(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 March 2019 (28.03.2019)

WIPO | PCT

(10) International Publication Number
WO 2019/057256 A1

(51) International Patent Classification:
A61F 13/00 (2006.01)

(21) International Application Number:
PCT/DK2018/050229

(22) International Filing Date:
18 September 2018 (18.09.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PA 2017 70707 20 September 2017 (20.09.2017) DK

(71) Applicant: **COLOPLAST A/S** [DK/DK]; Holtedam 1, 3050 Humlebaek (DK).

(72) Inventors: **IGWEBUIKE, Henning**; Solvaenget 2, 3540 Lynge (DK). **HOEIER NIELSEN, Kent**; Kildegaardsvej 3, 3650 Oelstykke (DK).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*
— *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

(54) **Title:** WOUND CARE DEVICE FOR DEBRIDING WOUNDS

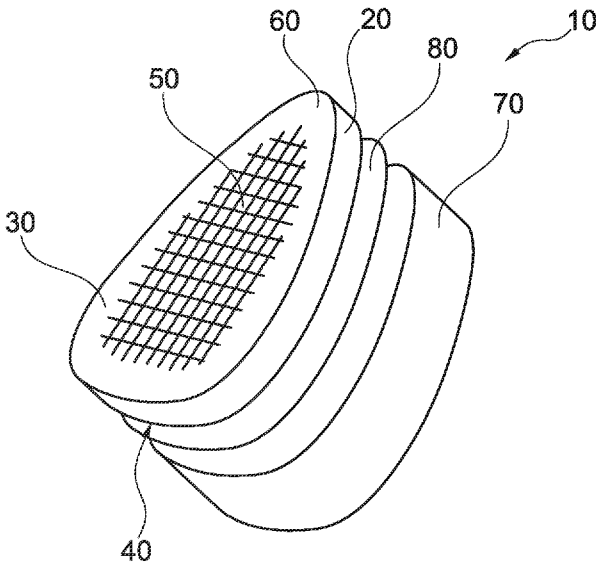

Fig. 1

(57) **Abstract:** A wound care device for debriding a wound, said device is in the form of a foam pad with two layers of different foams. At one surface of the device is provided a pattern of grooved at the central portion. The grooves improve the ability of removing and collecting debris from a wound during cleaning of such.

WO 2019/057256 A1

Wound Care Device for Debriding Wounds

The invention relates to a wound care device for debriding and cleaning wounds and a method of debriding and cleaning wounds.

Summary of the Invention

The present disclosure provides aspects of wound care device according to the appended claims. The disclosure further provides a method of cleaning a wound as disclosed herein.

Brief Description of the Drawing

The accompanying drawings are included to provide a further understanding of embodiments and are incorporated into and a part of this specification. The drawings illustrate embodiments and together with the description serve to explain principles of embodiments. Other embodiments and many of the intended advantages of embodiments will be readily appreciated as they become better understood by reference to the following detailed description. The elements of the drawings are not necessarily to scale relative to each other. Like reference numerals designate corresponding similar parts.

Figure 1 illustrates an isometric, exploded view of an embodiment.

Figure 2 illustrates an embodiment seen from a first surface of a first foam layer of the device.

Figure 3 illustrates a cross-section of the embodiment of Figure 2, cut along the A-A line.

Figure 4 schematically illustrates different embodiments of grooves of a first surface of a wound care device.

Figure 5 illustrates the influence of mesh design.

Figure 6 and 7 illustrate the influence of amount of test media.

Figure 8a and 8b show different foams compared to a debridement product.

Figure 9a and 9b show the influence of different cutting methods.

Figure 10 illustrates the influence of different depths of the grooves.

Detailed Description

Embodiments, and features of the various exemplary embodiments described in this application, may be combined with each other ("mixed and matched"), unless specifically noted otherwise.

In the following Detailed Description, reference is made to the accompanying drawings, which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. Because components of embodiments can be positioned in different orientations, the directional terminology is used for purposes of illustration and is in no way limiting. It is to be understood that other embodiments may be utilized, and structural or logical changes may be made without departing from the scope of the present invention. The following detailed description, therefore, is not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims.

The longitudinal direction herein describes the direction of a longitudinal axis extending from a distal end to a proximal end of the wound care device. The transverse or radial direction is the direction perpendicular to the longitudinal direction, which corresponds to the direction across the device.

The use of the phrase "substantially" as a qualifier of certain features or effects throughout this disclosure, is intended to simply mean that any deviations are within tolerances that would normally be expected by the skilled person in the relevant field.

Herein, the phrases "debris" and "slough" both address the greasy material that may be formed on the surface of a wound. Such debris may be home for bacterial growth as well as it may obstruct wound healing and is therefore desired to remove the debris and slough during cleaning of the wound.

Embodiments relate to a wound care device for debriding a wound, said device comprising a first foam layer having a first and a second surface, the first surface comprising a central portion and an edge portion, where the central portion is provided with a plurality of grooves and ridges (with the grooves being for accepting debris from the

wound), and the edge portion is continuous (grooves and ridges absent) and the second surface of the first foam layer is provided with a second foam layer.

The wound care device may be in the form of a foam pad for cleansing and debriding of wounds. The device comprises two different foam layers, such as a coarse foam and a soft foam, to provide optimal handling as well as multifunctionality.

Using a foam pad for cleaning and debriding of a wound provides an advantage that the foam pad distributes pressure over the wound more evenly compared to a cloth or tissue. Wound, especially chronic wound may be fragile and may be susceptible to be damaged if exposed to unnecessary pressure.

In embodiments, the first and the second foam layers are joined to each other by an adhesive, for example a hot-melt adhesive. In embodiments, the foam layers are joined to each other by welding or lamination.

In embodiments, at least one further layer is inserted between the first and the second foam layer. In one implementation, such layer is a reinforcing layer, providing more rigidity to the device.

In embodiments, the first and the second foam layers are joined to each other by a layer of double-sided adhesive tape.

In embodiments, the wound care device consists of a first foam layer and a second foam layer and a connecting layer, the first foam layer having a first surface and a second surface and the second surface of the first foam layer being joined to the second foam layer. The first and the second foam layers are joined to each other by a connecting layer such as an adhesive layer, double-sided adhesive tape or they may be joined by lamination.

The central portion of the first surface of the first foam layer is provided with grooves and ridges. The ridges are zones of the first foam layer without grooves, and the grooves are defined by side walls of the ridges. The ridges are zones of the first foam layer having a thickness corresponding to the overall thickness of the foam layer whereas the grooves have a smaller thickness than the overall thickness of the first foam layer, the grooves being slits cut in the first foam layer. The grooves are configured to accepting debris from

the wound. In embodiments, the grooves are in the form of grooves extending substantially perpendicular to the first surface of the first foam layer.

In embodiments, the side walls of the ridges have angular edges. The angular edges of the side walls help to assist in scraping off or otherwise obtaining the debris from the wound and directing the debris into the grooves. In embodiments, the grooves are only cut partly through the first foam layer, leaving an uninterrupted part of the first foam layer at a bottom of the grooves, next to the second surface of the first foam layer. In other words, in embodiments the grooves have a depth such that they extend partway, but not entirely, through a thickness of the first foam layer.

In embodiments, the grooves may be cut through the entire first foam layer, or even through a part of the second foam layer.

In embodiments, the grooves may be cut with a cutting apparatus or by laser. Cutting with a cutting apparatus, the grooves can be very narrow, whereas cutting by laser can create broader grooves as foam material is removed by burning during the process.

The grooves facilitate collection of sloughy material such as debris from a wound to the device. If a distance between any two grooves is too small, the ridges could potentially collapse under pressure or even break. On the other hand, if the distance between any two grooves is too high, the grooves could lose the ability to collect slough.

In embodiments, the grooves extend at least 50%, such as 60%, such as 70%, such as 80% or even 90% of the thickness of the first foam layer. In embodiments, the grooves have a depth of up to 100 % of the thickness of the first foam layer. In embodiments, the grooves may extend through the entire first foam layer and into the second foam layer. In embodiments, the grooves have a depth of 5-12 mm, such as 6-10 mm, such as 6-9 mm, such as 7-8 mm. The depth of the grooves can be determined as the distance from the surface of the first layer to the bottom of the groove, the distance being perpendicular to the first surface of the first foam layer. The thickness of the first foam layer can be determined as the distance from the first surface to the second surface, measured perpendicular to the first surface. In embodiments, the first foam layer has a uniform thickness over the entire layer.

In embodiments, the grooves are arranged in a pattern. In embodiments, the grooves are arranged in a pattern of parallel lines. In embodiments, the grooves are arranged in a pattern of a first set of parallel lines crossed by a second set of parallel lines, optionally being oriented perpendicular to the first set of lines, defining a pattern of square-shaped ridges between the grooves, a mesh like pattern. In embodiments, a first set of grooves extend in one direction and another set of grooves extend in a direction different to the direction of the first set of grooves.

The ridges are defined as the portion between the grooves. In embodiments, the ridges have shapes being square, rectangular, triangular or other geometric shapes defined by lines or curves. In embodiments, the distance between the grooves, herein called the mesh size, is 3-12 mm, such as 4-10 mm, such as 3-9 mm, such as 4-8 mm, or even 5-7 mm.

When cleaning or debriding a wound, the device can advantageously be moved in circular movements by a person, such as a health care professional, holding the wound care device in one hand, while applying a light pressure to the wound and the grooves will collect the debris from the wound. Providing the wound care device with grooves increases the cleaning surface capacity of the significantly.

The grooves increase the ability of the device to collect debris and slough from the wound. Furthermore, by providing the first foam layer with the grooves, it is possible to use a softer foam for the debridement of the wound, and a softer foam is more gentle to the wound.

In embodiments, the continuous/uninterrupted edge portion of the first surface has a width of 2-20 mm, such as 3-15 mm, such as 4-12 mm or even 5-10 mm. In one embodiment, the width of the continuous/uninterrupted edge portion is approximately 10 mm. In embodiments, the width of the continuous/uninterrupted edge portion is at least the same as the distance between two neighbouring grooves. The width of the continuous/uninterrupted edge portion is measured as the distance from an outer periphery of the first surface of the first foam layer to an outer periphery of the central portion, where the pattern of grooves end.

The edge portion of the first surface is in the form of a continuous/uninterrupted zone. The edge of the foam pad may be exposed to more stress than the central portion during use,

which could lead to foam breakage. Creating a continuous zone without grooves at the edge portion, surrounding the central portion having grooves, a more robust edge is created, because stress is distributed to a larger foam area.

The shape of the wound care device facilitates several purposes including among others good ergonomic handling such as the ability to use entire surface of the device while working with it. The shape of the device produces an intuitive understanding of how to orient/use the device.

In embodiments, the device has a first outer external surface – being the first surface of the first foam layer, and a second outer external surface – being the surface of the second foam layer facing away from the first foam layer. The edge of the first and the second outer external surface are connected by a side portion circumferencing the device. In embodiments, the side portion is substantially perpendicular to the first surface.

An outline of the wound care device, defined as the outer periphery of the first foam layer, can have any suitable shape. In embodiments, the shape is round, oval triangular, square, droplet-shape or other geometric or non-geometric shapes. In embodiments, the outline is defined by corners and substantially straight lines connecting the corners. In embodiments, the corners of the device are rounded. In embodiments, one or more of the corners of the device is/are more angular to facilitate cleaning narrow spaces in the wound. In embodiments, the shape may be ergonomic to provide a good hand-grip.

By substantially straight lines is here meant that a length of the curve defining the line between two corners is only slightly longer (less than 15%, or more preferred less than 10%, such as less than 5%) than the chord between the same two corners. In other words, a surface area of one side of the device is less than 15% (such as less than 10% or less than 5%) larger than an area of the plane spanned by the two corners of the side.

In embodiments, the device has rounded corners. By rounded corners is meant that the transition from one surface to another around a circumferential cross-section of the device follows a rounded curve.

Another way of describing this is that the outline of the device consists of a first three pieces having a first small curvature (large radius) joined alternately with a second three pieces having a second larger curvature (small radius).

In embodiments, the outline/shape of the wound care device is symmetrical around a central longitudinal axis. In embodiments, the device is longer in the axial direction than in the radial direction (being the direction perpendicular to the axial direction. In embodiments, the device is 5% longer in the axial direction, such as 10%, such as 15%, such as 20%, such as 25% or even 30% longer in the axial direction. In embodiments, the device is 20-25% longer in the axial direction than in the radial direction.

In embodiments, the outline/shape of the wound care device has a substantially triangular outline.

Both foam layers need to be of a type having tensile strength that is sufficient to avoid breaking of the foam when in contact with the wound and configured to avoid shedding foam particles into the wound during usage.

In embodiments, the first foam layer is a soft foam. In embodiments, softness can be defined by the perception of a polyester foam with a PPI (Pore per Inch) of 70 to 90 , and a CLD (Compression Load Deflection) of @25%=0.30 to 0.40psi /CLD@65% = 0.50 to 0.60 psi. In embodiments, the foam may appear soft and gentle to the patient as well as it is flexible enough to facilitate the grooves to collect debris when rubbed over a wound, while also having a tensile strength sufficient to avoid breaking when in contact with the wound and avoid shedding foam particles into the wound during usage.

In embodiments, the first foam layer comprises a hydrophilic foam. In embodiments, the first foam layer comprises a polyurethane foam such as a polyester polyurethane foam.

The first foam layer is intended for use on the wound bed and should maintain a level of softness that reduces the risk of pain during use as well as reducing the risk of damage to granulation tissue. In embodiments, the soft foam is able to absorb fluid and release it again under pressure, thereby donating moisture to the wound bed and support cleaning of it. In embodiments, the first foam layer is able to absorb/incorporate viscous material such as slough and debris into its structure.

In embodiments, the second foam layer is coarser than the first foam layer. The second foam layer serves at least two primary functions, it works as a grip for handling the device and it can be used on the wound bed and surrounding skin to remove skin scales and loosening debris/devitalised tissue in the wound bed.

In some implementations, the wound care device is used with the second foam layer facing the wound for initial cleaning and then turned around to make the first foam layer face the wound for further cleaning.

In embodiments, the second foam layer comprises a certain level of coarseness in order to function effectively while not becoming so coarse that there is a risk of injury to the wound. In embodiments, the second foam layer has a coarseness level higher than the first foam layer. In embodiments, coarseness can be defined by the perception of a polyester foam with a PPI of 40-50, and a CLD of @25% = 0.40 to 0.50 psi /CLD@65% = 0.65 to 0.75 psi.

In embodiments, the second foam layer is non-absorbing. In embodiments, the second foam layer is hydrophobic.

In embodiments, the first foam layer has a thickness less than the thickness of the second foam layer. In embodiments, the ratio between the thickness of the first and the second foam layer is 1:3, such as 1:2,5 and even such as 1:2. In embodiments the ratio between the thickness of the first and the second foam layer is between 1:1 and 1:3, such as between 1:1,5 and 1:2,5. In embodiments the ratio between the thickness of the first and the second foam layer is 1:2.

In embodiments, the first foam layer and the second foam layer have equal thickness.

In embodiments, the first foam layer is thicker than the second foam layer. In embodiments, the ratio between the thickness of the second and the first foam layer is 1:3, such as 1:2,5 and even such as 1:2.

In embodiments, the total thickness of the wound care device is between 25 mm and 40 mm, such as between 28 mm and 35 mm, or even between 30 mm and 33 mm.

In embodiments, the second foam layer has a substantially uniform thickness. In embodiments, the thickness of the second foam layer is between 10 mm and 30 mm, such as between 15 mm and 25 mm, such as between 18 mm and 23 mm.

In embodiments, the first foam layer has a substantially uniform thickness, apart from the grooves. In embodiments, the thickness of the first foam layer is between 5 mm and 15 mm, such as between 8 mm and 13 mm, such as between 9 mm and 11 mm.

In embodiments, the first foam layer is 10 mm thick. It has been found that the thickness of the first foam layer should strike a balance between slough incorporation capability and handling performance when wetted. In embodiments, the thickness of approximately 10mm of the first foam layer has been found to provide a good balance between handling, slough incorporation and ability to wet the wound bed being cleaned.

In embodiments, the second foam layer is 22 mm thick. The coarse structure of the second foam layer facilitates the second foam layer to retain its structure and stiffness even when wetted and serves as the primary layer for the user to hold on to when handling the product. In embodiments, a thickness of 22 mm provides good ergonomic handling.

In embodiments, the wound care device comprises one or more of antibacterial agents, cleaning agents, healing promoting compounds and/or skin soothing substances.

Embodiments further relate to a method of cleaning a wound, comprising the steps of providing a wound care device for debriding a wound, said device comprising a first foam layer having a first and a second surface, the first surface comprising a central portion and an edge portion, where the central portion is provided with a plurality of grooves and ridges, and the edge portion is continuous and the second surface of the first foam layer is provided with a second foam layer, bringing the first layer in contact with the wound, performing a rotating movement while applying a light pressure to remove slough and debris from the wound.

In embodiments, method further comprises the step of wetting the wound care before contacting the wound.

In embodiments, the method further comprises initially bringing the second foam layer in contact with the wound and using the second foam layer to remove rough debris.

In embodiments, the wound care device is contained in a package. In embodiments, the device may be provided in sterile packaging. In embodiments, the wound care device is stored in dry state. In embodiments, the device is stored in wetted state in the package.

In the following detailed description, reference is made to the accompanying drawings. The drawings form a part of this specification and illustrate exemplary embodiments for

practicing the invention. It is to be understood that other embodiments may be utilized, and structural or logical changes may be made without departing from the scope of the invention. The detailed description describes examples for practicing the invention and is not to be read to limit the scope of the invention. The scope of the invention is defined by the attached claims.

Figure 1 is an isometric and exploded view of an embodiment of the wound care device 10. The wound care device 10 comprises a first foam layer 20 having a first surface 30 and a second surface 40 opposite the first surface. The first surface 30 comprises a central portion 50 and an edge portion 60 circumferencing the central portion 50. The central portion 50 is provided with a pattern of grooves and ridges. On the second surface 40 of the first foam layer 20, a second foam layer 70 is attached. The second foam layer 70 is shown to be thicker than the first foam layer 20. The outline (shape) of the device 10 is substantially triangular with rounded corners. The device 10 of the illustrated embodiment is symmetric along a central longitudinal axis (Fig. 2). The triangular shape is ergonomic and pleasant to hold in the hand and work with cleaning a wound.

Figure 2 shows a plan view of the first surface 30 of the device 10 and Figure 3 shows a cross-section of the embodiment of Figure 2, along a central axis, marked A-A in Figure 2. The central portion 50 has a plurality of grooves 90 and ridges 100. The grooves 90 are defined by side walls 110 of the ridges 100. The grooves 90 are cut in the foam in a direction being substantially perpendicular to the first surface 30 of the first foam layer 30. In the illustrated embodiments, the side walls 110 of the ridges 100 have sharp edges. The grooves 90 are configured to collect debris from the wound. The sharp edges of the side walls 110 help to assist in scraping or otherwise obtaining the debris from the wound and getting the debris into the grooves 90. In the illustrated embodiment, the grooves 90 are arranged in a pattern of a first set of parallel lines crossed by a second set of parallel lines, optionally being perpendicular to the first set of lines, thereby defining a pattern of square-shaped ridges 100 between the grooves 90. The distance between the grooves of the first set of lines are marked in the Figure 2 as b and the distance between the grooves of the second set of lines are marked in the Figure 2 as c. The grooves 90 are cut partly through the first foam layer 20, leaving an uninterrupted part of the first foam layer 20 next to the second surface 40 of the first foam layer 20. The depth of the grooves is marked as d. The edge portion 60 is continuous in the sense it is not provided with grooves 90. The width of the continuous edge portion is marked in Figure 2 as a.

EXPERIMENTAL

The following Examples show tests which quantify the ability of a device to remove a test media from a test surface when pressed and repeatedly translated in a circular motion and conducted by a robot arm. Reported results are the weight of test substance [g] debrided by test specimen. The purpose of the test is to show the effect of the foam material and the effect of applying grooves to the wound care device.

The tests have been conducted with different foam types and compared with test results from a test performed on a known debridement product (not foam-based).

Materials:

Test media (artificial wound slough): Egg slough with controlled Viscosity. Egg slough consists of freeze-dried eggs suspended in water. The viscosity of the egg-slough is adjusted by the amount of water added.

Sample A:

Polyether based polyurethane foam sample size: 100x100x10mm. The specifications of the foam of Sample A appears from Table 1.

Sample B:

Polyester based polyurethane foam, sample size: 100X100x10 mm. The specifications of the foam of Sample B appears from Table 1.

Sample C:

DEBRISOFT debridement product, sample size 100x100x10 mm, the product consists of monofilament polyester fibres, with the reverse side being coated with polyacrylate.

TABLE 1

Property	Unit	specification	Sample B
Pore Size	Pores/cm	20-30	30 - 33

Density	Kg/m^3	24	28-35
Tensile Strength	KPa	125	206
Elongation	%	175	380
Tear Strength	N/cm	5,0	6.3
CLD@25%	KPa	2,6	1.37
CLD@65%	KPa	Max 15	2.75
Compression set @50%	%	-	20

Testing is done with Robot Setup UR3: Universal Robots, Denmark.

Grooves are cut with laser on a Universal Laser in "I" P55% and S90% resulting in grooves with depth of 7-8 mm. Test data rely on the following mesh design: 3mm, 5mm, 7mm, 9mm, 12mm and a reference sample without grooves. 10 mm edge portion is free off groves. All the mesh designs can be seen in Figure 4.

Before each test a well-defined amount of test media was added to the test surface to emulate a wound. The test then consisted of 6 test segments with measurements after each segment to provide thorough information about the debridement performance and mechanism. Reported results consist mainly of the weight of test media remaining on the test surface after each segment and the number of circular translations necessary to achieve acceptable cleaning (or if this is even possible).

One test segment consisted of compressing the sample and then performing a number of circular movements after which the sample was relieved of pressure and the remaining test media was inspected and weighed.

The less test media is left on the test surface the better the test specimen and the quicker that test media is removed, the better.

EXAMPLE 1

Testing mesh size versus repetitions

In this test was used egg slough with viscosity about 48 Pa.s and foam was Sample A.

The graphs in Figure 5 show that after 1 test segment (which is equal to 5 circular translations of the sample on the test surface) the sample with lower mesh spacing had higher adsorption. The 3mm mesh was best in the test series.

EXAMPLE 2

Testing effect of varying initial test media

Samples: Sample A, mesh sizes: 3, 5, 7, 9, 12mm and a reference sample (20mm).

Test media was used in three amounts: 5, 10, 15 g. Triple estimation.

Results from after the first test segment (5 circular motions) can be seen in Figure 6. The results show the same progress with use of different initial amounts of test media; that smaller mesh size provides the best absorption /adsorption. The tested samples generally achieve the best results with the smallest initial test media size of 5g.

The results after 3 segments (3*5 circular movements) can be seen in Figure 7. The results show the same progress as after the first segment, but the relative difference between groove designs was less pronounced. All tested designs continued to show the best result with a small initial test media size of 5g. Note that the reference sample with no grooves is shown as 25mm in the graph in Figures 6 and 7.

EXAMPLE 3

Comparison of different foams and debridement product

Samples: Sample A, B and C

In Figure 8 a one-way analysis of initial adsorption/absorption can be seen, both foam samples, Sample a and Sample B, are plain and have no grooves. The left figure shows the results after 1 segment, and it is very clear that Sample B has the best performance and Sample A the worst. The results are different if we see the results after 5 segments, here Sample B and Sample A show similar good performance while Sample C remains the worst with only a minor improvement with repeated movement.

Figure 8: Results from comparison of performance of Sample A, B and C. All the samples testes are plain and has no mesh design. Left figure shows performance after 1 segment and right figure shows performance after 5 segments.

In Figure 8a and 8b show the result of a one-way analysis of the two foams samples, Sample A and Sample B, compared to known debridement product, Sample C. Only test samples with mesh design of 5-7mm are included in the analysis. Sample C is not provided with grooves. Figure 8a shows the results after one segment, and it was very clear that Sample B has the best performance and Sample C the worst. The result after five segments had a completely different outcome, as shown in the Figure 8b. Here Sample C had only improves slightly and still ended up with worst performance, whereas Sample A and Sample B improve were ending up with almost equally good performance.

EXAMPLE 4

Testing laser cut versus knife-cut

In Figure 9a and 9b is shown a comparison of laser cut samples (Figure 9a) and knife-cut samples (Figure 9b), mesh size 7 mm and sample without grooves (shown as 25 mm) and 10g. initial test media with 48 Pa.s viscosity. The Samples used are Sample B. The first column represents results after 1 segment, the second column represents results after 3 segments and the third column represents results after 5 segments. No large significant effect is observed between the two ways of cutting the foam, both perform well.

EXAMPLE 5

Testing of slit depth

In Figure 10 is shown a bar diagram showing remaining test media as function as slit depth. All the samples (Sample A) have a slit size of 7mm. The test was made on three different slit depths; 3, 5 and 8mm and a sample without slits shown as 25 mm in the diagram). The different bars represent the data after 1, 3 and 5 segments, respectively. As can be seen from the Figure, the deeper slits, the better.

Claims

1. A wound care device for debriding a wound, said device comprising a first foam layer having a first and a second surface, the first surface comprising a central portion and an edge portion, where the central portion is provided with a plurality of grooves and ridges, and the edge portion is continuous, and the second surface of the first foam layer is provided with a second foam layer.

2. The wound care device according to claim 1, wherein the first foam layer is a hydrophilic foam.

3. The wound care device according to any of the preceding claims, wherein the second foam layer is a non-absorbent foam.

4. The wound care device according to any of the preceding claims, wherein the grooves are substantially parallel.

5. The wound care device according to any of the preceding claims, wherein a first set of grooves are in one direction and another set of grooves are in a direction perpendicular to the first set of grooves.

6. The wound care device according to any of the preceding claims, wherein the continuous edge portion has a width of 5-15 mm.

7. The wound care device according to any of the preceding claims, wherein the first and the second foam layer are joined to each other by an adhesive layer.

8. The wound care device according to any of the preceding claims, wherein the device has a substantially triangular outline.

9. The wound care device according to any of the preceding claims, wherein the first foam layer has a thickness being less than the thickness of the second foam layer.

10. The wound care device according to any of the preceding claims, wherein the ration between the thickness of the first and the second foam layer is 1:2.

11. The wound care device according to any of the preceding claims, wherein the device has rounded corners.

12. The wound care device according to any of the preceding claims, wherein second foam layer is coarser than the first foam layer.

13. The wound care device according to any of the preceding claims, wherein the grooves have a depth of 5-12 mm.

14. The wound care device according to any of the preceding claims, wherein the ridges have a width of 3-12 mm.

15. Method of cleaning a wound, comprising the steps of:

a. providing a wound care device for debriding a wound, said device comprising a first foam layer having a first and a second surface, the first surface comprising a central portion and an edge portion, where the central portion is provided with a plurality of grooves and ridges, and the edge portion is continuous, and the second surface of the first foam layer is provided with a second foam layer,

b. bringing the first foam layer in contact with the wound,

c. rotating the wound care device while applying a light pressure to remove slough and debris from the wound.

16. The method according to claim 15, wherein the method further comprises wetting the wound care device before contacting the wound with the wound care device.

17. The method according to claim 15 or 16, wherein the method further comprises initially bringing the second foam layer in contact with the wound and using the second foam layer to remove rough debris.

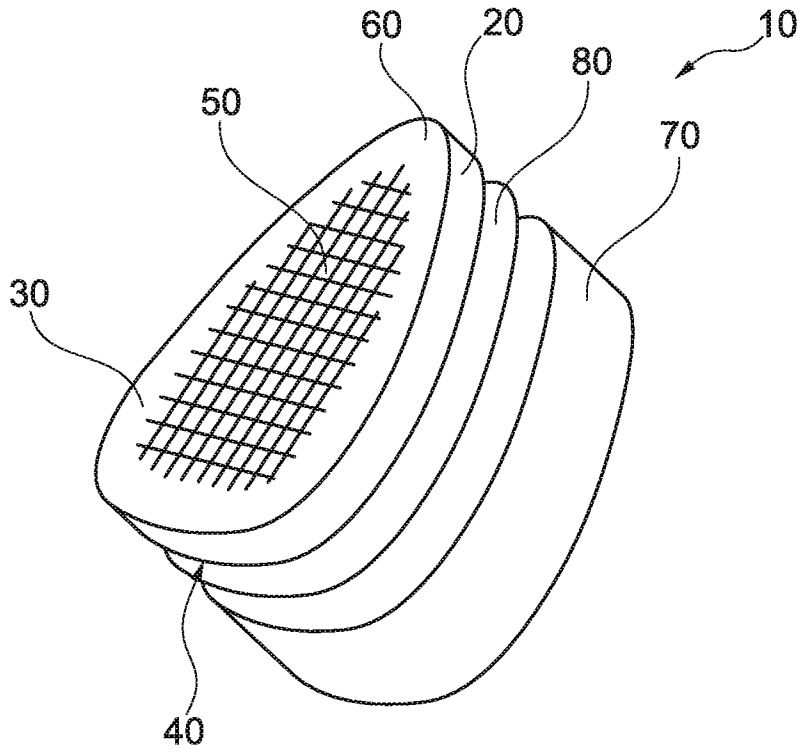

Fig. 1

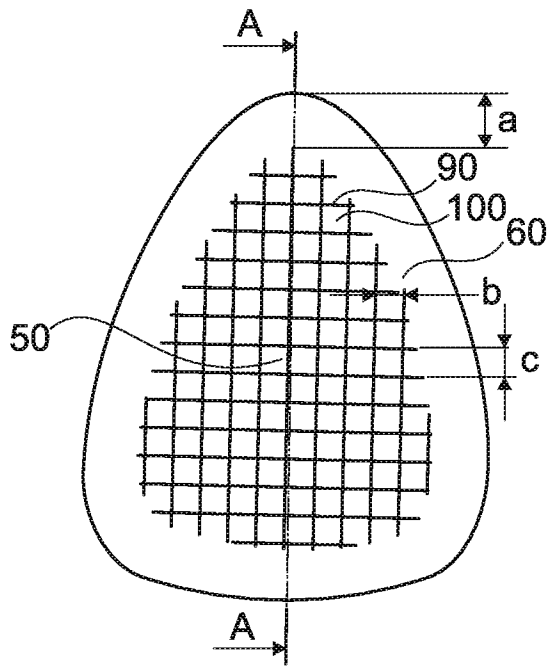

Fig. 2

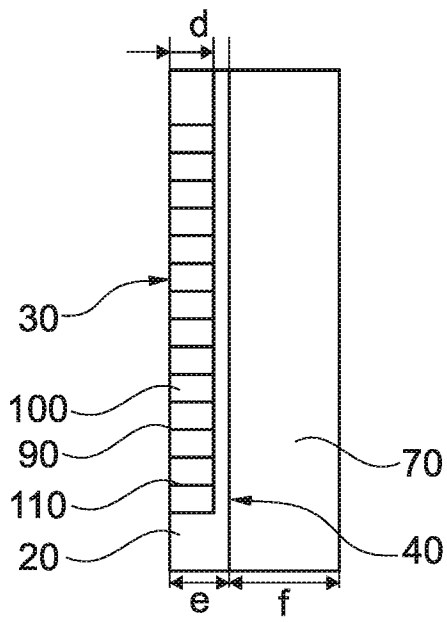

Fig. 3

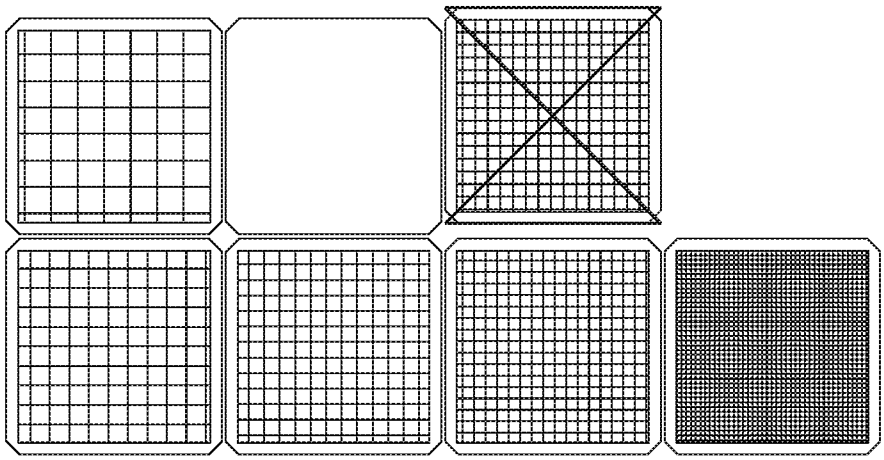

Fig. 4

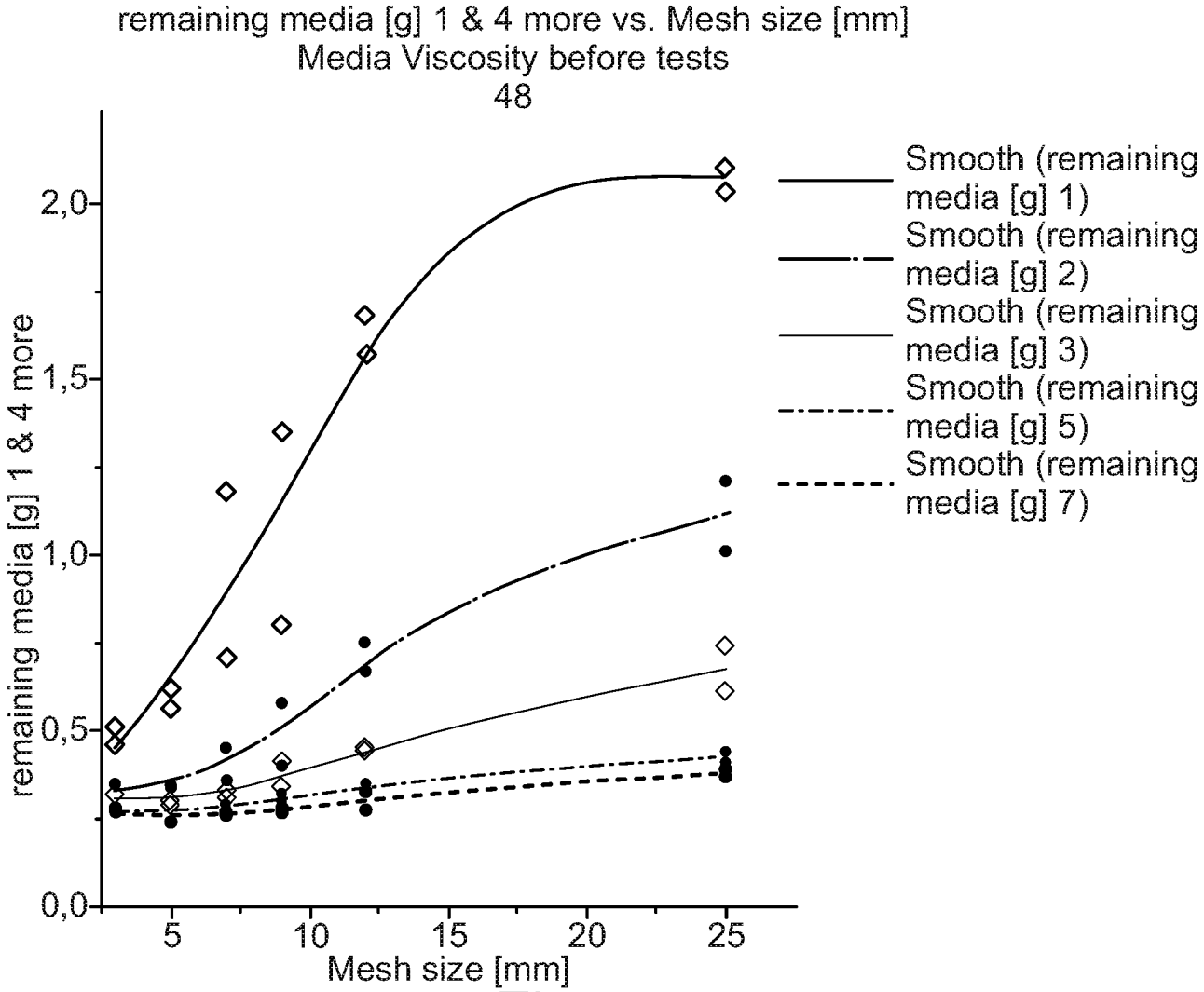
remaining media [g] 1 & 4 more vs. Mesh size [mm]
Media Viscosity before tests
48
remaining media [g] 1 & 4 more
2,0
1,5
1,0
0,5
0,0
5
10
15
20
25
Mesh size [mm]
Smooth (remaining media [g] 1)
Smooth (remaining media [g] 2)
Smooth (remaining media [g] 3)
Smooth (remaining media [g] 5)
Smooth (remaining media [g] 7)

Fig. 5

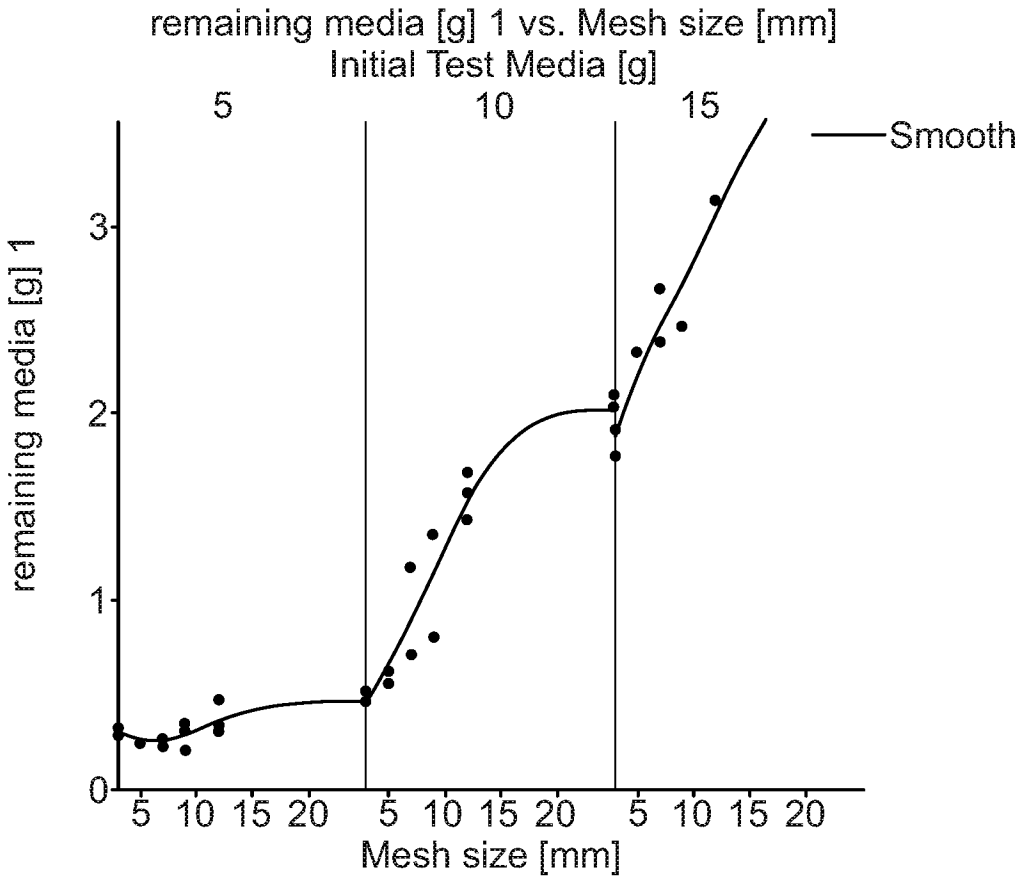
remaining media [g] 1 vs. Mesh size [mm]
Initial Test Media [g]
5
10
15
Smooth
remaining media [g] 1
0
1
2
3
5 10 15 20 5 10 15 20 5 10 15 20
Mesh size [mm]

Fig. 6

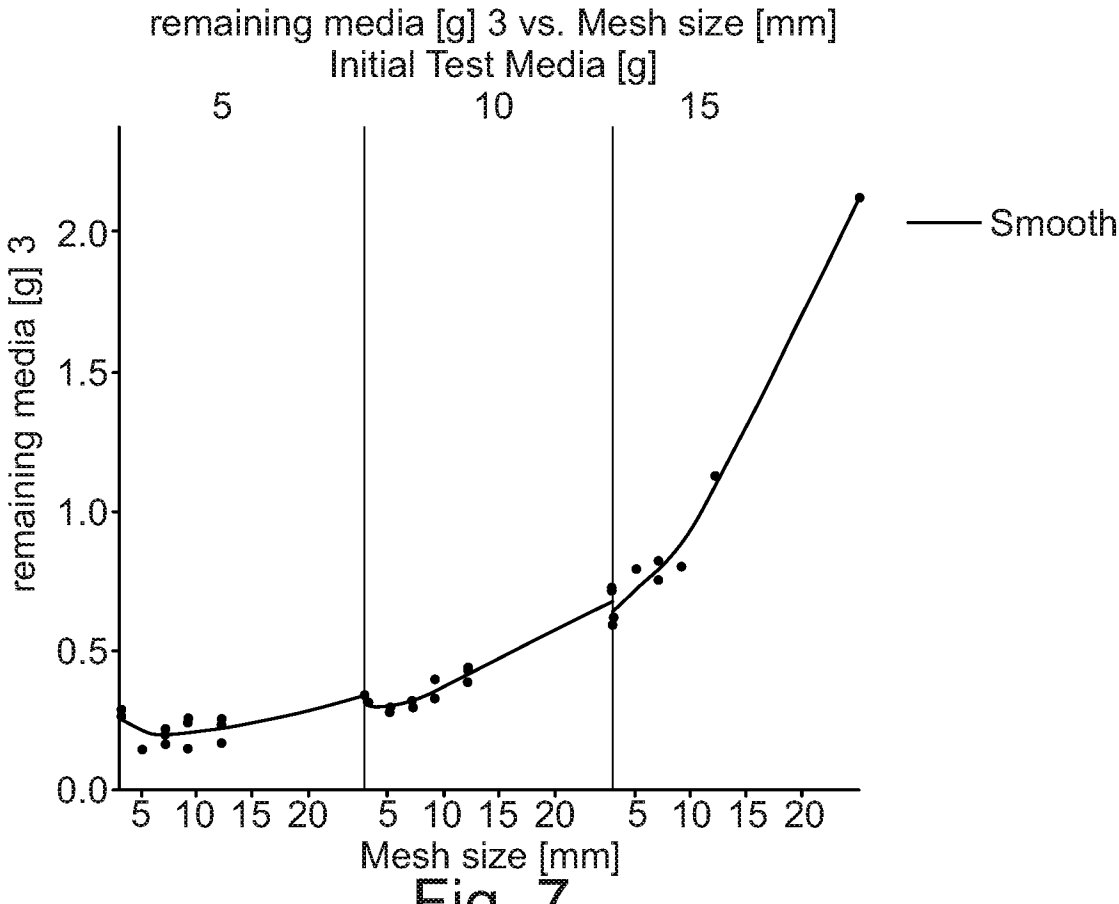
remaining media [g] 3 vs. Mesh size [mm]
Initial Test Media [g]
5
10
15
Smooth
remaining media [g] 3
0.0
0.5
1.0
1.5
2.0
5 10 15 20 5 10 15 20 5 10 15 20
Mesh size [mm]

Fig. 7

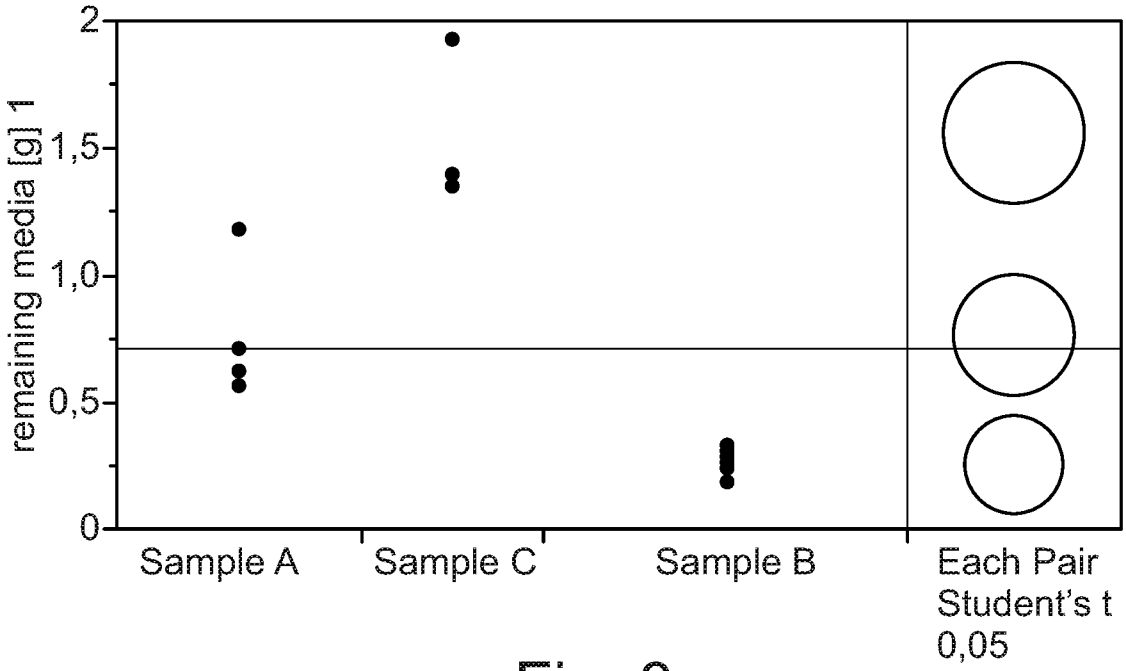
remaining media [g] 1
2
1,5
1,0
0,5
0
Sample A
Sample C
Sample B
Each Pair
Student's t
0,05

Fig. 8a

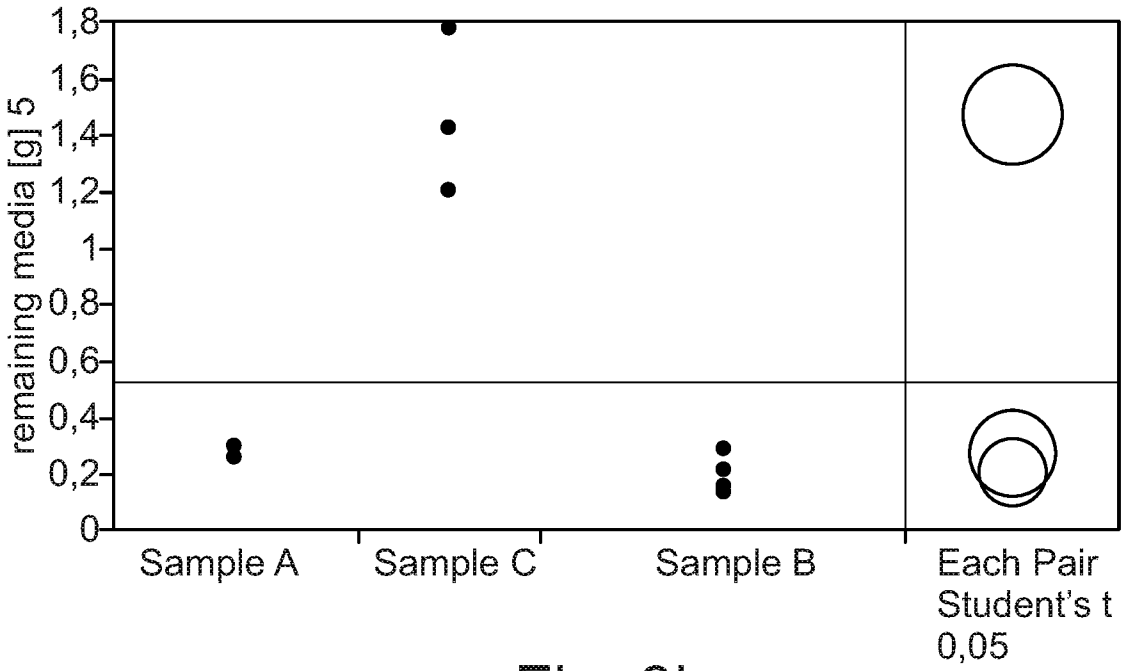
remaining media [g] 5
1,8
1,6
1,4
1,2
1
0,8
0,6
0,4
0,2
0
Sample A
Sample C
Sample B
Each Pair
Student's t
0,05

Fig. 8b

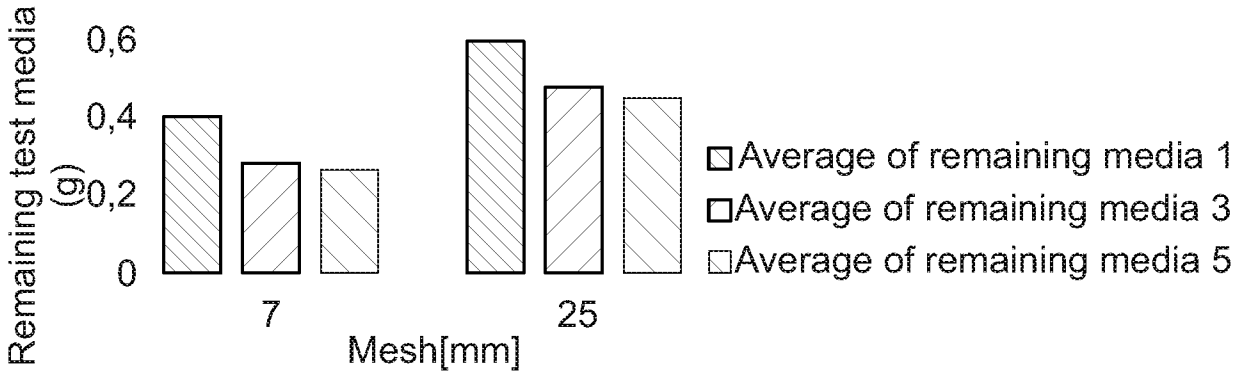
Remaining test media (g)
0,6
0,4
0,2
0
7
25
Mesh[mm]
Average of remaining media 1
Average of remaining media 3
Average of remaining media 5

Fig. 9a

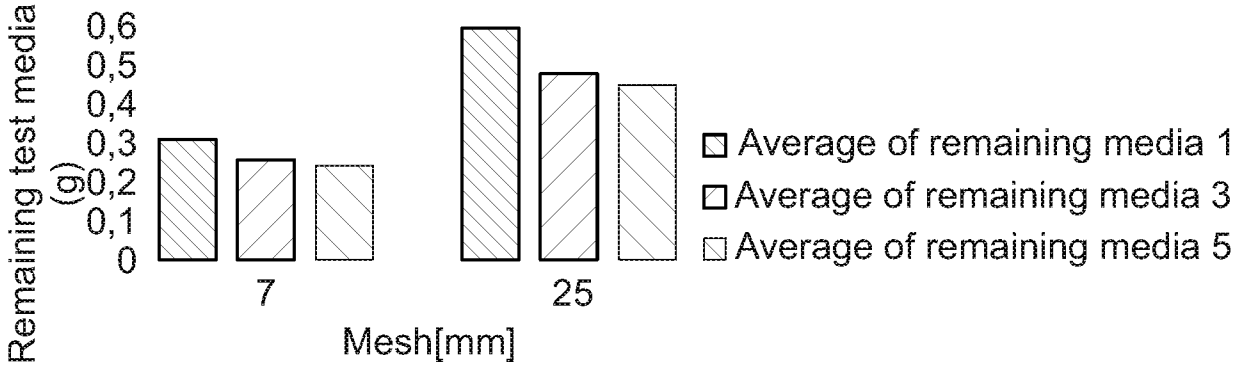
Remaining test media (g)
0,6
0,5
0,4
0,3
0,2
0,1
0
7
25
Mesh[mm]
Average of remaining media 1
Average of remaining media 3
Average of remaining media 5

Fig. 9b

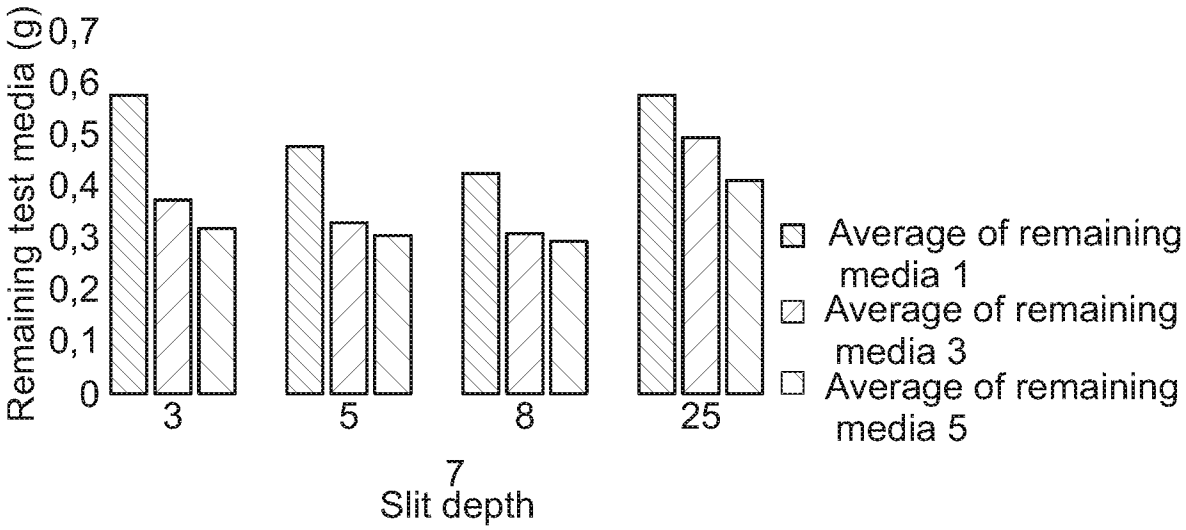
Remaining test media (g)
0,7
0,6
0,5
0,4
0,3
0,2
0,1
0
3
5
7
8
25
Slit depth
Average of remaining media 1
Average of remaining media 3
Average of remaining media 5

Fig. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/DK2018/050229

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/00
ADD.

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)
A61F A61L

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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 2017/019868 A1 (CURALINE INC [US]) 2 February 2017 (2017-02-02) examples 18,22 figures 1,3,6A,6B,7A-7F paragraphs [0002], [0005], [0006], [0025], [0078] - [0093], [0097], [0099] - [0111] -----	1,2,4,5, 8-14 1-14
X Y	WO 2015/169637 A1 (HARTMANN PAUL AG [DE]) 12 November 2015 (2015-11-12) claims 1,3-9 figures 1,3a,3b page 5, lines 23-33 page 8, line 16 - page 9, line 25 page 10, lines 28-33 -----	1-4,7-14 1-14
	-/--	

[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 application or patent 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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 November 2018	03/12/2018

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, Fax: (+31-70) 340-3016	Schmitt-Humbert, C

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK2018/050229

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.: 15-17
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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 all searchable 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 report covers 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.

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 2 985 013 A2 (BARBERIO ALESSANDRO [CA]) 17 February 2016 (2016-02-17) figures 1,2,15c claims 1,2,6,10 paragraphs [0013], [0026], [0037]	1-14
A	CATHERINE MEADS ET AL: "The Debrisoft? Monofilament Debridement Pad for Use in Acute or Chronic Wounds: A NICE Medical Technology Guidance", APPLIED HEALTH ECONOMICS AND HEALTH POLICY, vol. 13, no. 6, 1 December 2015 (2015-12-01), pages 583-594, XP055377171, ISSN: 1175-5652, DOI: 10.1007/s40258-015-0195-0 abstract section 3.2 Intervention	1-14
A	EP 0 552 933 A1 (MCNEIL PPC INC [US]) 28 July 1993 (1993-07-28) abstract claims 1-15	1-14
A	US 2004/092895 A1 (HARMON KIM R [US]) 13 May 2004 (2004-05-13) abstract figures 1,2 paragraphs [0010], [0023], [0024]	1-14

1

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 15-17

Claims 15-17 are directed to a method of cleaning a wound based on the use of a wound care device comprising a first foam layer and a second foam layer. The method uses the mechanical properties of the device in order to debride a wound. Claims 15-17 are thus considered to be directed to a method of treatment of the human or animal body using a device. Method of treatment of the human/animal body are excluded from patentability (Rule 39.1(iv) PCT).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/DK2018/050229

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2017019868 A1	02-02-2017	EP 3328460 A1	06-06-2018
		WO 2017019868 A1	02-02-2017
WO 2015169637 A1	12-11-2015	DE 102014106518 A1	12-11-2015
		EP 3139877 A1	15-03-2017
		WO 2015169637 A1	12-11-2015
EP 2985013 A2	17-02-2016	NONE	
EP 0552933 A1	28-07-1993	AT 154752 T	15-07-1997
		AU 666156 B2	01-02-1996
		BR 9300228 A	27-07-1993
		CA 2087674 A1	22-07-1993
		DE 69311743 D1	31-07-1997
		DE 69311743 T2	11-12-1997
		EP 0552933 A1	28-07-1993
		ES 2105094 T3	16-10-1997
		JP H0819567 A	23-01-1996
		KR 100248677 B1	15-03-2000
		TW 405401 U	11-09-2000
		US 5648141 A	15-07-1997
		ZA 9300396 B	20-07-1994
US 2004092895 A1	13-05-2004	NONE	