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(54) Title: DEVICE, SYSTEM AND METHOD FOR IMMOBILIZATION OF A HUMAN'S BODY PART

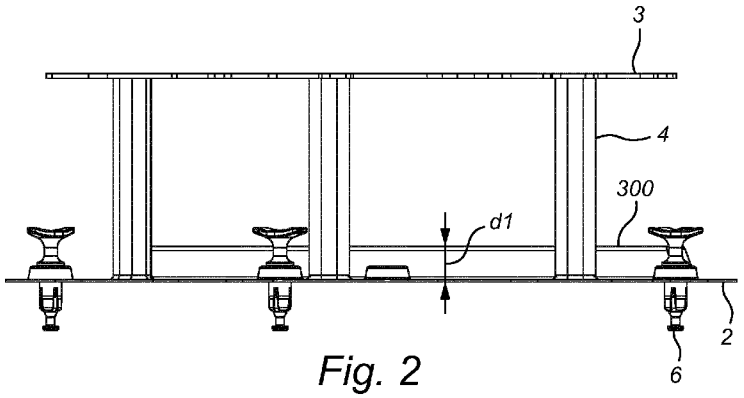


Fig. 2

(57) Abstract: The present invention provides a system for immobilization of a patient body part comprising at least one first sheet for covering a first area of said body part, and an immobilization device suitable to be mounted to a fixation surface. The immobilization device comprises a detachable support, such as a cushion, and a flanged support member provided with at least one attachment means for receiving and retaining the first sheet. The attachment point of the flanged support member which is most proximal to the fixation surface is positioned at a distance D1 from said fixation surface such that when the body part to be immobilized is placed on the detachable support and the first sheet is retained by the flanged support member, the first area of said body part covered by the first sheet is at maximum comprised between 1% and 40% of the total area of said body part.

# Device, system and method for immobilization of a human's body part

## Field of the invention

The present invention pertains to a device, a system and a method for immobilizing at least part of a human's body part for receiving radiation treatment. The invention is suitable for use in the medical field, particularly for immobilization purposes in radiotherapy and cancer treatment.

## Background

The treatment of patients having cancer frequently makes use of radiation therapy wherein radiation is directed to particular sites in the patient's body. Said radiation is applied more than once over several days. Therefore, these treatments require high precision, reliable and accurate patient set-up to position and immobilize the relevant part of the patient's body undergoing the radiation. Said immobilization should be reproducible with the same precision. Various devices and equipment are available for effecting such actions. For example, patient couches or tables are commonly provided at the radiation machine, e.g., linear accelerator, CT machine, MRI, etc., to support the patient in a prone or supine position while the relevant portion of the patient's body is held in a fixed or immobilized condition.

A frequently immobilized body part is the head and a commonly used restraint device is a mask that is placed over the face of the patient to hold the patient's head stationary. The back of the patient's head and contiguous portion of the patient's neck may be supported by a cushion which itself can be pre-contoured for a specific shape or can be conformed, e.g., molded, to the shape of the back of the patient's head. The mask itself can be pre-formed to a shape that will generally conform to the contours of the patient's face or may be molded on the patient's face to closely conform to the face contours.

US 5 702 406 discloses a system for noninvasive immobilization of a human head comprising a head ring having a pair of support legs adapted to be positioned at opposite sides of the head of a specific patient. The system also comprises a mask containing a plurality of separate parts capable of assuming a given conformation. A first part is adapted to be conformed to and to cover the anatomical contours of a first area of the specific patient's head. A second part is adapted to be conformed to and to cover the anatomical contours of a second area of the specific patient's head which is not covered by the first part. The first part and the second part are mountable on the head ring. The obtained mask has an open area on the cranial side and does not fully cover the head of a patient.

WO 2013/167689 describes a system for immobilization of a patient body part for radiotherapy applications comprising a device having at least one flanged support member which is suitable to be mounted to a fixation surface and is adapted to receive and retain at least two sheets, a first sheet for covering the anatomical contours of a first area of said body part, and a second sheet for covering the anatomical contours of a second area of said body part which is not covered by the first sheet.

Using the immobilization systems of the prior art, a large area of the body part to be immobilized is covered by a sheet which is attached to a fixed device (head ring in US 5 702 406 or flanged support member in WO 2013/167689). When the head is to be immobilized, generally the front head area comprising the facial area and the facial contours or the rear head area is covered by a sheet which should conform the anatomical contours of the body part. Each of the front head area and the rear head area represents about half of the head total area. Covering a large area of a body part by a sheet weakens the attachment between the sheet and the fixed device to which said sheet is mounted. Consequently a rigid attachment is not achieved and the sheet will not precisely conform the anatomical contours of the covered body part. As a result the body part to be treated can move under the sheet. This considerably reduces the reproducibility of the immobilization throughout the repetitive treatment thereby lowering the treatment efficiency.

The aim of the present invention is to provide a solution to overcome at least part of the above mentioned disadvantages. The invention thereto aims to provide a method, a device and a system which are highly effective in terms of immobilization and reproducibility of immobilization of a patient body part.

**SUMMARY**

The present invention provides a method for the immobilization of a patient body part, such as the head, for radiotherapy applications comprising the steps of:

- mounting an immobilization device comprising a detachable support, such as a cushion, and a flanged support member to a fixation surface; said flanged support member is adapted to receive and retain at least one first sheet;
- placing the patient body part to be immobilized on said detachable support; and
- mounting said first sheet to the flanged support member thereby covering the anatomical contours of a first area of said body part,

wherein the first area covered by said first sheet is at maximum comprised between 1% and 40% of the total area of the body part to be immobilized.

The present invention further provides a system for immobilization of a patient body part, such as the head, for radiotherapy applications comprising:

- at least one first sheet for covering the anatomical contours of a first area of said body part,
- an immobilization device suitable to be mounted to a fixation surface, said immobilization device comprises:
    i) a detachable support, such as a cushion, on which the body part is suitable to be placed, and
    ii) a flanged support member provided with at least one attachment means for receiving and retaining the first sheet,

characterized in that, the attachment point of the flanged support member which is most proximal to the fixation surface is positioned at a distance **D1** from said fixation surface such that when the body part to be immobilized is placed on the detachable support and the first sheet is retained by the flanged support member, the first area of said body part covered by the first sheet is at maximum comprised between 1% and 40% of the total area of said body part.

The present invention further provides an adjustment device for adjusting the position of a body part to be immobilized for radiotherapy applications, comprising a lower surface and an upper surface wherein the upper surface is inclined at an angle **β** with respect to the lower surface and/or wherein the lower surface and the upper surface are substantially parallel to each other and are separated from each other by a distance **d1**.

The invention provides several improvements and advantages compared to the systems and devices of the prior art. A major advantage arises from covering a limited body part area by a sheet which is attached to a fixed device. Covering a limited area of the body part is novel compared to the existing devices and methods, and provides a highly rigid and secure attachment of the sheet to the fixed device thereby improving the stabilization of the body part to be immobilized. Consequently, movement of the immobilized body under the sheet during the treatment is considerably reduced and avoided. This is also highly advantageous in case of repetitive radiation treatments as it provides for the exact reproduction of the immobilization position of said body part during each treatment. As a result, the efficacy of the treatment is enhanced and application of radiations to zones of the immobilized body part surrounding the specific zone to be treated is avoided.

## DESCRIPTION OF THE FIGURES

The invention will be further described in detail with reference to the exemplary embodiments represented by the accompanying figures, in which

**FIG. 1A** shows an example of setting a start point and an end point of a body part to be immobilized and the circumferences at said point delimiting said body part.

**FIG. 1** shows a perspective view of an immobilization device with an adjusting device according to an embodiment of the invention.

**FIG. 2** shows a side view of the immobilization device of **Fig. 1**.

**FIG. 3** shows a perspective view of an immobilization device with another adjusting device according to an embodiment of the invention.

**FIG. 4** shows a side view of the immobilization device of **Fig. 3**.

**FIG. 5** shows a perspective view of an immobilization device with another adjusting device according to an embodiment of the invention.

**FIG. 6** shows a side view of the immobilization device of **Fig. 5**.

**FIG. 7** shows a side view of the immobilization device of **Fig. 5** with the detachable support.

**FIG. 8** shows a perspective view of an immobilization device with another adjusting device according to an embodiment of the invention.

**FIG. 9** shows a side view of the immobilization device of **Fig. 8**.

**FIG. 10** shows a side view of the immobilization device of **Fig. 8** with the detachable support.

**FIG. 10'** shows a side view of an immobilization device with another adjusting device according to an embodiment of the invention.

**FIG. 11** shows a perspective view of the fixation surface according to an embodiment of the invention.

**FIG. 12** shows a perspective view of the fixation surface to which the immobilization device is mounted; said immobilization device comprises the detachable support according to an embodiment of the invention.

**FIG. 13** shows a first sheet according to an embodiment of the invention. The sheet is shown after being molded and cured. The sheet is provided with a circumferential rim.

**FIG. 14** shows a perspective view of a thermoplastic sheet designed for immobilizing a head, a neck and at least part of a patient's trunk according to an embodiment of the invention. The sheet is shown after being molded and cured. The sheet is provided with a circumferential rim and attachment edges.

**FIG. 15** shows an exploded view of the support fixation surface, the immobilization device having the detachable support, the molded thermoplastic sheet having a circumferential rim for immobilizing a head, a neck and at least part of a patient's trunk according to an embodiment of the invention.

**FIG. 16** shows a perspective view of the immobilization device to which a first sheet is mounted according to an embodiment of the invention. The immobilization device comprises the detachable support.

**FIG. 17** shows a side view of the immobilization device to which a first sheet is mounted according to an embodiment of the invention. The immobilization device comprises the detachable support and is mounted to the fixation surface. The detachable support is used to bring the body part closer to the flanged support member and further away from the fixation surface.

**FIG. 18** shows a side view of the immobilization device to which a first sheet is mounted according to an embodiment of the invention. The immobilization device comprises the

detachable support and is mounted to the fixation surface. The detachable support is used to bring the body part closer to the fixation surface and further away from the flanged support member.

**FIG. 19** shows a perspective view of the fixation surface provided with stabilization elements.

**FIG. 20** shows a perspective view of the fixation surface provided with stabilization elements and fixation members.

**FIG. 21** shows different views of the stabilization elements and its recess.

**Fig. 22** shows a perspective view of the fixation surface to which fixation means and a detachable support are attached.

**Fig. 23 A** and **B** shows a side view **Fig. 22** in the direction of arrow **Z**.

**Fig. 24** shows a perspective view of the immobilization device suitable to be fixed to the fixation surface provided with stabilization elements.

**Fig. 25** shows the immobilization device of **Fig. 24** to which an adjustment device is attached.

**Fig. 26** shows the immobilization device of **Fig. 24** to which an adjustment device and a detachable support are attached.

**Fig. 27** shows the immobilization device of **Fig. 24** to which a detachable support is attached.

**Fig. 28** shows the difference between the immobilization system of the present invention (**Fig. 28B**) and the immobilization system of the prior art (**Fig. 28A**).

## DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a method, a device and a system for the immobilization of a patient body part. The present invention can be used for the immobilization of any single body part of a human being. The present invention can also be used for the immobilization of more than one body part of a human being, such as the head, the neck and the shoulders and part of the trunk. The present invention is preferably used for the immobilization of a body part for radiotherapy applications. The body part is an external body part enclosing any organ of the patient such as the liver, the lungs or the prostate, to which radiation is to be delivered.

Unless otherwise defined, all terms used in disclosing the invention, including technical and scientific terms, have the meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. By means of further guidance, term definitions are included to better appreciate the teaching of the present invention.

As used herein, the following terms have the following meanings:

"A", "an", and "the" as used herein refers to both singular and plural referents unless the context clearly dictates otherwise. By way of example, "a compartment" refers to one or more than one compartment.

"About" as used herein referring to a measurable value such as a parameter, an amount, a temporal duration, and the like, is meant to encompass variations of +/-20% or less, preferably +/-10% or less, more preferably +/-5% or less, even more preferably +/-1% or less, and still more preferably +/-0.1% or less of and from the specified value, in so far such variations are appropriate to perform in the disclosed invention. However, it is to be understood that the value to which the modifier "about" refers is itself also specifically disclosed.

"Comprise," "comprising," and "comprises" and "comprised of" as used herein are synonymous with "include", "including", "includes" or "contain", "containing", "contains" and are inclusive or open-ended terms that specifies the presence of what follows e.g. component and do not exclude or preclude the presence of additional, non-recited components, features, element, members, steps, known in the art or disclosed therein.

The recitation of numerical ranges by endpoints includes all numbers and fractions subsumed within that range, as well as the recited endpoints.

The expression "% by weight" (weight percent), here and throughout the description unless otherwise defined, refers to the relative weight of the respective component based on the overall weight of the formulation.

The term "initial state" of a thermoplastic sheet used herein refers to a thermoplastic sheet which is still flat and not yet thermally deformed. The term "final state" of a thermoplastic sheet used herein refers to a thermoplastic sheet which has been deformed to conform the anatomical contours of a body portion and cured thereby having a rigid molded thermoplastic sheet.

The term "cured" used herein refers to a thermoplastic sheet that was heated, deformed according to a patient's body part anatomical contours and cooled to ambient temperature such as to rigidify.

The terms "support fixation surface" and "fixation surface" are used herein as synonyms and refer to a surface to which the immobilization device according to the present invention is suitable to be mounted and/or fixed. Said fixation surface might be a radiation table for instance.

Although the present invention is described with reference to the immobilization of a patient's head, it is to be understood that any other part or two or more parts of a patient's body is suitable to be immobilized using the method and/or the system and/or the devices according to any embodiment of the invention.

In a first aspect, the present invention provides a method for the immobilization of a patient body part, such as the head, for radiotherapy applications. The method comprises the steps of:

- mounting an immobilization device comprising a detachable support, such as a cushion, and a flanged support member to a fixation surface. The flanged support member replaces other frames used in conventional methods such as S-frame, U-frame or L-profiles. The flanged support member is adapted to receive and retain at least one first sheet;
- placing the patient body part to be immobilized on said detachable support; and
- mounting said first sheet to the flanged support member thereby covering the anatomical contours of a first area of said body part,

wherein the first area covered by said first sheet is at maximum comprised between 1% and 40% of the total area of the body part to be immobilized.

Covering a limited area of the body part and the use of a rigid flanged support member for strain transfer provides a highly rigid and secure attachment of the first sheet to the flanged support member of the immobilization device. This improves the stabilization of the body. Preferably the attachment of the sheet to the fixed device is a mechanical attachment.

Only the body part with the relevant surface area and anatomical reference points is covered by the first sheet. The remaining surface of the body part will be supported by a detachable support such as a cushion and/or an adjustment device. This avoids having a mechanical weak connection as it is the case of the connections described in the methods and the systems of the prior art wherein any created strain is transferred by the thermoplastic sheet. In the method of the present invention, a rigid support, namely the immobilization device, is used for transferring any created stress and strain.

The main advantage of the invention method and system compared to the systems and methods of the prior art is illustrated in **Fig. 28 A** and **B**. **Fig. 28A** shows the system of the prior art and **Fig. 28B** shows the system of the invention. In both systems one sheet is used for immobilizing a patient body part, i.e. the face in **Fig. 28**. In the system and method of the prior art, the sheet **11''** is placed on the body part and is overstretched until it reaches the surface to which it will be fixed **2'' (Fig. 28 A)**. Strain transfer is in this case supported by a thin stretched sheet – usually thickness is less than 2mm. This subjects the sheet itself to deformations thereby considerably lowering the stability of the immobilization and/or the patient's comfort. Lines **I** in **Fig. 28 A** represent the possible movements under

the mask of the prior art. The higher the number of lines, the bigger/larger is the room for movements under the mask. In the system and method of the present invention, the sheet **11'** is only placed on the body part and is fixed by the flanged support member of the immobilization device **(Fig. 28 B)**. The sheet is not overstretched and the strain transfer is supported by the immobilization device. This provides a better fixation of the sheet to the immobilization device and therefore increases the stability of the immobilization of the body part of interest and of the patient's comfort. Lines **I'** in **Fig. 28 B** show the extend of the possible movements under the mask of the prior art. Consequently, the present invention allows the use of the cured sheet for multiple treatments over time while the prior art methods and devices require more frequently a novel sheet as they are highly prone to deformation.

By total area of the body part, reference is made to the total skin surface of said body part. Said total area is determined or computed according to any plane of the body part or parts to be immobilized. Preferably, the total area is determined by setting up in the sagittal plane of the body part a start point and an end point. The circumferences of the body part at the start point and at the end point delimit the body part to be immobilized. The total area of the body part is the total skin surface comprised between the circumference of the body part at the start point and the circumference of the body part at the end point. It is to be understood that the start point and the end point of the body part are selected by the practitioner depending on the body part or body parts to be immobilized. Preferably, reliefs of the body part or body parts to be immobilized are taken into account for the determination of the total skin surface.

For instance, if the head of a patient is to be immobilized, the start point **A** and the end point **B** of the head are determined by the practitioner and shown in **Fig. 1A**, the total area corresponds to the total skin surface comprised between the circumference of the head at point $\mathbf{C_A}$ and the circumference of the head at point $\mathbf{C_B}$. Preferably, the total skin surface comprises the skin of the nose, the eyes and the mouth. It is to be understood that the start point **A** and the end point **B** shown in **Fig. 1A** are an example and that each of said points can be more proximal or more distal to the patient's frontal bone.

For determining the total area of several body parts to be immobilized, the total area of the different body parts are summed up. The position of the different body parts with respect to each other is preferably taken into consideration. For instance, if the head, the neck and part of the trunk are to be immobilized, and the arms are maintained in a position in which they are in touch with the chest, then the total area corresponds to the total area of the head + the total area of the neck + the total area of the trunk part. For each part a start point and an end point are defined by the practitioner. The person skilled in the art understands that the end point of the head part is the start point of the neck part and the end point of the neck part is the start point of the trunk part. For determining the total area

of the trunk, the position of the arms with respect to the chest is taken into account. In this case, each of the circumferences at the start point and at the end point of the trunk corresponds to the circumference of the chest which is in touch with the arms. This means that each circumference does not correspond to the sum of the circumference of the chest and the circumference of each arm.

In a preferred embodiment, the first area covered by said first sheet is at maximum comprised between 2 and 29%, preferably between 3 and 28%, more preferably between 4 and 27%, even more preferably between 5 and 26%, most preferably between 6 and 25% of the total area of the body part to be immobilized. In a more preferred embodiment, the first area covered by said first sheet is at maximum comprised between 7 and 24%, preferably between 8 and 23%, more preferably between 9 and 22%, even more preferably between 10 and 21%, most preferably between 11 and 20% of the total area of the body part to be immobilized. In a further preferred embodiment, the first area covered by said first sheet is at maximum comprised between 12 and 19%, preferably between 13 and 18%, more preferably between 14 and 17%, most preferably between 15 and 16% of the total area of the body part to be immobilized.

In a preferred embodiment, the method further comprises the step of placing an adjustment device between the fixation surface and the detachable support, thereby creating an angle **β** between the fixation surface and the detachable support. Wherein the immobilization device comprises a bottom plate, the adjustment device is placed between said bottom plate and the detachable support thereby creating an angle **β** between the bottom plate and the detachable support. This is advantageous as it allows adjusting the immobilization device for the immobilization of the head of a patient having a back and/or neck deformation such as kyphosis. The patient can comfortably lay down for immobilization of the head which reduces movement of the patient during the immobilization process. In addition, the present invention allows treating patients having a back and/or neck deformation without overstretching the thermoplastic sheet such that is covers the required body part as it is the case using the prior art systems. The system and/or the method of the present invention allow, thanks to the presence of the adjustment device, immobilization of the body part of interest without overstretching the thermoplastic sheet as shown in **Fig. 29**. This maintains the rigidity of thermoplastic material and strain transfer will take place over the rigid and strong legs of the immobilisation device and not over the overstretched and extended thermoplastic sheet.

Preferably, the angle **β** is comprised between 1 and 40°, preferably between 5 and 35°, more preferably between 10 and 25°, most preferably between 15 and 20° or any value comprised between the mentioned ranges.

In a preferred embodiment, the method further comprises the step of placing an adjustment device between the fixation surface and the detachable support, thereby creating a distance **d1** between the fixation surface and the detachable support. Wherein the immobilization device comprises a bottom plate, the adjustment device is placed between said bottom plate and the detachable support thereby creating a distance **d1** between the bottom plate and the detachable support. This is advantageous as it allows adjusting the immobilization such that to minimize the first area of the body part covered by the first sheet. The adjustment is made depending of the body part to be immobilized but also depending on the patient himself. For instance, for the immobilization of a child head, an adjustment device creating a distance **d1c** is needed while for the immobilization of an adult head, an adjustment device creating a distance **d1a** is needed. The distance **d1a** will be smaller than the distance **d1c**.

Preferably, the distance **d1** is comprised between 1mm and 2cm, preferably between 10mm and 1cm, more preferably between 20mm and 80mm, most preferably between 30mm and 60mm or any value comprised between the mentioned ranges.

In a preferred embodiment, the method further comprises the step of mounting a second sheet to the flanged support member prior to placing the patient body part to be immobilized on the detachable support. The use of a second sheet allows covering the anatomical contours of a second area of said body part which is not covered by the first sheet and thereby covering the total area of the body part.

In a preferred embodiment, the first and/or the second sheets are moldable and suitable to be placed on the patient body part such as to conform the anatomical contours of said patient body part. Said first and/or the second sheets might also be pre-formed sheets which are conform to the anatomical contours of the patient body part to be immobilized. Said pre-formed sheets might be obtained after scanning the body part to be immobilized. Further details with respect to the first and/or the second sheet are provided below. Any other sheets suitable to be used in the context of the present invention and known to the person skilled in the art are also included in the present invention.

Wherein the first sheet is suitable to be formed on the patient body part, a moldable thermoplastic sheet might be used. The method comprises the following steps:

- mounting an immobilization device to a support fixation surface which might be a table for radiation therapy, said immobilization device comprises a detachable support such as a cushion and a flanged support member,
- placing the patient body part to be immobilized on the detachable support,
- heating the first moldable thermoplastic sheet and mounting it to the flanged support member of the device. The heated sheet will deform into a shape which is conform and which covers the anatomical contours of a first area of the patient body part,

- cooling the first moldable thermoplastic sheet to ambient temperature to rigidify said sheet,

wherein the first area covered by said first sheet is at maximum comprised between 1% and 40% of the total area of the body part to be immobilized.

In a preferred embodiment, the first sheet is brought in contact with the patient's body part without pressing it against said body part. Preferably, the first sheet is provided with high elasticity such as it conforms the patient's body part anatomical contours without pressure requirement. In some cases and wherein the face is covered by the first sheet, it might be required to apply a light pressure on the bone of the nose, and/or the cheek bones and/or the orbital rim and/or any relevant anatomical structure to conform the sheet to the nose of the patient.

Wherein the first sheet is a pre-formed sheet, the method comprises the following steps:

- mounting an immobilization device to a support fixation surface which might be a table for radiation therapy, said immobilization device comprises a detachable support such as a cushion and a flanged support member,
- placing the patient body part to be immobilized on the detachable support, and
- mounting the first sheet to the flanged support member of the device thereby covering the anatomical contours of a first area of said body part

wherein the first area covered by said first sheet is at maximum comprised between 1% and 40% of the total area of the body part to be immobilized.

Wherein two sheets are used and they are suitable to be formed on the patient body part, moldable thermoplastic sheets might be used. The method comprises the following steps:

- mounting an immobilization device to a support fixation surface which might be a table for radiation therapy, said immobilization device comprises a detachable support such as a cushion and a flanged support member,
- heating a second moldable thermoplastic sheet and mounting it to the flanged support member of the device,
- placing the patient body part to be immobilized on said second heated moldable thermoplastic sheet such as to deform the sheet into a shape which is conform to the anatomical contours of a second area of the patient body part which will not be covered by the first sheet,
- cooling the second sheet to ambient temperature to rigidify said second sheet,
- heating the first moldable thermoplastic sheet and mounting it to the flanged support member of the device. The heated sheet will deform into a shape which is conform and which covers the anatomical contours of a first area of the patient body part,
- cooling the first moldable thermoplastic sheet to ambient temperature to rigidify said sheet,

wherein the first area covered by said first sheet is at maximum comprised between 1% and 40% of the total area of the body part to be immobilized.

Wherein two pre-formed sheets, the method comprises the following steps:

- mounting an immobilization device to a support fixation surface which might be a table for radiation therapy, said immobilization device comprises a detachable support such as a cushion and a flanged support member,
- mounting a second sheet to the flanged support member of the immobilization device,
- placing the patient body part to be immobilized on said second sheet thereby covering the anatomical contours of a second area of the patient body part which will not be covered by the first sheet,
- mounting the first sheet to the flanged support member of the immobilization device thereby covering the anatomical contours of a first area of the patient body part,

wherein the first area covered by said first sheet is at maximum comprised between 1% and 40% of the total area of the body part to be immobilized.

Wherein two sheets are used, the cured first and second sheets form an immobilization double shell mask covering the entire head of the patient. The double shell mask is personalized to the patient's head anatomy. In a preferred embodiment of the method, for mounting the first sheet, the patient is maintained in the same position as for mounting the second sheet. This is advantageous as a high level of stability is ensured during the production of the immobilization double shell mask, thereby providing a better fit of the mask to the anatomical contours of the patient's head.

For molding the first and/or the second moldable thermoplastic sheets, said sheets are heated at a temperature comprised between 70 and 90°C, preferably between 65 and 85°C. The sheets may be softened by warming them to a temperature above their glass transition temperature, for instance by immersion in warm water, at which temperature they becomes shapeable. In a preferred embodiment, the sheets are warmed by immersion in an aqueous liquid having a temperature comprised between 70-90 °C. The sheets are allowed to cool below their glass transition temperature, preferably to ambient temperature of 20°C to 30°C. Consequently, the sheets will rigidify and provide a form-fitting double shell mask.

Although warming of the thermoplastic sheets above their glass transition temperature will cause the sheets to become stretchable and deformable, they can be transported without damage by taking hold of the circumferential rims (described later) of the sheets and displacing them on the flanged support member of the immobilization device. Said circumferential rims can be permanently fixed to the moldable thermoplastic sheets or can be dismountably fixed to said sheets. The latter configuration is advantageous as it allows optimizing the cleaning of the sheets both in their initial and final state. Furthermore,

dismountable circumferential rims can be easily changed by new rims if required, for instance if the rim is damaged.

The present invention further provides a system for immobilization of a patient body part, such as the head, for radiotherapy applications. The system comprises:

- at least one first sheet for covering the anatomical contours of a first area of said body part,
- an immobilization device suitable to be mounted to a fixation surface, said immobilization device comprises:
    - i) a detachable support, such as a cushion, on which the body part is suitable to be placed, and
    - ii) a flanged support member provided with at least one attachment means for receiving and retaining the first sheet.

The system is characterized in that the attachment point of the flanged support member which is most proximal to the fixation surface is positioned at a distance D1 from said fixation surface such that when the body part to be immobilized is placed on the detachable support and the first sheet is retained by the flanged support member, the first area of said body part covered by the first sheet is at maximum comprised between 1% and 40% of the total area of said body part. The total area of the body part is as described above.

In a preferred embodiment, the first area covered by said first sheet is at maximum comprised between 2 and 39%, between 2 and 38%, between 2 and 37%, between 2 and 36%, between 2 and 35%, between 2 and 34%, between 2 and 33%, between 2 and 32%, between 2 and 31%, between 2 and 30%, between 2 and 29%, preferably between 3 and 28%, more preferably between 4 and 27%, even more preferably between 5 and 26%, most preferably between 6 and 25% of the total area of the body part to be immobilized. In a more preferred embodiment, the first area covered by said first sheet is at maximum comprised between 7 and 24%, preferably between 8 and 23%, more preferably between 9 and 22%, even more preferably between 10 and 21%, most preferably between 11 and 20% of the total area of the body part to be immobilized. In a further preferred embodiment, the first area covered by said first sheet is at maximum comprised between 12 and 19%, preferably between 13 and 18%, more preferably between 14 and 17%, most preferably between 15 and 16% of the total area of the body part to be immobilized.

In a preferred embodiment, the distance **D1** is measured from the attachment point of the flanged support member and perpendicularly to the fixation surface. **D1** is preferably comprised between 5 and 100 cm, preferably between 10 and 90 cm, more preferably between 15 and 80 cm, even more preferably between 20 and 70 cm, most preferably between 25 and 60 cm, even most preferably between 30 and 50 cm.

In a preferred embodiment, the flanged support member is mounted substantially parallel to the fixation surface. Preferably, the flanged support member is mounted such that it is contained in a plane which is substantially parallel to the plane of the fixation surface.

In a preferred embodiment, the flanged support member fixation means are selected from the group comprising upstanding circumferential support legs, upstanding walls provided with openings, upstanding pyramids, inverted pyramids or any other flanged support member fixation means known to the person skilled in the art. Said flanged support member fixation means can be of any shape.

In a preferred embodiment, the immobilization device further comprises a bottom plate. Said bottom plate can be permanently or dismountably connected to the flanged support member by the flanged support member fixation means. The bottom plate and the flanged support member might be connected by an open structure, for instance connected by upstanding circumferential support legs thereby creating said open structure. The bottom plate is provided with fixation means for mounting said bottom plate to a fixation surface.

In a preferred embodiment, the flanged support member fixation means separate the plane of the bottom plate or the plane of the fixation surface from the plane of the flanged support member by a distance **D1** comprised between 5 and 100 cm, preferably between 10 and 90 cm, more preferably between 15 and 80 cm, even more preferably between 20 and 70 cm, most preferably between 25 and 60 cm, even most preferably between 30 and 50 cm. Said distance **D1** being measured in a perpendicularly to the bottom plate or to the plane of the fixation surface.

In a preferred embodiment, the upstanding circumferential support legs are substantially perpendicular to the bottom plate and/or to the flanged support member and are separated from each other, at the level of the bottom plate or at the level of the fixation surface by a distance **D** comprised between 8 and 30 cm, preferably between 10 and 20 cm. The upstanding circumferential support legs might also be positioned such that each leg forms an angle with the bottom plate and/or with the flanged support member. Said angle is comprised between 45° and 90°. In a preferred embodiment, the device is provided with 2 to 20, preferably 3 to 15, more preferably 4 to 10 upstanding circumferential support legs. In a preferred embodiment, the device comprises at least 6 upstanding circumferential support legs. Preferably, the support legs consist of a carbon fiber tube produced using uni-directional braided or weaved carbon fibre epoxy combinations. Said tube has a wall thickness of 0.2-2.0mm and a weight between 150 and 250gr/$m^2$. For optimal dosimetric properties, the wall thickness is between 0.2 and 0.5mm. The support legs might be glued to the flanged support member and/or to the bottom plate. In the gluing areas the tubes are filled with low density foam, e.g. Rohacell 51 or 71, with a maximum length of 10-15mm.

Preferably, the upstanding circumferential support legs form an angle α (shown in **FIG. 1**) with the bottom plate or with the fixation surface. Said angle α is at least 90° and is comprised between 90° and 150°, preferably between 100° and 140° More preferably between 110° and 135°.

In a preferred embodiment, the immobilization device comprises at least one flanged support member having a plurality of attachment means adapted to receive at least one sheet or two sheets. The plane of the bottom plate and the plane of the flanged support member are substantially parallel to each other or form two angled planes to preposition the patient's body part depending on the treatment.

Preferably, the flanged support member **3** of the immobilization device has a flat shape (**FIG. 1**). The flanged support member **3** is adapted to receive at least one sheet or two moldable thermoplastic sheets having each a circumferential rim (will be detailed further). In a preferred embodiment, the circumferential rim of each sheet and the flanged support member are, at least partially, superimposable (as shown in **FIG. 16**).

In a preferred embodiment, the immobilization device of the present invention has a shape which is open at one end; said shape is preferably a U shape. In a preferred embodiment, the flanged support member **3** and the circumferential rim **12'** of the sheet presented in the figures have a U shape as said figures show an immobilization device adapted a human head. It is to be understood that the flanged support member **3** and the circumferential rim **12'** can have any other shape adapted to immobilize any other part of a human body. For instance the immobilization device might comprise two flanged support members each having a shape which is parallel to the contours of the trunk of a patient. The two flanged support members might be substantially linear members whereby one member is placed at the right and the other member is placed at the left of the body part to be immobilized.

In a preferred embodiment, the flanged support member is provided with attachment means **5**. Said attachment means **5** are selected from the group comprising: snap fit means connections and openings for receiving rivets, screws or bolts (**FIG. 1**). In a preferred embodiment, the flanged support member is provided with 5 to 30, preferably 10 to 25, more preferably 12 to 22 attachment means.

In a preferred embodiment, the bottom plate **2** is provided with fixation means **6** for mounting the bottom plate **2**, and hence mounting the immobilization device, to a support fixation surface **7** such as table for radiation therapy (**FIG. 17**). The support fixation surface **7** is also provided with immobilization device fixation means **9** which correspond to the bottom plate fixation means **6** (**FIG. 15**). The fixation means of the bottom plate and the corresponding fixation means of the support fixation surface are selected from the

group comprising: rivets, screws, bolts and nuts, and snap fit means connections and foam or plastic pads or parts that will fit in recesses in the support fixation surface or the bottom plate. Preferably, the fixation means **6** of the bottom plate **2** comprise snap fit connections and rivets. In a preferred embodiment, the bottom plate is provided with 3 to 30, preferably 5 to 25, more preferably 10 to 20 fixation means. Wherein the flanged support member is mounted on the fixation surface using flanged support member fixation means, the fixation surface is adapted to receive and fix said fixation means.

In a preferred embodiment, the immobilization device is manufactured from a material having a low density. In a further preferred embodiment, the device is manufactured from a carbon composite material, more preferably from a carbon composite polymer, most preferably from carbon fiber reinforced plastics. This is advantageous as the device will have a low specific weight while having the necessary strength for holding the patient's head during the production of the double shell mask. In a preferred embodiment, the weight of the device is comprised between 50 and 1000g, preferably between 100 and 900 g, more preferably between 150 and 800g.

In a preferred embodiment, the first sheet is a moldable thermoplastic sheet comprising a circumferential rim which is provided with connection means such that said connection means are corresponding to all or to some attachment means of the immobilization device. Preferably, the connection means are regularly distributed on the circumferential rim. It is to be understood that all features of the first sheet also apply to the second sheet.

In a preferred embodiment, the circumferential rim is manufactured from a material having high temperature tolerance. In a further preferred embodiment, the circumferential rim is manufactured from a carbon composite material having low density, more preferably from a carbon composite polymer, most preferably from carbon fiber or carbon fiber reinforced plastics. This is advantageous as the thermoplastic sheets will have a low weight facilitating their used and manipulation by the practitioner.

In a preferred embodiment, the first and/or the second sheet might be provided with one or more openings. For instance an opening can be provided in the sheet covering the face of the patient. Said opening will be positioned such as to be at the level of the nose and/or the mouth and or the eyes of the patient.

In a preferred embodiment, the thermoplastic sheet and the circumferential rim are physically (i.e. heat bonding), mechanically (i.e. clamping) or chemically bonded (i.e. glued). In another preferred embodiment, the thermoplastic sheet and the circumferential rim are dismountably fixed to each other, via snap-fit system for instance.

It is to be understood that the first sheet can be also be used to cover the side of the patient comprising the rear head, the rear neck and the back of the patient.

Wherein two sheets are used, the circumferential rims of said sheets are each provided with a number of connection means for mounting said sheets to the flanged support member. Preferably, said circumferential rims are designed to be superimposable. The connection means are selected from the group comprising: rivets, screws, bolts and nuts, and snap fit means connections or any other type of connections means known to the person skilled in the art. The connection means can also be simply openings wherein a fastening means such as rivets or bolts can be introduced and used. In a preferred embodiment, each circumferential rim is provided with 3 to 30, preferably 5 to 25, more preferably 10 to 20 connection means.

In a preferred embodiment, the connection means of the circumferential rim of the first sheet are positioned such that they correspond to all or to a part the connection means of the circumferential rim of the second thermoplastic sheet and/or to all or to a part of the attachment means of the flanged support member of the immobilization device when the first and the second thermoplastic sheets are simultaneously attached to the flanged support member.

In a preferred embodiment, the connection means of the circumferential rim of the second sheet are positioned such that they correspond to all or to a part of the connection means of the circumferential rim of the first thermoplastic sheet and/or to all or to a part of the attachment means of the flanged support member of the immobilization device when the first and the second thermoplastic sheets are simultaneously attached to the flanged support member.

In a preferred embodiment, the connection means are positioned on the circumferential rim such as to correspond intermittently with all or with a part of the attachment means of the flanged support member. For instance, each attachment means of the flanged support member corresponding with a connection means of the first thermoplastic sheet will have a left and right neighboring attachment means that correspond with two connection means of the second thermoplastic sheet. Similarly, each attachment means of the flanged support member corresponding with a connection means of the second thermoplastic sheet will have a left and right neighboring attachment means that correspond with two connection means of the first thermoplastic sheet.

The moldable thermoplastic sheets of the invention can be of any composition known to the person skilled in the art and/or described in the prior art and/or available on the market. The thermoplastic sheet can be a single sheet or a laminate which is perforated or non-perforated. The laminate can comprise one or more core thermoplastic layers bound to a support which comprises a mesh and/or a layer of cotton and/or a layer of elastic cotton

and/or open cell foam and/or silicone and/or any other soft fabric for providing a comfortable feeling to the patient. The perforations diameter is comprised between 0.1 mm and 3 mm and preferably between 0.5 and 2 mm, more preferably between 1 to 1.3 mm. Said perforations may be positioned in rows separated by 1 mm to 5 mm. The perforations may represent 10% to 90%, preferably 20% to 80%, more preferably 30% to 70% of the sheet surface. The perforations allow the skin of the patient to breathe even after application of the thermoplastic sheets.

In a preferred embodiment, when cured, the thermoplastic sheet of the invention shows limited shrinking and is soft such as to provide comfort to the patient. Preferably, the thermoplastic sheet is directly moldable on the human body and presents the advantage that it is unbreakable in case of hard handling or after falling. Moreover, the thermoplastic sheet is optically transparent which gives the possibility to observe whether or not it has been properly molded to the body part. The thermoplastic sheet can also be semi-transparent or opaque.

The sheet can also be pre-formed and is herein called cast. Preferably, the cast is a 3D printed cast that conforms and covers the body part to be immobilized. The cast is suitable to be connected and retained by the immobilization device, more in particular by the flanged support member of said device. The cast may be produced using any tool or system known to the person skilled in the art. Preferably said cast is printed according to the patient's body part to be immobilized. For instance, the body part to be immobilized can be scanned and the cast printed using a 3D printer.

Preferably, the moldable thermoplastic sheet or any other pre-formed sheet or cast, is treated with an antibacterial product before being used. In a preferred embodiment, said sheet comprises at least one antibacterial compound or a mixture of antibacterial compounds. Further, the sheet is not susceptible to any crimping during use or storage.

In a preferred embodiment, the immobilization device comprises a detachable support such as a cushion. The body part to be immobilized can rest on the detachable support for further stabilization of said body part during the immobilization process.

In a preferred embodiment, the detachable support is also used for optimizing the position of the body part to be immobilized with respect to the flanged support member of the immobilization device. More in particular, the height of the detachable support is used for optimizing the position of the body part. Said height is defined by the distance between the lower surface of the detachable support and its upper surface when the support is attached to the immobilization device or to the fixation surface. The person skilled in the art understands that the lower surface is the surface in contact with the immobilization device bottom plate or with the fixation surface. The upper surface is the surface of the detachable

support on which the body part rests. Optimizing the position of the body part to be immobilized with respect to the flanged support member of the immobilization device, comprises either (i) bringing the body part closer to the flanged support member and further away from the fixation surface (**Fig. 17**) or (ii) bringing the body part closer to the fixation surface and further away from the flanged support member (**Fig. 18**). The final goal is either case to position the body surface such that the first area covered by the first sheet is at maximum comprised between 1% and 40% of the total area of the body part to be immobilized.

If required, the lower surface of the detachable support can be positioned at a distance from the flanged support member which is higher than the distance separating the flanged support member and the bottom plate of the immobilization device as shown in **Fig. 18**. This can be performed for bringing the body part closer to the fixation surface and further away from the flanged support member. It is to be understood that the immobilization device and the detachable support will be specifically designed for achieving the assembly shown in **Fig. 18**.

The detachable support can be made of a material that conforms the body part to be immobilized. Said detachable support will conform to the area of the body part which is not covered by the first sheet. The detachable support can temporarily conform the body part and in this case it can be used with different patients. The detachable support can also permanently conform the body part and in this case it will be specifically adapted to one patient body part.

In a preferred embodiment, the detachable support is at least partially made of a plastic material. The detachable support may be attached to the fixation surface, the bottom plate or to the adjustment device by a clamp and bolts or with any other means known to the person skilled in the art.

The invention further provides an adjustment device for adjusting the position of a body part to be immobilized for radiotherapy applications, comprising a lower surface and an upper surface wherein the upper surface is inclined at an angle **β** with respect to the lower surface and/or wherein the lower surface and the upper surface are substantially parallel to each other and are separated from each other by a distance **d1**. The adjustment device can be a part of the system of the invention.

In a preferred embodiment, the system comprises an adjustment device for adjusting the positioning of the body part to be immobilized; said adjustment device comprises a lower surface and an upper surface. The lower surface of the adjustment device is the surface of the device which is in contact with the fixation surface or the bottom plate when said adjustment device is used. The upper surface of the adjustment device is the surface of the

device which is not in contact with the fixation surface or the bottom plate when said adjustment device is used. Said upper surface might be in contact with the detachable support of the immobilization device.

The adjustment device can have any shape such as rectangular, square, triangular, parallelogram, etc. The adjustment device is removably attached to the fixation surface or to the bottom plate of the immobilization device. Said adjustment device can also be removably attached to the detachable support of the immobilization device. The adjustment device can be made of any non-metallic material and is preferably made of carbon fiber epoxy or aramide fiber composite.

In a preferred embodiment, the lower surface of the adjustment device is inclined at an angle **β** with respect to the lower surface of said device. Preferably, the angle **β** is comprised between 1 and 40°, preferably between 5 and 35°, more preferably between 10 and 25°, most preferably between 15 and 20° or any value comprised between the mentioned ranges. Preferably, the system comprises a plurality of adjustment devices having different angle **β** values. The user is thereby provided with multiple adjustment options. Preferably, the system comprises between 1 and 20 adjustment devices having different angle **β** values.

In a preferred embodiment, the lower surface and the upper surface of the adjustment device are substantially parallel to each other and are separated from each other by a distance **d1**. Said distance **d1** is measured starting from a point in the upper surface and perpendicularly to the lower surface. The distance **d1** can also be considered the height of the adjustment device when said device maintained in use position. Preferably, the distance **d1** is comprised between 1mm and 2cm, preferably between 10mm and 1cm, more preferably between 20mm and 80mm, most preferably between 30mm and 60mm or any value comprised between the mentioned ranges. Preferably, the system comprises a plurality of adjustment devices having different distance **d1** values. The user is thereby provided with multiple adjustment options. Preferably, the system comprises between 1 and 20 adjustment devices having different distance **d1** values.

In a preferred embodiment, the adjustment device may be attached to the fixation surface or to the bottom plate by a clamp and bolts, by a snap fit system or with any other means known to the person skilled in the art. In a preferred embodiment, the adjustment device may be attached to the detachable support of the immobilization device plate by a clamp and bolts, by a snap fit system or with any other means known to the person skilled in the art.

It is to be understood that the system according to any embodiment of the present invention can be used to achieve immobilization of a patient's body part. In use, said

system can comprise the immobilization device and/or the detachable support and/or the adjustment device. For instance, the detachable support might be directly fixed to the immobilization device. In this case, the system will be devoid of adjustment device. The use of each component of the system depends on the anatomy of the patient.

In a preferred embodiment, the system further comprises a second sheet for covering the anatomical contours of a second area of the body part which is not covered by the first sheet. Said second sheet might have the same characteristics and features as the first sheet or might be different from said first sheet. Preferably, the first and the second sheets comprise each a circumferential rim provided with a number of connection means for mounting said sheets to the flanged support member.

The invention will be now described with reference to the accompanying figures. **Fig. 1** shows a perspective view of the immobilization device **1** to which an adjustment device **300** is attached. The immobilization device **1** comprises a bottom plate **2** and a flanged support member **3** attached to each other by upstanding circumferential support legs **4**. The bottom plate **2** and the flanged support member **3** are separated from each other by a distance **d**. Each upstanding circumferential support leg **4** forms an angle with the bottom plate **2** of the immobilization device. The bottom plate **2** is provided with fixation means **6** for mounting said bottom plate **2** and thereby the immobilization device to a support fixation surface. The flanged support member **3** is provided with a plurality of attachment means **5** adapted to receive at least one sheet. The adjustment device **300** shown in **Fig. 1** is provided with a lower surface and an upper surface which are separated from each other by a distance **d1**.

**Fig. 2** shows a side view of the immobilization device **1** and the adjustment device **300** of **Fig. 1. Fig. 3** shows a perspective view of the immobilization device **1** shown in **Fig. 1** to which an adjustment device **300** is attached. The lower surface and an upper surface of said adjustment device **300** of **Fig. 3** are separated from each other by a distance **d1** which is higher than the distance **d1** of the adjustment device **300** shown in **Fig. 1**. **Fig. 4** shows a side view of the immobilization device **1** and the adjustment device **300** of **Fig. 3.**

**Fig. 5** shows a perspective view of the immobilization device **1** shown in **Fig. 1** to which an adjustment device **300'** is attached. The lower surface and the upper surface of said adjustment device **300'** are separated from each other by an angle **β**. **Fig. 6**, shows a side view of the immobilization device **1** and the adjustment device **300'** of **Fig. 5. Fig. 7** shows a side view of the immobilization device **1** and the adjustment device **300'** of **Fig. 5** to which a detachable support **200** is attached.

**Fig. 8** shows a perspective view of the immobilization device **1** shown in **Fig. 1** to which an adjustment device **300'** is attached. In said adjustment device **300'**, the lower surface and

the upper surface are separated from each other by an angle **β** which is higher than the angle **β** of the adjustment device **300'** shown in **Fig. 5**. **Fig. 9** shows a side view of the immobilization device **1** and the adjustment device **300'** of **Fig. 8. Fig. 10** shows a side view of the immobilization device **1** and the adjustment device **300'** of **Fig. 8** to which a detachable support **200** is attached. Using the devices shown in **Fig. 5** to **Fig. 10** the neck of the patient rests on the area of the immobilization device in which the lower surface and the upper surface of are most proximal to each other. It is to be understood that the adjustment device can be attached to the immobilization device **1** such as the neck of the patient rests on the area of the immobilization device in which the lower surface and the upper surface of are most distant from each other (**Fig. 10'**).

**Fig. 11** shows a perspective view of a fixation surface **7** to which the immobilization device **1** can be attached and fixed. The fixation surface **7** is provided with immobilization device fixation means **9** which correspond to the bottom plate fixation means **6** or which are suitable for receiving and attaching the support member fixation means, such as the support legs, to the fixation surface. The fixation surface **7** is further is further provided with other fixation means **9'** for attaching the fixation surface **7** to any other surface such as a table for instance. It is to be understood that within the frame of the present invention, the fixation surface can itself be a radiation table provided with fixation means **6** for attaching and fixing the immobilization device **1**. The fixation surface **7** shown in **Fig. 11** is for immobilizing the head, neck and trunk of a patient. The fixation surface might further comprise a depression **50** or a concave shape at the area of the fixation surface which received the back of the patient. This allows minimizing the trunk area which will be covered by the first sheet thereby providing for a more rigid and stable immobilization of the patient's trunk. The fixation surface might also be provided with attachment means **51** for at least partially attaching the first sheet to the fixation surface **7**.

**Fig. 12** shows a perspective view of a fixation surface **7** to which the immobilization device **1** is be attached and fixed. The immobilization device **1** comprises a bottom plate **2**, a detachable support **200** and a flanged support member **3** adapted to receive and retain at least one first sheet.

**Fig. 13** shows a first sheet for covering the face of a patient according to an embodiment of the invention. The sheet is provided with a circumferential rim **12'** which comprises connection means **8'**. The sheet can be a preformed sheet or a sheet moldable directly on the patient's face. Wherein the sheet is moldable on the patient's face, said sheet is obtained after heating and fixing the heated sheet to the flanged support member **3** of the immobilization device **1**. Said fixation is achieved using the attachment means **5** of the flanged support member and the connection means **8'** of the circumferential rim **12'** of the sheet. The heated sheet **11'** will deform according to the anatomical contours of the patient's face. The sheet **11'** is then allowed to cool down such as to obtain a cured sheet

**11'** as shown in **FIG. 13**. Said cured sheet **11'** comprises a protrusion **15** corresponding to the nose of the patient and is provided with an opening **13'** corresponding to the mouth of the patient and openings **15'** corresponding to the eyes of the patient. The sheet can also be devoid of said openings or provided with one opening type **13'** or **15'**. The sheet can be perforated or non-perforated. Alternatively, when a pre-formed sheet is used, the first sheet is fixed, via the connection means **8'** of its circumferential rim **12'**, to the flanged support member attachment means. The sheet might be disconnected from the circumferential rim **12'** which for instance allows optimization of the cleaning of the molded sheet thereby improving the hygiene of the treatment.

In a preferred embodiment, the system, the immobilization device and the method of the invention are suitable for immobilizing the head and the neck and the trunk of a patient. It is to be understood that any other part of the body can be immobilized. In a preferred embodiment, the trunk is at least partially immobilized by the present invention.

**Fig. 14** shows the first sheet **100** comprising a part **HN** designed to cover the head and the neck of a patient and part **T** designed cover at least partially the trunk of a patient. The sheet is provided with a circumferential rim **112** which comprises connection means **108**. The sheet can be a preformed sheet or a sheet moldable directly on the patient's face. Said sheet is provided in its **T** part with apertures (not shown) for mounting attachment edges **113** to the sheet **100**. The attachment edges **113** are provided for fixing and attaching the sheet and in particular the **T** part of the sheet **100** to a fixation surface. Preferably said apertures are provided on either side with respect to the sagittal plane of the body, i.e. on the left and on the right of the longitudinal central axis **A-A'** of the sheet (**Fig. 14**). The sheet might be provided with one or more openings **101, 115** which might correspond to the mouth and/or the eyes of the patient.

In a preferred embodiment, the area **HN**, designed to be molded and to cover a first area of the head and the neck of a patient, is connectable to a circumferential rim **112** (**Fig. 14**). The area **T**, designed to be molded and to cover a first area of the trunk of a patient, is connectable to attachment edges **113** via the apertures provided in said **T** part. In a preferred embodiment, the circumferential rim **112** and/or the attachment edges **113** of the moldable thermoplastic sheet **100** are provided with a number of connection means **108**, **126** for attaching the sheet **100**, including part **T** and **HN**, to a fixation surface. The circumferential rim can be permanently fixed to the moldable thermoplastic sheets or can be dismountably fixed to said sheet.

**Fig. 15** shows an exploded perspective view of the immobilization device, the fixation surface and the first sheet according to an embodiment of the invention. The immobilization device is suitable to be mounted to the fixation surface **7** using the fixation means **6** of the immobilization device and the immobilization device fixation means **9** of the fixation surface

**7**. The immobilization device comprises the detachable support **200** and the first sheet **100** is suitable to be attached and fixed to the flanged support member **3** of the immobilization device. Although not shown in **Fig. 15**, the person skilled in the art understands that a patient's head and trunk are respectively positioned on the detachable support **200** and on the depression **50** of the fixation surface **7**. The **T** part of the first sheet is attachable to the fixation surface **7** using the attachment means **51** of the fixation surface **7** and the connection means **126** of the attachment edges **113** of the first sheet **100**.

**Fig. 16** shows a perspective view of the first sheet **100**, its rim **112** and its attachments edges **113**. The **HN** part of the mask is attached to the flanged support member **3** of the immobilization device. Said immobilization device comprises the detachable support **200**. The immobilization device can be attached to a fixation surface via the fixation means **6** provided on the bottom plate **2** of said device and via the connection means **126** provided on the attachment edges **113** of the first sheet **100**.

**Fig. 17** shows a side view of the first sheet **100** attached to the fixation surface **7.** The **T** part of said sheet is attached to the fixation surface **7** via the connection means **126** provided on its attachment edges **113**. The **HN** part of the sheet is attached to the flanged support member **3** of the immobilization device which is itself connected to the fixation surface **7**. The immobilization device comprises a detachable support **200** which is herein used to bring the body part closer to the fixation surface and further away from the flanged support member.

**Fig. 18** shows a side view of the first sheet **100** attached to the flanged support member **3** of the immobilization device. Said immobilization device comprises a detachable support **200** which is herein used to bring the body part closer to the fixation surface and further away from the flanged support member.

In a preferred embodiment, the fixation surface **7** comprises at least one stabilization element **10** (**Fig. 19**). Said stabilization element is preferably provided in the area of the fixation surface to which the immobilization device is to be attached. The stabilization element can have any size and shape such as rectangular, triangular, pyramidal - and is preferably protruding from the surface of the fixation device. The stabilization element can be made of the same or from different material compared to the material of the fixation surface. A plurality of stabilization elements **10** can be provided to one fixations surface. Preferably, each stabilization element **10** is designed and adapted to receive at least one fixation member **11**. Said fixation member is preferably a fixation rim as shown in **Fig. 20**. Each fixation member has preferably an L shape or L profile. The fixation members **11** are attachable to the fixation surface using any attachment means **5'** known to the person skilled in the art. Said means are selected from the group comprising: snap fit means connections and openings for receiving rivets, screws or bolts or any combination thereof.

In a preferred embodiment, each fixation member **11** comprises at least one recess **12** in which the stabilization element **10** (**Fig. 21**) of the fixation surface can be introduced. When the stabilization element **10** of the fixation surface is introduced into the recess **12** of the fixation member **11**, the L profile of the fixation member **11** is attached to the fixation surface. In a preferred embodiment, the stabilization elements **10** and/or the fixation members **11** are positioned such as to delimit the detachable support **200** (**Fig. 22**) thereby maximizing the stability of said support during use for immobilization of a patient's body part. **Fig. 23 A** and **B** show side view, in the direction of arrow **Z**, of the fixation surface shown in **Fig. 22**. The stabilization elements **10** and/or the fixation members **11** might also be used and positioned such as to delimit the adjustment device thereby maximizing the stability of said support during use for immobilization of a patient's body part. In general said stabilization elements **10** and/or fixation members **11** are used to further stabilize the device which will be directly attached to the fixation surface. Whenever the adjustment device and/or the detachable support is directly fixed to the fixation surface, the sheet placed on the patient's body part might be directly attached to the fixation member. Said attachment might be performed by gluing the sheet to the fixation member.

It is to be understood that the immobilization device can be adapted to be fixed to the fixation surface which comprises stabilization elements. Said immobilization device will be provided with openings **13** which number and/or position and/or size correspond to said stabilization elements as shown in **Fig. 24**. This further stabilizes the attachment of the immobilization device to the fixation surface. It is to be understood that any adjustment device and/or detachable support described in the present invention might be attached or fixed to the immobilization device of **Fig. 24**. This is shown in **Fig. 25**, **Fig. 26** and **Fig. 27**. The adjustment device and the detachable support are as described in the present invention. Whenever the support member is fixed to the fixation surface, the sheet placed on the patient's body part might be attached to the rim of said immobilization member.

The present invention further provides a kit for immobilization of a patient body part, such as the head, for radiotherapy applications. The kit comprises:

- at least one first sheet for covering the anatomical contours of a first area of said body part,
- an immobilization device suitable to be mounted to a fixation surface, said immobilization device comprises:
    - i) a detachable support, such as a cushion, on which the body part is suitable to be placed, and
    - ii) a flanged support member provided with at least one attachment means for receiving and retaining the first sheet,

- at least one adjustment device for adjusting the positioning of the body part to be immobilized, said adjustment device comprises a lower surface and an upper surface, and
- at least one leaflet comprising instructions to the user.

The first sheet, the immobilization device and the adjustment device are as described above. The leaflet comprises instructions to the user relative to the use of the different components of the kit and the different method steps to follow for using said kit.

The invention further provides a method for the immobilization of a body part wherein the sheet or the sheets are pre-formed. A pre-formed sheet is herein called cast. Preferably, casts are 3D printed casts that conform and cover the body part to be immobilized. The cast or casts are suitable to be connected and retained by the immobilization device of the present invention. In a preferred embodiment, the casts are produced using any tool or system known to the person skilled in the art. Preferably said casts are printed according to the anatomy of the patient's body part to be immobilized.

In a preferred embodiment, the body part to be immobilized is scanned and the casts printed using a 3D printer. The scanning can be performed using a 3D imaging or scanning apparatus thereby obtaining a 3D image or scan of the patient's body part. The 3D imaging or scanning apparatus may comprise a scanning unit or detector for visualising internal structures such as bone structures, such as e.g. a seismographic 3D scanner. The system might be further provided with a detector unit which transmits the data acquired by said 3D imaging apparatus to an acquisition unit, such as a computer, for acquiring the data collected by the 3D imaging or scanning apparatus and for processing said data to obtain a model for two 3D casts. After processing the data collected by the 3D imaging or scanning apparatus in the acquisition unit, instruction is send to the 3D printing device for printing the cast which conforms the anatomical contours of the scanned body part.

The collected data comprises parameters selected by the operator. Said parameters comprise the length, the width, the muscle content and the fat content of the body part to be immobilized or any combination thereof. After processing the data in the acquisition unit, the operator can choose the material of the casts which is most appropriate for the immobilization of the body part. Said casts can be made from a material selected from the group comprising rigid-elastic material, plastics, polyethylene, polypropylene, polyvinylchloride, polystyrene, polyethylene terephthalate, polycarbonate or any combination thereof.

In a preferred embodiment the invention provides a method for the production of casts. The method comprises the steps of (i) scanning the body parts of interest; (ii) determining body part characteristics for instance by the acquisition unit; (iii) sending instructions to a 3D printer; and (iv) obtaining said pre-formed 3D printed casts.

The system and the method according to an embodiment of the invention wherein the body part to be immobilized is scanned for producing casts are advantageous. Said system and method provide for personalized casts which might be adapted to any variation of the body part – weight gain or loss for instance. Furthermore, the cast's material is selected according to the patient's specific body composition – fat, muscles.

The immobilization device according to any embodiment of the present invention is suitable to be used in the system according to any embodiment of the present invention. Further, in the method according to any embodiment of the present invention, the system and/or the immobilization device as provided by the invention are suitable to be used.

It is to be understood that the features described for an embodiment of the present invention are suitable to be applied to any other described embodiment of the invention without departing from the scope of this invention which is defined by the appended claims.

Although the present invention has been described with reference to preferred embodiments thereof, many modifications and alternations may be made by a person having ordinary skill in the art without departing from the scope of this invention which is defined by the appended claims.

**Claims**

1. A method for the immobilization of a patient body part, such as the head, for radiotherapy applications comprising the steps of:
   - mounting an immobilization device comprising a detachable support, such as a cushion, and a flanged support member to a fixation surface; said flanged support member is adapted to receive and retain at least one first sheet;
   - placing the patient body part to be immobilized on said detachable support; and
   - mounting said first sheet to the flanged support member thereby covering the anatomical contours of a first area of said body part,
   wherein the first area covered by said first sheet is at maximum comprised between 1% and 40% of the total area of the body part to be immobilized.
2. The method according to claim 1 wherein the first area covered by said first sheet is at maximum comprised between 5 and 25%, preferably between 6 and 20%, more preferably between 8 and 18% of the total area of the body part to be immobilized.
3. The method according to any of claims 1 or 2 further comprising the step of placing an adjustment device between the fixation surface and the detachable support, thereby creating an angle **β** between the fixation surface and the detachable support.
4. The method according to any of claims 1 or 2 further comprising the step of placing an adjustment device between the fixation surface and the detachable support, thereby creating a distance **d1** between the fixation surface and the detachable support.
5. The method according to any of claims 1-4 further comprising the step of mounting a second sheet to the flanged support member prior to placing the patient body part to be immobilized on said detachable support thereby covering the anatomical contours of a second area of said body part which is not covered by the first sheet and thereby covering the total area of the body part.
6. The method according to any of claims 1-5, wherein the first and/or the second sheets are moldable and suitable to be placed on the patient body part such as to conform the anatomical contours of said patient body part.
7. The method according to any of claims 1-6, wherein the first and/or the second sheets are pre-formed sheets which are conform to the anatomical contours of the patient body part.
8. A system for immobilization of a patient body part, such as the head, for radiotherapy applications comprising:
   - at least one first sheet for covering the anatomical contours of a first area of said body part,
   - an immobilization device suitable to be mounted to a fixation surface, said immobilization device comprises:
      i) a detachable support, such as a cushion, on which the body part is suitable to be placed, and

ii) a flanged support member provided with at least one attachment means for receiving and retaining the first sheet,

characterized in that, the attachment point of the flanged support member which is most proximal to the fixation surface is positioned at a distance **D1** from said fixation surface such that when the body part to be immobilized is placed on the detachable support and the first sheet is retained by the flanged support member, the first area of said body part covered by the first sheet is at maximum comprised between 1% and 40% of the total area of said body part.

9. The system according to claim 8 further comprising an adjustment device for adjusting the positioning of the body part to be immobilized, said adjustment device comprises a lower surface and an upper surface.
10. The system according to any of claims 8-9 wherein the lower surface of the adjustment device is inclined at an angle **β** with respect to the lower surface of said device.
11. The system according to any of claims 8-10 wherein the lower surface and the upper surface of the adjustment device are substantially parallel to each other and are separated from each other by a distance **d1**.
12. The system according to any of claims 8-11 further comprising a second sheet for covering the anatomical contours of a second area of said body part which is not covered by the first sheet.
13. The system according to any of claims 8-12, wherein the first and the second sheet comprise each a circumferential rim provided with a number of connection means for mounting said sheets to the flanged support member.
14. An adjustment device for adjusting the position of a body part to be immobilized for radiotherapy applications, comprising a lower surface and an upper surface wherein the upper surface is inclined at an angle **β** with respect to the lower surface and/or wherein the lower surface and the upper surface are substantially parallel to each other and are separated from each other by a distance **d1**.
15. A kit for immobilization of a patient body part, such as the head, for radiotherapy applications comprising:

at least one first sheet for covering the anatomical contours of a first area of said body part,

an immobilization device suitable to be mounted to a fixation surface, said immobilization device comprises:

i) a detachable support, such as a cushion, on which the body part is suitable to be placed, and

ii) a flanged support member provided with at least one attachment means for receiving and retaining the first sheet,

at least one adjustment device for adjusting the positioning of the body part to be immobilized, said adjustment device comprises a lower surface and an upper surface, and

at least one leaflet comprising instructions to the user.

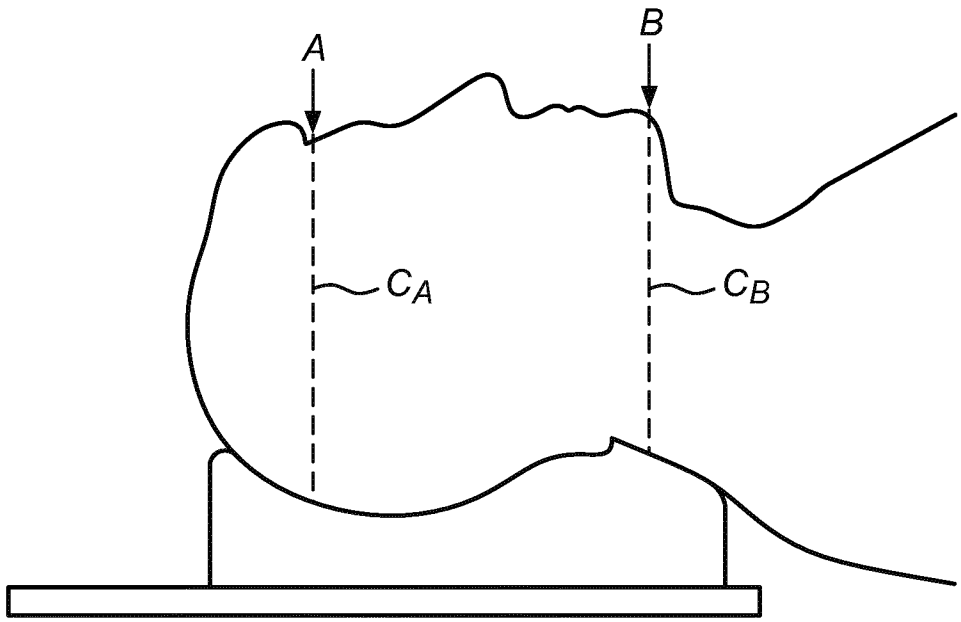


Fig. 1A

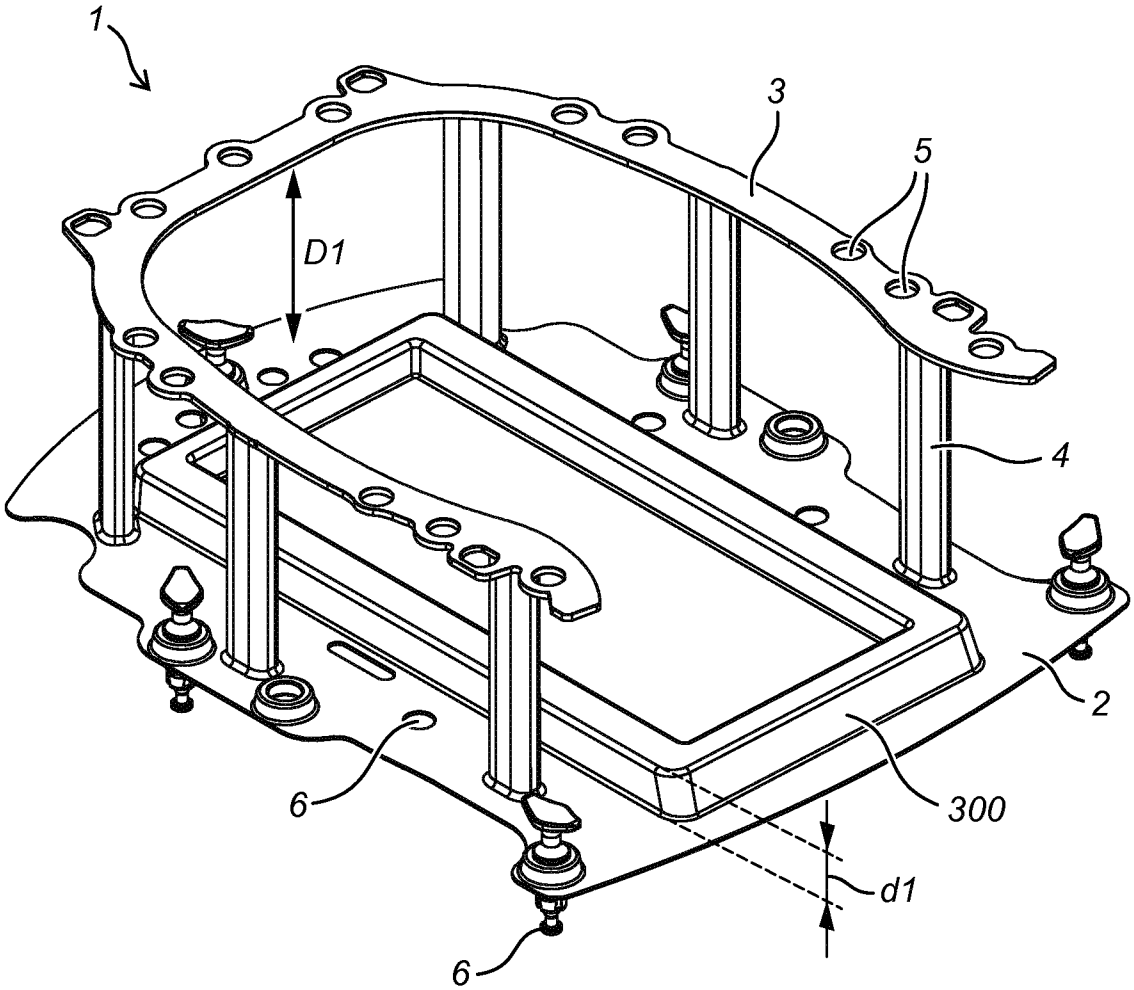


Fig. 1

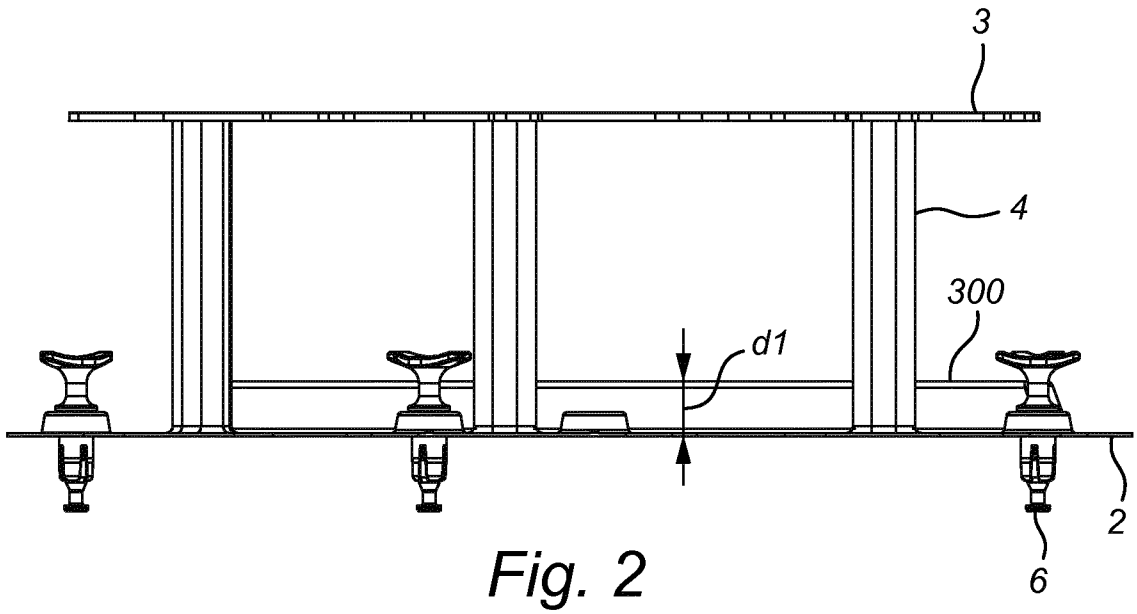


Fig. 2

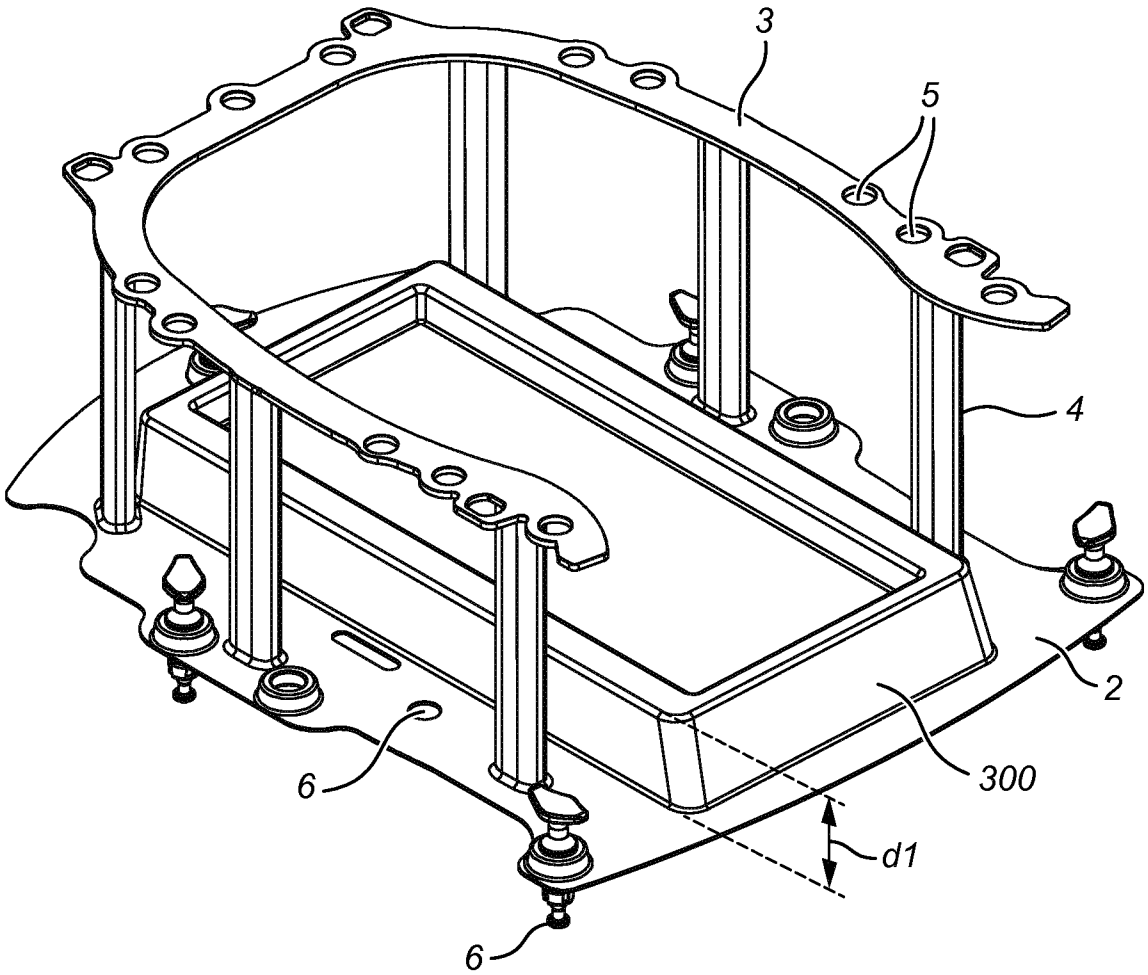


Fig. 3

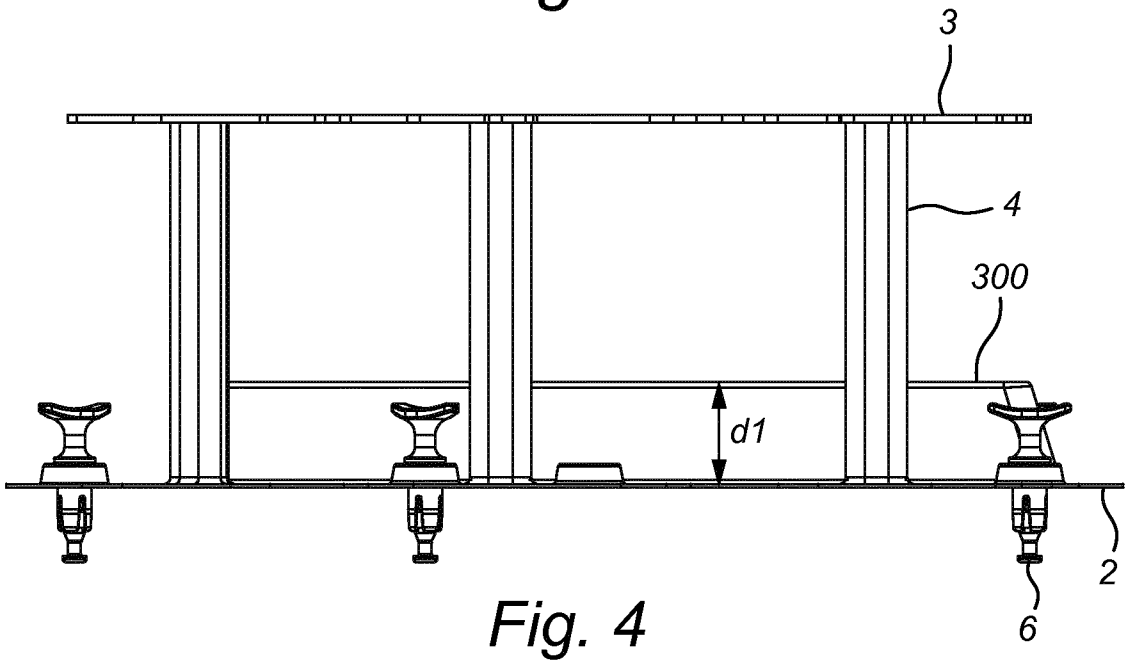


Fig. 4

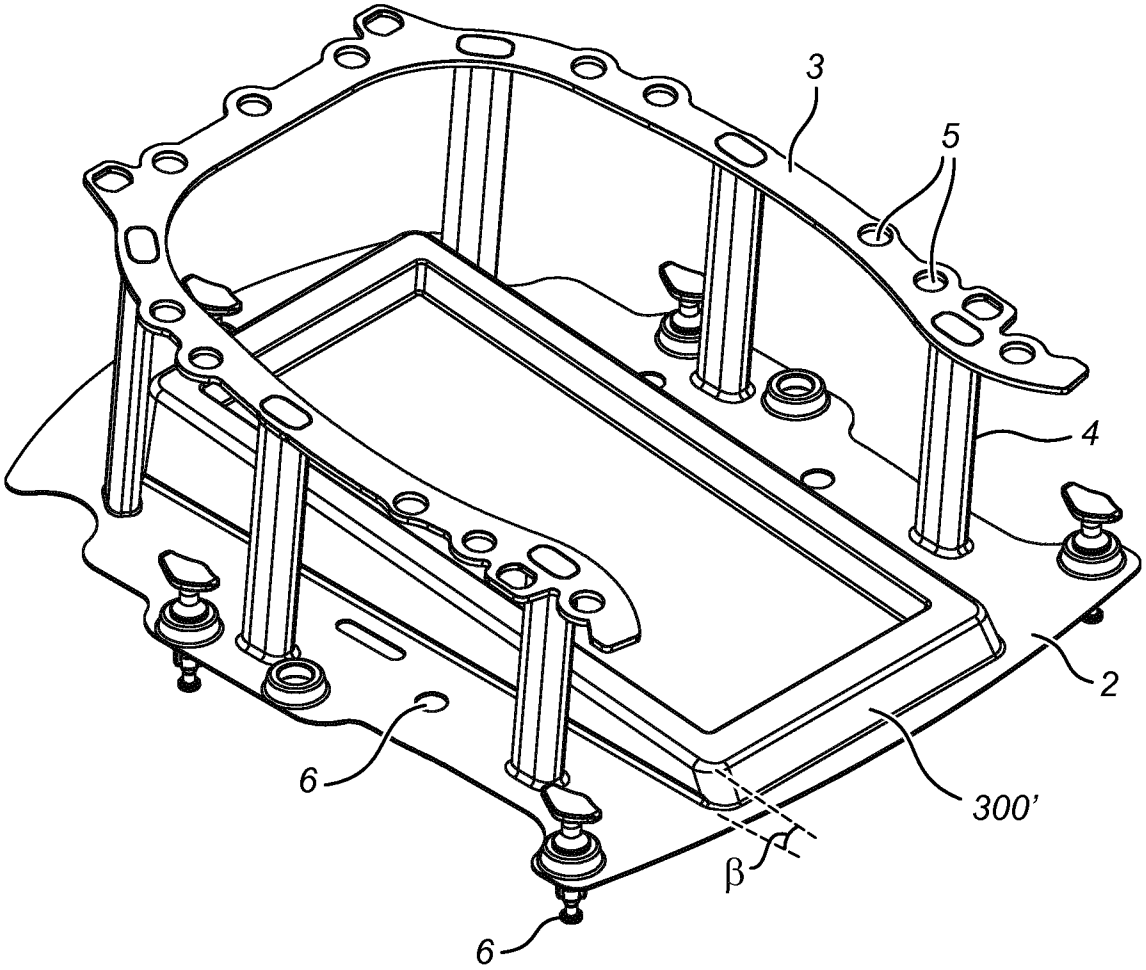


Fig. 5

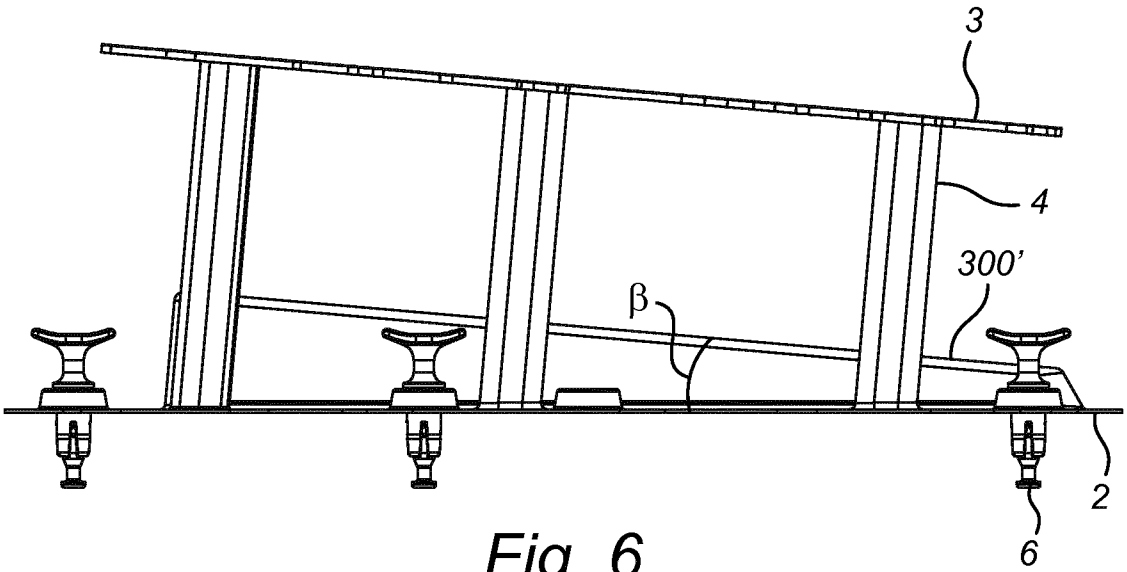


Fig. 6

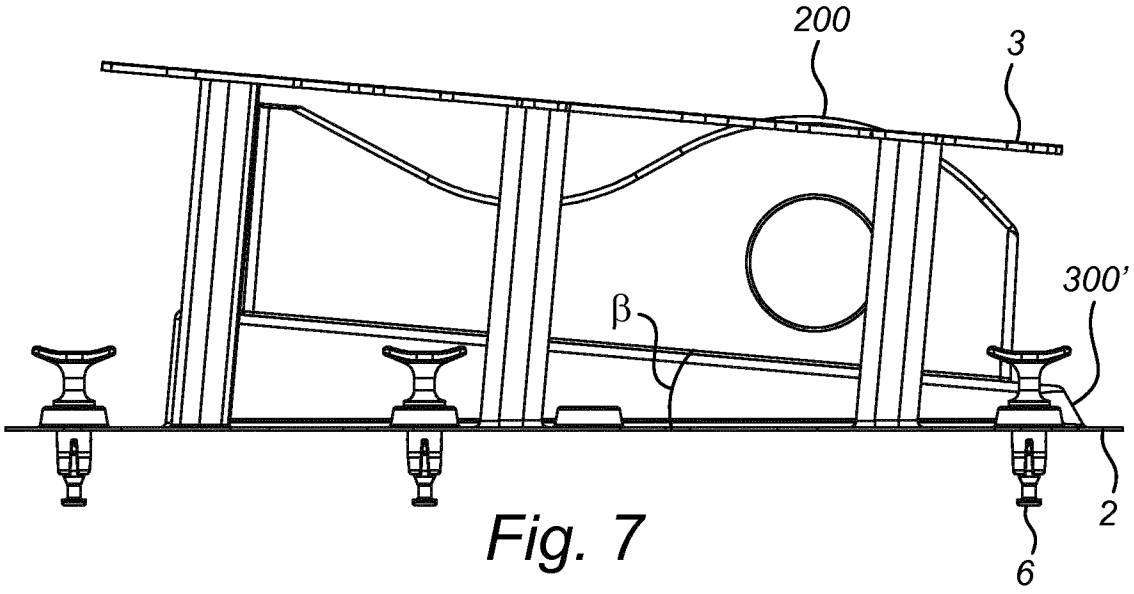


Fig. 7

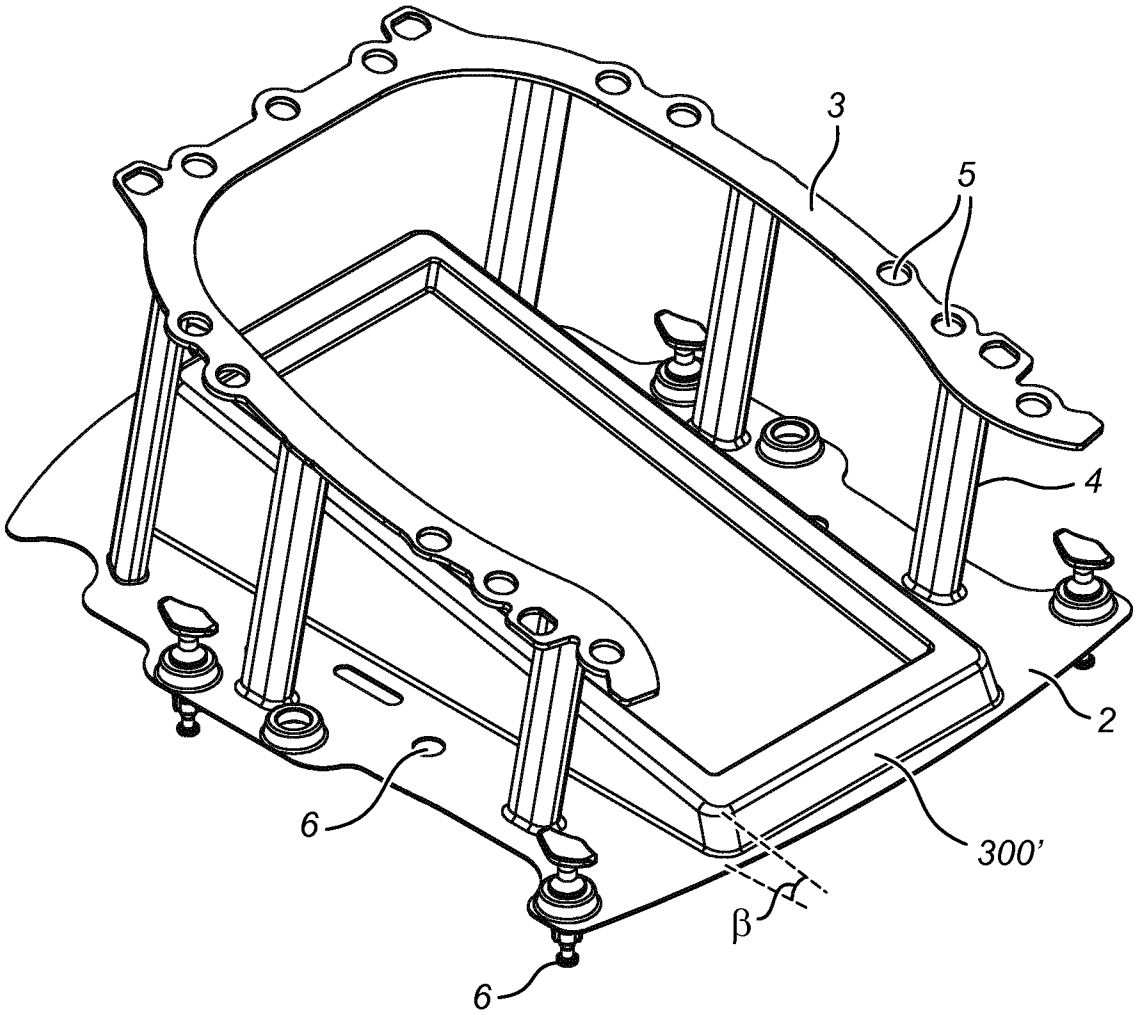


Fig. 8

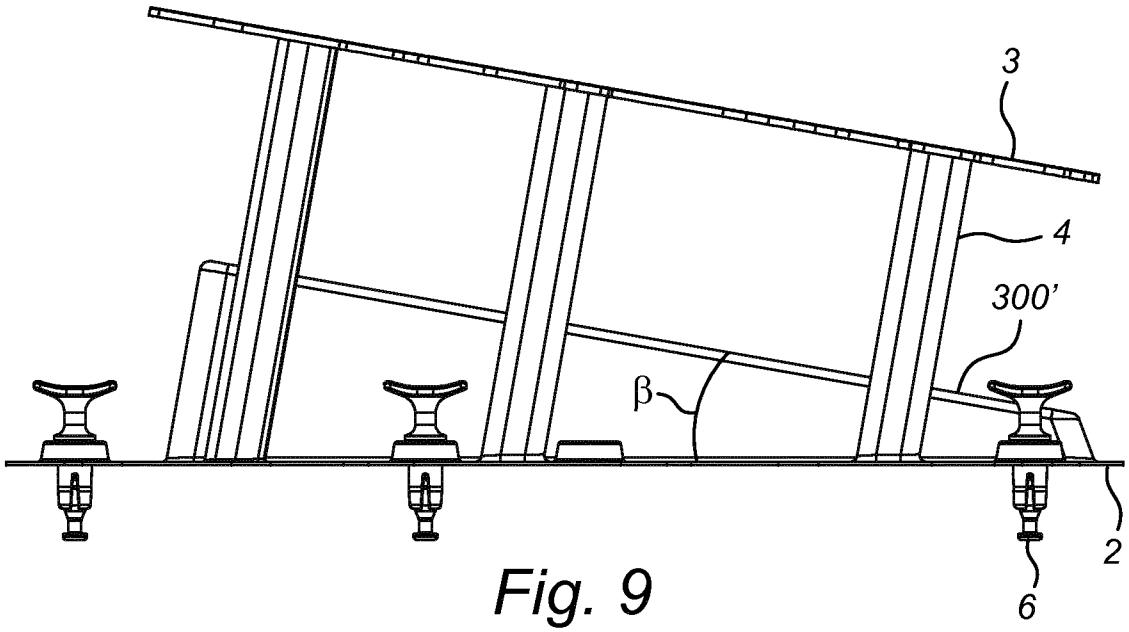


Fig. 9

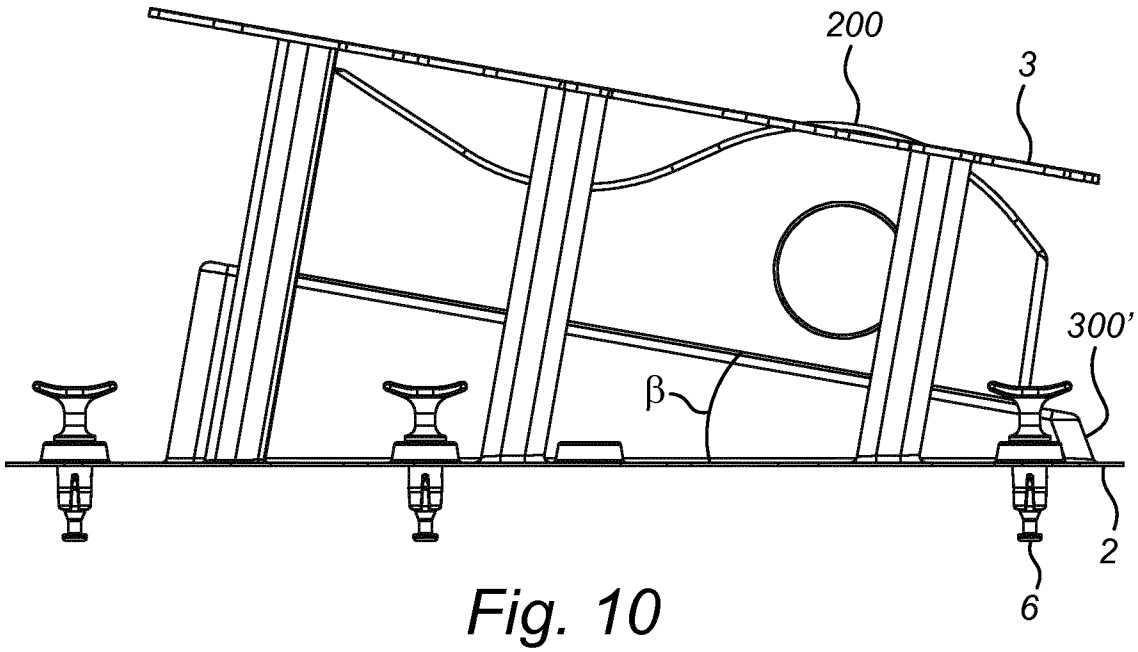


Fig. 10

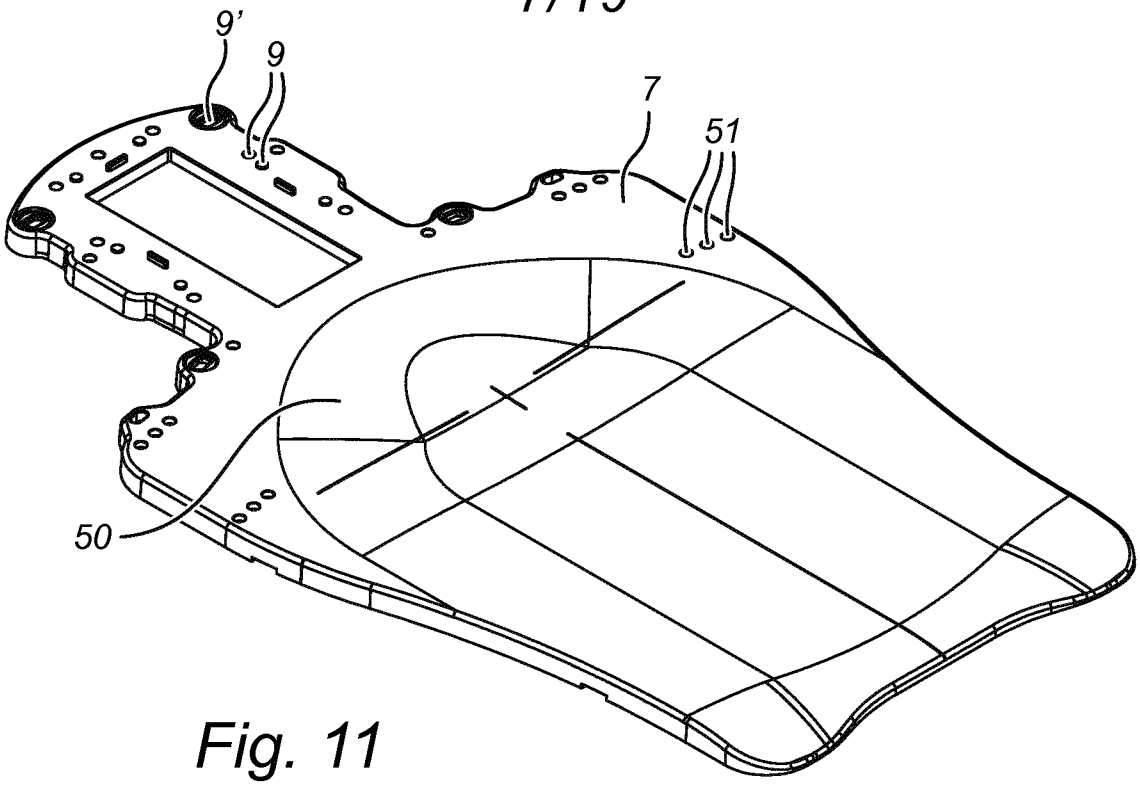


Fig. 11

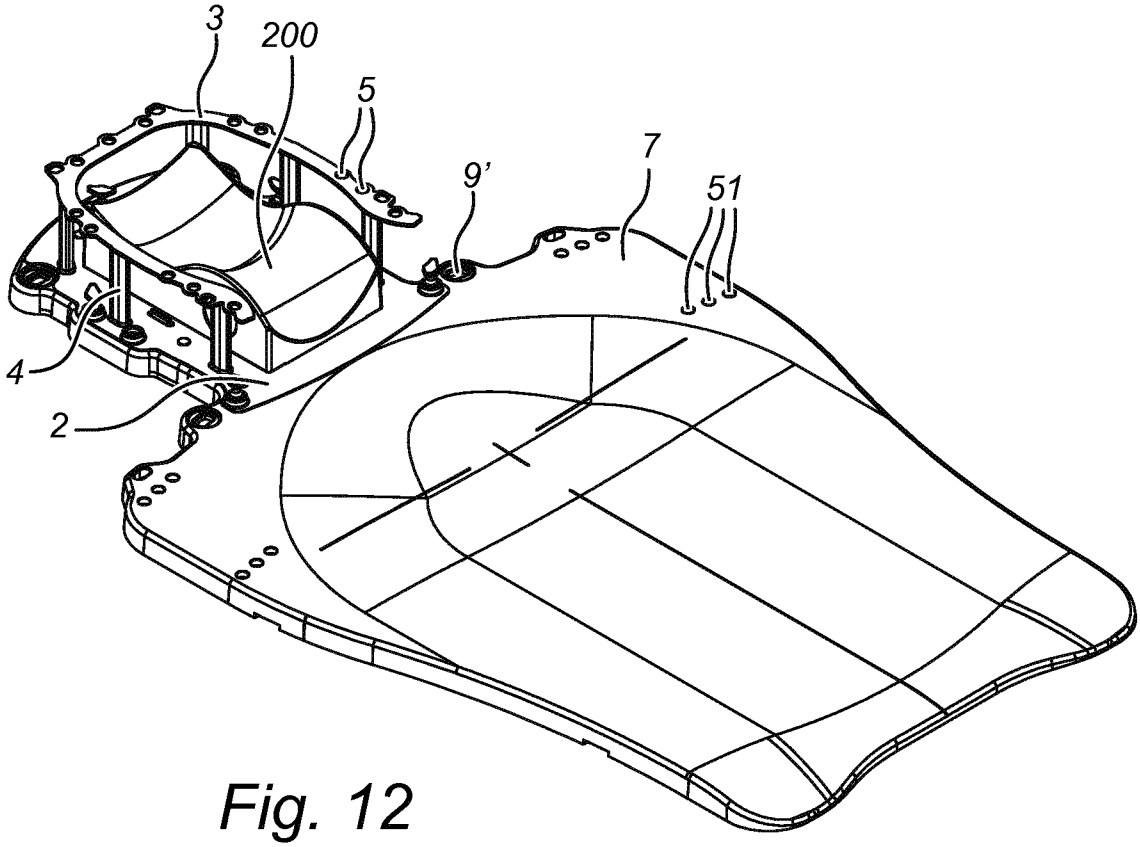


Fig. 12

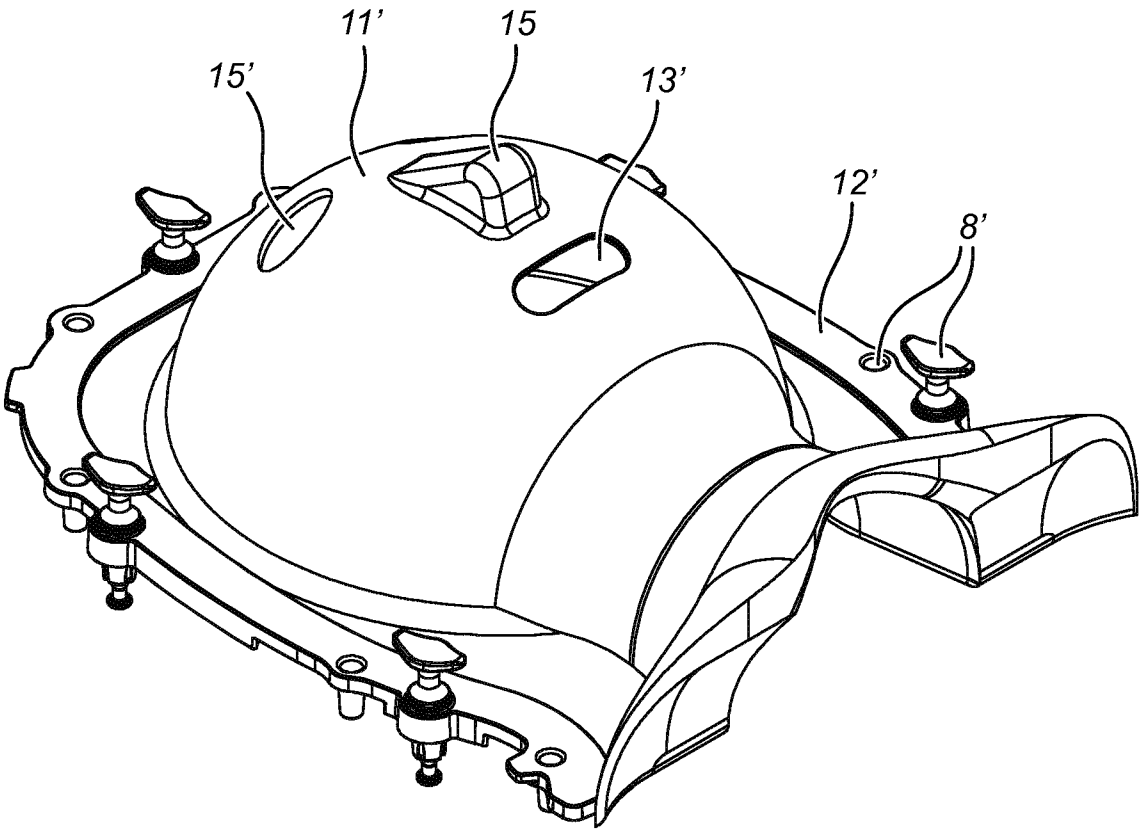


Fig. 13

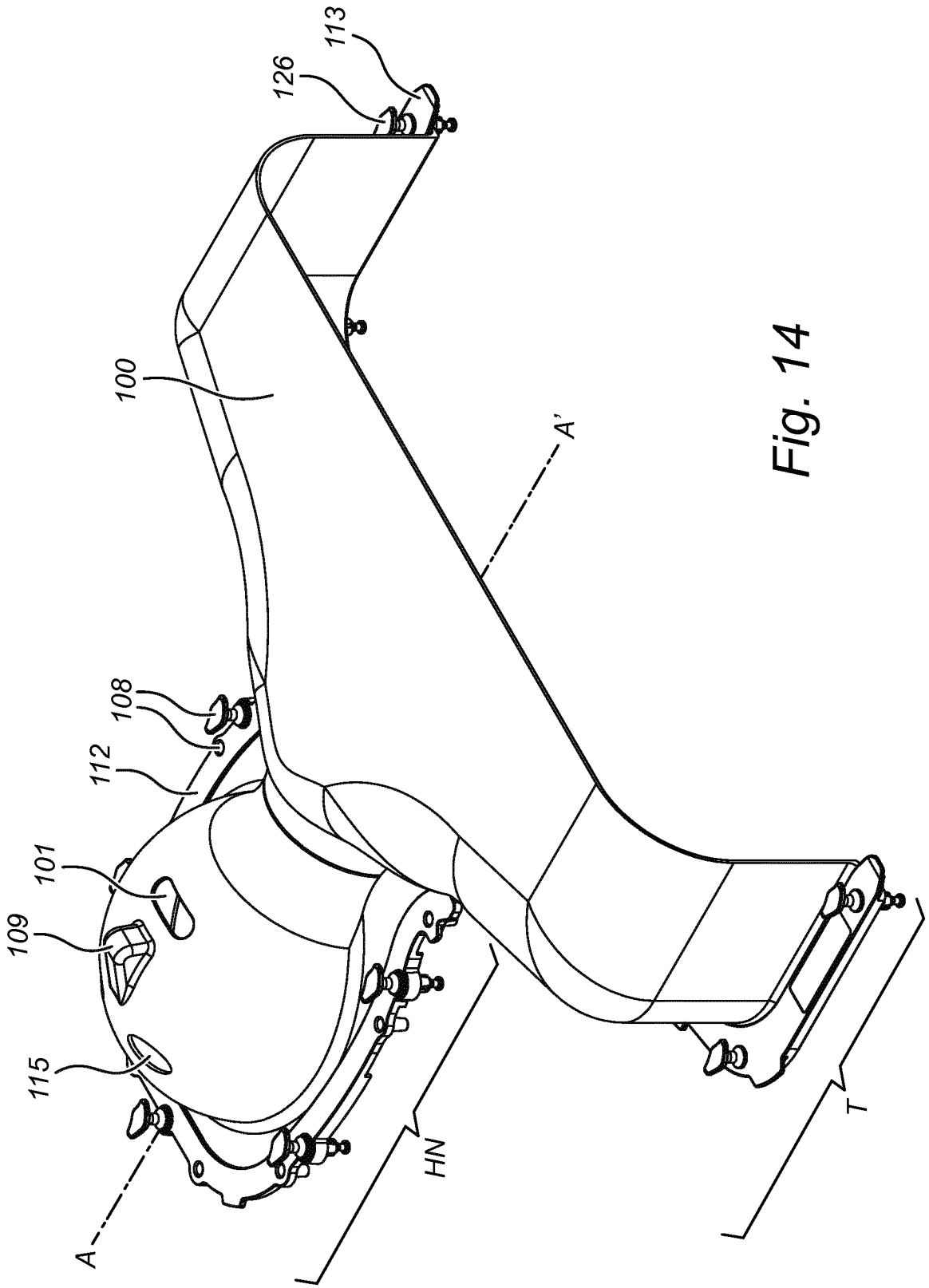


Fig. 14

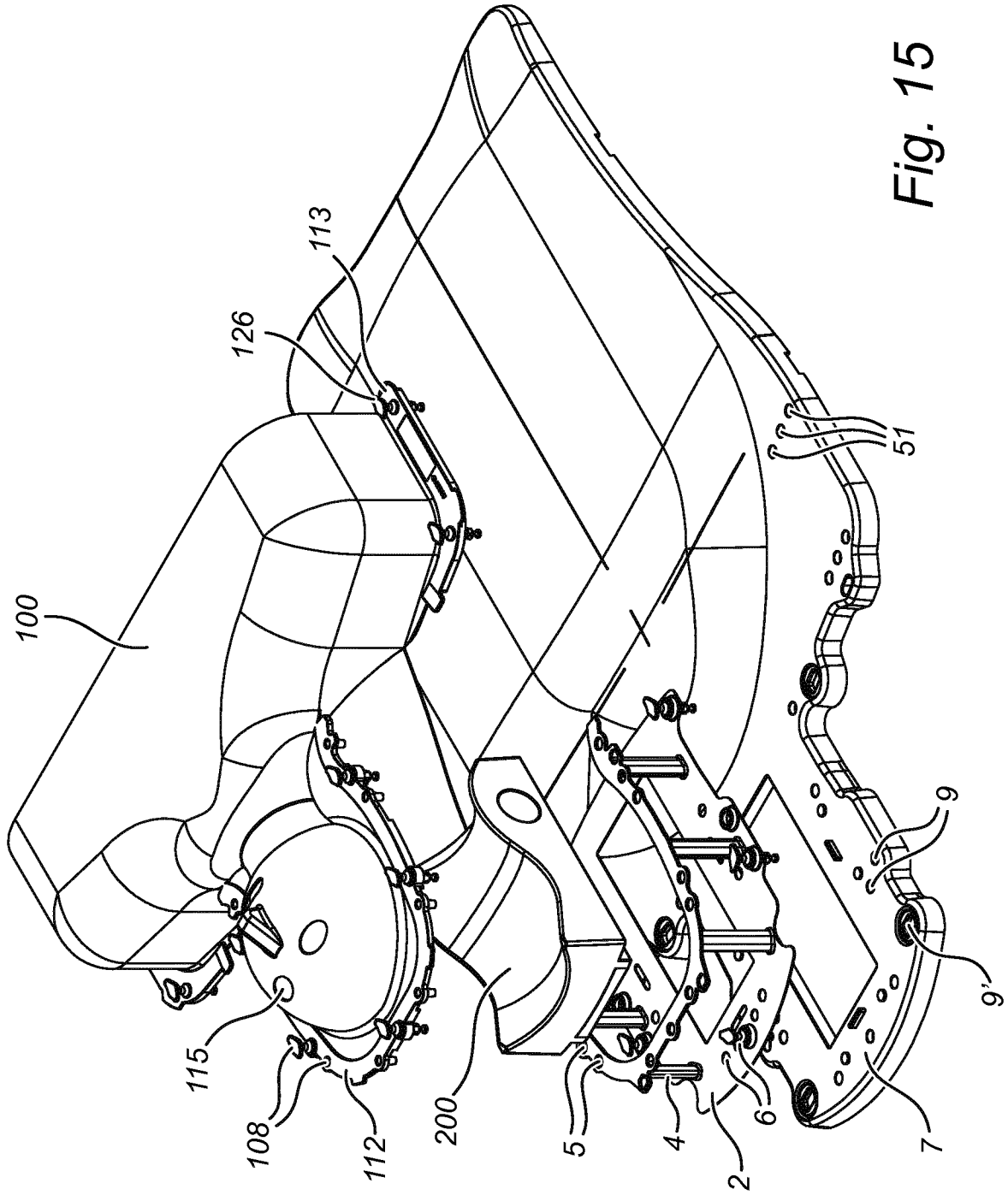


Fig. 15

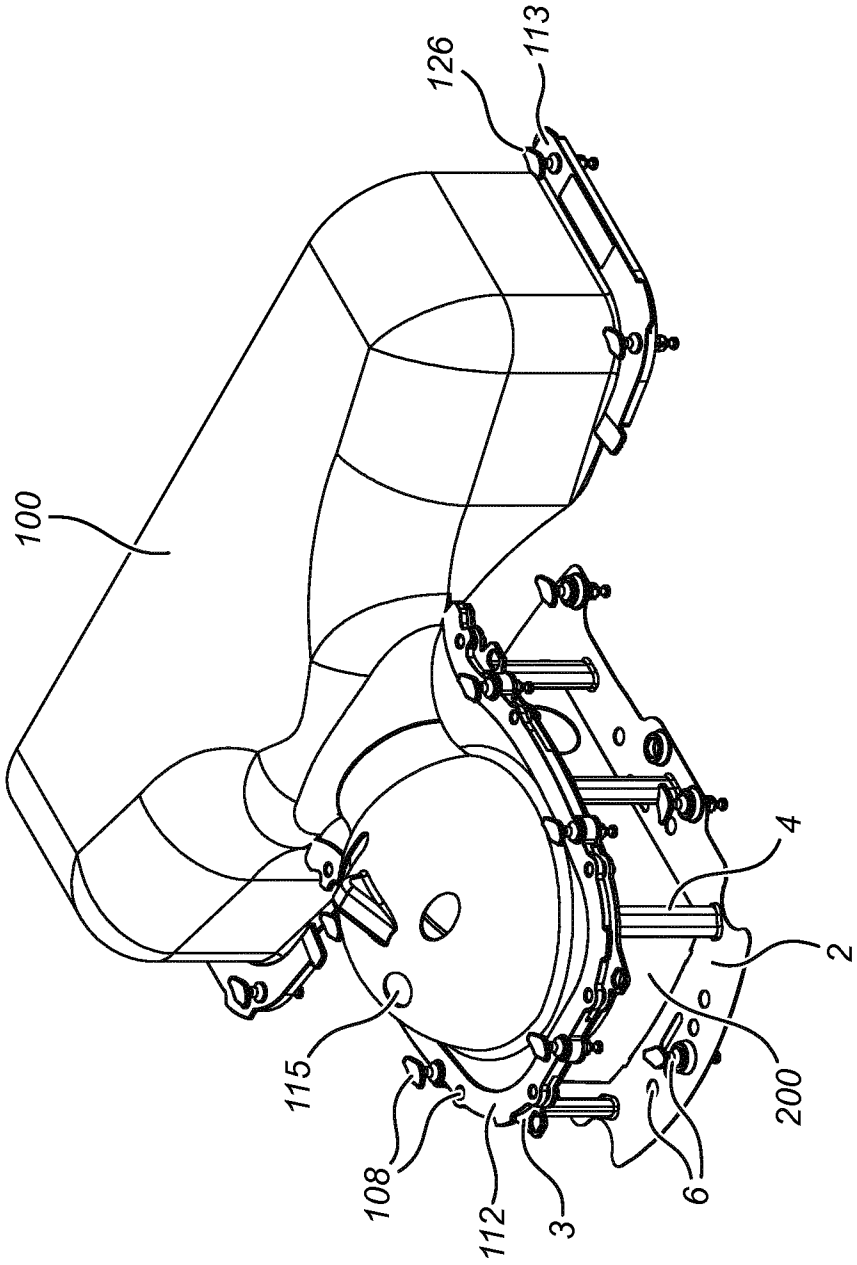


Fig. 16

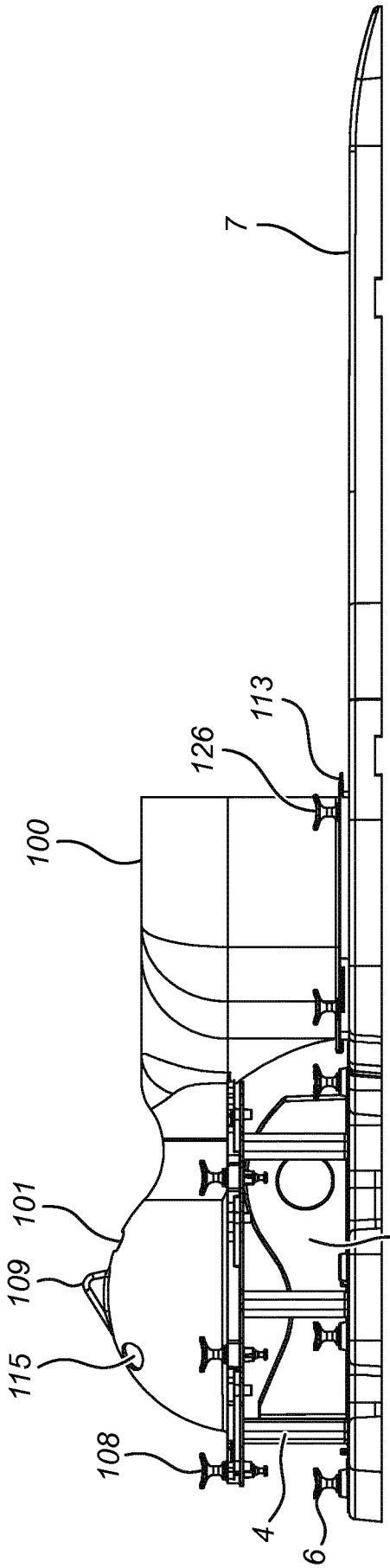
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Fig. 17

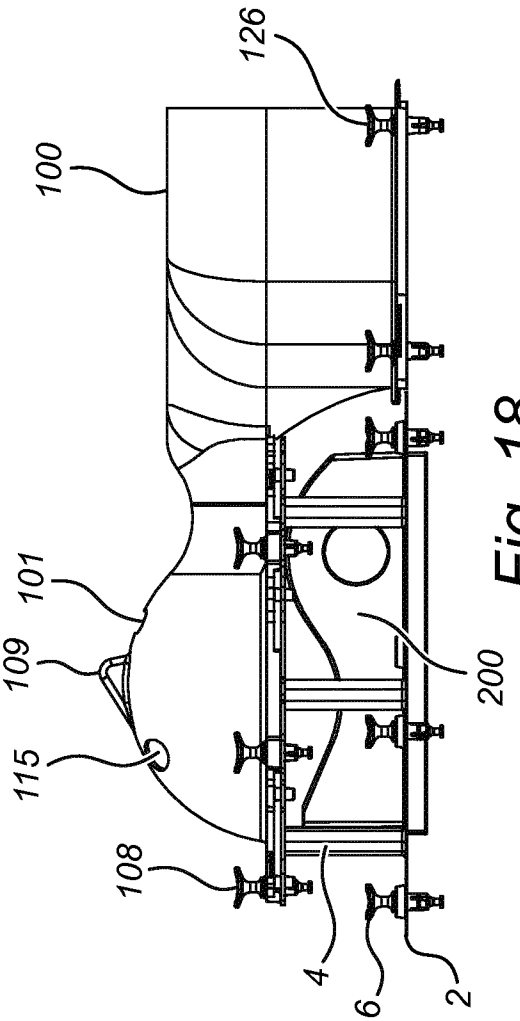
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Fig. 18

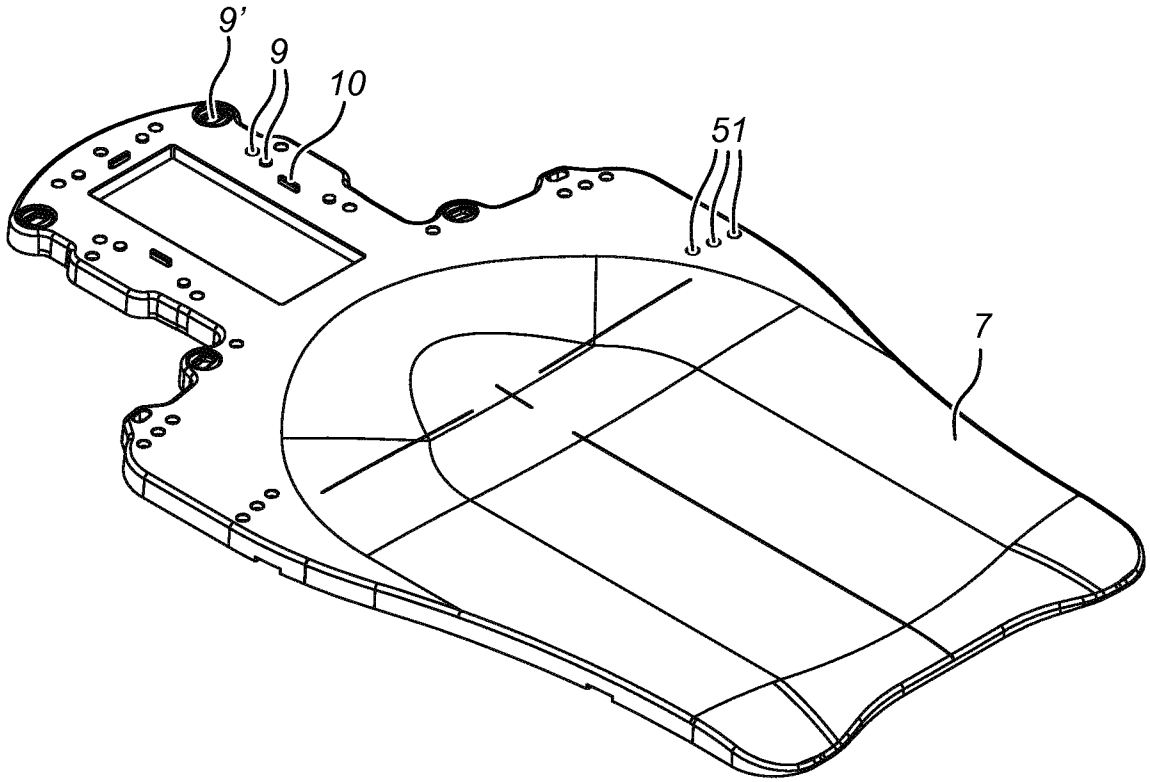


Fig. 19

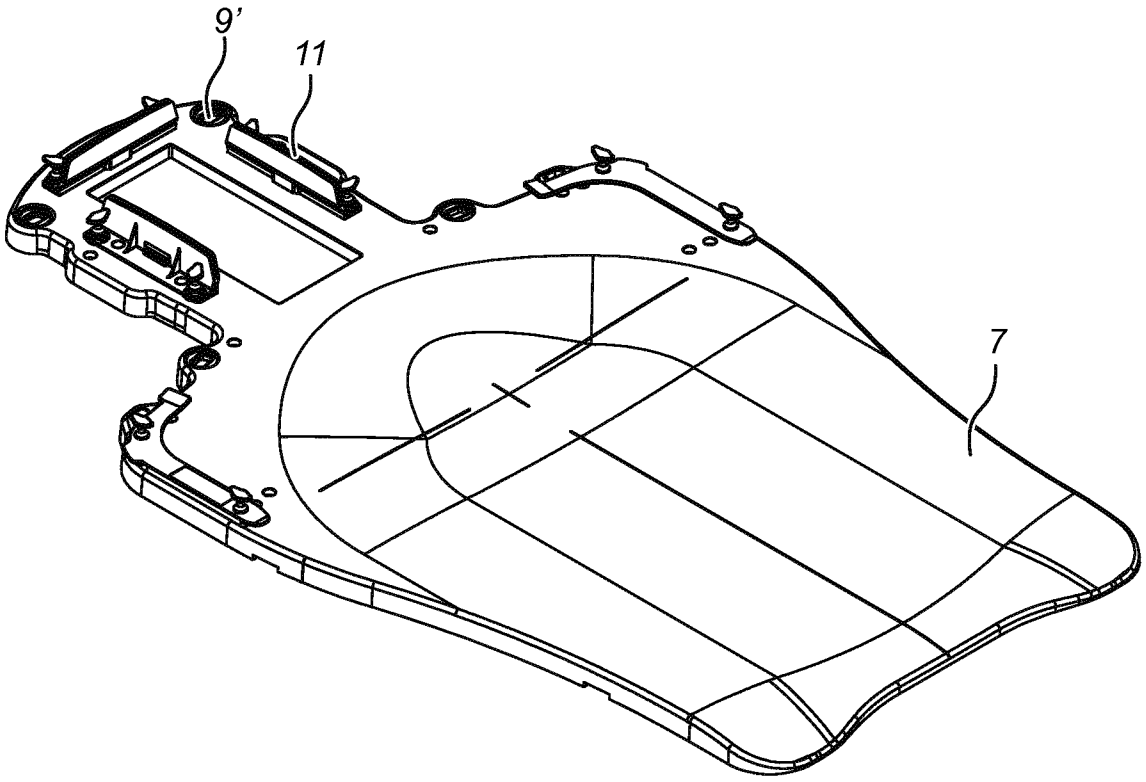


Fig. 20

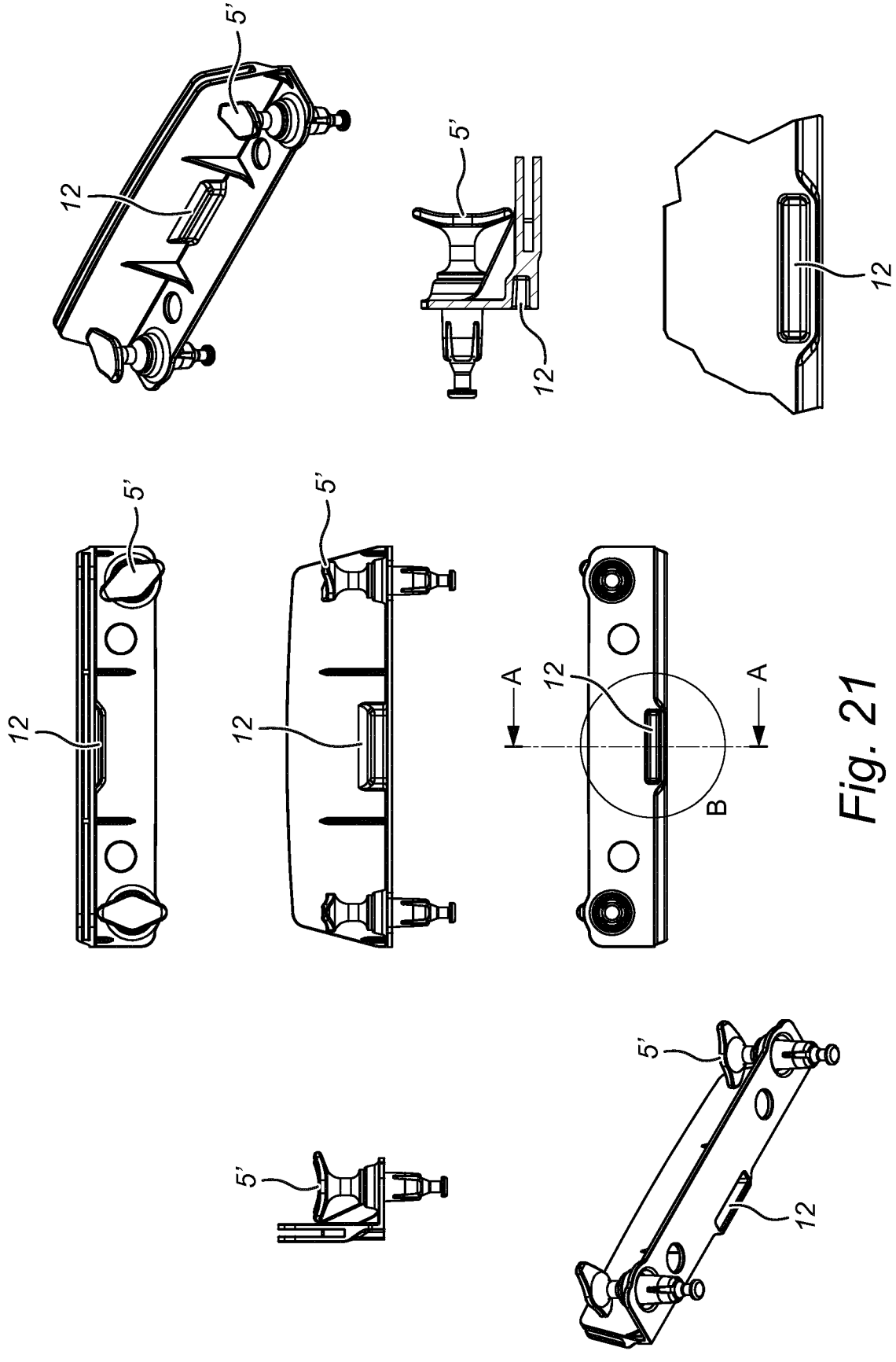


Fig. 21

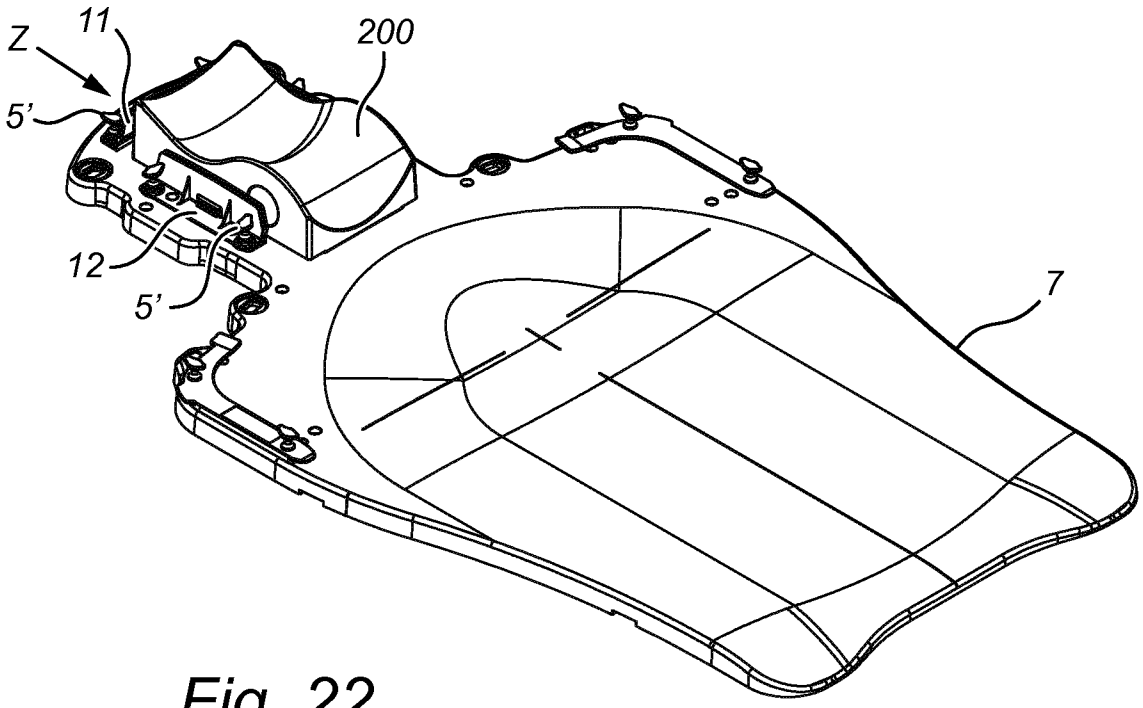


Fig. 22

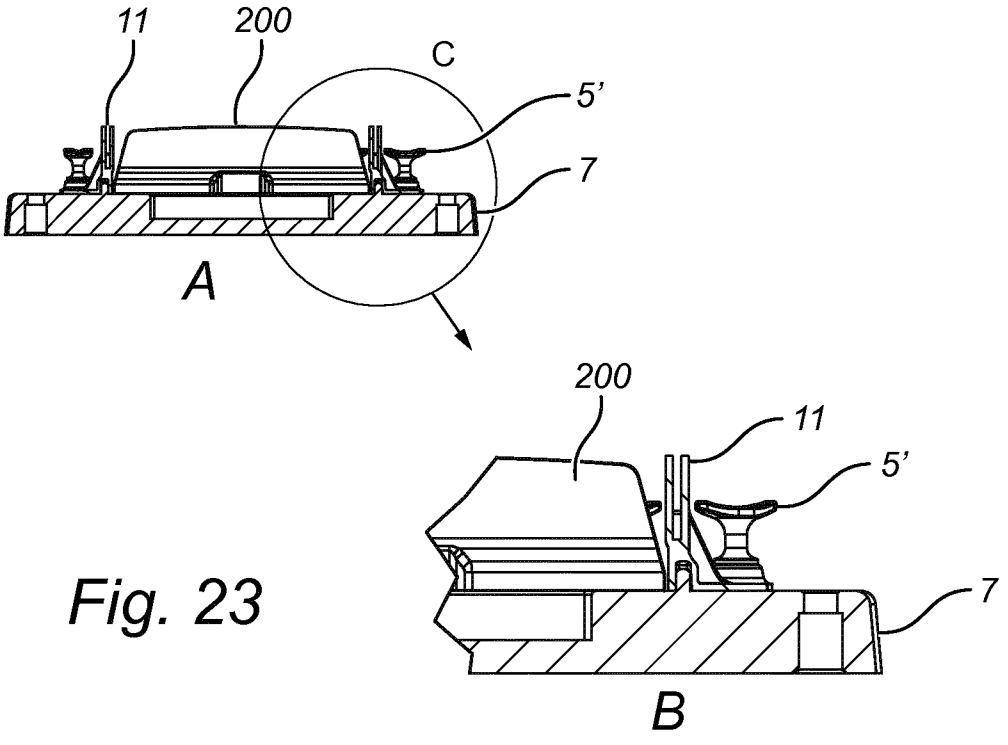


Fig. 23

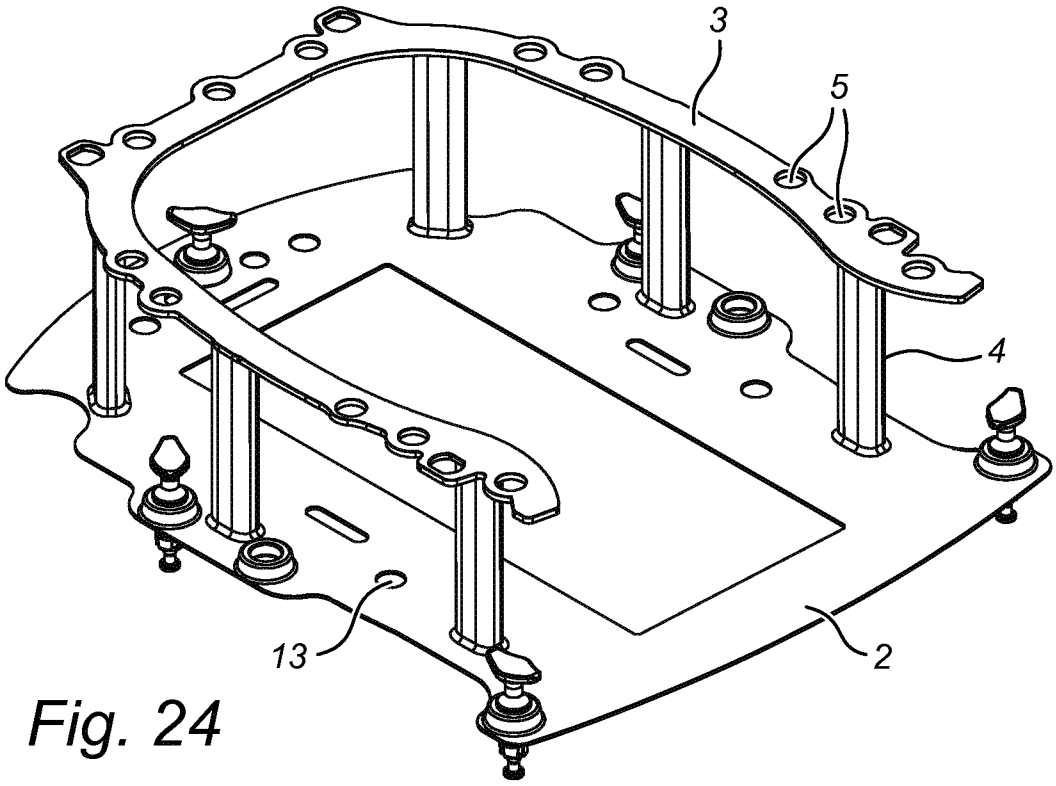


Fig. 24

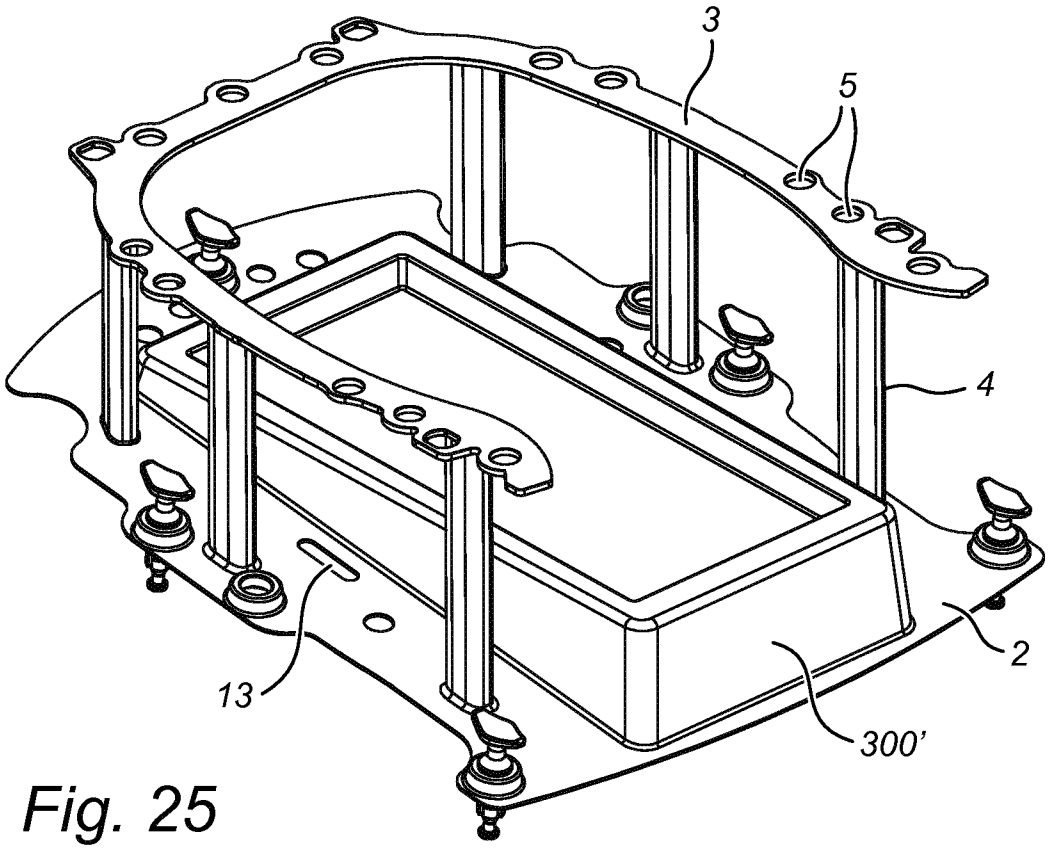


Fig. 25

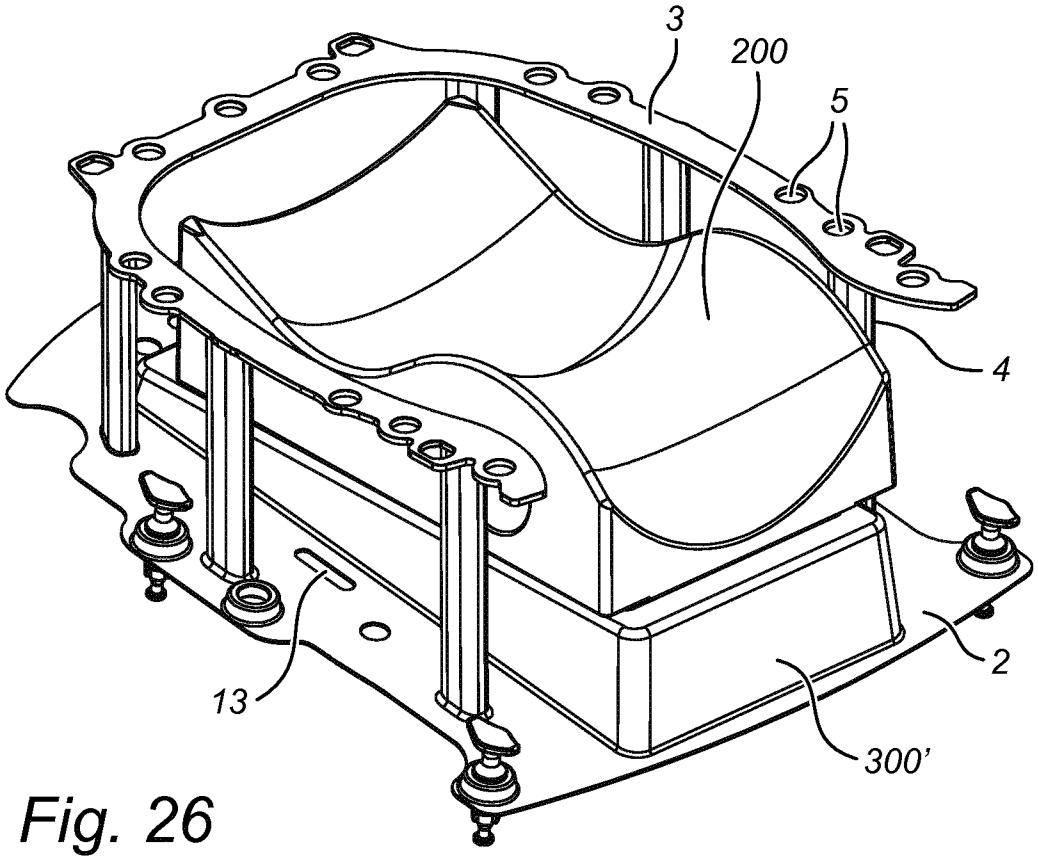


Fig. 26

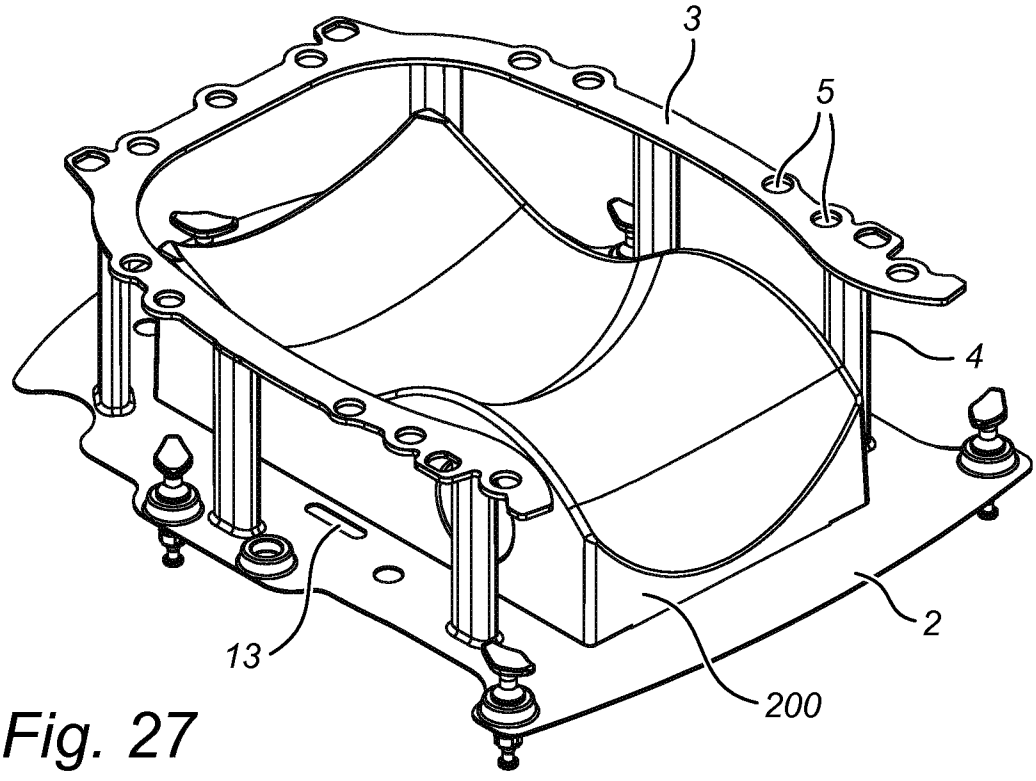


Fig. 27

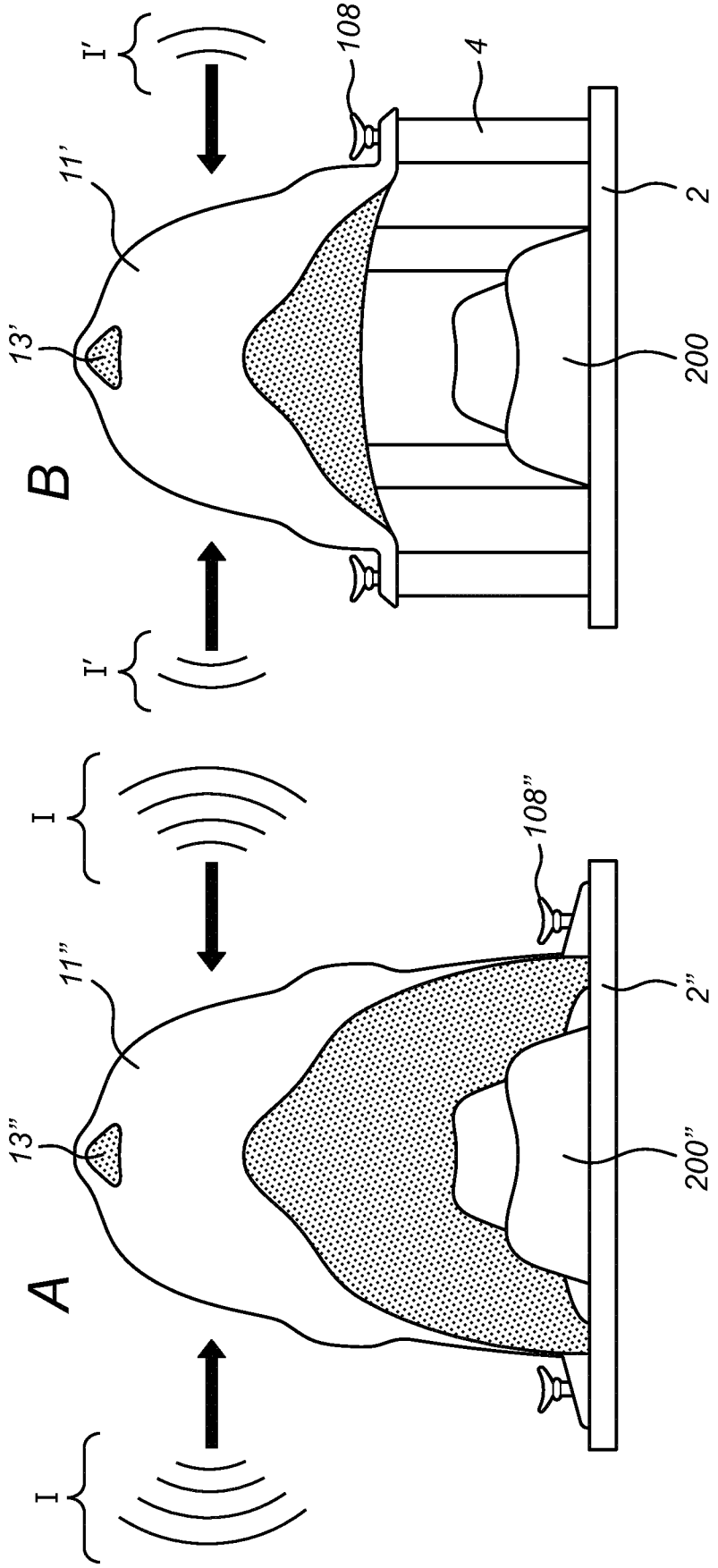


Fig. 28

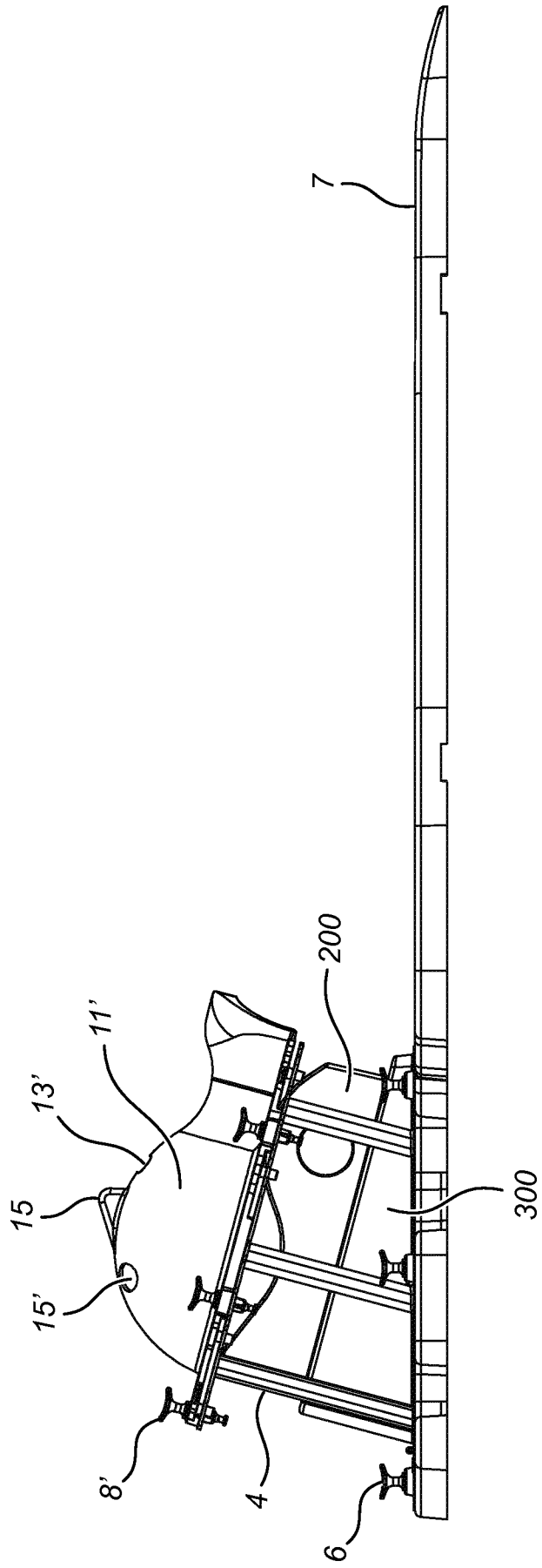


Fig. 29

# INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/052267

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B6/04
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)
A61B A61N

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<br>A | WO 2013/167688 A1 (NIEBERDING REGINALD [BE]) 14 November 2013 (2013-11-14)<br>page 11, line 9 - page 33, line 7; figures | 1,6-8,13<br>3,4,9, 10,14,15 |
| X | DE 33 40 482 A1 (FRITSCH ORTHOPAEDIE TECHNIK IN [DE]) 23 May 1985 (1985-05-23)<br>page 6, line 6 - page 7, line 23; figures | 1,6-8 |
| X | US 5 081 665 A (KOSTICH JEFFREY V [US])<br>14 January 1992 (1992-01-14)<br>column 3, line 12 - column 5, line 59; figures | 1,2,4,8, 9,11,14, 15 |

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[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 |
|---|---|
| 25 September 2015 | 19/10/2015 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Strubel, Christine |

1

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 5 702 406 A (VILSMEIER STEFAN [DE] ET AL) 30 December 1997 (1997-12-30)<br>cited in the application<br>column 5, line 64 - column 9, line 23;<br>figures<br>----- | 1,5-8,12 |

1

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2015/052267

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
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| | | EP 2846694 A1 | 18-03-2015 |
| | | US 2015047652 A1 | 19-02-2015 |
| | | US 2015053213 A1 | 26-02-2015 |
| | | WO 2013167688 A1 | 14-11-2013 |
| | | WO 2013167689 A1 | 14-11-2013 |
| DE 3340482 A1 | 23-05-1985 | NONE | |
| US 5081665 A | 14-01-1992 | NONE | |
| US 5702406 A | 30-12-1997 | DE 4432891 A1 | 21-03-1996 |
| | | US 5702406 A | 30-12-1997 |