



(51) International Patent Classification:

A61F 7/00 (2006.01) A61H 1/02 (2006.01)
A61F 5/042 (2006.01) A61H 15/00 (2006.01)

(21) International Application Number:

PCT/CA20 14/000761

(22) International Filing Date:

24 October 2014 (24.10.2014)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/903,702 13 November 2013 (13.11.2013) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available):

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

(84) Designated States (unless otherwise indicated, for every kind of regional protection available):

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

Published:

— with international search report (Art. 21(3))

(54) Title: METHODS FOR TREATING INFLAMMATORY SYMPTOMS ASSOCIATED WITH PLANTAR FASCIITIS

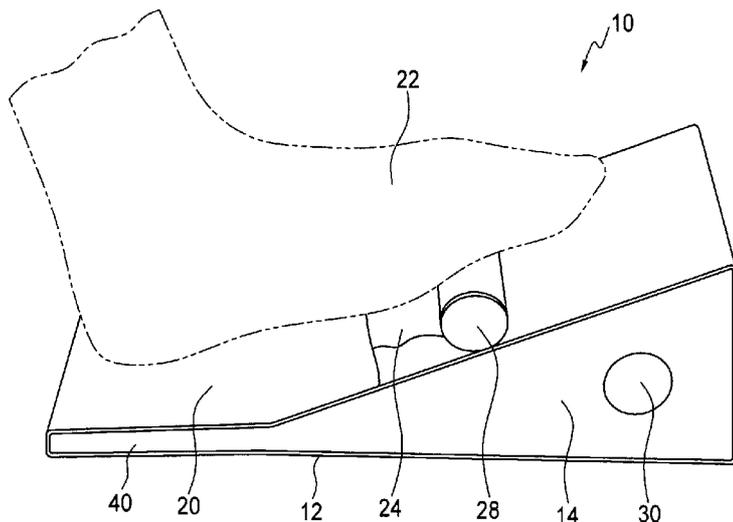


FIG. 4

(57) Abstract: The present invention relates to a method for treating inflammatory symptoms associated with plantar fasciitis in a foot. The method involves stretching gastrocnemius and soleus muscles associated with the foot by placing the sole of the foot on an inclined ramp surface and cooling at least one portion of the sole of the foot. The method may further involve providing localized pressure to at least one portion of the plantar fascia, and to a portion of the foot below the toes, to cause dorsiflexion thereof.



METHODS FOR TREATING INFLAMMATORY SYMPTOMS ASSOCIATED WITH PLANTAR FASCIITIS

CROSS REFERENCE TO RELATED APPLICATION

5 This application claims priority from United States Provisional Patent Application Serial Number US 61/903,702 filed on November 13, 2013, entitled METHOD FOR TREATING INFLAMMATORY SYMPTOMS ASSOCIATED WITH PLANTAR FASCIITIS, which is expressly incorporated by reference herein to the extent permitted by law.

10

BACKGROUND

Field of Invention

The present invention relates to a method for treating inflammatory symptoms associated with plantar fasciitis in a foot, as well as an apparatus for carrying out
15 such method. More particularly, the method involves stretching gastrocnemius and soleus muscles associated with the foot and simultaneously cooling at least one portion of the sole of the foot.

Description of Related Art

20 Plantar fasciitis is an inflammatory condition involving the connective tissue of the sole of a human foot. Overstressing this connective tissue can lead to inflammation and an afflicted individual will commonly suffer from mild to severe heel pain. If left untreated, plantar fasciitis can severely impact an individual's walking and other daily activities.

Plantar fasciitis is a very prevalent inflammatory condition. According to the American Academy of Orthopaedic Surgeons, approximately 2 million Americans are treated for plantar fasciitis each year; the costs associated with
5 treating plantar fasciitis run into the hundreds of millions of dollars on an annual basis (see, for e.g.: Singh et al. BMJ 315(7101): 172-175). Despite the significant prevalence of this inflammatory condition, there are limited options available for successfully treating plantar fasciitis and the inflammatory symptoms related thereto.

10

For example, U.S. Patent 8,241,232, which issued to Sanders, describes a foot pain relief device that contains a toe strap. The toe strap is fastened around the ankle and the toes to attempt to flex the toes upward. A second strap, referred to in the '232 Patent as a ball strap, can be coupled with the toe strap and a ball,
15 threaded to such ball strap, can be used to provide directed pressure on a component of the plantar fascia.

U.S. Patent 6,110,078, which issued to Dyer, describes a passive stretching device consisting primarily of two hinged plates with a variably tensioning
20 mechanism. Applied to the foot and lower leg, the device purports to provide a progressive stretch of the plantar fascia, Achilles tendon and related muscles.

Other known treatments for plantar fasciitis include the use of steroid-containing compositions (see, for e.g., WO2010131038, which was applied for by Hulley et

a/). Additionally, other known treatments for these plantar fasciitis-related symptoms include the use of non-steroidal anti-inflammatory drugs, the use of modified footwear, for example by using custom foot orthotics, and, in some instances, invasive surgery.

5

Accordingly, there remains a need for devices and methods that can efficiently and effectively treat plantar fasciitis, and the inflammatory symptoms related thereto.

10 **SUMMARY OF INVENTION**

In one aspect, a method for treating inflammatory symptoms associated with plantar fasciitis in a foot is disclosed. The method involves stretching gastrocnemius and soleus muscles associated with the foot by placing the sole of the foot on an inclined ramp surface, and cooling at least one portion of the
15 sole of the foot.

The method may further involve providing localized pressure to at least one portion of the plantar fascia. The method may also further involve providing localized pressure to a portion of the foot below the toes, to cause dorsiflexion
20 thereof.

The method may involve at least two of the foregoing steps being carried out simultaneously. Further, the method may further involve at least three of the foregoing steps being carried out simultaneously.

In another aspect, an apparatus for treating inflammatory symptoms associated with plantar fasciitis in a foot is disclosed. The apparatus includes an inclined ramp surface for stretching gastrocnemius and soleus muscles associated with the foot, and cooling means engageable with the inclined ramp surface for cooling at least one portion of the sole of the foot while the gastrocnemius and soleus muscles are being stretched.

The apparatus may include a pocket for retaining the cooling means in a fixed position. The apparatus may also include a flat surface adjacent the ramp surface and means engageable with the flat surface for providing localized pressure to at least one portion of the plantar fascia. The means engageable with the flat surface may also be engageable with the ramp surface to provide localized pressure beneath the toes of the foot. The means engageable with the flat surface may comprise a dowel that is reliable along the flat surface.

In another aspect, a use of the apparatus detailed herein is disclosed for treating inflammatory symptoms associated with plantar fasciitis in a foot. In yet another aspect, a kit for treating inflammatory symptoms associated with plantar fasciitis in a foot is disclosed. The kit includes an apparatus as detailed herein and instructions for use of such apparatus.

Further aspects and advantages of the present invention will become apparent upon considering the following drawings, description, and claims.

BRIEF DESCRIPTION OF THE FIGURES

In representative photographs which illustrate non-limiting embodiments of the invention:

5 **Figure 1** is a perspective view of an apparatus for treating inflammatory symptoms associated with plantar fasciitis in a foot, according to a first embodiment of the invention.

Figure 2 is a perspective view of the apparatus of Figure 1 detailing a dowel that engages the ramp surface of the apparatus.

10 **Figure 3** is a side elevational view of the apparatus of Figure 1 detailing the dowel in a storage position.

Figure 4 is a perspective view of the apparatus of Figure 1 demonstrating a foot being placed on the apparatus to stretch the gastrocnemius and soleus muscles, as described herein.

15

DETAILED DESCRIPTION

The invention will be more fully illustrated by the following detailed description of non-limiting, specific embodiments in conjunction with the aforementioned figures.

20

Referring first to Figure 1 herein, an apparatus 10 is disclosed for treating inflammatory symptoms associated with plantar fasciitis in a foot. The apparatus 10 has a base 12, two spaced-apart sides 14 and 16 (not shown), respectively, and an upstanding portion 18 that, in totality, define the apparatus 10. The

apparatus 10 has an inclined ramp surface 20, as shown, for example, in Figure 1. The apparatus 10 also has a flat surface 40, adjacent the ramp surface 20, as shown in Figure 1.

5 As utilized herein, the term "plantar fasciitis" also includes the related medical condition known as plantar fasciosis.

As utilized herein the term "inflammatory symptoms" includes acute and chronic inflammatory symptoms, such as acute and chronic inflammation. The
10 inflammatory symptoms are associated directly or indirectly with the condition commonly referred to as plantar fasciitis. Inflammatory symptoms also include tendonitis and tendonosis in the foot.

The apparatus 10 is optionally produced from a solid foam construction but it
15 can be made up of other materials, such as molded plastic and the like, so long as it can withstand reasonable downward pressure from a foot 22, as shown, for example in Figure 4 herein, and preferably so long as there is some padded heel cushion for comfort. Preferably, the apparatus 10 is produced from ethylene vinyl acetate and is a "closed cell" foam so that it can be cleaned
20 without absorbing moisture. Additionally, the apparatus 10 is preferably formed from a constructive material so that it is lightweight and non-latex due to the prevalence of latex allergies in the population.

The inclined ramp surface 20 can be of varied degrees of inclination (with reference being made to the flat surface 40), depending on the degree of stretching required of the foot-associated gastrocnemius and soleus muscles. Preferably, the inclined ramp surface 20 is between 10 degrees and 45 degrees.

5 More preferably, the inclined ramp surface is between 15 degrees and 30 degrees. It will be appreciated by those persons skilled in the art to which this specification relates, that the degree of inclination shown in the accompanying Figures is a non-limiting embodiment.

10 The apparatus 10 also includes cooling means 24 that is engageable with the inclined ramp surface 20 for cooling at least one portion of the sole of the foot 22, for example the heel portion, while the foot 22 is being stretched. The cooling means 24 may include, but is not limited to, commercially available ice packs or gel packs. Preferably, the cooling means 24 is retained in a fixed

15 position within a pocket 26 that is incorporated into the inclined ramp surface 20. This is shown, for example, in Figure 1 where the cooling means 24 is partially exposed from the pocket 26. However, as shown in Figures 2-4, in operation, the cooling means 24 is preferably maintained in a non-exposed position within the pocket 26. In an alternative embodiment, a heat pack can be utilized instead

20 of cooling means if increased circulation and/or tissue relaxation is preferred. It is specifically contemplated that variants of the pocket 26 and its interaction with the cooling means 24 or the heat pack could be introduced into the apparatus

10.

The apparatus 10 preferably contains means 28 that are engageable with the flat surface 40 for providing localized pressure to at least one portion of the plantar fascia. In addition to the flat surface 28, the means 28 can engage with the surface of a floor (not shown) adjacent the inclined ramp surfaces 20. The
5 means 28 are also engageable with the inclined ramp surface 20 for providing localized pressure to a portion of the foot 22 beneath the toes. When pressure is applied to this region of the foot, dorsiflexion of the toes (*i.e.*, upward flexing) can be accomplished. The means 28 may be in the form of a dowel and can be formed of wood or other hard materials, such as formed plastic or cork. In an
10 alternative embodiment, the means 28 may have beveled edges which are preferable for carrying out cross-friction massage on the plantar fascia. In a non-limiting, alternative embodiment, the means 28 may have be hour-glass shaped.

As shown, for example, in Figure 2 herein, the apparatus 10 optionally contains
15 a hole 30 initiating from one of the sidewalls 12 or 14 of the apparatus 10 for storing the means 28. Preferably the hole 30 is of a similar shape to the means 28 so as to maintain the means 28 in a tight, though accessible, storage position.

20 In operation, and as shown generally in Figure 4, the sole of a foot 22 is placed on the inclined ramp surface 22 of the apparatus 10. This position allows for suitable stretching of the foot-associated gastrocnemius and soleus muscles (not shown). A portion of the sole of the foot 22 is cooled by engaging the cooling means 24. Because plantar fasciitis often afflicts the heel portion of the

foot 22, the cooling means 24 preferably is positioned to engage the heel portion of the foot 22 when utilizing this apparatus 10. Preferably the stretching and cooling steps disclosed herein occur simultaneously. As previously noted, a heat pack can be utilized instead of cooling means if increased circulation and/or
5 tissue relaxation is a preferred outcome.

Additionally, localized pressure can be applied to at least one portion of the plantar fascia of the foot 22 by rocking the foot over the means 28, preferably when the means 28 engages the flat surface 40 (not shown). Additionally,
10 localized pressure can be applied to a portion of the foot 22 beneath the toes by rocking this portion of the foot 22 over the means. When pressure is applied to this region of the foot, dorsiflexion of the toes (*i.e.*, upward flexing) can be accomplished. A dowel-like shape is preferable for allowing this pressure to be localized. As noted above, the dowel-like shape may have beveled edges which
15 are preferable for carrying out cross-friction massage on the plantar fascia.

Preferably, the stretching, cooling, and localized pressure steps disclosed herein occur simultaneously or nearly simultaneously. In addition, the apparatus 10 detailed herein can be packaged as a kit (not specifically shown) for treating
20 inflammatory symptoms associated with plantar fasciitis in a foot. In addition to the apparatus 10, or similar embodiments thereof, the kit would also include instructions for the use thereof. The apparatus 10 can also be used to treat hypertonicity of the muscles in the foot.

Example 1. Treating inflammatory symptoms associated with plantar fasciitis in a foot.

NS, a female individual suffering from inflammatory symptoms associated with plantar fasciitis in her foot, utilized the apparatus 10 detailed herein as follows.

5 Specifically using the apparatus 10, NS cooled the heel of her foot, and stretched her gastrocnemius and soleus muscles, fascia and toes for 5 minutes at a time, on an hourly basis during the day, both at home while standing at a counter and at work while sitting at her desk or standing in her office. NS reported immediate pain relief from the inflammatory symptoms associated with
10 plantar fasciitis in her foot after each therapeutic session. Full recovery from the inflammatory symptoms associated with plantar fasciitis in her foot were achieved within approximately two (2) weeks.

Additionally, NS continues to maintain good foot health by using the apparatus
15 described herein on both of her feet twice daily (for a period of 5-10 minutes per session) to prevent future onset of plantar fasciitis. Accordingly, the apparatus and method described herein can be used not only to treat inflammatory symptoms associated with plantar fasciitis, but they can also be used to help prevent the onset of the condition.

20

Example 2. Treating inflammatory symptoms associated with plantar fasciitis in a foot.

JD, a 51 year-old female, was instructed by her Chiropractor to use the device
25 10 immediately after being diagnosed with plantar fasciitis. She utilized the

apparatus 8 - 10 times throughout the day, both at home and at work, to cool the heel of her foot and stretch her gastrocnemius and soles muscles, fascia and toes. She held each stretch for approximately 30 seconds to approximately one minute with the exception of use of the cooling means 24, 5 which was used for 2 - 3 minutes at a time to relieve pain and swelling, and other associated inflammatory symptoms. JD reported that after three weeks of the above-mentioned treatment, her pain was relieved by approximately 90% and her mobility increased by approximately same.

10 Thus, it will be seen from the foregoing embodiments and description that there has been described a method of treating inflammatory symptoms associated with plantar fasciitis in a foot using an apparatus substantially as described herein.

While specific embodiments of the invention have been described and 15 illustrated, such embodiments should be considered illustrative of the invention only and not as limiting the invention as construed in accordance with the accompanying claims. It will be understood by those skilled in the art that various changes, modifications and substitutions can be made to the foregoing embodiments without departing from the principle and scope of the invention 20 expressed in the claims made herein.

CLAIMS**WHAT IS CLAIMED IS:**

1. A method for treating inflammatory symptoms associated with plantar fasciitis in a foot, the method comprising:
 - 5 (a) stretching a gastrocnemius muscle and a soleus muscle associated with the foot by placing the sole of the foot on an inclined ramp surface; and
 - (b) cooling at least one portion of the sole of the foot.
2. The method of Claim 0, further comprising:
 - 10 (c) providing localized pressure to at least one portion of the plantar fascia of the foot.
3. The method of Claim 1 or 2, further comprising:
 - (d) providing localized pressure to a portion of the foot below the toes to cause dorsiflexion of the toes.
- 15 4. The method of any one of Claims 1-3, wherein at least two of the steps occur simultaneously.
5. The method of any one of Claims 0-3, wherein steps (a) and (b) occur simultaneously.

6. The method of any one of Claims 1-3, wherein at least three of the steps occur simultaneously.
7. The method of Claim 3 or 4, wherein steps (a), (b), and (c) all occur simultaneously.
- 5 8. An apparatus for treating inflammatory symptoms associated with plantar fasciitis in a foot, the apparatus comprising:
 - an inclined ramp surface for stretching a gastrocnemius muscle and a soleus muscle associated with the foot; and
 - cooling means engageable with the inclined ramp surface for
10 cooling at least one portion of the sole of the foot while the gastrocnemius muscle and the soleus muscle are being stretched.
9. The apparatus of Claim 8, wherein the inclined ramp surface contains a pocket for retaining the cooling means in a fixed position.
10. The apparatus of Claim 8, further comprising:
 - 15 means engageable with the ramp surface for providing localized pressure to at least one portion of the plantar fascia of the foot.
11. The apparatus of Claim 10, wherein the means engageable with the ramp surface comprise a dowel that is reliable along the ramp surface.

12. Use of the apparatus of any one of Claims 8 - 11 for treating inflammatory symptoms associated with plantar fasciitis in a foot.
13. A kit for treating inflammatory symptoms associated with plantar fasciitis in a foot, comprising:
 - 5 (a) the apparatus of any one of Claims 8 - 11; and
 - (b) instructions for use.

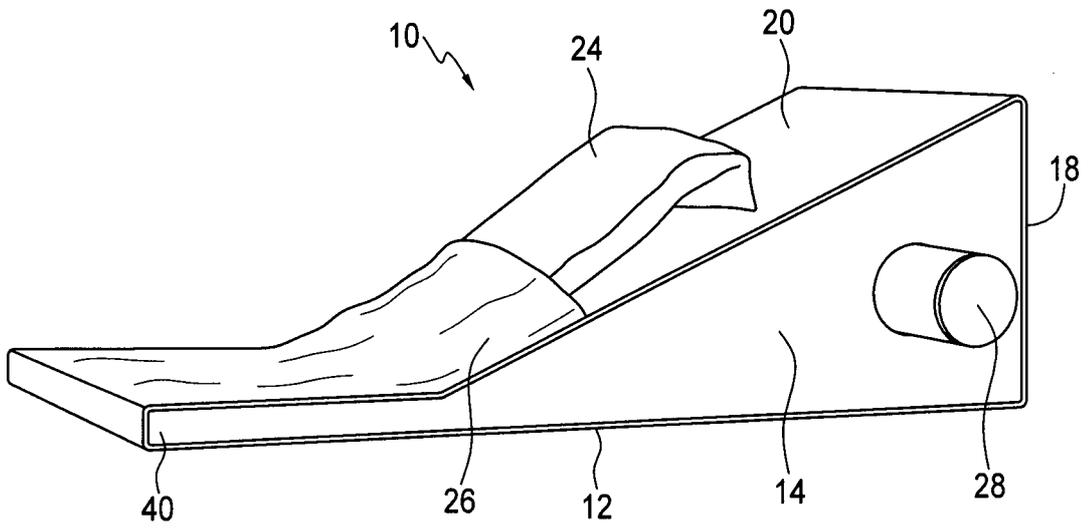


FIG. 1

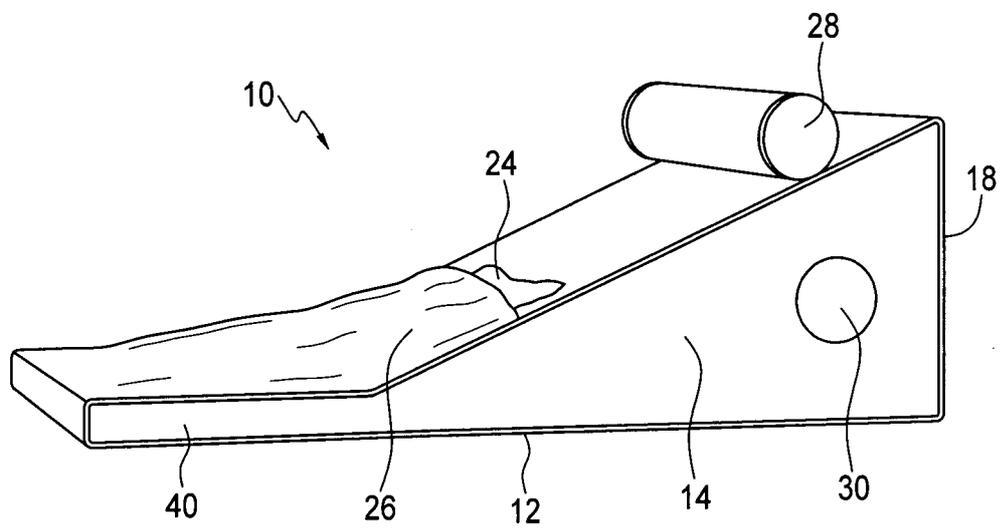


FIG. 2

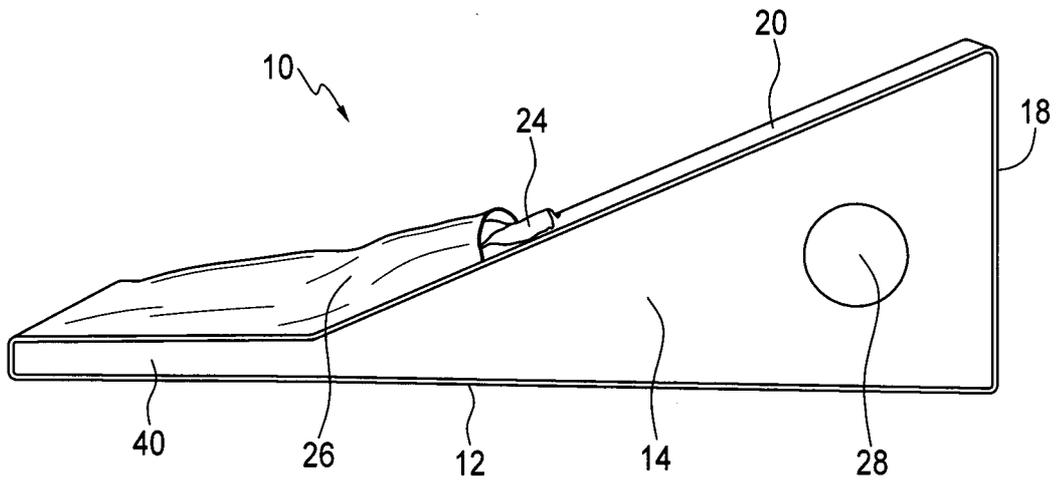


FIG. 3

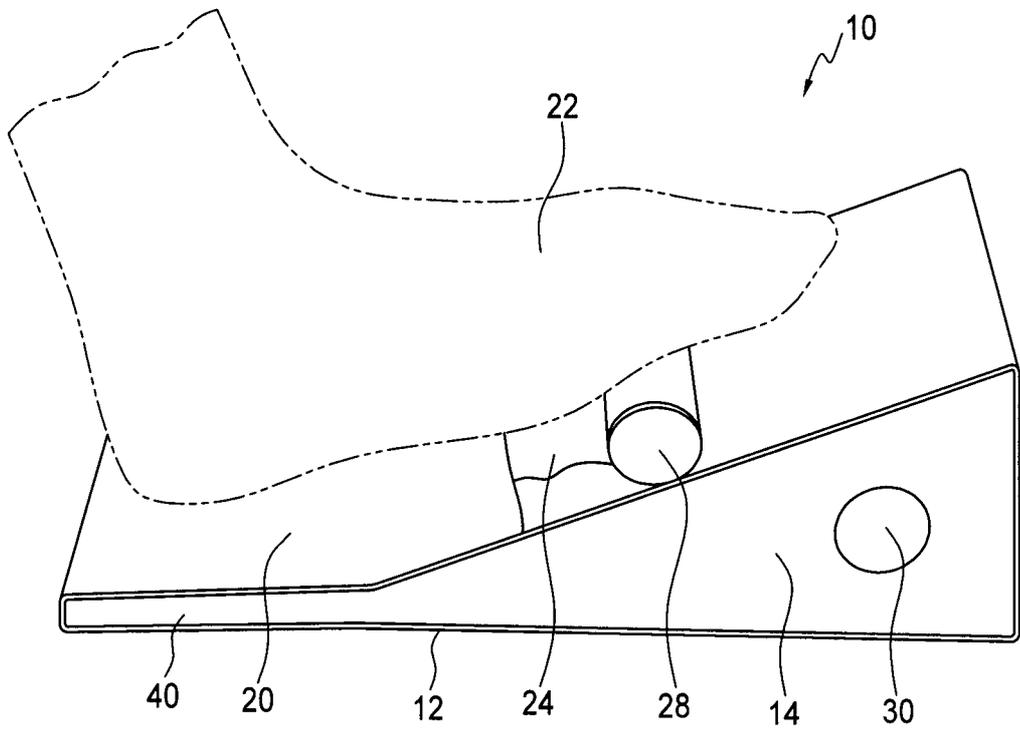


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2014/000761

A. CLASSIFICATION OF SUBJECT MATTER
 IPC: **A61F 7/00** (2006.01) , **A61F 5/042** (2006.01) , **A61H 1/02** (2006.01) , **A61H 15/00** (2006.01) ,
A61H 15/02 (2006.01)

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F (2006.01), **A61H** (2006.01)

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

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
 Electronic Database: Total Patent
 Keywords: foot, cool, cold, therm, temperature, muscle, exercise, roller, dowel, cylinder, ball, plantar fasciitis

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US660221 2B1 (Ahn, B.) 05 August 2003 (05-08-2003)	1-8 and 10-11
Y		9 and 12-13
Y	WO20040581 32A1 (Elias, B.) 15 July 2004 (15-07-2004)	9
Y	US61 10078A (Dyer, A.) 29 August 2000 (29-08-2000)	12-13
Y	US607441 4A (Haas, M.) 13 June 2000 (13-06-2000)	12-13

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

P See patent family annex.

* "A" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance earlier application or patent but published on or after the international filing date 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) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	"T" "X" "Y" "&"	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 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 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
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Date of the actual completion of the international search
 08 December 2014 (08-12-2014)

Date of mailing of the international search report
 12 February 2015 (12-02-2015)

Name and mailing address of the ISA/CA
 Canadian Intellectual Property Office
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 Heather Scott (819) 953-0767

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2014/000761

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US7399285B2 (Stein, H.) 15 July 2008 (15-07-2008)	1-13
A	CN20231 4287U (Limei, X.) 11 July 201 2 (11-07-201 2)	1-13
A	US8241 232B2 (Sanders, J.) 14 August 201 2 (14-08-201 2)	1-13
A	US8475397B2 (Ching-Hua, C.) 02 July 201 3 (02-07-201 3)	1-13

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

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

1. Claim Nos.: 1-7
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 1-7 are directed to a method for treatment of the human or animal body by surgery or therapy, which the International Searching Authority is not required to search under Rule 39.1(iv) of the PCT. However, this Authority has carried out a search based on the alleged effect or purpose/use of the product defined in claims 1-7.
2. Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

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 additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2014/000761

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
US660221 2B1	05 August 2003 (05-08-2003)	US660221 2B1 AU2001 242836B2 CN1404380A CN1203828C EP1 267793A1 EP1 267793A4 JP200450251 1A JP3590400B2 MXPA02002784A WO02074223A1	05 August 2003 (05-08-2003) 08 April 2004 (08-04-2004) 19 March 2003 (19-03-2003) 01 June 2005 (01-06-2005) 02 January 2003 (02-01-2003) 15 December 2004 (15-12-2004) 29 January 2004 (29-01-2004) 17 November 2004 (17-11-2004) 12 August 2004 (12-08-2004) 26 September 2002 (26-09-2002)
WO20040581 32A1	15 July 2004 (15-07-2004)	WO20040581 32A1 AU2002348692A1	15 July 2004 (15-07-2004) 22 July 2004 (22-07-2004)
US61 10078A	29 August 2000 (29-08-2000)	None	
US607441 4A	13 June 2000 (13-06-2000)	None	
US7399285B2	15 July 2008 (15-07-2008)	US200501 5032A1 US200501 5025A1	20 January 2005 (20-01-2005) 20 January 2005 (20-01-2005)
CN202314287U	11 July 2012 (11-07-2012)	None	
US8241 232B2	14 August 2012 (14-08-2012)	US201 1054368A1	03 March 2011 (03-03-2011)
US8475397B2	02 July 2013 (02-07-2013)	US201 1172578A1 TW201 1241 25A TWI374733B	14 July 2011 (14-07-2011) 16 July 2011 (16-07-2011) 21 October 2012 (21-10-2012)