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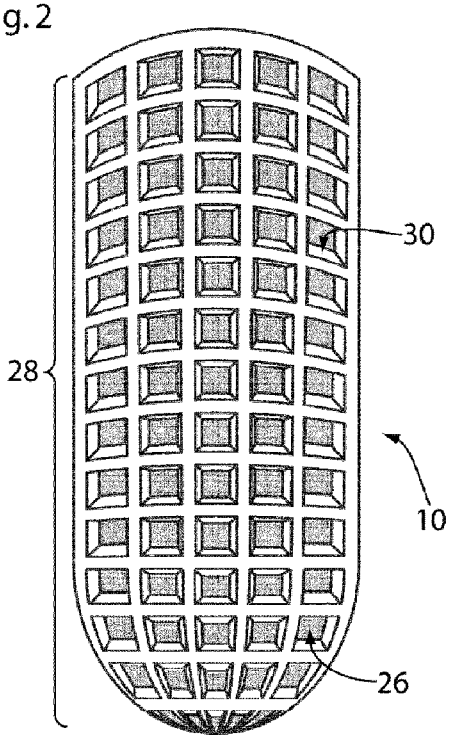
[Continued on next page]

(54) Title: DIAGNOSTIC LINERS SYSTEM FOR PROSTHETIC SOCKETS

Fig. 2



(57) Abstract: A diagnostic liner system for visual assessment of prosthetic limb socket fit, comprising a diagnostic sheath that fits within a check socket, the sheath having a surface with an array of compressible elements that are compressed within the check socket in proportion to pressure exerted on areas of the sheath by areas of a residual limb inserted into the check socket. A transparent test socket can be used as the check socket.

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Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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DIAGNOSTIC LINERS SYSTEM FOR PROSTHETIC SOCKETS

SPECIFICATION

FIELD OF INVENTION

This invention relates to the general field of aids to prosthetic limbs, and more specifically to a diagnostic liner system enabling the optimal measurement and fitting of prosthetic sockets used for the eventual permanent fitting of definitive prosthetic limb sockets.

BACKGROUND OF THE INVENTION

A prosthetic check socket is a temporary socket used to determine the optimal fit and dynamic alignment for an amputee's definitive socket. As a residual limb heals, its volume and configuration can change drastically. Multiple assessments are often required to determine optimal fit of a check socket before the definitive prosthetic socket is made. Because a check socket is most often made from transparent thermoplastic, it has been the practice to diagnose fit by looking at the pressure marks made on the skin by the socket. With the advent of prosthetic liners, this visual clue is no longer available because the liner is too thick or is opaque.

An artificial limb (prosthesis) has several parts, the components which are purchased from the manufacturers and the socket which is designed and manufactured by the prosthetist. The socket is the part that interfaces with the body, and transfers the weight of the person through to the components. There is usually a silicone or "gel" liner that is worn between the prosthetic socket and the skin in order to reduce shear forces and provide some cushioning. The components are everything attaching to an adapter plate under the socket such as the prosthetic knee, leg, or foot.

When there is excess pressure on an area of the residual limb (stump), it will eventually cause skin breakdown. The socket is designed as to take weight where the body can tolerate, and offload where it cannot. There are several areas on the residual limb where even a small amount of pressure can cause residual breakdown. When fitting a new prosthesis, a prosthetist first completes what is called a check socket, or diagnostic socket. It is a clear thermoplastic "prototype" that is used to determine the fit before continuing on to more expensive materials. It is also a see-through and heat moldable material, so changes can be made as needed before going on to the "definitive" socket.

When fitting the check socket, there is no way of telling the skin pressure that is being applied to each part of the residual limb until the prosthesis is taken off and the liner removed. Before liners became common practice in prosthetics, the prosthetist could see the skin directly through the check socket plastic, and the color changes would show the pressures being applied. With liners, this is no longer possible, as one cannot see the thickness of the silicone or any color changes that allow one to diagnose the pressure on the skin. One can look for red areas on the skin after the prosthesis is taken off, but this method

is not always predictive as the red areas could be caused by factors other than pressure.

Known prior art solutions include the use of liners with surface variations such as rings or other features devised so that liner will grip the inside of the socket and provide appropriate cushion and ventilation. These features are not intended to be used to diagnose or fit a check socket, and therefore are not optimal solutions. Another method is the use of liners embedded with electronic pressure sensors or with materials able to detect and display specific pressures by means of color changes. The first method requires specialized electronic equipment to interpret and localize the pressure readings, and the second method is not reusable. Both methods are not optimal given the global need for accurate inexpensive prosthetic limb fittings. An even more specialized and expensive solution is the use of 3D laser scanning of the residual limb in order to 3D print a check socket.

An inexpensive, simple & reusable diagnostic liner is needed.

BRIEF SUMMARY OF THE INVENTION

The disclosed diagnostic liner system is designed to provide visual and quantifiable assessment of check socket fit. It is easier to use than prior art solutions, less expensive, and reusable. The diagnostic liner is pulled over the generic liner, and fits inside the check socket. The diagnostic liner is a thin prosthetic sheath that has silicone or gel compressible elements that allow the prosthetist to see exactly how much pressure is being applied over all surface areas of the residual limb. The diagnostic liner system provides a quantitative evaluation of

the fit of the check socket, so that the prosthetist can design a definitive socket that fits comfortably, securely, and prevents pressure sores, residual limb degradation and prosthetic instabilities.

Essentially the invention provides a diagnostic liner system for visual assessment of prosthetic limb socket fit, comprising a diagnostic sheath that fits within a check socket, the sheath having a surface with an array of compressible elements that are compressed within the check socket in proportion to pressure exerted on areas of the sheath by areas of a residual limb inserted into the check socket. A transparent test socket can be used as the check socket. However, the invention will work also if a definitive socket on a prosthetic limb is used as the check socket. The sheath can likewise be specific to the diagnostic phase and additional to a generic liner, but a functional equivalent would be to have the compressible elements are embodied directly into a generic liner as the sheath.

In a preferred embodiment,

a) the array of compressible elements comprises projections of a regular geometric shape;

b) the check socket is transparent and an extent of compression of the compressible elements is visible through the check socket;

c) the compressible elements are made of elastomeric material that compresses when stressed, and retains a resulting shape when a compression force is released;

The invention also discloses a method for visual assessment of prosthetic limb socket fit, using a diagnostic sheath that fits within a check socket, the sheath having a surface with an array of compressible elements that are compressed within the check socket in proportion to pressure exerted on areas of the sheath by areas of a residual limb inserted into the prosthetic limb socket to detect specific areas of the check socket that create too great or too little pressure on the residual limb.

The compressed element pattern is used by a prosthetist to quantify a shape of a deformity by visibly marking the compressed element pattern onto an outside surface of the check socket. Preferably, the check socket is transparent, and the prothetist visually checks for areas of noticeable compression of the compressible elements. Compressed projections forming the compressible elements are measured, compression of the compressible elements is accurately characterized in detail, and requisite adjustment information is marked on the check socket for later adjustment of the check socket. After the diagnostic sheath is removed from the check socket, the check socket is reshaped by referring to the corrective information provided by the diagnostic sheath and its compressed elements for correct shape to fit a residual limb and the check socket is then used as a template for a definitive (final) socket.

A luminescent dye used in the compressible elements can be illuminated with a black light. A visual check is then made of the diagnostic sheath within otherwise opaque laminations of a even the definitive socket, and calibrations and fine adjustments are made to the definitive socket.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1a shows the side view of the basic elements of a prior art prosthetic leg and liner as worn.

Fig. 1b shows an isometric view of a prior art check socket.

Fig. 2 shows a front view of a diagnostic liner employing the grid compression method.

Fig. 3a shows a closeup of the grid area. Fig. 3b shows a raised area on a residual limb. Fig. 3c shows a simplified version of the grid area in Fig. 3a. Fig. 3d shows the compression of a portion of the grid caused by the raised area on a residual limb.

Fig. 4 shows a front view of a diagnostic liner employing the projection compression method.

Fig. 5a shows a closeup of an array of projections attached to the diagnostic liner sheath. Fig. 5b shows a side view of a closeup of two projections in contact with the inside of the check socket. Fig. 5c shows Fig. 5a with a raised area compressing projections. Fig. 5d shows a side view of the projections compressed by the check socket.

DETAILED DESCRIPTION

All elements will now be introduced by reference to figures. The function of each element and its interaction with other elements will then be described where necessary.

Fig. 1a shows the side view of the basic elements of a prior art prosthetic limb 38 with a generic liner 16 as worn over the residual 14 portion of the amputated limb 12, and fitted into a prosthetic socket 18, which attaches to assistive components 22 by means of an adapter 20. Fig. 1b shows an isometric view of a translucent prior art check socket 24 with its component adapter 20.

Fig. 2 shows a front view of the preferred embodiment of a diagnostic liner 10 with a grid 28 of evenly spaced walls 30 protruding from a thin inner sheath 26.

Fig. 3a shows a closeup of the grid 28 area made of compressible walls 30. Fig. 3b shows a raised area 42 on a residual limb 14. Fig. 3c shows a simplified version of the grid 28 area in Fig. 3a in order to illustrate the effect of the raised area 42 as it compresses the grid 28 against the inside surface of the check socket 24. Note: the transparent check socket 24 is assumed to be in a plane covering, but not obscuring the elements of Figs. 3a-c & 5a & 5c. (see Figs. 5b & 5d) Fig. 3d shows compressed elements 34 (walls) of the grid 28 caused by the raised area 42 (hatched ellipse), and how the extent of compression 36 would be measurable through the check socket 24. The raised area 42 signifies a part of the residual limb 14 which exerts unwanted pressure on the check socket 24 in spite of the use of a generic liner 16.

Fig. 4 shows a front view of an alternate embodiment of a diagnostic liner 10 with an array 40 of projections 32 (hemispherical nubs) protruding from the surface of the underlying sheath 26.

Fig. 5a shows a closeup of an array 40 of projections 32 on the sheath 26 of a diagnostic liner 10 as shown in Fig. 4. Fig. 5b shows a side closeup view of the two central projections 32 from Fig. 5a in contact with the inside surface of the check socket 24 (as explained in the note about Fig. 3c above). Fig. 5c shows Fig. 5a with a raised area 42 pressing the proximate projections 32 upwards into the inside surface of the check socket 24 and revealing the extent of compression 36 visible through the check socket 24. Fig. 5d shows a side closeup view of two compressed elements 34 and the measurable extent of their compression 36 caused by the raised area 42 (hatched ellipse in Fig. 5c) compressing the projections 32 and underlying sheath 26 into the inside of the check socket 24.

The diagnostic liner system 10, will now be described in detail, beginning with the preferred embodiment, the grid compression implementation, and then an alternate embodiment, the projection compression implementation.

As outlined in the background, there is a need for a diagnostic liner and method of implementation 10 which permits the prosthetist to readily and affordably detect specific areas of the check socket 24 that either create too great or too little pressure on the residual limb 14. A raised area 42 on a residual limb 14 represents potentially harmful pressure point, and a depressed area represents a potential area of prosthetic socket 18 instability.

The grid compression implementation employs a diagnostic liner 10 as shown in Fig. 2 which is able to detect and quantify a raised area 42 as illustrated in Fig. 3d. The walls 30 of the grid 28 are compressed by the raised area 42 pressing the diagnostic liner 10 into the inside of the check socket 24 as indicated by the compressed element 34 which is visible through the wall

of a check socket 24. By this means, the compressed element 34 pattern created by a raised area 42 can allow the prosthetist to quantify the shape and height of the underlying deformity by visibly marking the compressed element 34 pattern onto the outside of the check socket 24. Once removed, the thermoplastic check socket 24 can then be reshaped by a heat gun by referring to the corrective information provided by the diagnostic liner 10.

It is anticipated that standards of measuring the compressed element 34 could be used to design diagnostic protocols that would allow the prosthetist to make precise and consistent shape modifications to a check socket 24. Shape modifications could be quantified by known deformation rates of thermoplastics, as determined by quantified heating rates, distances and angles of a heat gun. By means of the grid compression implementation of the diagnostic liner 10, a check socket 24 can be tailored precisely to fit the unique shape of an amputee's residual limb 14.

The diagnostic liner 10 may be worn over, or may take the place of the generic liner 16 during the fitting analysis, depending on its chosen thickness. It is conceivable that a selection of diagnostic liners 10 of graduated thicknesses will be employed. The prosthetist should select a diagnostic liner 10 thick enough so that the majority of its grid 30 surface is in equal contact with the inside of the check socket 24, but not so thick that only compressed elements 34 are detectable. At the end of the diagnostic fittings and check socket 24 adjustments, the diagnostic liner 10 should contact all areas of the inside of the check socket 24 equally and without undue compression 36.

An alternate embodiment of the diagnostic liner system 10, the projection compression

implementation will now be described. Other embodiments are not ruled out or similar methods leading to the same result. The projection compression implementation employs a diagnostic liner 10 as shown in Fig. 4 with an array 40 of projections 32 (hemispherical nubs) on its sheath 26. As shown in Figs. 5a & 5b, when the diagnostic liner 10 is in equal contact with the check socket 24, only the zenith of each projection 32 is in contact with its inner surface. Figs. 5c & 5d show how a raised area 42 of the residual limb 14 causes noticeable compression 36 of the top of nearby projections 32 which provide a visual indication through the transparent check socket 24 of an area of greater pressure. A diagnostic protocol comparable to the grid implementation would include measuring the diameter of the compression 36 of projections 32 as well as displacement from the center-point of each projection 32 if apparent. The raised area 42 would then be accurately characterized in detail, and this information could be visibly marked on the check socket 24 for adjustment as described above.

In both grid 28 and projection 32 implementations, the density, distances between, and size of the diagnostic elements, namely grid walls 30 or nub projections 32, would be determined by the object of providing the most accurate and useable information for the prosthetist. If the grid 28 is too dense, its walls 30 will not splay sufficiently to be measurable through the check socket 24. If the grid 28 is too wide, it cannot provide enough information for an optimal fit. If the walls 30 are too thin, they cannot show sufficient compression 36. If the projections 32 are too few or too small, an optimal fit is not possible, whereas if they are too large or too close together, they cannot provide useful information because their compression may not be detectable. Also, the density and malleability of the material used to construct the diagnostic liner 10 will also play a part in determining the physical parameters of its surface

features. In the present embodiments, the grid walls 30 are 1 centimeter (cm) wide, 3 cm apart, and 2 – 5 mm above the 1 mm thick sheath 26, whereas projection nubs 32 are 1 cm in diameter, 3 cm apart and 2 – 5 mm above the 1 mm thick sheath 26. Note that while Figs. 2 & 4 show a cylindrical shape of the liner 10, alternate liner shapes, including a cone like geometry or combinations thereof, are claimed as part of the invention. Application research will determine the appropriate shape required to provide optimal check socket 24 fitting.

Other variations of the grid compression implementation include a grid 28 comprised of interconnecting shapes of any appropriate geometry, such as triangles, pentagons, hexagons, etc. Variations of the projection compression implementation can include any shape of projection 32 that provides equivalent outcomes such as 3 or 4 sided pyramids, small spheres attached to a supporting substructure, flattened cones, etc. The diagnostic liner and method 10 could also be employed as an upper limb prosthetic check socket fitting tool.

The preferred materials for constructing a diagnostic liner 10 will now be described. The diagnostic liner 10 will be preferably made from silicone or gel like material. Silicone has the unique property that it does one “creep” when stressed, and retains its shape when compressed and released. Other materials of similar properties or capable of achieving equivalent objects are being investigated and may be utilized. The sheath 26 can be made from the same material, and the entire diagnostic liner 10 may be bonded together in several stages or molded as a complete unit. Alternately, the sheath 26 may be made from a generic liner 16 material, and either grid 28 or projections 32 would be embedded into or formed onto its surface. The top surface of the diagnostic liner 10 may be formed from a less sticky material than silicone so that it can be properly inserted into the check socket 24. A lubricant

spray may be required to ensure proper pre-diagnostic alignment of the grid 28 or projections 32 within the check socket 24.

The description of the preferred and alternate apparatus, method of installation and use should be considered as illustrative only, and not limiting. Other forming techniques and other materials or methods may be employed towards similar ends. For example, an additional embodiment of the disclosed invention incorporates a liner sock inside the novel diagnostic liner mesh. Liner socks are used to allow easy fitting of a socket onto the limb by providing a low friction surface such as nylon or similar fabric. By this means the liner sock is fitted over one's residual limb and then the check socket (or diagnostic liner) can be easily fitted without abrasion to the residual limb. This embodiment provides for the low friction liner sock to be made together with the diagnostic liner as one unit. By this means the diagnostic liner can be fitted over the residual limb with ease and then the check socket may be properly fitted by analyzing the deformation of the diagnostic liner.

Another embodiment includes the addition of fluorescent, luminescent, phosphorescent or equivalent dyes into the elastomeric material (silicone gel or equivalent) during the manufacturing of a diagnostic liner. Fluorescent silicone or similar products can glow if illuminated by a black light. By making the diagnostic liner more visible through the transparent check socket, the diagnostician can more readily detect small variations in the compressed elements or grid elements of the liner, and thereby provide a more definitive assessment of proper check socket fitting as a guide to designing the best fitting definitive socket.

The definitive (or final) socket is made using the diagnostic socket as a template by laminating with fabric and resin which makes it stronger and lighter, but is also not transparent under normal conditions. By using a fluorescent diagnostic liner and by illuminating the definitive socket with a black light, the diagnostician can observe visible distortion of the silicone liner through the socket normally opaque laminations. By this means, a fluorescent diagnostic liner can be used to calibrate the correct fitting of both check and definitive sockets.

Various changes and modifications will occur to those skilled in the art, without departing from the true scope of the invention as defined in the present disclosure and associated drawings.

DIAGNOSTIC LINERS SYSTEM FOR PROSTHETIC SOCKETS

CLAIMS

1. A diagnostic liner system for visual assessment of prosthetic limb socket fit, comprising a diagnostic sheath that fits within a check socket, the sheath having a surface with an array of compressible elements that are compressed within the check socket in proportion to pressure exerted on areas of the sheath by areas of a residual limb inserted into the check socket.

2. The diagnostic liner system of Claim 1, in which the array of compressible elements is a grid of evenly spaced compressible walls.

3. The diagnostic liner system of Claim 1, in which the array of compressible elements comprises projections attached to the diagnostic liner sheath

4. The diagnostic liner system of Claim 3, in which the projections are nubs of a regular geometric shape.

5. The diagnostic liner system of Claim 1, in which the check socket is transparent and an extent of compression of the compressible elements is visible through the check socket.

6. The diagnostic liner system of Claim 1, further comprising a selection of like diagnostic liners of graduated thicknesses.

7. The diagnostic liner system of Claim 2, in which the compressible elements are 1 cm. wide, 3 cm. apart, and in a range of 2 to 5 mm. above the surface of the sheath.

8. The diagnostic liner system of Claim 1, in which the sheath is 1 mm. thick in areas between the compressible elements.

9. The diagnostic liner system of Claim 1, in which the sheath is a substantially cone-shaped.

10. The diagnostic liner system of Claim 1, in which the compressible elements are made of elastomeric material that compresses when stressed, and retains a resulting shape when a compression force is released.

11. The diagnostic liner system of Claim 1, in which the sheath is formed from a generic liner, and the array of compressible elements is formed onto the surface of the sheath.

12. The diagnostic liner system of Claim 1, in which an opposing surface of the diagnostic sheath is formed from a less sticky material than an elastomeric material used for the array of compressible elements, for the diagnostic sheath when fitted on a residual limb to be easily inserted into the check socket.

13. The diagnostic liner system of Claim 1, in which the elastomeric material includes luminescent dye to facilitate visibility of distortion of the compressible elements through a normally opaque socket when illuminated by a black light.

14. The diagnostic liner system of Claim 1, in which:

a) the array of compressible elements comprises projections of a regular geometric shape;

b) the check socket is transparent and an extent of compression of the compressible elements is visible through the check socket;

c) the compressible elements are made of elastomeric material that compresses when stressed, and retains a resulting shape when a compression force is released;

15. The diagnostic liner system of Claim 1, in which the elastomeric material is silicon.

16. A method for visual assessment of prosthetic limb socket fit, using a diagnostic sheath that fits within a check socket, the sheath having a surface with an array of compressible elements that are compressed within the check socket in proportion to pressure exerted on areas of the sheath by areas of a residual limb inserted into the prosthetic limb socket to detect

specific areas of the check socket that create too great or too little pressure on the residual limb.

17. The method of Claim 16, in which the diagnostic sheath is pulled over a generic liner on a residual limb and inserted inside the check socket.

18. The method of Claim 16, in which a compressed element pattern is used by a prosthetist to quantify a shape of a deformity by visibly marking the compressed element pattern onto an outside surface of the check socket.

19. The method of Claim 16, in which after the diagnostic sheath is removed from the check socket, the check socket is reshaped by referring to the corrective information provided by the diagnostic sheath and its compressed elements.

20. The method of Claim 16, in which standards of measuring the compressed elements are used to design diagnostic protocols that allow a prosthetist to make precise and consistent shape modifications to a check socket.

21. The method of Claim 16, in which shape modifications to the check socket are quantified by known deformation rates of thermoplastics, as determined by quantified heating rates, distances and angles of a heat gun for a check socket made of thermoplastic material.

22. The method of Claim 16, in which a prosthetist selects from a selection of diagnostic sheaths of graduated thicknesses one that is thick enough so that the majority of its compressible elements are in equal contact with an inside surface of the check socket, but not so thick that only compressed elements are detectable after insertion of the residual limb with the diagnostic sheath into the check socket.

23. The method of Claim 16, in which the check socket is transparent, and a prothetist visually checks for areas of noticeable compression of the compressible elements.

24. The method of Claim 16, in which a diameter of compressed projections forming the compressible elements is measured.

25. The method of Claim 16, in which displacement by compression from a center-point of each projection is measured.

26. The method of Claim 16, in which compression of the compressible elements is accurately characterized in detail, and requisite adjustment information is marked on the check socket for later adjustment of the check socket.

27. The method of Claim 16, in which a liner sock having a low friction surface is fitted around the sheath on a residual limb to facilitate insertion into the check socket.

28. a lubricant spray is used to facilitate precise movement of a residual limb and the diagnostic sheath within a check socket to ensure proper pre-diagnostic alignment of the array of compressible elements within the check socket.

29. The method of Claim 16, in which the check socket is adjusted for correct shape to fit a residual limb and is then used as a template for a definitive socket.

30. The method of Claim 16, in which a luminescent dye used in the compressible elements is illuminated with a black light, a visual check is made of the diagnostic sheath within otherwise opaque laminations of a definitive socket, and calibrations and reshaping adjustments are made to the definitive socket.

31. The method of Claim 18, in which:

a) the check socket is transparent, and a prothetist visually checks for areas of noticeable compression of the compressible elements;

b) compressed projections forming the compressible elements are measured, compression of the compressible elements is accurately characterized in detail, and requisite adjustment information is marked on the check socket for later adjustment of the check socket;

c) after the diagnostic sheath is removed from the check socket, the check socket is reshaped

by referring to the corrective information provided by the diagnostic sheath and its compressed elements for correct shape to fit a residual limb and the check socket is then used as a template for a definitive socket.

32. The method of Claim 31, in which a luminescent dye used in the compressible elements is illuminated with a black light, a visual check is made of the diagnostic sheath within otherwise opaque laminations of a definitive socket, and calibrations and reshaping adjustments are made to the definitive socket.

Fig. 1a

PRIOR ART

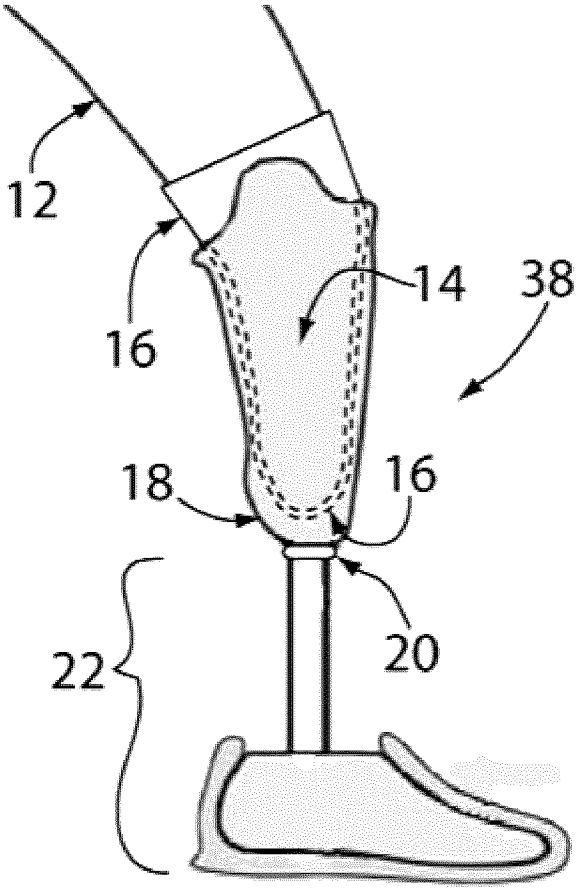


Fig. 1b

PRIOR ART

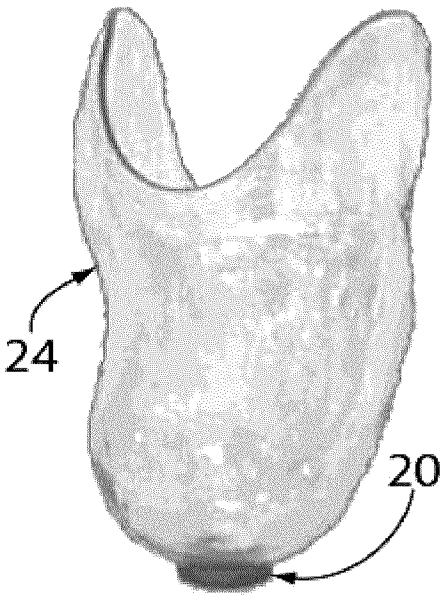


Fig. 2

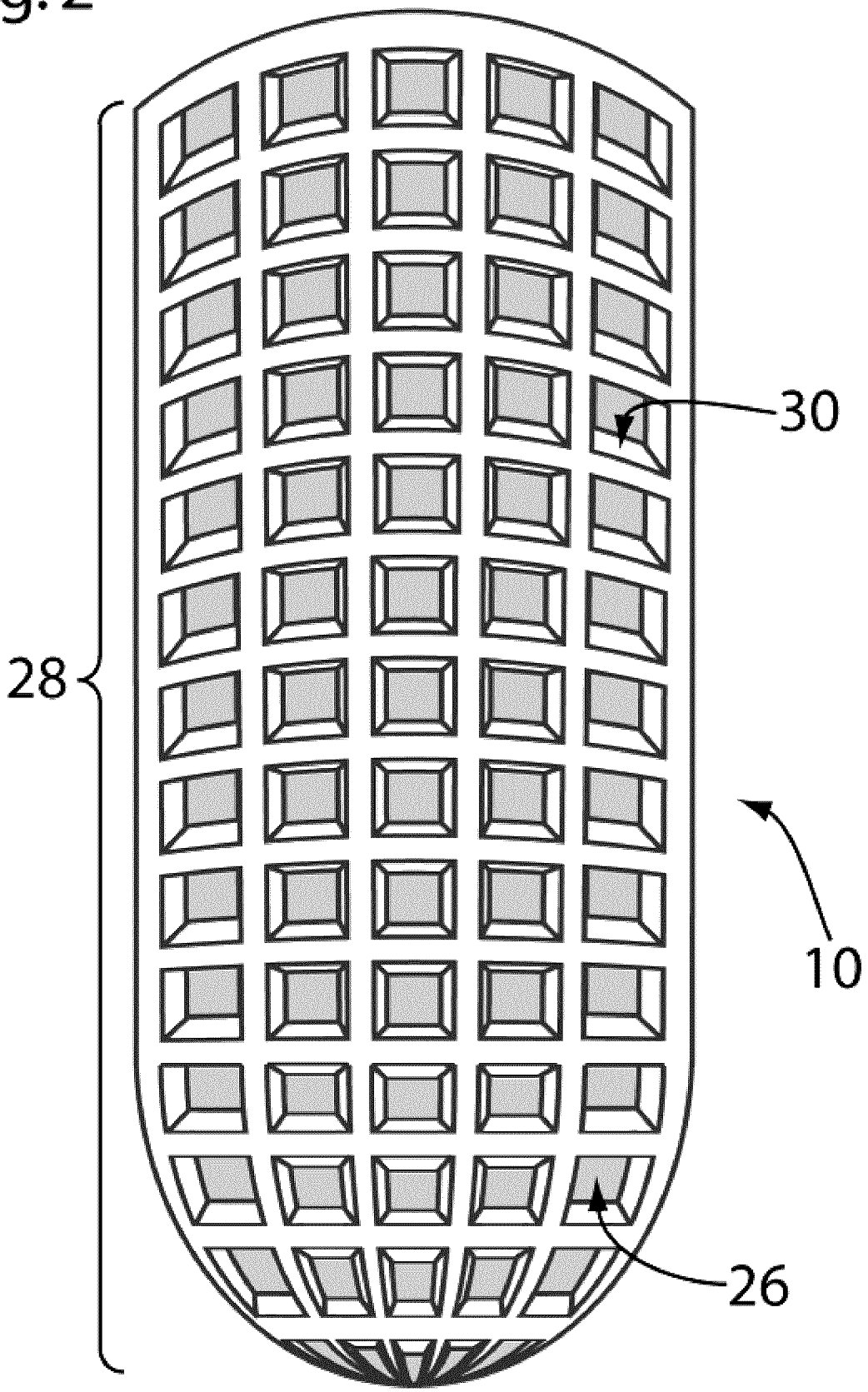


Fig. 3a

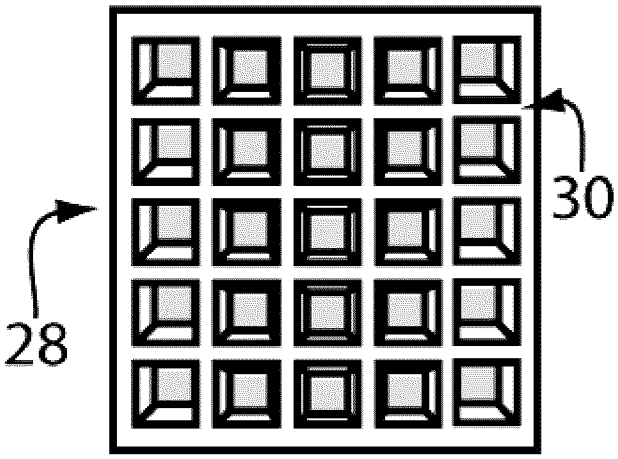


Fig. 3b

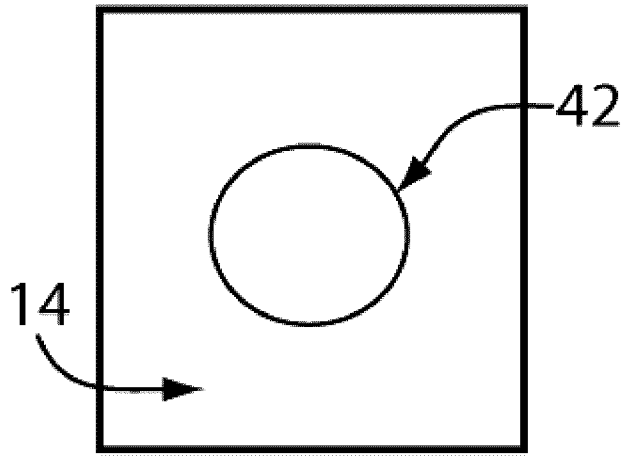


Fig. 3c

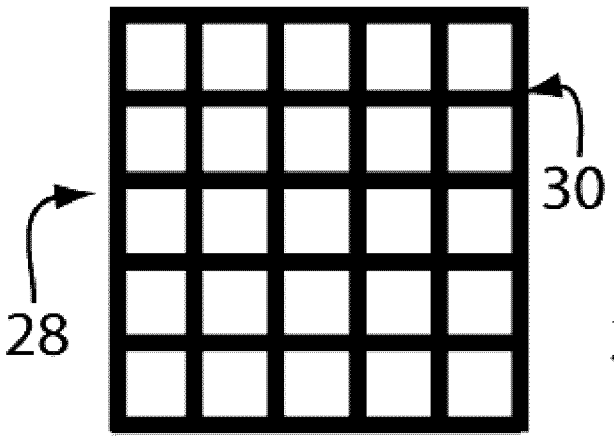


Fig. 3d

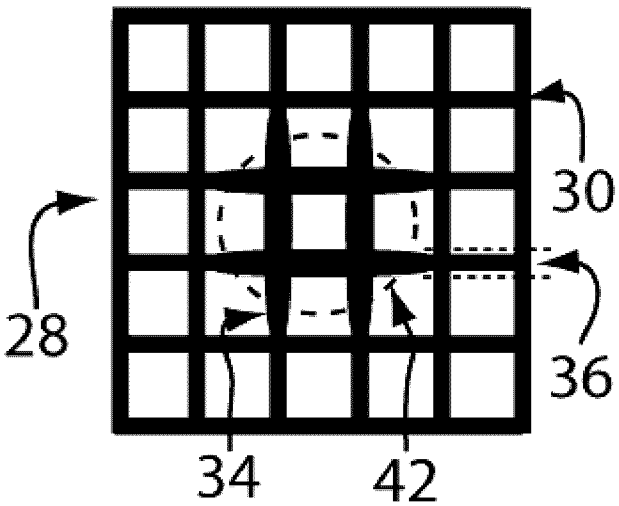


Fig. 4

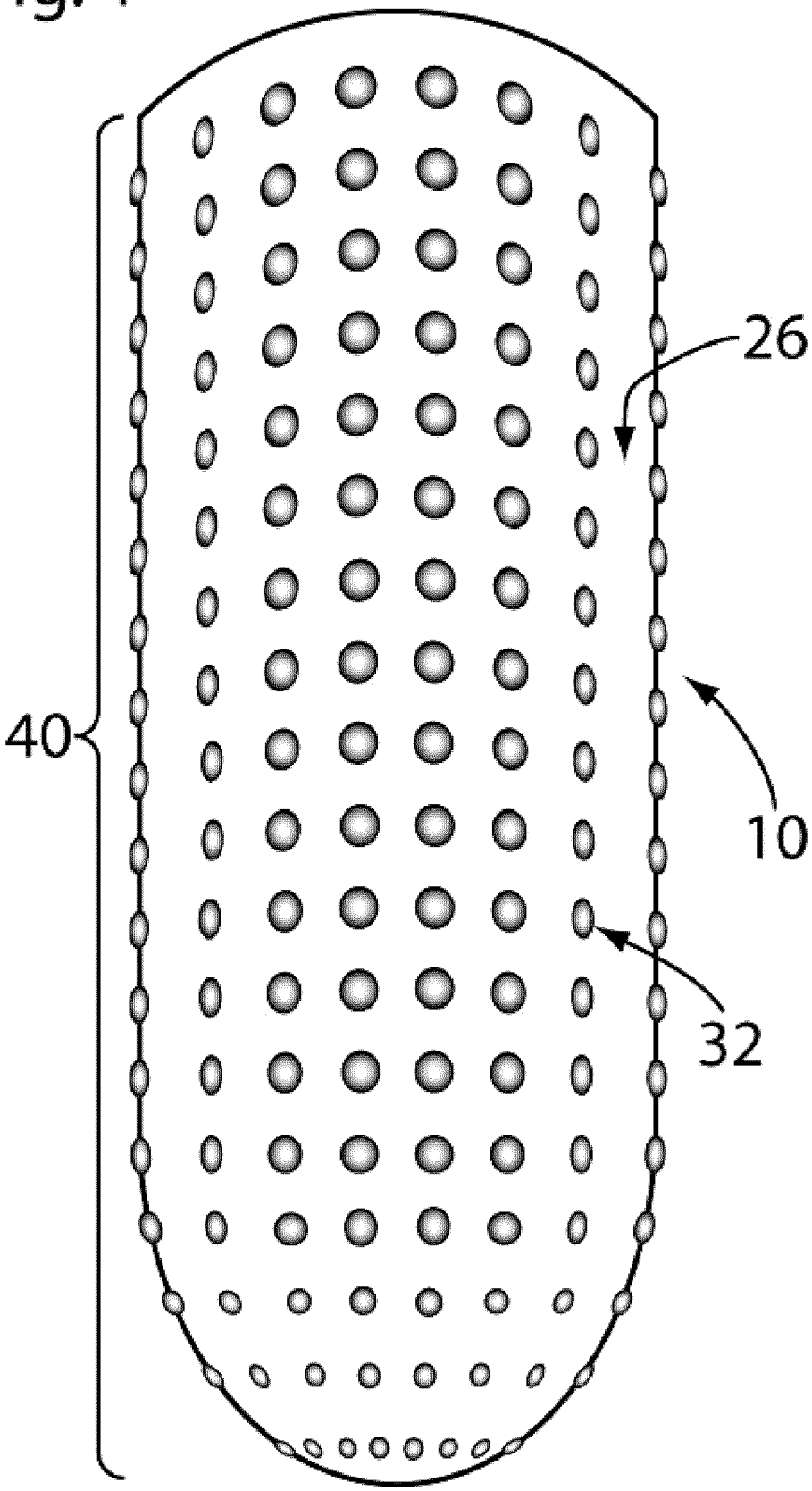


Fig. 5a

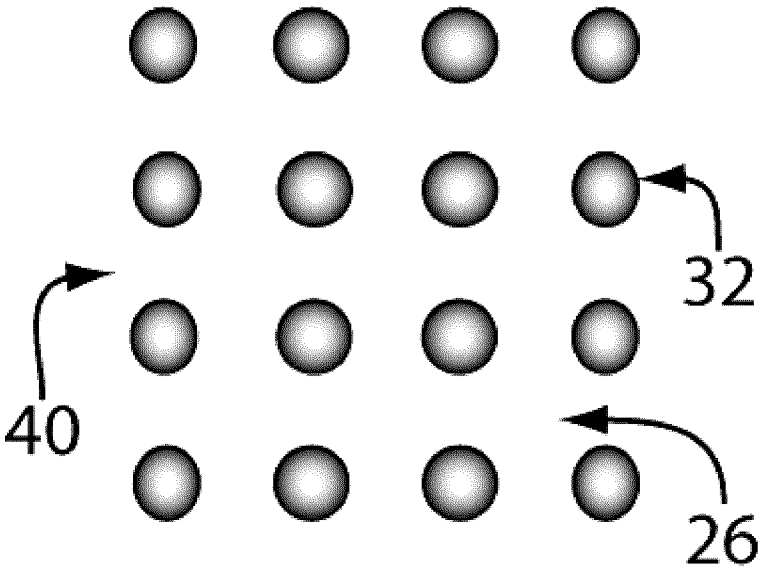


Fig. 5b

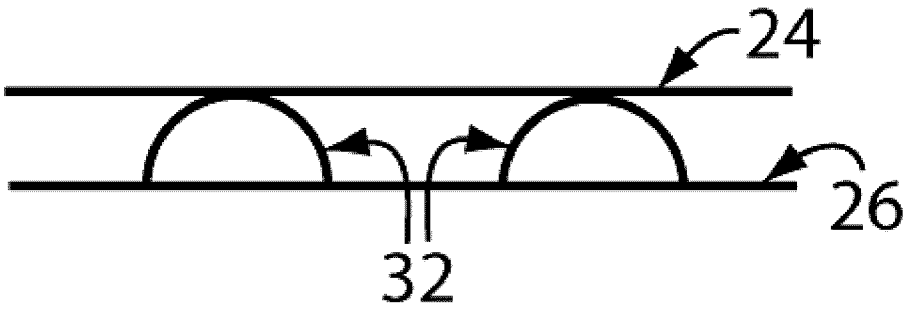


Fig. 5c

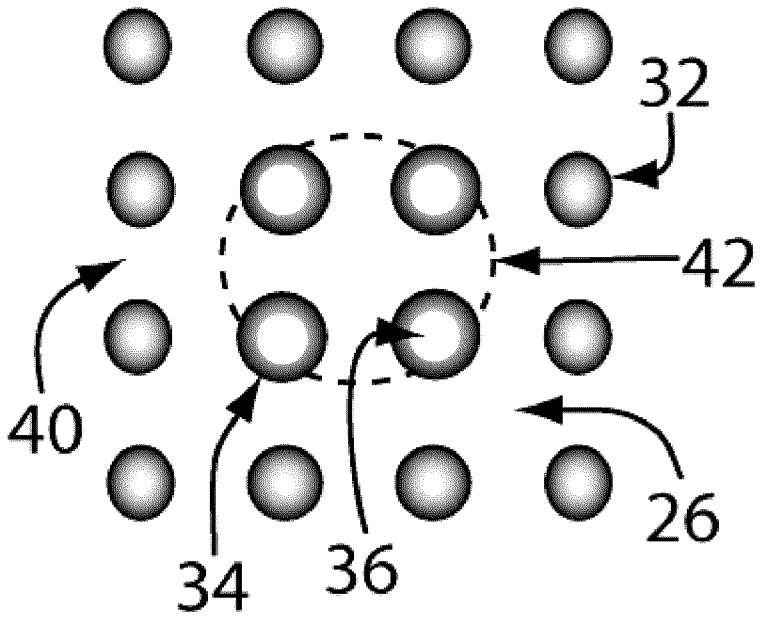
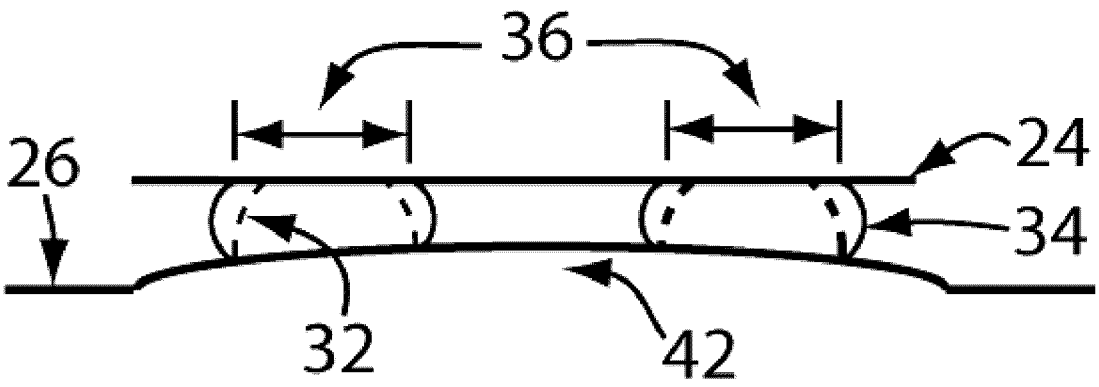


Fig. 5d



INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2012/050387

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***A61F 2/76*** (2006.01) , ***A61F 2/80*** (2006.01)
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)
IPC and ECLA: A61F 2/76, A61F 2/80, A61F 2/78

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
none

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
Epoque (EPODOC, full-text), Canadian Patents Database
keywords: liner, pad, sock, pressure, fit, diagnos+, crush, compress+, deform+, array, protrusion, protuberance, dimple

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US3732578A (POLLACK) 15 May 1973 (15-05-1973) *col. 1, lines 43-60; col. 5, lines 1-23; col. 1, line 61-col. 2, line 9*	1-17, 19, 21, 24-27, 29-30
Y	US2010/0161076A1 (PALLARI) 24 June 2010 (24-06-2010) *figs. 6, 9, 14; para. 62; para. 40; para. 51*	1-17, 19, 21, 24-27, 29-30
X	US5658353A (LAYTON) 19 August 1997 (19-08-1997) *abstract*	28
A	EP2327378A1 (PIERACCINI) 1 June 2011 (01-06-2011)	

[ ] 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
14 September 2012 (14-09-2012)	14 September 2012 (14-09-2012)

Name and mailing address of the ISA/CA	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Andrew Davidson (819) 953-4505

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2012/050387

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the 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] Claim Nos. : 18, 20, 22-23, 31, 32

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

These claims are directed to a purely mental act to which no international search report has been established and need not be the subject of a written opinion. The subject matter accomplishes a result by means of a person's reasoning, in which the quality or character of the result may vary depending upon the skill, interpretation, or judgement of the person performing the method or process.

2. [ ] Claim 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. [ ] Claim 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 :

Group A: Claims 1-27, 29-32 are directed to a diagnostic liner system and method of assessment of prosthetic limb fit; and
Group B: Claim 28 is directed to the use of a lubricant spray.

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

2. [X] As all searchable claims could be searched without effort justifying 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 claim 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 claim 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/CA2012/050387

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
US3732578A	15 May 1973 (15-05-1973)	None	
US2010161076A1	24 June 2010 (24-06-2010)	EP2196173A2 GB0822590D0	16 June 2010 (16-06-2010) 21 January 2009 (21-01-2009)
US5658353A	19 August 1997 (19-08-1997)	None	
EP2327378A1	01 June 2011 (01-06-2011)	EP2327378A1 ITFI20090247A1	01 June 2011 (01-06-2011) 26 May 2011 (26-05-2011)