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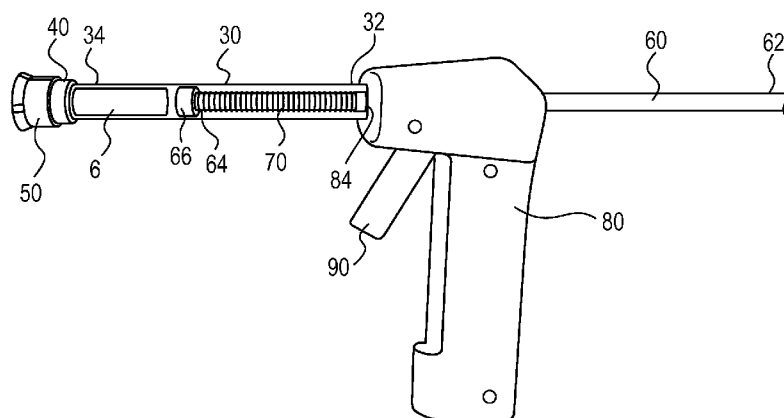
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(54) **Title:** CRYOTHERAPY DEVICE AND METHOD FOR THE TREATMENT OF CERVICAL PRECANCEROUS LESIONS

**FIG. 1(c)**

(57) **Abstract:** A device (1) for providing a cryotherapy ablation treatment includes a piping assembly (10) and a snow horn (26) adapted to create a spray of snow from a pressurized source of a low-temperature liquid, a tubular applicator (30) for collecting a mass of snow at a prescribed density that is sufficient to allow the mass to serve as the needed, low temperature, thermal reservoir for the device (1) after the applicator's distal end (34) has been disconnected from the snow horn end so that it can be used during the treatment process, and an applicator tip (50) adapted to allow it to connect to the applicator's distal end (34) and be used to treat those specific locations which are to receive this treatment.



1 CRYOTHERAPY DEVICE AND METHOD FOR THE TREATMENT
2 OF CERVICAL PRECANCEROUS LESIONS
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7 CROSS-REFERENCE TO RELATED APPLICATION
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9 This application claims the priority and benefits of U. S. Regular Patent
10 Application No. 13/898,961, filed May 21, 2013 by the present inventors and entitled
11 “CRYOTHERAPY DEVICE AND METHOD FOR THE TREATMENT OF
12 CERVICAL PRECANCEROUS LESIONS.” The teachings of this application are
13 incorporated herein by reference to the extent that they do not conflict with the
14 teaching herein.
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19 BACKGROUND OF THE INVENTION
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22 1. FIELD OF THE INVENTION

23 The present invention relates generally to surgery devices and methods.
24 More particularly, the present invention relates to a cryotherapy device and method to
25 treat, destroy or ablate a patient’s abnormal tissues or lesions, e.g., for the ablation of
26 cervical, precancerous lesions to prevent cervical cancer.
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30 2. DESCRIPTION OF THE RELATED ART

31 Cervical cancer is the third most common cancer in the world. Moreover,
32 eighty percent of all cervical cancer cases occur in the developing world. With

1 approximately 500,000 new cases each year, cervical cancer is responsible for over
2 250,000 deaths per year, making it the second leading cause of death in developing
3 countries. Many of these deaths are women in their late 30s and early 40s, thus
4 compromising the health and well-being of the surrounding family. Indeed, this is
5 especially true for the children of these women, who often fall behind in their
6 education and may be abandoned, without a mother.

7 While steps, such as annual PAP smears and other interventional methods,
8 have been taken to eradicate cervical cancer in the developing world, cervical cancer
9 still remains a large burden for these countries. Its prevalence in the developing
10 world can in large part be attributed to a lack of appropriated technologies for
11 screening and treatment.

12 A “single visit” approach has been developed and includes a screening by
13 visual inspection with acetic acid and a point-of-diagnosis cryotherapy treatment.
14 This approach for screening and treatment has provided a safe, acceptable, and
15 feasible option in low-resource settings.

16 Cryotherapy includes freezing the abnormal cervical tissue with a coolant
17 such as carbon dioxide, CO₂, and has been used for over forty years to treat cervical
18 dysplasia. This process uses what is called a “double freeze procedure.” One freezes
19 the cervix for three minutes and then allows it to thaw for five minutes, then it is
20 frozen again for an additional three minutes. This procedure maximizes the amount
21 of tissue that is frozen more so than just doing one extra-long freeze because the
22 frozen tissue becomes more thermally conductive after the first freeze so the second
23 freeze penetrates quicker and subsequently deeper into the affected tissue.

24 Cryotherapy is the leading method for the ablation of cervical precancerous
25 lesions for the prevention of cervical cancer, especially in the developing world.
26 Despite proven efficacy of cryotherapy as a mode of ablating precancerous lesions,
27 the current state of the art used to facilitate cryotherapy is not sufficiently designed
28 for widespread and reliable use in the developing world.

29 While this single visit approach or “screen and treat” program has been shown
30 to be effective in prevention of cervical cancer, there still remains a hurdle to scaling
31 up such a program for widespread impact. While cryotherapy using CO₂ has been

1 shown to be safe and effective, even in the hands of low-level health care workers,
2 the equipment is not necessarily suitable to be widely dispersed. Indeed, cryotherapy
3 tools can be expensive, technically complex, lacking portability, and difficult to repair
4 in the field.

5 Currently, the developing world utilizes cryoguns, see, for example, USPN
6 4,377,168 which discloses expanding pressurized CO₂ (or N₂O in some instances
7 when a country or program can afford the added expense of the N₂O) against a
8 thermally conductive tip. The expansion of the CO₂ in this closed system creates a
9 temperature of approximately -50 to -70 degrees C on the surface of the tip which is
10 in contact with a lesion.

11 With carbonated beverage manufacturers being widely dispersed in the
12 developing world, and often using carbon dioxide to produce their carbonated
13 beverages, carbon dioxide manufacturers are also widely dispersed in the developing
14 world. This has led to cryoablation being conducted with carbon dioxide as the
15 primary source of coolant.

16 The current design of cryotherapy tools suffers from several flaws when
17 utilized with carbon dioxide tanks, including: water vapor leaving the tank causes tip
18 blockages, non-medical grade carbon dioxide may have particulates, which cause tip
19 blockages, and a pressure drop may occur in the cylinder through the cooling process
20 during extended use which results in warmer and less effective tip temperatures.

21 Additionally, the equipment was never originally designed for use within the
22 extreme conditions of the developing world where there are high volumes of ablations
23 along with environmental abuse of the product. First, the tips on the current
24 cryotherapy tools are manufactured with gold or chrome plating, which not only
25 makes the tip expensive, at approximately three hundred dollars per tip, but these tips
26 also suffer from corrosion from the chlorine disinfection method - the widely
27 available method for sterilization in the developing world.

28 Improper cleaning and storage of these tips also leads to clogs, requiring
29 replacement. Additionally, the overall cost of the equipment is around thirteen
30 hundred to two thousand dollars per device. Moreover, with the complexity of this
31 equipment's engineering design, there is a lack of repair knowledge and backup parts

1 when the equipment breaks down. Unfortunately, when the cryotherapy equipment
2 malfunctions in the field, the device becomes unused and is rarely capable of being
3 easily fixed.

4 Finally, the amount of carbon dioxide required per treatment limits the
5 portability of the device. A tank containing 50 lbs of CO₂, weighs approximately 160
6 lbs total, and treats only about 10 to 15 patients. These large tanks are therefore
7 difficult to transport to the rural areas where women need to be screened and treated,
8 either in the context of health centers, mobile health vehicles or organized screen &
9 treat camps. Therefore, these characteristics of current cryotherapy equipment
10 prohibit its massive scale-up for widespread impact on reducing the burden of
11 cervical cancer.

12 It would therefore be advantageous to provide a device and method that could
13 safely, effectively, and in a low-cost manner treat, destroy or ablate cervical,
14 precancerous lesions in order to prevent cervical cancer.

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SUMMARY OF THE INVENTION

Recognizing the need in emerging nations for the development of improved cryotherapy techniques, the present invention is generally directed to satisfying this need. The present invention's method of treatment or process for providing cryotherapy ablation utilizes a pressurized tank of a low-temperature liquid as its source for the low-temperature, thermal reservoir that is needed to conduct by this process.

A preferred embodiment of the present invention takes the form of a device that includes: (a) a piping assembly having a configuration adapted to allow the assembly's distal end to connect to the pressurized tank's outlet and thereby allow the low-temperature liquid to exhaust through the assembly in such a manner that yields the proper liquid flow conditions at the assembly's proximal end so as to create a spray of snow as a result of the freezing of the low-temperature liquid as it exhausts from the piping assembly, (b) a tubular, snow horn having a boundary wall that extends between distal and proximal ends and has a configuration adapted to allow the snow horn's distal end to connect to the piping assembly's proximal end so as to cause the exhausting low-temperature liquid to flow through the snow horn and create the flow conditions in the snow horn that will enable a prescribed mass of this snow of a desired density to be collected in a specified period of time, (c) a tubular applicator having a configuration adapted to allow the applicator's distal end to temporarily connect to the snow horn's proximal end in order to enable the prescribed mass of this snow to be collected and wherein this mass of collected snow is sufficient to allow it to serve as the needed, low temperature, thermal reservoir for the device after the applicator's distal end has been disconnected from the snow horn end so that the applicator can be used during the cryotherapy ablation process, and (d) an applicator tip having a configuration adapted to allow the applicator tip to connect to the applicator's distal end and used during a cryotherapy ablation process to locate on a patient those specific locations which are to receive this treatment.

A first variant of this preferred embodiment further includes a hand-operable handle having a configuration adapted to allow it to control the positioning of the

1 applicator's distal end during a cryotherapy ablation treatment.

2 A second variant of this preferred embodiment further includes a push rod
3 having a configuration adapted to allow the push rod's distal end to variably extend
4 into the applicator so as to allow a base attached to the push rod's distal end to serve
5 as the furthest point in the applicator, as measured from its distal end, that the spray
6 of snow can collect.

7 A third variant of this preferred embodiment further includes a means for
8 biasing the push rod so that its base pushes the mass of collected snow towards and
9 against the applicator tip during a cryotherapy ablation process.

10 A fourth variant of this preferred embodiment further includes adapting the
11 configuration of the push rod so that it can interact with the handle to control the
12 location of the push rod's base relative to the applicator's distal end.

13 A fifth variant of this preferred embodiment includes further configuring all
14 of the elements of the device so that optimally suited for use in a cryotherapy ablation
15 process which utilizes the low-temperature liquid of carbon dioxide.

16 A sixth variant of this preferred embodiment includes further configuring all
17 of the elements of the device so that optimally suited for use in a cryotherapy ablation
18 process associated with the removal of cervical, precancerous lesions for the
19 prevention of cervical cancer.

20 Another preferred embodiment of the present invention takes the form of a
21 method for providing a patient with cryotherapy ablation and the steps of this method
22 include utilizing the device as recited in any one of its variations that are summarized
23 above.

24 Thus, there has been summarized above (rather broadly and understanding
25 that there are other preferred embodiments which have not been summarized above)
26 the present invention in order that the detailed description that follows may be better
27 understood and appreciated.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1(a) is a perspective view of the piping assembly of the present invention.

FIG. 1(b) is a perspective view of the snow horn of the present invention.

FIG. 1(c) is a perspective view of the, assembled and filled with CO₂ snow, applicator, applicator tip, push rod, spring and handle of the present invention.

FIG. 2 is an exploded, perspective view of the elements of the present invention shown in FIG. 1(c).

FIG. 3 is a perspective view of an applicator tip that is suitable for use in the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Before explaining at least one embodiment of the present invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and to the arrangements of the components or elements set forth in the following description or illustrated in the drawings. This invention is capable of being practiced and carried out in various ways. Therefore, it is to be understood that the present invention is not to be limited to the specific embodiment disclosed herein, and that its many variants are intended to be included within the scope of the appended claims. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of description and should not be regarded as limiting. In the accompanying drawings, like numbers refer to like elements throughout.

A preferred embodiment in accordance with the present invention **1** provides an apparatus or device and method that utilizes cryotherapy to treat, destroy or ablate a patient's abnormal tissues or lesions, e.g., for the ablation of cervical, precancerous lesions for the prevention of cervical cancer. The device includes an auxiliary piping assembly **10** that is configured to be connected to the typically horizontally-directed outlet of a pressurized, carbon dioxide tank in the bottom of which resides liquid carbon dioxide, CO₂, or other suitable fluid that freezes at a comparatively low temperature (i.e., a low-temperature liquid).

The purpose of this piping assembly and its configuration is adapted to yield the proper flow conditions for the beginning of the creation of the CO₂ snow from the distal end of the piping assembly when the pressurized tank of carbon dioxide is allowed to exhaust through the piping assembly at operating pressures in the range of 750 – 850 psig and the CO₂ freezes as it exits the assembly. See US Patent Number (USPN) 6,543,251 and European Patent Number (EP) 1,046,614B1 for background technology related to the creation of CO₂ snow. One variant for the configuration of this piping assembly **10** includes a distal end **12** that has an adapter **14** which allows the piping assembly to be connected and firmly affixed to the tank's outlet **2**, while also reducing the diameter of the pipe through which the exhaust is flowing. See

FIG. 1(a).

A pressure gauge **16** that is sized to measure and read pressures up to approximately 700 - 1,000 psig is included in this piping assembly so as to check to ensure that the tank pressure is adequate to support the creation of CO₂ snow. It also includes a valve **18** that regulates flow through the piping assembly, a ninety degree elbow **20** that is used to redirect the normal direction of the flow from the tank from being horizontal to vertical, and a proximal end **22** to which is attached a nozzle **24** whose outlet or orifice **24a** diameter is critical to the efficient operation of the piping assembly and it's on-demand, capability to begin the creation of CO₂ snow.

A preferred variant of this piping assembly's distal end has the diameter of the pipe to which the nozzle connects being 1/8 of an inch and the diameter of the nozzle's orifice **24a** being in the range of 0.005 – 0.050 inches, with a preferred value of 0.016 inches. Downstream from this nozzle and its orifice **24a** is a snow horn **26** which has a boundary wall **26c** and a configuration adapted to create the final flow conditions for the collection of CO₂ snow having a desired density. Alternatively, the snow horn has a configuration adapted to create the proper flow conditions at the snow horn's proximal end so as to enable a prescribed mass of the snow of a desired density to be collected in a specified period of time. See FIG. 1(b). This snow horn has a distal end **26a** that has a configuration that allows it to be locked to a comparable fitting (e.g., 1/8 inch NPT tap) on the proximal end **22** of the piping assembly. The proximal end **26b** of this snow horn has a special fitting or coupling **28** that allows for it to be easily connected to and disconnected from the distal end **34** of the device's applicator **30**. This coupling **28** is also configured as the element of the device which has the least structural strength. The purpose of this is to ensure that the device will break apart at this coupling during a situation in which an accident were to occur and an excess CO₂ pressure were to be applied to the device.

The CO₂ snow's desired density is chosen so that the mass of CO₂ snow collected is sufficient to provide the needed low temperature reservoir while also allowing the scale of the device to be such that it is appropriate for the desired

1 cryotherapy procedure. Experimentation has shown that a CO₂ snow density in the
2 range of 8 – 11g/in³ allows the required mass of snow to be in the range of 8-10g
3 for a normal preventive, ablation of cervical, precancerous lesions procedure.

4 The present invention also includes a hollow, tubular applicator **30** which has
5 proximal **32** and distal **34** ends. As its name implies, this part of the present
6 invention is used by a health care provider to help precisely locate the point/s on a
7 patient where the invention's cryotherapy will be applied. This applicator **30** has a
8 configuration that is adapted to collect and temporarily store in its interior **36** and
9 proximate its distal end the mass **6** of CO₂ snow that is required (i.e., sufficient to
10 allow the mass of collected snow to serve as the low temperature thermal reservoir
11 for the device after the applicator's distal end has been disconnected from the snow
12 horn and the applicator's tip attached so the applicator and its tip together can be used
13 to perform a cryotherapy ablation).

14 See FIG. 1(c). See also FIG. 2 which is an exploded, perspective view of the
15 elements of the present invention that are shown in FIG. 1(c).

16 A flow-through fitting **40** is provided at the applicator's distal end that is
17 configured to allow for, among other things, the attachment and detachment of the
18 applicator's distal end to and from the coupling **28** on the distal end of the snow
19 horn during the part of the process in which the applicator is filled with CO₂ snow.
20 This same fitting **40**, upon being decoupled from the snow horn, is also configured
21 to allow it to be used for attaching to the applicator's distal end an especially
22 designed applicator cap or tip **50** which is the part of the device that actually comes
23 into contact with a patient's body where it is desired to freeze and ablate targeted
24 tissues or cells.

25 The proximal end **32** of the applicator has an opening **38** that allows access
26 to the applicator's interior from this proximal end. This opening allows for a base
27 **66** at the distal **64** end of a retractable, push rod **60** to be inserted to different
28 distances into the applicator. The outer boundaries of this base have a configuration
29 that is adapted to allow them to provide a sliding seal against the applicator's
30 interior wall **42**. The distal portion of this base, when the push rod is adjustably
31 inserted into the applicator, thus forms the furthest boundary at which CO₂ snow

1 may accumulate in the applicator. The wall **42** of the applicator is also provided
2 with a number of vent holes **44** by which gases can be vented during the CO₂ snow
3 filling process.

4 In the alternate venting pattern, channels running parallel to the axis of the
5 cylinder allow gas venting to the atmosphere at both the proximal **32** and distal **34**
6 ends of the applicator. The opening to each of the channels is sufficiently small such
7 that the particles of snow do not coagulate in this region in such a way as to block the
8 channels. The channels may also serve to vent the sublimating gas during a
9 cryotherapy treatment procedure and thereby prevent accumulation of the sublimate
10 in the vaginal cavity which inhibits the device operator's ability to see the distal end
11 of the applicator..

12 The exact dimensions of such an applicator will obviously be a function of
13 the type of cryotherapy procedure that is desired to be performed using the present
14 invention. For a normal preventive, ablation of cervical, precancerous lesions
15 procedure, typical dimensions for this applicator are: outer diameter = 5/8 inch, wall
16 thickness = 1/16 inch when polycarbonate extruded tubing is being used as the
17 material from which to fabricate the tube, length in the range of 6 – 8 inches, vent
18 holes: diameters in the range of 0.02 – 0.03 inches and 15 – 20 in number and
19 spaced at 0.25 inch intervals along the length of the tube. For an applicator sized in
20 this manner, typical snow horn dimensions would then be: length = 7 – 9 inches,
21 inside tube diameter = 3/8 inch and where it may be fabricated from an assortment
22 of plastics, including polycarbonate, acrylic, polysulfone, ABS, acetal copolymer,
23 or polypropylene.

24 Once the applicator is sufficiently filled with CO₂ snow, the applicator is
25 disconnected from the snow horn and an applicator cap or tip **50** is attached to the
26 fitting **40** on the applicator's distal end **34**. During a cryotherapy treatment process,
27 the mass or plug **6** of CO₂ snow must be continually pressed up against the inner
28 side **52** of the applicator cap to ensure that the plug has good thermal contact with
29 the applicator cap **50**. An appropriately sized spring or other suitable biasing means
30 **70** is fitted around the push rod and travels along with the push rod and up into the
31 applicator's interior. The distal end **72** of this spring presses against the back side

1 of the base of the applicator while its proximal end **74** rest against a portion of an
2 especially configured handle **80** that has a configuration adapted to allow the handle
3 to be hand-operated to control the positioning of the applicator's tip **50** and either
4 lock in position or incrementally advance the push rod and the plug of CO₂ snow.

5 Since, during a cryotherapy procedure, the plug **6** of CO₂ snow is slowly
6 moving towards the distal end of the applicator, the interior wall **42** of the applicator
7 near its distal end has been provided with a slight outward taper in order to aid the
8 forward movement of this plug. For a normal preventive, ablation of cervical,
9 precancerous lesions procedure, and consistent with the typical dimensions
10 previously given for an applicator, a typical taper is in the range of 0.5 – 1.0
11 percent.

12 The handle **80** of the present invention is of a two-piece **82a, 82b**
13 construction and contains an opening **84** in the front face **86** of the handle and into
14 which the proximal end **32** of the applicator is press fitted. This opening extends all
15 the way through the handle and therefore allows the proximal end **62** of the push
16 rod to extend from the rear face **88** of the handle. A spring-loaded trigger **90** is
17 affixed to the handle and is configured such that a boundary edge **92** of the trigger
18 interacts with grooves **60a** on the push rod to provide the handle with its ability to
19 incrementally advance or lock the push rod's position relative to the handle. The
20 retraction of the push rod is handled manually (for example, to allow for the filling
21 of the distal end of the applicator with CO₂ snow), i.e., the handle's trigger is pulled
22 backward to release the push rod while the proximal end of the push rod is grasped
23 in the free hand of the one who is holding the device's handle and pulled backward
24 to retract the push rod.

25 This device's applicator cap or tip **50** has a configuration adapted to allow it
26 to be attached to and detached from the fitting **40** applicator's distal end and provide
27 good thermal transfer through it since it is this tip that comes into contact with a
28 patient and therefore needs an adequate rate of low-temperature thermal transfer
29 from the mass of collected snow to the patient for the cryotherapy ablation process
30 to be successful. This capability is provided by forming its outer surface **54** which
31 comes into contact with a patient from metal while the remainder of the tip is

1 normally formed from plastic. FIG. 3 shows an exploded perspective view of such
2 an applicator tip where an intermediate ring **56** is used to help attaching the taps **54a**
3 of the metal outer surface to the ring **56** and it to the tip's connector **58** which has
4 protrusions **58a** on either side of it that aid in gripping the applicator tip. The
5 intermediate ring **56** is then attached, usually via gluing, to the tip's connector **58**.

6 The method or steps for using the present invention include:

- 7 1. Attaching the piping assembly to a siphoned CO₂ tank such that it's distal
8 end points downward (note: if using a non-siphoned CO₂ tank, the distal end
9 should point upward when the tank is valve side up),
- 10 2. Opening the outside packaging of the high level disinfected and/or
11 sterilized components (i.e., snow horn, applicator, push rod, applicator cap, spring,
12 handle) of the present invention without touching the interior of the wrapping.
- 13 3. Wiping down a small work surface on which to place the components that
14 are to assembled to make the handle with a solution of 70% or 99% isopropyl
15 alcohol
- 16 4. Wiping down the assembled handle and the on/off lever of the piping
17 assembly with a solution of 70 or 90% isopropyl alcohol,
- 18 5. Putting on sterile or disinfected gloves,
- 19 6. Removing the snow horn and threading or attaching it to the distal end of
20 the piping assembly until they are hand-tight, locked together,
- 21 7. Removing an applicator and inserting its proximal end into the opening in
22 the handle's front face,
- 23 8. Dropping the spring into the applicator,
- 24 9. Placing the push rod into the applicator and spring with its proximal end
25 going into and through the handle (squeeze the trigger to allow the push rod to
26 pass all the way through), pulling back on the rod's proximal end once it is
27 through the handle (rather than pushing from the rod's distal end) to completely
28 retract the push rod and then releasing the trigger (don't release the push rod until
29 trigger is completely locked into the grooves of the push rod),

1 10. Sliding the assembled handle and applicator into the snow horn, the tabs on
2 the applicator's distal end go into the coupling on the snow horn's distal end (a
3 click will indicate that it is fully seated),

4 11. On the piping assembly, turning the on/off valve to on; keeping it on until
5 the CO₂ snow is visible above the fitting on the end of the snow horn – then,
6 turning the valve to off,

7 12. Disconnecting the assembled handle and applicator from the snow horn by
8 sliding it out the way it went in,

9 13. Sliding the applicator cap onto the distal end of the applicator and twisting
10 it to lock it in place, the device is now ready to perform a freeze,

11 14. To freeze, simply squeeze the trigger, there will be a slight popping sound
12 as the spring is released,

13 15. At the end of the freeze, release the trigger and it will lock the push rod in
14 place; for a more rapid defrost, squeeze the trigger and retract the push rod to pull
15 the CO₂ snow back away from the cap and release the trigger to lock the push rod,
16 and

17 16. After the defrost, squeeze the trigger to unlock the push rod and pull the
18 applicator out of the handle and drop the push rod, spring, applicator, and its cap
19 into a decontaminating, chlorine solution.

20 For a cryotherapy process directed to the ablation of cervical, precancerous
21 lesions to prevent cervical cancer, and utilizing what is called a “double freeze
22 procedure,” a second freeze would be completed by completing steps 7 through 16
23 after a five minute thaw cycle is completed and by using a second applicator set
24 (i.e., push rod, spring, applicator and its cap) that would be provided with the
25 device.

26 An alternative way to describe the method of the present invention is note
27 that it is a method for providing a patient with cryotherapy ablation in which the
28 steps for performing this method utilizing a connection to the outlet of a pressurized
29 tank of a low-temperature liquid in association with the device as disclosed in the
30 prior paragraphs.

31 Finally, it can be seen that the current invention eliminates many of the

1 previously noted disadvantages (e.g., frequent tip blockages in the very expensive,
2 gold or chrome plated nozzles that do not hold up well to frequently being
3 disinfected; current devices on which these nozzles are used cost around thirteen
4 hundred dollars per device; often considerable difficulty in maintaining such devices;
5 need to transport with these devices fifty pound tanks of carbon dioxide tank;
6 difficulty in scaling up the current process to accommodate large numbers of
7 patients) in traditional cryotherapy processes.

8 The many features and advantages of the present invention are apparent
9 from the detailed specification, and thus, it is intended by the appended claims to
10 cover all such features and advantages of the invention which fall within the true
11 spirit and scope of the invention. Further, since numerous modifications and
12 variations will readily occur to those skilled in the art, it is not desired to limit the
13 invention to the exact construction and operation illustrated and described, and
14 accordingly, all suitable modifications and equivalents may be resorted to and are
15 considered to fall within the scope of the present invention.

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CLAIMS

We claim:

1. A device (1), that connects to the outlet of a pressurized tank of a low-temperature liquid, for providing a patient with cryotherapy ablation, said device comprising:

a piping assembly (10) having a distal (12) and a proximal (22) end and a configuration adapted to allow said distal end (12) to connect to said pressurized tank outlet and to create the proper flow conditions at said proximal (22) end so as to create a spray of snow as a result of the freezing of said low-temperature liquid upon its exhaustion from said piping assembly (10),

a tubular, snow horn (26) having a distal (26a) and a proximal (26b) end, a boundary wall (26c) extending between said ends and enclosing the interior region of said snow horn, said snow horn also having a configuration adapted to allow said snow horn distal end (26a) to connect to said piping assembly proximal (22) end and to create the proper flow conditions at said snow horn proximal (26b) end that enable a prescribed mass of said snow of a desired density to be collected in a specified period of time,

a tubular applicator (30) having a distal (34) and a proximal (32) end and a configuration adapted to allow said applicator distal (34) end to temporarily connect to said snow horn proximal (26b) end in order to collect said prescribed mass of said snow during said specified period of time and wherein said mass of collected snow is sufficient to allow said mass of collected snow to serve as the low temperature thermal reservoir for said device after said applicator distal (34) end has been disconnected from said snow horn proximal (26b) end so as to be used during said process of providing said cryotherapy ablation, and

an applicator tip (50) having an inner (52) and an outer (54) surface and a configuration adapted to allow said applicator tip to connect to said applicator distal (34) end during said process of providing said cryotherapy ablation and to allow said outer (54) surface of said applicator tip to come into contact with said patient for the purpose of providing a rate of low-temperature thermal transfer from said mass of

1 collected snow to said patient that is sufficient for said cryotherapy ablation process.

2 2. The device as recited in Claim 1, further comprising:

3 a handle (80) having a configuration adapted to allow said handle to be hand-
4 operated to control the positioning of said distal end (34) of said tubular applicator
5 during said process of providing said cryotherapy ablation.

6 3. The device as recited in Claim 1, further comprising:

7 a push rod (60) having a distal (64) and a proximal (62) end and a base (66)
8 attached to said push rod distal (64) end and having a configuration adapted to allow
9 said push rod distal (64) end to variably extend into said tubular applicator (30) from
10 said applicator proximal (32) end so as to allow said push rod base to serve as the
11 furthest point in said applicator from said applicator distal (34) end that said spray of
12 snow can collect.

13 4. The device as recited in Claim 2, further comprising:

14 a push rod (60) having a distal (64) and a proximal (62) end and a base (66)
15 attached to said push rod distal (64) end and having a configuration adapted to allow
16 said push rod distal (64) end to variably extend into said tubular applicator (30) from
17 said applicator proximal (32) end so as to allow said push rod base to serve as the
18 furthest point in said applicator from said applicator distal (34) end that said spray of
19 snow can collect.

20 5. The device as recited in Claim 3, further comprising:

21 a means for biasing (70) said push rod (60) so as to cause said push rod base
22 (66) to push said mass of collected snow towards and against said applicator tip (50)
23 during said cryotherapy ablation process.

24 6. The device as recited in Claim 4, further comprising:

25 a means for biasing (70) said push rod (60) so as to cause said push rod base
26 (66) to push said mass of collected snow towards and against said applicator tip (50)
27 during said cryotherapy ablation process.

28 7. The device as recited in Claim 3, wherein:

29 said push rod (60) configuration further adapted to interact with said handle
30 (80) to control the location of said base (66) relative to said applicator distal (34) end.

31 8. The device as recited in Claim 4, wherein:

1 said push rod (60) configuration further adapted to interact with said handle
2 (80) to control the location of said base (66) relative to said applicator distal (34) end.

3 9. The device as recited in Claim 1, wherein:

4 said low-temperature liquid is carbon dioxide

5 10. The device as recited in Claim 1, wherein:

6 said piping assembly (10), snow horn (26), applicator (30) and applicator tip
7 (50) configurations are all further adapted for the specific cryotherapy ablation
8 process associated with the removal of cervical, precancerous lesions for the
9 prevention of cervical cancer.

10 11. A method for providing a patient with cryotherapy ablation, said method utilizing
11 a connection to the outlet of a pressurized tank of a low-temperature liquid and
12 comprising the steps of utilizing the device (1) as recited in any one of claims 1 – 10.

1/3

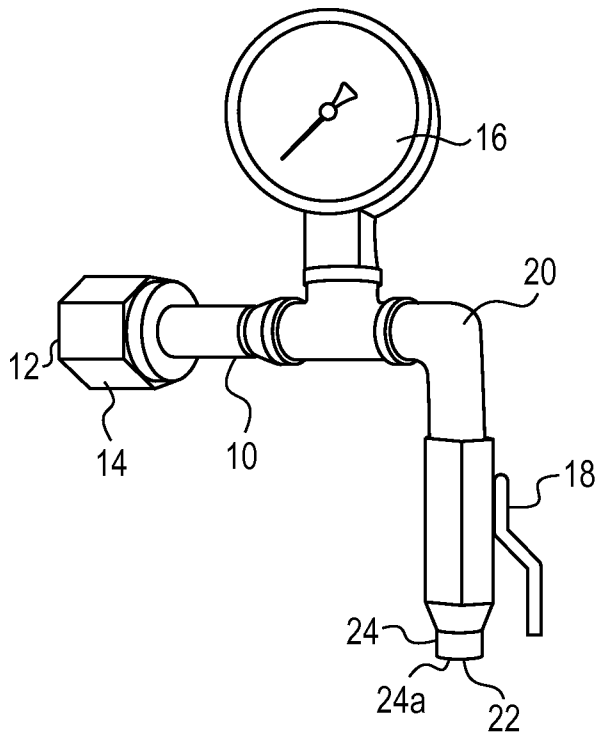


FIG. 1(a)

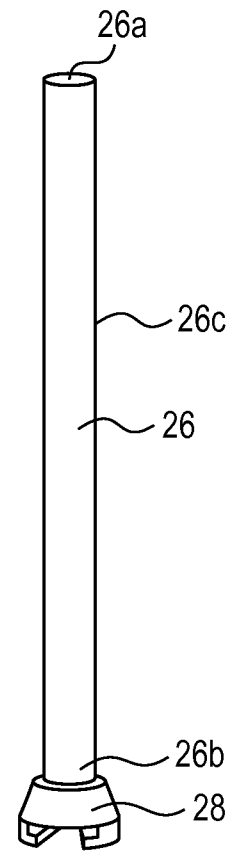


FIG. 1(b)

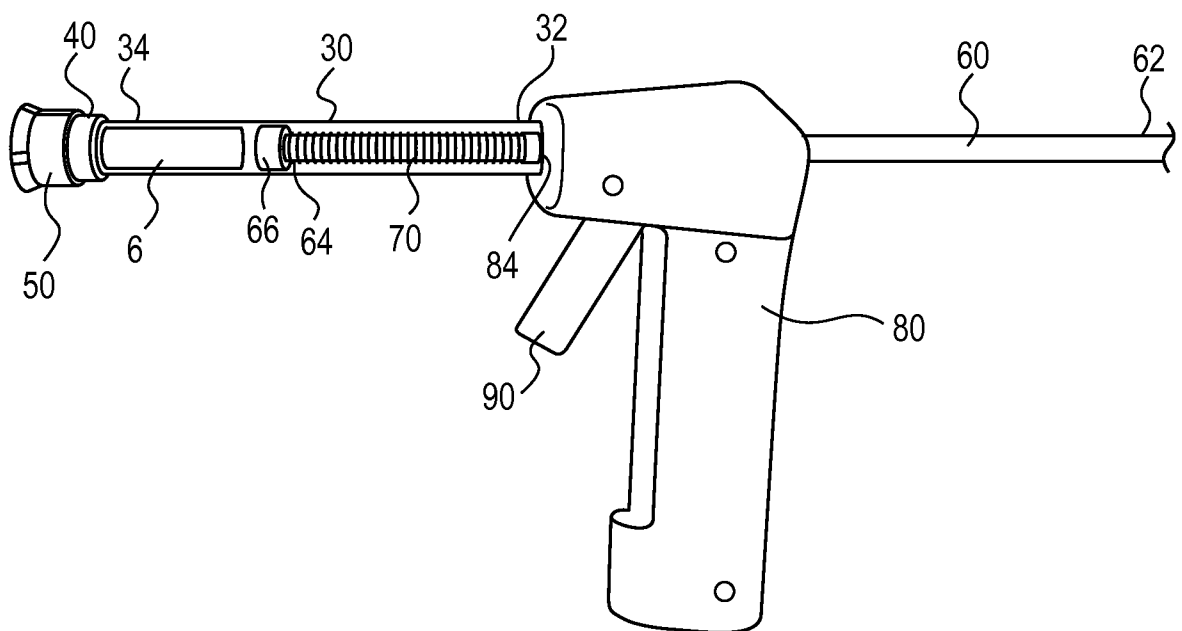


FIG. 1(c)

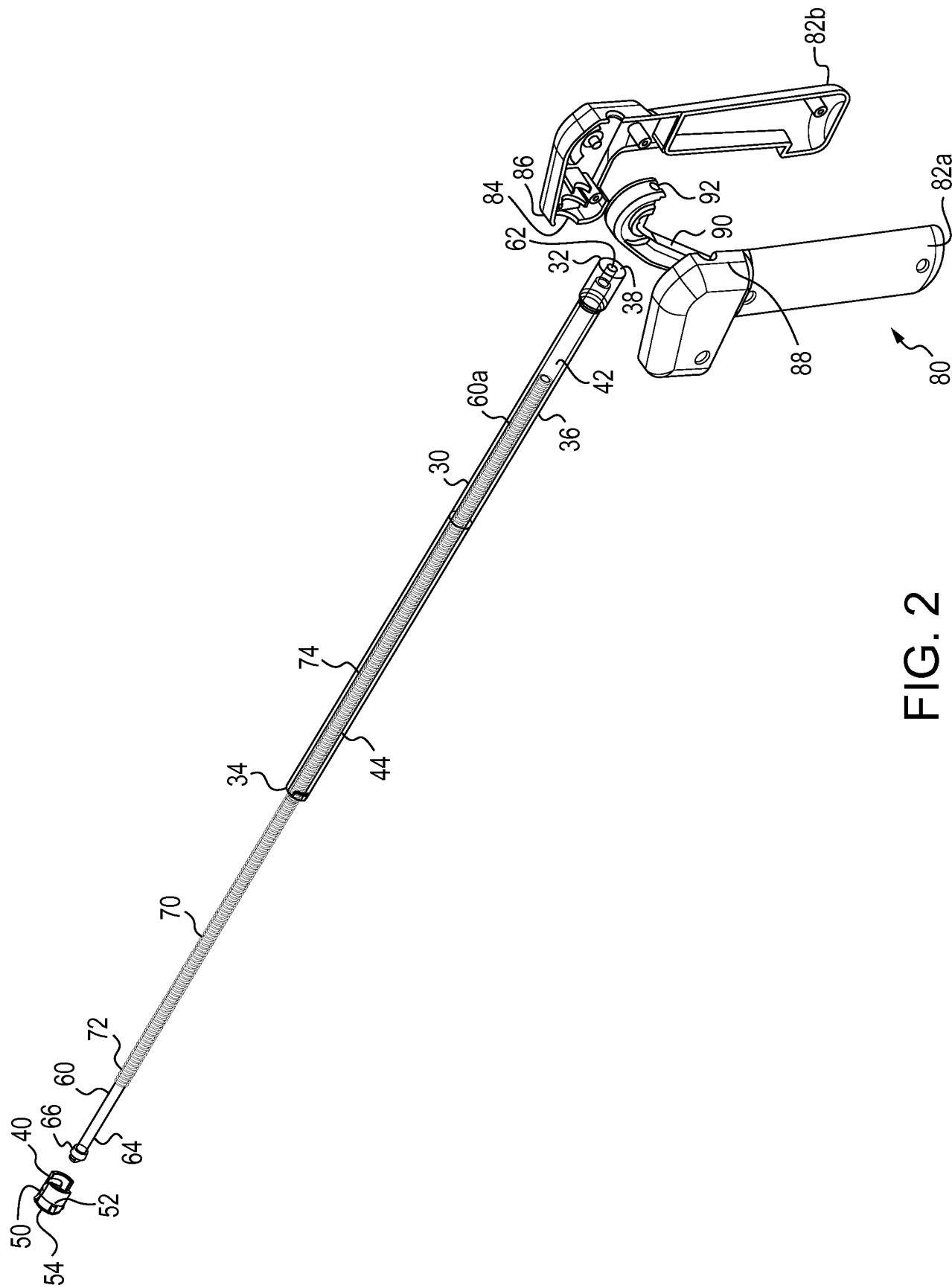


FIG. 2

3/3

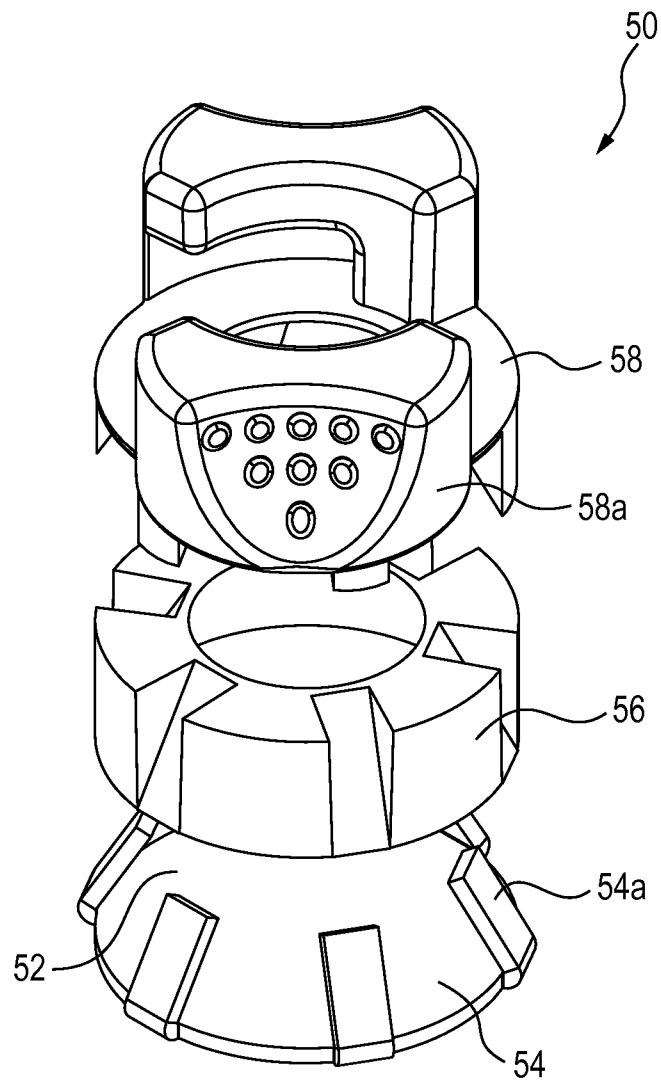


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/038924**A. CLASSIFICATION OF SUBJECT MATTER****A61B 18/02(2006.01)i, A61B 17/3203(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)

A61B 18/02; F25D 3/00; F25B 21/00; A61M 11/00; A61B 18/18; F17C 9/02; A61B 17/3203

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: cryotherapy ablation, piping assembly, snow, tubular snow horn, tubular applicator, applicator tip, handle, push rod

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008-0119839 A1 (VANCELETTE, DAVID W.) 22 May 2008	1, 10
Y	See paragraphs [0017]-[0022], [0024]-[0027]; and figures 1-3.	2-9
Y	US 2013-0079761 A1 (BAUST et al.) 28 March 2013	2-9
	See paragraphs [0029], [0030], [0033], [0034], [0041], [0042], [0046]; and figures 1, 3, 4.	
A	US 6141985 A (CLUZEAU et al.) 7 November 2000	1-10
	See column 2, line 59-column 4, line 32; column 5, lines 31-41; and figure 1.	
A	US 6629417 B2 (HAAS et al.) 7 October 2003	1-10
	See abstract; column 7, line 53-column 9, line 20; and figures 1-4C, 6.	
A	US 2006-0213509 A1 (MARIN et al.) 28 September 2006	1-10
	See paragraphs [0021], [0024], [0025], [0028]-[0033]; and figures 1-3.	
A	US 6960202 B2 (CLUZEAU et al.) 1 November 2005	1-10
	See abstract; claims 1-12; and figures 1-7.	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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

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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

05 September 2014 (05.09.2014)

Date of mailing of the international search report

05 September 2014 (05.09.2014)

Name and mailing address of the ISA/KR

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INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US2014/038924**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.: 11
because they relate to subject matter not required to be searched by this Authority, namely:
Claim 11 pertains to methods for treatment of the human body by therapy, and thus relates to a subject-matter which this International Searching Authority is not required, under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv), to search.
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).

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 an additional fees, this Authority did not invite payment of any 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 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 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/US2014/038924

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 6960202 B2	01/11/2005	AT 291882 T AU 2002-10639 A1 CA 2425328 A1 CN 1219495 C CN 1474670 A DE 60109801 D1 DK 1328205 T3 EP 1328205 A1 EP 1328205 B1 ES 2240529 T3 FR 2815246 A1 FR 2815246 B1 JP 04078204 B2 JP 2004-515270 A PT 1328205 E US 2004-0102768 A1 WO 02-30309 A1	15/04/2005 22/04/2002 18/04/2002 21/09/2005 11/02/2004 04/05/2005 08/08/2005 23/07/2003 30/03/2005 16/10/2005 19/04/2002 24/01/2003 23/04/2008 27/05/2004 31/08/2005 27/05/2004 18/04/2002