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[Continued on next page]

(54) Title: FAR INFRARED RADIATION HEAT PATCH

(57) Abstract: A thermal treatment device comprising a far infrared ray material(20), a radiation reflection layer(30), and a heat energy source(40), wherein the radiation reflection layer(30) is positioned between the far infrared ray material(20) and the heat energy source(40).

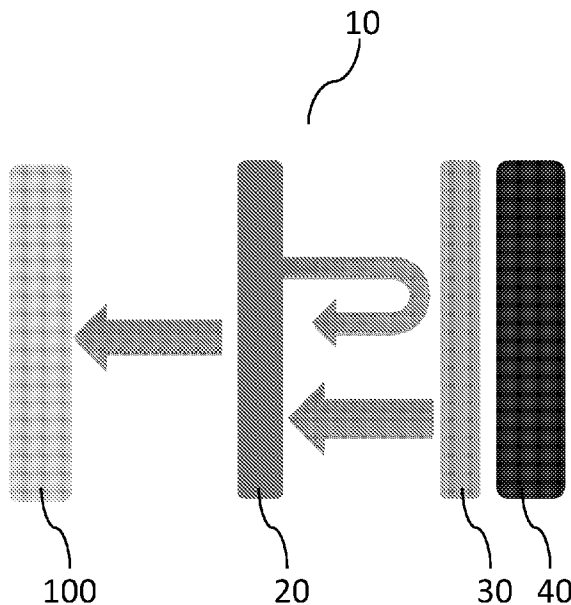


FIG. 3

WO 2017/152379 A1

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))

FAR INFRARED RADIATION HEAT PATCH

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to therapeutic treatment devices (e.g., patches). More particularly, the present invention relates to therapeutic treatment devices using far infrared radiation (FIR).

Related Background Art

[0002] People suffering from chronic pain typically take pain medicines to relieve the pain. However, the relief from pain is only temporary. Pain medicines may also have undesirable side effects.

[0003] Some people seek alternative treatments such as traditional Chinese medicine (TCM) and/or physical treatment(s). One alternative treatment option is far infrared radiation treatment. FIR has been used to provide instant pain relief and to activate the immune system to provide long term restoration to damaged muscles. FIR covers the electromagnetic spectrum with wavelengths between 3 and 100 μm . Of particular interest are wavelengths between about 3 to about 25 μm , more specifically from about 5 to about 25 μm .

[0004] The present invention helps prevent and relieve pain, especially chronic muscle pain. It provides pain relief without having to ingest drug medications and without the side effects of drug medications. The present invention utilizes FIR to provide pain relief in the form of a heat patch applied to the skin of a subject. The FIR device is designed for people to wear anytime

and anywhere. FIR patches provide low energy to the skin of a subject and have pain relieving effects.

SUMMARY OF THE INVENTION

[0005] The present invention is directed to a thermal treatment device comprising a far infrared ray material, a radiation reflection layer, and a heat energy source, wherein the radiation reflection layer is positioned between the far infrared ray material and the heat energy source.

[0006] The present invention includes a thermal treatment device comprising a far infrared ray material, a radiation reflection layer, and a heat energy source, wherein the radiation reflection layer is positioned between the far infrared ray material and the heat energy source, and wherein the device has an emissivity of at least 0.75 at about 40°C to about 45°C.

[0007] The present invention also includes a process for making a thermal treatment device, comprising the steps of providing a far infrared ray material and a heat energy source, and placing a radiation reflective layer between the far infrared material and the heat energy source.

[0008] The present invention further includes a method of treating body pain, comprising the step of applying a thermal treatment device to a subject, wherein the device comprises far infrared ray material, a radiation reflection layer, and a heat energy source, wherein the radiation reflection layer is positioned between the far infrared ray material and the heat energy source.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The detailed description will be better understood in conjunction with the accompanying drawings, wherein like reference characters represent like elements, as follows:

[0010] FIG. 1 depicts a FIR measuring device;

[0011] FIG. 2A, 2B and 2C illustrate FIR heat patch devices of the prior art;

[0012] FIG. 3 illustrates one embodiment of the inventive FIR Heat Patch Device; and

[0013] FIG. 4 illustrates an alternative embodiment of the inventive FIR Patch Device.

DETAILED DESCRIPTION OF THE INVENTION

[0014] As used herein, “emissivity” refers to the measure of an object's ability to emit infrared energy. The energy emitted provides an indication of the temperature of the object. Emissivity can have a value from 0 (e.g., a shiny mirror) to 1.0 (e.g., a blackbody).

[0015] The emissivity is determined using a FIR measuring device like the one depicted in FIG. 1. Measurements were performed with an FTIR system, which consists of a heating system and a detecting system. The heating system includes a sample heater and a type IR563/301 blackbody with a temperature stability up to 0.2 K per 24-h period. The heating system is fixed on a moveable platform, which is enabled to switch between the heated sample and the blackbody for radiation detection with the same optical path length. The detecting system consists of a Bruker Corporation type EQUINOX55 Fourier-transform infrared spectrometer, an aperture and an off-axis parabolic mirror. The diameter of the off-axis parabolic mirror is 80 mm with 200 mm focal length. Two apertures are used to limit stray light.

[0016] The normal spectral emissivity of sample, ϵ_x , is calculated by the formula,

$$\epsilon_x = \frac{M_x}{M_B} \epsilon_B$$

where M_x is the radiation from the heated sample;

M_B is the radiation from the blackbody at the same temperature and

ϵ_B is the normal spectral emissivity of the blackbody.

[0017] The emissivity at different wavelengths with a desired temperature was determined following the methods described above. The average of the emissivity for wavelength range of 5 μm –25 μm was used to represent the emissivity of different samples.

[0018] During the measurement, the wavenumber resolution of the sampling was fixed at 4 cm^{-1} over the range 4000 cm^{-1} –400 cm^{-1} (2.5 μm –25 μm), with scans repeated up to 1000 times to improve the signal-to-noise ratio. At least half an hour was needed to establish thermal equilibrium at any new temperature point for sample preparation.

[0019] As used herein, “transmissivity” refers to the degree to which a medium allows electromagnetic radiation to pass through it.

[0020] As used herein, “energy density” is calculated using the equation below:

$$M(\lambda_1 - \lambda_2, T) = \int_{\lambda_1}^{\lambda_2} \frac{2hc^2}{\lambda^5} \cdot \frac{1}{e^{\frac{hc}{\lambda kT}} - 1} d\lambda$$

where λ_1 and λ_2 are the wavelengths of radiation at the starting and ending point, respectively;

k is Boltzmann’s constant;

t is temperature;

h is Planck’s constant;

c is the speed of light in the medium, whether material or vacuum;

$M(\lambda, T)$ is the amount of energy it gives off as radiation of different wavelength; and

$M(\lambda_1-\lambda_2, T)$ is the amount of energy the black body gives off as radiation between the wavelength range of $\lambda_1-\lambda_2$ at the specified temperature.

[0021] The present invention is directed to a thermal treatment device comprising a far infrared ray material, a radiation reflection layer, and a heat energy source, wherein the radiation reflection layer is positioned between the far infrared ray material and the heat energy source.

[0022] The far infrared material is typically positioned in direct contact with the subject using the device. The far infrared material may be, for example, a fiber or fabric (e.g., a nonwoven, a woven, or combination thereof) or a film (e.g., polyethylene, polypropylene, polyethylene terephthalate, polyamide, and combinations thereof). Moreover, the far infrared ray material typically includes black carbon, ceramic powder, or mixtures thereof. Typically, black carbon or ceramic powder is impregnated into the fiber or film of the far infrared material.

[0023] Ideally, the far infrared ray material has an emissivity greater than 0.55. In one embodiment, the FIR material has an emissivity greater than 0.75.

[0024] Another essential feature of the inventive device is a radiation reflection layer, which is positioned between the far infrared material and the heat energy source. In one embodiment, the radiation reflection layer includes a metal. Suitable metals include, for example, aluminum, copper, gold, steel, zinc, and combinations thereof. In another embodiment, the radiation reflection layer has a conductivity of at least about 10 W/mK. In addition, it is desirable that the reflection layer has a thickness from about 1 micron to about 1000 microns.

[0001] The thermal treatment device includes a heat energy source. The heat energy source may be any suitable source capable of generating or holding heat. In one embodiment, the heat energy source emits heat from about 1°C to about 10°C above the skin surface temperature of a human.

[0002] In one particular embodiment, the heat energy source comprises thermal fill materials that are a mixture of substances that chemically react exothermically. For example, several commercial hand warmers and therapeutic heat products contain an iron powder based mixture that liberates heat as the iron is oxidized upon exposure to air. These types of systems are described in detail, for example, in U.S. Patent No. 5,918,590. It is known in the art to formulate these mixtures to maintain a temperature of at least about 40°C for at least 4 hours, and up to 24 hours. Depending upon the application or desired product design, the temperature may be maintained for at least about 8 hours, at least about 10 hours, at least about 12 hours, at least about 16 hours, or whatever time period desired.

[0003] In another embodiment, the heat energy source comprises a thermal composition, which includes a microwavable heat retaining material. Suitable heat retaining materials include, for example, rice, corn, barley, cherry stones, starch-based synthetic pellets, and the like. Such materials typically retain a suitable level of heat for about 20 to about 60 minutes.

[0004] In another embodiment, the heat energy source comprises a thermal composition that includes electrically heated articles, such as a resistive heater, or a thermoelectric heating element, such as a Peltier element.

[0005] In one embodiment, the heat energy source provides heat energy at a temperature from about 38°C to about 48°C. In particular, it is desirable that the heat energy source emits heat from about 40°C to about 45°C, when the device is applied to the skin of a subject.

[0006] It is also desirable that the thermal treatment device have an energy density from about 10.83 mW/cm² to about 15.45 mW/cm² for the wavelength range of 5 to 25 μm.

Correspondingly, the emissivity of the thermal treatment device should be at least about 0.75 and the surface temperature of the FIR material about 40°C to about 45°C. Preferably, it has an energy density from about 11.55 mW/cm² to about 15.45 mW/cm² for wavelength range of 5 to 25 μm which has a corresponding emissivity of the thermal treatment device of at least about 0.8 and the surface temperature of the FIR material of about 40°C to about 45°C.

[0007] In one preferred embodiment, the thermal treatment device comprises a far infrared ray material that is a nonwoven, a radiation reflection layer that is a metal, and a heat energy source, wherein the radiation reflection layer is positioned between the far infrared ray material and the heat energy source, and wherein the device has an energy density from about 10.83 mW/cm² to about 15.45 mW/cm² for wavelength range of 5 to 25 μm which means the emissivity of at least about 0.75 and the surface temperature of far infrared ray material is about 40°C to about 45°C.

[0008] The thermal treatment device may be conformed or are shaped to fit various parts of the body. For example, the thermal treatment device may be designed to the particular shape of a muscle or muscle group, such as the back, neck or shoulder of the human body.

[0009] It should be understood that the thermally conductive component can be of a various shapes, including round, semi-spherical, elongated, ellipsoidal, cylindrical, star shaped, mushroom shaped, or similar shapes. According to an embodiment of the present invention, the

shapes of the thermally conductive component at the interfaces to the individual's body can be flat or non-flat, including but not limited to semi-spherical, pyramidal, conical, concave, convex, bumped, or contain an array of smaller shapes, e.g., semi-spherical protrusions.

[0010] The accompanying drawings of the present invention will now be described in detail with reference to embodiments thereof as illustrated in the accompanying drawings. However, those skilled in the art will readily appreciate that the detailed description given herein with respect to these figures is for explanatory purposes as the invention extends beyond these limited embodiments.

[0011] FIGS. 2A, 2B, and 2C provide examples of currently available FIR patch devices. In FIG. 2A, FIR patch 15 is essentially made of FIR material 25, which is applied to skin 100. FIG. 2B depicts another embodiment of a prior art FIR patch device 15, where an energy source 45 is added adjacent to FIR material 25. In FIG. 2C, FIR patch device 15 is shown, having an FIR material 25, an energy source 45, and a reflective layer 35, where the energy source is positioned between the FIR material and the reflective layer. In this particular configuration, the heat patch 15 will absorb all the reflection from the reflection layer 35 and transfer it into heat energy. The reflection layer 35 can only help maintain the temperature.

[0012] In FIG. 3, the inventive FIR heat patch device 10 is shown, having FIR material 20, reflective layer 30, and energy source 40, wherein the reflective layer is positioned between the FIR material and the energy source. The present inventors have found that by positioning the reflective layer 30 between the FIR material 20 and the energy source 40 there is a noticeable improvement in the emissivity of the device.

[0013] In FIG. 4, an alternative embodiment is depicted where reflective layer 130 is located adjacent to FIR material 120 in FIR patch device 110. Here again, in this particular configuration, there is a noticeable improvement in the emissivity of the device.

[0014] The present invention also includes a process for making a thermal treatment device, comprising the steps of providing a far infrared ray material and a heat energy source, and placing a radiation reflective layer between the far infrared material and the heat energy source.

[0015] The present invention also includes a method of treating body pain, comprising the steps of applying a thermal treatment device to a subject, wherein the device comprises far infrared ray material, a radiation reflection layer, and a heat energy source, wherein the radiation reflection layer is positioned between the far infrared ray material and the heat energy source.

[0016] The following example is provided to further illustrate the compositions and methods of the present invention. It should be understood that the present invention is not limited to the examples described.

[0017] Examples of various patch configurations were prepared and tested for Emissivity

EXAMPLE 1

Preparation of various reflective layer types to test Emissivity

[0018] Films produced by Clopay Plastics (Clopay FIR film D5) were used for the FIR (Far Infrared) material. Various reflective layers were combined with the Clopay FIR film D5, where the thickness of the FIR material was varied. The Emissivity of the combination was determined and presented in Table 1.

Table 1

	Reflective Layer Type	Material Thickness of FIR material (μm)	Emissivity of FIR material	Final Emissivity
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				(□)
1	Copper	500	0.77	0.82
2	Aluminum	500	0.77	0.86
3	Copper	75	0.77	0.85
4	Aluminum	75	0.77	0.83

*Clopay FIR film D5 is made of polyester and bamboo charcoal

[0019] The data shows that the thickness of the FIR film layer does not substantially affect the final Emissivity.

EXAMPLE 2

Preparation of various reflective layer types combined with various FIR Materials

[0020] Various reflective layer types were combined with various types of film materials to determine Emissivity. The black aperture film and white films were sourced from Clopay Plastics. The data is shown in Table 2.

Table 2

	Reflective Layer Type	FIR Material Type	Emissivity of FIR material	Final Emissivity (□)
1	Copper	Black Aperture Film	0.20	0.40
2	Aluminum	Black Aperture Film	0.20	0.46
3	Copper	White nonwoven film	0.40	0.60
4	Aluminum	White nonwoven film	0.40	0.58
5	Copper	White film (Clopay)	0.25	0.49
6	Aluminum	White film (Clopay)	0.25	0.49
7	Aluminum	Clopay FIR Film D5 + Aperture HTA	0.77	0.74
8	Aluminum	Clopay FIR Film D5 + HTA	0.77	0.76
9	Aluminum	Clopay FIR Film D5	0.77	0.83

Black aperture film is Clopay's aperture FIR film (combination of polyester and bamboo charcoal) with a hole size of 100 to 200 microns and with of 26.8 gsm (gram per square meter) and thickness of 0.38 mm.

White film is Clopay's apertured film (polyester with no FIR actives) with a hole size 100 to 200 microns.

White nonwoven film is a standard wet wipe material which is made of Cellulose fibers and

Polyester with 40~60 gsm and 0.25~0.4 mm thickness commercial available from Nbond Nonwovens Ltd.
HTA is a kind of nonwoven material.

[0021] The data demonstrates that different types of reflective layers can boost the Emissivity when using different types of FIR materials (e.g., films).

EXAMPLE 3

Preparation of various reflective layer types and various Films with Heat sources

[0022] Various reflective layer types and various types of film materials were combined with exothermic heat patches to provide heat and FIR treatment for muscle pain relief and restoration.

The data in Table 3 shows the Emissivity of the device.

Table 3

	Heat Source (Patch) temperature (°C)	Reflective Layer Type	FIR Material Type	Emissivity of FIR material	Final Emissivity (□)	Final Energy density(mW/cm ²)
1	>49°C	Copper	Emana ¹ FIR fiber textile	0.56	0.71	>11.55 mW/cm ²
2	>45°C	Copper	Clopay FIR Film D2	0.56	0.76	>11.55 mW/cm ²
3	>38°C	Copper	Clopay FIR Film D5	0.77	0.85	>11.55 mW/cm ²
4	>38°C	Gold on Copper	Clopay FIR Film D5	0.77	0.84	>11.55 mW/cm ²
5	>38°C	Steel	Clopay FIR Film D5	0.77	0.86	>11.55 mW/cm ²
6	>44°C	None	Clopay FIR Film D5	0.77	0.77	>11.55 mW/cm ²
7	>44°C	Silver (92.5%)	Clopay FIR Film D5	0.77	0.77	>11.55 mW/cm ²
8	>40°C	Stainless Steel	Clopay FIR Film D5	0.77	0.80	>11.55 mW/cm ²

1: Commercially available from Emana Fiber Transforma (Emana FIR fiber textile is made of 81% Polyamide and 19% Spandex with 250 gsm)???

[0023] The data shows that different types of reflective layers can boost the Emissivity when using different types of FIR materials. The optimum ranges include a temperature above 40°C and an Emissivity above 0.8.

[0024] While the invention has been described above with reference to specific embodiments thereof, it is apparent that many changes, modifications, and variations can be made without departing from the inventive concept disclosed herein. Accordingly, it is intended to embrace all such changes, modifications, and variations that fall within the spirit and broad scope of the appended claims. All patent applications, patents, and other publications cited herein are incorporated by reference in their entirety.

WHAT IS CLAIMED:

1. A thermal treatment device comprising:
a far infrared ray material;
a radiation reflection layer; and
a heat energy source,
wherein the radiation reflection layer is positioned between the far infrared ray material and the heat energy source.
2. The device of claim 1, wherein the far infrared ray material comprises black carbon or ceramic powder.
3. The device of claim 1, wherein the far infrared ray material is a fiber or film.
4. The device of claim 3, wherein the fiber is selected from the group consisting of a nonwoven, a woven, and combinations thereof.
5. The device of claim 3, wherein the film is selected from the group consisting of polyethylene, polypropylene, polyethylene terephthalate, polyamide, and combinations thereof.
6. The device of claim 1, wherein the far infrared ray material has an emissivity greater than about 0.55.
7. The device of claim 1, wherein the radiation reflection layer includes a metal.
8. The device of claim 7, wherein the metal is aluminum, copper, gold, steel, zinc, and combinations thereof.
9. The device of claim 1, wherein the radiation reflection layer has a conductivity of at least

10 W/mK.

10. The device of claim 1, wherein the heat energy source provides heat energy at a temperature from about 38°C to about 48°C.
11. The device of claim 1, wherein the heat energy source emits heat from about 40°C to about 45°C, when the device is applied to the skin of a subject.
12. The device of claim 1, wherein the heat energy source is provided by a chemical reaction or by electrical energy.
13. The device of claim 1, wherein the heat energy source comprises a microwavable heat retaining material.
14. The device of claim 1, wherein the device has an emissivity of at least 0.75 at about 40°C to about 45°C.
15. A thermal treatment device comprising a far infrared ray material that is a nonwoven, a radiation reflection layer that is a metal, and a heat energy source, wherein the radiation reflection layer is positioned between the far infrared ray material and the heat energy source, and wherein the device has an emissivity of at least 0.75 at about 40°C to about 45°C.
16. A process for making a thermal treatment device, comprising the steps of providing a far infrared ray material and a heat energy source, and placing a radiation reflective layer between the far infrared material and the heat energy source.
17. A method of treating body pain, comprising the step of applying a thermal treatment device to a subject, wherein the device comprises far infrared ray material, a radiation reflection layer, and a heat energy source, wherein the radiation reflection layer is positioned between the far infrared ray material and the heat energy source, and wearing the thermal treatment device for

a time period sufficient to reduce the body pain.

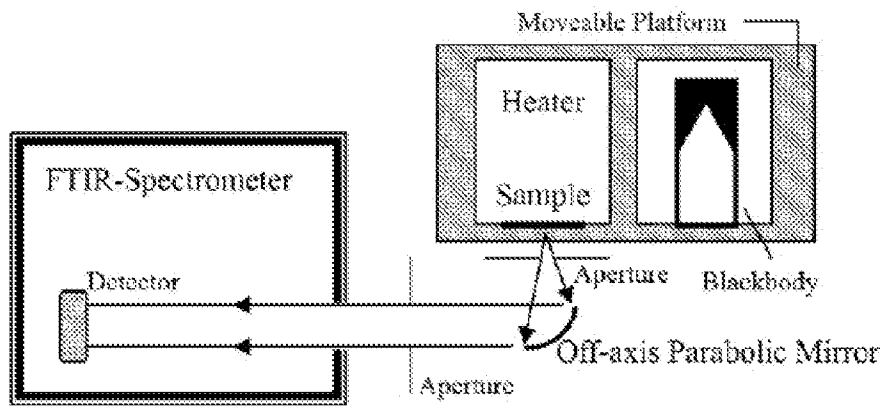


FIG. 1

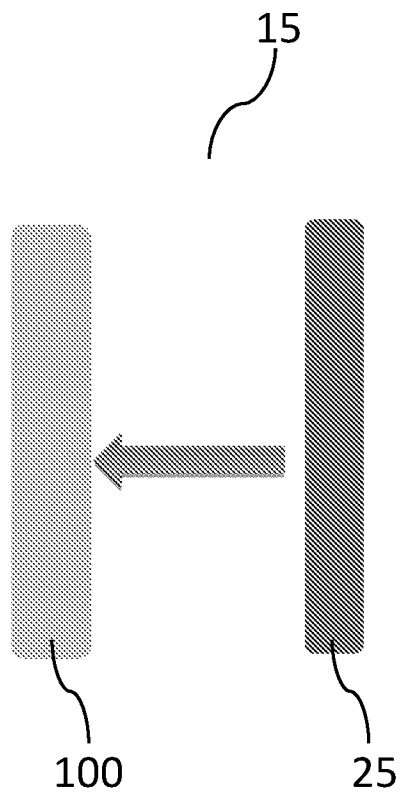


FIG. 2A

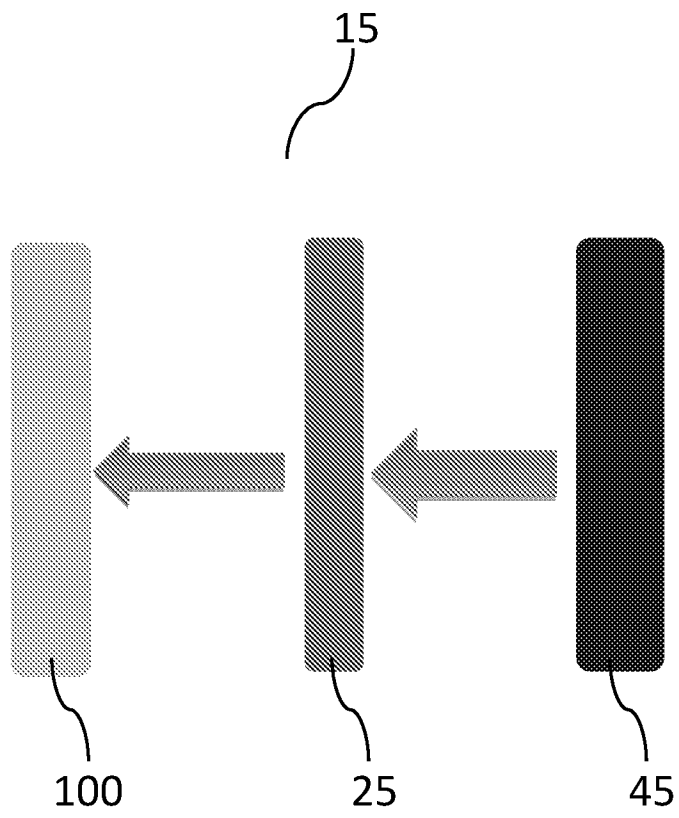


FIG. 2B

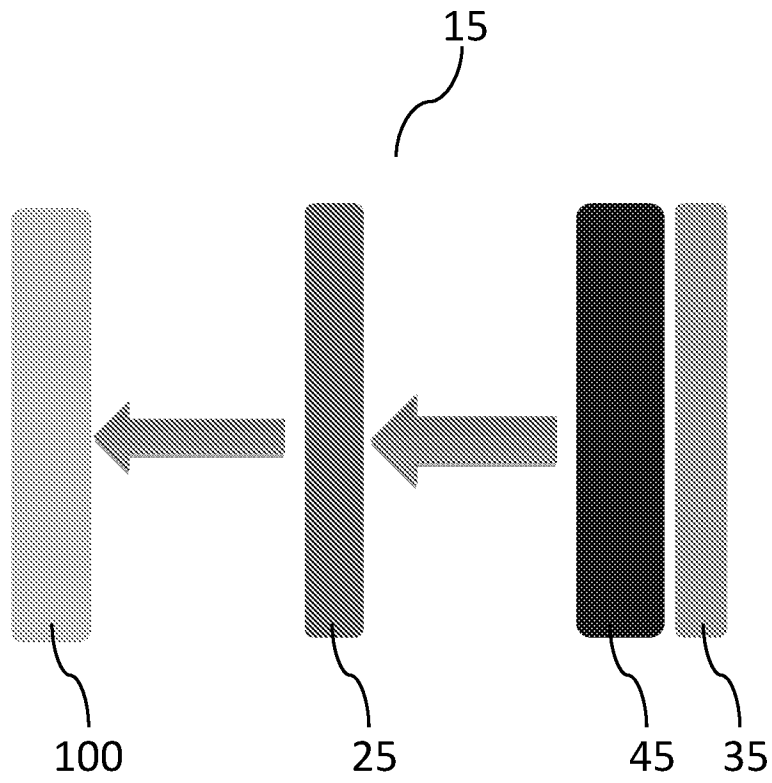


FIG. 2C

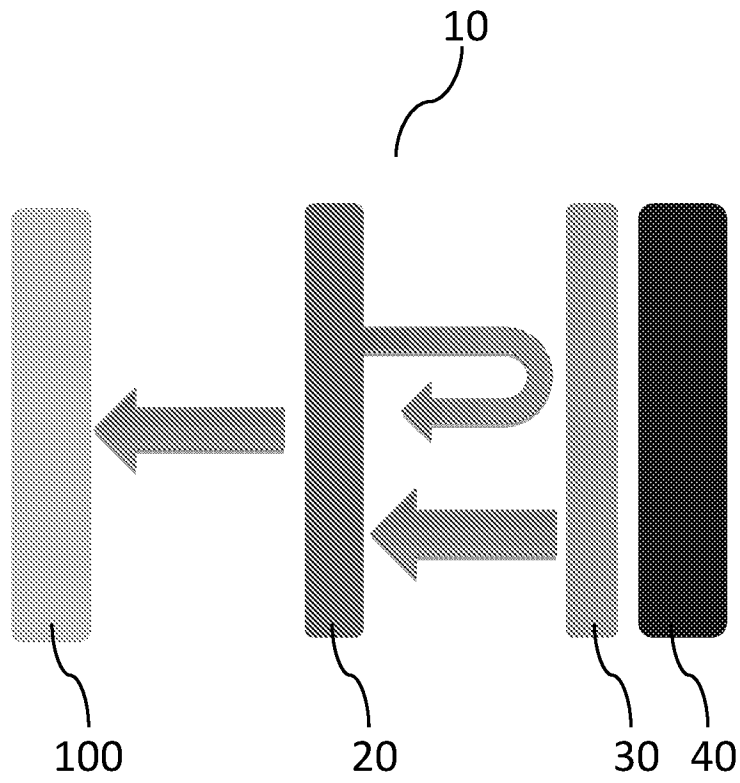


FIG. 3

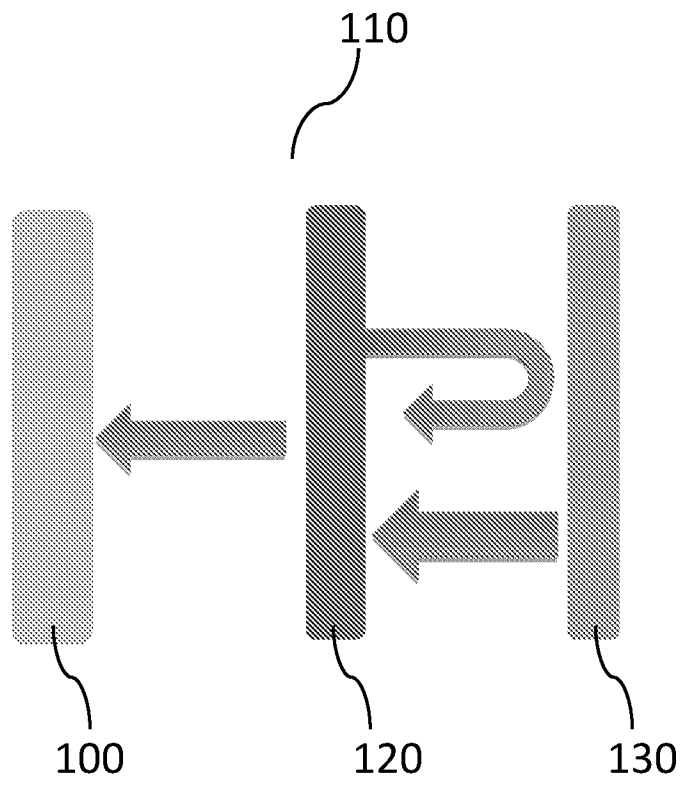


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN2016/075918

A. CLASSIFICATION OF SUBJECT MATTER A61N 5/06(2006.01)i 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) A61N 5/- 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) WPI, EPODOC, CNKI, CNPAT, Web of Knowledge:慢性疼痛,近红外,垫,治疗,金属,加热,treat+,metal,far,infrared,ray, reflection,heat		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP H1043319 A (JAMCO CORP.) 17 February 1998 (1998-02-17) abstract, paragraphs [0002]、 [0004]、 [0017]-[0019] in the description, figure 3	1-6、 8-14、 16
Y	JP H1043319 A (JAMCO CORP.) 17 February 1998 (1998-02-17) abstract, paragraphs [0002]、 [0004]、 [0017]-[0019] in the description, figure 3	2、 7、 15
Y	CN 1161870 A (IWASAKI SEIKI K.K.) 15 October 1997 (1997-10-15) claims 2-4	2、 7、 15
A	CN 201085373 Y (SHI, XINZHU) 16 July 2008 (2008-07-16) the whole document	1-16
A	US 6108581 A (JUNG, YEON-KWEON) 22 August 2000 (2000-08-22) the whole document	1-16
A	JP 0197476 A (TAKEBE, NORICHIKA) 14 April 1989 (1989-04-14) the whole document	1-16
A	CN 2732088 Y (AROMATIC CYPRESS CULTURAL ENTERPRISE CO., LTD.) 12 October 2005 (2005-10-12) the whole document	1-16
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
<p>* Special categories of cited documents:</p> <p>“A” document defining the general state of the art which is not considered to be of particular relevance</p> <p>“E” earlier application or patent but published on or after the international filing date</p> <p>“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)</p> <p>“O” document referring to an oral disclosure, use, exhibition or other means</p> <p>“P” document published prior to the international filing date but later than the priority date claimed</p> <p>“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</p> <p>“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</p> <p>“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</p> <p>“&” document member of the same patent family</p>		
Date of the actual completion of the international search 15 November 2016		Date of mailing of the international search report 30 November 2016
Name and mailing address of the ISA/CN STATE INTELLECTUAL PROPERTY OFFICE OF THE P.R.CHINA 6, Xitucheng Rd., Jimen Bridge, Haidian District, Beijing 100088 China		Authorized officer HU, Yating
Facsimile No. (86-10)62019451		Telephone No. (86-10)52871091

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN2016/075918

Box No. 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. Claims Nos.: 17
because they relate to subject matter not required to be searched by this Authority, namely:
[1] Claim 17 relates to a method for treatment of the human or animal body by surgery.

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

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/CN2016/075918

Patent document cited in search report			Publication date (day/month/year)	Patent family member(s)			Publication date (day/month/year)
JP	H1043319	A	17 February 1998	None			
CN	1161870	A	15 October 1997	JP	H09276420	A	28 October 1997
CN	201085373	Y	16 July 2008	None			
US	6108581	A	22 August 2000	EP	0963138	A2	08 December 1999
				KR	20-0164701	Y1	15 February 2000
JP	0197476	A	14 April 1989	None			
CN	2732088	Y	12 October 2005	None			