasant and perturbing, and for preventing lesions of the skin, which could effect by friction.

In addition, without any heat insulating layer, in normal tempered ambience, it can come to hypothermia at the affected parts of the body. For an intermediate layer between skin and LIGASANO® green are exemplary suitable: stockings, clothing, bed sheet and especially a layer of LIGASANO® white with a thickness of 0.5 or 1 cm. It is important, that the intermediate layer is likewise permeable to air.

▶ To obtain a good pressure relief by pressure distribution, you can cut LIGASANO® green to fit with a pair of scissors.

▶ For the application **without** contact to skin you can use LIGASANO® green often for weeks. Soiled material is washable up to 95° C / 203° F without suffering much under this procedure. Drying is unnecessary in most cases. After the spin cycle or the spinning by hand the material is almost dry. For this use the reconditioning by sterilisation with steam, up to 20 min. at 134° C / 273° F (we recommend 4 minutes) is allowed.

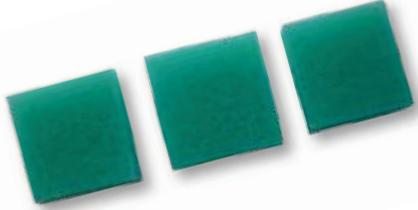
There are no specific risks at the use of LIGASANO® green for pressure relief and hygiene without contact to skin if you follow the general rules for care and our special instructions.



## 2. LIGASANO® for Wound Treatment

### 2.1. For mechanical debridement: Wundputzer® made of LIGASANO® green

Wundputzer® wound cleaning sponge. We don't need to say many words to present this new and helpfully product to you:



⇒ **easy to use**: the size 5x5x2cm lies perfect in the hand.

⇒ **effective & rather painless**: you can vary the intensity of the wound cleaning effect with the pressure power - adjusted to the need of your patient. Because of its structure you don't disperse the coatings in the wound, but retrieve it.

⇒ **hygienic**: three pieces in one peel pack. Thus you can clean the wound from the coated surface to the bottom of the wound always with a fresh wound cleaning sponge.

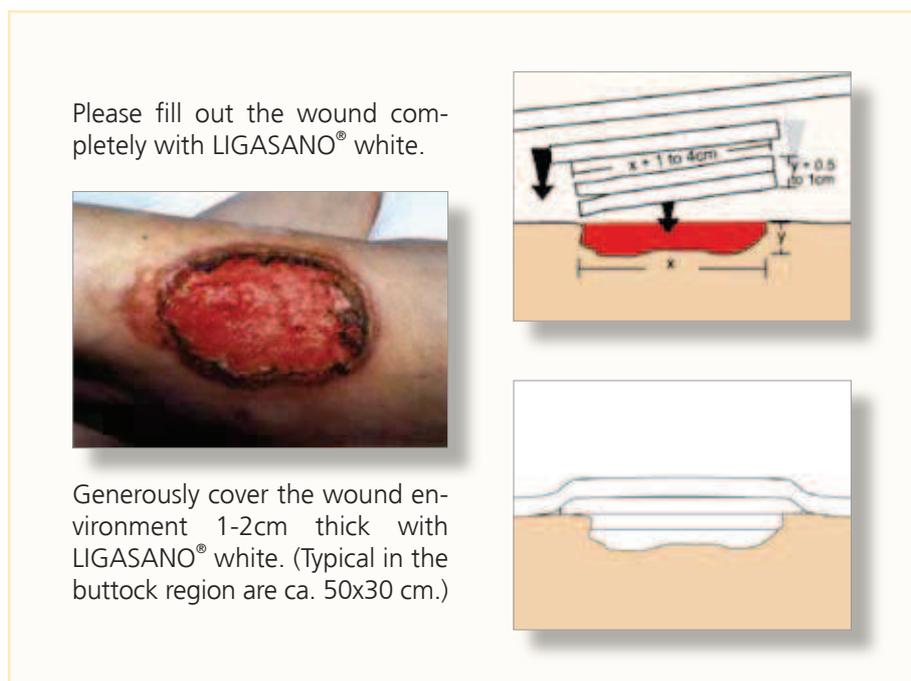


**Ask for samples, because trying is better than looking at pictures and reading!** Send us an e-mail to [info@ligamed.de](mailto:info@ligamed.de) with the notation „samples wound cleaning sponge“. Don't forget to name your address!

## 2.2. General Information about the Application of LIGASANO® white for Wound Treatment

You can use LIGASANO® white for all kinds and phases of wounds. You will find many examples in the following chapters 2.3. and 2.4. Also the presurgical conditioning of wounds is possible with LIGASANO® white.

LIGASANO® white is available in sterile and non-sterile form. It must always be applied by a physician or medically trained personnel.



In so far as the wound allows the outflow of secretion, you can treat it directly with LIGASANO® white without any pre-treatment. Fill the wound completely out with LIGASANO® white. Observe that complete contact with the wound is insured, also at the wound edges. You have to fill out existing pockets, too.

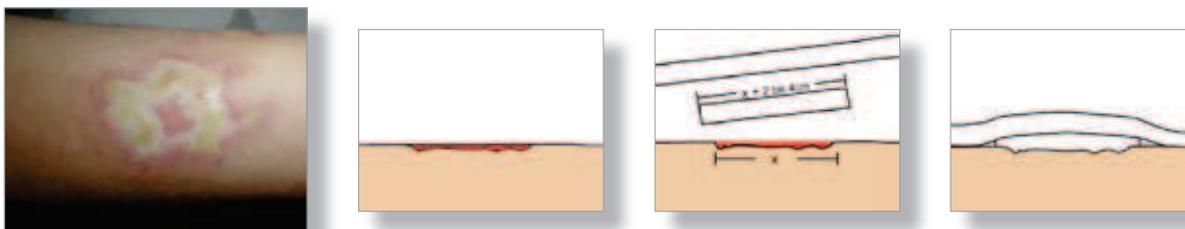


Therefore cut LIGASANO® white to somewhat larger than the wound diameter. Insert it into the wound with slight compression, to make reliable contact everywhere. Only where LIGASANO® white has contact, it does works.

Then the wound is covered with another layer of LIGASANO® white, overlapping the wound edges by at least 1-2 cm. Above it put a great sheet LIGASANO® white for the treatment of wound environment. Rule of thumb: the greater the area of the treated wound environment, the better the effect. Fixation must always be permeable to air. Good qualified for this are fixation pants, tubular bandages or at the best LIGAMED® *fix*, item no. 10305-003 (see page 56).

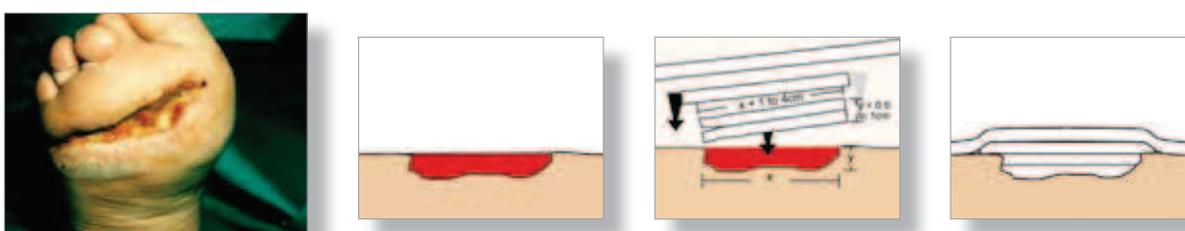
## 2.3. Application at Different Wounds

### 2.3.1. Skin deep wounds (up to a depth of 0.5 cm)



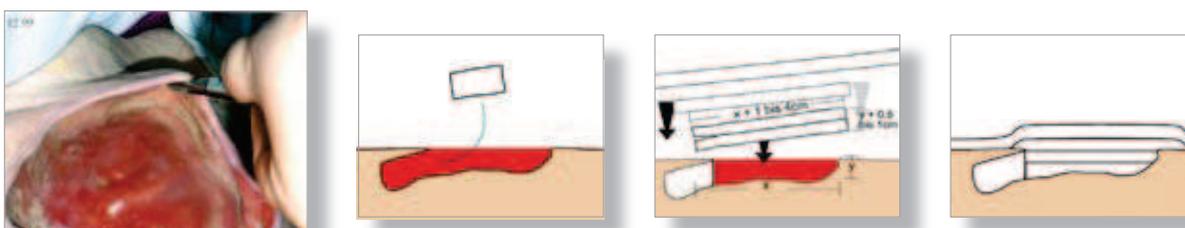
Cover the wound 1-2 cm thick with LIGASANO® white, overlap the wound edges by at least 1-2 cm. Observe during fixation that complete contact with the wound is also insured on deeper locations of the wound. Generously cover the wound environment 1-2 cm thick with LIGASANO® white for local promotion of blood flow. Air-permeable fixation.

### 2.3.2. Deep Wounds



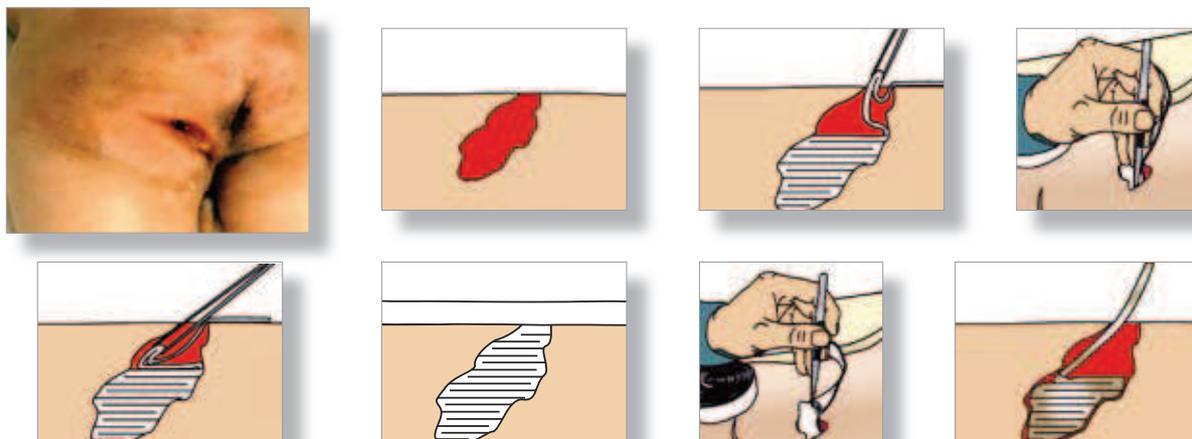
Completely fill the wound with LIGASANO® white. Therefore cut LIGASANO® white to somewhat larger than the wound diameter and to somewhat thicker than the wound depth. Insert LIGASANO® white into the wound with slight compression. The aim: contact to the wound everywhere, also at the wound edges. Generously cover the wound environment 1-2 cm thick with LIGASANO® white for local promotion of blood flow. Air-permeable fixation.

### 2.3.3. Deep Wounds with pockets



First, completely fill out the pocket and then the wound with LIGASANO® white. Therefore cut LIGASANO® white to somewhat larger than the wound diameter and to somewhat thicker than the wound depth. Insert it with slight compression into the wound. The aim: contact to the wound everywhere, also at the wound edges. Generously cover the wound environment 1-2 cm thick with LIGASANO® white for local promotion of blood flow. Air-permeable fixation.

### 2.3.4. Wounds with Narrow Opening / Fistulas



Completely fill out the wound with LIGASANO® white - wound strip (item no. 15370-010) with slight compression. Firstly explore direction and depth of the wound, so that you can reliably reach the bottom of the wound. The wound strip should assume a zigzag pattern in the wound. Almost no friction is generated when extracting the strip from the wound. Changing wound dressing is quick and simple. A premature, superficial closure of the wound will be prevented. Generously cover the wound environment 1-2 cm thick with LIGASANO® white for local promotion of blood flow. Air-permeable fixation.

## 2.4. Examples for the Treatment of Wounds with Different Genesis

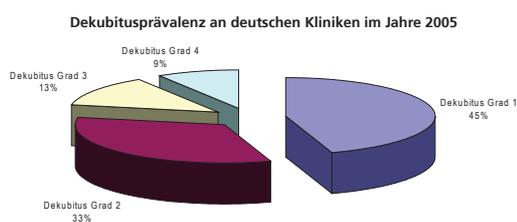
### 2.4.1. Decubital Pressure Ulcer

The area of a local damage of the skin and the subjacent tissue, caused significantly by too high and/or too long pressure on skin and tissue, is termed decubitus ulcer (pressure ulcer). If the extrinsic pressure, which impacts on the vessels, exceeds the capillary pressure of the vessels, it comes to trophic (concerning the nutrition of the tissue) impairments. Mostly the own weight of the particular unmoved body part suffices. Different studies for the determination of the capillary pressure show pressure values between 32 and 70 mmHg, that lead to an interruption of the blood supply. If this pressure load persists for a longer time, it comes - as a result of an undersupply of the cells with oxygen and nutrients - to a decrease of the partial oxygen pressure to 0 mmHg (ischaemia) as well as an accumulation of toxic metabolites and conse-

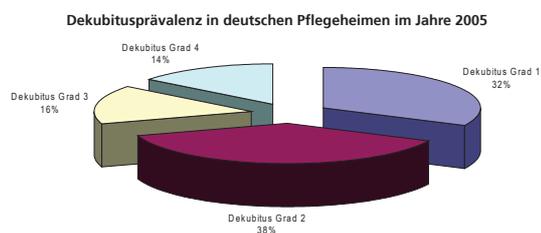
quential to sphacelation of the tissue and irreversible damage of nerve cells.

At healthy persons the decrease of toxic metabolites actuates a reflex that causes a relocation and thus a pressure relief of the imperilled skin area, before it comes to a persistent damage of the affected area. At elder and sick persons this reflexes are often only limited or lacking and thus the necessary pressure relief of the tissue does not happen. To this hyperacidity of the tissue the body reacts with vascular dilatation, so that this areas are better supplied with blood. The implication is a non blanchable redness, that does not subside after the pressure is relieved, a decubitus stage I.

Especially at risk are areas with little soft tissue covering and outward curved abutements, as sacrum region, heels, femoral trochanter and ankles.



Source: Thomas Wild, Josef Auböck (Hrsg.), Manual der Wundheilung, p. 182



Source: Thomas Wild, Josef Auböck (Hrsg.), Manual der Wundheilung, p. 182

The following table shows reasons for increased and/or prolonged effect of pressure and/or shearing forces.

Reasons for increased and/or prolonged effect of pressure and/or shearing forces
<p><b>Reduction of activity</b>  <b>Definition:</b> degree, in which a patient is able to move from one place to another.            Limitations (selection):</p> <ul style="list-style-type: none"> <li>• dependency of walking frames or staff assistance at walking</li> <li>• dependency at transfer</li> <li>• dependency of wheel chairs</li> <li>• bedriddenness</li> </ul>
<p><b>Reduction of Mobility</b>  <b>Definition:</b> degree, in which a patient or inhabitant is able to change his/her body's position            Limitations (selection):</p> <ul style="list-style-type: none"> <li>• dependency of staff assistance at transposition at bed</li> <li>• hardly or no control of body positions in sitting or lying positions</li> <li>• incapability also of small changes of position (micro movements) in sitting or lying positions</li> </ul>
<p><b>Extrinsic bzw. iatrogen caused exposition against pressure and/or shearing forces (selection):</b></p> <ul style="list-style-type: none"> <li>• catheters and tubes, which impress on the body's surface; or objects, which lie in bed or on the chair (e.g. remote control) and devices respectively (e.g. hearing aid)</li> <li>• nasal tubes</li> <li>• splints, dressings, prostheses, which are too tight or ill-fitting</li> <li>• insufficient pressure distributing devices for positioning</li> <li>• sustained operations</li> </ul>

Source: Deutsches Netzwerk für Qualitätsentwicklung in der Pflege (Hrsg.), Expertenstandard Dekubitusprophylaxe in der Pflege, page 23; 1. actualisation 2010, ISBN 978-3-00-009033-2

Risk factors for the development of a pressure ulcer lie in some extend with the patients themselves (intrinsic factors), as for example reduced mobility, old age, malnutrition, dehydration, weight, additional diseases, infections, urinary and/or anal incontinence, disturbed sensibility, etc.; and on the other hand the risk factors lie in the patients' environment (extrinsic factors), as for instance mobilisation, time intervals of bedding, skin care. Further extrinsic factors, which may cause a pressure sore, are shearing forces, friction, too high temperatures and heavy moisture (maceration of the skin). Open decubital ulcers can be a portal of entry for germs, which are able to cause not only a local but a generalised infection.

Source: • Panfil, Eva-Maria und Schröder, Gerhard (Hrsg.): Pflege von Menschen mit chronischen Wunden, Verlag Hans Huber, Bern  
 • [www.pflegewiki.de](http://www.pflegewiki.de)

The best therapy of a pressure ulcer is still its prevention! Don't let it come to this. Examples for pressure relief you will see in chapter 3 (page 35 - 42).

#### International NPUAP-EPUAP Pressure Ulcer Classification System :

##### Category/Stage I: Non-blanchable redness of intact skin

Intact skin with non-blanchable erythema of a localized area usually over a bony prominence. Discoloration of the skin, warmth, edema, hardness or pain may also be present. Darkly pigmented skin may not have visible blanching. Further description: The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category/Stage I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" persons.

##### Category/Stage II: Partial thickness skin loss or blister

Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled or sero-sanguinous filled blister. Further description: Presents as a shiny or dry shallow ulcer without slough or bruising. This category/stage should not be used to describe skin tears, tape burns, incontinence associated dermatitis, maceration or excoriation.

##### Category/Stage III: Full thickness skin loss (fat visible)

Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Some slough may be present. May include undermining and tunneling. Further description: The depth of a Category/Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III pressure ulcers. Bone/tendon is not visible or directly palpable.

##### Category/Stage IV: Full thickness tissue loss (muscle/bone visible)

Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. Often include undermining and tunneling. Further description: The depth of a Category/Stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed bone/muscle is visible or directly palpable.

Source: EPUAP, Pressure Ulcer Treatment, Quick Reference Guide, page 8

**Example:**



Fig. 1:

93 years old, female, completely immobile, incontinent, in bad general condition and nutrition status too, was found at home bedragned. Hitherto her sons attended to her, but now she is accommodated in a nursing home, for the present short-time care. Multiple pressure sores at the heels and both trochanters. Pre-existing diseases: hemiparesis at the right side due to apoplexy two years ago, no diabetes mellitus. Medication: until her accommodation none, now for the treatment of an urinary infection a therapy with antibiotics. Findings on admission at 11/10/2007: after removal of the hitherto used hydrocolloid dressing and systematic cleaning of the wound with saline solution (0.9%), appears a great and moist necrosis with a dimension of 6.0x4.0cm over the sacrum. The surrounding wound area was reddened, up to 15cm around the wound, over-heated and macerated, partly ablation of the epidermis. Multiple smaller pressure ulcers due to the wrinkled hydrocolloid dressing (fig. 1)

The dressing with LIGASANO® white was arranged in layers: one sterile compress of LIGASANO® white with a thickness of 1cm, moistened with Octenisept® and applied to the wound. The covering is made with another sterile compress with the size 24x16cm and on it one piece of unsterile LIGASANO® white, cut to a size of ca. 25x25cm. Fixation around with strips of dressing film, because the patient has shown a cutaneous reaction to conventional plaster. It is good to see the property of the vertical absorption of exudate of LIGASANO® white (fig. 2). The exudate is steadily drained off outwards. Already 24 hours later we could open the necrosis. It has shown a pocket that goes up to 3.0cm to cranial. This wound pocket and the undermined wound edges, which developed during the proceeding wound cleaning, were packed with stripes of LIGASANO® white. The large-area use of LIGASANO® white has proved very favourably, especially for the use at pressure ulcers. By this the effect that is favouring the blood flow and the property of pressure relief is used on the greatest possible area. The patient was badly approachable, but this has been improved during her stay considerably. Already two weeks later she was partly mobilised. A communication was possible, but hindered because of her extreme amblycusia.



Fig. 2:



Fig. 3:



Fig. 4:



Fig. 5:

Findings at 19/10/2007: the lesions of the surrounding skin areas are healed to a large extent. The reddening results of a meantime occurred intestinal infection with watery diarrhoea. This healed within three days, while we changed the dressing more often. Dressing change up to now once daily. Apart from remaining small fibrinous coatings in the pocket, the wound is well supplied with blood, clean and granulating (fig. 3).

Findings at 14/11/2007: granulating wound, epithelisation from the wound edges. The surrounding wound area is intact and stable. Dressing change is now every 2-3 days, depending on her defaecation frequency. We retained the size of the outer dressing to maintain the pressure relief furthermore (fig. 4).

Findings at 20/12/2007: the wound is clean, the surrounding area is intact and not irritated (fig. 5). Findings at 11/01/2008: the epithelisation is nearly completed. The patient is mobilised and increasingly participates in the daily routine of the nursing home (fig. 6).



Fig. 6:

#### Summary:

Due to the easy application of LIGASANO® white (only one product for wound healing, dressing change quick and easy), its effect of favouring the blood flow and its property of pressure relief you can realise satisfying results even in the case of complicated initial situations.

### 2.4.2. Ulcus cruris

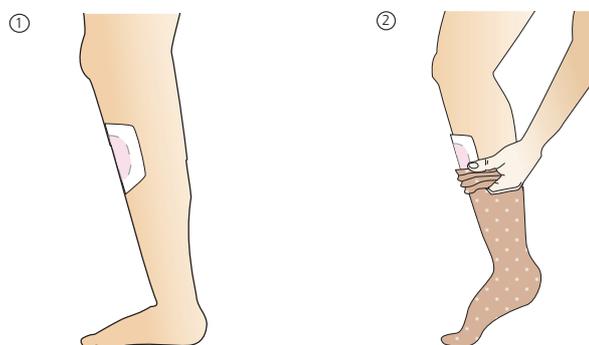
The ulcus cruris, an ulcer at the lower leg, is an open, mostly weeding wound ("ulcerated leg"), which does not heal during a long time. This type of ulcer is known since time immemorial. In the majority of cases elder people with different underlying diseases are struck, women more often than men. According to information of the AOK (the biggest german health insurance), in Germany more than one million people suffer from this so-called ulcerated legs. About 80-85% are of venous origin, approximately 10% are of arterial origin and the rest are arterial-venous mixed ulcerations of other genesis. The fundamental reason of all types of leg ulcers is the lacking perfusion of the tissue. This lacking perfusion is responsible both for the development of the ulcus cruris and for its bad healing.

#### a) Ulcus cruris venosum

The venous ulcus cruris is caused by a chronic phlebasthenia (chronic venous insufficiency, CVI) and appears in most cases interior of the lower leg, little above the ankle. Inspection and measuring of the ulcer, preferably with photographic documentation, facilitate the subsequent evaluation of the therapeutic method and the patient's cooperation, too. As a diagnostic method for the genesis of the disease the duplex sonography of the veins is used.

The elimination of the primary cause is often not easy. Because of the (mostly) multiple diseases, several elements determine the chronicity of the patients wounds. At venous insufficiency you can prevent the permanent and proceeding damage of the smallest vessels by a bypass of the affected vein segments.

Application tip: venous ulcus cruris



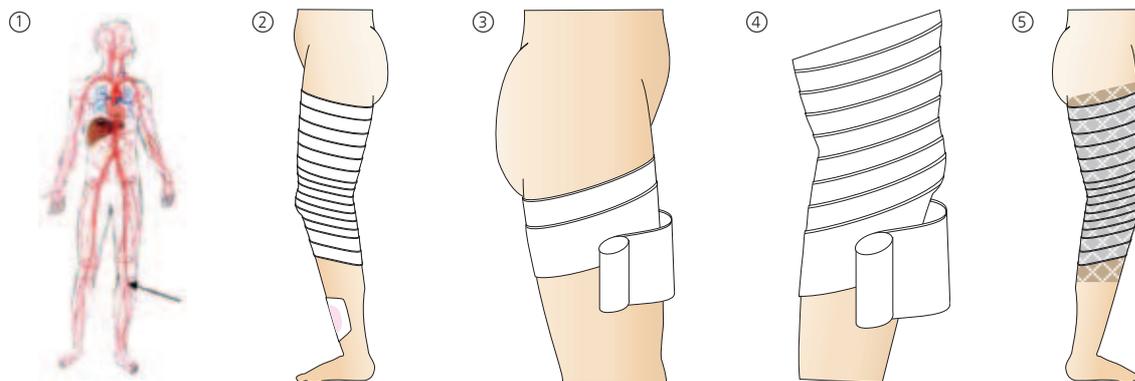
- ① Typically the venous ulcus cruris is a very heavily exudating wound. The main problem is, to absorb great amounts of exudate and to canalise in the way that it does not overflow to the wound edges. Fill the heavily exudating wound with LIGASANO® white and cover the wound edges, overlapping at least 2 cm, also with LIGASANO® white. The overflow of the wound edges is impossible, if you change the dressing in time. Surplus of exudate is absorbed.
- ② The concomitant therapy (compression bandage, compression stocking) can be carried out as usual.

### b) Arterial leg ulcer

The arterial ulcerus cruris is caused by arterial insufficiency and appears in most cases at the exterior of the lower leg. Inspection and measuring of the ulcer, preferably with photographic documentation, facilitate the subsequent evaluation of the therapeutic method and the patient's cooperation, too. As diagnostic methods for the genesis of the disease, duplex sonography and angiography is used.

The elimination of the primary cause is often not easy. Because of the (mostly) multiple diseases, several elements determine the chronicity of the patients' wounds. At arterial insufficiency you have the possibility of balloon angioplasty or the treatment by vascular prosthesis.

Application tip: Arterial ulcerus cruris



- ① Arterial perfusion disorders usually start below the knee. If there is no arterial occlusion, the LIGASANO® white bandage can serve your patient very well.
- ② Locally treat the leg or foot lesion with LIGASANO® white. The LIGASANO® white bandage (300x10x0.3cm) generates the blood flow promotion effect.
- ③ Start rolling the LIGASANO® white bandage as near to the inguinal region as possible, ½ overlapping, completely without traction.
- ④ In the joint region ¾ overlapping until below the knee.
- ⑤ The LIGASANO® white bandage mostly does not get out of place. Additionally it can be fixed with a tubular net bandage or LIGAMED® *fix*.

### c) Ulcus cruris venosum-arteriosum

This mixed ulcer is especially difficult to treat, because actually reasonable therapies are contradictory. To stimulate the venous return, a compression therapy is indicated; but this constricts the arterial influx, which is already too low, even more.

Application tip: Arterial-venous ulcerus cruris



- ① The arterial-venous leg ulcer is particularly difficult to treat, because on the one hand the required blood flow is missing and it is additionally hindered by compression measures due to the insufficient drainage.
- ② Fill the usually exudating wound with LIGASANO® white and cover the wound edges, overlapping at least 2cm, also with LIGASANO® white. The overflow of the wound edges is impossible, if you change the dressing in time.
- ③ Apply the LIGASANO® white bandage, 5 or 10cm wide, just like a normal padding bandage under the compression dressing or the compression stocking. You achieve padding and promotion of blood flow at the same time.

### Example 1:

88 years old, female, partly mobile, moves with assistance up to 20 steps with the walking frame, otherwise in the wheel chair, moves hardly independently. Very fearful, walk insecure, intellectual agile, little hearing impaired. Lives with her children and grandchildren at home. She is supported in the basic care by them and a nursing service.

Arterial-venous mixed ulcer, skin and lower leg very dry and scaly. According to information of her family members, she suffers from dry skin and pruritus and reacts sensible to body care products and plaster.

Pre-existing diseases: cardiac insufficiency, arthrosis of the hips, recurrent water retentions in the lung and both lower legs, no diabetes mellitus.

Medication: beta blocker, diuretic agents if required, medication for decholesterolisation.

Diagnostic findings of the ulcerations at 12/10/2007: very painful wounds, a lot of fibrinous coatings and in places dry necrosis. Oedema at both lower legs; the skin is dry, stretched and shiny.

After consulting the family doctor we have begun the treatment with sterile LIGASANO® white, all in all with a thickness of 2cm, overlapping the wounds generously. Daily dressing change.

Findings at 05/11/2007 the ulcerations show defined wound edges. In all three wounds are very tight fibrinous coatings, in the upper ulcer precipitate spalls of chalk, which we can remove only badly and painfully for the patient (fig. 1).



Fig. 1:



Fig. 2:

Findings at 04/12/2007: considerable reduction of the lower ulcer. The middle ulcer is granulated except for slack fibrinous coatings, which we can remove mechanically. The upper ulcer is granulated to the niveau of the skin and is now in the phase of epithelisation (fig. 2).

Findings at 04/12/2007: because of an allergic reaction to a skin care product, a new ulcer at the left inner ankle developed. Here we use the same dressing system with LIGASANO® white, covering the complete ankle (fig. 3).



Fig. 3:

Findings at 19/03/2008: state of the ulcer of the left lower leg, inner ankle: with the extensive use of LIGASANO® white the bland plaques have loosened in the wound environment of the inner ankle and have begun to weep heavily. The primary ulcer granulated well and begins to minimise.

Dressing change every 2-3 days, depending on the quantity of exudate (fig. 4).



Fig. 4:



Fig. 5:

Findings at 19/03/2008: state of the ulcer of the left lower leg, tibia and lateral ankle: the lower ulcer is granulated almost up to skin niveau, with beginning epithelisation. The middle ulcer is already significantly smaller and the upper ulcer is nearly closed (fig. 5).

Findings at 24/04/2008: state of the ulcer of the left lower leg, inner ankle: complete epithelisation at the inner ankle, only skin care, yet (fig. 6).

Findings at 24/04/2008: state of the ulcer of the left lower leg, tibia and lateral ankle: the lower ulcer is granulated up to skin niveau, the epithelisation proceeds. The middle ulcer is epithelised, the wound environment is intact (fig. 7).



Fig. 6:



Fig. 7:

#### Summary:

In this case the easy application of LIGASANO® white and its reliable effect of favouring the blood flow has shown, that it is possible to heal an arterial-venous mixed ulcer only with one product.

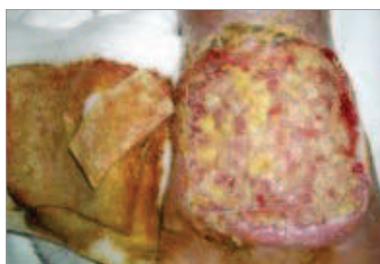
#### Example 2:

**Leg ulcer treatment by tangential excision and skin grafting (SCHMELLER'S METHOD), by Adrian Botan MD, senior consultant plastic surgeon, chief of the burn centre & plastic surgery department, county emergency hospital of Targu-Mures/Romania.**

Leg ulcers are over 50% of all chronic wounds operated in our department, and for this reason, in the last 6-7 years, we have imagined a "treatment protocol" for large lesions (over 8-10 cm diameter) especially. The most part of these ulcers are first cared in the office for about 6-8 weeks, with the polyurethane foam dressings LIGASANO® which are changed at three, five either seven days, depending on the exudate quantity of every wound. (**Annotation of LIGAMED®: according to our instructions for use, the LIGASANO® dressing has to be changed at the latest after three days.**) The LIGASANO® foam is always combined with compression therapy by elastic bandages. After the complete "passive debridement" by this method (which we call "synthetic maggot therapy"), all patients with large ulcers are admitted for surgery in the hospital.

All wounds are clean, granulate and have a small quantity of exudates; beside this, the bacterial population decrease and change into a less aggressive one, as well as the area of lipodermatosclerosis decrease in size and the wound edges soften. LIGASANO® dressings are also used during the first 10-14 days in the hospital, before surgery, after that the ulcers are debrided by tangential excision (SCHMELLER'S METHOD); the final result of this "shaving" is a supple, well bleeding, pre-fascial surface. The hard, infiltrated edges of the ulcers are also excised, that is why the remaining wound is always larger than the initial one. We could notice that in the rare cases when we did not use (for different reasons) the LIGASANO® foam dressing before surgery, we could not obtain the same well vascularised wound bed and beside this, the area of lipodermatosclerosis did not decrease in size and wound edges did not soften. After this tangential excision, the remaining bleeding surface was covered immediately by meshed split skin grafts (when brisk bleeding occurs, skin grafting can be delayed for 24-48 hours); 10-14 days after full take of grafts, the LIGASANO® dressing and compression therapy are resumed (but the dressings are now changed after 14-21 days). This treatment is maintained for another 3-4 months and is then replaced by medical compressive stockings, antithrombotic creams and gels and oral Detralex. Even though this good surgical management, we could notice a 30% rate of recurrences during the next two years after treatment.

Treatment of a 57 years old male patient with an extended ulcus cruris of the left leg. Preparation of the wound bed with LIGASANO® white, afterwards tangential excision and skin grafting. Wound healing takes place within eight weeks.



### 2.4.3. Lesions of Diabetic Feet

Due to a sample of their insureds of the German health insurance AOK Hesse in the year 2004 and a projection to the German population, 7.6% of the inhabitants in Germany were under medical treatment because of diabetes. A great number of unreported cases has to be added. Because more and more diabetics live always longer with their disease, thus the diabetes caused late damages have increased. The long-term diabetic syndrome may become manifest in micro-angiopathy (diabetic nephro- and retinopathy, somatic micro-angiopathy), polyneuropathy (sensorimotor and autonomic neuropathy, mononeuropathy) and macro-angiopathy (coronary sclerosis/ischaemic heart disease, cerebral sclerosis/chronic venous insufficiency) and leads to the diabetic feet syndrome. In the last decades the diabetic foot develops to a focal point in the diabetic treatment, which is a considerable cost factor with at least 20% of the whole therapy expenditures.

Types of the diabetic feet lesions are a) the infected neuropathic foot, b) the ischaemic-gangrenous foot at peripheral arterial occlusive disease, c) the infected foot at diabetic polyneuropathy and peripheral arterial occlusive disease and d) foot infection at bad diabetic metabolic status without a proved relevant neuro- or angiopathy.

The treatment of a diabetic foot lesion needs patience and expert knowledge. The therapy of the basic disease, i.e. stabilisation of the diabetes for example with an intensified insulin therapy, increases the efficiency of the anti-infective treatment and decreases the secondary increase of blood lipids, especially these of the viscosity elevating LDL as well as fibrinogen. Further you have to relieve the ulcer or gangrene.

An initial exhaustive wound cleaning and sanitation of the wound area is the quickest and safest way to control the infection and to sanitize the wound. In most cases this is made by surgical debridement as well as physical debridement using special wound dressings. Conditioning and composition of granulation tissue and afterwards epithelisation tissue is effected with "moist wound treatment".

To prevent this lesions, the patient has to be urged necessarily to care and especially to daily inspections of his feet.

The excerpt of a study regarding the use of LIGASANO® white as primary wound dressing at diabetic feet lesions from Dr. med. Carola Zemlin, internist/diabetologist, shows possibilities for the treatment. The article is also published in the professional journal "Lazarus" (year 16, issue 18, Sept. 2001, page 24).

„The diabetic foot syndrome undoubtedly belongs to the most grave complications of diabetes: a high rate of amputations, high costs for the health insurance and increased extra charges for the persons concerned, long stay in hospitals, loss of working hours and/or early invalidism, to be dependent on outside help, immobility, restricted participation on social life, frustration, despair – this all we associate with the problem "diabetic foot" for the present. As a result of published experience of diabetic-foot-ambulances in the USA, in England and Scandinavia, there is rethinking also in Germany.

It shows that interdisciplinary care concepts, structured diagnosis and therapy, as well as "lifelong foot care" in the case of high risk patients can improve the situation, described at the beginning, significantly. On the one hand it is important to throw overboard obsolete doctrines and clichés ("diabetic feet don't heal or only heal badly, therefore amputating them rather high") as well as unsighted, expensive(!) polypragmatis of local wound healing and inadequate orthopedical shoe technique.

On the other hand you have to seek for effective, biologically well tolerated and economy-priced wound dressings at the same time for treating as much patients as possible without cost pressure. The following contribution deals in a broad sense with the wound treatment at patients with diabetic foot lesions and in a narrow sense with the application of LIGASANO® foam in wounds and wound healing impairments respectively, of the above mentioned patients.



#### 1. Patients and Methods:

In the period from March 1998 until January 2000 we have treated 15 patients (12 male, 3 female) with an average age of 54 years. Listed were:

- kind of lesion: wound healing impairment after amputation/resection, ulcers of the heels, malum perforans, wounds after sequestrum cut by diabetic neuro-osteo-arthropathy (= DNOAP, syn. Charcot's syndrome)
- extend of the wound (WAGNER stage and wound phase)
- classification according to ARLT (A=peripheral arterial occlusive disease, B=polyneuropathy, C=A+B=mixed type)
- duration of the wound
- methods of preliminary treatment
- days of hospital stay during preliminary treatment
- proceeded amputations on the same or contralateral leg
- days of hospital stay during the current treatment
- methods of the current treatment
- number of the ambulant consultations
- duration of healing under the current therapy
- dressing change

Apart from tabular charts there were made detailed case descriptions with photo documentations about every treated patient.

#### 2. Results and Summary:

The results (see table on the next page) speak for themselves. Details about deficiency in work are not necessary, because all patients are pensioners or invalids.

I have used LIGASANO® white polyester foam since already 1994 for wound treatment. The material was first introduced to me by Mr. Rettig, a nurse and enthusiastic wound therapist from Lüchow-Dannenberg (Germany). Little by little I have recognised and appreciated the multi-purpose possibilities of LIGASANO®. It has excellent qualities as padding material over regions with a high pressure load (heels, edges of feet, plantar at malum perforans, interdigital, toe-tips) and is very helpful for the soft debridement. In doing so LIGASANO® white is soaked with Ringer®'s solution and then the wound will be cleansed. Due to the high frictional resistance of LIGASANO® white, necrotic layers and detritus of cells are removed from the wound gently. The debridement with a sterile toothbrush, as recommended in some literature, is superfluous.

We use LIGASANO® white as a primary wound dressing for about two years and were surprised of its stimulating effects in secretion and granulation! And precisely in deep wounds LIGASANO® white is obviously superior to alginates and hydrocolloids, above all as a result of its additional capillar effect.

For the application of LIGASANO® white in deep wounds we cut the material in various sizes and shrink-wrap it. Subsequently the stripes are going to be sterilised by steam

and distributed for the home-care. If the dressing is not changed by nursing staff but by the patient or his relatives, we prescribe sterile one-way tweezers.

Finally we use LIGASANO® white also as a secondary wound dressing for padding over every wound dressing, as it is the uppermost layer, because a soft drainage pressure and warmth is also necessary for wound cleaning. For this purpose LIGASANO® bandages are best qualified for.

Beside the above mentioned multi-purpose application possibilities of LIGASANO® the comparatively low costs of this material are a further great advantage! For this reason LIGASANO® white belongs to our foot ambulance as an unrenouncable part of dressings.

#### Dates of Patients / Case History

Number of patients:	15
Age of the patients:	Average age 54 years (41 - 69)
Sex of the patients:	12 male, 3 female
Diabetes diagnosed since:	Average 17 years
Amputations before starting the treatment:	3 patients with amp. of the lower leg 9 patients with amp. of the toes
Further planned amputations:	at 6 patients the lower leg
Duration of treatment before:	Average 300 days (0 - 1095)
Days thereof stationary:	Average 74 days (0 - 270)
<b>Result of the treatment:</b>	<b>No wound healing</b>
Estimated cost of treatment:	
Average outpatient	226 days at 30 € = 6.780,-- €
Average inpatient	74 days at 270 € = 19.980,-- €
<b>Average total:</b>	<b>26.760,-- €</b>

#### Treatment by Dr. Zemlin with LIGASANO® white

Duration of treatment:	Average 90 days (18 - 450)
Days thereof stationary:	0 days
Realised/necessary amputations:	None!
<b>Result of the treatment:</b>	<b>Wound healing</b>
Estimated cost of treatment:	
Average outpatient:	90 days at 30 € = 2.700,-- €
Average inpatient:	0 days at 270 € = 0,-- €
<b>Average total:</b>	<b>2.700,-- €</b>

### Example

#### Patient 1

58 years old, female, type 2 diabetes mellitus, duration of 22 years, dialysis since 1994 because of diabetic nephropathy, laser coagulated retinopathy, insulin therapy 3x normal at night NPH insulin, coronary heart disease, cardiac dysrhythmia.

1992 resection of the 2<sup>nd</sup> left metatarsal bone because of a perforating ulcer of the foot; at that time this is healed completely. At 05/05/1998 first visit in our ambulance by reason of a 26 month old recurrent perforating ulcer of the right foot with projection to the 3<sup>rd</sup> metatarsal bone. Hitherto hospital stay 81 days without drastic improvement. No decompression measures took place. The amputation of the lower leg was advised.

#### Local pre-therapy:

Ointment containing chlorophyll, irrigation with H<sub>2</sub>O<sub>2</sub> solution and hypertonic NaCl solution, antiseptic gauze. Change of dressing two times daily by nursing service, referral by the dialysis practice.

#### Actual findings at 05/05/1998:

Distinct prominence of the forefoot, plantar, bilateral, claw toes, arterial pulses strong, dry and scaly skin, hypaesthesia, sensibility for temperature and pain lapsed, no provocation of patellar and achilles reflex; indolent ulcer, plantar, 1.6 x 1.1cm with a depth of 2cm; the exploring forceps breaks into crumbled structures.



Fig. 1: findings at 05/05/1998



Fig. 2: control of the wound at 07/07/1998

Resection of bone and cartilage debris with a bone curette and Luer's bone nibblers, irrigation with Oxoferin®, inlay with a sterile LIGASANO® white pack, cut to fit, which is changed once daily and soaked with Ringer's solution, and over this a mull dressing. Because fixative bandages are not tolerated by the patient, we fix the dressing with hypoallergenic plaster.

Adequate instruction of the very cooperative patient, which on her part informs the nursing service. We provide her with sterile LIGASANO® white packs (cut to fit, sterilised with steam and heat-sealed in our ambulance). Decompression: decompressive bandage shoe. During wound inspection at 14/05/1998 measurement for orthopaedic foot wear. Already in 07/07/1998 remains only a very plain wound.

Closure since 1998/08/10. Until the complete healing 7 ambulant consultations. Supply with orthopaedic boots. „



Fig. 3: August 1998

#### 2.4.4. Postsurgical Wound Treatment

The wound treatment is made according to the kind of wound and its size (examples for filling and covering of the different wound types see page 16-18). At bleeding wounds please pay attention to moisten LIGASANO® white with Ringer® solution or similar previously, because otherwise LIGASANO® may stick to the wound. Especially at postsurgical wound healing disturbances LIGASANO® white is the remedy you should choose.

##### Examples:

Fig. 2.1. to 2.4. show, how a wound in the inguinal region (state after abscess removal) with a depth of 3cm and a wound undermining to medial 8cm, is dressed with LIGASANO® white.



Fig. 1



Fig. 2.



Fig. 3

In this case we decided for LIGASANO® white with a thickness 1cm to tampon respectively fill the wound. Alternatively you can work with the LIGASANO® white wound strip, too. The wound was covered with LIGASANO® white with a thickness of 2cm and fixed with an elastic bandage.



Fig. 4



Fig. 5

After two days LIGASANO® white was changed, because its absorptive capacity was exhausted. LIGASANO® white allows to be removed from the wound atraumatic and without pain (fig. 5.).

The therapeutic effect of LIGASANO® white was shown especially at the care of abdominal, postoperative wound healing impairments. During the phase of secretion LIGASANO® white was changed once daily, until the bottom of the wound was clean and began to granulate. In the second phase of the wound healing the dressing was changed once every two days. We paid attention that there was no adhesion between dressing and the new constituted tissue.



Fig. 1



Fig. 2



Fig. 3

From fig. 1 to 3 three weeks passed. Additional to the therapy with LIGASANO® white the wound edges were adapted during the phase of granulation with steristrips, to reduce the wound furthermore in size and to achieve a good cosmetic result.

## 2.4.5. Burn Wounds

A burn is a traumatic damage of the skin by the effect of heat (flames, liquids, electricity). The treatment of the burned wound goes by its depth and dimension. The dimension of a burn is indicated by the part of the affected skin in relation to the body surface in percent. Large-area burns, that means from 20% of the body's surface on (adults and children) respectively 5% at infants, are a vital threat. By means of the so-called **niner rule** the dimension of burns can be estimated (see figure 1). At children under 8 years and infants you have to use age-adjusted values.

	Adults	Children	Infants
Head	9%	14%	18%
Torso	2 x 18%	2 x 18%	2 x 18%
Arms	2 x 9%	2 x 9%	2 x 9%
Legs	2 x 18%	2 x 16%	2 x 14%
Genitals	1%		

Fig. 1: partitioning of the body surface according to Wallace's niner rule

The profundity of burns is classified in three degrees of severity and results of the depth of the damaged skin:

**1° burn:** painful erythema as a result of oedema of the epidermis and hyperemia of the corium.

**Prognosis:** spontaneous healing without scarring.

**2° burn:** at second-degree burns also the dermis is damaged. It is further classified in superficial (2a°) and deep (2b°) burns.

**2a°:** the epidermis is destroyed until the superficial corium layer, cutaneous appendages (hair, nails) and glandulas are preserved and intact. Formation of blisters caused by albuminous exudation of liquid between corium and epidermis.

**Prognoseis:** spontaneous healing without scarring.

**2b°:** at deep second-degree burns the damage goes up to the deep layers of the corium, with a distinct reduction of sensibility and beginning circulatory disturbance of the subcorial dermal vascular net.

**Prognosis:** healing with scarring, depending on its extension in the depth. Possibly chirurgical wound treatment and transplantation is necessary.

**3° burn:** subdermal burn, combustion necrosis of all layers of epidermis and dermis including cuteaneous appendages. White-brown or black discolouration of the often leather-like skin. The sensibility is completely lapsed, because the nerve endings, which are lying under the skin, are burned.

**Prognose:** in the case of third-degree burns a spontaneous healing is hardly possible. Surgical excision and wound covering with skin grafts is mostly not avoidable.

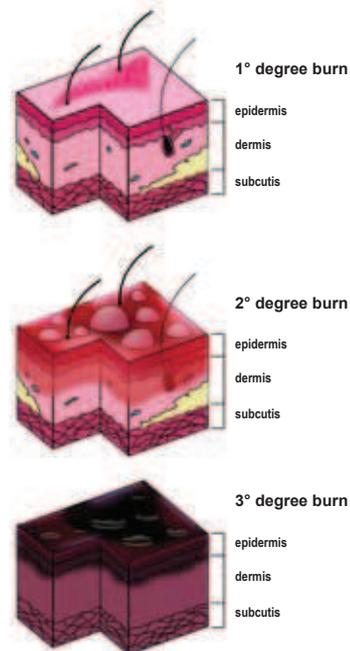


Fig. 2: structure of the dermis and classification of the burn depth. Source: K. Aainsqatsi, Wikimedia Commons, licenced under GNU license for free documentation

The burn wound itself is classified again in three zones, the hyperaemic zone ❶, the zone of the stasis ❷ and the coagulation zone ❸.

The coagulation zone is the central part of the burn wound. The whole area is characterised by denaturation and necrosis; there is no blood circulation. The tissue is no more able to regenerate itself.

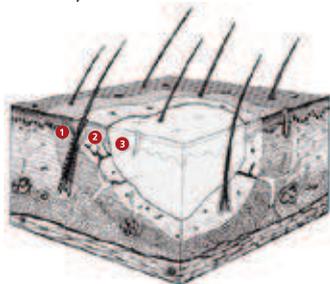


Fig. 3: combustion zones (according to Jackson)  
from: Merz, Katrin Maria „Mikrozirkulation und Heilungsverlauf von Verbrennungswunden“, dissertation at Medizinische Fakultät der Eberhard-Karls-Universität Tübingen/Germany, 2007

The zone of the stasis follows directly the coagulation zone. Here metabolism and blood circulation are highly constricted. Initially the cells are still active, but if the stasis continues for a longer time, the cells may collapse, caused by vasoconstriction, swelling of endothelial cells, platelet thrombus, fibrin deposition, amongst others. Further damage of this zone, caused e.g. by pressure or infection, may lead at any time to change to the coagulation zone.

The hyperaemic zone is localised at the exterior border of the burn wound and appears as a red zone. With pressure the tissue colours to white, and becomes red at decompression again. Microcirculation and metabolism are defective, the cells of this zone are hardly destroyed and the tissue is able to regenerate itself completely.

### Therapeutic advantage of LIGASANO® white for the treatment of patients with heavy burn injuries:

Because of its therapeutic effects (see page 12-14) LIGASANO® white is used in several burn centres for cleaning and conditioning of burn wounds before surgical treatment. For this see also chapter 2.3.6.: wound conditioning before surgical treatment.

#### Example 1:

41 years old, male, extensive full-thickness circumferential flame burn of the right lower limb; tangential excision followed by passive debridement with LIGASANO® white and skin grafting. Complete healing within two month.



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6

#### Example 2:

76 years old, female, with full-thickness hot liquid burn of the left axilla, shoulder, arm and breast, severe cardiac failure and other cardiovascular problems; passive debridement with LIGASANO® white, followed by STSG. Complete healing in about two month.



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6

## 2.4.6. Conditioning of Wounds before Surgical Debridement

According to Dorland's Illustrated Medical Dictionary, debridement means "the removal of foreign material and devitalized or contaminated tissue from or adjacent to a traumatic or infected lesion, until surrounding healthy tissue is exposed". The same work classifies debridement into four categories:

- natural spontaneous debridement (also called "physiological" either "autolytic")
- passive debridement by different specialized dressings
- enzymatic debridement
- surgical debridement.

This topic analyses all four categories listed above with all advantages and disadvantages of these methods, underling the passive debridement and that by polyurethane foam dressing especially. The last three methods already mentioned support and facilitate in fact the natural autolytic debridement process, every one having particular indication and benefit which should be adapted to each case. No one of these methods is never considered to be a panacea which means that each one should be used when only the advantages are greater from a distance than the disadvantages. Concerning the passive debridement by polyurethane foam (LIGASANO®), this one has all the advantages of "maggot therapy" with no one of its disadvantages, that is why we called this method "synthetic maggot therapy". In short, the amazing effects of LIGASANO® PUR foam are due to the special structure and properties of this dressing which give particular qualities such as:

- "wound activation" by mechanical stimulation (micromassage) of the lesion surface and surrounding tissues improving the blood and nutrients supply of all area
- decrease of pressure on the wound surface which facilitates collagen deposition and granulation
- amazing suction power of exudates and debris, maintaining a permanent wet wound environment which improves autolytic debridement
- improves the cost/efficiency ratio by avoiding expensive surgical techniques, decreasing the inpatient period and the frequency of dressing change, and decreasing the total treatment cost as well by improving the social and professional reconnection of the most part of patients treated in this way.

These are some advantages of passive debridement, a complex treatment in which, according to the author's experience, Dr. Adrian Botan, LIGASANO® PUR foam dressing has the most qualities.

### Example:

72 years old paraplegic male patient with a huge neglected sacral sore.



**Fig. 1**  
Initial aspect, before any treatment with LIGASANO® white



**Fig. 2**  
LIGASANO® white with a thickness of 2 cm is applied multilayered (3-4 layers of foam) and covered with sterile gauze padding: one can see the amazing absorption power of LIGASANO® white.



**Fig. 3**  
The dressing has been replaced every week because the patient couldn't come more frequently to the office for a new dressing. At least one half of the huge pressure sore has been debrided and granulated after 4-5 weeks of treatment with LIGASANO® white.



**Fig. 4**  
Fig. 4: In order to compare the two PUR foams, LIGASANO® white was replaced with Alleyn, but after two such dressings, we had to return to LIGASANO® white, because Alleyn has had to be replaced at least three times a week. Beside this, the debridement was not as effective like that with LIGASANO® white.



**Fig. 5**  
After two weeks of treatment with LIGASANO® white again, the most part of the eschar disappeared and the bottom of the large wound was filled with very good granulation tissue. This case is still in process and could need surgical closure eventually.

### 2.4.7. Other Wounds

This chapter contains all other wounds, which does not fit into the previous categories. It is possible to categorise ice burns and chemical burns to flame burns, because their symptoms are similar, but we decided to discuss them in this chapter.

#### Example 1:

38 years old, male, with third degree frostbite at both feet; inpatient for three days, then treated as an outpatient.



**Fig. 1**  
Initial aspect under LIGASANO® white treatment.



**Fig. 2**  
Initial aspect under LIGASANO® white treatment.



**Fig. 3**  
Some aspects after surgical debridement followed again by LIGASANO® white dressing.



**Fig. 4**  
Some aspects after surgical debridement followed again by LIGASANO® white dressing.



**Fig. 5**  
final aspect (after three month) with complete wound healing and an acceptable scar.

#### Example 2:

49 years old female patient, with type II diabetes treated with insuline and diet. This patient has had a small contusion on her left elbow, from which an extensive sepsis has developed, involving her arm, forearm and hand.



**Fig. 1**  
Initial aspect on admission, with extensive septic epidermolysis and blistering on her left upper limb.



**Fig. 2**  
The volar aspect reveals the circumferential involvement of the left forearm by the septic process.



**Fig. 3**  
Surgical debridement began by cutting incisions through the dermis in order to interfere with the lymphatic vessels and stopping the lymph flow and thus the potential septic dissemination of the extensive soft tissue infection.



**Fig. 4**  
Four days after initial debridement (septic lesions have been dressed every day with argentic sulphadiazine 5% cream), oedema decreased and necrotic area are well separated from the surrounding healthy structures.



**Fig. 5**  
The most part of the septic discharges are drained off and the necrotic skin is now separated. A small septic discharge still persists from the open dorsal compartment. This is the moment in which the passive debridement with LIGASANO® white has begun.



**Fig. 6**  
After about two weeks of passive debridement with LIGASANO® white, a spectacular granulation has been obtained and all debris and septic sloughs have been removed.

## 2.5. General Information about the Application of LIGASANO® green for Wound Treatment

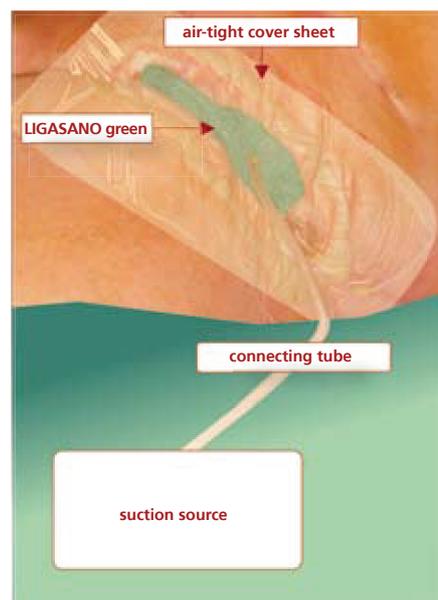
LIGASANO® green is an elastic, expanded polyurethane (PUR), which is almost always pervious to air and liquids (e.g. water) - imagine a three-dimensional sieve. It has a coarse texture and rough surface.

LIGASANO® green is used for wound treatment and care, if a strength and elastic material with high permeability to air and liquid is required.

The surface of LIGASANO® green is relatively rough. If it is used in wounds or on skin lesions may occur, especially by friction.

**The application of LIGASANO® green has to take place always by medics or medically trained personnel.**

### 2.4.1. Possible Use for Hospitals

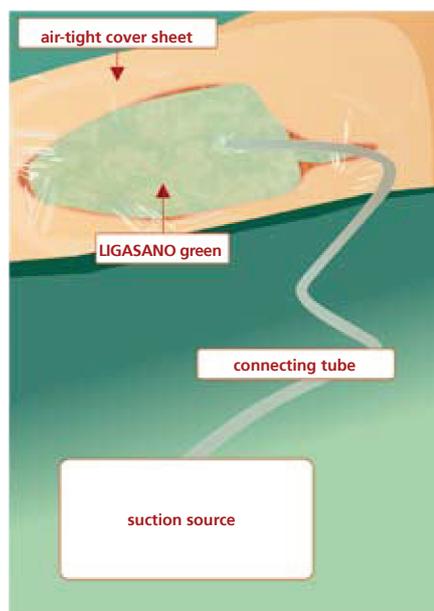


► With LIGASANO® green you can cover or fill wounds. It countervails a collapse of wounds by effect of external pressure or suction, e.g. during an active wound drainage.

► By the special properties of its surface a mechanical stimulus is caused on the area of contact, favouring the blood flow, and hence stimulates at contaminated or infected wounds the normal body reaction "wound cleaning by secretion". Moreover the transportation of substances should be stimulated hereby in the wound and so effects a promotion of granulation. This active principle is known and approved since decades by LIGASANO® white.

► You can apply LIGASANO® green also on skin, especially in the wound area. Thus you can utilise the above described mechanical stimulus on a greater area to stimulate the wound healing.





► By the described open structure of LIGASANO® green wound irrigations are possible in spite of the filled wound.

► A drainage of exudate, irrigation etc., following the gravitation down out of the wound is made possible.

► LIGASANO® green is able to be combined with LIGASANO® white in some cases of application.

► A combination makes sense if e.g. a considerable quantity of exudate has to be subdued, which exceeds the absorption capacity of LIGASANO® white.

► At urinary incontinence an urinary outflow should be made possible within the usual incontinent care with a common underlay or trousers, down, away from the skin, so that the skin is protected against this duressis.

► The decision about the particular kind of application of LIGASANO® green is determined by medic or medically trained personnel and is adapted and appropriated in every single case.



## 3. LIGASANO® for Prevention, Positioning and Hygiene

### 3.1. Facts, Data, Expert Standard Decubitus Prophylaxis

According to deliberate estimations, in Germany annually more than 400000 persons develop a pressure ulcer in need of therapy. Trusted data for the incidence are available only rudimentary, in particular for the domestic sector. In agreement with the actual issue of „Expert Standard Decubitus Prophylaxis in Care“ the decubitus prevalences in hospitals range between 18 and 24%, and in long-term care facilities about 30%. The measured decubitus frequency in German care settings is significantly less.

Pressure sores are a great strain for the persons concerned, the treatment is expensive and intricate and the healing is tedious. Hence, it must be the topmost concern to prevent decubital ulcers; from medical, nursing, ethical and health economical point of view. Namely by means of effective and cooperative provided preventive measures. The authors of the Expert Standard Decubitus Prophylaxis say that the development of decubitus in facilities of the Medicare is nationally and internationally a sensitive indicator for the quality of care. Although in practice not all pressure ulcers are generally avoidable. Apart from that pressure ulcers become increasingly subjects of legal disputes.

In 2002, the German Network for Quality Development in Care (DNQP) has published the **Expert Standard Decubitus Prophylaxis in Care** for the first time. Meanwhile a second edition with an updated literature survey is available and it announces the nursing staff more certainty in acting (see Heilberufe 03/2011). In view of the present knowledge regarding the possibilities of prevention of pressure ulcers, the reduction to minimum has to be aimed. It is of outstanding meaning, that the nursing staff provides for systematic risk assessment, instruction of patient respectively persons concerned, exercise support, pressure reduction and continuity of prophylactic measures. As written in Heilberufe 03/2011, the Expert Standard 2010 differs with regards to content not fundamentally from the version of the year 2000; but since that time exist better scientific findings to the several criteria. Thus the revision helps to eliminate obscurities and to convey confidence in handling in practice for nursing staff and institutional organisations. Changes are however in risk identification and in prophylactic measures.

Structure	Process	Result
<b>The qualified nurse...</b> <b>S1</b> - ... has actual knowledge about the genesis of pressure sores as well as competence to calculate the risk of decubital ulcers.	<b>The qualified nurse...</b> <b>P1</b> - ... evaluates the decubital risk of all patients/inhabitants, where the endangering is not eliminated. The nursing staff does this directly at the beginning of the nursing order and afterward in individually timed intervals; and immediately, if mobility or activity changes or if external factors (e.g. tubes, catheters), which may lead to higher and/or longer exposure of pressure and/or shearing forces.	<b>E1</b> An actual systematic evaluation of the decubital risk is existent.
<b>The qualified nurse...</b> <b>S2</b> - ... handles methods of skin and tissue gentle movement, positioning and transfer.	<b>The qualified nurse...</b> <b>P2</b> - ... ensures, on the basis of an individual kinetherapeutic plan, immediate pressure relief by regularly exercises with the patient/inhabitant, micro-motions, transfer with low shearing forces, and promotes the spontaneous movement of the patient/inhabitant, as far as possible.	<b>E2</b> An individual kinetherapeutic plan is existent.
<b>The qualified nurse...</b> <b>S3a</b> - ... has the competence to estimate the need and suitability of pressure distributing aids. <b>S3b</b> Pressure distributing aids, according to the risk of the patient/inhabitant (e.g. cushions and mattresses for soft positioning, special beds) are available immediately.	<b>The qualified nurse...</b> <b>P3</b> - ... uses suitable pressure distributing aids, additional to pressure reducing aids, if the patient's/inhabitant's condition disallows sufficient promotion of movement.	<b>E3</b> The patient/inhabitant resides immediately at a pressure reducing support, which fits to him/her.
<b>The qualified nurse...</b> <b>S4</b> - ... has the ability as well as information material and internal training material for the instruction and advice of patients/inhabitants and their relatives for the promotion of exercises, for skin observation and for the handling with pressure distributing aids.	<b>The qualified nurse...</b> <b>P4</b> - ... defines the decubital danger and the need of prophylactic measures and their evaluation; and plans this individually with the patient/inhabitant and his/her relatives.	<b>E4</b> The patient/inhabitant and his/her family know the reasons of the decubital risk as well as the planned measures and take part in its implementation, based on their possibilities.
<b>The institution...</b> <b>S5</b> - ... ensures that all persons, which are involved in the patient's/inhabitant's care, do know the correlation between continuity of interventions and the success of decubitus prophylaxis. The institution also ensures the transfer of information concerning the decubital risk to external involved persons.	<b>The qualified nurse...</b> <b>P5</b> - ... informs the involved persons, which participate in the treatment of the patient/inhabitant with the risk of decubital ulcer, about the necessity to continue the intervention constantly (e.g. employees at medical practices, surgical and radiological department or transport services).	<b>E5</b> The decubital risk and the necessary measurements are known to all persons, which are involved to the patients/inhabitants care.
<b>The qualified nurse...</b> <b>S6</b> - ... has competence to evaluate the effectiveness of the prophylactic measurements.	<b>The qualified nurse...</b> <b>P6</b> - ... examines the dermal situation of the patient at risk in individually determined intervals.	<b>E6</b> The patient/inhabitant has no decubital ulcer.

#### Risk Assessment / Risk Scales for the Evaluation of the Decubital Risk:

The practice guideline „decubitus prophylaxis in care“ says, that over 100 risk factors are known for the development of a decubital ulcer and that many of these factors are part of more than 30 instruments for the evaluation of decubital risk, so-called risk scales. In 5 systematic summary essays and 13 prospective diagnostic studies, the prognostic validity of particular risk factors and risk scales is illustrated by means of sensitivity, specificities, positive and negative predictive values, roc curves or odds ratios. Reference criterion is the appearance of decubitus.

Regarding to Pancorbo-Hidalgo et al. (2006) and Bolton (2007) the Braden scale outplays the other risk scales relating to validity. In contrast Schlömer (2003) notices that the test quality of the Braden scale and the other scales is little and that they are not suited for risk screening.

In the year 1987 the Braden scale was designed from Barbara Braden and Nancy Bergstrom and is based on a sum score, that has max. 23 points and min. 6 points. The risk danger increases with decreasing number of points. According to expert knowledge, a decubital danger is existent at ca. 16 points.

At risk assessment, now the group of experts does not advise risk scales. Because it was impossible to verify, that scales are more applicable than a systematic clinical assessment, nor are they a positive aid. In fact studies are available, that come from a considerable misinterpretation when using such instruments (see the periodical „Heilberufe“ issue 03/2011).

	1 point	2 points	3 points	4 points
<b>sensory perception</b> ability to respond meaningfully to pressure related discomfort	<b>completely limited</b> unresponsive (does not moan, flinch or grasp) to painful stimuli, due to diminished level of consciousness or sedation or limited ability to feel pain over most of the body	<b>very limited</b> responds only to painful stimuli, cannot communicate discomfort except by moaning or restlessness or sensory impairment which limits the ability to feel pain or discomfort over half of the body	<b>slightly limited</b> responds to verbal commands but cannot always communicate discomfort or the need to be turned or sensory impairment which limits ability to feel pain or discomfort in one or two extremities	<b>no impairment</b> responds to verbal commands, has no sensory deficit which would limit ability to feel or voice pain or discomfort
<b>activity</b> degree of physical activity	<b>bedfast</b> confined to bed	<b>chairfast</b> ability to walk severely limited or non-existent; cannot bear own weight and/or must be assisted into chair or wheelchair	<b>walks occasionally</b> walks occasionally during day, but for very short distances, with or without assistance; spends majority of each shift in bed or chair	<b>walks frequently</b> walks outside room at least twice a day and inside room at least once every two hours during waking hours
<b>mobility</b> ability to change and control body position	<b>completely immobile</b> does not make even slight changes in body or extremity position without assistance	<b>very limited</b> makes occasionally slight changes in body or extremity position but unable to make frequent or significant changes independently	<b>slightly limited</b> makes frequent though slight changes in body or extremity position independently	<b>no limitation</b> makes major and frequent changes in position without assistance
<b>moisture</b> degree to which skin is exposed to moisture	<b>constantly moist</b> skin is kept moist almost constantly by perspiration, urine, etc.; dampness is detected every time patient is moved or turned	<b>very moist</b> skin is often but not always moist; linen must be changed at least once a shift	<b>occasionally moist</b> skin is occasionally moist, requiring an extra linen change approximately once a day	<b>rarely moist</b> skin is usually dry, linen only requires changing at routine intervals
<b>nutrition</b> usual food intake pattern	<b>very poor</b> never eats a complete meal, rarely eats more than 1/3 of any food offered; eats two servings or less of protein (meat or dairy products) per day; takes fluids poorly; does not take a liquid dietary supplement or is NPO and/or maintained on clear liquids or infusions for more than five days	<b>probably inadequate</b> rarely eats a complete meal and generally eats only 1/2 of any food offered; protein intake includes only three servings of meat or dairy products per day; occasionally will take a dietary supplement or receives less than optimum amount of liquid diet or tube feeding	<b>adequate</b> eats over half of most meals; eats a total of four servings of protein (meat, dairy products) per day; occasionally will refuse a meal, but will usually take a supplement when offered or is on a tube feeding or TBN regimen which probably meets most of nutritional needs	<b>excellent</b> eats most of every meal; never refuses a meal; usually eats a total of four or more servings of meat and dairy products; occasionally eats between meals; does not require supplementation
<b>friction and shearing forces</b>	<b>problem</b> requires moderate to maximum assistance in moving; complete lifting without sliding against sheets is impossible; frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance; spasticity, contractures or agitation leads to almost constant friction	<b>potential problem</b> moves feebly or requires minimum assistance; during a move skin probably slides to some extent against sheets, chair, restraints or other devices; maintains relatively good position in chair or bed most of the time but occasionally slides down	<b>no apparent problem</b> moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move; maintains good position in bed or chair	
	<b>low risk</b>	<b>medium risk</b>	<b>high risk</b>	<b>very high risk</b>
	<b>18-15 points</b>	<b>14-12 points</b>	<b>11-9 points</b>	<b>&lt; 9 points</b>

The Braden scale holds two main elements responsible for the development of pressure ulcers:

1. **Duration and intensity of pressure**, that depends on the sensoric abilities, the activity and the mobility of the patient.

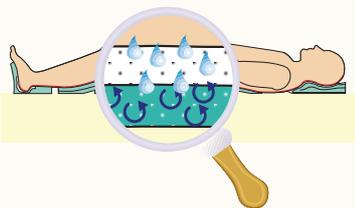
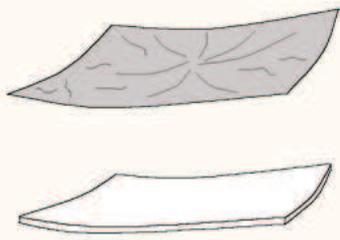
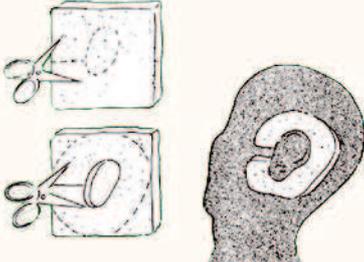
2. **Tissue tolerance of the skin**, that depends on humidity, nutrition and friction resp. shearing forces.

Depending on the number of scale points, the intervals for the repeat of the rating act on: At values between 6 and 9 points (very high risk) it should evaluate newly every day, at values between 10 and 14 points every two days. At patients with a value of 15 to 18 points you need to do the risk evaluation only two times a week, at patients with a value over 19 points only once weekly. In case of serious changes (for example tube feeding, impairment of the health situation) the evaluation for decubital risk has to be made anew immediately.

### 3.2. Possibilities of Bedding with LIGASANO® white and LIGASANO® green

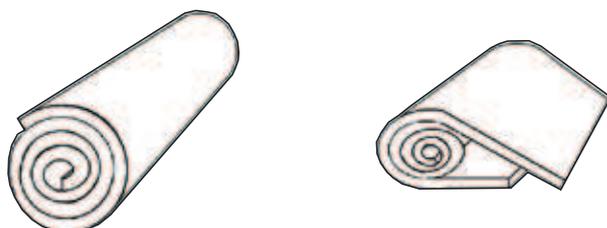
Decubitus prophylaxis through active changing of a patients position. The rapid drop in pressure tension of LIGASANO® white enables almost even distribution of pressure from the surface padding and thus avoids the dreaded pressure points. LIGASANO® white and LIGASANO® green can simply be cut to fit. This is how aids such as pulleys, wedges and heel shoes, for example, are created for changing patients position, having been adapted by imaginative health care professionals. The mechanical stimulus of LIGASANO® white promotes the peripheral blood supply where there is contact to skin, and the patients residual pressure increases. Surplus sweat is absorbed, leaving normal skin moisture, and care of the skin is also associated with the mechanical stimulus. If LIGASANO® white has the appropriate thickness it does not form any folds, thus actively preventing a further risk of pressure ulcer. Patients are always placed onto LIGASANO® white ensuring skin contact.

**These properties of LIGASANO® will help you:**

		
<ul style="list-style-type: none"> <li>• improved blood flow</li> <li>• improved supply with substances</li> <li>• higher inner vessel pressure</li> </ul>	<ul style="list-style-type: none"> <li>• quick reduction of compressive stress</li> <li>• pressure relief</li> </ul>	<ul style="list-style-type: none"> <li>• LIGASANO® white absorbs</li> <li>• LIGASANO® green ventilates</li> <li>• no accumulation of heat and moisture</li> </ul>
		
<ul style="list-style-type: none"> <li>• textiles form folds</li> <li>• LIGASANO® never</li> </ul>		<ul style="list-style-type: none"> <li>• may be cut as required</li> <li>• will suit any situation</li> </ul>

#### LIGASANO® is multifunctional

With the simplest of tools you solve even difficult tasks in patient's positioning



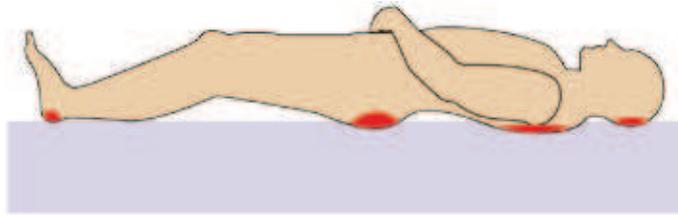
On the following pages you will find some suggestions:



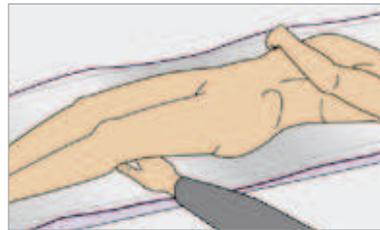
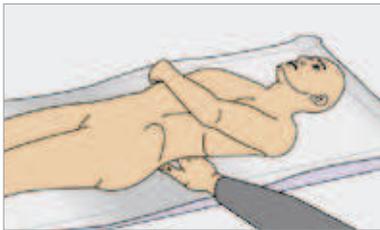
## Positioning with Lying Patients (The Anatomic Correct Bedding)

The LIGASANO® positioning can be arranged at nearly every bed.

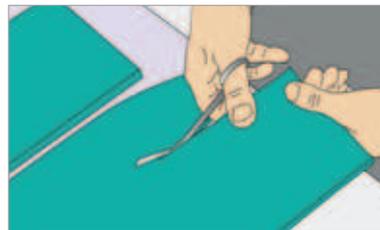
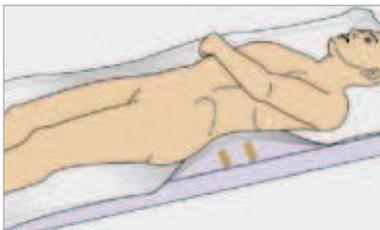
*Starting point:* the patient lies in bed, you will just make the bed anyway.



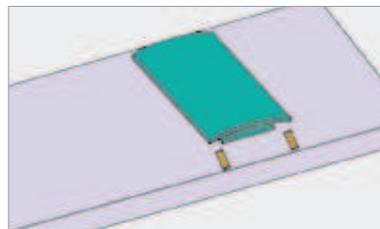
Feel where the patient's weight does not rest fully on the bed.



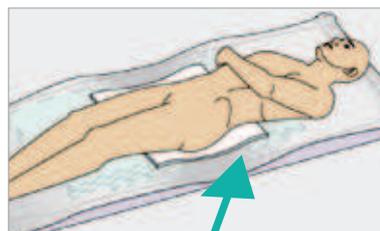
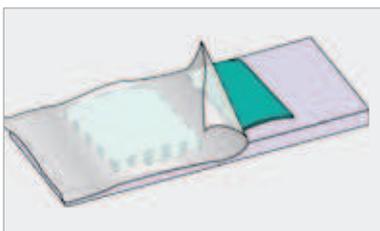
Fold the bed sheet back on the edge, so that you can apply plaster strips as marks directly on the mattress.



Mark the positions on the mattress that you would like to underpad.

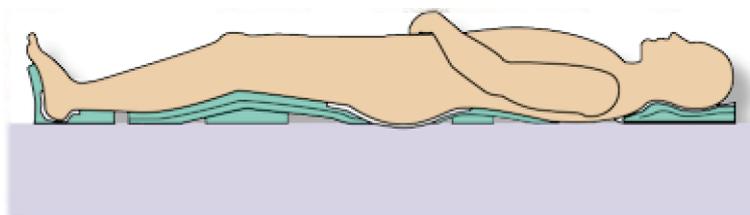


Cut fitting pads and place them on the marked positions.



Cover with the normal bed sheet and the patient may return to bed.

1 cm LIGASANO® white directly on the skin avoids folds, promotes the blood flow and regulates the skin moisture



You only need to do this positioning once; the pads always remain on the bed, directly on the mattress. Optimally you cover the mattress with the applied LIGASANO® green pads with an elastic bed sheet. This bed sheet and the pads are now an integral part of the mattress.

The objective is, that the patient distributes his resting pressure evenly (= pressure relief by pressure distribution). Your flat hand under the patient's body is a very sensitive measuring instrument.

The patient now will not slide from top to bottom or the other way around, because he feels comfortable as well as lying orthopedically correct. When doing it the first time, you might have to touch it up a bit at the first and second day, but you will see how simple it is, once you have some experience.

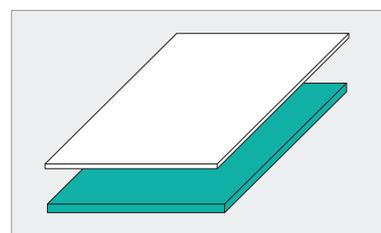
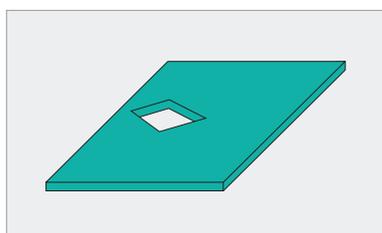
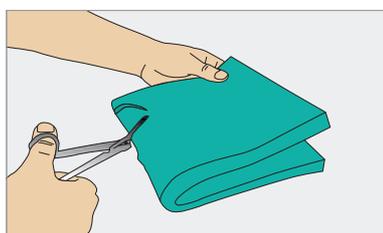
Time required: once about 10 - 15 minutes.

**The above described positioning doesn't release you from changing your patients position in appropriate intervals and is normally suited without change for tilted and side positions, too.**

Extraordinary bodily conditions (e. g. contractures) may also be balanced by the adaption of these paddings.

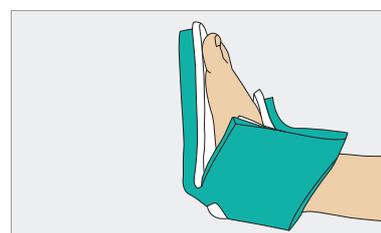
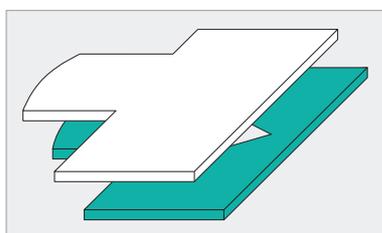
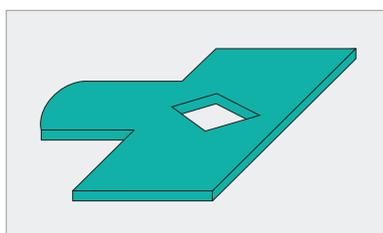


### Individual Heel Shoes: model 1



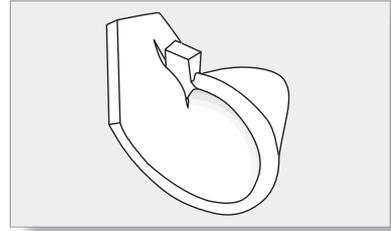
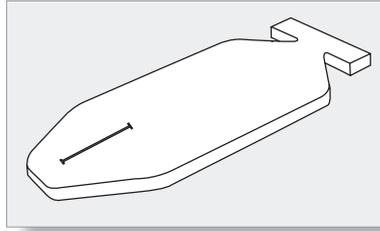
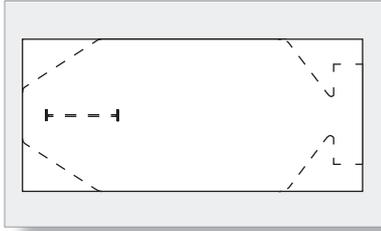
Fixation e.g. with the cut-off foot end of nylon stockings and plaster strips

### Individual Heel Shoes: model 2



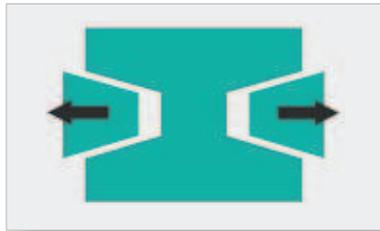
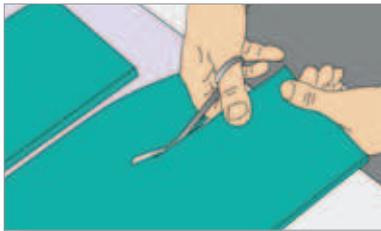
## Knee Pad

for padding the knees in tilted or side position; holds without additional fixation

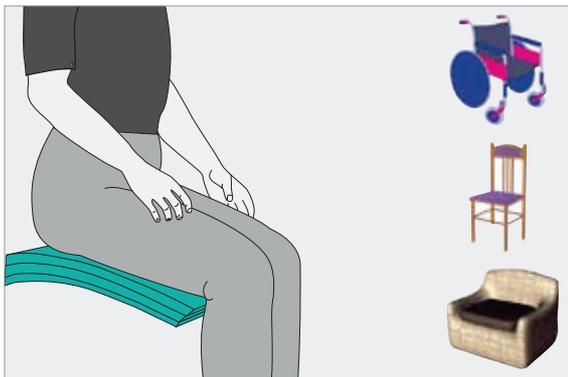


## Orthopedic Pillow

within 5 minutes adapted individually + orthopedically optimal



## Sitting without Perspiration



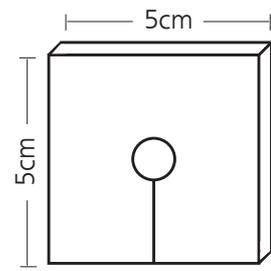
Wheel chair drivers in particular have the problem, especially in summer, that their buttock by sitting for a long time becomes moist and therefore more sensitive for pressure ulcer, fungal infections, inflammations, etc. It makes no difference if you fold LIGASANO® green as shown or simply lie some sheets on the top of the other, the accumulation of heat is over, the buttock is well ventilated.

**Individual sitting pads. Completely permeable to air and washable.**

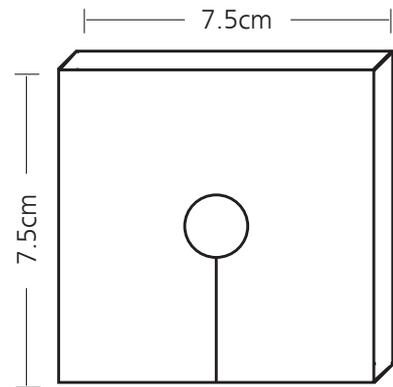
## Slit compresses



Slit compresses made of LIGASANO® white for protection against pressure



**Item no. 15063-020**  
20 pcs. 5 x 5 x 1 cm



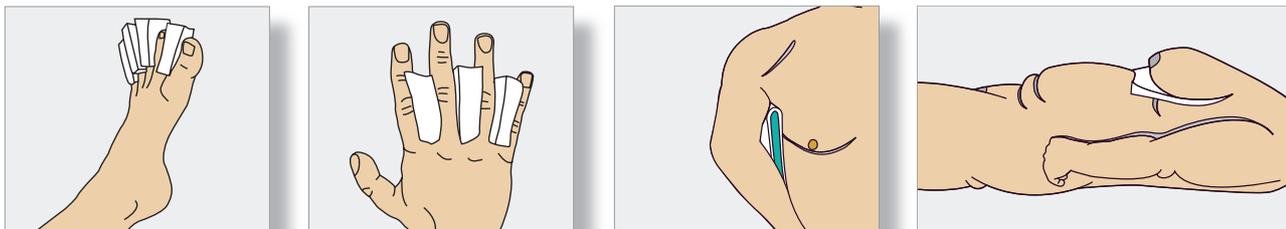
**STERILE**  **Item no. 15165-020**  
20 pcs. 7.5 x 7.5 x 1 cm

### 3.3. Prevention of Contractures and Hygiene

At bedridden patients and at immobilisation of articulations a contracture (ankylosis) and muscular atrophy (contraction of the muscles) may develop. Especially patients with phlogistic or degenerative arthropathy are at risk; but also patients with immobilised joints, e.g. by relieving posture, palsy or weakness. Measures for the maintenance of an intact musculoskeletal system are kinetotherapeutic exercises, mobilisation and adequate positioning.

In the following we show you some suggestions for the prophylaxis of contractures and intertrigo:

#### Prevention of Skin-to-Skin contact (Prophylaxis and Therapy of Intertrigo)



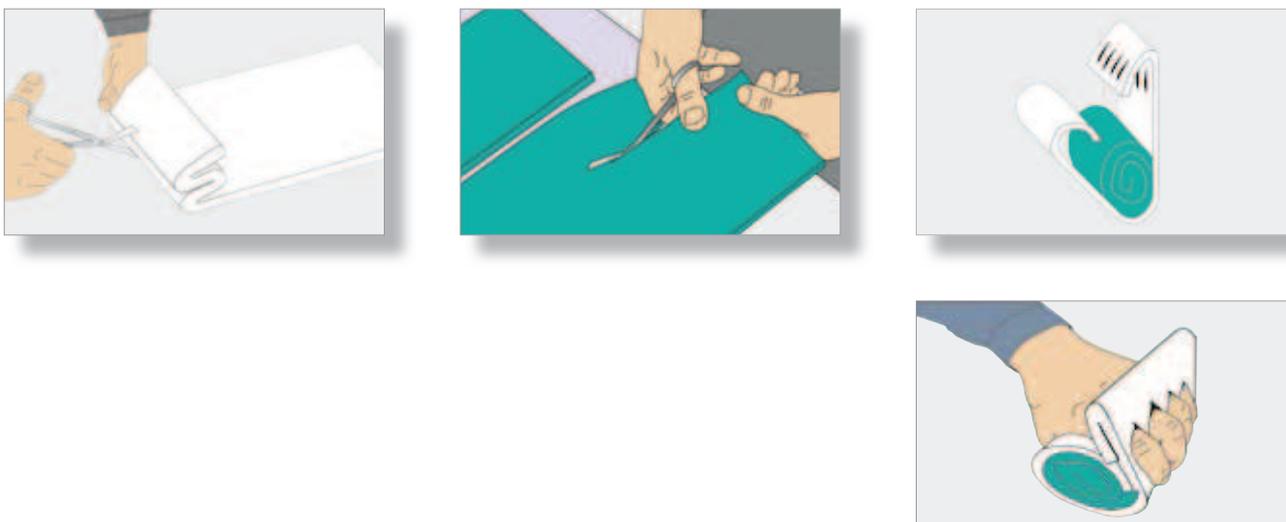
Not only for prevention but also as a concomitant therapy at mycosis treatment in connection with an antimycotic or a single therapy, if the skin is only irritated or inflamed.

#### Simple Finger Separator

manufactured in one minute; prevents contractures and separates the fingers



#### Finger Separator / Positioning at atonic paralysis



### 3.4. The Use of LIGASANO® in Podiatry

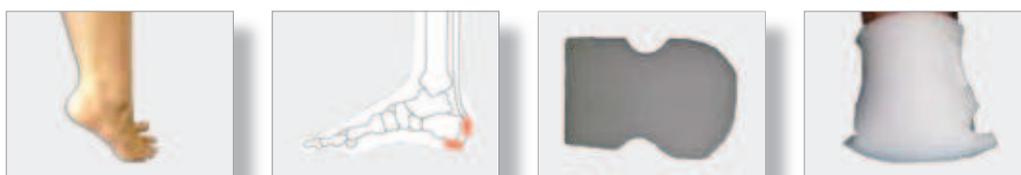
In podiatry LIGASANO® is used especially in the following areas:

- protection against pressure, e.g. at hallux valgus and calcaneal spur
- interdigital protection against pressure
- protection against friction
- protection against pressure after removal of a clavus (corn)
- tamponing of the nail fold, particularly at unguis incarnatus (incarnated nail)
- interdigital at mycosis
- treatment and prevention at diabetic feet (see also page 26-27 and report of practical experience no. 2 and page 21-31 in our brochure "practical experiences" respectively)

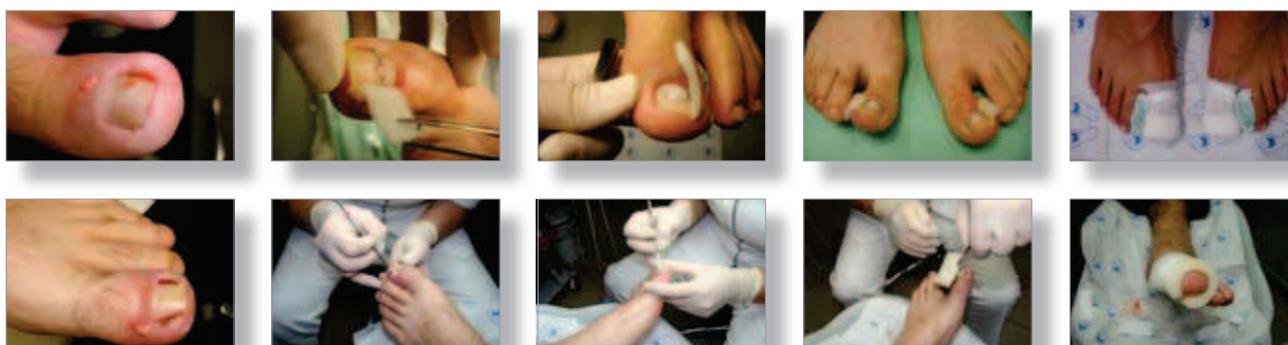
#### Pressure Protection with LIGASANO® white at Hallux valgus



#### Pressure Protection with LIGASANO® white at Calcaneal Spur



#### Padding with LIGASANO® white at application of a 3TO clip



#### Application of the LIGASANO® tube for toes in podiatric practice



### 3.5. Prefabricated Positioning Aids

## Plantar Dressing made of LIGASANO® white, incl. scissors & fixation

For relief and prevention. Surely you know this by own experience: if you have job-related to stand on your feet for the whole day or after a long day at the fair ... always if your feet hurt, the LIGASANO® plantar dressing helps.

However the effect of the LIGASANO plantar dressing is not comparable to conventional pads made of silicone, latex, etc. Mostly this products are not absorptive; the treated areas become sweaty, macerated and for this particularly sensitive. The LIGASANO plantar dressing protects against pressure, it air-conditions, absorbs sweat and promotes the perfusion - at the same time!

#### Plantar dressing for the whole foot:



Art.-no. 15093-008 for size 36-41

Art.-no. 15095-008 for size 42-46

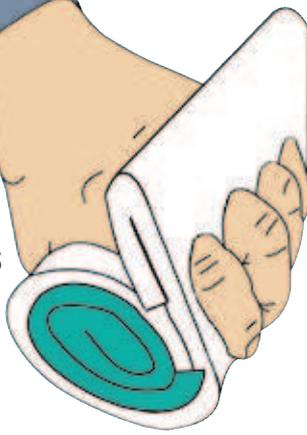


#### Plantar dressing for parts of the foot:



A perfect solution for healthy feet as well as for feet in need of care

CE 1275



# Palm Dressing

made of LIGASANO® white and LIGASANO® green  
item no. 15090-012

1



**Image 1:**

The palm-dressing made of LIGASANO® white has two rows each with four notches for the fingers.

2



**Image 2:**

By bending down you can bring the two rows one upon the other. Now stick the fingers through the both layers.

3



**Image 3:**

Please note: the shorter end always has to lie towards the palm.

4



**Image 4:**

By this you can treat or prevent intertrigo, dents and hurts of the palms and between the fingers. The mechanical stimulus, which effects the LIGASANO® white to the palm, is favouring the local blood flow; non vital dermal cells peel away.

5



**Image 5:**

Additionally you can insert a spiral roll of LIGASANO® green to get a workout effect or even to open it a little bit once again by permanent light counter pressure. Due to the special properties of the material you can prevent accumulation of heat or moisture. If there exists a risk of spacity in case of contact with the palm, this application is contra-indicated .

6



**Image 6:**

You can adapt the diameter as well as the strength of the LIGASANO® green spiral roll. If you open the roll and coil it up stronger, a smaller diameter with higher strength results. If a smaller diameter without higher strength is favoured, you can cut a part of the outer coat.

7



**Image 7:**

Also in the case of completely closed hands you can utilize and adapt the LIGASANO® hand dressing easily, with all the known advantages in avoiding the skin-to-skin contact.

8



**Image 8:**

An efficient fixation can be made with LIGAMED® *fix*.

The palm-dressing made of LIGASANO® white is a disposable product, that loses its properties after a few days. Except for infected dressings, you can dispose it with the household waste. The spiral rolls made of LIGASANO® green are utilizable for a longer time (e.g. for a workout of the hands), are washable up to 95°C and sterilisable with steam (if required please ask for our special information brochure).

## 4. Advanced Training

### 4.1. Topics of our Courses

The LIGAMED® Inhouse Seminars are informative and exciting. Indeed, we cannot renounce for the „less exciting“ theory, but the practical part will balance it entirely. We teach you how to make chronic wounds to healing wounds by treating the patient with care. And how to reach an effective prevention against this kind of wounds by using simple means.

Our seminars are an absolutely necessity if you are engaged with the treatment of chronic wounds and the care of temporarily or permanently immobile patients.

Course No.	Title / Subject-matter	Duration	Min. Participants	Suitable for
10	<b>Basic course „LIGASANO®-Therapy + Prevention“</b> <ul style="list-style-type: none"> <li>reliable healing of chronic wounds</li> <li>better and more individual prevention + hygiene with little expenditure of time and less costs</li> </ul> Concentrated information in a compact and practical course. The following subjects are treated: Particularly pressure ulcer, ulcus cruris, diabetic caused lesions, under special consideration of the meaning of sufficient blood supply and appropriate nutrition. Physical and biological principles, case history, diagnosis, technics of bedding and bandaging, promotion of pressure resistance of the patients, pressure release, skin care, wound cleaning, examples for effective application.	ca. 180 minutes	Not less than 10, optimal are 20-30 participants	Physicians and nurses in hospitals, nursery homes, schools The access into the LIGASANO®-Therapy or as a refresher course
12	<b>Basic course „Podiatry“</b> Concentrated information in a compact and practical course. The following subject are treated: <ul style="list-style-type: none"> <li>Wound treatment with LIGASANO® white (e.g. at diabetic caused lesions at the feet or inflamed nail folds)</li> <li>Preventive measures with LIGASANO® white and LIGASANO® green (e.g. pressure protection and antifriction at hallux valgus, dry rhagades, clavus mollis, hygienic measurements of fungal infections)</li> </ul>	ca. 120-180 minutes	optimal are 10-20 participants	Podiatrists and pedicurists, vocational schools for podiatrists  The access into the LIGASANO®-Therapy or as a refresher course
14	<b>Continuation course / Workshop</b> Subjects and duration are decided by the participants. Examples are: <ul style="list-style-type: none"> <li>Exercises in wound treatment with the wound phantom</li> <li>Practical exercises in prevention</li> <li>Discussion and add-on of knowledge for certain applications</li> </ul> In order that the lecturer is able to prepare the subjects, please name the desired main focuses already with booking.	ca. 120-180 minutes	optimal are 5-10 participants	Only for LIGASANO® users with knowledge and practice of the basic course

Our professional and experienced speakers lecture about 250 courses every year, in most cases with phenomenal success, as shown by the evaluations of the participants.

**See for yourself and arrange your desired!** See the application form you on the back. If you want to save paper please find an application form at [www.ligasano.com](http://www.ligasano.com) to send via e-mail. **We look forward to see you!**

State: March 2012	1 excellent	2 good	3 satisfactory	4 sufficient	5 unsatisfactory	6 very poor	Ø average
<b>Content:</b>							<b>1,43</b>
-quality of content	61,95%	34,76%	2,47%	0,46%	0,21%	0,15%	1,43
-practical usability	57,53%	35,92%	4,87%	1,00%	0,45%	0,23%	1,53
-useful information	70,32%	24,97%	3,44%	0,74%	0,32%	0,21%	1,43
<b>Speaker:</b>							<b>1,36</b>
-competence	71,43%	24,42%	2,85%	0,80%	0,29%	0,21%	1,36
-understandability	66,78%	30,33%	2,43%	0,13%	0,13%	0,20%	1,35
<b>Dauer der Veranstaltung:</b>	perfect	a bit too short	a bit too long				too long
	78,18%	3,98%	16,18%				1,66%
							<b>1,45</b>