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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 December 2024 (19.12.2024)

WIPO | PCT

(10) International Publication Number
WO 2024/257011 A1

(51) International Patent Classification:
A41D 13/05 (2006.01) *A41D 13/015* (2006.01)
A41D 13/12 (2006.01) *A41B 9/12* (2006.01)

(21) International Application Number:
PCT/IB2024/055800

(22) International Filing Date:
13 June 2024 (13.06.2024)

(25) Filing Language: Italian

(26) Publication Language: English

(30) Priority Data:
102023000012345 15 June 2023 (15.06.2023) IT

(71) Applicants: **FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI** [IT/IT]; Via Venezian, 1, I-20133 Milano (MI) (IT). **POLITECNICO DI MILANO** [IT/IT]; Piazza Leonardo da Vinci, 32, I-20133 Milano (MI) (IT).

(72) Inventors: **SPREAFICO, Filippo**; c/o Fondazione IRCCS - Istituto Nazionale dei Tumori, Via Venezian, 1, I-20133 Milano (MI) (IT). **RODRIGUEZ MATAS, José Félix**; c/o Politecnico di Milano, Piazza Leonardo da Vinci, 32, I-20133 Milano (MI) (IT).

(74) Agent: **DE BONIS, Paolo**; c/o Buzzi, Notaro & Antonielli d'Oulx S.p.A., Corso Vittorio Emanuele II, 6, I-10123 Torino (IT).

(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, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, MG, MK, MN, MU, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, 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, ME, 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).

(54) Title: A PROTECTIVE DEVICE FOR MONORENAL SUBJECTS OR SUBJECTS WITH RENAL DISEASE

(57) Abstract: There is described a protective device (1) for monorenal subjects or subjects with renal disease, comprising : - a garment (2) wearable by a subject (P) at least at a lumbar region (L) of the subject (P), - at least one protective element (4) installed on said garment (2) at a portion thereof configured to be positioned at the lumbar region (L) of the subject (P) when the garment (2) is worn by the subject (P), - a belt element (6) configured to at least partially encircle the torso of the subject (P) in the lumbar region (L) and to exert a compressive action of the at least one protective element (4) against the lumbar region (L) of the subject (P).

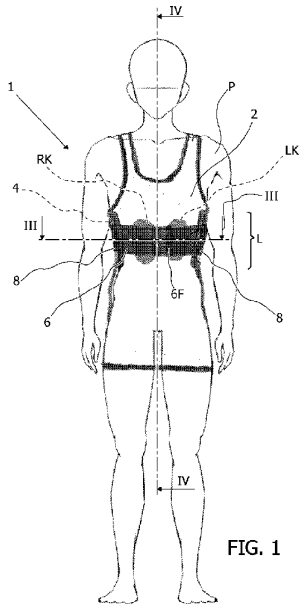

FIG. 1

WO 2024/257011 A1

[Continued on next page]

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*

"A protective device for monorenal subjects or subjects with renal disease"

****

DESCRIPTION

Field of the Invention

Children, teenagers and young adults who were born with a single kidney (a situation defined as renal agenesis or solitary kidney), or who develop an acquired solitary kidney condition due to surgery (nephrectomy, i.e. kidney removal surgery, e.g. because of a tumour) or due to disease (solitary functioning kidney) are at a risk of completely losing the (vital) renal functionality if the remaining kidney is subjected to damage due to a trauma. The most common situations which may bring about a severe kidney damage are road, bicycle or motorcycle accidents, or accidental traumas during sport or recreational activities which involve a contact or a collision with another participant or against an object (e.g. mountain bike, rugby, football, hockey, skiing, skating, horse-riding and, less frequently, soccer, basketball and volleyball).

The most frequent situation causing the acquired loss of a kidney in children and teenagers is a kidney tumour. For the children, the teenagers and the young adults who have survived a kidney tumour, the possibility of freely and constantly participating in physical activities is considered by the World Health Organization a vital requirement for a satisfying physical and mental health of the subject.

The object of the present invention aims at providing a tool which enables a monorenal subject, as well as all the subjects who have been cured from a kidney tumour, to practice recreational or sport activities, beside some everyday activities, in complete safety, by limiting the risks connected to severe traumas

on the only kidney remaining. Estimates indicate that approximately 1 child out of 2000 is born with a solitary kidney, and that approximately 1600 new cases of kidney tumour in pediatric age are diagnosed every year in Europe and in the USA.

Moreover, in 2020 as many as 431,288 new cases of kidney tumour in adults have been estimated: such a situation leads to a surgically acquired solitary kidney, and this highlights the fact that the problem concerns subjects of every age.

No effective solution is known to this problem (apart from primary prevention, i.e. preventing monorenal subjects from practicing risky activities); in other words, there are no protective devices which monorenal children, teenagers and young adults may wear during the recreational or sport activities which are most likely to be associated with the risk of a kidney trauma.

Although it is difficult to quantify the risk of a genito-urinary trauma which is so severe as to cause the loss of a kidney, such an event is neither foreseeable nor evitable in the absence of protections, and it is a major obstacle which prevents monorenal subjects from practicing recreational and sport activities in safe and carefree conditions. In the absence of a kidney protective device which is effective and minimally intrusive, which does not hamper the freedom of movement of the subject, to this day the health professionals and the authorities responsible for issuing medical certificates of fitness for competitive sports have no choice but to evaluate each case individually, and possibly to prohibit the participation in competitive sports which involve contact or collision.

Object of the Invention

The invention aims at solving the technical

problems outlined in the foregoing. Specifically, the aim of the invention is to enable monorenal subjects to practice sport activities in safety, even when such activities imply a contact or a collision, without precluding the enjoyment of such activities, i.e. without imposing a protective equipment which may hinder the subject's mobility.

Summary of the Invention

The object of the invention is achieved by means of a device having the features outlined in the claims that follow, which form an integral part of the technical disclosure provided herein in relation to the invention.

Brief Description of the Figures

The invention will now be described with reference to the annexed Figures, which are provided by way of non-limiting example only and wherein:

- Figure 1 is a schematic front view of a human figure wearing a device according to the invention (see arrow I of Figure 3),
- Figure 2 is a schematic rear view of the human figure of Figure 1, wearing the device according to the invention (see arrow II of Figure 3),
- Figure 3 is an axial section view according to line III-III of Figure 1,
- Figure 4 is a sagittal section view according to line IV-IV of Figure 1,
- Figure 5 and Figure 6 show possible configurations of a component of the device according to the invention, and
- Figure 7 shows a further aspect of the device according to the invention.

Detailed Description

Reference 1 in Figures 1 to 4 generally designates a protective device for (surgically or functionally) monorenal subjects according to the invention. The

protective device 1 generally comprises a garment 2 wearable by a subject at least at a lumbar region L of the subject, at least one protective element 4 installed on the garment 2 at a portion thereof configured to be positioned at the lumbar region L of the subject when the garment is worn by the subject, and a belt element 6 configured to encircle, at least partially and preferably fully, the torso of the subject in the lumbar region L, and to exert a compressive action of the protective element 4 against the lumbar region L of the subject.

Positioning the protective element 4 at the lumbar region L enables the same to act as a bumper, by absorbing and dissipating, without causing traumas to the subject, the energy deriving from possible impacts in the lumbar region L, where the kidney(s) of the subject is/are located. With reference to figures 1, 2 and in particular figure 3, it can be observed how in a preferred embodiment the extension of the protective element 4 at the lumbar region L is so as to cover the waist of the subject, thereby protecting the subject from lateral or oblique traumas.

The garment 2 is preferably an undergarment, particularly – with reference to the embodiment depicted in the Figures – a bodysuit. Of course it is possible to vary the style according to needs, so that the embodiment in the Figures, combining the shape of boxer shorts and the shape of a sleeveless vest, may be implemented in a different style, e.g. a short-sleeved or long-sleeved vest and high-cut briefs, or short or long trousers. Preferably, the garment 2 is made of a stretchy fabric (e.g. Lycra®) so as to closely adhere to the body of the subject P, therefore avoiding undesirable movements of the protective element 4 with respect to the body of the subject P. As an alternative, it is possible to implement

the garment 2 as an undergarment which does not cover the torso, but which is shaped as high-waist pants or trousers, in such a way as to support to and/or to house the at least one protective element 4 at the lumbar region L when it is worn by subject P.

Preferably, with reference to Figures 3 and 4, the garment 2 comprises a pocket 2P provided at the portion thereof configured to be positioned at the lumbar region L of the subject when the garment 2 is worn by the subject P. The pocket 2P houses the at least one protective element 4. Preferably, the pocket 2P is an open pocket, thus enabling the insertion and the removal of the protective element 4 according to needs, e.g. in order to wash the garment 2 after the sport activity. In preferred embodiments, the pocket 2P comprises an opening which is closable, e.g. by means of a zip, a strip of Velcro® or a series of snap fasteners or buttons, wherein the closable opening is configured for the insertion and the extraction of the at least one protective element 4. In other embodiments, the pocket 2P may be configured as a closed perimeter pocket, i.e. wherein the at least one protective element 4 is permanently housed within the pocket 2P. In such embodiments, the pocket 2P is made during the manufacturing of garment 2, and the perimeter is sewn or otherwise closed (in the case of a synthetic fiber garment 2, the closed perimeter may be obtained by heat sealing) directly around the protective element 4.

Preferably, the pocket 2P is provided at an external surface of garment 2, i.e. a surface which does not contact the subject's skin. This configuration is visible in Figures 3 and 4: the protective element 4 contacts the external surface of the garment 2 and a cover of fabric – made either of the same material as element 2 or of a different fabric, e.g. Nylon® or

Cordura®.

However, embodiments are possible wherein the pocket 2P is positioned on an inner surface of garment 2; in such cases, it is preferable to use a cover of the same fabric as garment 2 in order to implement the pocket 2P.

However, it must be borne in mind that the pocket 2P is not strictly necessary: the at least one protective element 4 may be applied directly to the fabric of garment 2, e.g. by sewing along a perimeter flange of the protective element 4: the stitching traverses the perimeter flange and the fabric of garment 2 in the lumbar region L, thereby fixing the protective element 4 to the garment 2. Moreover, it is possible to provide the protective element 4 of a back part joined by stitching, glueing of welding, and the back part may be provided with a coupling tape which mates with a corresponding coupling tape being sewn or applied onto an external surface of garment 2, wherein the coupling tapes implement a loop-and-hook connection such as Velcro®. In the latter case, the (at least one) protective element 4 may be removed from garment 2.

In other words, the pocket 2P is not strictly necessary, because the (at least one) protective element 4 is required to extend around the torso of the subject, in such a way as to encircle a region of the lumbar area L whereat there are located a right kidney RK and a left kidney Lk, or either of them in the case of proper monorenal subjects.

As regards the belt element 6, it may be implemented as a band or belt of a material which may be stretchy or substantially resistant to traction, extending at least for the same length of the at least one protective element around 4 around the torso of the subject P. In this way, it is possible to position the belt element 6

in such a way as to exert a radial compressive action by the protective element 4 against the lumbar region L of the subject, therefore further limiting the movement of said element 4. Preferably, the belt element 6 is configured to fully encircle the torso of the subject (Figure 3, Figure 4) and it comprises free ends which may be coupled by means of a connection 6F, which may comprise a pair of loop-and-hook tapes, such as Velcro®, a buckle (such as used for trousers belts, or else a self-locking buckle as used in backpacks), or else a so-called “double D” buckle, as used in the chin straps of motorcycle helmets. The solutions envisaging a buckle which are mentioned in the present description may be used when the protective device 1 is employed in sport activities wherein the contact occurs not with another person but with a moving object, such as e.g. a tennis ball.

Whatever the implementation of connection 6F, as shown in Figures 3 and 4, there is provided an overlapping area between the free ends, so as to enable the coupling thereof and the consequent tensioning of the belt element.

Advantageously, the belt element 6 is provided with one or more loops 8 which are sewn or otherwise attached on the undergarment 2, through which the belt element 6 is arranged. The loops help the subject in the correct positioning of the belt element 6, guaranteeing an optimal radial compression onto the protective element 4.

In the embodiments wherein the belt element 6 does not fully encircle the torso of the subject P, the belt element may be configured as a band which may overlap the protective element 4 and may be fixed in a tensioned condition to the garment 2 by means of Velcro®, buttons, or a buckle. In an embodiment, an end of the belt element

may be sewn or otherwise attached to the garment 2 in a position circumferentially external to the surface of element 4, the opposite end being attachable – while tensioning the belt element 6 – in a position with is equally circumferentially external to the surface of the protective element, but which is opposed to the first end. Again, the fixation may be achieved by means of Velcro®, buttons, a buckle, etc.

With reference to Figures 5 and 6, there will now be described some preferred configurations of the protective element 4. As can be seen in these Figures, the protective element 4 is preferably configured as a flexible plate, adapted to conform to the lumbar region of the subject and having a texture with an auxetic structure. Figure 5 shows a protective element 4 which has an auxetic structure with sinusoidal grating, while Figure 6 shows a protective element 4 having an auxetic structure with a bidimensional re-entrant grating. Of course, Figures 5 and 6 show two possible examples, but other known auxetic textures may be employed as well. Preferably, whatever the auxetic texture may be, the protective element 4 comprises a non-Newtonian fluid, the response whereof to deformation, depending on the speed of the deformation, optimizes the properties of kinetic energy absorption of said element 4. Again preferably, and not necessarily linked to the implementation of the protective element with an auxetic structure (hence what follows applies both to the protective element 4 made as a "solid" slab free of auxetic texture or as a slab with auxetic texture), a material that can be used for the implementation of the protective element 4 comprises a non-Newtonian fluid with density comprised between 0.2 g/cm^3 and 1.2 g/cm^3 and thickness comprised between 2 mm and 10 mm, with peak value of the transmitted force lower than 10 kN in

the impact test (according to UNI EN 1621 (10J)) for a slab having a thickness of 6mm.

Although the preferred embodiments – shown in Figure 3 – envisage one single protective element 4 extending along an arch which covers at least the left kidney LK, the paravertebral muscles PM and the spinal column SC, and the right kidney RK of subject P, it is however possible to envisage embodiments wherein the protective device 1 comprises more than one protective element 4, for example two distinct elements arranged at the right and at the left kidney RK and LK, or else three distinct elements arranged at the kidneys RK, LK and at the spinal column SC (visible in Figure 3), while also implementing a partial coverage of the paravertebral muscles PM. Whatever the number of elements 4, they may have the same auxetic structure, or else they may have different auxetic textures selected on the basis of the anatomical site whereat the element 4 is located when the garment 2 is worn. For example, embodiments may be envisaged wherein the auxetic structure is the same at the kidneys RK, LK, while it varies at the spinal column SC and/or at the paravertebral muscles PM. This may apply both to the case of three separate elements 4 and to the case of a single element 4, which in the latter case exhibits an auxetic structure which varies along the extension thereof.

Finally, with reference to Figure 7, the protective device 1 may be provided with equipment sensing the intensity of the blows encountered during the sport activity, so that, at the end of such activity, the subject may inform a physician about the stresses he has undergone, and the physician may consider possible further diagnostic inquiries. For example, it is possible to apply a film 10 responsive to pressure on the side of the protective element 4 facing outwards of

the subject's body. The film 10 may be applied by adhesive means and may be removed after each use, replacing it with a new film 10. An example of such a film comprises the product having the commercial name "Prescale", manufactured by Fujifilm.

Thanks to the device 1 according to the invention, it is possible to offer to every monorenal subject an extremely effective and safe support for sport activities involving contact (and for other activities), thereby preventing renal or urinary injuries which are potentially critical for the subject. The device 1 is easy to use and to wear, as it substantially corresponds to a so-called "technical" undergarment. The subject must simply tension the belt element 6, so as to apply a radial compression on the protective element 4, thereby fixing the position thereof with respect to the lumbar region L. The structure and the material of the protective element 4 absorb any blow which may be potentially harmful to the kidneys RK and/or LK, and dissipate the kinetic energy thanks to the auxetic structure and/or the implementation by means of a non-Newtonian fluid.

Of course, the implementation details and the embodiments may vary, even appreciably, with respect to what has been described and illustrated, without departing from the extent of the present invention as defined by the annexed claims.

CLAIMS

1. A protective device (1) for monorenal subjects or subjects with renal disease, comprising:

- a garment (2) wearable by a subject (P) at least at a lumbar region (L) of the subject (P),
- at least one protective element (4) installed on said garment (2) at a portion thereof configured to be positioned at the lumbar region (L) of the subject (P) when said garment (2) is worn by said subject (P),
- a belt element (6) configured to at least partially encircle the torso of the subject (P) in the lumbar area (L) and to exert a compressive action of the at least one protective element (4) against the lumbar area (L) of the subject (P).

2. The protective device (1) according to claim 1, wherein the garment comprises a pocket (2P) provided at the portion thereof configured to be positioned at the lumbar area (L) of the subject (P) when the garment (2) is worn by the subject (P), the pocket (2P) housing said at least one protective element (4).

3. The protective device (1) according to claim 2, wherein said pocket (2P) is an open pocket.

4. The protective device (1) according to claim 3, wherein said pocket (2P) comprises a closable opening, said opening being configured for insertion and extraction of said at least one protective element (4).

5. The protective device (1) according to claim 2, wherein said pocket (2P) is a closed perimeter pocket, wherein said at least one protective element (4) is permanently housed within said closed perimeter pocket (2P).

6. The protective device (1) according to any one of the preceding claims, wherein said belt element (6) is configured to fully encircle the torso of the subject.

7. The protective device (1) according to any one of the preceding claims, wherein said garment (2) is an undergarment, in particular a bodysuit.

8. The protective device (1) according to claim 1 or claim 6, comprising one or more loops (8) through which said belt element (6) is arranged.

9. The protective device (1) according to any one of the preceding claims, wherein said at least one protective element (4) is a plate with a texture having an auxetic structure.

10. The protective device (1) according to claim 1 or claim 9, wherein said at least one protective element (4) comprises a non-Newtonian fluid.

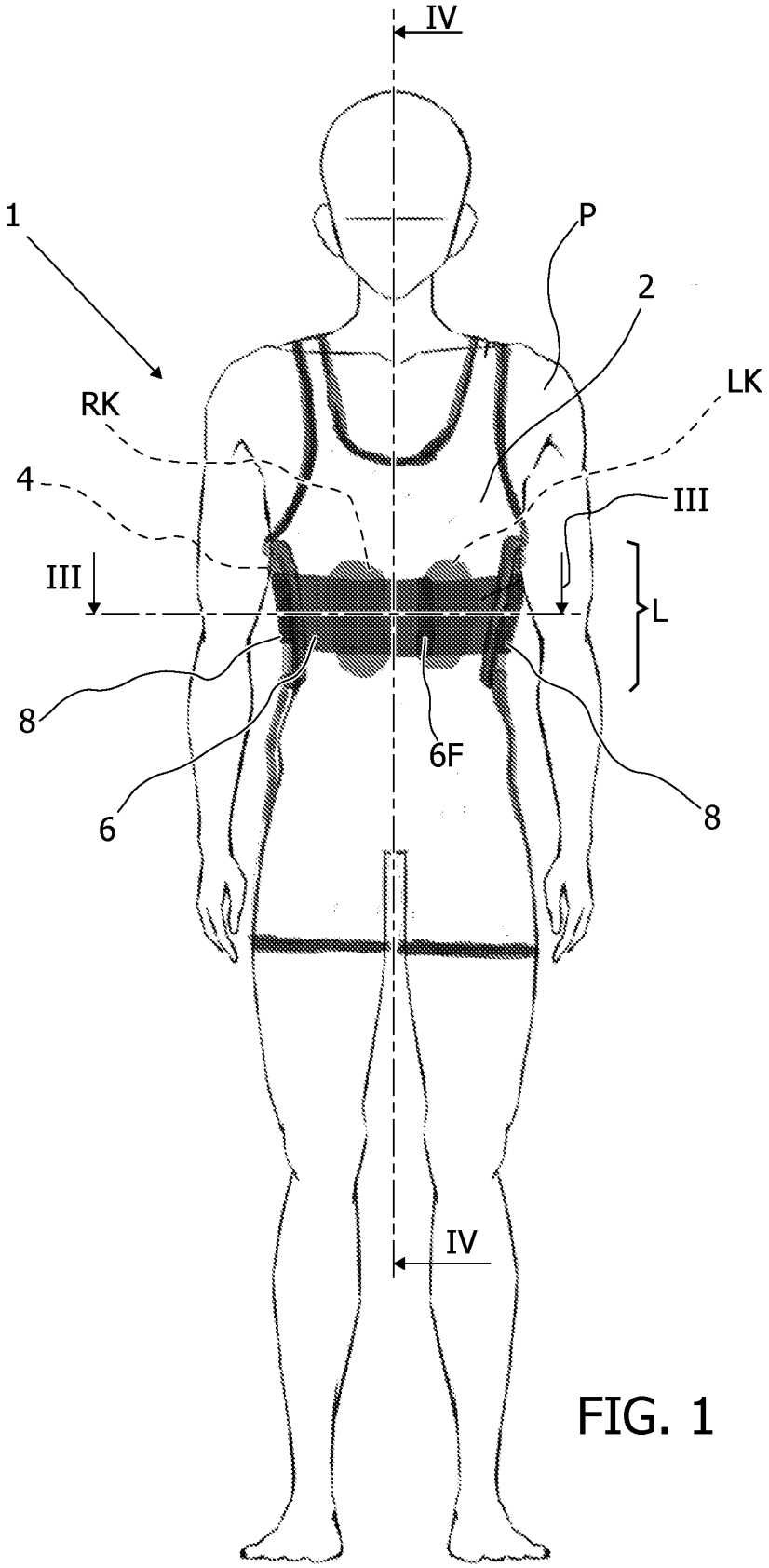

FIG. 1

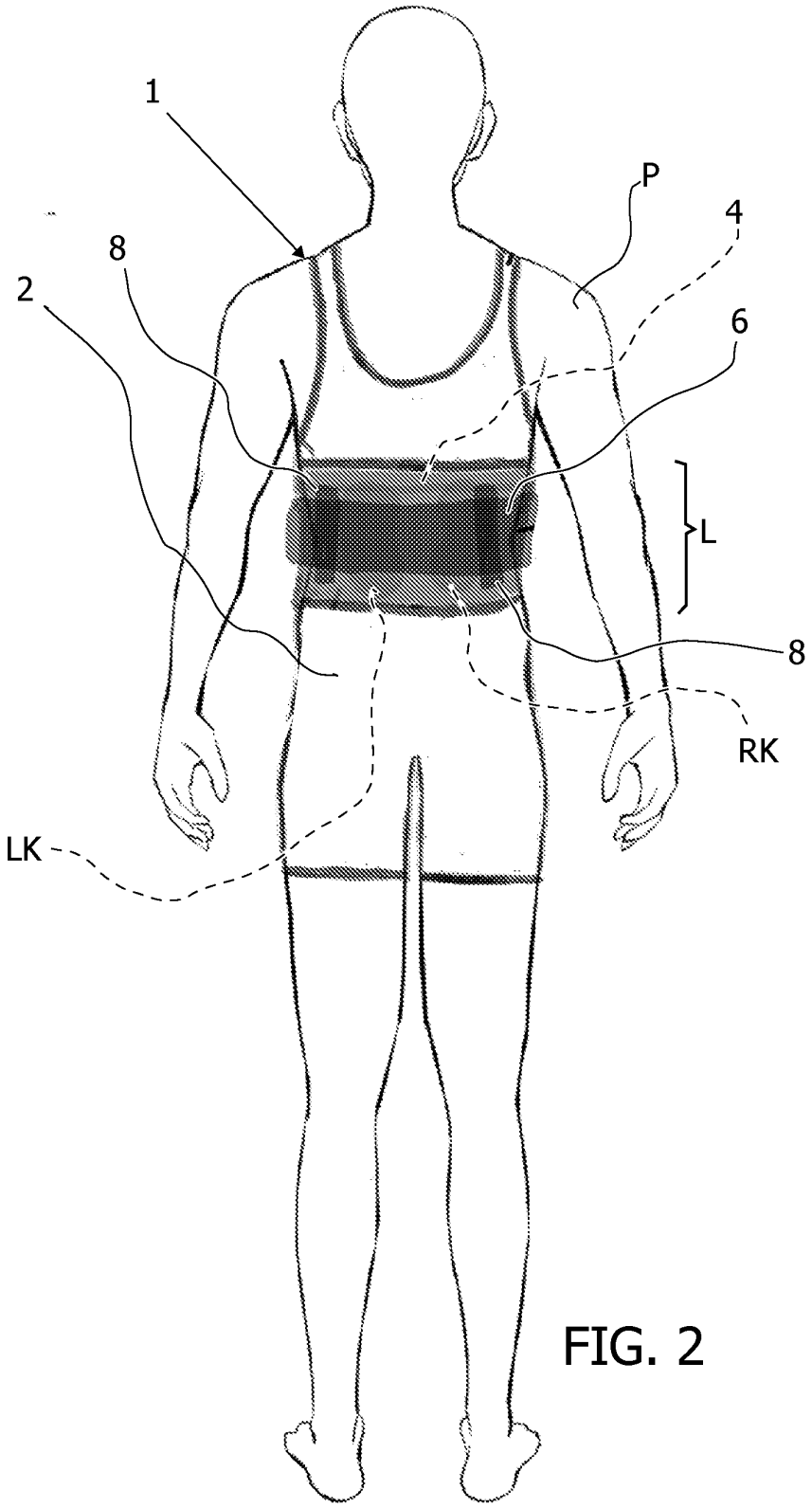

FIG. 2

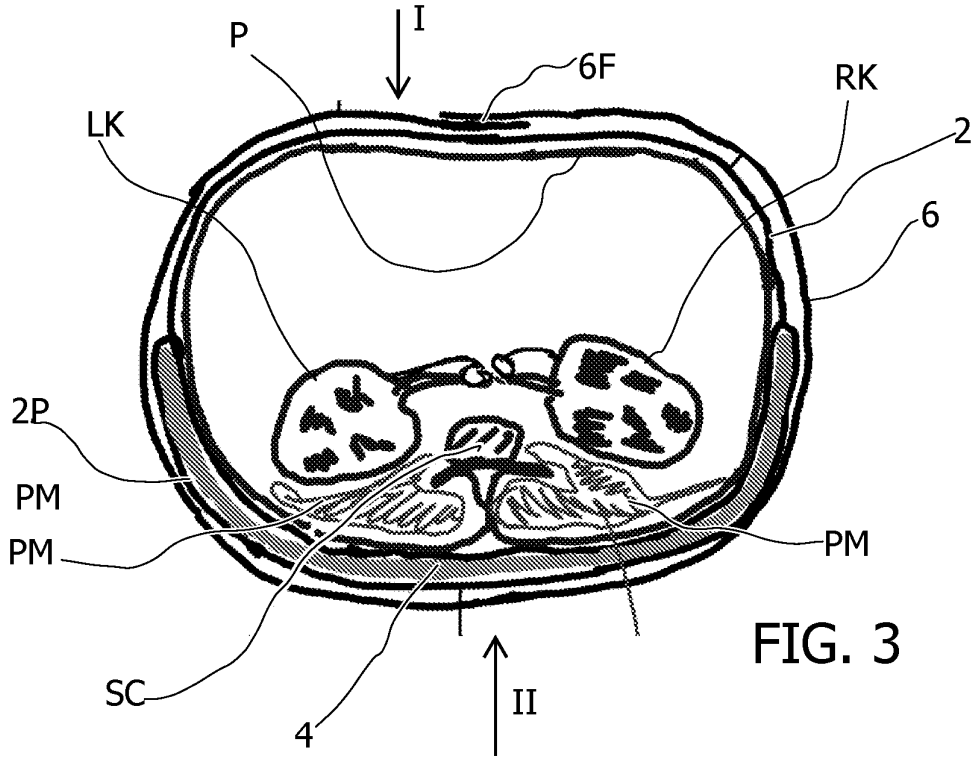

FIG. 3

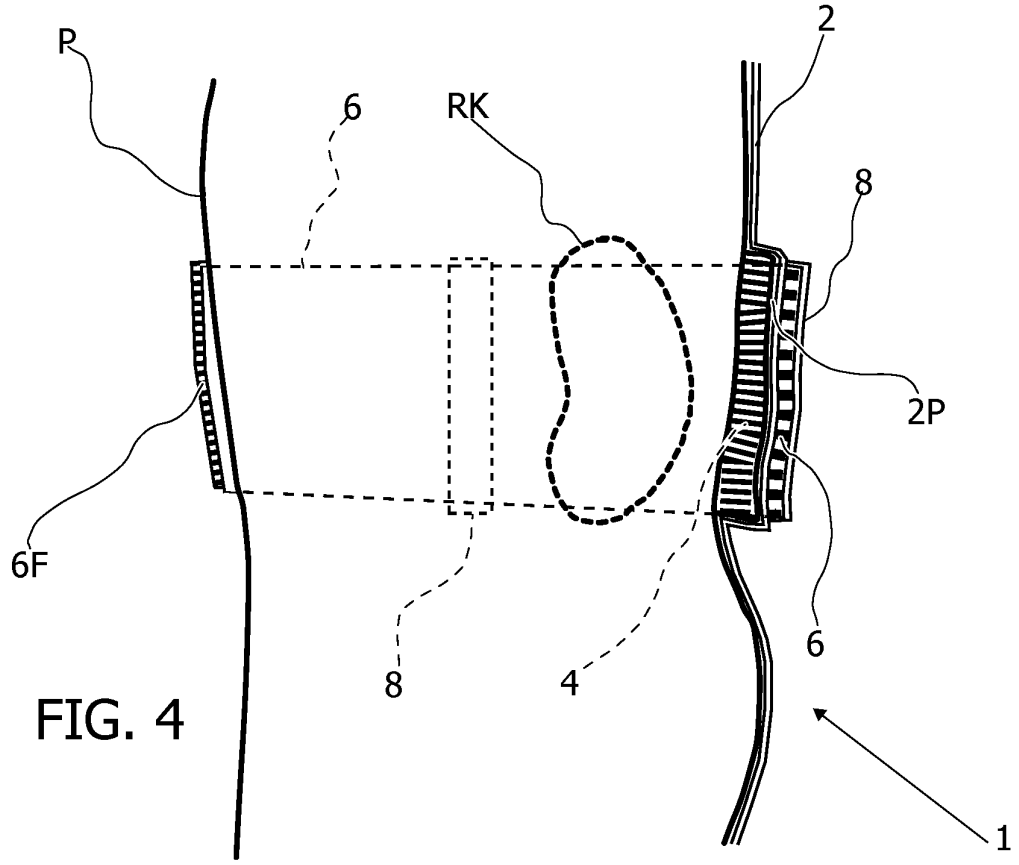

FIG. 4

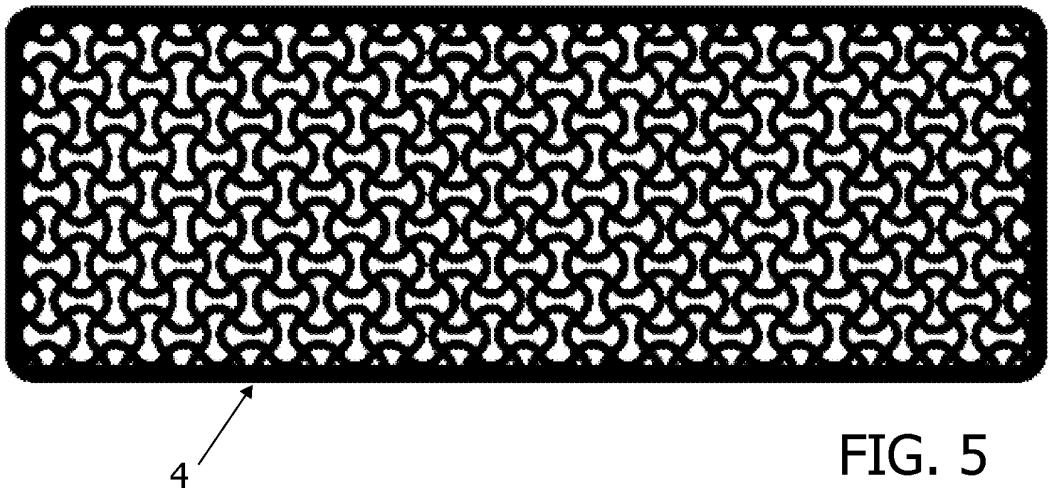

FIG. 5

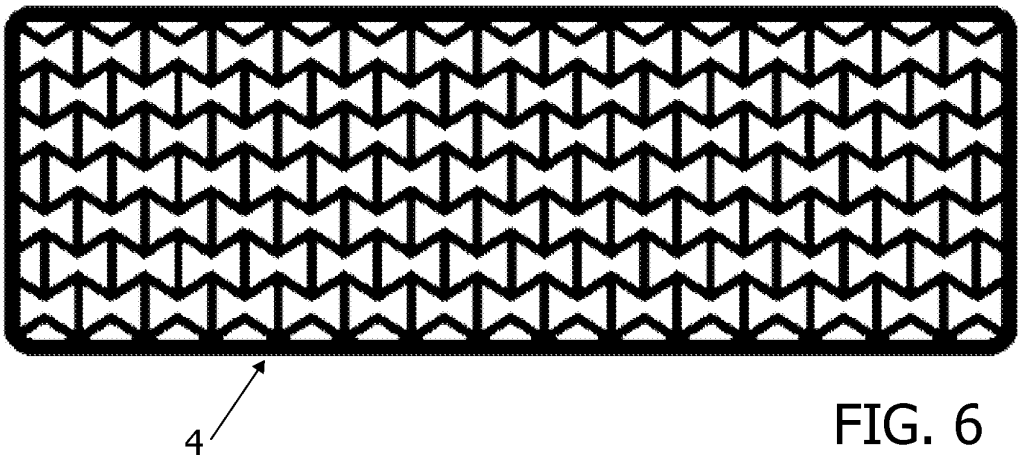

FIG. 6

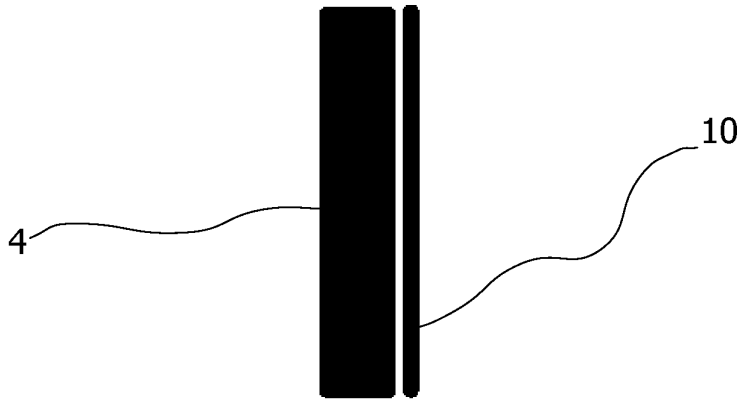

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2024/055800

A. CLASSIFICATION OF SUBJECT MATTER

INV. A41D13/05 A41D13/12 A41D13/015 A41B9/12
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)
A41D A41B

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2020/367582 A1 (WILLINGER NADAV [IL]) 26 November 2020 (2020-11-26) paragraphs [0018], [0053]; figure 1	1-10
A	US 4 022 197 A (CASTIGLIA IGNATIUS F) 10 May 1977 (1977-05-10) column 4, paragraph 47 - paragraph 49; figures 1-5	3-6

☐ Further documents are listed in the continuation of Box C.

☒ 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
19 July 2024	12/08/2024

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	van Voorst, Frank

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2024/055800

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2020367582 A1	26-11-2020	NONE	
US 4022197 A	10-05-1977	NONE	