IMMOLIZATION DEVICE FOR IMMOBILIZING A LOWER LEG, PRESSURE DEVICE APPARENTLY SUITABLE FOR USE IN THE IMMOLIZATION DEVICE, AND METHOD FOR MANUFACTURING THE PRESSURE DEVICE

Immobilization device (1) for immobilizing a lower leg (2), provided with a support device (4), for substantially securing bones and/or broken bone parts of the lower leg relative to each other, and a pressure device for applying a varying pressure to the lower leg, which pressure device is provided with at least one pumping chamber (8), at least one flexible chamber (10) and at least one fluid communication (12) between the at least one pumping chamber and the at least one flexible chamber (1), while in use, the at least one pumping chamber extends, at least partly, under a sole of a foot of the lower leg and the at least one flexible chamber extends at least partly between the support device and the lower leg, the pressure device being filled, in use, at least partly, with a fluid.
Title: Immobilization device for immobilizing a lower leg, pressure device apparently suitable for use in the immobilization device, and method for manufacturing the pressure device.

The invention relates to an immobilization device for immobilizing a lower leg. The invention further relates to a pressure device apparently suitable for use in the immobilization device and to a method for manufacturing the pressure device.

Immobilization devices for immobilizing a lower leg are known per se and are for instance used for substantially securing broken bone parts of the lower leg relative to each other after a lower leg fracture, or immobilizing the lower leg after, for instance, a strain or a tendon injury.

The known immobilization devices have the drawback that the blood circulation in the lower leg of a patient can be hindered, for which, as a rule, anticoagulants are administered to the patient. Another drawback is that long-term immobilization of the lower leg with the known devices can lead to weakening or reduction of muscle tissue in the lower leg, which can adversely affect the healing process.

It is an object of the invention to meet at least a part of the above-mentioned drawbacks.

According to the invention, to this end, an immobilization device is provided for immobilizing a lower leg, the device being provided with a support device which, in use, encloses at least the lower leg for substantially securing bones and/or broken bone parts of the lower leg relative to each other, and a pressure device for applying a varying pressure to the lower leg, which pressure device is provided with at least one pumping chamber, at least one flexible chamber and at least one fluid communication between the at least one pumping chamber and the at least one flexible chamber, the pressure device being designed such that in use, the at least one pumping chamber extends, at least partly, under a sole of a foot of the lower leg, and the at least one flexible
chamber extends, at least partly, between the support device and the lower leg, while in use, the pressure device is filled, at least partly, with a fluid so that, when the foot is placed on an underground, as during walking, the fluid will flow, at least partly, from the at least one pumping chamber via the at least one fluid communication to the at least one flexible chamber, and, when the foot is lifted, the fluid will flow, at least partly, from the at least one flexible chamber via the at least one fluid communication to the at least one pumping chamber for applying the varying pressure to the lower leg with the at least one flexible chamber.

This offers the advantage that when load is applied to the lower leg on which the immobilization device is provided, for instance during walking, a varying fluid pressure is applied to the lower leg structure, so that the lower leg is stimulated in a biomechanical manner. This biomechanical stimulation has a positive effect on the blood circulation and healing of the bone in the lower leg. Furthermore, the biomechanical stimulation decreases the reduction of muscle tissue.

Preferably, the support device comprises a plaster cast, synthetic cast, substantially rigid sleeve and/or walker. As a result, it is possible to modify known immobilization devices and immobilization techniques for applying the varying fluid pressure to the lower leg.

Preferably, the pressure device is provided with a first sheet-shaped wall, in use proximal to the lower leg, and a second sheet-shaped wall, in use remote from the lower leg, which are each non-transmissive to the fluid and which, combined, form the at least one flexible chamber, the at least one fluid communication and the at least one pumping chamber. This offers the advantage that the pressure device of the immobilization device has a simple structure which can be manufactured in a simple and inexpensive manner.

In the following, the invention is further elucidated by way of example, with reference to the drawing. In the drawing:
Fig. 1 shows a schematic cross-section of an example of an immobilization device according to the invention;

Fig. 2a shows a side view of an example of a pressure device of the immobilization device according to the invention;

Fig. 2b shows a perspective view of the pressure device shown in Fig. 2a;

Fig. 3a shows a sheet-shaped wall for manufacturing the pressure device shown in Figs. 2a and 2b;

Fig. 3b shows an alternative sheet-shaped wall; and

Fig. 3c shows a second alternative sheet-shaped wall.

Fig. 1 shows a schematic cross-section of an example of an immobilization device 1 according to the invention for immobilizing a lower leg 2 of a person. In Fig. 1, the immobilization device 1 is provided with a preferably substantially rigid support device 4, in this example a plaster cast, such as walking plaster, which, in use, encloses at least the lower leg 2. In this example, the immobilization device 1 is further provided with a pressure device 6 for applying a varying pressure to the lower leg 2. In Fig. 1, the pressure device 6 is provided with a pumping chamber 8, a flexible chamber 10 and a fluid communication 12 between the pumping chamber 8 and the flexible chamber 10. The pumping chamber 8 extends, at least partly, under a sole of a foot of the lower leg 2. The flexible chamber 10 extends, at least partly, between the support device 4 and the lower leg 2, in this example substantially between the support device 4 and a rear side and/or at least one side of the lower leg 2, for applying the varying pressure to the lower leg 2. The flexible chamber 10 is in fluid communication, via the fluid communication 12, with the pumping chamber 8.

In use, the pressure device 6 is filled, at least partly, with a fluid, for instance water. The operation of the immobilization device 1 is as follows. The preferably substantially rigid support device 4 is fitted to the lower leg 2 for substantially securing bones and/or broken bone parts of the lower leg 2.
relative to each other, for instance for allowing a lower leg fracture or a different injury to heal. When the foot of the lower leg 2 is placed on an underground, as during walking, the pumping chamber 8 is pressurized. The fluid will flow, at least partly, from the pumping chamber 8 via the fluid communication 12 to the flexible chamber 10. The fluid flowing upward to the flexible chamber 10 applies an upward stimulating action to the lower leg 2. The pressure in the flexible chamber 10 will increase and the flexible chamber 10 will apply pressure to the lower leg 2. Preferably, the support device 4 is rigid to such an extent that when the flexible chamber 10 swells as a result of the fluid flowing to the flexible chamber 10, the flexible chamber 10 can bear against the support device 4 for applying the pressure to the lower leg 2. When the foot is lifted, the pressure in the pumping chamber 8 will be at least partly removed. The fluid will flow, at least partly, from the flexible chamber 10 via the fluid communication 12 to the pumping chamber 8. As a result, the pressure in the flexible chamber 10 will decrease and the flexible chamber 10 will apply no pressure, at least less pressure, to the lower leg 2. Thus, the varying pressure is applied to the lower leg 2, during, alternately, placing the foot on the underground and lifting the foot from the underground, as during walking. The wall of the flexible chamber 10 is for instance inelastic, so that the flexible chamber 10 applies pressure to the lower leg 2 in a predetermined manner and/or at predetermined locations.

Fig. 2a shows an example of a side view of the pressure device 6 of the immobilization device 1. Fig. 2b shows a perspective view of the pressure device shown in Fig. 2a. In Fig. 2b it can be seen that the pressure device 6 is provided with a pressure chamber 8, a first flexible chamber 10.1, a second flexible chamber 10.2, a first fluid communication 12.1 and a second fluid communication 12.2. The first fluid communication 12.1 forms a fluid communication between the pressure chamber 8 and the first flexible chamber 10.1, and the second fluid communication 12.2 forms a fluid communication between the pressure chamber 8 and the second flexible chamber 10.2. In the
example of Fig. 2b, the first flexible chamber 10.1 and the second flexible chamber 10.2 are separated by a seam 16. In this example, the flexible chambers 10.1, 10.2, the fluid communication 12.1, 12.2 and the pumping chamber 8 from an integral whole.

The operation of the pressure device 6 shown in Figs. 2a and 2b corresponds to the operation of the pressure device as described with reference to Fig. 1. When the pumping chamber 8 is pressurized, for instance when the foot of the lower leg 2 is placed on the underground, the fluid will flow, at least partly, from the pumping chamber 8 via the fluid communications 12.1, 12.2 to the flexible chambers 10.1, 10.2. The fluid, flowing upwards to the flexible chambers 10.1, 10.2 applies an upward stimulating action to the lower leg 2. The pressure in the flexible chambers 10.1, 10.2 will increase, and the flexible chambers 10.1, 10.2 will apply the pressure to the lower leg 2. When the foot is lifted, the pressure in the pumping chamber 8 will, at least partly, be removed. The fluid will flow, at least partly, from the flexible chambers 10.1, 10.2 via the fluid communications 12.1, 12.2 to the pumping chamber 8. As a result, the pressure in the flexible chambers 10.1, 10.2 will decrease and the flexible chambers 10.1, 10.2 will apply no pressure, at least less pressure to the lower leg 2. Thus, the pressure varying in time is applied to the lower leg 2 when, alternately, the lower leg 2 is, and is not loaded, for instance when the foot is alternately placed on and lifted from the underground, as during walking.

In the example of Figs. 2a and 2b, the heel of the lower leg 2 is left free by the pressure device 6. Leaving the heel free offers the advantage that the upward stimulating action and/or the varying pressure are applied to the lower leg 2 more effectively when the lower leg 2 is being alternately loaded and not loaded, than when the heel is enclosed by the pressure device 6. As a result, the injury can heal more effectively than when the heel is enclosed by the pressure device 6. In Figs. 2a and 2b, the pressure device 6 is provided with a filling opening 14, in the example a valve, for instance on the lateral side at the location of the knee. This offers the advantage that the pressure,
the pressure device 6 applies to the lower leg 2 can be adjusted by introducing more or lesser fluid, such as water, into the pressure device 6. Furthermore, the pressure device 6 can be transported or stored without fluid, which reduces the risk of leakage of fluid which, especially with liquids, can be very bothersome. It is also possible that the pressure device 6 is not provided with the filling opening 14, while during manufacture of the pressure device 6, the pressure device 6 can be provided with a predetermined amount of fluid that cannot be modified after manufacture.

One wall of the at least one flexible chamber 10, the at least one fluid communication 12 and the at least one pumping chamber 8 of the pressure device 6 as shown in Figs. 1, 2a and 2b, can be manufactured from, for instance, a sheet-shaped material, for instance a plastic foil such as polyethylene or polyurethane, optionally applied to a woven tissue such as nylon. In Figs. 1, 2a and 2b, by way of example, the pressure device 6 is provided with a first sheet-shaped wall 18, in use proximal to the lower leg 2, and a second sheet-shaped wall 20, in use remote from the lower leg, which are each non-transmissive to the fluid and, in this example, combined, form the flexible chambers 10.1, 10.2, the fluid communications 12.1, 12.2 and the pumping chamber 8. It will be clear that thus, in use, the first sheet-shaped wall 18 is included between the second sheet-shaped wall 20 and the lower leg 2. This offers the advantage that the pressure device 6 of the immobilization device 1 has a simple structure, which can be manufactured in a simple and inexpensive manner. Furthermore, in this manner, the pressure device 6 can be manufactured with a relatively limited thickness, measured from the first to the second sheet-shaped wall, so that the pressure device 6 can simply be utilized with known support devices such as plaster cast, synthetic cast, substantially rigid sleeves or walkers. Here, the known support device can be utilized while the support device needs hardly be adjusted, if at all, for receiving the pressure device.
Preferably, the pressure device 6 is free from regulating elements such as valves, to obtain a simple structure. Moreover, the pressure device 6 that is free from regulating elements can simply be used with known support devices such as plaster cast, synthetic cast, substantially rigid sleeves or walkers. The known support device can be utilized here, while the support device needs hardly be adjusted, if at all, for receiving the pressure device, as no space and/or feed-through opening is required where regulating elements are to be placed and/or fed through.

The pressure device 6 can be manufactured by means of the following method. The first sheet-shaped wall 18 and the second sheet-shaped wall 20 of a sheet-shaped material are provided, which first and second sheet-shaped wall 18, 20 are substantially identical in form, and which have a shape such that, combined, they can form the at least one flexible chamber 10, the at least one fluid communication 12 and the at least one pumping chamber 8.

Figs. 3a-3c show examples of the sheet-shaped walls. The first and second sheet-shaped wall 18, 20 are placed one on the other in, for instance, a substantially overlapping manner, and are connected in a fluid-tight manner, for instance along their circumference so that the first and second sheet-shaped wall 18, 20 with the fluid-tight connection enclose the at least one pumping chamber, the at least one flexible chamber 10 and the at least one fluid communication 12, by means of, for instance, a sealing seam, that may be formed through high-frequency welding. In this manner, between the first and the second sheet-shaped wall 18, 20 a hollow inside space is formed which forms the at least one pumping chamber 8, the at least one fluid communication 12 and the at least one flexible chamber 10. A first part of the first and/or second sheet-shaped wall 18, 20, indicated in interrupted lines 22 in Figs. 3a-3c, a second part of the first and/or second sheet-shaped wall 18, 20 indicated in interrupted line 24 in Figs. 3a-3c are connected such that in use, the pressure device 6 encloses the rear side of the lower leg 2 and the underside of the foot.
Fig. 3a shows the sheet-shaped wall for manufacturing the pressure device 6 shown in Figs. 2a and 2b. The first and second sheet-shaped wall 18, 20 are substantially symmetrical with respect to a virtual line which, in use, extends substantially in sagittal direction under the middle of the foot. With this pressure device 6, the first and second sheet-shaped wall 18, 20 extend, in use, substantially from a first side of the lower leg 2, passing under the sole of the foot, to a second side of the lower leg 2. After the first and second sheet-shaped wall 18, 20 are fluid-tightly connected, for instance along their circumference, the first and second part 22, 24 are connected, while the connection between the first and second part 22, 24 extends, in use, substantially in vertical direction along the rear side of the lower leg 2. The first and second part 22, 24 are connected by means of, for instance, a seam 16, for instance a second sealing seam, for instance formed through high-frequency welding as shown in Fig. 2b. It therefore applies that the first and second part 22, 24 of the assembly of the first and second sheet-shaped wall 18, 20 are connected thus that, in use, the pressure device 6 encloses the rear side of the lower leg 2 and the underside of the foot. By way of example, the heel of the lower leg 2 is left free by the pressure device 6 which is formed from the first and second sheet-shaped wall 18, 20 as shown in Fig. 3a. The thus obtained pressure device 6 comprises one pressure chamber 8, two fluid communications 12.1, 12.2 and two flexible chambers 10.1, 10.2.

Fig. 3b shows an alternative sheet-shaped wall for manufacturing the pressure device 6. In Fig. 3b, the first and second sheet-shaped wall 18, 20 are substantially symmetrical with respect to a virtual plane which extends, in use, substantially in sagittal direction through the middle of the lower leg. With this pressure device 6, the first and second sheet-shaped wall 18, 20 extend, in use, substantially from the first side of the lower leg 2, passing behind the lower leg 2, to the second side of the lower leg 2. After the first and second sheet-shaped wall 18, 20 are fluid-tightly connected, for instance along their circumference, the first and second part 22, 24 are connected while the
connection between the first and second part 22, 24 extends, in use, substantially in sagittal direction along the underside of the foot. The thus obtained pressure device comprises two pressure chambers, two fluid communications 12.1, 12.2 and one flexible chamber 10.

Fig. 3c shows a second alternative sheet-shaped wall for manufacturing the pressure device 6. With this pressure device 6, the first and second sheet-shaped wall 18, 20 extend, in use, substantially from the first side of the lower leg 2, passing behind the lower leg 2, to the second side of the lower leg 2 and passing under the sole of the foot, to the second side of the lower leg 2. After the first and second sheet-shaped wall 18, 20 are fluid-tightly connected, for instance along their circumference, the first and second part 22, 24 are connected in a manner such that, in use, the pressure device 6 encloses the rear side of the lower leg 2 and the underside of the foot. The thus obtained pressure device comprises one pressure chamber, one fluid communication 12 and one flexible chamber 10.

With reference to Fig. 3a, it applies that it is also possible that first, the first and second sheet-shaped wall 18, 20 are each (fluid-tightly) connected, while, in use, the connection extends in vertical direction along the rear side of the lower leg 2, and that then, the first and second sheet-shaped wall 18, 20 are connected fluid-tightly along their circumference. The thus obtained pressure device comprises one pressure chamber 8, two fluid communications 12.1, 12.2 and one flexible chamber 10. The same applies, mutatis mutandis, to the sheet-shaped walls shown in Figs. 3b and 3c.

In Fig. 2a, by way of example, the pressure device 6 is provided in the at least one fluid communication 12 with spacing means 26, in this example two elongated strips, for instance of plastic or rubber. In the example, the spacing means 26 extend between the first and the second sheet-shaped wall 18, 20. The spacing means 26 keep the fluid communication between the pumping chamber 8 and the flexible chamber 10 open, for instance when the foot is moved relative to the lower leg. It will be clear that, in principle, the
spacing means 26 can be utilized in any embodiment of the pressure means 6. The spacing means 26 are particularly effective when the at least one fluid communication 12 is manufactured from sheet-shaped material.

It is also possible that the pressure device 6 is provided, adjacent the at least one fluid communication 12, with reinforcing means, for substantially preventing the fluid communication 12 from being closed off in use. The reinforcing means can be provided both internally in the pressure device 6 and externally on the pressure device 6.

By way of example, the immobilization device 1 can be fitted on the lower leg 2 by means of the following method. Around the lower leg 2, for instance, but not necessarily, an underlay is provided, for instance a tricot stocking. On the underlay, the pressure device 6 is provided in a manner such that the pressure device 6 encloses at least a part of the lower leg, for instance the rear side of the lower leg 2, and the underside of the foot. The pressure device 6 may already have been partly filled with the fluid, for instance water, which can simplify positioning of the pressure device 6. Over the pressure device 6, a cotton wool bandage may be provided. The layer of cotton wool bandage is provided with, for instance, pre-tape. Over the layer of cotton wool bandage, plaster is applied. When the plaster has hardened, the pressure device 6 can be filled with the fluid. The required amount of fluid can be determined by measuring the pressure in the pressure device 6 in an unloaded situation (pressure chamber 8 not pressurized when, for instance, the foot is lifted) and in a loaded situation (pressure chamber 8 pressurized when, for instance, the foot is placed on an underground). The required pressure in the pressure device 6 can depend on the nature of the injury and the phase the healing process is in. The pressure device 6 may be filled, at least partly, with fluid, for instance water. More particularly, the pressure device may be filled with fluid for 20 – 80%, preferably for 40 – 60%. By way of example, the pressure device 6 is provided with an amount of fluid which is smaller than 500 ml, preferably smaller than 400 ml, more preferably smaller than 200 ml.
By way of example, the pressure device 6 is provided with the amount of fluid which is greater than 10 ml, preferably greater than 50 ml, more preferably greater than 100 ml. More particularly, the pressure device 6 is for instance provided with 10 – 500 ml of fluid, preferably 50 – 400 ml, more preferably 100 – 200 ml.

After fitting the immobilization device 1, the varying pressure can be applied to the lower leg 2, during, alternately, applying the load on and removing it from the lower leg 2, for instance placing the foot on the underground and lifting the foot from the underground, as during walking.

Thus, a method is provided for treating lower leg injuries, for instance a lower leg fracture.

In the examples, the support device comprises a plaster bandage, such as walking plaster. However, it is also possible that the support device comprises synthetic bandage, a substantially rigid sleeve and/or a walker (prefabricated boot-like support device for immobilizing a lower leg). When using a walker, the cotton wool bandage may be replaced by a part, such as a stocking, of the walker.

In the examples, the flexible chamber of the pressure device encloses, at least partly, the rear side and sides of the lower leg. However, it is also possible that the flexible chamber encloses the entire circumference of the lower leg or engages only at least one side, or the rear side of the lower leg.

In the examples, the pressure device comprises the first and second sheet-shaped walls. However, it is also possible that the pressure device comprises only one sheet-shaped wall, or more than two sheet-shaped walls.

Such variations are all understood to fall within the framework of the invention.
Claims

1. An immobilization device for immobilizing a lower leg, the device being provided with
   a support device which, in use, encloses at least the lower leg, for substantially securing bones and/or broken bone parts of the lower leg relative to each other; and
   a pressure device for applying a varying pressure to the lower leg, which pressure device is provided with at least one pumping chamber, at least one flexible chamber and at least one fluid communication between the at least one pumping chamber and the at least one flexible chamber,
   wherein the pressure device is designed such that, in use, the at least one pumping chamber extends, at least partly, under a sole of a foot of the lower leg, and the at least one flexible chamber extends, at least partly, between the support device and the lower leg,
   wherein, in use, the pressure device is filled, at least partly, with a fluid so that, when the foot is placed on an underground, as during walking, the fluid will flow, at least partly, from the at least one pumping chamber via the at least one fluid communication to the at least one flexible chamber, and, when the foot is lifted, the fluid will flow, at least partly, from the at least one flexible chamber via the at least one fluid communication to the at least one pumping chamber for applying the varying pressure to the lower leg with the at least one flexible chamber.

2. An immobilization device according to claim 1, characterized in that the support device comprises a plaster cast, synthetic cast, substantially rigid sleeve and/or walker.

3. An immobilization device according to claim 1 or 2, characterized in that the pressure device is designed in a manner such that, in use, the at least
one flexible chamber extends, at least partly, between the support device and a rear side and/or at least one side of the lower leg.

4. An immobilization device according to any one of the preceding claims, characterized in that the pressure device is designed in a manner such that, in use, the heel of the lower leg is left free by the pressure device.

5. An immobilization device according to any one of the preceding claims, characterized in that one wall of the at least one flexible chamber is at least substantially inelastic.

6. An immobilization device according to claim 5, characterized in that, in use, the pressure device is filled, at least partly, with the fluid, so that when the foot is placed on an underground, as during walking, the fluid flowing to the flexible chamber applies a stimulating action to the lower leg.

7. An immobilization device according to claim 6, characterized in that the immobilization device is designed such that the stimulating action is directed upwards.

8. An immobilization device according to any one of claims 1 – 7, characterized in that a wall of the at least one flexible chamber, a wall of the at least one fluid communication and/or a wall of the at least one pumping chamber is manufactured from a sheet-shaped material.

9. An immobilization device according to claim 8, characterized in that the wall of the at least one flexible chamber, the wall of the at least one fluid communication and/or the wall of the at least one pumping chamber is manufactured from a plastic such as polyethylene or polyurethane, optionally applied to a woven fabric such as nylon.

10. An immobilization device according to any one of the preceding claims, characterized in that the at least one flexible chamber, the at least one fluid communication and the at least one pumping chamber form an integral whole.

11. An immobilization device according to claim 9, characterized in that the pressure device is provided with a second sheet-shaped wall, in use remote
from the lower leg, and a first sheet-shaped wall included, in use, between the second sheet-shaped wall and the lower leg and, in use, proximal to the lower leg, which are each non-transmissive to the fluid and which, combined, form the at least one flexible chamber, the at least one fluid communication and the at least one pumping chamber.

12. An immobilization device according to claim 11, characterized in that the first and second sheet-shaped wall are substantially identical in shape.

13. An immobilization device according to claim 11 or 12, characterized in that the first and second sheet-shaped wall are fluid-tightly interconnected so that the first and the second sheet-shaped wall with the fluid-tight connection enclose the at least one flexible chamber, the least one fluid communication and the at least one pumping chamber.

14. An immobilization device according to claim 13, characterized in that the first and second sheet-shaped wall are fluid-tightly interconnected along their circumference.

15. An immobilization device according to claim 13 or 14, characterized in that the first and second sheet-shaped wall are fluid-tightly interconnected by means of a sealing seam.

16. An immobilization device according to any one of claims 13 – 15, characterized in that a first and second part of the assembly of the first and second sheet-shaped wall are connected such that, in use, the pressure device encloses the rear side of the lower leg and the underside of the foot.

17. An immobilization device according to claim 16, characterized in that the first and second part are connected by means of a second sealing seam.

18. An immobilization device according to any one of claims 11 – 17, characterized in that, in use, the first and second sheet-shaped wall extend substantially from a first side of the lower leg, passing under the sole of the foot, to a second side of the lower leg.
19. An immobilization device according to claims 16 and 18, characterized in that, in use, the connection between the first and second part extends, substantially in vertical direction, along the rear side of the lower leg.

20. An immobilization device according to any one of claims 11-17, characterized in that, in use, the first and second sheet-shaped wall extend substantially from a first side of the lower leg, passing behind the lower leg, to a second side of the lower leg.

21. An immobilization device according to claims 16 and 20, characterized in that, in use, the connection between the first and second part extends substantially in sagittal direction along the underside of the foot.

22. An immobilization device according to any one of the preceding claims, characterized in that in the at least one fluid communication, the pressure device is provided with spacing means for, in use, keeping open the at least one fluid communication between the at least one pumping chamber and the at least one flexible chamber.

23. An immobilization device according to any one of the preceding claims, characterized in that the pressure device is provided, adjacent the at least one fluid communication, with reinforcing means, for substantially preventing the at least one fluid communication between the at least one pumping chamber and the at least one flexible chamber from being closed off in use.

24. An immobilization device according to any one of the preceding claims, characterized in that the pressure device comprises a filling opening such as a valve.

25. An immobilization device according to any one of the preceding claims, characterized in that the fluid comprises a liquid, such as water.

26. A pressure device of the immobilization device according to any one of claims 1 - 25.
27. A method for manufacturing a pressure device apparently suitable for use in an immobilization device according to any one of claims 1 – 25, wherein the method comprises the steps of
   - providing a first sheet-shaped wall and a second sheet-shaped wall of a sheet-shaped material, which first and second sheet-shaped wall are substantially identical in shape, and which have a shape such that, combined, they can form the at least one flexible chamber, the at least one fluid communication and the at least one pumping chamber,
   - connecting in a fluid-tight manner the first and second sheet-shaped wall so that the first and second sheet-shaped wall with the fluid-tight connection enclose the at least one flexible chamber, the at least one fluid communication and the at least one pumping chamber,
   - connecting a first and second part of the first and/or second sheet-shaped wall in a manner such that, in use, the pressure device encloses the rear side of the lower leg and the underside of the foot.

28. A method according to claim 27, wherein further in use, the first and second sheet-shaped wall extend substantially from a first side of the lower leg, passing under the sole of the foot to a second side of the lower leg,
   while upon connection of the first and second part, the connection between the first and second part extends, in use, substantially in vertical direction along the rear side of the lower leg.

29. A method according to claim 27, wherein further in use, the first and second sheet-shaped wall extend substantially from a first side of the lower leg, passing behind the lower leg, to a second side of the lower leg,
   while upon connection of the first and second part, the connection between the first and second part extends, in use, substantially in sagittal direction along the underside of the foot.
30. A method according to any one of claims 27 – 29, wherein the first and second part of the first and/or second sheet-shaped wall are connected in a manner such that the pressure device, in use, encloses the rear side of the lower leg and the underside of the foot, while the heel of the lower leg is left free by the pressure device.

31. A method according to any one of claims 27 – 30, wherein the first sheet-shaped wall and the second sheet-shaped wall are, at least substantially, inelastic.

32. A method according to any one of claims 27 – 31, wherein the method further comprises providing a filling opening, such as a valve, in the first and/or second sheet-shaped wall.

33. A method for treatment of a lower leg fracture, wherein the steps are carried out of
- fitting a pressure device to the lower leg for applying a varying pressure to the lower leg, which pressure device is provided with at least one pumping chamber, at least one flexible chamber and at least one fluid communication between the at least one pumping chamber and the at least one flexible chamber while, in use, the at least one pumping chamber extends, at least partly, under a sole of a foot of the lower leg,
- providing a support device around the lower leg, while, in use, the at least one flexible chamber extends, at least partly, between the support device and the lower leg, and
- filling the pressure device, at least partly, with a fluid, so that, when the foot is placed on an underground, as during walking, the fluid will flow, at least partly, from the at least one pumping chamber via the at least one fluid communication to the at least one flexible chamber and, when the foot is lifted, the fluid will flow, at least partly, from the at least one flexible chamber via the at least one fluid communication to the at least one pumping chamber for applying the varying pressure to the lower leg with the at least one flexible chamber.
34. A method for treating a lower leg fracture, wherein the steps are carried out of
   - fitting a pressure device to the lower leg for applying a varying pressure to the lower leg, which pressure device is provided with at least one pumping chamber, at least one flexible chamber and at least one fluid communication between the at least one pumping chamber and the at least one flexible chamber while, in use, the at least one pumping chamber extends, at least partly, under a sole of a foot of the lower leg
   - providing a support device around the lower leg, while in use, the at least one flexible chamber extends, at least partly, between the support device and the lower leg,
   - filling the pressure device, at least partly, with a fluid so that, when the foot is placed on an underground, as during walking, the fluid will flow, at least partly, from the at least one pumping chamber via the at least one fluid communication to the at least one flexible chamber and, when the foot is lifted, the fluid will flow, at least partly, from the at least one flexible chamber via the at least one fluid communication to the at least one pumping chamber for applying the varying pressure to the lower leg with the at least one flexible chamber, and
   - applying the varying pressure to the lower leg.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F5/01  A61F5/058

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>column 2, line 29 - line 66 column 3, line 49 - column 4, line 30 column 5, line 2 - line 10; claims 4,7; figures 1,2,4,5</td>
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<td>Y A</td>
<td>US 2003/153857 A1 (MCCARTHY FABIAN ET AL) 14 August 2003 (2003-08-14) paragraphs [0002], [0006], [0023], [0024], [0040] - [0046]; figures 1-4,6,7</td>
<td>1-21,24, 25 27-30</td>
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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 document but published on or after the international filing date
  *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  *O* document referring to an oral disclosure, use, exhibition or other means
  *PP* document published prior to the international filing date but later than the priority data claimed

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

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

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"8" document member of the same patent family

Date of the actual completion of the International search 24 August 2006

Date of mailing of the International search report 06/09/2006

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel.(31-70) 340-2040, Tx. 31 651 epo nl, Fax (31-70) 340-3018

Authorized officer Merté, B
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<th>Relevant to claim No.</th>
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<tr>
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<td>US 2003/028135 A1 (FLICK ROLAND E ET AL) 6 February 2003 (2003-02-06)</td>
<td>1-5, 8-10, 12, 14-21, 25-30</td>
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<td>paragraphs [0009], [0038]; claims 1-3, 15, 34; figures 1, 3-5, 7</td>
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<td>A</td>
<td>US 5 078 128 A (GRIM ET AL) 7 January 1992 (1992-01-07)</td>
<td>1, 2, 5, 10</td>
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<td>column 10, line 32 - line 68</td>
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<td>column 11, line 50 - column 12, line 17; claims 71, 76; figures 3, 3A, 3B</td>
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Continuation of Box II.1

Claims Nos.: 26, 33, 34

Rule 39.1(iv) PCT – Method for treatment of the human or animal body by therapy
A method for treatment of a lower leg fracture as claimed in claims 33 and 34 is clearly a method for treatment of the human or animal body by therapy that is intended to re-establish the healthy state of intact bones.

Continuation of Box II.2

Claims Nos.: 26

Claim 26 is directed to a pressure device that is intended for the immobilization device of the preceding claims. It is however not clear, which technical constructional features are necessary to make this intended use possible. The claim hence lacks clarity. A comparison to known prior art pressure devices is not possible.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matters which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.
INTERNATIONAL SEARCH REPORT

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. **X** Claims Nos.: 26, 33, 34 because they relate to subject matter not required to be searched by this Authority, namely:
   - Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
   - Method for treatment of a lower leg fracture as claimed in claims 33 and 34 is clearly a method for treatment of the human or animal body by therapy that is intended to re-establish the healthy state of intact bones.

2. **X** Claims Nos.: 26 because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
   - see FURTHER INFORMATION sheet PCT/ISA/210

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

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

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

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

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

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

Remark on Protest

- [ ] The additional search fees were accompanied by the applicant's protest.
- [ ] No protest accompanied the payment of additional search fees.
<table>
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