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(54) Title: PRESSURE-DISTRIBUTING ELEMENTS FOR USE WITH NEGATIVE PRESSURE THERAPY

(57) Abstract: A pressure-distributing element for use as a wound-contacting element in connection with negative pressure therapy is provided. This pressure-distributing element is made of a non-absorbing elastomeric material having a shore-value of between 5 and 60 shore A. Further the element is provided with diffuse pathways having a size of between 0,5 and 10 mm s. Such an element will be flexible in use and would enable the user to retain control over the element during use. The element may comprise strands, beads, sheets, interconnected ring-elements and elements having cavities and walls. Further it may comprise combinations thereof. A system for use in connection with NPWT is further provided. This system comprises a pump, a canister an enclosure for the wound and a pressure-distributing element. A method of use is also provided.

Pressure-distributing Elements for use with Negative Pressure Therapy

This invention relates to the field of negative pressure wound treatment and to pressure-distributing elements for use as wound-contacting elements.

Background

Applying negative pressure to wounds is particularly useful to promote wound healing of high exudating wounds or wounds, which have difficulty in healing. For this purpose, a system comprising a pump for providing the negative pressure, a film for covering the wound thereby forming an enclosure and a tube for connecting the pump to the enclosure may be used. When such a system is used it is beneficiary to use a wound-contacting element in form of a pressure-distributing element in connection with the system. When using a pressure-distributing element the pressure is distributed over a larger area so suction is applied to almost the complete area covered by the pressure-distributing element. If no pressure distribution were present suction may only be applied to the area in the near vicinity of the inlet to the tube. Furthermore, when a wound is healing it should preferably heal from the bottom and sides of the wound cavity. If negative pressure is applied to a wound cavity, the edges of the wound may tend to close and heal the wound from the top. In worst case the edges will touch each other and grow together leaving a fistula below. To avoid this situation it is useful to apply a pressure-distributing element into the wound so it also act as a filler preventing collapsing of the wound edges during the negative pressure therapy.

Description of Related Art

US2005/00228329 provides a wound packing material consisting of polyester felt. The material may also be a polyester textile such as a knitted, weaved or braided material.

WO2006/087021 discloses a wound packing material of textile with a biocompatible surface. The structure of the surface should prevent the ingrowths of the wound tissue into the wound packing material.

US2006/00412747 – wound insert of a generally thin, flexible body of medical grade silicone or other type of elastomer.

Summary of the Invention

The invention relates to pressure-distributing elements for use in connection with negative pressure therapy for assisting in wound healing. The elements all comprise part having shore-values of 5-60 shore A and pathways having a size of 0,5-10 mm's. The elements may comprise strands, sheets, interconnected ring-elements, beads and/or elements having cavities and walls. The individual parts of the element are of a size of 0,25-5 mm's. All of the elements are flexible in use and they will not considerably alter their flexibility during influence of negative pressure therapy. At the same time the porosity of the elements will only alter slightly, which means that complete control over the pressure is maintained during therapy. The element may comprise just one type of the mentioned parts or it may comprise combinations of the parts. Furthermore, the invention provides for a 3-dimensional element so in most situations the caregiver only needs to handle a single element. This greatly reduces the risk of parts being forgotten in the wound. The element may be adapted to fit the wound by cutting it using scissors or by tearing it apart.

The invention also provides for a system comprising a pump, canister, enclosure and a pressure-distributing element as described. Furthermore, the invention provides for a method of treating a wound using negative pressure therapy.

Detailed Description of the Invention

In a first aspect the invention relates to a pressure-distributing element for use as a wound-contacting element in connection with negative pressure therapy, which element comprises a 3-dimensional structure of pathways in-between material components, the material components being made of non-absorbing, elastomeric material having shore values between 5 shore A and 60 shore A where the inscribed circle of the cross section is between 0,25 mm's and 5 mm's, wherein the pathways have a diffuse structure with a circumcircle of between 0,5 and 10 mm's.

A 3-dimensional structure includes a structure having at least two layers of material. In most situations the element will be made with more layers. Such a structure makes it possible to adapt the element in all shapes by cutting it or tearing it, thereby making it adaptable to all wound cavities.

A structure with more layers will have diffuse pathways. This has the effect that the pathways for the exudates may be controlled so as to ensure that free flow of the exudates are possible at all times. Generally, the pathways may not be genuine channels but may be pathways through several layers of the structure. In other words the pathways may be disorganized. Wound exudate will be able to enter into the structure through a perforated hole or between two parts of the element and then it will travel along the parts of the element and exit at the surface form where it will be removed by suction. The size of the pathways ensures that there will be no confinements of wound exudates. The structure constituting the pressure-distributing element will have diffuse pathways through the structure but may have more restricted pathways through a single layer.

The pressure-distributing element may also be designed with different layers, but still the element will be in the form of a one-piece element. This may be advantageous in assisting a proper and faster wound healing. Different layers may also have the effect of reducing pressure marks and prevent the element from being stuck in the wound. If the layers were separate and they were provided to a caregiver in a package, the caregiver has to provide the layers in the right order into the wound cavity. This would be a source of error, as the caregiver may accidentally confuse the layers. Using a one-piece element of a 3-dimensional structure makes it possible to cut the structure in all shapes thereby adapting it to all wound cavities. Furthermore, the fact that a one-piece element is used will prevent small parts from being forgotten in the wound. This is due to the structure having a certain extent.

The dimensions of the material components of the structure are so big that tissue is not able to attach to other tissue around the parts of the structure. Thereby the structure will be easier to change for a caregiver. Furthermore such a structure would still have interconnected channels during negative pressure therapy. Hence, complete control of the negative pressure is maintained across the element. The material and the structure is such that even if the structure is crumpled as it is packed into the wound, the structure will not collapse entirely but will maintain pathways through the structure.

The combination of the materials and construction of the pressure-distributing element provides an excellent surface preventing or reducing the risk of ingrowths as well as creating a low cohesion between wound and pressure distributing element, which will benefit the patients and the caregiver in several ways. The patient will experience it less painful and traumatic when the pressure-distributing element is changed every 2-3 days. The risk of damaging new tissue during pressure-distributing element change will also be reduced so there will be less risk of prolonged healing time. The low cohesion between wound and pressure distributing element as well as the reduced risk of ingrowths will also make the work easier and faster for the caregivers when the pressure-distributing element is being changed. Furthermore the combination of the structure and material will reduce or eliminate the risk of material residues left in the wound and therefore avoid a lot of disadvantages.

The pressure-distributing elements of this invention will only be relatively slightly compressed or contracted when negative pressure is applied that is during the in-use condition. This means that the elements are able to almost maintain the porosity, flexibility or conformability while at the same time maintain the softness of the elements. The maintained porosity counteracts clotting of the elements and hence a pressure difference across the element. This is to be avoided as this may result in an unknown negative pressure for the treatment. Furthermore, as the flexibility and the hardness of the material components are (at least almost) maintained in the in-use condition, pressure necrosis and discomfort for the patient are reduced.

If the exudate stays in the wound for long time, the risk of maceration and infection in the wound increases. For chronic wounds there is another risk factor due to the fact that MMP's (Matrix Metallo proteases) then may inhibit optimal wound healing. When the number of MMP's gets too high, as they may in chronic wounds, the MMP will have a tendency to decompose the essential growth factors.

Usually, elements having a high porosity are used so as to be able to remove the exudate from the wound cavity. When using open-celled foam elements, the porosity will need to be rather high due to comfort reasons. If the porosity gets too low, a foam element would be rather hard and uncomfortable to wear.

However, a high porosity delays transportation of exudate from the wound bed and away, in that sense that the porosity can be considered a delay volume. If a cavity ulcer has a volume of 100ml at e.g. 150mmHg negative pressure and is filled with open-celled foam, the porosity of 80% means that the delay volume is 80ml. An exudation of e.g. 20ml per hour will lead to a time for the exudate to actually leave the cavity of 4 hours. If, on the other hand, the porosity is lower e.g. 40%, the delay volume is just 40ml and the time for exudate to leave the cavity is just 2 hours. In other words, delay volume of the wound dressing or pressure-distributing element is defined as volume fraction where exudate can flow. Due to this, a high porosity during negative pressure wound therapy is undesirable.

A non-absorbing material is a material having a substantially closed surface so that wound exudates will be able to travel through the structure without “entering” into the material as such. In other words the material as such does not expand upon wetting and a part of the material would not gain weight upon wetting with a physiological 0,9% saline solution.

As appropriate materials both thermosetting and thermo-elastic polymers may be used. Styrenic polymers like SEBS, SBS and SIS based polymers, EVA, urethanes and silicones are possible materials for use.

The hardness of the solid material for the present invention is between 5 ShoreA and 60 ShoreA, preferable between 5 ShoreA and 40 ShoreA, more preferred between 10 ShoreA and 30 ShoreA.

The size of the pressure-distributing element is preferably between 2 x 2 cm and 30 x 60 cm, while the thickness of the element depends on the number of layers and may preferably be anywhere between 2 mm’s and 50 mm’s.

The inscribed circle of the cross-section of the material components is defined as diameter of the inscribed circle of the cross-section of the material components. The inscribed circle is defined as the circle having a centre at the centre of the cross-section of the material component and where the periphery of the circle lies within the cross-section through the entire periphery. Thus if the cross-section of the material components defines a quadrangle then the diameter of the inscribed circle corresponds to the length of an edge of the quadrangle.

The circumcircle of the cross-section of the pathways is defined as the diameter of the circumcircle of the cross-section. The circumcircle is defined as the circle having a centre at the centre of the cross-section of the pathway and where the periphery of the circle touches the point of the cross-section farthest from the centre. Thus if the cross-section of the pathways defines a quadrangle then the diameter of the circumcircle of the cross-section corresponds to the diagonal of the quadrangle.

In an embodiment the internal air-volume in the unloaded condition is between 5 and 70%. In related embodiments the air-volume may have other values such as 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60% or 65%. Preferred intervals may be 30%-70% or 50%-70%. By unloaded condition is meant a condition in which, the structure is not subjected to any kind of pressure or load. E.g. the condition corresponds to the structure lying on the table under normal atmospheric condition and without being touched by anything.

The in-use condition is a condition, where the structure is subjected to negative pressure. Usually negative pressure values between 50 - 200 mm Hg are used. In this condition the mesh structure will have an internal air-volume of between 5 % and 65 %. This means that elements having a low internal air-volume in the unloaded condition (e.g. 5-10%) would not alter the internal air-volume significantly during negative pressure therapy, while elements having a higher internal air-volume may have the internal air-volume more significantly reduced - e.g. by 5-20 % of the overall internal air-volume.

In an embodiment the pressure-distributing element further comprises an outer layer having a shore A value of between 0-5 shore A, such as 1 shore A, 2, 3 or 4 shore A. A soft outer layer provides an enhanced comfort for the user as it provides softness towards the wound surface. Furthermore, the pressure-distributing element still retains its structure, as only the outermost layer will have the very low shore-value. So even though the outermost layer may partly collapse during influence of negative pressure the pressure-distributing element as such will retain its pathways through the structure.

An embodiment relates to the pressure-distributing element being a 3-dimensional lattice structure, which is defined as a structure having material components connected or bonded to each other in 3 dimensions.

In one embodiment it may constitute an open framework, which is overlapped or overlaid in a regular, usually crisscross pattern in at least 3 directions. Another way of describing this structure is as a 3-dimensional mesh-structure.

Another embodiment relates to the lattice-structure having interconnected ring-elements constituting the material components and where holes in the ring-elements or gaps between ring-elements in consecutive layers are at least partly overlapping each other.

The lattice structure may also be defined as beads physically bound together at their surfaces, thereby forming one integral element having gaps in the element. In this embodiment the beads constitute the material components.

A 3-dimensional lattice structure will provide pathways for wound exudates in at least 3 directions through the structure, so as to make it easier for the exudates to be removed from the wound and to prevent confinement of exudates within the wound cavity. Such a structure will also provide a flexible element, which will not entirely collapse during influence of negative pressure, and at the same time it provides for transport of exudate through the element.

According to an embodiment of the invention the framework structure comprises strands as material components. The strands may have circular or quadrangular cross-sections but all shapes may be used, e.g. angular with any number of sides such as 3 or 6 or the cross-section may be ellipsoid. A related embodiment concerns a layer of the structure comprising substantially straight strands that is, the strands form substantially straight lines. A further embodiment has strands oriented in the same direction within a layer. Other layers of the structure may then have strands oriented in an oblique direction compared to each other. Particular two layers next to each other may have strands obliquely oriented compared to each other. This will provide for strands in one layer being bonded to a high number of strands in the other layer. As a consequence, it will provide for a stable structure even if the wound packing should be crumpled during packing.

Another possibility is that at least one layer has strands laid out in a wavy configuration. A structure like this will have manufacturing advantages, as it is possible to extrude them in an undulating manner. Preferably the waves or undulations have amplitudes such that each strand is connected to at least two upper or lower strands.

The strands may be solid, hollow, or partially hollow. By partially hollow is meant they may be alternating with a hollow part, solid part and so on – e.g. 10 mm hollow part, followed by 3 mm solid part followed by 10 mm hollow part etc.. Each of the type of strands may also be filled with air bubbles. This means that a strand may be hollow and filled with air bubbles in the parts surrounding the through going hole, a strand may be solid and filled with air bubbles or a strand may be partially hollow and filled with air bubbles in the solid parts. For thick strands (having the smallest dimension of more than 2 mm) a hollow, partially hollow or air bubble filled structure will help provide the necessary flexibility in the structure and further it would reduce consumption of the material. However, the necessary flexibility of thick strands may also be obtained using solid strands by adjusting the materials characteristic. Typical values for the hardness of the solid strands are 5-30 Shore A.

In an embodiment the strands may be having a rather stiff core and a softer sheath. The stiff or hard core may have a Shore-value of about 15-30 Shore A whereas the softer sheath may have a Shore-value of about 0-10 Shore A. A pressure-distributing element comprising such strands will have the necessary strength due to the stiffer core but at the same time the comfortable touch due to the softer sheath. Such strands may be made by co-extruding.

In another embodiment at least some of the layers comprise strands oriented in the same direction within each layer and where consecutive layers have obliquely oriented strands.

The lattice structure may also include pillars or columns perpendicular to the layered configuration. Such a structure may be injection moulded in multiple layers. A structure comprising pillars or columns may also include strands, pillars or columns having a rather stiff core and a softer sheath thereby achieving the strength as well as the comfortable touch. The Shore-values may be 15-30 Shore A for the stiffer core and 0-10 Shore A for the softer sheath. Such a structure may be insert moulded or 2-component moulded.

The distance between two bonds of the framework structure is defined as the distance between the bonds of two parallel strands to the subsequent layer. This distance is preferably between 0,5 mm and 10 mm depending on the dimensions of the elements in the structure. The distance between two bonds may depend on the structure. For thin strands (0,5-3 mm), the distance between two bonds of the lattice structure is preferably between 0,5-7 mm. For thicker strands the bonding distance is preferably between 1,5 and 10 mm.

The lattice structure may also comprise interconnected ring-elements as material components. The ring-elements are defined as planar elements of a thickness between 0,5 mm's and 5 mm's and where the elements have a hole in the middle defined by the inner periphery of the element. These ring-elements may be connected to each other at outer peripheral points such that gaps are formed between the elements. The ring elements may be rounded such as circular or oval, e.g. ellipsoid, but they may also be angular with any number of sides. When the ring-elements are angular the elements may be connected to adjacent elements along an entire rim of the elements such that no gaps are formed between the elements. In a related embodiment the elements may share the rim or side of the element with adjacent elements such as in the well-known honeycomb pattern. If layers above or below also consist of interconnected ring-elements the layers are preferably displaced in directions parallel to the plane of the layer such that holes of the ring-elements or gaps between the ring-elements are at least partly overlapping each other in consecutive layers. The width of the rim of the element is defined as the shortest distance between the outer and inner periphery of the element. Preferably the width is 1-5 mm's, such as 2, 3 or 4 mm's. The size of the holes of the rings is defined as the shortest distance between two inner peripheral points placed farthest from each other. The size of the holes of the rings is preferably between 1 and 10 mm's, such as 2, 3, 4, 5, 6, 7, 8 or 9 mm's. The ring elements may be made of solid material or they may be made of material comprising air bubbles. When using ring-elements the wound exudates is prevented from travelling from one part of the wound to another as it only has limited possibility of transverse movement within a layer due to the closed ring-elements. Therefore, the exudates will mostly travel upwards through the element, away from the wound bed towards the source of suction. This provides for easy removal of the exudate. Furthermore, using ring-elements directly on the wound surface or the skin may reduce pressure marks occurring from the pressure-distributing element.

In an embodiment the pressure-distributing element comprises a plurality of beads, where the individual beads are substantially stable during negative pressure, which beads are physically bound together at their surfaces, thereby forming one integral element having gaps/passages in the element. In this embodiment the beads constitute the material components.

The individual beads need to be stable during negative pressure at in-use condition so that even though they may be slightly compressible they will almost maintain their original shape. This will help maintaining a high degree of the original porosity of the pressure-distributing element during the negative pressure therapy and thereby prevent the pathways through the element from being blocked. The original porosity corresponds to the porosity in an unloaded condition. Typically the beads have hardness with Shore-values between 5 Shore A and 60 Shore A. Another way of expressing that the beads are physically bound together is that the pressure-distributing element comprises compound beads. By compound beads is meant beads connected to each other by sintering, gluing or other ways so as to make the beads firmly connected to each other yet able to be separated by the care-giver by tearing by hands. This makes the pressure-distributing element easy to adapt to size. Furthermore, the beads will create concave gaps between them for the exudate, which means that the exudate will be able to be removed from the pressure-distributing element even when the element has a relatively low porosity.

In an embodiment the beads are bound together in spots. Perfect spheres being put together will only touch each other in a single point. However, the beads of this invention may not be entirely perfect spheres and furthermore they may be deformed slightly during production of the element. This means that the spots referred to in this application may have a slight dispersal.

The distribution of the beads in the element may be randomized, but may also be at least partly organized in one or two directions. In an embodiment they may be organized. Beads can be melted together as a mono-layers, bi-layers or multi-layers. The orientation of the beads in the pressure-distributing element may be body centered cubic, close packed hexagonal or which ever is optimal for different sizes and shapes of wound cavities. The orientation of the beads will depend upon how the element is made. In one extreme the beads are simply poured into a mould defining the pressure-distributing element and then the orientation of the beads will be completely randomized. In another extreme the beads are controlled as they are laid in a mould, for example such that they define a layered structure. The orientation may be structured in aligned rows giving a cubic orientation or in displaced rows giving a hexagonal orientation. Typically the structure will be irregular to some extent.

The beads may be rounded and may be absolutely spherical i.e. the dimensions in the X-, Y-, and Z-plane are identical. If one dimension is too predominant, the structure will not be optimal. When defining the X-plane as direction of longest dimension, Y-plane as direction of intermediate dimension and Z-plane as direction of the smallest dimension, it is preferred that the ratio of X to Z dimensions is less than 5:1, preferably 3:1, preferably 3:2. However, the shape of beads according to this invention is not limited to regular shapes and the shape and surface of the beads may be irregular. The important aspect is that there are gaps between the individual beads enabling wound exudate to pass through the element.

The size of beads in the X-direction is preferably 0,5-10 mm, e.g. 1-5 mm or 2-3 mm. The relatively large size of the beads prevents ingrowth, as wound tissue will not be able to overgrow the beads when the pressure-distributing element is used for the usually 1-7 days. The relatively large size is also advantageous in case of any residues left in the wound cavity in form of beads. They will be easy to detect in the wound as they can be seen with the naked eye. The advantage of smaller beads is that the structure would then be more difficult to adapt to size. Furthermore too large beads may lead to pressure marks in the wound cavity.

The individual beads may be weight-reduced so as to reduce the weight and material consumption of the element. One way of achieving the weight reduction is to make the beads hollow. In a related embodiment the beads contain substantially disconnected air bubbles. The air bubbles may be a result of foaming agents (e.g. Expancel ® spheres) being added to the beads during production of the beads. Typically, the process will take place on an extruder, where the beads are mixed with filler at melting temperature and at elevated pressure so the Expancel ® does not release its gas out of the polymer material. When the material is extruded and chopped into beads, the Expancel ® will make the beads expand and thus decrease density. By this way, the material consumption can be reduced. Alternatively the beads may be protruded with soluble Nitrogen introduced to the polymer during processing at a very high pressure e.g. 1000atm. When pressure drops, the Nitrogen will undergo phase transition into vapor, thus leaving holes in the material and thereby decreasing the density of the material.

Furthermore the individual beads may be made from two different materials – a core material providing the beads with the necessary hardness and resistance to the negative pressure and a sheath material or surface covering material providing the ability to being bonded to neighboring beads, e.g. by sintering or chemically bonding. The sheath material may have a relatively low shore A value of e.g. 0-10 shore A.

In an embodiment the element comprises a 3-dimensional layered structure, with at least two layers bonded together, where the structure comprises at least one layer of a non-planar sheet material having holes perpendicular to the layer. In this embodiment the sheets constitute the material components.

The thickness of the sheet is in this case defined as the smallest dimension of the material and the diameter of the holes of the sheets may in this case be 0,5 mm’s to 10 mm’s. Like with the other types of elements, the sheets may also be made of either solid material or material comprising air bubbles.

In an embodiment the sheet may comprise strands connected along their length or at least partly connected along their length. The holes perpendicular to the layer may in this embodiment be placed along the connecting line or may be placed in the strands.

In further embodiments the sheets may be corrugated. There are several ways of making the corrugation of the sheets. The cross-section may be softly curved, it may be pointedly curved (zigzagged) or it may be trapezoidal. The sheets may also be provided with tops or bumps making a bumpy sheet. The sheet may be provided with undulations in one or two directions. If two subsequent layers comprise sheets having a corrugated surface, the directions of the corrugations in the layers may be oriented in an oblique angle. The corrugations may have amplitudes from the lowest point to the highest point of between 1 and 10 mm's. The sheets may also be hollow or partially hollow or they may be provided with grooves or slots of a size of between 0,5 mm's and 5 mm's. The length of the grooves or slots may correspond to the length of the sheet but interrupted grooves or slots may also be provided such as e.g. 1 cm groove, 1 cm without groove, 2 cm grooves, 2 cm without grooves and so forth.

Like with the strands and beads, the sheets may comprise a stiffer core and softer sheath thereby providing an element with the necessary strength but a soft, comfortable touch. The same Shore-values as for the strands may be used that is 15-30 Shore A for the core and 0-10 Shore A for the softer sheath. Such sheets may be co-extruded or 2-component moulded.

For the layered 3-dimensional structure of corrugated sheets, the bonds occur between valleys in one layer and the tops in a subsequent layer. The distance between bonds is defined as the distance between two parallel valleys, where they are bonded to the tops of the next layer. The distance between two bonds may in this case be between 1,5 and 10 mm's.

A sheet construction may be easily produced e.g. by extrusion or injection moulding using relatively simple tools. The holes may then be made during the extrusion or moulding or in a separate process afterwards by punching or use of cylinder rolls having spikes distributed over the surface of the rolls.

Yet another embodiment relates to the pressure-distributing element being in the form of an element having channels comprising cavities and walls, where the channels have an axial direction and perforations in at least one direction defining an angle to the axial direction of the channels. The walls of such an element may be considered the material component of the pressure-distributing element.

This structure provides the element with channels for exudate in at least two directions that is the axial direction of the channels and the direction of the perforations.

The element may be manufactured by extruding the element with channels having the desired cross-section so that the extrusion head defines the cavities and the walls of the channels. That way the walls are defined corresponding to the holes in the extrusion head and the cavities as the areas between. Following the extrusion process the element is perforated by perforation techniques well known in the art, e.g. by punching, piercing, water cutting, laser cutting or by penetrating the structure by a heated mandrel. The only limitation is that the disintegration of the 3-dimensional structure should be avoided. The perforations are preferably circular but other shapes, such as angular or oval are also possible. The size of the perforations is preferable 1-5 mm in the largest dimension of the cross-section. The element may also be injection molded.

When the element is placed on a flat surface having the channels extending parallel to that surface, then the top of the element may be defined as the side of the element facing upwards and being predominantly parallel to the surface upon which the element is placed. The bottom of the element is correspondingly defined as the side of the element facing downwards and predominantly touching the surface (e.g. the wound surface) upon which the element is placed.

In an embodiment of the invention the direction of the perforations are perpendicular to the axial direction of the channels. When the perforations are perpendicular to the axial direction of the channels, two well-defined directions of the channels for the exudate across the structure are achieved. This may be advantageous when the element is to be used in connection with shallow wounds, as suction in only one direction is needed. For this use the through going extruded channels is mainly used to provide the element with the necessary flexibility. Furthermore the pressure-distributing element according to this aspect of the invention may prevent maceration of the healthy (but maybe thin and vulnerable) skin surrounding the wound due to the element not leading the wound exudate to the surrounding skin hence keeping the healthy skin substantially dry during therapy. Another way of using an element having two distinct channel directions is to roll the element at least partly into a cylindrical roll or at least a curved shape and then place it vertically into the wound with the perforations facing the sides of the wound and the channels facing the bottom of the wound. This way suction at all sides is achieved even if the element itself is only able to provide suction in 2 directions. Finally, an element according to this embodiment of the invention may have manufacturing advantages as an element like this is easy to control during manufacturing due to the stability at least in directions parallel to the channels.

In another preferred embodiment, the direction of the perforations has projections in planes perpendicular to the axial direction as well as in planes parallel to the axial direction meaning that the direction of the perforations is oblique when compared to the axial direction of the channels. This will provide the finished pressure-distributing element with transport for the exudate in 3 directions, while perforating only in one direction.

The perforations may also be provided in at least two directions. If the element is perforated in more than one direction then it is ensured that the final pressure-distributing element will have exudate transport in 3 directions. This will ensure a prime removal of exudate from the wound cavity and prevent enclosure of exudate anywhere in the cavity. The element may be perforated in more than 2 directions; it may be perforated diffusely in any number of directions so as to obtain a diffuse channel structure in the element.

The cross-section of the channels is defined as the cross-section of a channel transversely of the axial direction of the channel. The cross-section of the element (the pressure-distributing element) is likewise defined as the cross-section transversely of the axial direction of the channel.

The cross-section of the cavities of the extruded channels may have any shape. The cross-section may be rounded (e.g. circular, ellipsoid or oval) or angular having any number of sides, e.g. triangular, quadrangular or hexagonal. Compared to rounded cross-sections, hexagonal shaped channels may be preferred as they have the least tendency to accumulate material in the areas between the individual channels. At the same time hexagonal channels are more stable to compression than square or triangular channels due to the obtuse angles in all corners providing a good distribution of the applied pressure. If the shape of the individual channels are triangular the channels may be placed in rows where one row has a pointed end towards the top and the adjacent rows has the pointed ends towards the bottom and placed between two triangles of an adjacent row. This will help prevent accumulation of material in the intervening spaces between the individual triangular channels so as to keep the material consumption as low as possible. Quadrangular shaped channels may be placed so the sides of the quadrate are parallel to the top and bottom of the element. Particularly in that case the element is advantageously perforated in angles oblique to the direction of the channels. By perforating in oblique directions an element having channels for exudate in 3 directions is achieved. Quadrangular channels may also be placed so the cross section of the element illustrates a Harlequin shaped pattern that is the channels are placed with the corners pointing towards the top and bottom of the pressure-distributing element. Furthermore quadrangular shaped channels may be placed in a displaced Harlequin pattern that is every other row of quadrangular shaped channels are displaced compared to the adjacent rows. The displacement may be adjusted for obtaining the desired flexibility or compressibility. Oval shaped channels in the cross-sections provide for channels, which may be more difficult to deform than channels having other shapes. The cross-section may also have a clover-shape, e.g. shaped like a four-leaf clover, which may be advantageous in enhancing the capillary effect when removing the negative pressure. This is due to the exudate being “captured” in the individual leaves of the clover.

The size of the cross-section of the channels is defined by the radius of a circle having a center corresponding to the center of the cross-sectional view of the channel. The periphery of the circle touches the point of the cross-sectional view having the largest distance to center of the circle. That is the circle corresponds to the circumcircle of the cross-section. The diameter of the circumcircle of the cross-section is preferably between 0,5-10 mm, more preferably between 1-5 mm. In most cases the size of the cross-section of all the channels in the pressure-distributing element would be equal, however, it may be beneficial to have different sizes of the cross-sections of the channels in order to optimize the flow of wound exudate, compressibility, flexibility or reduce the ingrowths.

An embodiment of the invention concerns a pressure-distributing element, which has a surface, defined by border walls extending in the axial direction and which are surrounding the channels. By providing the element with border walls a more stable element is obtained hence the element is easier to handle during the perforation process. By providing an element with border walls and perforating the element from one side only e.g. from the top to the bottom, then the element will only have channels to 4 of the sides – e.g. the two sides between which the extruded channels extend and the two sides connected by the perforations. This may be advantageous in use with shallow wounds, as it may help prevent maceration of the healthy skin surrounding the wound.

The gaps of the perforations are defined as the point where the perforation communicates with the wound bed that is the inlet to the perforation. The distance between the gap of a perforation and the gap of the perforation adjacent to it should be approximately 1mm or more.

An embodiment of the invention relates to the surface of the element being deformed between the gaps of the perforations. Particularly if the element is provided with border walls at the surfaces, a pressure-distributing element according to the invention may have a smooth or plain surface without any bumps, indentations or other kinds of irregularities. If the surface of the element is smooth, the exudate, which is between gaps, may move along the surface to a gap nearby and then it will travel along the perforations to the top of the element from where it will be removed by suction. It may be able to move along the smooth surface as the wound bed has indentations and bumps, which will provide the necessary pathways for the exudate. Hot stamping, channeling or calendaring can provide a deformed surface having bumps or indentations. The only limitation is that compression of the element should be avoided so as to avoid closing of the extruded channels. A bumpy surface will ensure that the element touches the wound bed only in points corresponding to the top of the bumps. Then the exudate will be able to travel between the points and subsequently through a gap into a perforation. More preferred the bumps and indentations are provided such that the surface of the element is raised between the gaps and has indentations surrounding the gaps. This embodiment ensures that all of the gaps are placed at low points of the surface thereby providing the prime access to the perforations. Furthermore it ensures that all of the gaps are useful for removal of exudate, as none of them will be placed in the contact points between the element and the wound bed.

A preferred embodiment of the invention concerns channels having a Harlequin-shaped pattern in the cross section of the channels and where the channels have no border walls. The perforations are made in directions defining an angle to the lines of the Harlequin-shaped pattern. Such an element can be made using only few manufacturing steps and an element having an uneven surface; exudate transport in 3 directions and flexibility in the cross section is achieved.

Preferably the thickness of the walls in the extruded channels is between 0,25 mm and 5 mm, more preferred between 0,5 mm and 2 mm and most preferred approx. 1 mm. A wall thickness of approximately 1 mm ensures a good balance between desire to keep the material consumption as low as possible and at the same time it definitely assures a stable pressure-distributing element, which will not easily collapse in the in-use condition.

An extruded element may be made of the materials mentioned earlier and may have a foaming agent added to the material.

In an embodiment the pressure-distributing element is stratified or layered.

If the element consists of a mesh-structure the strands in the mesh may be laid out in a layered structure. That is the structure consists of several generally planar layers, which are placed one on top of each other. In other words the stratified mesh-structure constitutes a layered structure with easily distinguishable layers.

If the pressure-distributing element consists of a structure comprising beads then the beads may be laid out in a layered structure. In such a structure a layer will typically correspond to the height of a bead, where the height of a bead is defined as the dimension, e.g. the diameter, of the bead in the layered direction.

If the pressure-distributing element consists of a structure comprising an extruded element then the structure may comprise layers having the same structure but made of different materials or the structure may comprise layers made of the same material but having different materials characteristics. One example may be a product where either the bottom layer or both top and bottom layer is made of silicone and the middle layers are made of thermo plastic elastomer. This will utilize the ability of silicone to provide an improved non-stick effect to the wound surface or the skin. Another example may be a product where either the bottom layer or both top and bottom layer is made of a very soft elastomer with e.g. a hardness of 0 shore A and the middle layers of an elastomer with a hardness of e.g. 20 shore A. The soft layer in contact with the wound will provide less pressure on the wound surface and conform better to the wound bed, and the less soft material in the middle will give the product more strength and reduce the risk of collapse when negative pressure is applied.

The element may also comprise several extruded layers on top of each other, where one layer comprise channels having one cross-section and the adjacent layer may comprise channels having another cross-section. Furthermore an element may comprise several extruded layers in a side-by-side relationship and again one layer may have one cross-section and other layers may have other cross-sections. The layers will at least partly be attached together at their surfaces in the axial direction of the channels either in the top-bottom direction or in the side-by-side direction. The attachment may occur as a result of the extruded sections being partly melted at their surfaces as they exit the extruder and two or more sections are immediately brought into contact with each other. Hence the surfaces of two neighboring sections will partly melt together and this way forming one element.

Parts of the pressure-distributing elements e.g. beads, sheets, strands, ring-elements and/or extruded elements may also be provided in a disorganized manner. E.g. the strands may be provided in an entangled manner having ring-elements bonded in between and having extruded elements at the sides to provide stability. Furthermore, beads may be used in a disorganized manner if the element is considered to be too porous in structure.

If the layers form channels in especially one direction, it is preferred that these channels are arranged in an oblique angle compared to or even perpendicular to the direction of channels of consecutive layers in the construction. This will provide the structure with pathways allowing the wound exudates to pass through the structure.

The 3-dimensional structure may be made of layers of the same kind or several types of layers of material components may be provided in a structure. For example, the first layer may be made of strands, the second of a sheet-material and the third of interconnected ring elements. Another example is that the structure may be made of several layers of strands or sheets bonded together, which will make it easier to apply it in a cavity wound compared to a system consisting of many single layers that will be more difficult to handle e.g. cut to the appropriate size, packing of the wound and risk of residues left in wound. Furthermore the structure may be made in a sandwich way with a combination of different materials or different structures in the layers. This may improve physical properties such as e.g. strength, elasticity, softness, reduced risk of collapse, improved exudates transportation and visual appearance. It may also improve clinical properties such as reduction or elimination of ingrowths as well as low cohesion between wound and pressure distributing element.

Elements having strands in the layer touching the wound may have a particularly beneficiary contact with the wound bed, as the strands during the influence of negative pressure will attain a more oval configuration when compared to the unloaded condition. This means that in the in-use condition the strands will be slightly compressed such that e.g. strands having a circular cross-section will have a more ellipsoid cross-section under influence of negative pressure. During the therapy the wound tissue from the wound bed will grow slightly into the gaps between the strands. When the negative pressure is removed the strands will return to their usual configuration thereby releasing the wound tissue from the gasp between the strands. The strands are then left touching the wound bed only along the lengths of each strand.

Due to this behaviour of strands during therapy it may be advantages to combine strands with elements having cavities and walls (the extruded elements) and/or sheet-elements.

The 3-dimensional structure may also comprise layers having the same structure but made of different materials or the structure may comprise layers made of the same material but having different materials characteristics. One example may be a product where either the bottom layer or both top and bottom layer are made of silicone and the middle layers are made of thermo plastic elastomer. This will utilise the ability of silicone to provide an improved non-stick effect to the wound surface or the skin. Another example may be a product where either the bottom layer or both top and bottom layer are made of a very soft elastomer with e.g. a hardness of 0 shore A and the middle layers of an elastomer with a hardness of e.g. 20 shore A. The soft layer in contact with the wound will provide less pressure on the wound surface and conform better to the wound bed, and the less soft material in the middle will give the product more strength and reduce the risk of collapse when negative pressure is applied.

Combinations of sheets and elements having cavities and walls may also be provided. Like with other combinations the sheets may then be made by one material and the channelled elements may be made by another material.

As mentioned earlier ring-elements may be softer and more flexible against the wound-surface. Therefore combinations comprising ring-elements and elements having cavities and walls (extruded elements) and/or sheet material may be favourable.

Thin elements e.g. made of sheets, ring-elements or the elements having channels with cavities and walls may also be used in cavity wounds. This may then be done by rolling the element and placing it on the side in the cavity wound such that the side of the element usually facing upwards will face the side of the wound and a side of the element will touch the wound bed. Several elements may be inserted like this vertically in the cavity wound.

The pressure-distributing element may also comprise a central part having a 3-dimensional structure with diffuse channels as described above, which structure is surrounded by a border part having pathways only in the vertical direction. This may help prevent maceration of the vulnerable skin surrounding the wound, as the exudate will not be able to permeate through the structure to the border of the wound. Such a border part may function as a barrier for the exudate.

The 3-dimensional structure may comprise strands, sheets, ring-elements or beads, which are bonded together, each of these constituting material components of the structure. In some combinations even extruded elements may be bonded to other parts. In this context bonding includes bonding as occurs between two layers of material, which are extruded one layer on top of the other. Bonding also includes the connection points occurring in an injection-moulded structure, which is moulded of the same material. Furthermore, bonding includes welding of layers together so as they are permanently attached to each other. Finally, bonding includes gluing of layers using non-separable glue.

Bonding may also be the bonding occurring as the physically bonding between beads. The beads may be bound together by sintering the surfaces together using heat or welding using ultrasound. The temperature should not be too high as the beads then may completely disintegrate and the element no longer consists of well-defined elements. On the other hand the temperature should be high enough to make the surfaces melt slightly so as to attach the beads together. The processing temperature should be so that the surface of the beads is able to flow into adjacent surfaces of other beads.

One condition for this is that the melting temperature or the glass transition temperature (Tg.) is exceeded. For SEBS e.g. where Tg. of the styrenic domains is approximately 95°C, there will not be any flow at temperatures just above the temperature that will be relevant for short production times. Processing should be well above 95°C and recommended extrusion temperature for SEBS Dryflex(R) temperature is 150-210° C. The reason for that is that the Styrenic domains not are miscible with the Ethylene-Butadiene of the block copolymer.

At lower temperatures e.g. at storage, where temperature is ambient or higher, there is also seen some binding of the individual beads. This is presumed to be due to long time flow caused by the Ethylen butadiene mid-block of the polymer. High content of plasticizing oils may also be causing some binding of the beads.

By sintering the beads together, the porosity of the structure is essentially retained and beads are melted together by their surfaces so the can be handled as one units and still be tear-able by hand.

The bonding of the beads may also be done using chemical reaction by using a binder for the attaching the beads together. Preferred binders are urethane-, epoxy-, vinyl-, anhydride-based binders.

The force needed to tear the element comprising beads apart is preferably between 5N and 50N, such as 10N-40N, 10N-30N or 10N-20N. This may also be expressed using the work, which needs to be provided to tear the element apart. Values for the work are preferably between 0,10J and 2,5J. What is important is that the bonding forces are such that the beads are kept together as one unit but the individual beads can be broken off the structure. The elongation of break of the structure is very little due to the “bottle-neck” connection between the beads. This makes this kind of pressure-distributing element easy to tear apart by hand. The caregiver should be able to tear the element apart so as to size-adapt the element. On the other hand the element should not disintegrate neither during transport or appliance of the element nor during the negative pressure therapy. The force of these bonds also has to exceed the force of removal of the entire pressure distributing elements form the wound, which may wary, depending on the degree of ingrowth. According to present invention the neglible degree of ingrowth will result in low required force of the bonds.

In a use-situation several pressure-distributing elements may be used to constitute a wound-filling material. They may then be placed one on top of each other or adjacent each other.

In an embodiment the wound-filling material may also include several pressure-distributing elements, which are attached to each other in a non-bonding manner so the elements may be separated from each other. The attachment force may occur as simple cohesion between two or more injection moulded elements placed on top of each other. It may also occur as a separable adhesive applied to the elements. Other methods may also be used, e.g. mechanical attachment methods well known in the art. The attachment force should be balanced in such a way that the elements do not separate unintentionally when the wound-filling material is under negative pressure or during transport of the wound-filling material. On the other hand, the elements should be separable by a caregiver. A way of expressing this is that the delamination strength should be much less than the tearing strength of the element.

Another aspect of the invention relates to a negative pressure therapy system comprising a pump including a canister, a tube, a wound cover and a wound-contacting element in form of a pressure-distributing element as mentioned above. Such a system would provide a pressure therapy system with improved effects compared to other systems known and in use. The pressure-distributing element, which is a part of the system, provides an excellent removal of wound exudates as the negative pressure is applied. The ability to prevent collapse of the element is also particularly useful when negative pressure is applied.

A still further aspect concerns a method of treating a wound using negative pressure therapy, the method comprising

- adapting a wound packing material to fit the wound cavity or flat wound
- placing the adapted wound packing material in the wound cavity or at the wound surface
- covering the wound packing material and the wound with a cover film to form an enclosure
- connecting the enclosure to a pump via a tube
- applying negative pressure to the wound for a predetermined period

In one embodiment adapting of the wound packing material may be done by cutting. In another embodiment the adapting can be done by tearing the element apart. This is particularly true for an element comprising beads as the bonding between the beads are such that it may be manually torn apart. Another example is elements being attached either mechanically together or by simple cohesion between extruded elements.

The negative pressure may be applied in several periods during the treatment or it may be applied as a continuous low pressure for a longer period. The periods may be e.g 5 min under pressure followed by 2 min without pressure followed again by 5 min under pressure and so forth when using the alternating method. A typical period for treatment may be 7-30 days and the pressure-distributing element is typically changed every 1-3 days. During change there is no application of negative pressure.

Brief Description of the Drawing

Figure 1 illustrates an embodiment of a lattice structure made of perpendicular strands

Figure 2 illustrates a wavy configuration of the strands

Figure 3 illustrates a zigzag configuration of the strands

Figure 4 illustrates a 3-dimensional layered structure comprising sheets.

Figure 5 illustrates a corrugated sheet having soft corrugations

Figure 6 illustrates a corrugated sheet having pointed (zigzagged) corrugations

Figure 7 illustrates a sheet embodiment having strands connected along their length

Figure 8 illustrates a lattice structure constituted of ring elements.

Figure 9 shows a pressure-distributing element comprising beads according to the invention.

Figure 10 shows an outline of the distribution of exudate in an element like the foam element used for making comparative tests mentioned in Example 5 – Testing of Compression and Flow Resistance and Example 6 – Testing of Tearing Strength,

Figure 11 shows an outline of the distribution of exudate in an element comprising beads according to the invention,

Figure 12 shows an example of a hexagonal orientation of the beads,

Figure 13 shows an example of a cubic orientation of the beads,

Figure 14 shows an example of a randomized orientation of the beads,

Figure 15 shows the test set-up used for testing of flow resistance,

Figure 16 shows the test set-up used for testing of tearing strength of the element comprising beads.

Figures 17a and 17b illustrate side view and top view respectively of an embodiment of the invention prior to perforation, and figures 17c and 17d illustrate the same views after perforation,

Figures 18a and 18b illustrate side view and top view respectively of the embodiment of figures 17a and 17b provided with border walls, and prior to perforation, and figures 18c and 18d illustrate the same views after perforation,

Figures 19-22 illustrate other embodiments of the invention prior to and after perforations.

Figures 23-25 illustrate other embodiments of the channels,

Figure 26 illustrates a thin element placed on a shallow wound.

Detailed Description of the Drawing

Figure 1 illustrates an embodiment of a finished lattice structure **1** with 5 layers **2** bonded together and where each layer consists of parallel straight strands generally referred to as **3**. Any number of layers may be used. As shown in the figure, the orientation of the strands **3** is parallel to one of the sides of the finished structure **1**. However, the strands may also be at angle (e.g. 45 degrees) to the sides of the finished structure. In two subsequent layers **2** the strands are preferably substantially perpendicular to each other, but they may also be oriented at an oblique angle to each other. Wound exudate from the wound may permeate into the structure from the bottom or the sides through the gap **4** between two strands **5**. Exudates present at the bottom layer will travel along the gap **4** due to the negative pressure being applied to the top layer. When possible the exudates will enter the gap **6** between two strands **7** in the next layer and travel along this gap **7** until it is possible to enter the following layer. When the exudates reach the top layer, it will be removed by suction.

Figures 2 and 3 illustrate other embodiments of the lattice structure **11**, **21**. Only two layers **12**, **22** are illustrated, (the lighter one on top of the black) however, more layers may be used. In this embodiment the strands **13**, **23** are gently curved (figure 2) or more pointed zigzagged (figure 3) such that each strand **13**, **23** are bonded to at least two overlying or underlying strands **14**, **24**. The figures illustrate all strands in a layer to be parallel. However, other configurations are also possible such as some of the strands may be displaced in the lengthwise direction or some of them may be mirrored compared to the others. Like mentioned in connection with the embodiment shown in figure 1, wound exudates from the wound will most likely permeate into the structure from the bottom or from the sides. When present in the structure it will travel along the strands and through the gaps **15** between the strands in each of the layers. Finally, it will be removed from the structure **11**, **21** by suction.

Figure 4 illustrates an embodiment of the 3-dimensional structure **41**. In this embodiment the layers **42** consist of corrugated sheets. The sheets are placed on top of each other and bonded together such that a valley **43** of one layer are bonded to a top **44** of the subsequent layer. The embodiment illustrates 3 layers **42** however any number of layers may be used. Figures 5-6 illustrate embodiments of the sheets of the 3-dimensional structure **51**, **61** where each layer consists of a corrugated sheet **52**, **62**. Only one layer is illustrated, however at least two layers are used to make the 3-dimensional structure. The sheets are bonded to the sheet below at valleys **53**, **63** of the corrugation and to the sheet above at tops **54**, **64** . In a direction substantially perpendicular to each layer, the sheets **52**, **62** are provided with holes. Wound exudates permeating into the structure **51**, **61**will enter at a valley **53**, **63**. It will travel along this valley and enter the next layer upwards through one of the holes **55**, **65**. From the top layer it will be removed from the structure **51**, **61** by suction.

Figure 7 illustrates a further embodiment of the sheet material **71**. Only one layer is illustrated however any number of layers may be used. If several layers are used, two subsequent layers are preferably oriented at an oblique angle to each other. In this embodiment the strands **73** are bonded together lengthwise in each layer. Furthermore, in the figure the strands are hollow as shown at **74**. However, the strands may also be semi-hollow or solid. In a direction substantially perpendicular to each layer, the structure is provided with holes **75**, preferably placed in the connection between two strands. Wound exudates will enter this structure at the valleys formed by the connection between the strands. When entered into a valley it will travel along this and enter the next layer through one of the holes **75**. As it reaches the top layer, it will be removed by suction.

Figure 8 illustrates an embodiment of the lattice structure **81** where each layer **82** consists of interconnected ring elements **83** having holes in the middle **84**. The ring elements **83** are connected to each other at peripheral points so that gaps **85** are formed between the ring elements. A layer **82** is displaced compared to the layer above and below. The displacement is such that each hole **84** or gap **85** in a layer is in contact with a hole **84** or gap **85** in the layer above or below. In the figure the ring elements **83** are illustrated as circular rings. Other embodiments of the ring elements are possible, such as angular with any number of sides, ellipsoids, honeycombs etc. The only limitation is that the elements must form holes within each element or gaps between them (or both) and that these holes or gaps must be in contact in two consecutive layers. Wound exudates entering into the structure will be caught in a hole or gap in the layer but will be able to permeate to the next layer as there is a hole or gap in this layer in contact with the exudates. In this way, exudates will be able to pass through the structure from the bottom or side to the top layer from which, it will be removed by suction.

Figure 9 illustrates an embodiment of the invention where the pressure-distributing element **90** consists of substantially spherical beads **91** bonded together in a randomized structure.

Figure 10 illustrates the distribution of exudate **93** in a segment **94** of an element having convex pores **95**, e.g. foam. The figure only illustrates a 2-dimensional outline of the exudate in a foam element.

Figure 11 illustrates the distribution of exudate **96** in a segment **97** of an element according to the invention and where the element has concave gaps **98**. The figure illustrates how the exudate is distributed differently in an element according to the invention and in an element having convex pores.

Figures 12 -14 illustrate segments of embodiments **120**, **130**, **140** in which the beads **121**, **131**, **141** are organized in three different ways. In figure 12 the beads have a hexagonal orientation, which is illustrated in the beads **121** clearly being oriented in displaced rows **122**. In figure 13 the beads have a cubic orientation illustrated as the beads **131** being oriented in aligned rows **132**. Figure 14 illustrates an embodiment **140** where the beads **141** are randomized.

Figure 15 illustrates the test set-up **150** used for testing flow resistance. A sample **151** is placed on a lower circular glass sinter **152a** in a cylindrical chamber **153** having a fixed circular plate **152b** near the top of the chamber. Attached to and through the lower glass plate **152a** is an inlet **156** for artificial exudate and a lower pressure sensor **159a**. Likewise the upper glass sinter **152b** has an outlet **157** and an upper pressure sensor **159b**. The artificial exudate is supplied and removed through tubes **158** in connection with a peristaltic pump **154** for supplying the exudate and negative pressure means **155** for providing the negative pressure to the sample **151**.

Figure 16 illustrates the test set-up **160** for testing tearing strength. Prior to testing the sample - indicated in torn condition at **161** and **162** - is in one piece. The set-up has two lower plates **163a** and **164a**, where one of them **163a** is fixed and the other **164a** is able to rotate around the higher attachment pin **165**. The set-up further comprises two upper plates **163b** and **164b**, which are clamped to the lower plates **163a**, **164a**. The attachment pin **165** carrying the plates are itself attached to a stand **166** having two feet **167**, **168**. A pulling pin **169** has one end attached to an end of the rotatable plates **164**. The other end of the pulling pin is attached to the test machine. The starting position is where the two sets of plates **163** and **164** are in parallel alignment. As the test machine is started the pulling pin is moved upwards as indicated by the arrows. This results in the plates **164** being pulled out of parallel alignment with the plates **163** as also indicated by the arrow. The end position is where the two sets of plates are displaced close to 90 degrees as shown in the figure.

Figure 17a illustrates a side view of an element during the manufacturing process that is, an element as it looks prior to the perforation process. The unfinished pressure-distributing element **170** comprises quadrangular channels **171** placed with the sides parallel to the top and bottom of the element. The channels comprise walls **172** and cavities **173** as illustrated in the figure. In the finished element the cross-section may of course comprise more channels in the x-direction as well as in the z-direction than illustrated in the figure, but for simplicity of the figure only three neighboring channels are illustrated. The axial direction of the channels corresponds to the y-direction, while the z-direction correspond to the top-bottom direction and the x-direction corresponds to the transverse direction. The direction should not be seen as a limitation on how the element is placed in the wound but only to be able to explain the configuration of the elements. When placed in the wound the element may be placed such that the axial direction of the channels (the y-direction) extends from the bottom of the wound to the top of wound, while the x- and z-directions extend transversely of the wound. The element may also be placed such that the x-y plane faces the bottom of the wound or it may be placed such that the y-z plane faces the bottom of the wound. In both cases the axial direction (the y-direction) extends transversely of the wound.

Figure 17b illustrates a top view of the same element prior to the perforation process. The longitudinal direction of the channels (in the y-direction) appears from this figure as the walls **172** stretch in the y-direction. The need for perforation also appears from this figure. If the channels were un-perforated (as they are shown in this figure) then the exudate will be able to travel only in the y-direction. Depending on how the pressure-distributing element is placed in the wound this means that the exudate would only be able to travel from one side to the other or from the bottom to the top.

Figure 17c illustrates a side view of a finished embodiment of the invention that is a pressure-distributing element **170** corresponding to that of figure 17a after the perforation process. As mentioned earlier the element has channels **171** provided with walls **172** and cavities **173**. Furthermore the element is provided with perforations **174**, which in this case extend in an angle α obliquely to the x- and z-direction and the cross-section of the walls **172**. The angle α is defined as the smallest angle between the direction of the perforations and the z-direction of the element.

Figure 17d illustrates the distribution of the perforations **174** across the surface of the element **170**. In the illustrated embodiment the perforations **174** are distributed evenly that is the centers of the holes constituted by the perforations are placed equally apart in the x- and y-directions. However, other distributions of perforations are also possible, ranging from the even distribution illustrated in this figure to a complete randomized distribution.

Figures 18a and 18b illustrates a side view and a top view of another element **180** during the manufacturing process. Like with figures 17a and 17b the element **180** is shown as it is after extruding but prior to the perforation process. This element **180** has channels **181** extending in the axial direction (= y-direction) and the channels have walls **182** and cavities **183**. The difference between the element **180** and the element **170** is that the element **180** has border walls **185** that is walls extending around the edge of the cross-section of the element when the cross section is transversely of the axial direction. An element as illustrated in these figures will have a larger structural stability than an element without border walls. This element should preferably be perforated either obliquely or in several directions to provide exudate transport through the element in all directions.

Figures 18c and 18d illustrates an embodiment of the invention corresponding to the element shown in figures 18a and 18b; only the finished embodiment of figures 18c and 18d is provided with perforations **184**. The same reference numbers are used for the same objects as in figures 18a, 18b. The perforations are stretching in an angle α obliquely to the x- and z-direction as it is explained in connection with figure 17c and 17d. When the element is perforated obliquely the exudate will be able to travel in all directions through the element.

Figures 19-22 illustrate different embodiments of the cross-section of the element where each element is illustrated prior to and following perforation. Figures 19a, 20a, 21a and 22a illustrate the elements prior to perforation and figures 19b, 20b, 21b and 22b illustrate the elements following perforation. Figure 19a illustrates an element **190** prior to perforation where the element has channels **191** in a Harlequin pattern that is each channel is quadrangular having the corners of the quadrangle extending towards the top of the element (in the z-direction). Furthermore a corner of a quadrangle in a row touches a corner of the quadrangle in the row immediate above or below it. The channels have walls **192** and cavities **193**. In figure 19b the same element is illustrated only this is the finished embodiment with perforations **194**. As the walls **195** of the channels extend in an angle with respect to the vertical z-direction this embodiment may be perforated vertically or horizontally – along the z- or x-direction. It may also be perforated in angles with respect to the z- and x-direction but perforations along the same angle as the walls of the channels should be avoided. Figures 20a and 20b illustrate elements very like the ones of figures 19a and 19b. The elements **200** have channels **201** with walls **202** and cavities **203**. In figure 19b the finished embodiment having perforations **204** is illustrated. The difference between the element **190** of figures 19a and 19b and the element **200** of figures 20a and 20b is that the element of figures 20a and 20b are provided with border walls **205**. Figures 21a and 21b illustrate an element **210** before and after perforation where the element has channels **211** with walls **212** and cavities **213**. The channels of the element constitute a displaced Harlequin pattern. This means that the channels of the element are quadrangular having the corners of the quadrangle extending towards the top of the element (in the z-direction). Furthermore a corner of a quadrangle in a row touches a midpoint of a side of the quadrangle in the row immediate above or below it. Figures 22a and 22b illustrate elements very like the ones of figures 21a and 21b. The elements **220** have channels **221** with walls **222** and cavities **223**. In figure 21b the finished embodiment having perforations **224** is illustrated. The difference between the element **210** of figures 21a and 21b and the element **220** of figures 22a and 22b is that the element of figures 22a and 22b are provided with border walls **225**. The embodiment illustrated in figure 22b does only provide for exudate transport in two directions corresponding to the y- and z-direction of the element. This is due to the border walls **225** at the sides of the element having no perforations through them as the perforations **224** are made vertically (along the z-direction). As earlier mentioned such an element may have advantages when used in connection with shallow wounds, see figure 26.

Figures 23-25 illustrate other embodiments **230**, **240**, **250** of the cross-section of the channels. The embodiments are all perforated prior to use but this is not illustrated in the figures. All embodiments have channels **231**, **241**, **251** with walls **232**, **242**, **252** and cavities **233**, **243**, **253**. Figure 23 illustrates an embodiment **230** where the channels **231** are ellipsoidal shaped. This embodiment further has border walls **235**, but as explained earlier they are optional. Figure 24 illustrates hexagonal shaped channels **241**. This embodiment is illustrated without the border walls, which may be provided. Figure 25 illustrates triangular channels **251** and border walls **255**. Again the border walls are optional.

Figure 26 illustrates a rather thin element **260** used on a shallow wound **267**. The shallow wound **267** has healthy skin **268** surrounding it. The thin element **260** has perforations **264** in one direction through the element. The advantage of this element on shallow wounds is illustrated as it is evident from the figure that exudate will only be able to travel upwards through the element and will not be able to infect the healthy skin **268** at the borders of the wound **267**.

Materials and Methods

Example - Testing of tearing strength of framework structures.

The tearing strength of framework structures was measured on two samples. Sample 1 consisted of a honeycomb structure made of Mediprene ® of a hardness of 20 Shore A. The strings used in the honeycomb structure were 3 mm's wide and 1 mm thick in the cross section. Two layers were used given a total thickness of the pressure-distributing element of 2 mm's. The element was tested to failure which occurred at 0.55 N/12mm at an elongation of 217%. For the tear strength measurements a sample of 12 mm x 65 mm was cut from the pressure-distributing element. The tear rate was 100 mm/min

The second sample consisted of a framework structure of Mediprene ® with a hardness of 12 Shore A. The strands in the structure had a cross-section with a width of 3 mm and a thickness of 1.5 mm. The structure consisted of 2 layers giving the structure a total thickness of 3 mm. This element was also tested to failure, which occurred at 1.16 N/12 mm at an elongation of 706%. For the tear strength measurements a sample of 12 mm x 65 mm was cut from the pressure-distributing element. The tear rate was 100 mm/min

Testing of Elements Comprising Beads

Several tests were performed on elements comprising beads.

Materials

As appropriate materials both thermosetting and thermo-elastic polymers can be used. Styrenic polymers like SEBS, SBS and SIS based polymers, EVA, urethanes and silicones are preferred materials for use.

Different materials have been evaluated for their usefulness for the present invention. The result is shown in Table 1:

Grade	Shore A Hardness	Hardness	Porous under compression?
Santoprene 8281 35MED	35	fine	yes
Evatane 3325	66	too hard	yes
Dryflex 500000	0	fine	no
Dryflex 500120	12	fine	yes

Table 1. Evaluation of different materials

The material having the high Shore A value (Evatane 3325) of 66 is assessed to be too hard for the present use. This kind of material would create too much discomfort for the patient and may lead to pressure marks when used. Furthermore a hard material would be more difficult to adapt in the cavity. The material having the low Shore A value (Dryflex 500000) of 0 is assessed to be too soft for the present use in that sense that it would not remain porous under compression. The other two types of material are assessed to be useful for the element according to the invention.

Example 1. Manufacturing of a Pressure-distributing Element Using Sintering

A portion of polymer, which was supplied as beads of an appropriate size, was put in a mould. The mould was shaped like a cavity mould with net on top and bottom and a metal wall portion. Warm air was then blown from the bottom, through the lower net, through the beads and the upper net, so that the beads were just melting at their surfaces in order to sinter the beads together. 3 different samples, samples C-E were made using this process. For an overview of the processing used for the samples, see Table 2.

Example 2. Manufacturing of a Pressure-distributing Element Using Sintering in water.

As an alternative to example 1 it would be possible to pour beads into a mould with grid top and bottom and disperse into a liquid which is insoluble with the beads. For SEBS water and silicone oil are examples of liquids suitable for the application. The advantage is that the relative density of the beads is the difference between the polymer and the liquid, thus minimizing the Gradual force from pressure from top to bottom, when using air as heating environment. In fact water has a slightly higher density than SEBS thus giving a situation with floating beads to be sintered.

By heating SEBS Dryflex 500120 for 30 minutes at 125Centigrades at elevated pressure (in an autoclave) the beads were sintered together. One sample, sample B, was made using this process. For an overview of the samples, see Table 2.

Example 3. Manufacturing of a Pressure-distributing Element Using Binder

Beads of Mediprene 500120 from Elastoteknik were put in an open mould having net on top and bottom. The diameter of the mould was 100mm and the height was 12mm. The net was a Teflon coated glass fibre net.

A solution of Silopren LSR 2010 TP3740 silicone A+B component from Bayer/GE was dissolved in a Hexamethyldisiloxane solvent following which the solvent solution (33% w/w) was poured over the beads. Excess solution flowed through the bottom net. When no more solvent was visible, the mould was put in an oven for vulcanising at 130° for 20 minutes. One sample, sample A, was made using this process. For an overview of the samples, see Table 2.

Example 4. Manufacturing of a Pressure-distributing Element Using Sintering on Surface Coated Beads

A modification of example 1 using surface coated beads may be feasible. In this example the inner core of the bead was an elastomer e.g. SEBS. This part made the primarily contribution to the final structure of the pressure-distributing element. A surface/outer shell of e.g. reactive polymer or thermoplastic polymer contributed to connection of the beads. If a reactive polymer is used any reactive polymer system is suitable. In case a thermoplastic polymer is used, the shell material must have a lower melting point than the inner core of the beads.

Above examples are not seen as limitations in production and they may be combined to each other and may also be combined with other ways of production e.g. moulding extruding welding etcetera. Emulsions e.g. water based emulsion may also be used as binder for the beads. Table 2 shows an overview of the manufacturing used for preparing samples A-E.

Sample	Material	Binder	Processing	Temp (°C)	Time (min)
A	SEBS Dryflex 500120	Silopren LSR 2010 TP3740 silicone A+B	oven	120	20
B	SEBS Dryflex 500120	no	immersed into water and heated	125	30
C	SEBS Dryflex 500120	no	oven	120	10
D	SEBS Dryflex 500120	no	oven	130	10
E	SEBS Dryflex 500120	no	oven	200	6

Table 2. Overview of manufacturing of samples A-E

Example 5 – Testing of Compression and Flow Resistance

This example concerns testing of materials properties more specifically testing of the degree of compression and the flow resistance of an element according to the invention and a foam element.

The set-up consisted of a uni-directional cylindrical chamber with a fixed plate on top. The top had an outlet for artificial exudate while at the same time acting as a source of vacuum. On the top an electronic pressure sensor was placed.

The testing sample was placed under the top, and afterwards a bottom part with a pressure sensor and an inlet for artificial exudate was placed inside the cylindrical chamber below the testing sample. A peristaltic pump supplied the artificial exudate at a defined speed.

The bottom part placed within the cylinder was not fixed and was able to move upon application of vacuum. As vacuum was applied the bottom part moved upward until forces from the vacuum and counterforce from the samples inside were of the same size.

The diameter of the cylinder was 61mm and the cylinder was made from a PMMA tube. The top and bottom was made from an aluminum ring and contained a sealing ring in order to maintain vacuum. The bottom ring was lubricated with silicone paste in order to minimize friction in the system.

Pressure sensors used were electronic SMC sensors model PSE532.

The vacuum system used consisted of a pump, a 1 litre buffer chamber, a throttle valve and a pressure sensor. The valve was set in such a way that the output from the pressure sensor was 125mmHg.

The artificial exudate was made from 1:1:1 mix CMC (Aquasorb A500), CMC (Blannose) and Calcium alginate (Aldrich) respectively in water and was adjusted to a viscosity of 500cp.

Materials: V.A.C. ® Granufoam ® dressing as marketed by KCI and pressure-distributing elements made according to Table 2.

The results of testing the flow resistance appear from Table 3.

	Foam	Sample A	Sample B	Sample C	Sample D	Sample E
Diameter (d) (mm)	61	61	60	97	97	87*87
Thickness (t), ambient (mm)	30	12,9	13,9	13,85	11,4	13,96
Thickness (t), neg. press. (mm)	6,7	12,8	13,9	13,8	11,4	13,9
Weight (m) (g)	1,9	23,5	15,6	42,5	37,5	45,5
Volume (V), ambient (ml)	87,7	37,7	39,3	102,3	84,2	105,7
Volume (V), neg. press. (ml)	19,6	37,4	39,3	102,0	84,2	105,2
Density (ρ), ambient (g/ml)	0,022	0,623	0,396	0,416	0,445	0,431
Density (ρ), neg. press. (g/ml)	0,097	0,628	0,396	0,417	0,445	0,433
Press. diff. (mmHg)	2,2	1,4	8,5	N/A	N/A	N/A

Table 3. Results from testing of flow resistance

Samples C-E were used for testing the tearing strength hence no results concerning pressure difference were obtained. However, the samples were put in the set-up and the thickness under negative pressure was measured to give an indication of whether these samples would have the same resistance to the influence of the negative pressure as the other samples. Through the test, the thickness but not the diameter of the samples altered as the pressure difference was only in the direction of the thickness, while there was no pressure difference along the surface of the samples. The diameter and the thickness of the samples were measured using a sliding caliper. The samples were weighed on a regular electronic scale. The volume may then be calculated as:

$$V = \pi \cdot \left(\frac{d}{2}\right)^2 \cdot t$$

where V is the volume in ml (= cm^3), d is the diameter in cm and t is the thickness in cm. Having the mass of the sample and the volume, the density may be calculated as:

$$\rho = \frac{m}{V}$$

where ρ is the density in g/ml, m is the mass in g and V the volume in ml of the samples.

As it appears from the table, the thickness of all of the pressure-distributing elements was hardly altered during the testing. As opposed to this, the thickness was significantly altered for the foam element during the testing. None of the other parameters were changed during testing hence the same difference applies for the volume and the density as well.

The pressure difference was measured as the difference between the top and bottom pressure sensors. The pressure difference was measured for three samples only, the foam sample and samples A and B according to the invention. The pressure differences were of the same level for the elements according to the invention, as it was for the foam material (1,4 and 8,5 mmHg for samples A and B and 2,2 mmHg for the foam). The uncertainty level for the measurements was so high that the only conclusion possible is that all measurements were below 10mmHg. The pressure difference is an expression for the elements ability to let exudate pass through the element. The lower the pressure difference, the less resistance to let exudate pass through the element. The pressure difference for the pressure-distributing element should be seen in the light of the porosity calculated according to the following equation:

$$por. = (1 - \frac{\rho}{\rho_{bulk}}) \cdot 100\%$$

where por. is the porosity in %, ρ is the density of the sample and ρ_{bulk} is the theoretical density of the bulk material, which is set to 1 g/ml.

The porosity of the pressure-distributing elements was rather low between 37% and 60 % by volume compared to the foam element, which had a measured porosity of approximately 90 % even under negative pressure. It is quite surprising that an element having such a low porosity shows such a little resistance to letting exudate pass through the element, when an element (foam) having a much larger original porosity shows a resistance of the same level to allowing the exudate to pass through the element.

Example 6 – Testing of Tearing Strength

A set-up was made for testing tearing strength of the pressure-distributing element made according to Table 2. Two parallel plates were put on a set-up where one was fixed in an angle of 45 degree from horizontal and the other was able to flip from the angle of 45 degree from horizontal, that is parallel to the first plate, to 45 degrees from horizontal perpendicular to the first plate. The plate was flipped around an axis placed in the higher end of the plates right under the two plates in their parallel position prior to testing.

Cylindrical samples of a diameter of 10 cm and 12 mm thickness were prepared. During testing the sample was placed centered on the two plates. Further two plates were clamped on top of the sample so that the sample was sandwiched between the two bottom plates and the two top plates. The clamps were each able to fixate half of the sample during the tearing test.

Prior to testing the load cell was calibrated to Zero Newton and the testing was carried out. The equipment used for the test was Lloyd tensile testing equipment.

Table 4 shows the results obtained by testing of tearing strength.

Samples	Maximum force (N)	Work (J)
Foam	N/A	N/A
A	14	0,190
B	7,7	0,398
C	5,4	0,180
D	43,0	2,102
E	> 235	N/A

Table 4. Result from testing of tearing strength

The samples A-D are all relatively easy to tear apart for a caregiver. Sample E was produced at such a high temperature (200 degrees centigrade) that the beads of the element were melted together instead of only bonded at their surfaces. Accordingly the sample seemed to be too strong to tear apart.

Claims

1. A pressure-distributing element for use as a wound-contacting element in connection with negative pressure therapy, which element comprises a 3-dimensional structure of pathways in-between material components, the material components being made of non-absorbing, elastomeric material having shore values between 5 shore A and 60 shore A where the inscribed circle of the cross section of the material components is between 0,25 mm's and 5 mm's, wherein the pathways have a diffuse structure with a circumcircle of the cross-section of the pathways between 0,5 and 10 mm's.

2. The pressure-distributing element according to claim 1 wherein the elastomeric material is selected from the group comprising thermosetting and thermo-elastic polymers.

3. The pressure-distributing element according to claim 2 wherein the materials are selected from the group comprising styrenic polymers, EVA, urethanes and silicones.

4. The pressure-distributing element according to any of the preceding claims where the structure has an internal air volume of between 5 % and 70 % when the element is in an unloaded condition.

5. The pressure-distributing element according to any of the preceding claims, where the reduction of the internal air volume is less than 20 % during influence of negative pressure.

6. The pressure-distributing element according any of the preceding claims where the element further comprises an outer layer having a shore-value of 0-5 shore A

7. The pressure-distributing element according to any preceding claims wherein the 3-dimensional structure is a lattice-structure.

8. The pressure-distributing element according to claim 7 wherein the element comprises an open framework, which is overlapped or overlaid in a regular, usually crisscross pattern in at least 3 directions.

9. The pressure-distributing element according to any of claims 7-8 wherein the framework structure comprises strands.

10. The pressure-distributing element according to any of claims 7-9 wherein at least one of the layers in the structure comprises substantially straight strands.

11. The pressure-distributing element according to any of claims 7-10 wherein at least one of the layers in the structure comprises strands of a wavy configuration.

12. The pressure-distributing element according to any of claims 7-11, wherein the strands are hollow or partially hollow.

13. The pressure-distributing element according to any of claims 7-11, wherein the strands are solid.

14. The pressure-distributing element according to any of claims 7-13, wherein the strands comprise a rather stiff core and a softer sheath.

15. The pressure-distributing element according to any of claims 7-14, wherein at least some of the layers comprise strands oriented in the same direction within each layer and where consecutive layers have obliquely oriented strands.

16. The pressure-distributing element according to any of claims 7-15, wherein the structure further comprises pillars/columns.

17. The pressure-distributing element according to any of claims 7-16 wherein the lattice structure comprises interconnected ring-elements.

18. The pressure-distributing element according to claim 17 wherein the ring-elements are angular.

19. The pressure-distributing element according to any of claims 17-18 wherein the ring-elements are rounded such as circular or oval – e.g. ellipsoid.

20. The pressure-distributing element according to any of claims 17-19 wherein the ring-elements constitute a honeycomb structure.

21. The pressure-distributing element according to any of claims 17-20, where holes in the ring-elements or gaps between ring-elements in consecutive layers are at least partly overlapping each other.

22. The pressure-distributing element according to claim 7 where the element comprises a plurality of beads, where the individual beads are substantially stable during negative pressure, which beads are physically bound together at their surfaces, thereby forming one integral element having gaps/passages in the element.

23. The pressure-distributing element according to claim 22, wherein the beads are bound together in spots.

24. The pressure-distributing element according to any of claims 22-23, wherein the distribution of the beads in the element is randomized.

25. The pressure-distributing element according to any of claims 22-24, wherein the distribution of the beads in the element is at least partly organized.

26. The pressure-distributing element according to claim 25, wherein the beads in the element defines a layered structure.

27. The pressure-distributing element according to any of claims 22-26, wherein the beads are rounded.

28. The pressure-distributing element according to any of claims 22-27, wherein the size of the beads are between 0,5 mm and 10,0 mm.

29. The pressure-distributing element according to any of claims 22-28, wherein the individual beads are weight-reduced.

30. The pressure-distributing element according to claim 29, wherein the individual beads contain substantially disconnected air-bubbles.

31. The pressure-distributing element according to any of claims 22-30, wherein the beads are made of two types of material, a core material and a surface covering material

32. The pressure-distributing element according to any of claims 22-31, wherein the beads are sintered together.

33. The pressure-distributing element according to any of claims 22-31, wherein the beads are bound together using a binder based on urethane, epoxy, vinyl, or anhydride.

34. The pressure-distributing element according to any of claims 22-33, wherein the force needed to tear the element is between 5N and 50N.

35. The pressure-distributing element according to any of claims 22-34, wherein the work needed to tear the element apart is between 0,10J and 2,5J.

36. The pressure distributing element according to any of claims 1-6, the element comprising a 3-dimensional layered structure, with at least two layers bonded together, where the structure comprises at least one layer of a non-planar sheet material having holes perpendicular to the layer.

37. The pressure distributing element according to claim 36, wherein the sheet comprises strands connected at least partly along their length.

38. The pressure distributing element according to claims 36-37 wherein at least some of the layers comprise sheets having a corrugated surface, where the direction of the corrugations in two subsequent layers are oriented in an oblique angle.

39. The pressure distributing element according to claim 36-38 wherein the sheet comprise a rather stiff core and a softer sheath.

40. The pressure-distributing element according to claims 1-6 where the element is provided with channels comprising cavities and walls, where the channels have an axial direction and perforations in at least one direction defining an angle to the axial direction of the channels.

41. The pressure distributing element according to claim 40 wherein the direction of the perforations are perpendicular to the axial direction of the channels.

42. The pressure distributing element according to claim 40 wherein the direction of the perforations has projections in planes perpendicular to the axial direction as well as in planes parallel to the axial direction.

43. The pressure distributing element according to any of claims 40-42 wherein the perforations are provided in at least two directions.

44. The pressure distributing element according to any of claims 40-43 wherein the channels of the element are extruded.

45. The pressure distributing element according to any of claims 40-44 wherein the cross-section of the cavities of the extruded channels are hexagonal.

46. The pressure distributing element according to claims 40-44 wherein the cross-section of the cavities of the extruded channels are triangular.

47. The pressure distributing element according to claims 40-44 wherein the cross-section of the cavities of the extruded channels are quadrangular.

48. The pressure distributing element according to claim 47 wherein the cross section of the element defines a Harlequin pattern.

49. The pressure distributing element according to claims 40-44 wherein the cross-section of the cavities of the extruded channels are of a rounded shape.

50. The pressure distributing element according to claims 40-44 wherein the cross-section of the cavities of the extruded channels are clover-shaped.

51. The pressure distributing element according to any of claims 40-50 wherein the size of cross-section of the cavities of the extruded channels varies.

52. The pressure distributing element according to any of claims 40-51 wherein the thickness of the walls in the extruded channels is between 0.25 mm and 5 mm.

53. The pressure-distributing element according to any of claims 40-52 wherein the element has a surface defined by border walls extending in the axial direction and which are surrounding the channels.

54. The pressure-distributing element according to any of claims 40-53 wherein the surface of the element is deformed between gaps of the perforations.

55. The pressure-distributing element according to claim 54 wherein the surface of the element is raised between the gaps and has indentations surrounding the gaps.

56. The pressure-distributing element according to any of claims 40-55 wherein the element has several layers of channels.

57. The pressure-distributing element according to any preceding claims wherein the structure is stratified.

58. The pressure-distributing element according to any preceding claims, wherein the element comprises at least one layer of sheet material and at least one layer comprising strands.

59. The pressure-distributing element according to any preceding claims, wherein the element comprises combinations of elements having cavities and walls and sheet-elements.

60. The pressure-distributing element according to any preceding claims, wherein the element comprises at least a layer of strands and an element having cavities and walls.

61. The pressure-distributing element according to any preceding claims, wherein the element comprises combinations of ring-elements and elements having cavities and walls.

62. The pressure-distributing element according to any preceding claims, wherein the element comprises at least a layer of ring-elements and an element having cavities and walls.

63. The pressure-distributing element according to any preceding claims, wherein the element comprises a border part having only vertical pathways surrounding the central part of the pressure-distributing element.

64. A negative pressure therapy system comprising a pump including a canister, a tube, a wound cover and a wound-contacting element in form of a pressure distributing element according to any of the preceding claims.

65. Method of treating a wound using negative pressure therapy, the method comprising

- adapting a pressure distributing element according to claim to fit the wound
- placing the adapted element in or at the wound
- covering the element and the wound with a cover film to form an enclosure

- connecting the enclosure to a pump via a tube
- applying negative pressure to the wound for a predetermined period

66. The method of treating a wound according to claim 65 wherein the adapting is done by cutting.

67. The method of treating a wound according to claim 65 wherein the adapting is done by tearing the element apart.

68. Method of treating a wound according to any of claims 65-67 wherein the negative pressure is applied in alternating periods during the treatment.

Fig. 1

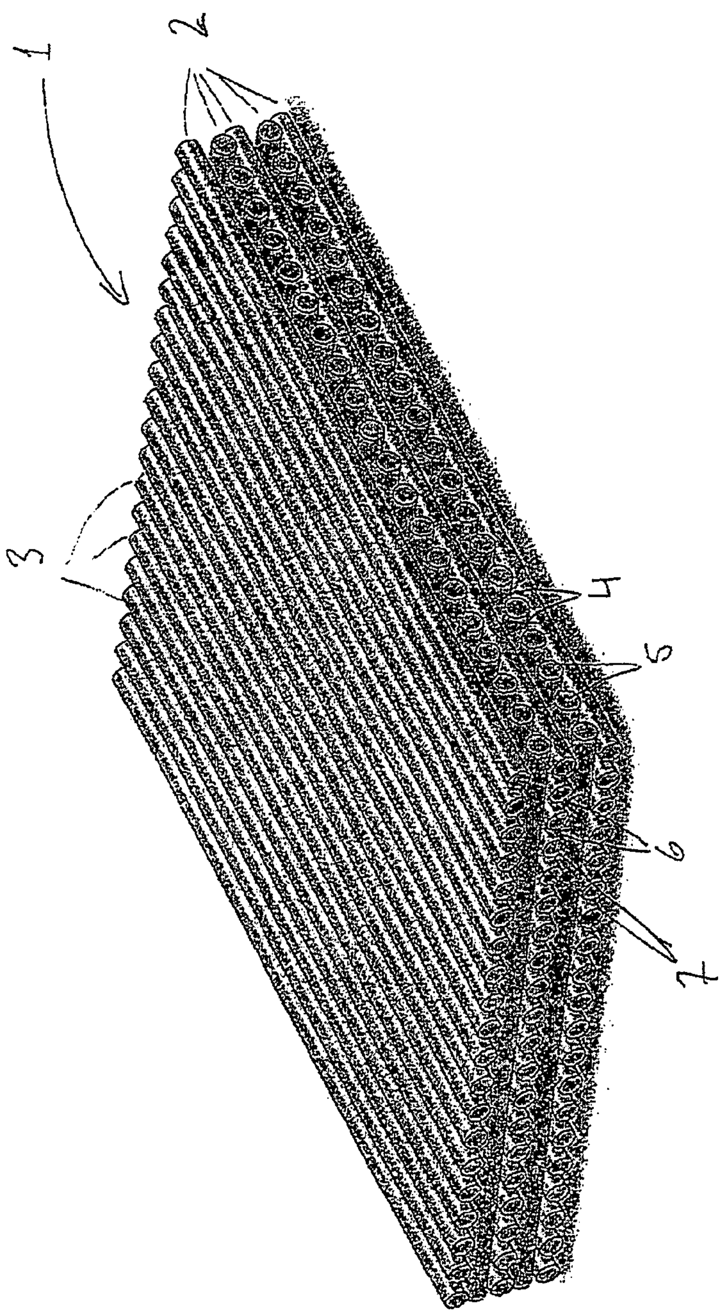


Fig. 2

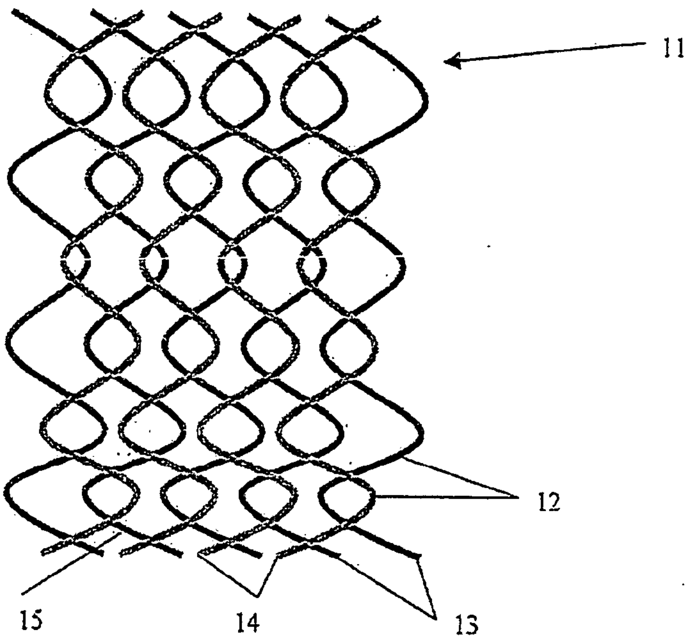


Fig. 3

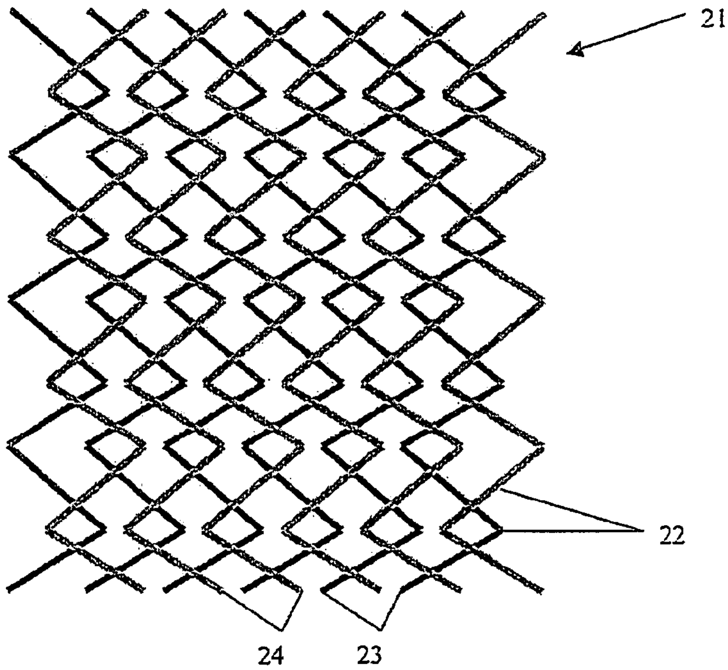


Fig. 4

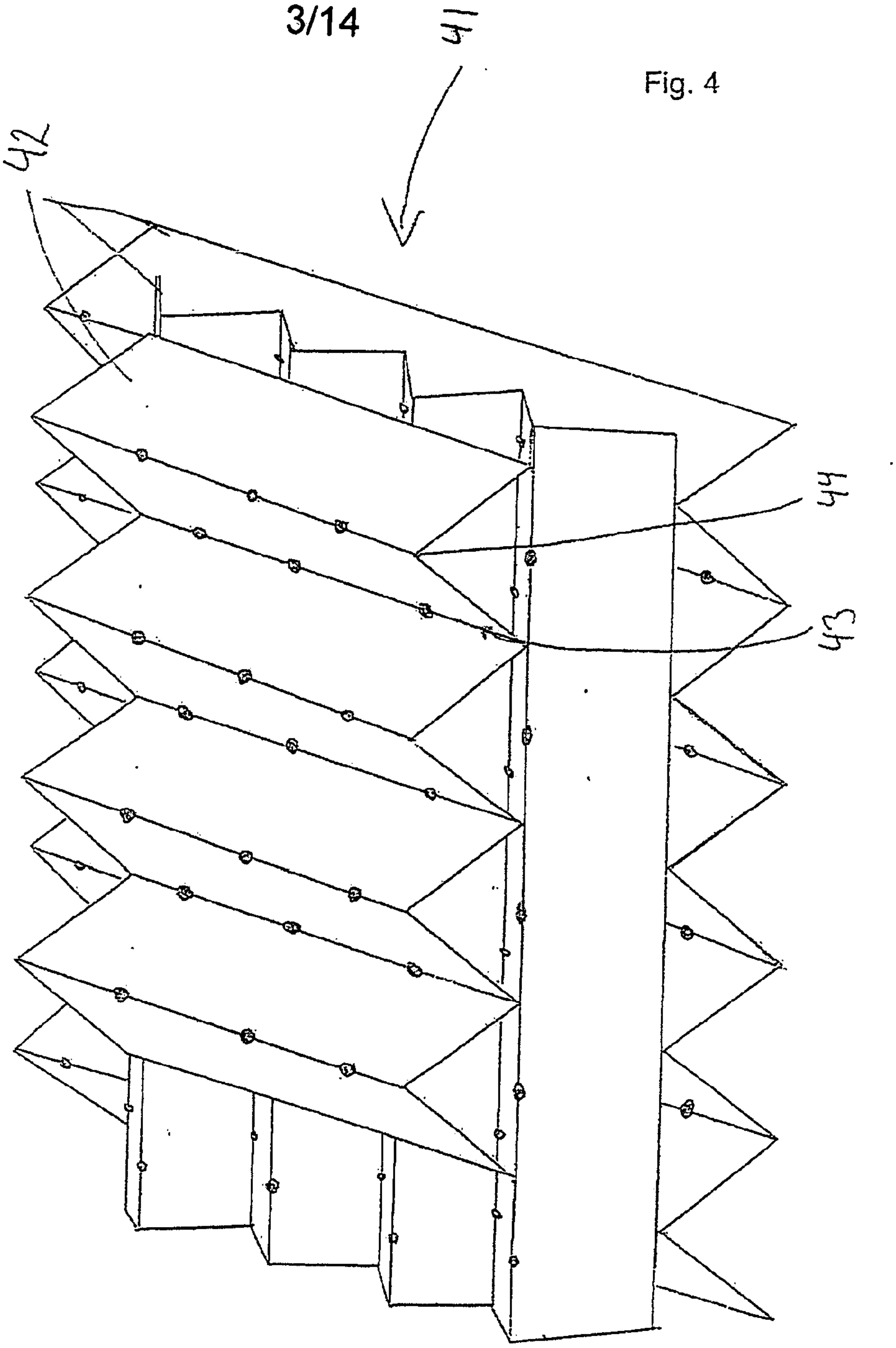


Fig. 5

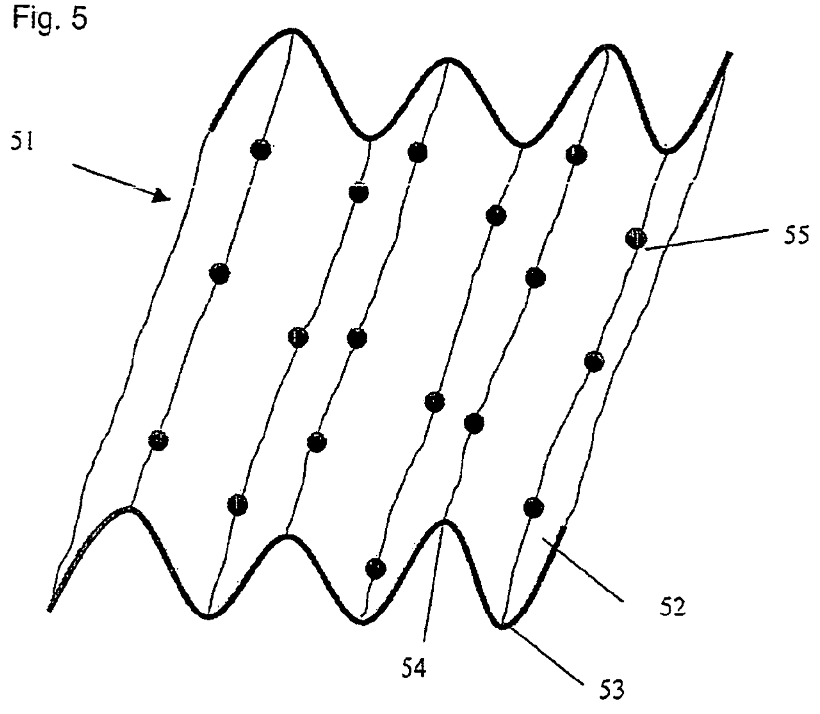


Fig. 6

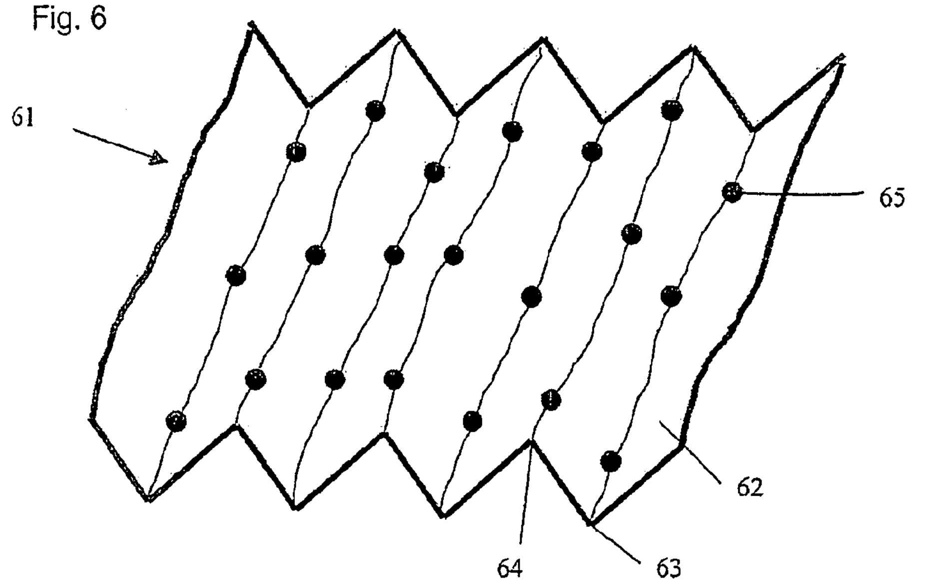


Fig. 7

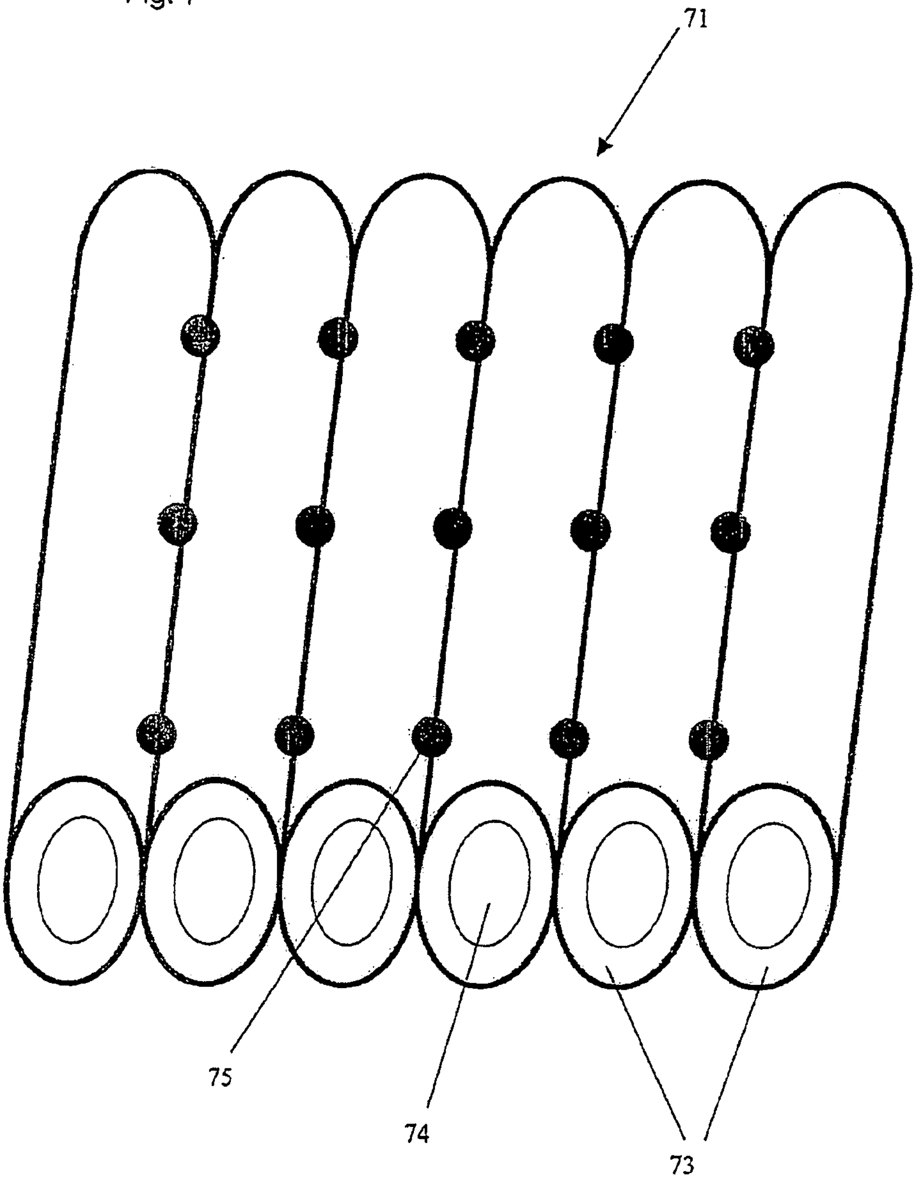


Fig. 8

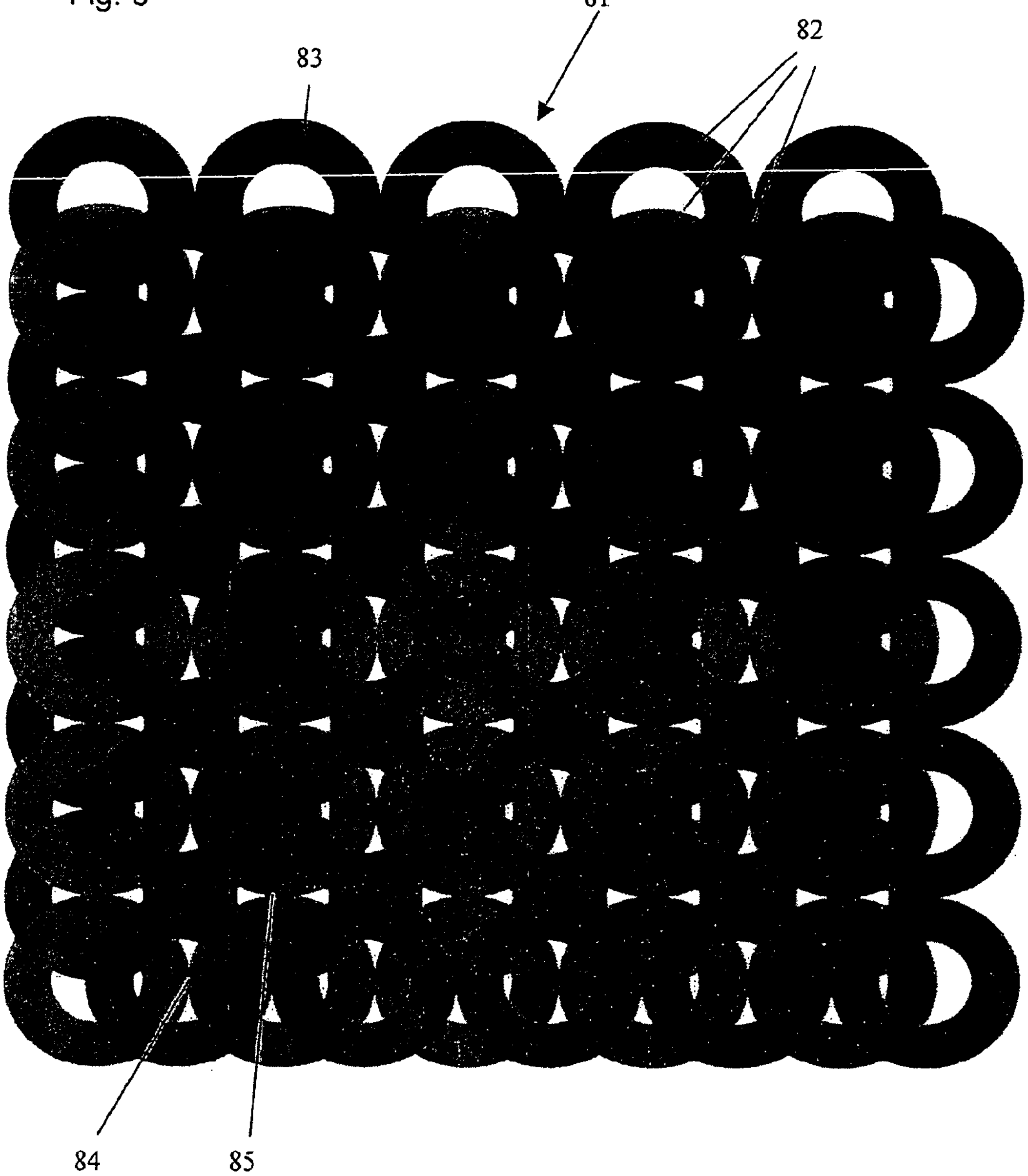


Fig. 9

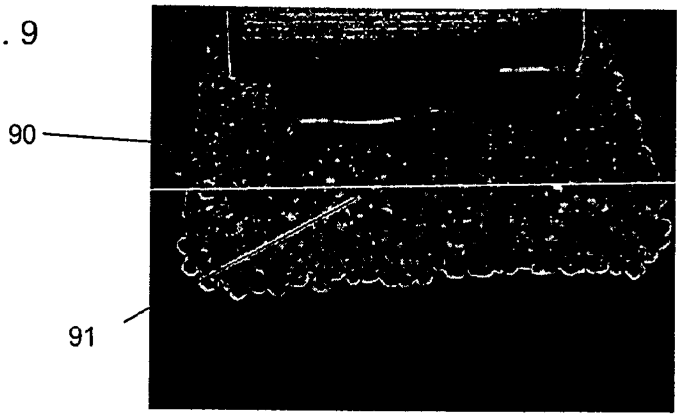


Fig. 10

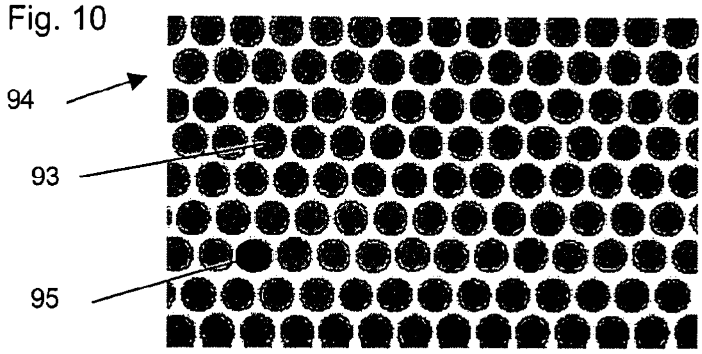


Fig. 11

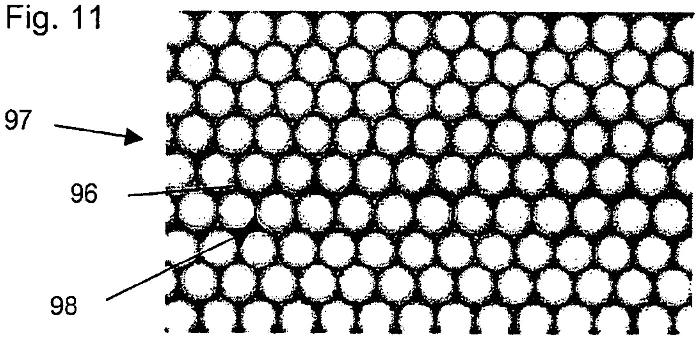


Fig. 12

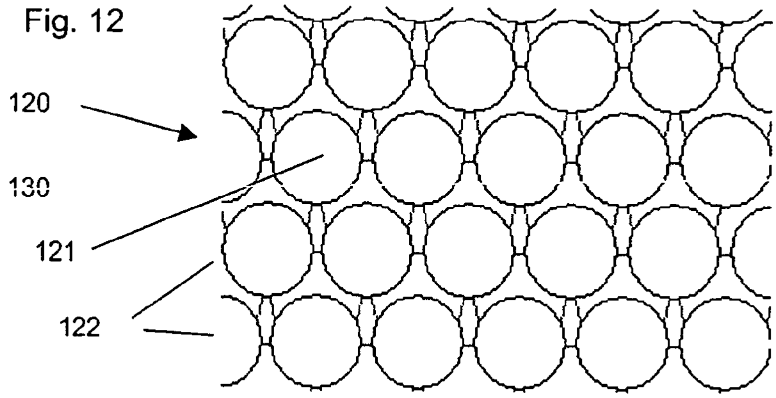


Fig. 13

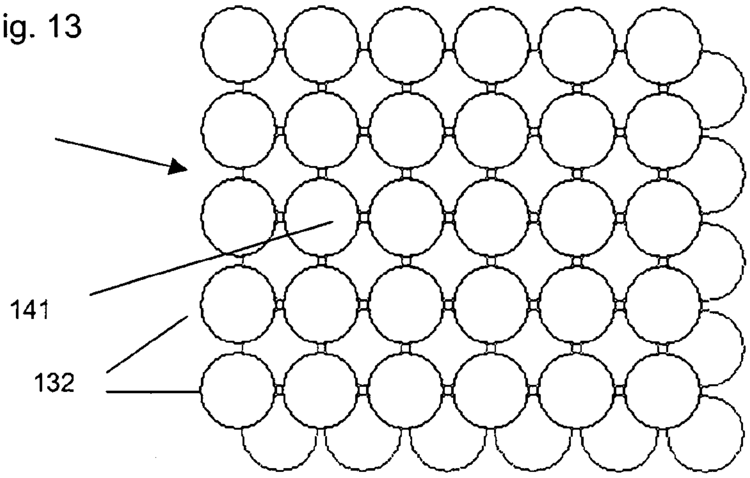


Fig. 14

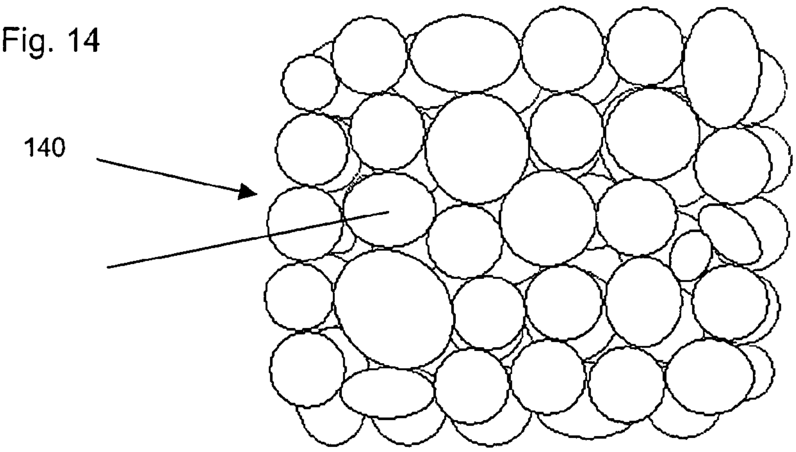


Fig. 15

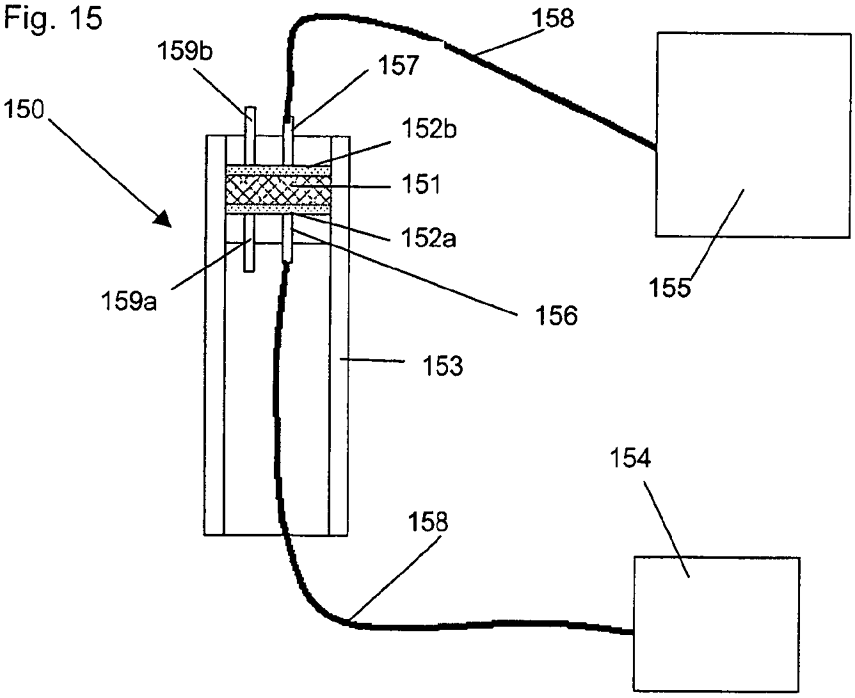


Fig. 16

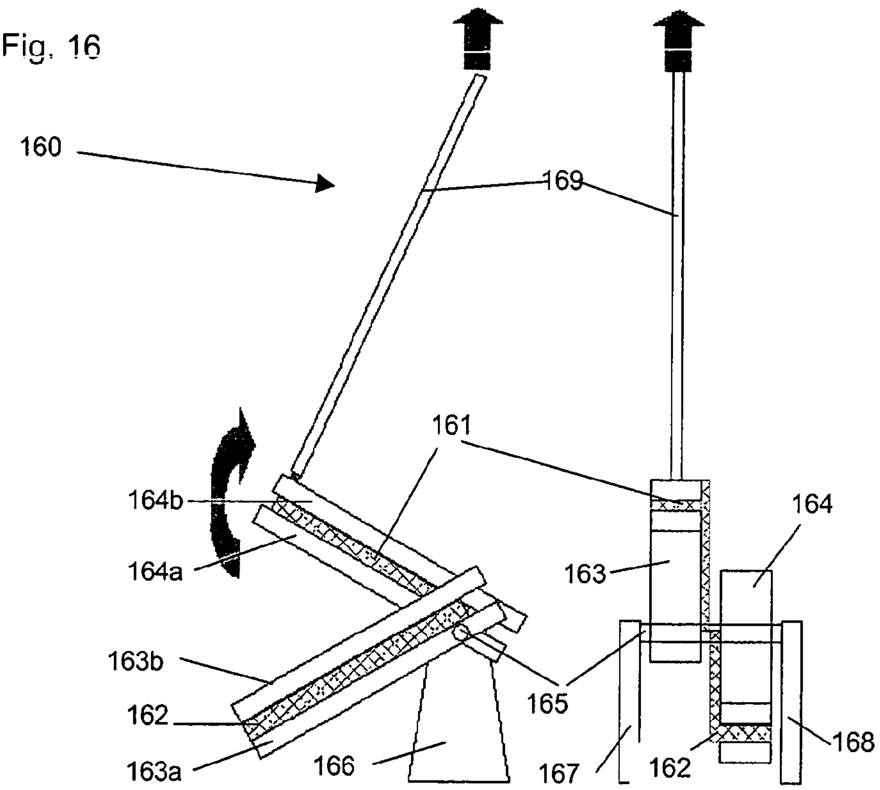


Fig. 17a

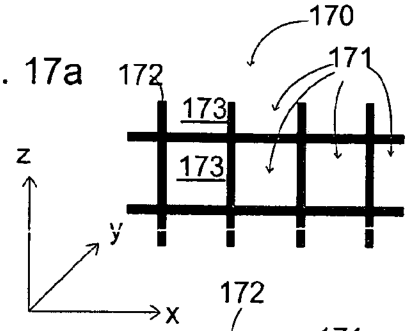


Fig. 17c

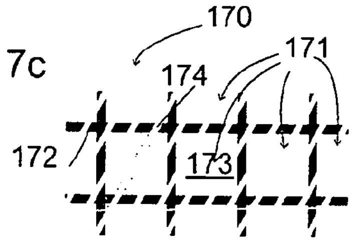


Fig. 17b

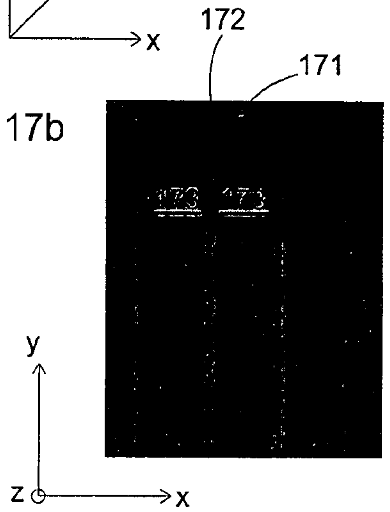


Fig. 17d

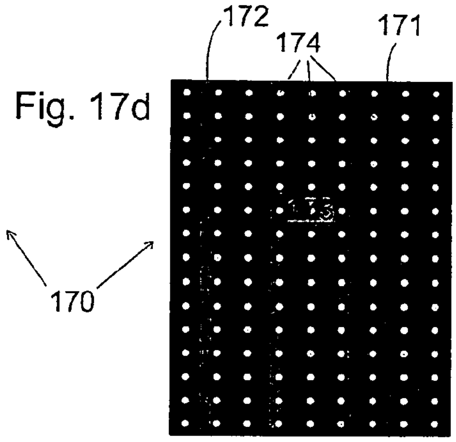


Fig. 18a

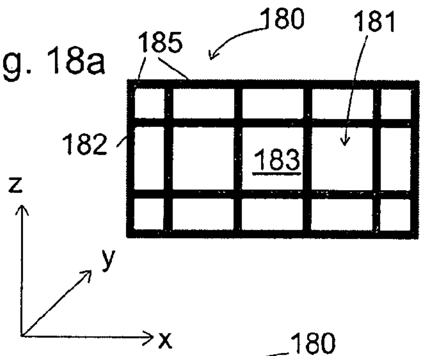


Fig. 18c

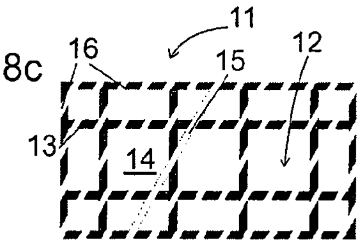


Fig. 18b

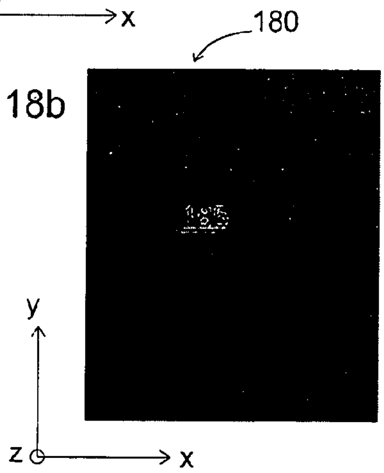


Fig. 18d

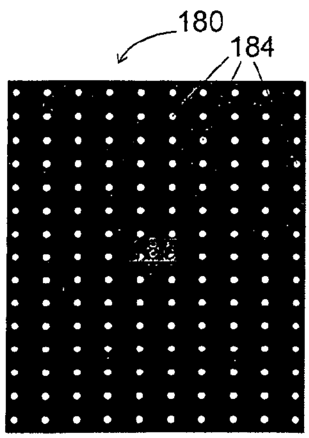


Fig. 19a

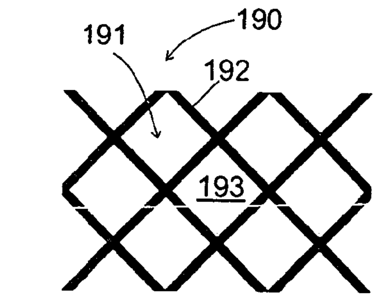


Fig. 19b

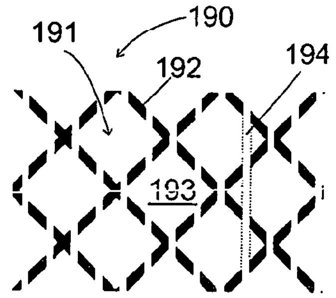


Fig. 20a

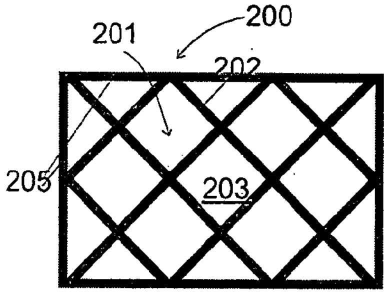


Fig. 20b

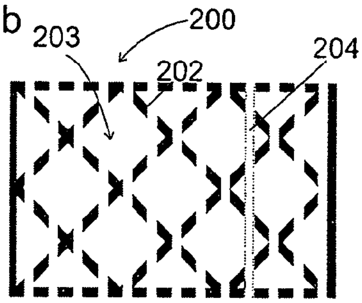


Fig. 21a

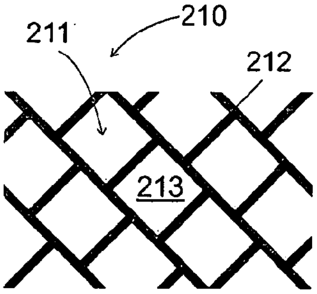


Fig. 21b

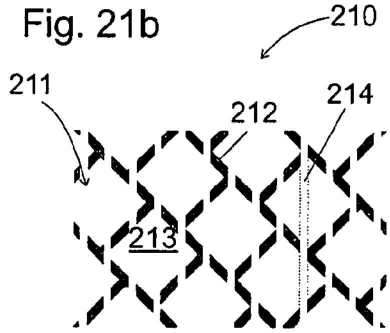


Fig. 22a

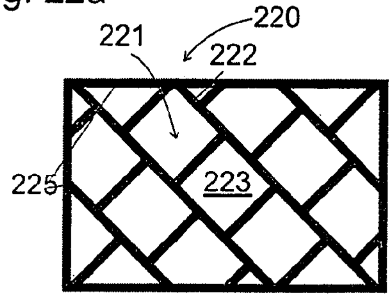


Fig. 22b

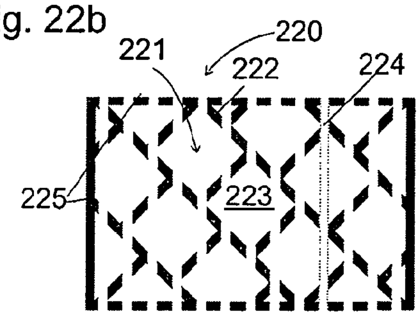


Fig. 23

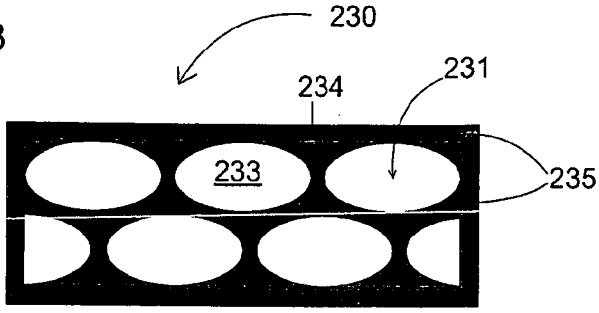


Fig. 24

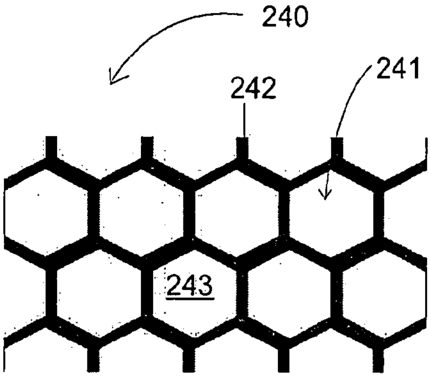


Fig. 25

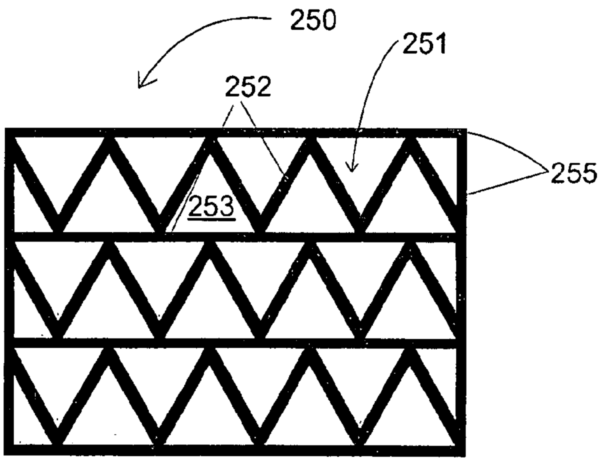
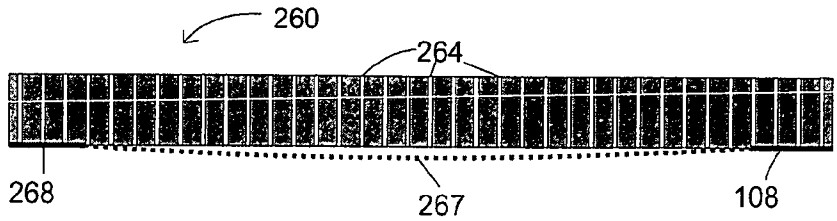


Fig. 26



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/052577

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/00 A61F13/02 B32B25/04 B32B3/28 A61L15/42
C08J9/232 C08J9/236

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61F B32B A61L C08J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2007/019038 A (VOGEL RICHARD C [US]) 15 February 2007 (2007-02-15) paragraphs [0011], [0031], [0056], [0057]; figure 9	1,64
A	WO 2005/123170 A (ETHICON INC [US]; WATT PAUL WILLIAM [GB]; GREGORY SARA JAYNE [GB]; TRO) 29 December 2005 (2005-12-29) page 20, line 10 - line 14; figure 4	1,64
A	US 2004/091677 A1 (TOPOLKARAEV VASILY A [US]) 13 May 2004 (2004-05-13) paragraphs [0018], [0038], [0085]; figures 1,2	1

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 July 2008	24/07/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Lakkis, Angeliki

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/052577

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 02/43634 A (HILL ROM SERVICES INC [US]) 6 June 2002 (2002-06-06) page 11, line 15 - line 24 page 12, line 16 - page 13, line 27; figures 2,3,5 page 23, line 4 - line 6; figure 26 page 20, line 17 - line 22; figure 21	1,64
A	US 2006/041247 A1 (PETROSENKO ROBERT [US] ET AL) 23 February 2006 (2006-02-23) cited in the application paragraphs [0034], [0039], [0040], [0042], [0044]; figures 5,7,9,12	1,64
A	WO 2005/046761 A (SMITH & NEPHEW [GB]; BLOTT PATRICK LEWIS [GB]; GREENER BRYAN [GB]; HAR) 26 May 2005 (2005-05-26) page 63, line 13 - line 22 page 64, line 6 - line 22; figure 10ac page 65, line 1 - line 10	1,64
A	WO 2005/091884 A (BOEHRINGER LAB INC [US]; BOEHRINGER JOHN R [US]; KARPOWICZ JOHN [US];) 6 October 2005 (2005-10-06) the whole document	1,64
A	EP 0 648 480 A (JOHNSON & JOHNSON MEDICAL [US]) 19 April 1995 (1995-04-19) column 5, line 37 - line 43; figure 1	1,64
A	US 4 837 285 A (BERG RICHARD A [US] ET AL) 6 June 1989 (1989-06-06) claim 1	1,64

INTERNATIONAL SEARCH REPORT

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 65-68
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgeryRule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2008/052577

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
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