US012383422B2

(12) **United States Patent**
Manstein et al.

(10) **Patent No.: US 12,383,422 B2**
(45) **Date of Patent: Aug. 12, 2025**

(54) **SYSTEMS AND METHODS FOR THERMAL TREATMENT OF TISSUE**

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(72) Inventors: **Dieter Manstein**, Coral Gables, FL (US); **Seyed Reza Monazami Miralipour**, Cambridge, MA (US)

(73) Assignee: **The General Hospital Corporation**, Boston, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1700 days.

(21) Appl. No.: **16/478,839**

(22) PCT Filed: **Jan. 19, 2018**

(86) PCT No.: **PCT/US2018/014578**
§ 371 (c)(1),
(2) Date: **Jul. 17, 2019**

(87) PCT Pub. No.: **WO2018/136830**
PCT Pub. Date: **Jul. 26, 2018**

(65) **Prior Publication Data**

US 2020/0054482 A1 Feb. 20, 2020

Related U.S. Application Data

(60) Provisional application No. 62/541,650, filed on Aug. 4, 2017, provisional application No. 62/532,343, filed
(Continued)

(51) **Int. Cl.**
A61F 7/00 (2006.01)
A61F 7/02 (2006.01)
A61F 7/12 (2006.01)

(52) **U.S. Cl.**
CPC ***A61F 7/00*** (2013.01); *A61F 2007/0058* (2013.01); *A61F 2007/0068* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61F 7/00; A61F 2007/0058; A61F 2007/0068; A61F 2007/0096;
(Continued)

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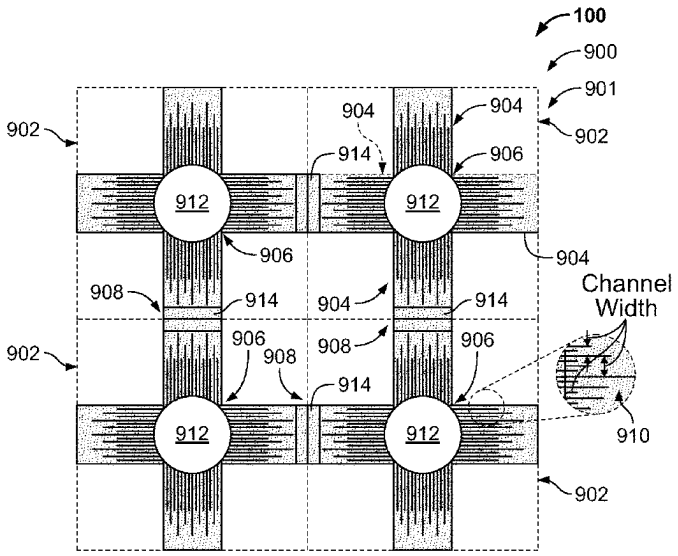
Assistant Examiner — Adam J Avigan
(74) *Attorney, Agent, or Firm* — QUARLES & BRADY LLP

(57) **ABSTRACT**

Systems and methods for a medical device configured to provide cooling to a tissue region are provided. The medical device may be configured to noninvasively or invasively cool the tissue region to a predetermined operating temperature via a two-phase heat transfer process.

20 Claims, 33 Drawing Sheets



Related U.S. Application Data

on Jul. 13, 2017, provisional application No. 62/523,492, filed on Jun. 22, 2017, provisional application No. 62/511,837, filed on May 26, 2017, provisional application No. 62/500,047, filed on May 2, 2017, provisional application No. 62/482,027, filed on Apr. 5, 2017, provisional application No. 62/447,997, filed on Jan. 19, 2017.

(52) **U.S. Cl.**
CPC *A61F 2007/0096* (2013.01); *A61F 2007/0258* (2013.01); *A61F 2007/126* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2007/0258; A61F 2007/126; A61F 7/007; A61F 2007/0059; A61F 2007/0215; A61F 2007/0226; A61F 2007/026; A61F 2007/0268; A61F 7/02; A61F 7/0053; A61F 7/12; A61F 2007/0086; A61F 2007/029; A61B 2018/00011; A61B 2018/00029; A61B 18/203; A61B 2018/00452; A61B 2018/00577; F28D 15/046
See application file for complete search history.

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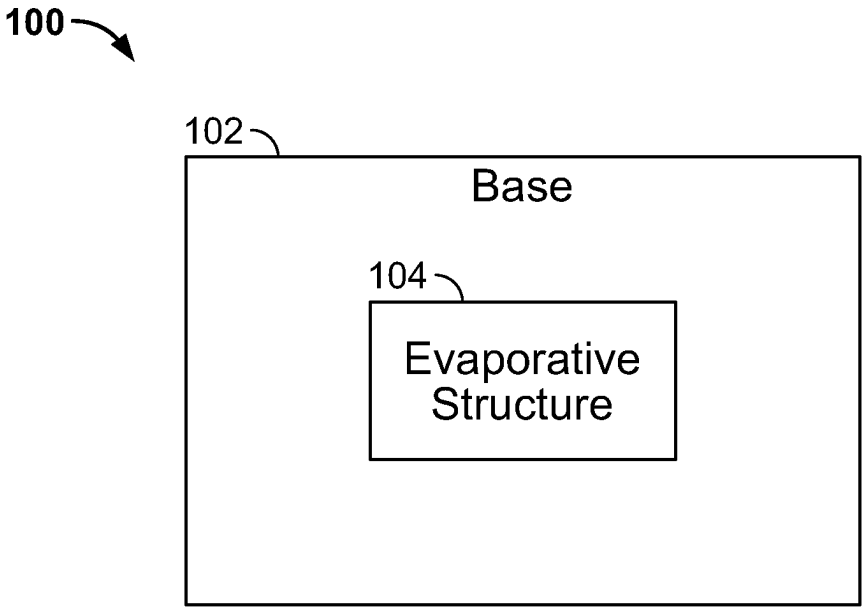

100
102
Base
104
Evaporative Structure

FIG. 1

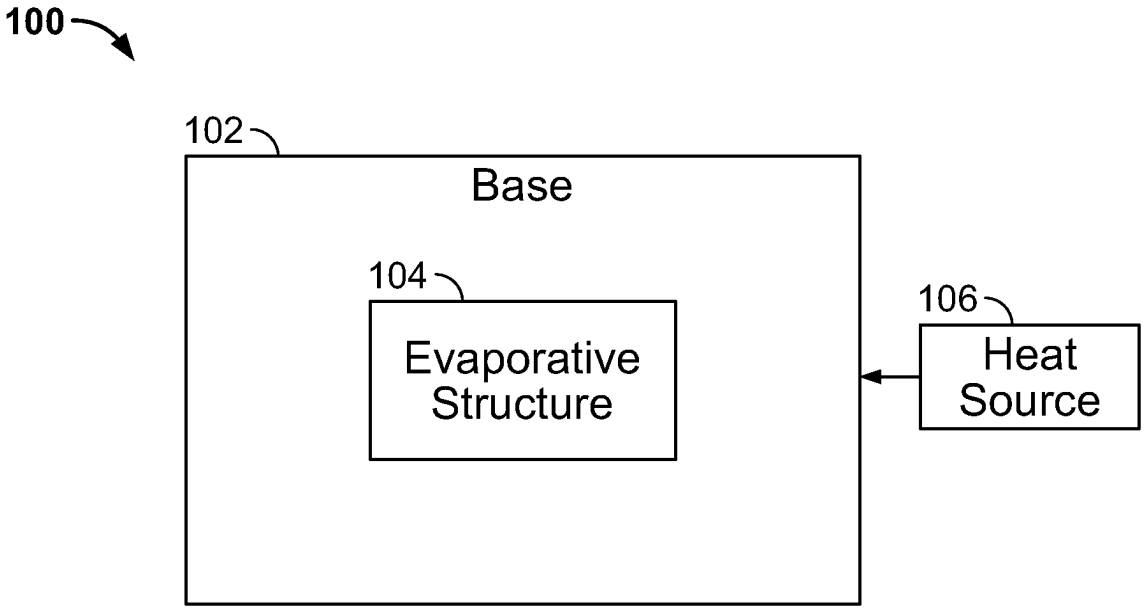

100
102
Base
104
Evaporative Structure
106
Heat Source

FIG. 2

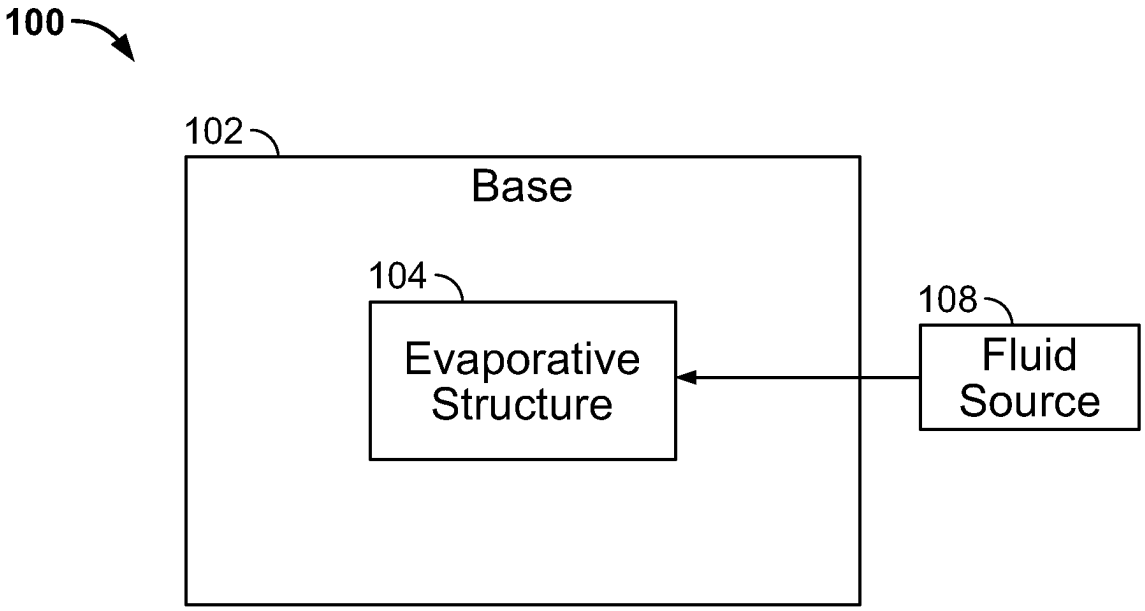

100
102
Base
104
Evaporative Structure
108
Fluid Source

FIG. 3

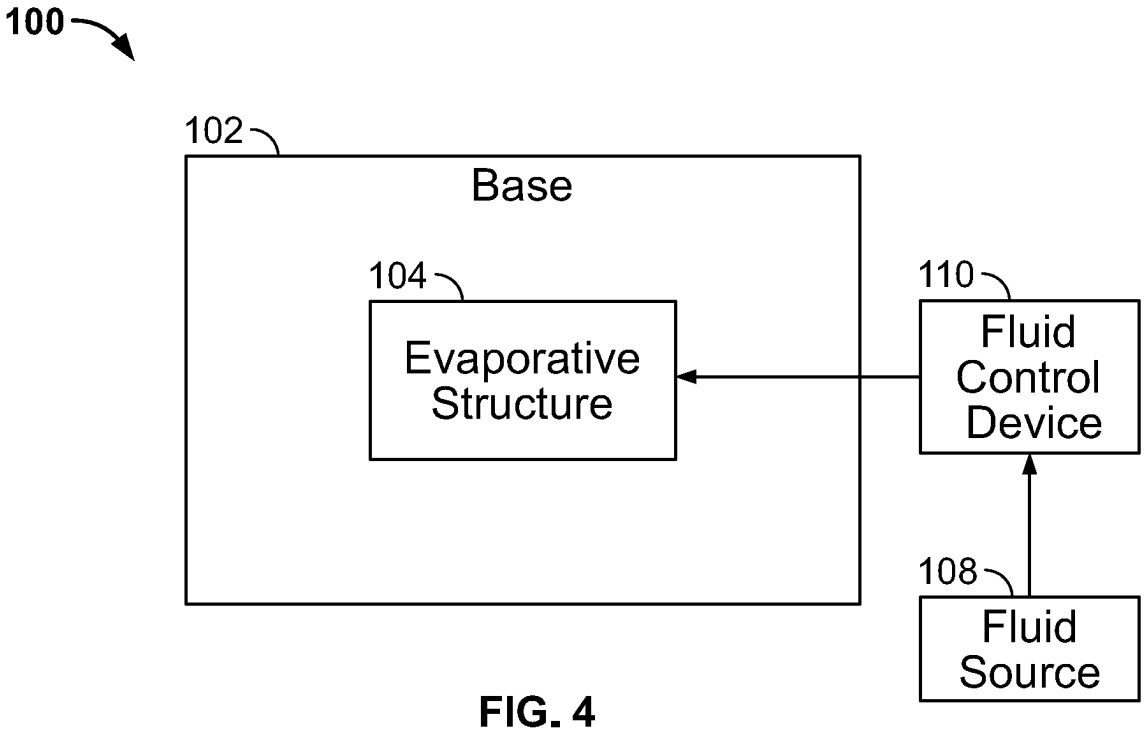

100
102
Base
104
Evaporative Structure
110
Fluid Control Device
108
Fluid Source

FIG. 4

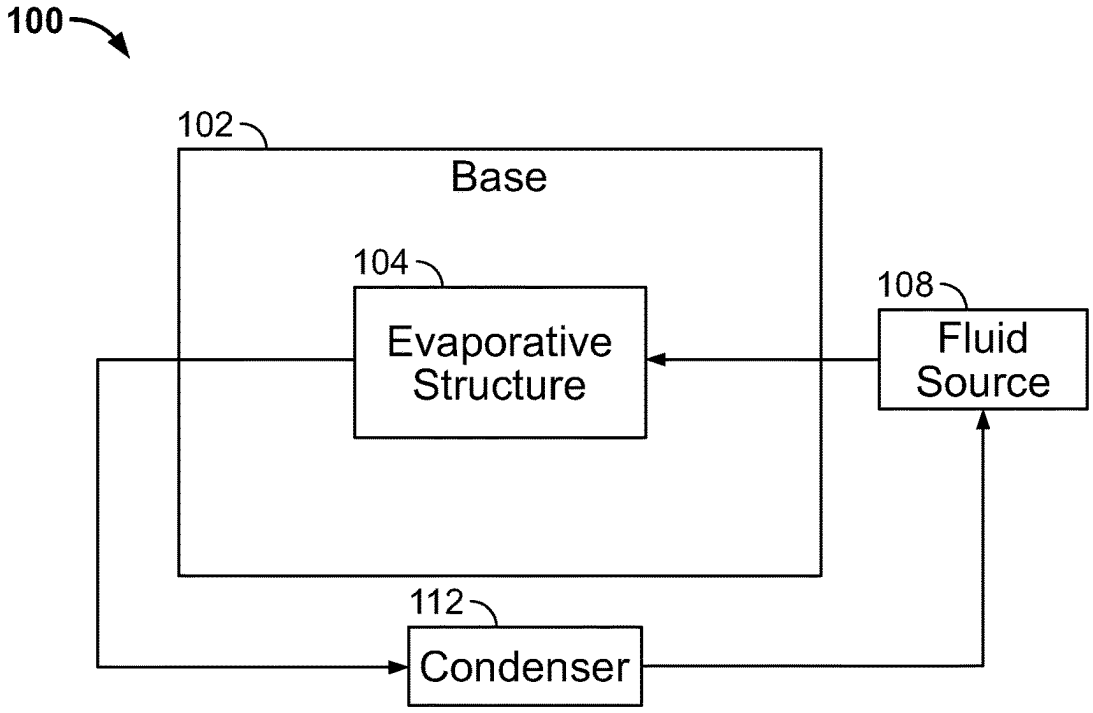

100
102
Base
104
Evaporative Structure
108
Fluid Source
112
Condenser

FIG. 5

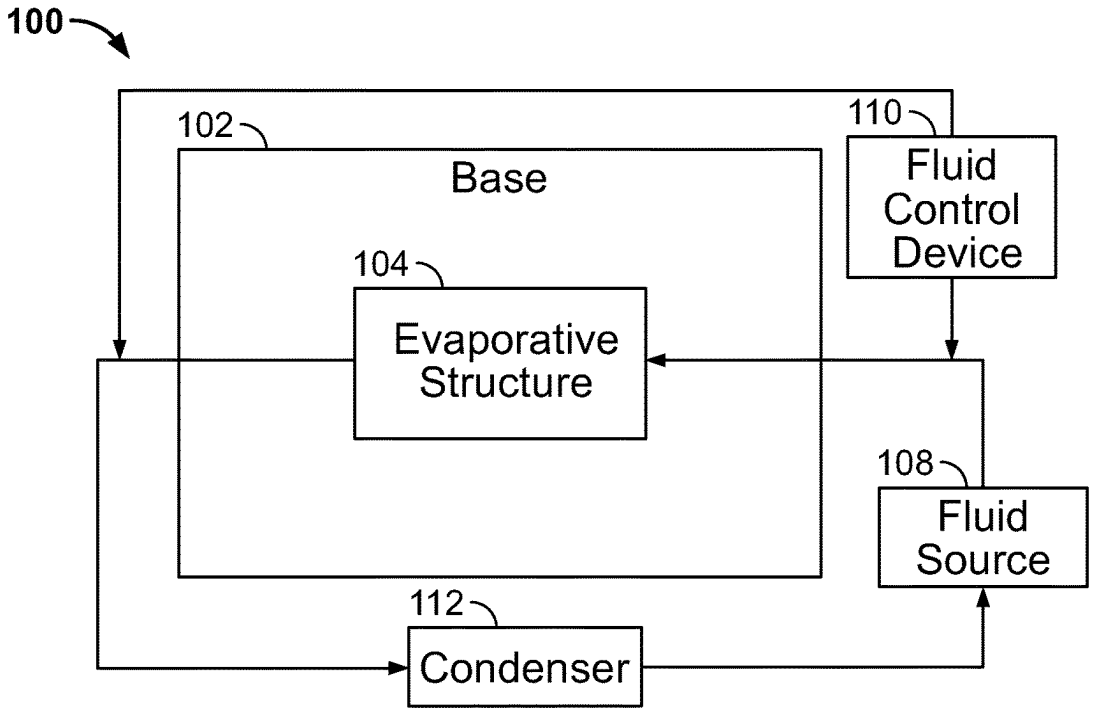

100
102
Base
110
Fluid Control Device
104
Evaporative Structure
108
Fluid Source
112
Condenser

FIG. 6

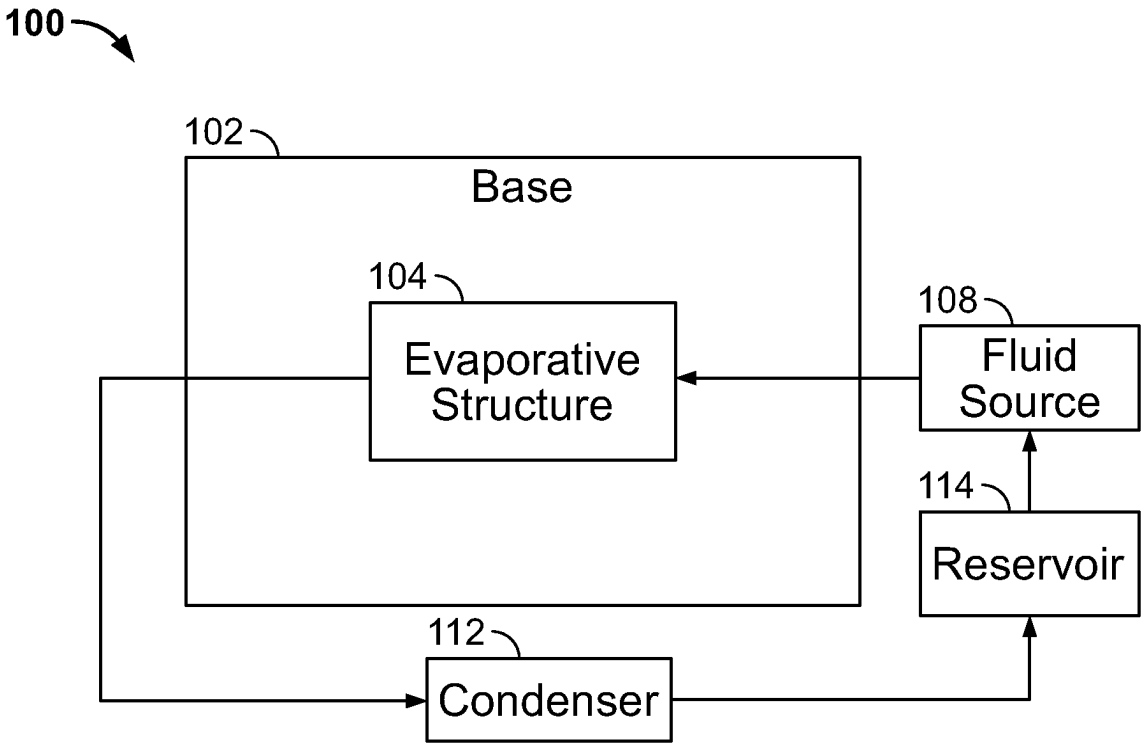
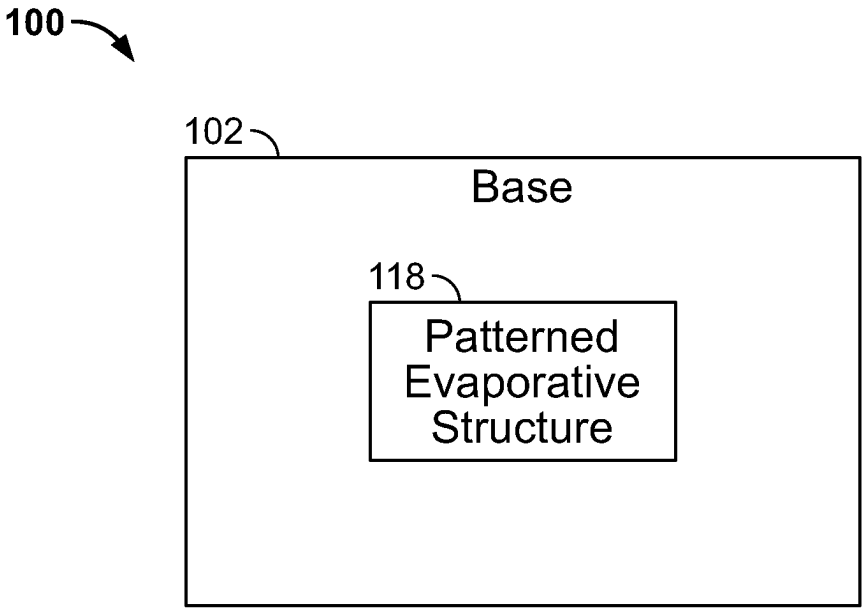

100
102
Base
104
Evaporative Structure
108
Fluid Source
114
Reservoir
112
Condenser

FIG. 7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102
Base
118
Patterned Evaporative Structure

FIG. 8

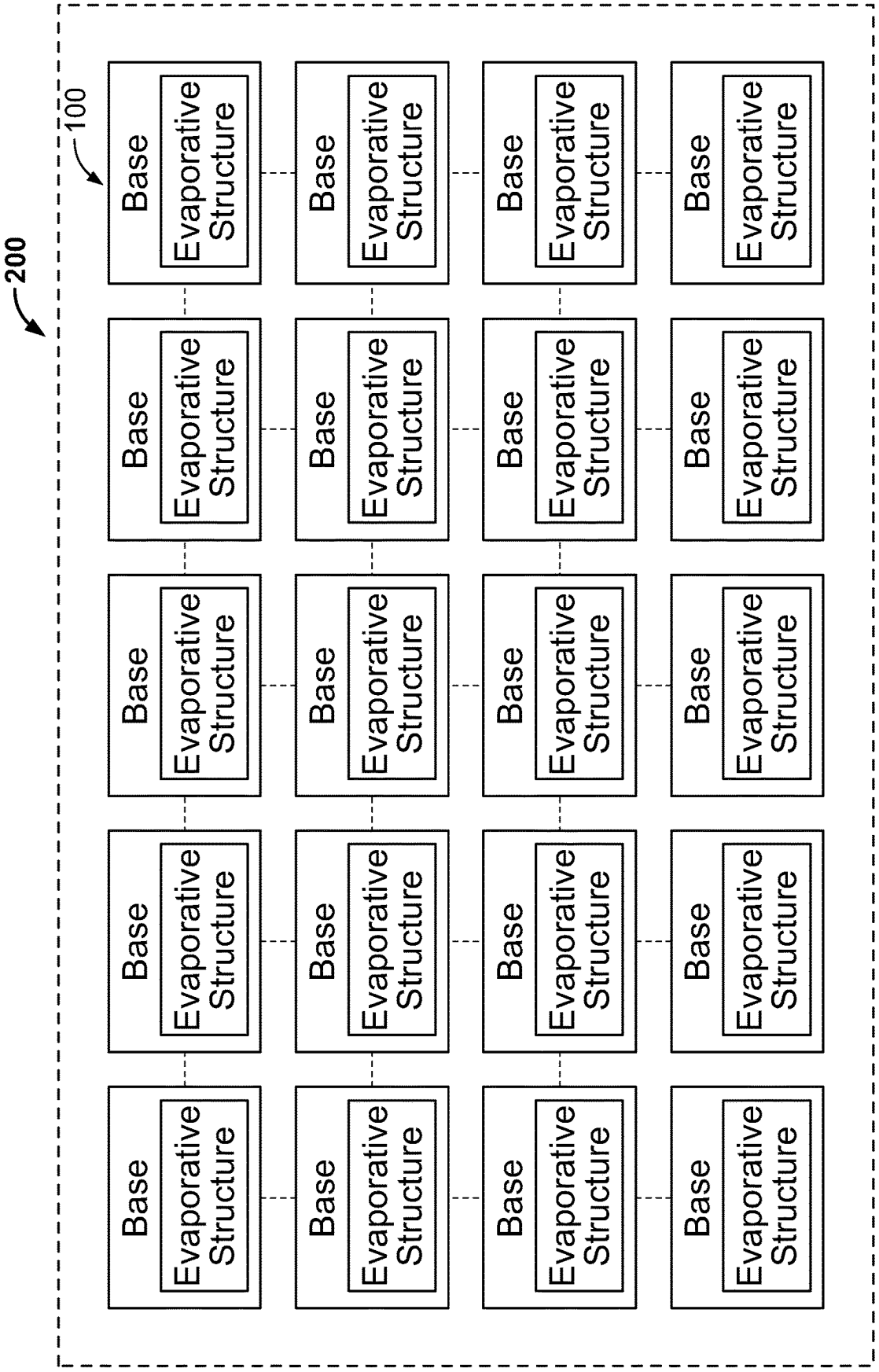


FIG. 9

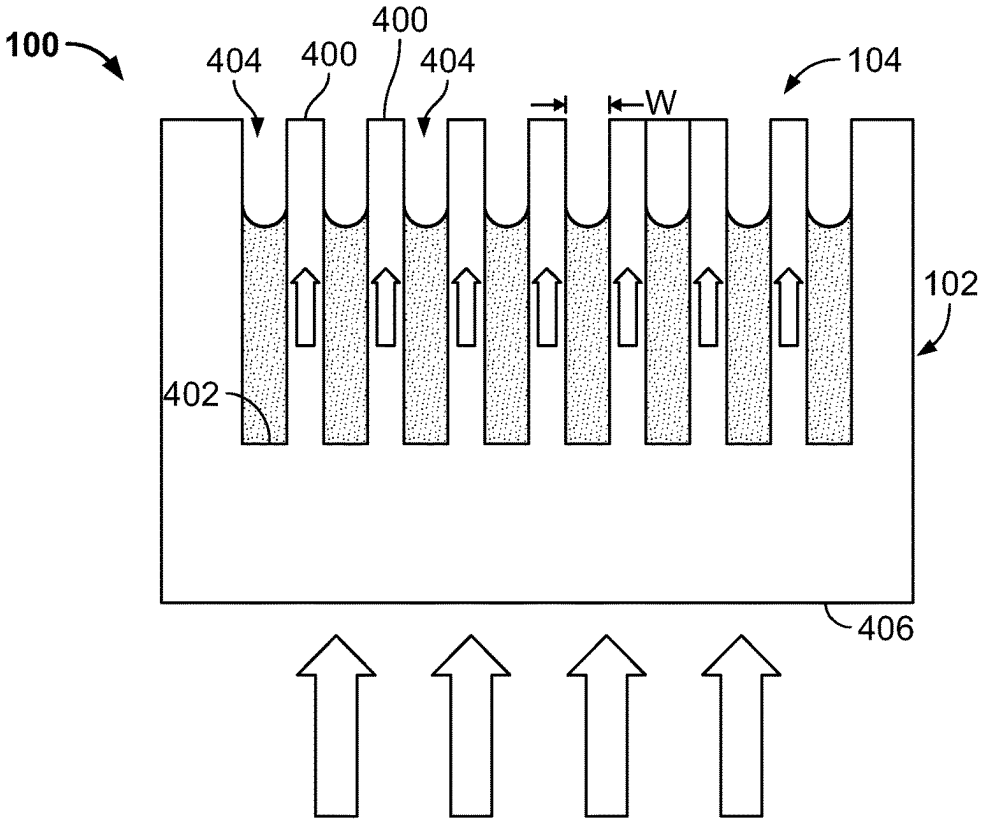

100
404
400
400
404
W
104
102
402
406

FIG. 10

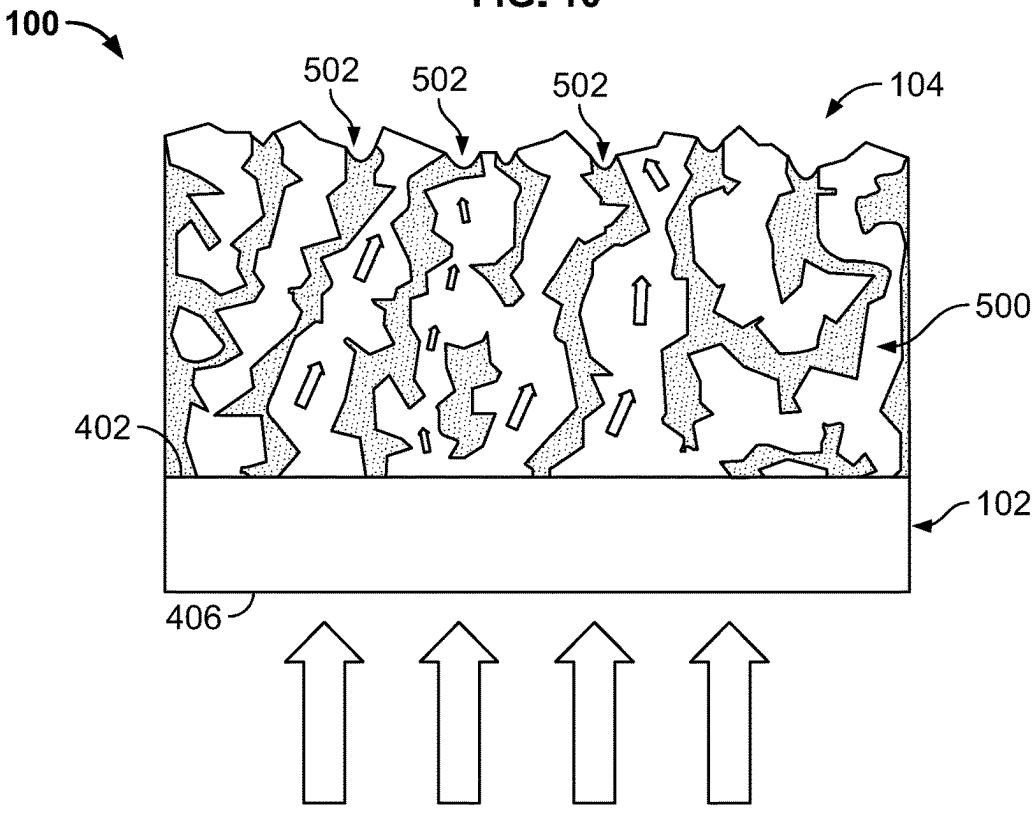
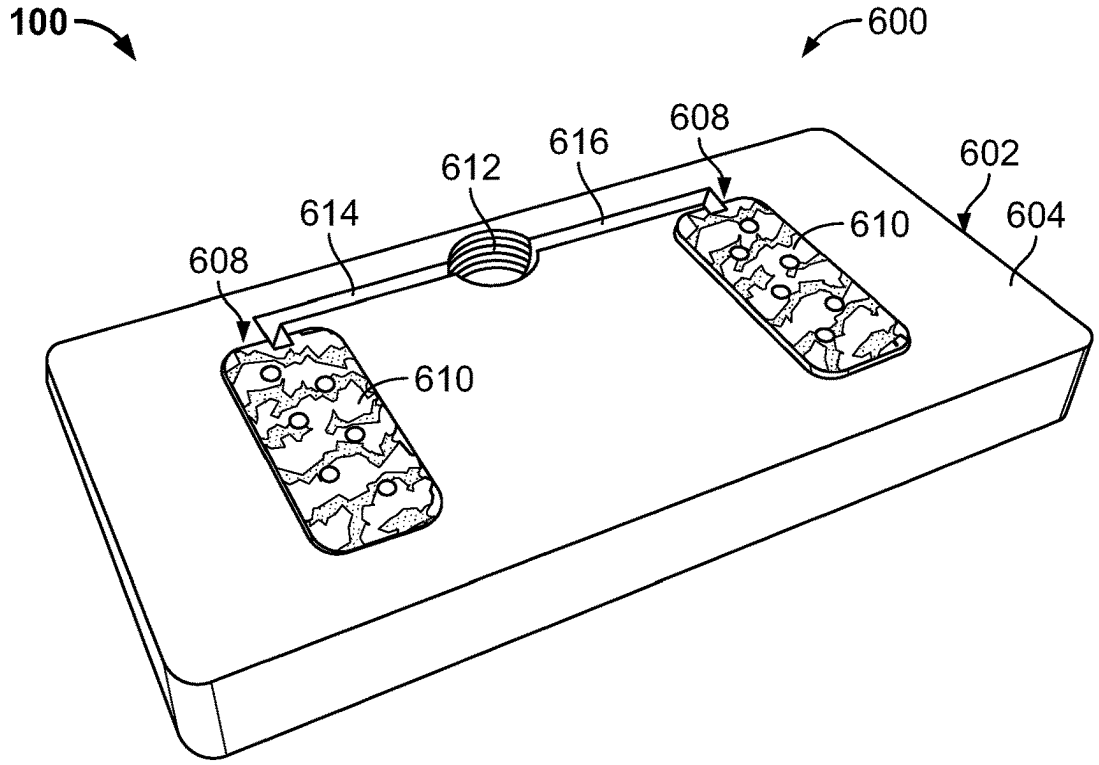

100
502
502
502
104
500
402
102
406

FIG. 11



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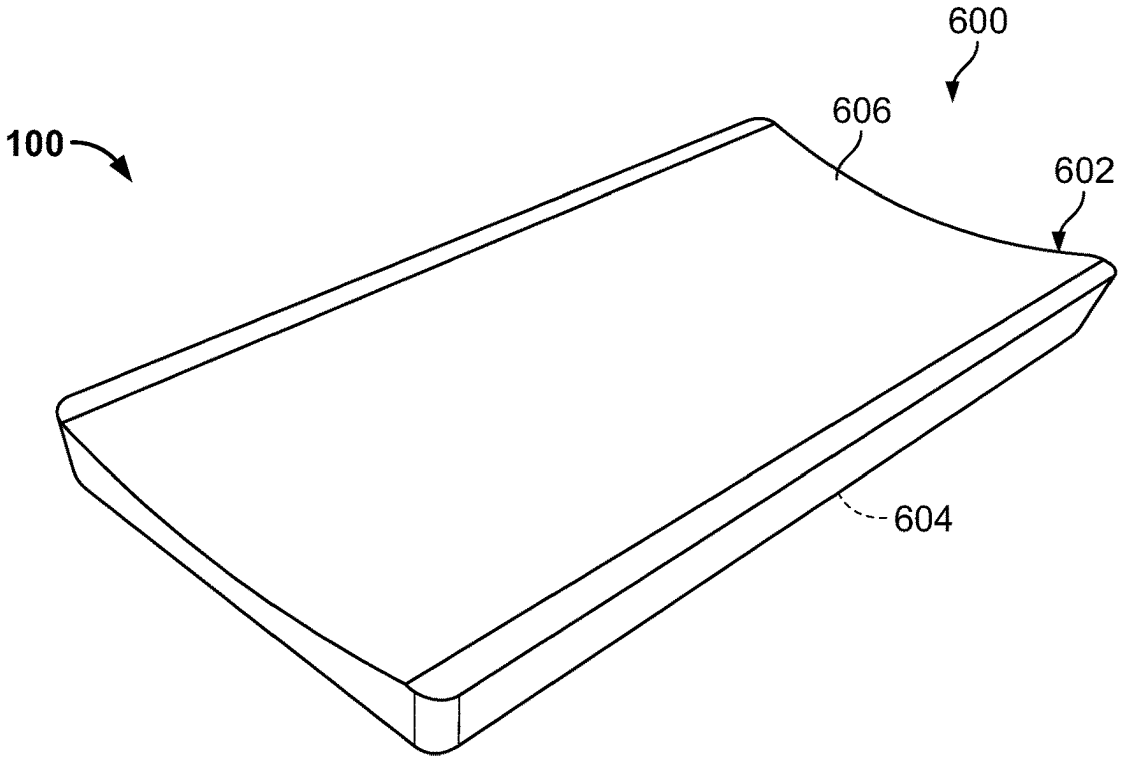


FIG. 13

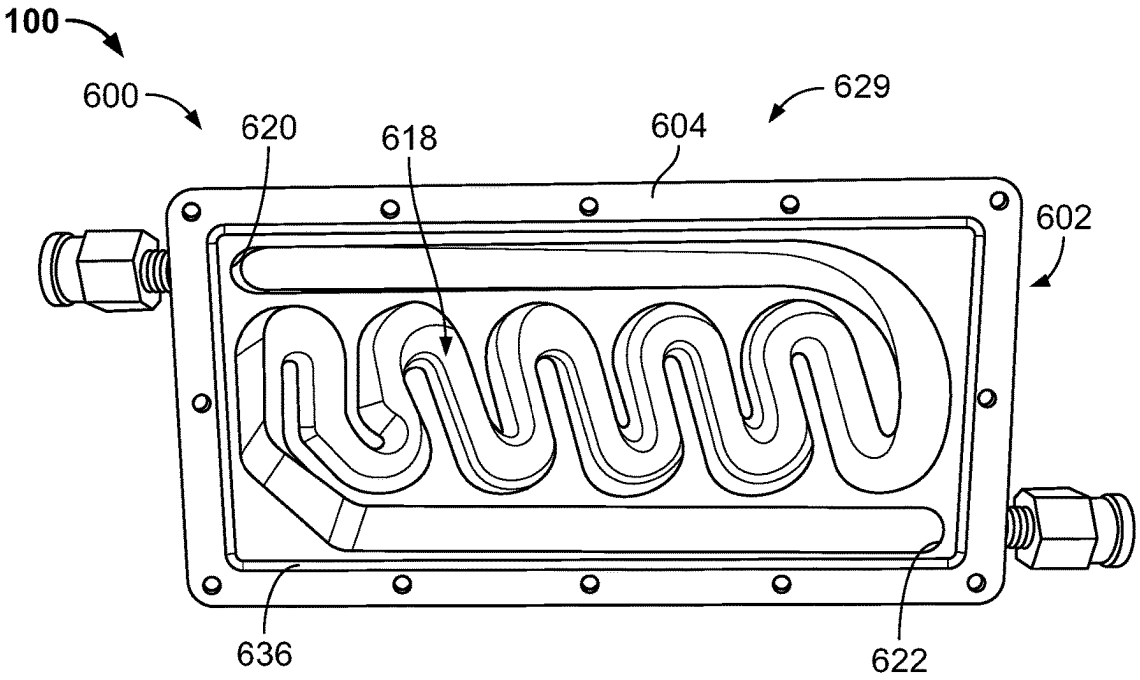


FIG. 14A

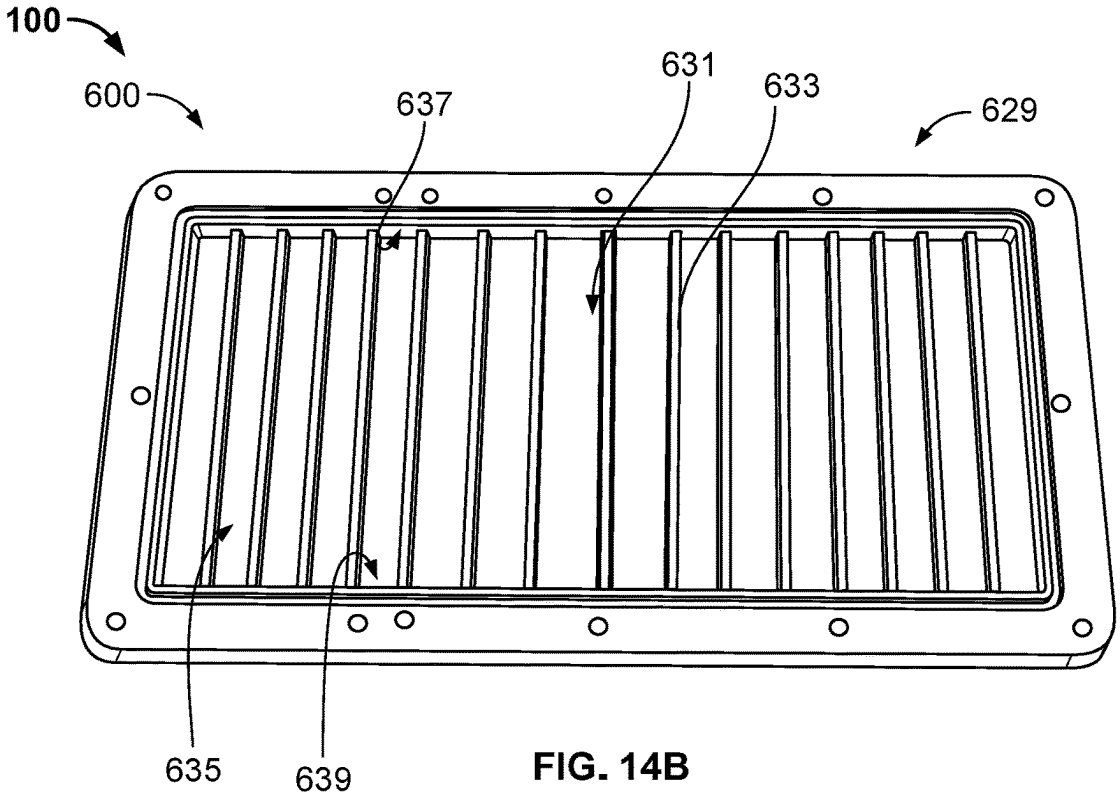


FIG. 14B

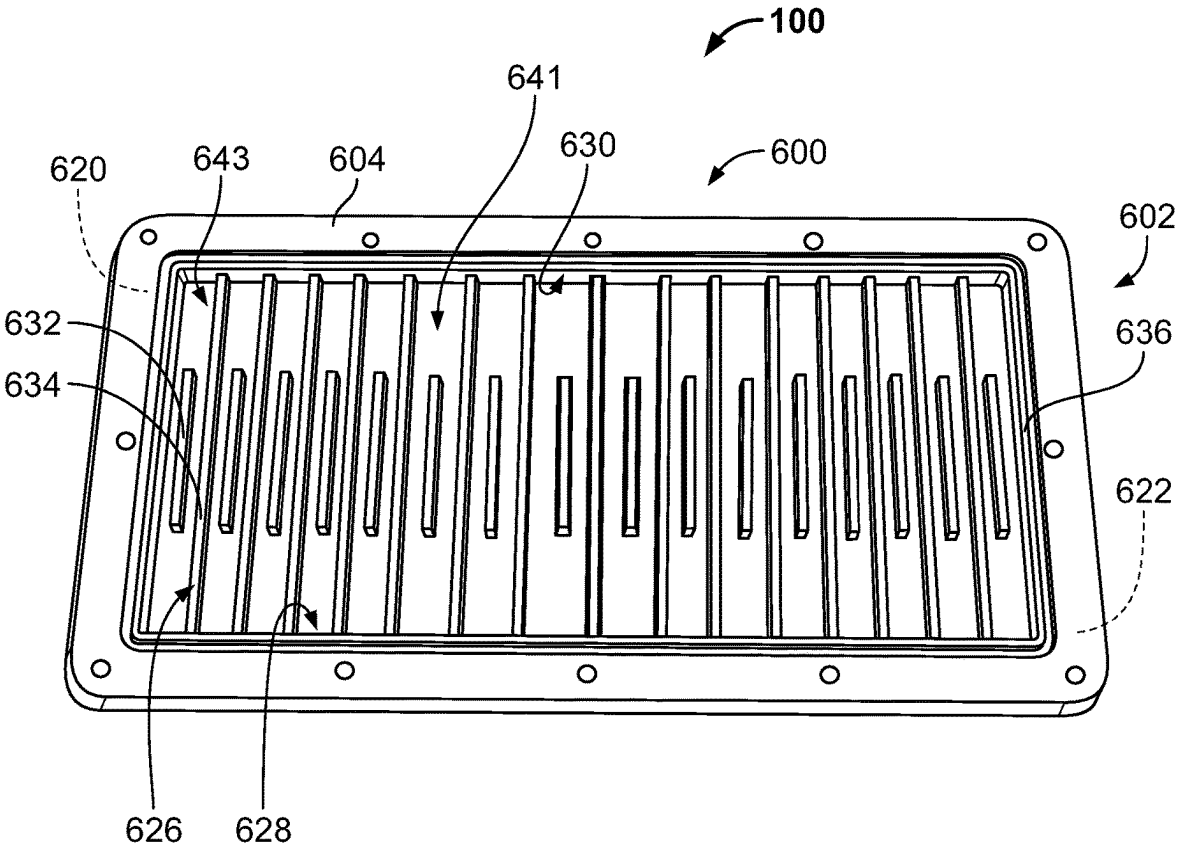


FIG. 15

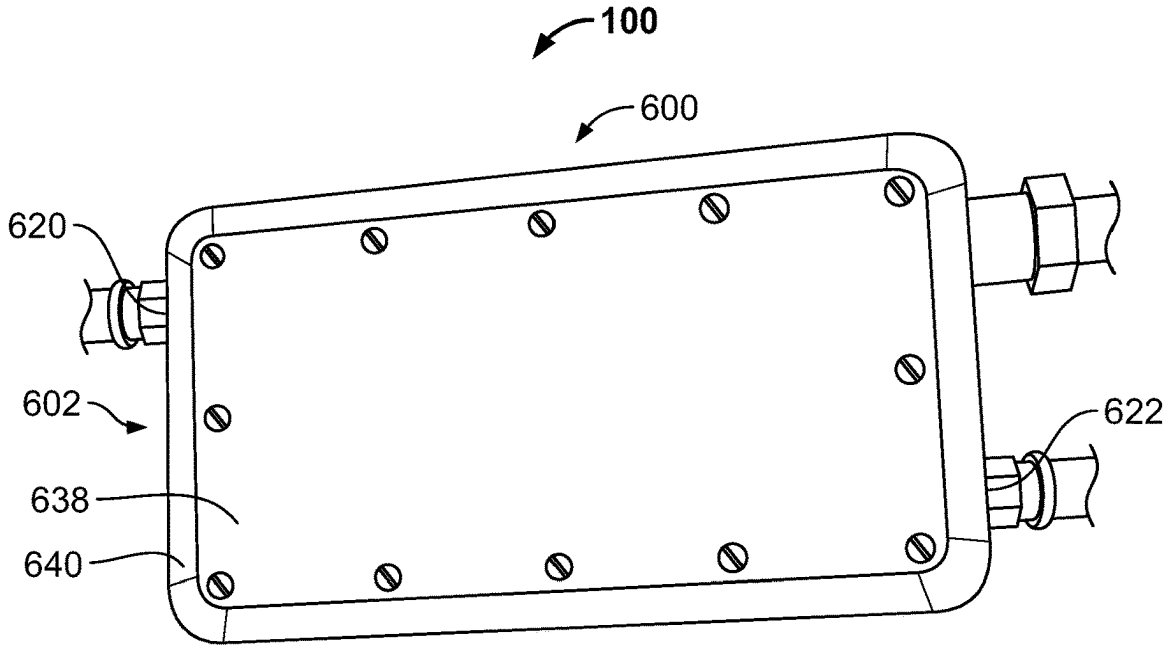


FIG. 16

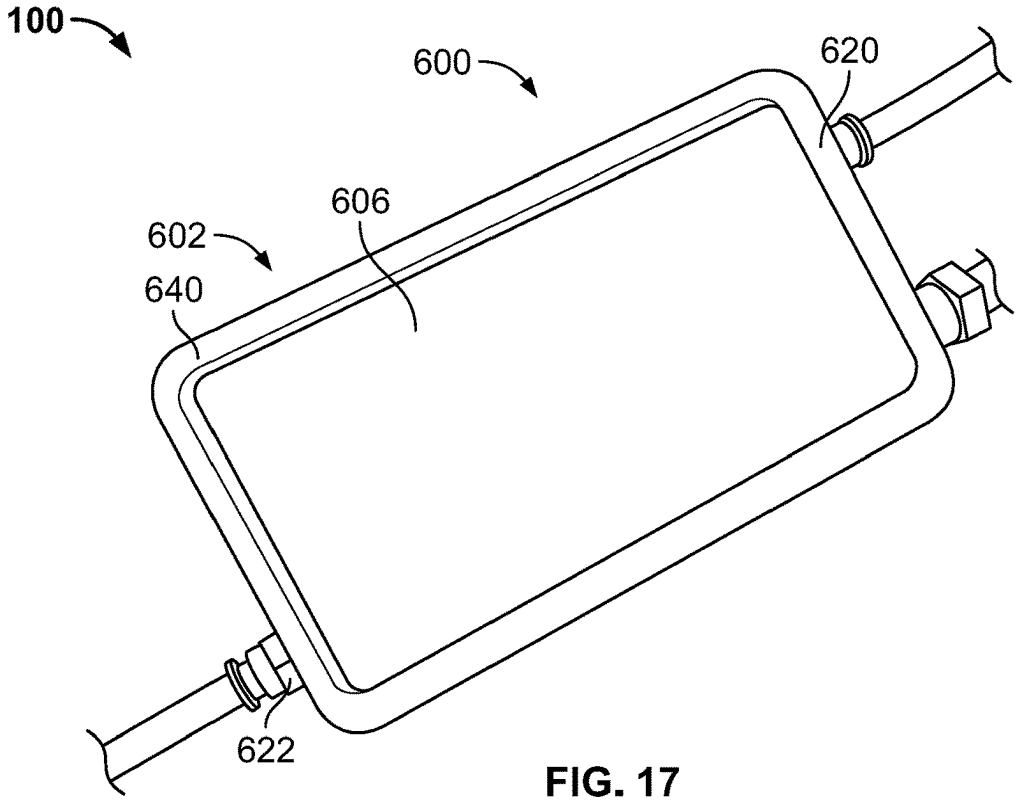


FIG. 17

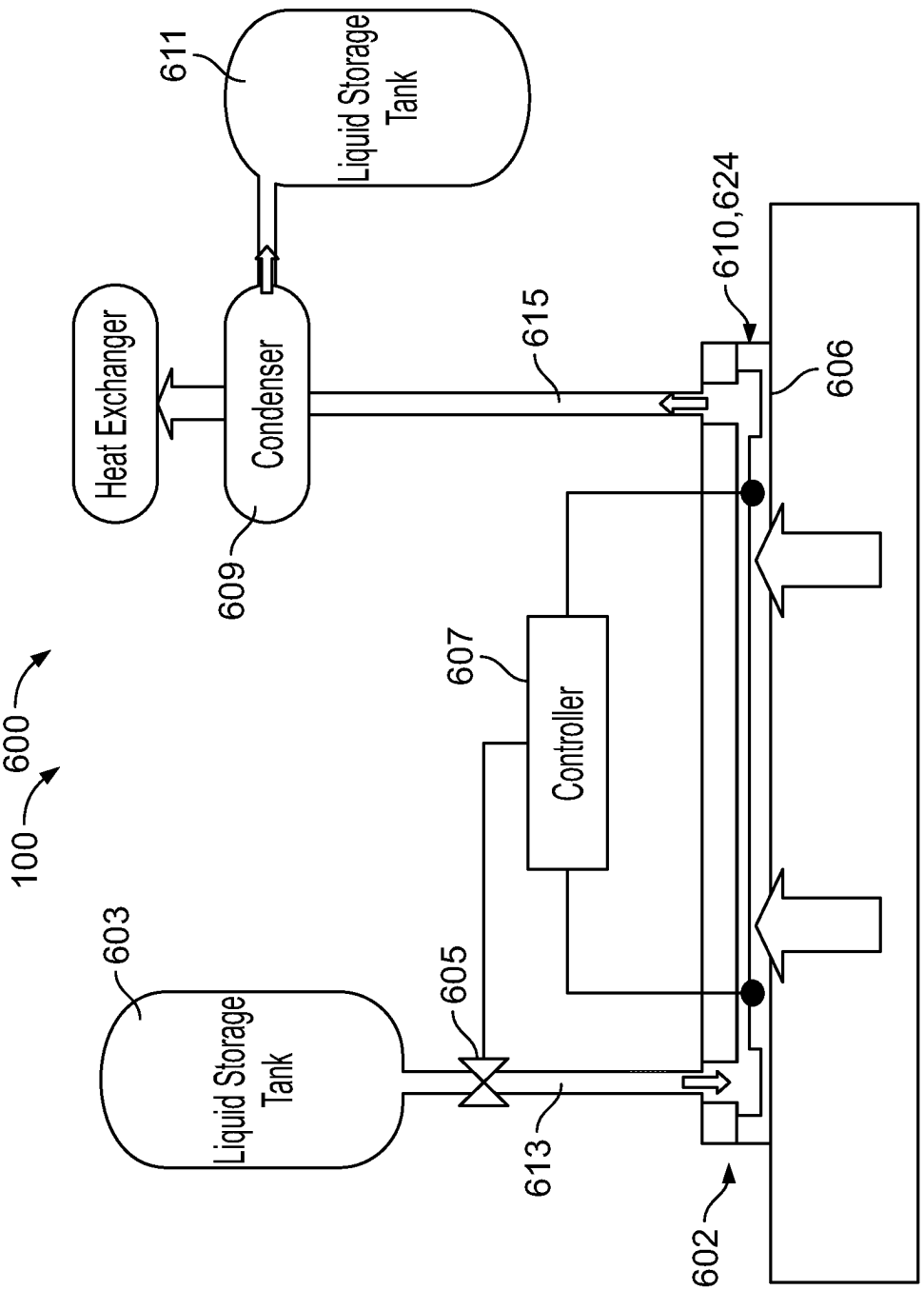

611
Liquid Storage Tank
610,624
615
606
Heat Exchanger
Condenser
609
607
Controller
600
100
603
Liquid Storage Tank
605
613
602

FIG. 18

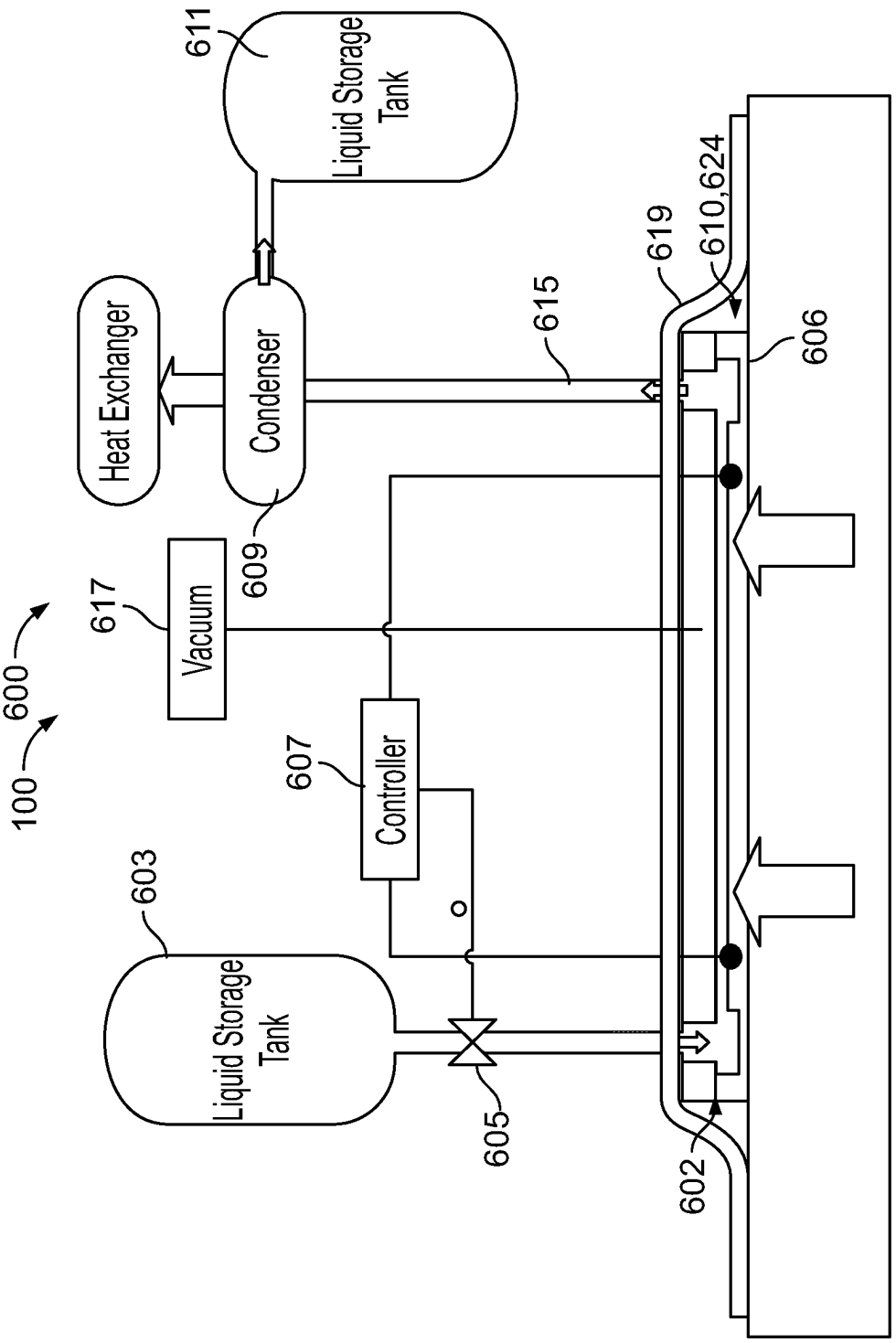

611
Liquid Storage Tank
619
610,624
615
606
Heat Exchanger
Condenser
609
617
Vacuum
600
100
607
Controller
603
Liquid Storage Tank
605
602

FIG. 19

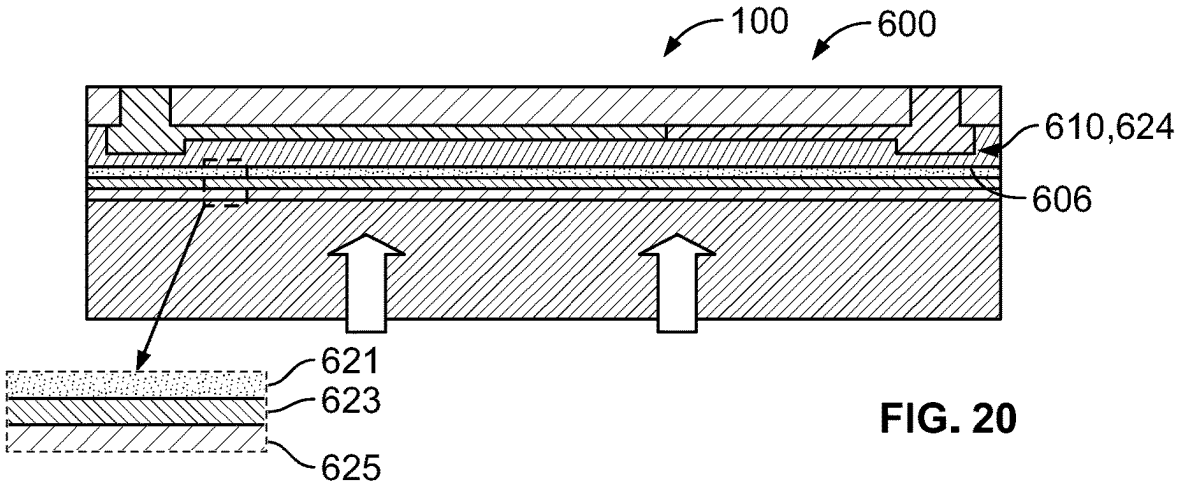


FIG. 20

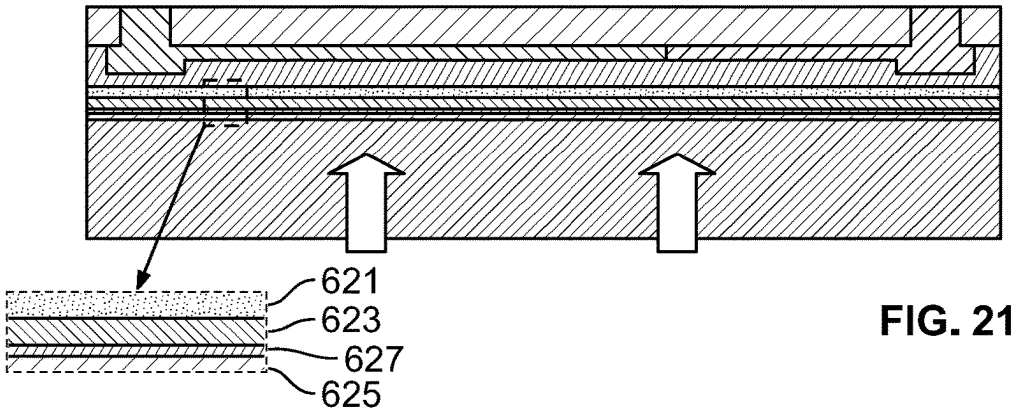


FIG. 21

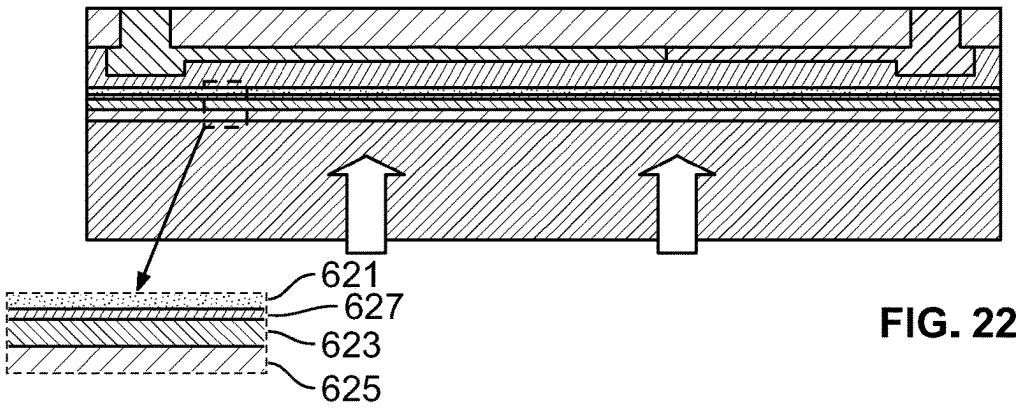
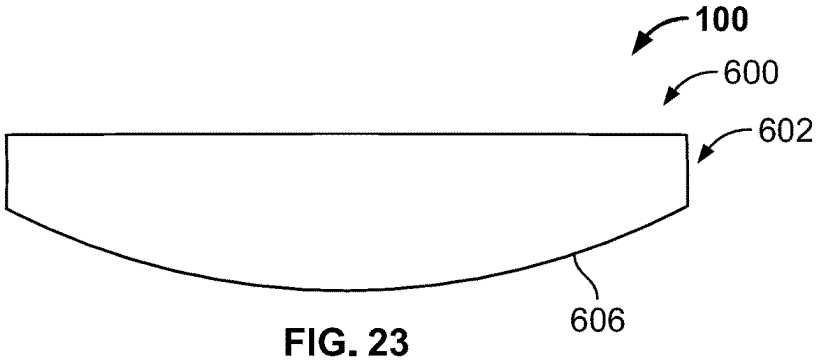


FIG. 22



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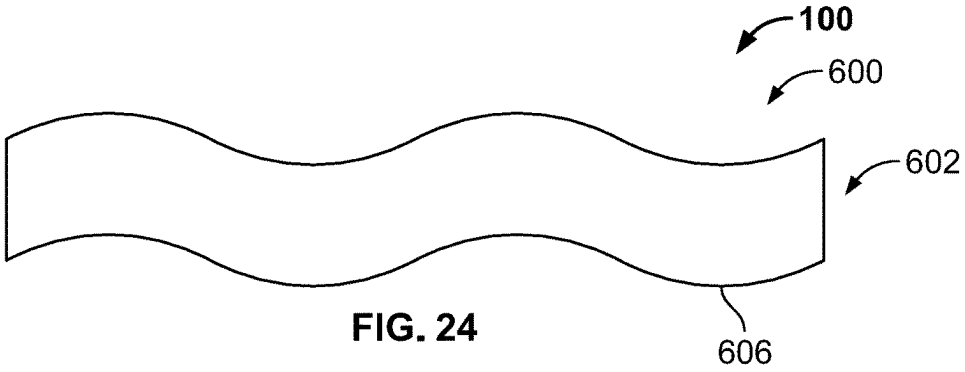


FIG. 24

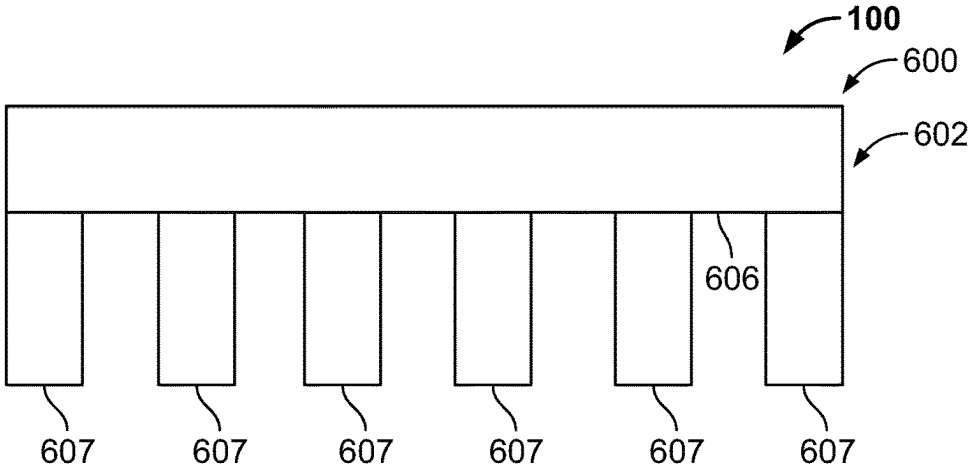


FIG. 25

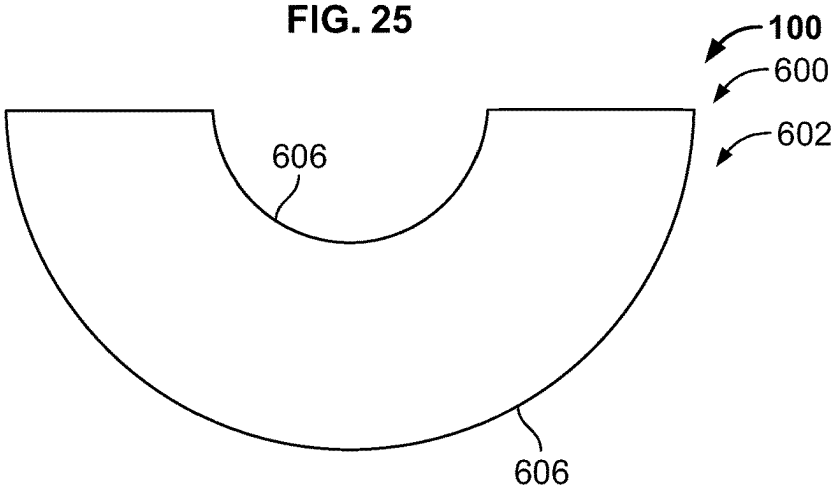
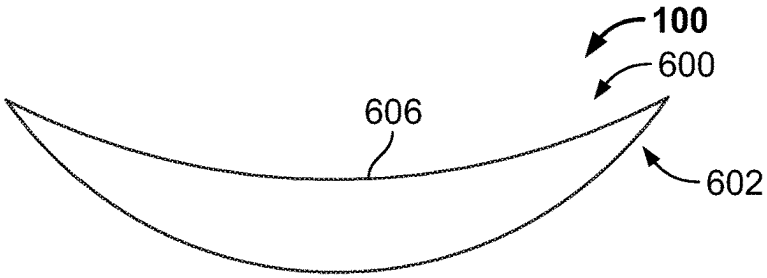


FIG. 26



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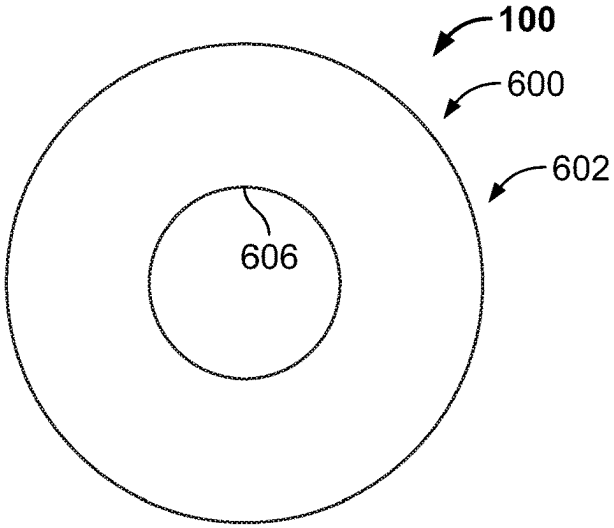


FIG. 28

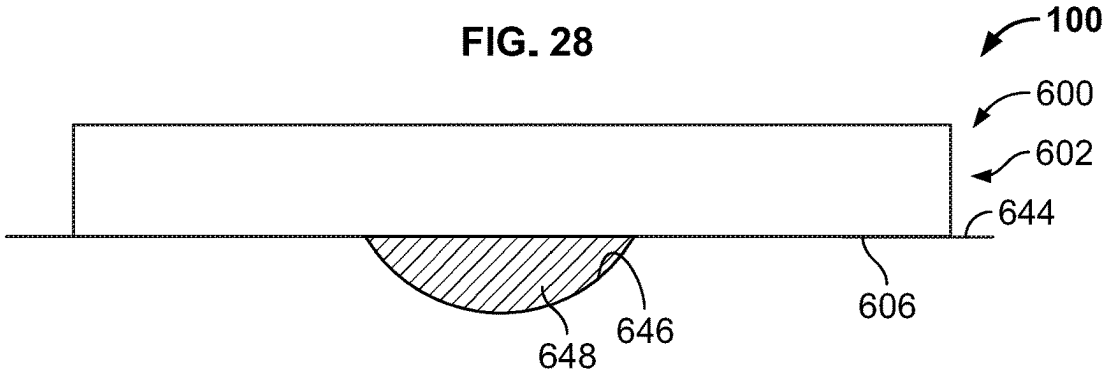
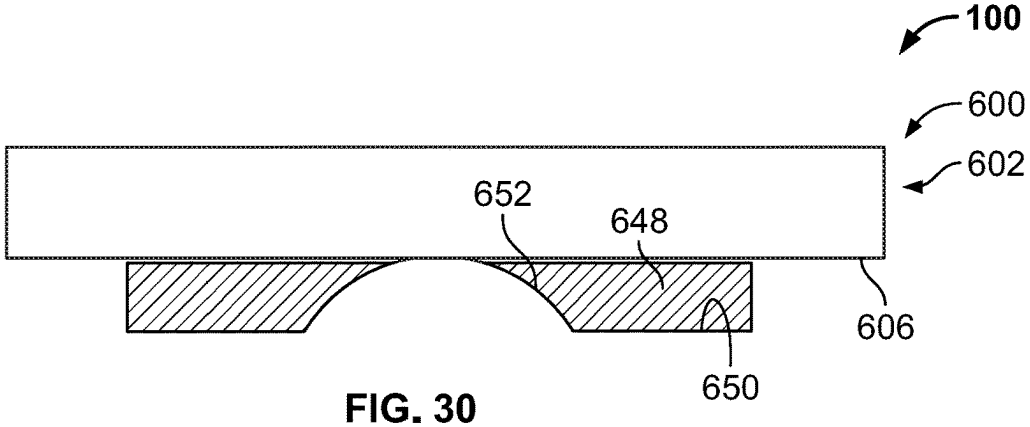


FIG. 29



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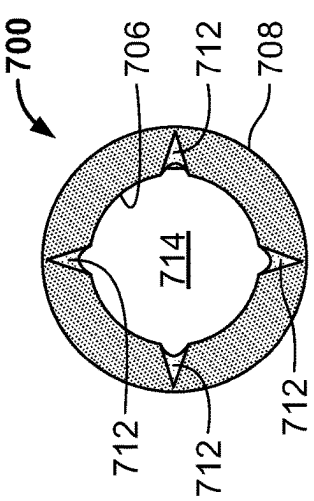

FIG. 33

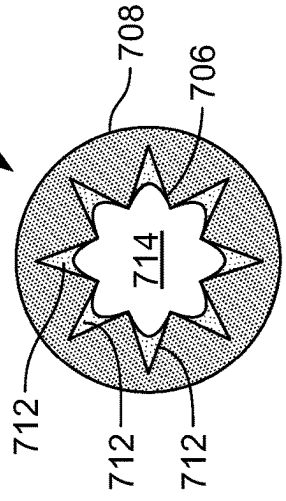

FIG. 34

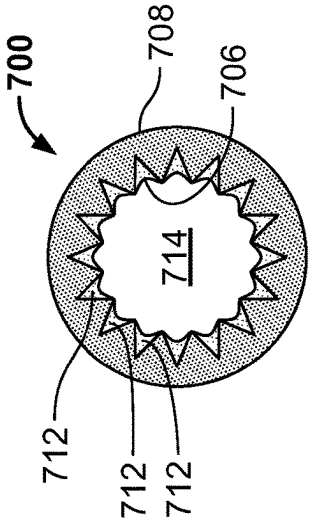

FIG. 35

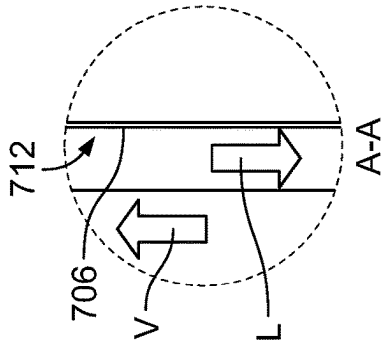

FIG. 32

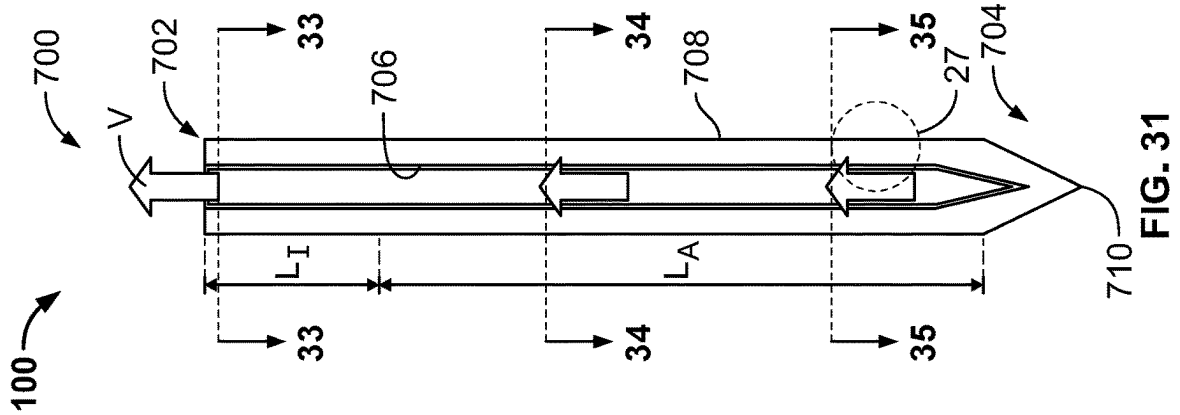

FIG. 31

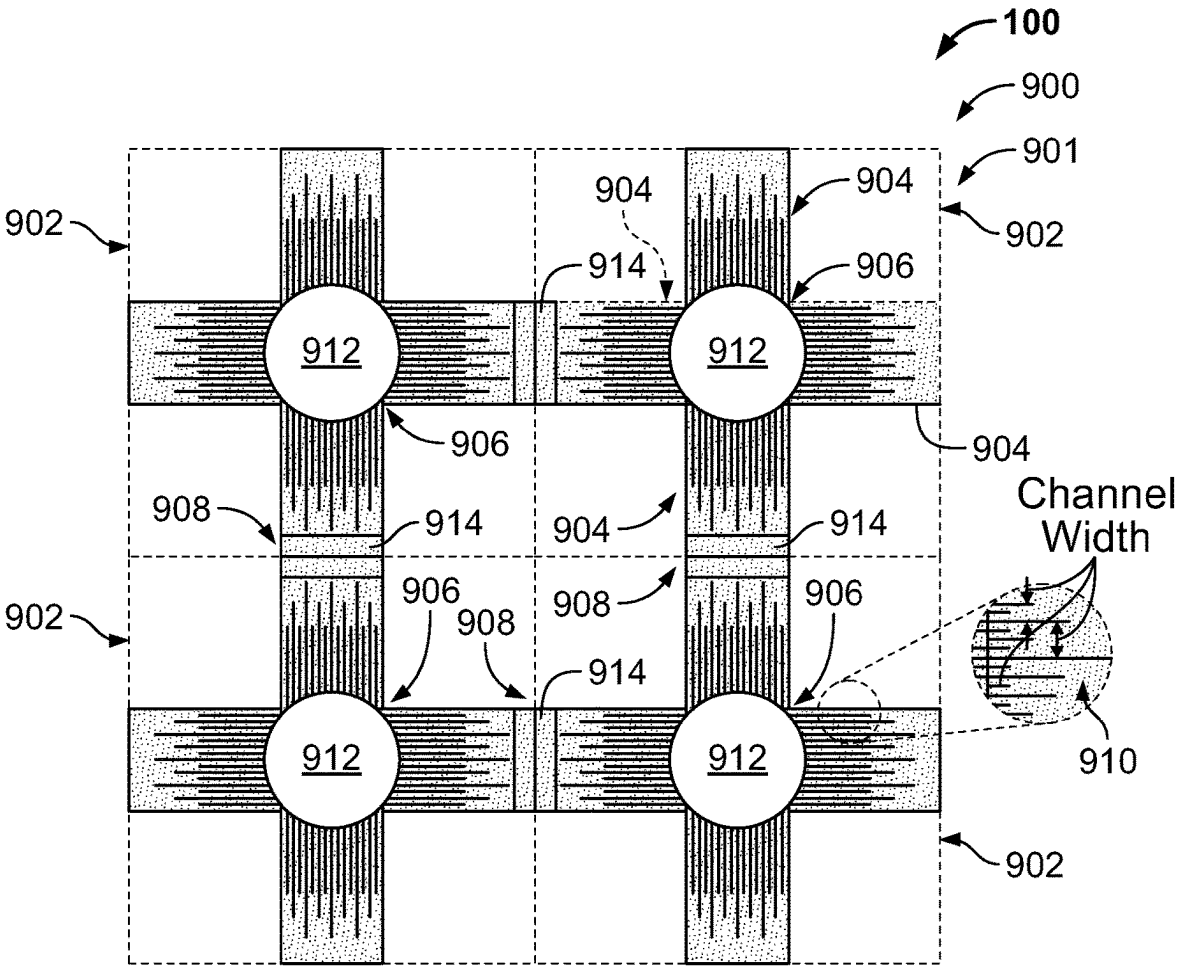
100
900
901
902
904
914
906
912
908
Channel Width
910

FIG. 36

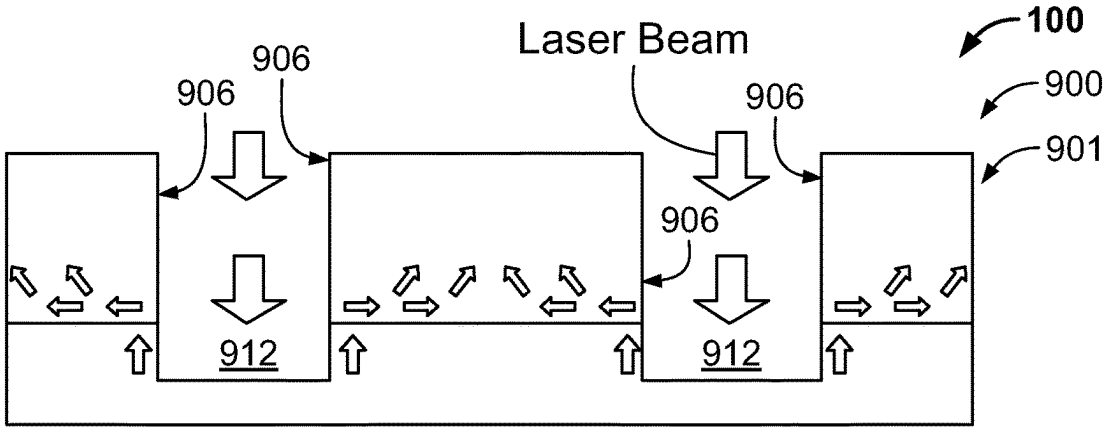
Laser Beam
100
900
901
906
912

FIG. 37

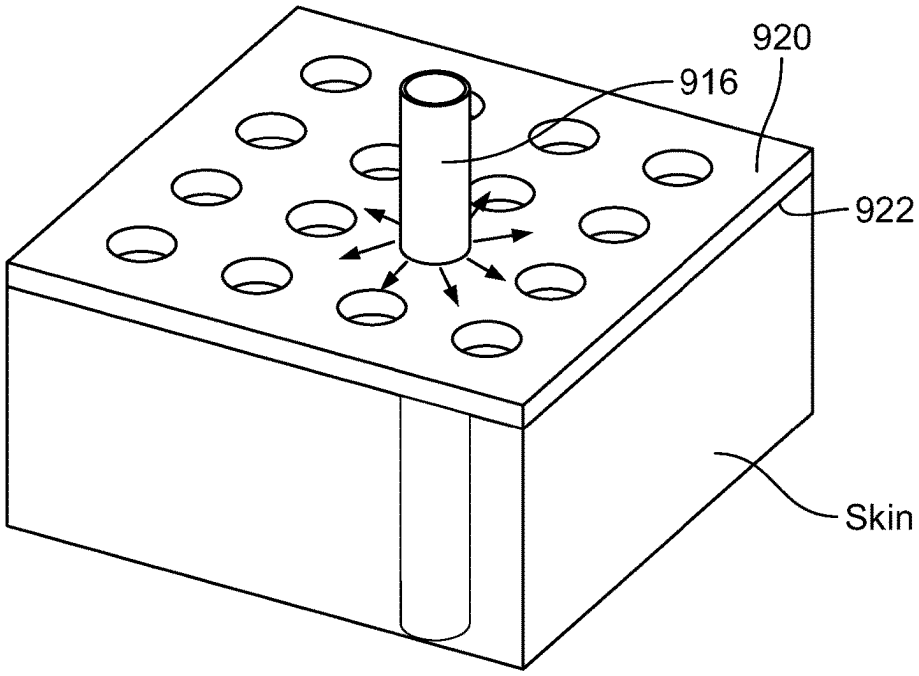
920
916
922
Skin

FIG. 38

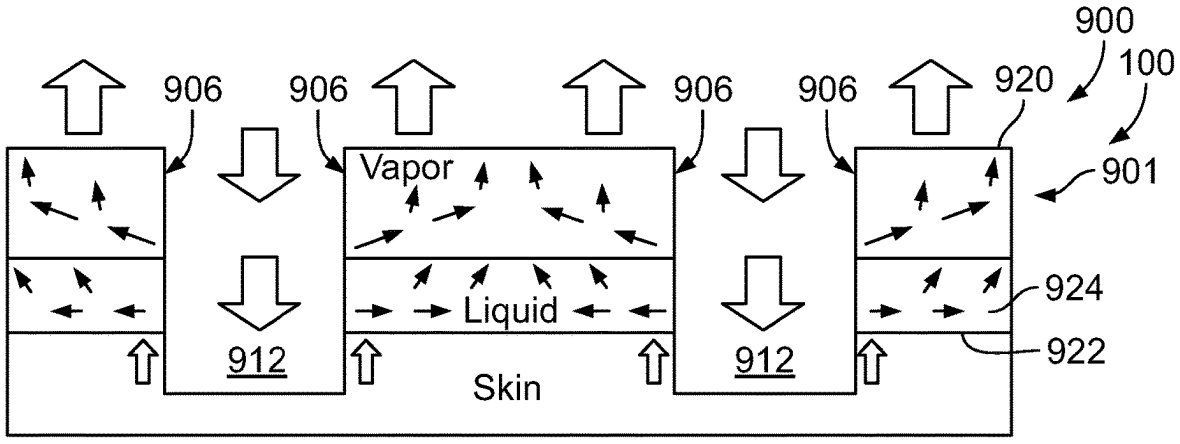
900
100
906
906
906
906
920
901
Vapor
924
Liquid
912
912
922
Skin

FIG. 39

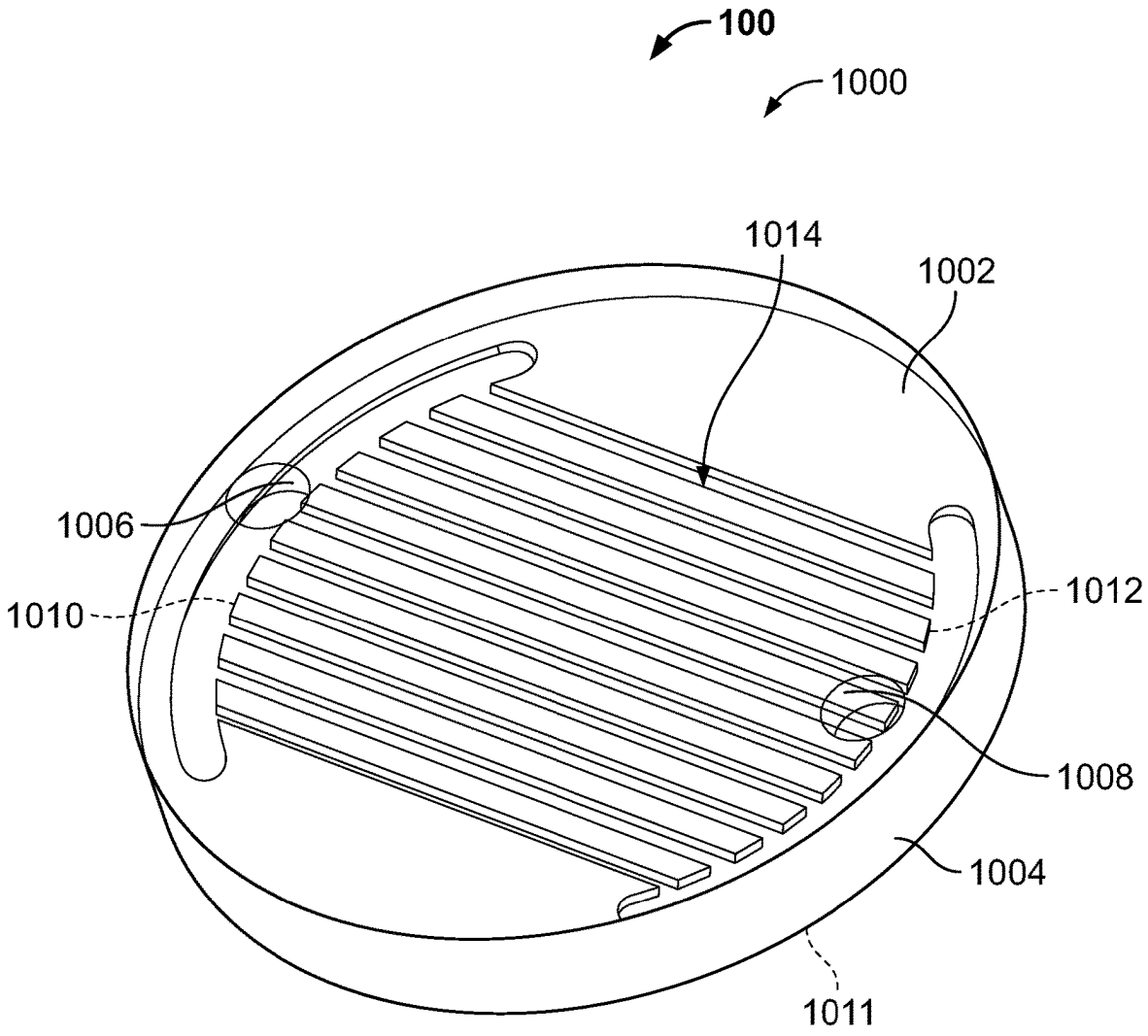

FIG. 40

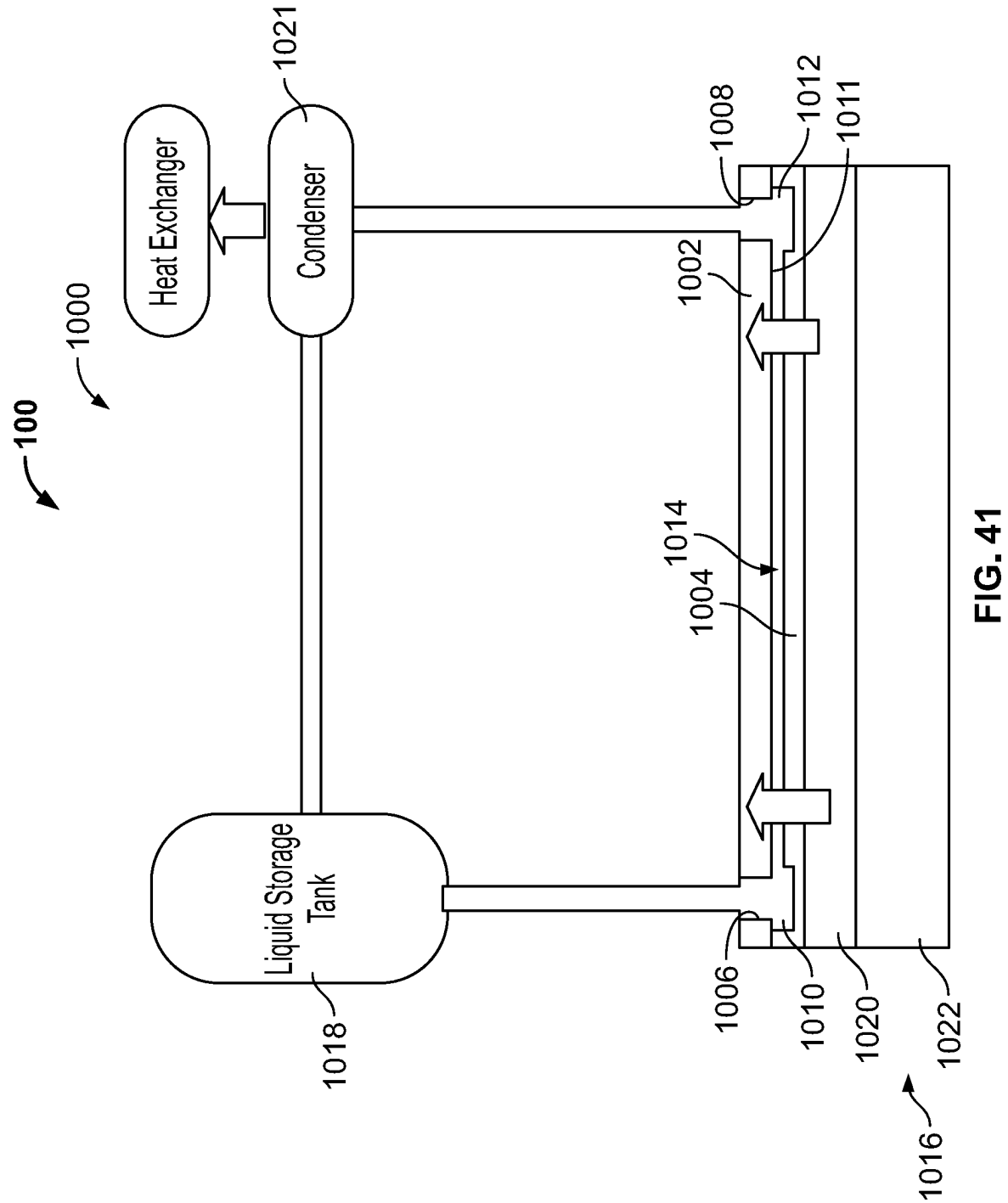
100
1000
Heat Exchanger
Condenser
1021
Liquid Storage Tank
1018
1002
1004
1006
1008
1010
1011
1012
1014
1016
1020
1022

FIG. 41

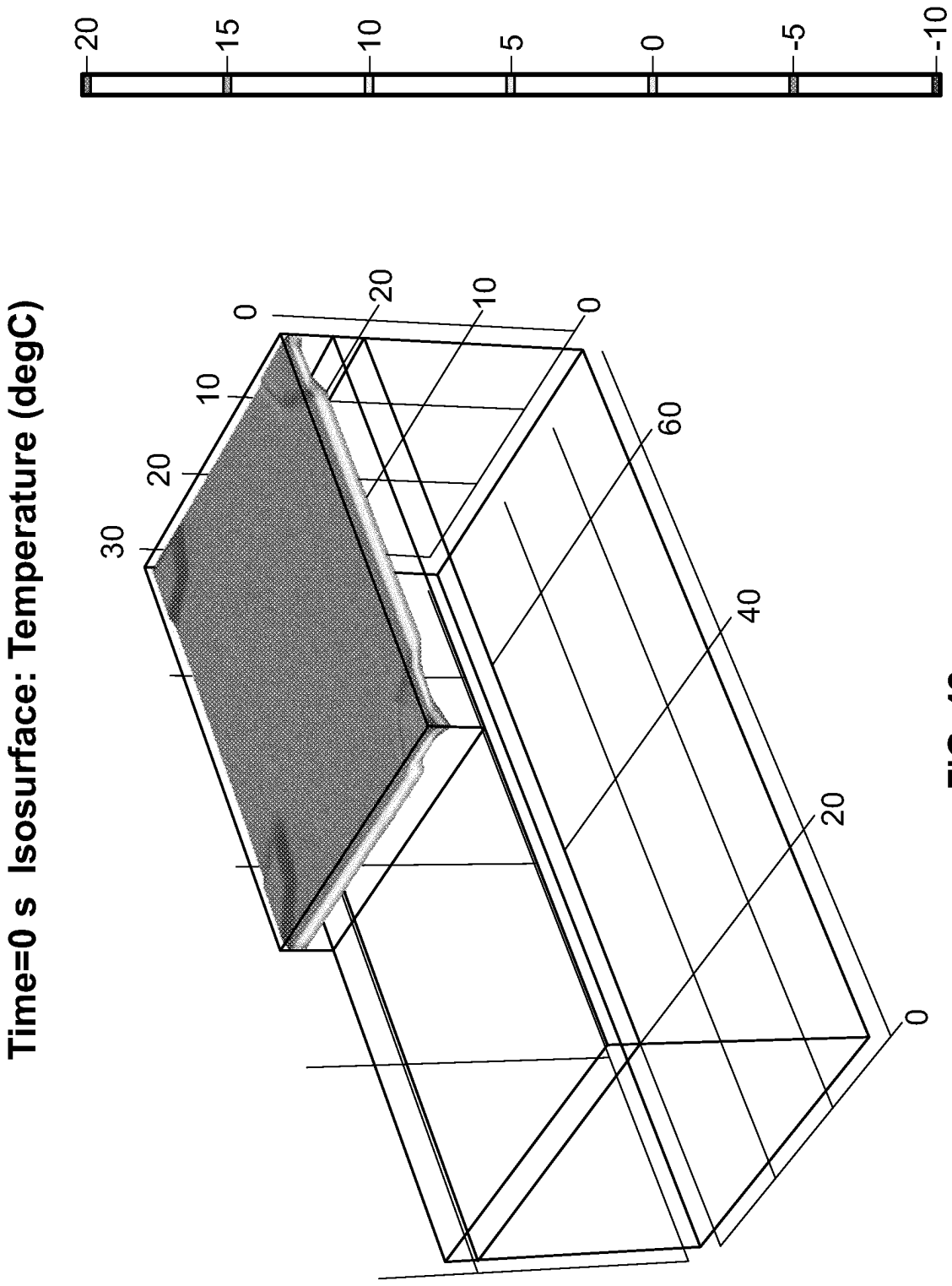
20
15
10
5
0
-5
-10
Time=0 s Isosurface: Temperature (degC)
0
10
20
30
20
10
0
60
40
20
0

FIG. 42

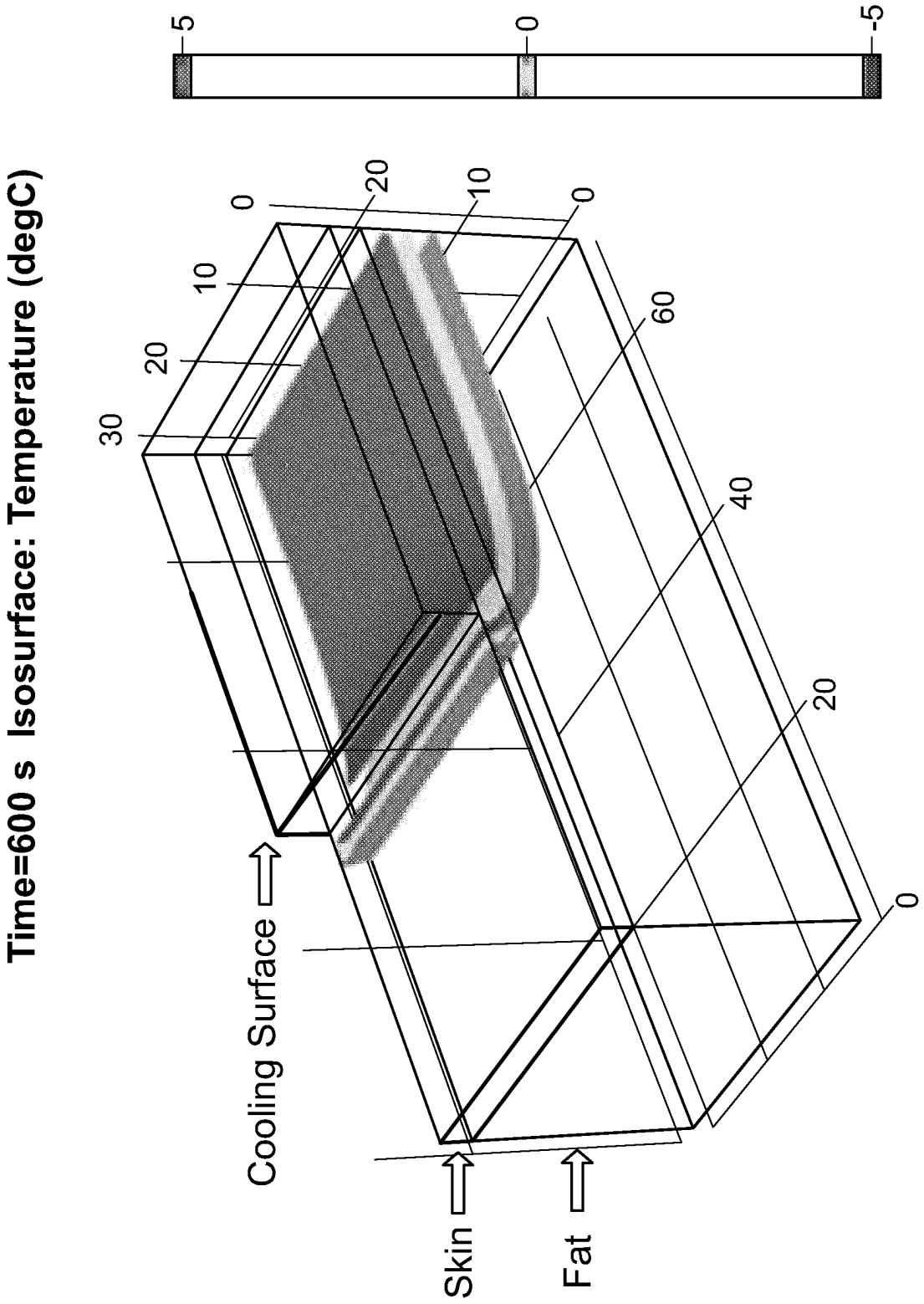
Time=600 s Isosurface: Temperature (degC)
5
0
-5
0
10
20
30
0
10
20
0
60
40
20
0
Cooling Surface
Skin
Fat

FIG. 43

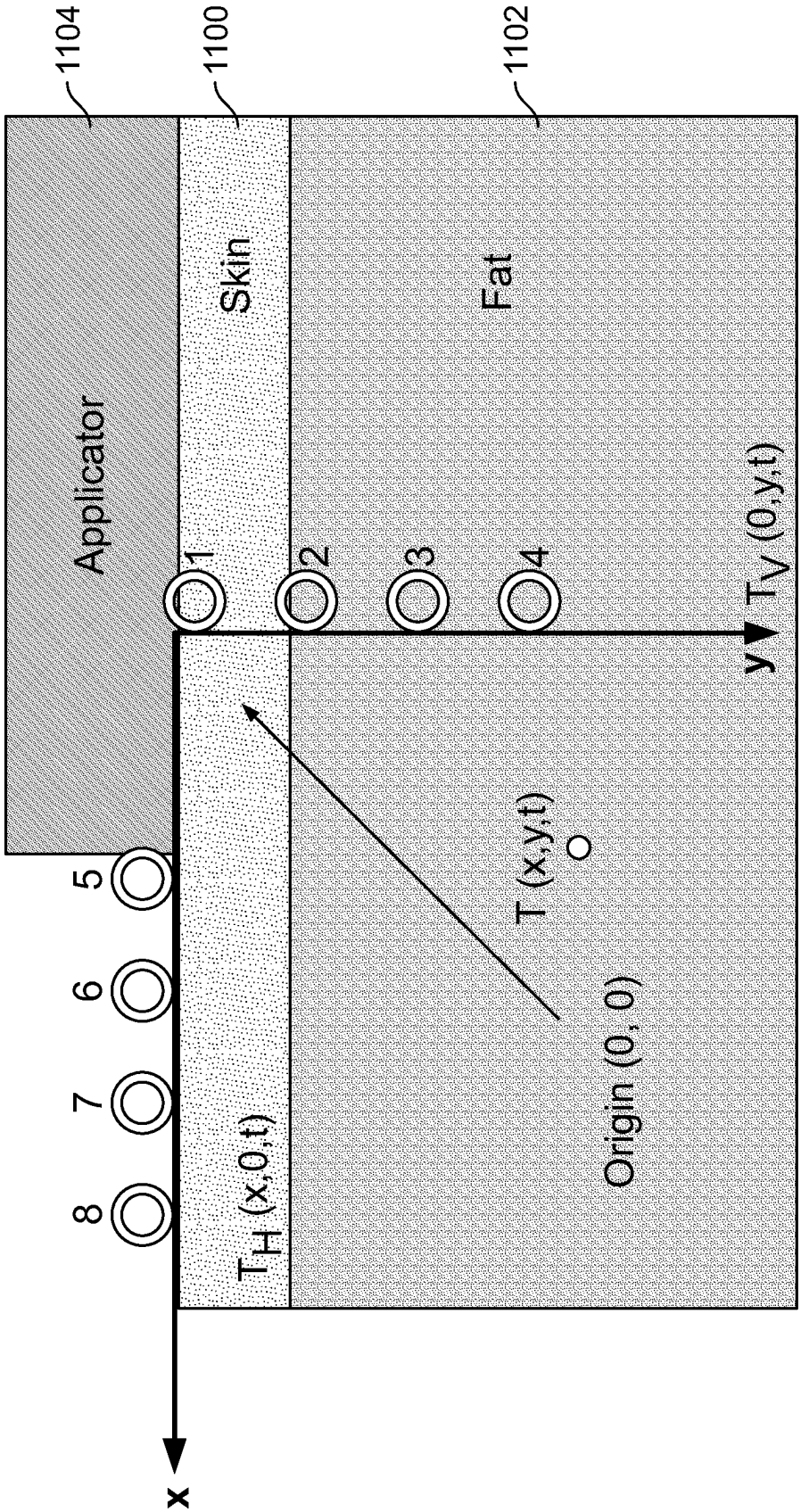
1104
1100
1102
Applicator
Skin
Fat
1
2
3
4
5
6
7
8
y
$T_V(0,y,t)$
T (x,y,t)
O
Origin (0, 0)
$T_H(x,0,t)$
x

FIG. 44

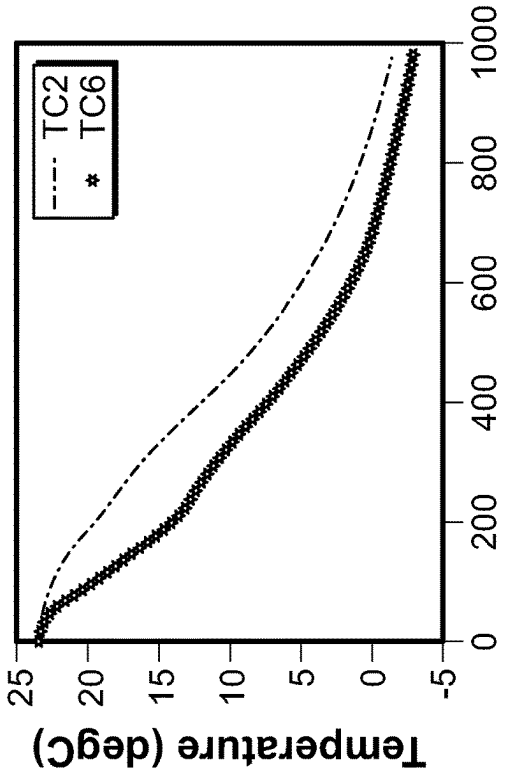

FIG. 45

FIG. 46

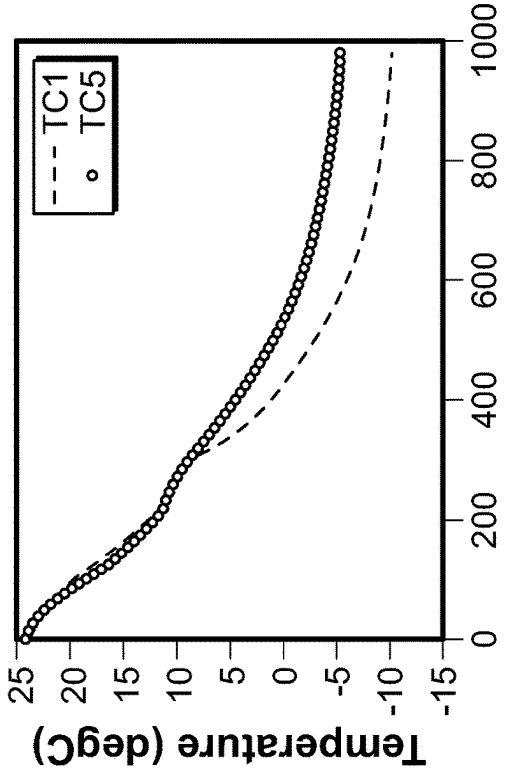

FIG. 47

FIG. 48

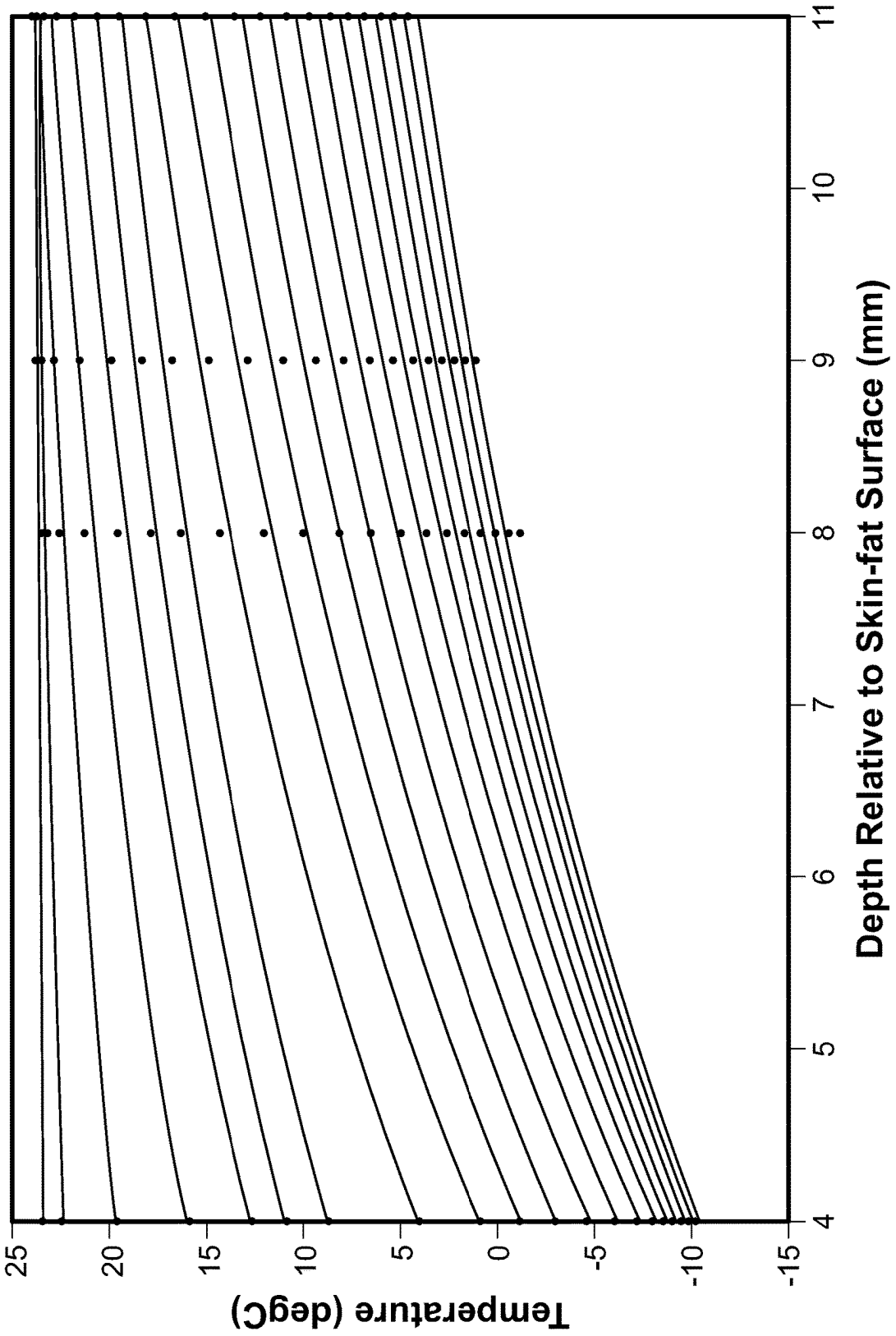
Temperature (degC)
25
20
15
10
5
0
-5
-10
-15
Depth Relative to Skin-fat Surface (mm)
4
5
6
7
8
9
10
11

FIG. 49

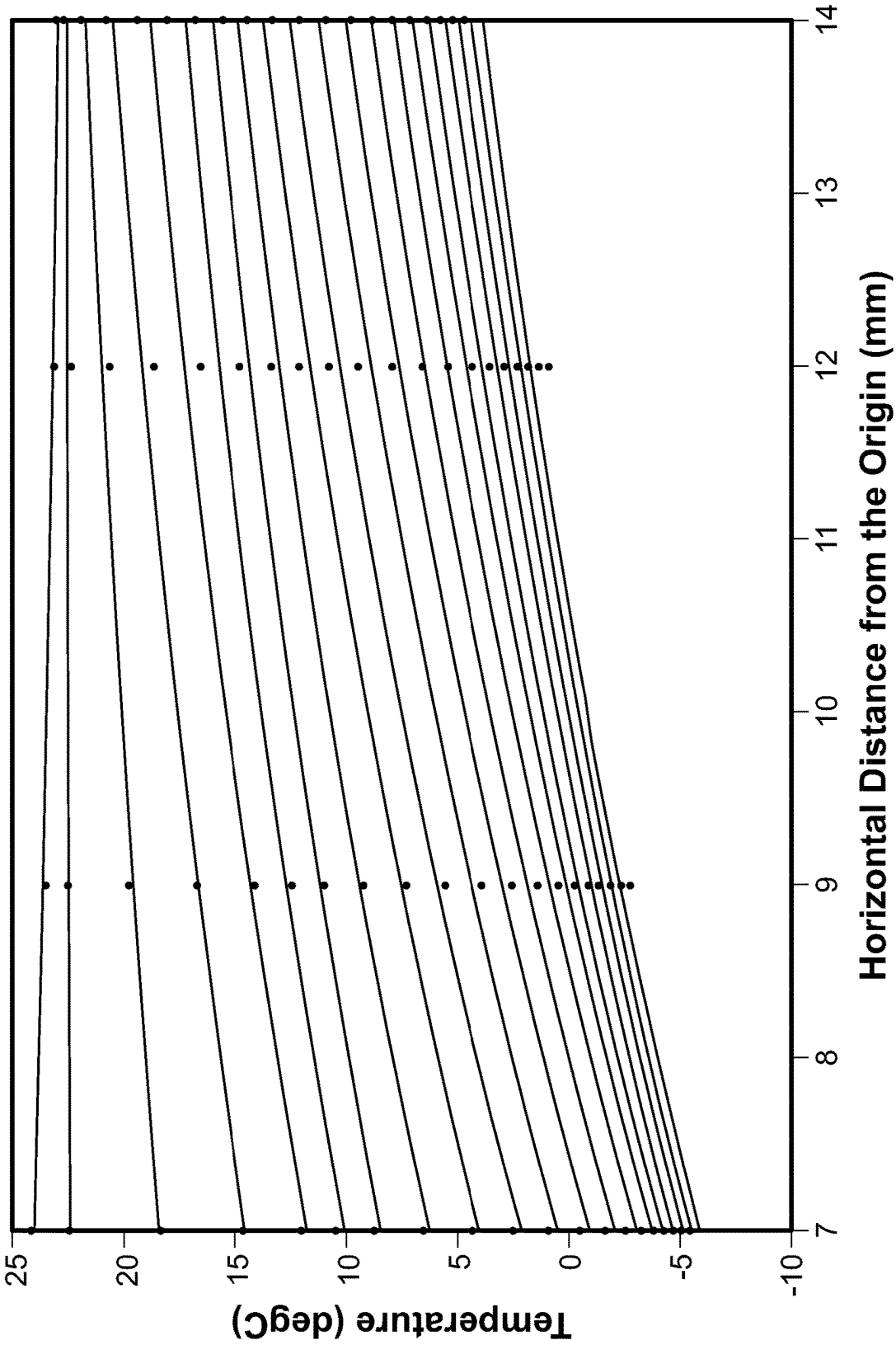
Temperature (degC)
25
20
15
10
5
0
-5
-10
Horizontal Distance from the Origin (mm)
7
8
9
10
11
12
13
14

FIG. 50

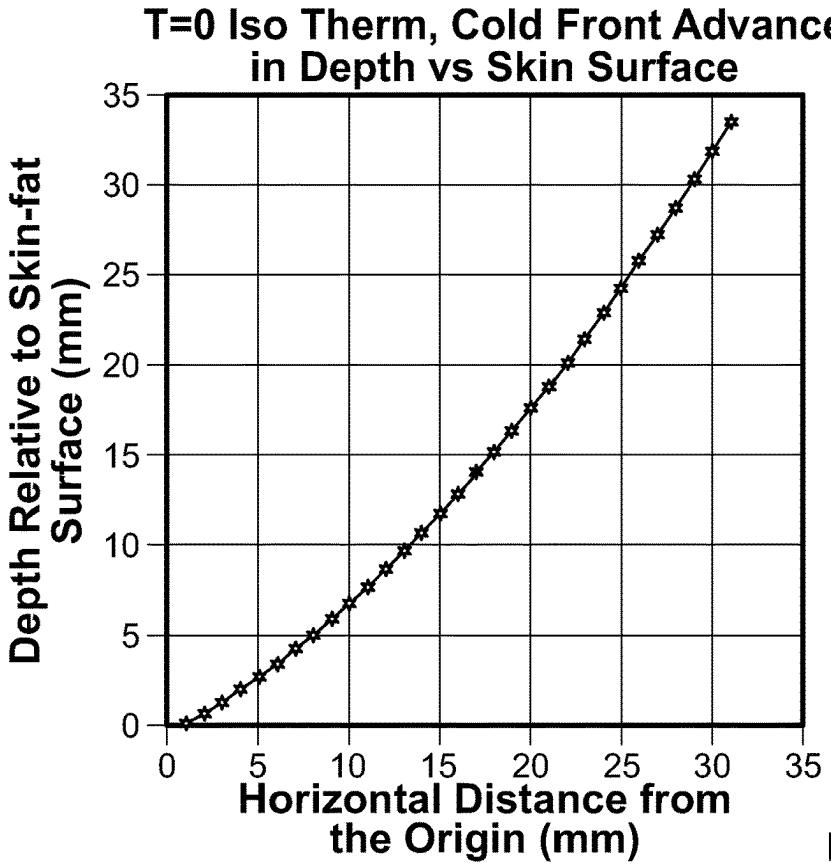
T=0 Iso Therm, Cold Front Advance in Depth vs Skin Surface
Depth Relative to Skin-fat Surface (mm)
0
5
10
15
20
25
30
35
Horizontal Distance from the Origin (mm)

FIG. 51

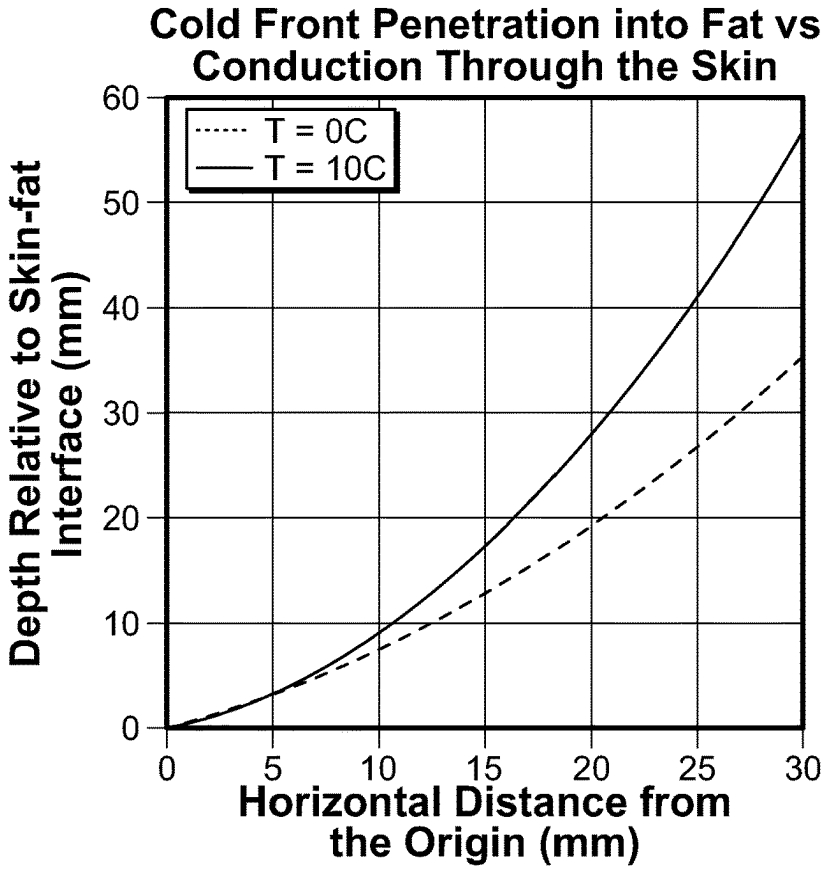
Cold Front Penetration into Fat vs Conduction Through the Skin
T = 0C
T = 10C
Depth Relative to Skin-fat Interface (mm)
0
10
20
30
40
50
60
Horizontal Distance from the Origin (mm)

FIG. 52

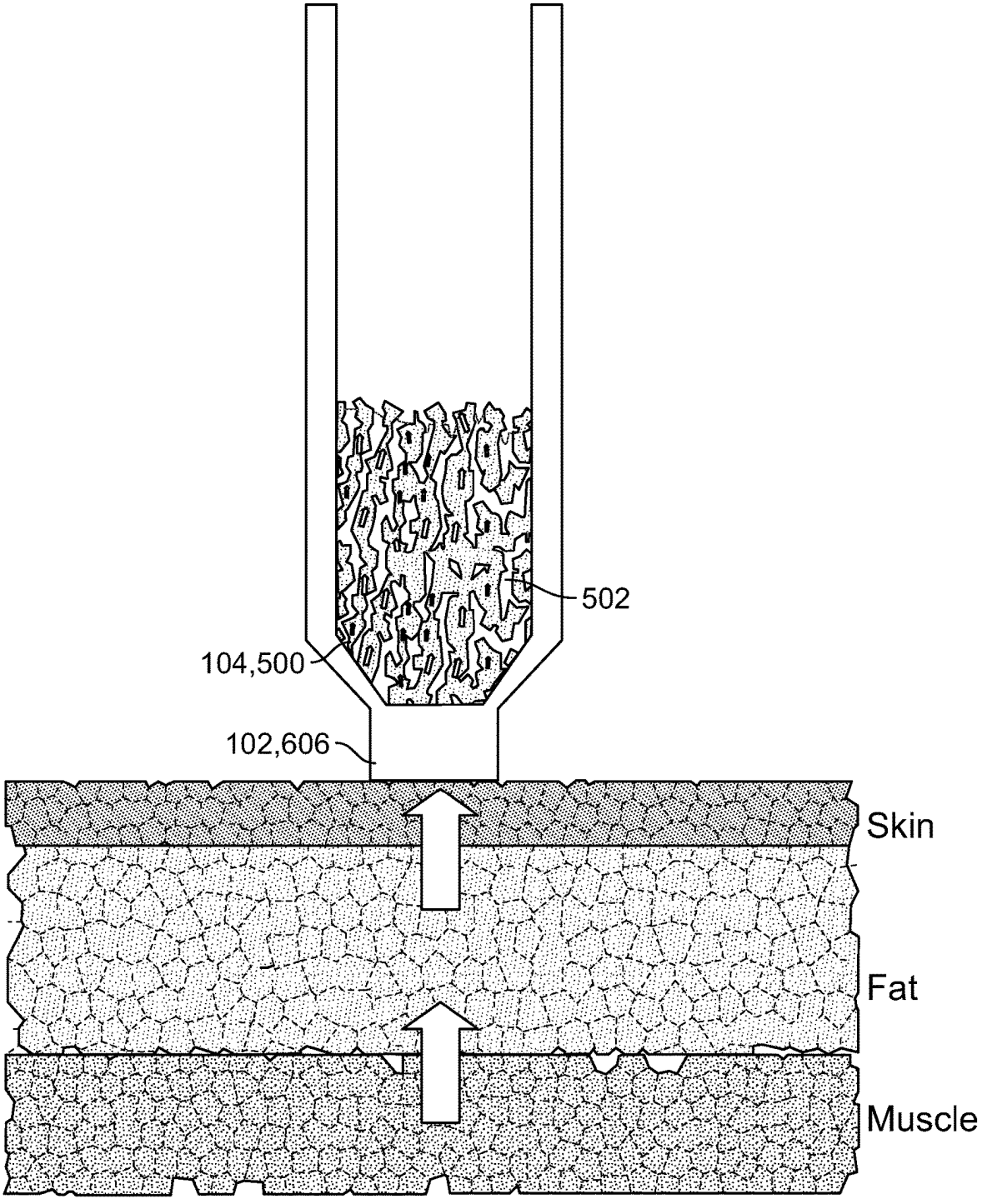

FIG. 53

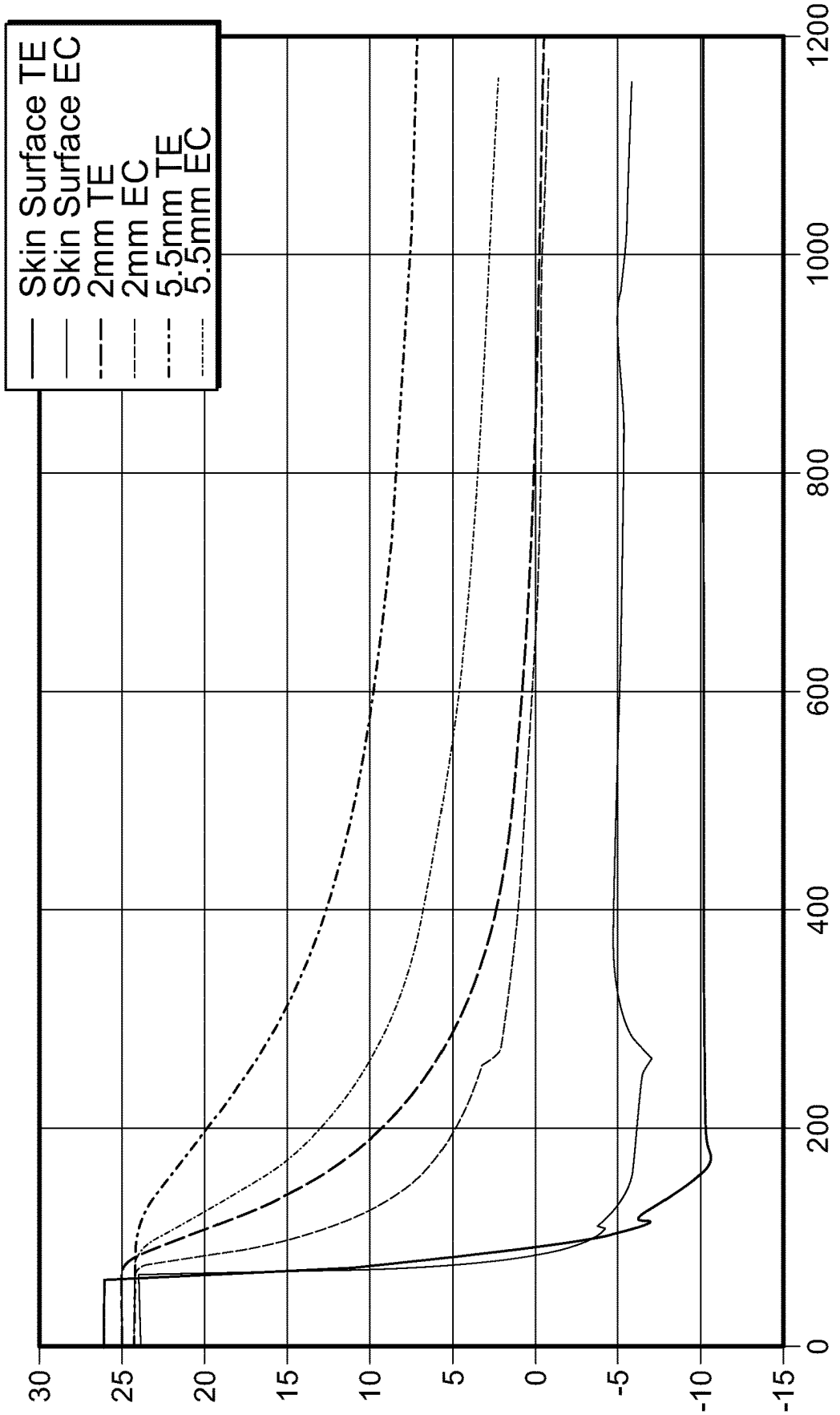
Skin Surface TE
Skin Surface EC
2mm TE
2mm EC
5.5mm TE
5.5mm EC
30
25
20
15
10
5
0
-5
-10
-15
0
200
400
600
800
1000
1200

FIG. 54

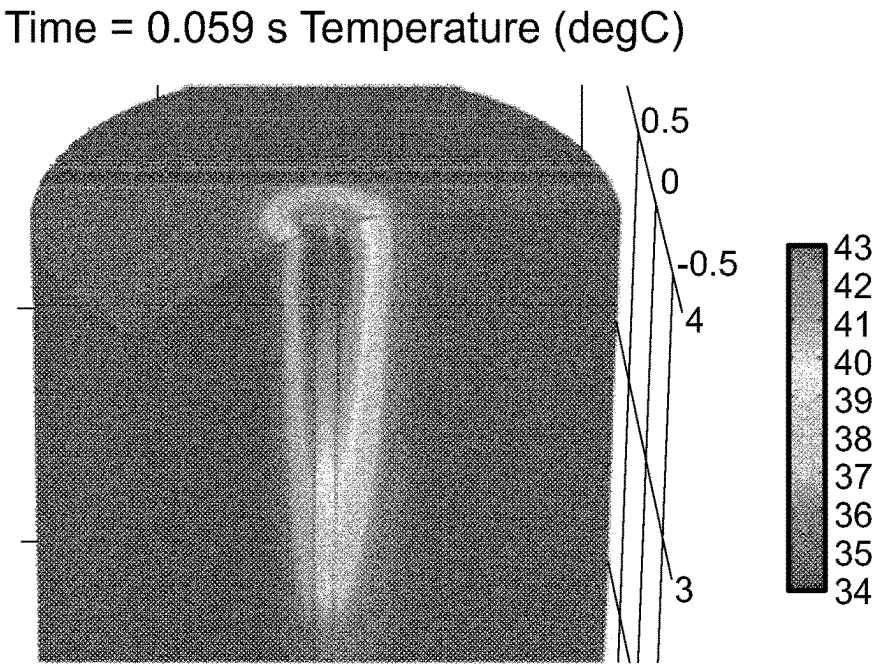
Time = 0.059 s Temperature (degC)
0.5
0
-0.5
4
3
43
42
41
40
39
38
37
36
35
34

FIG. 55

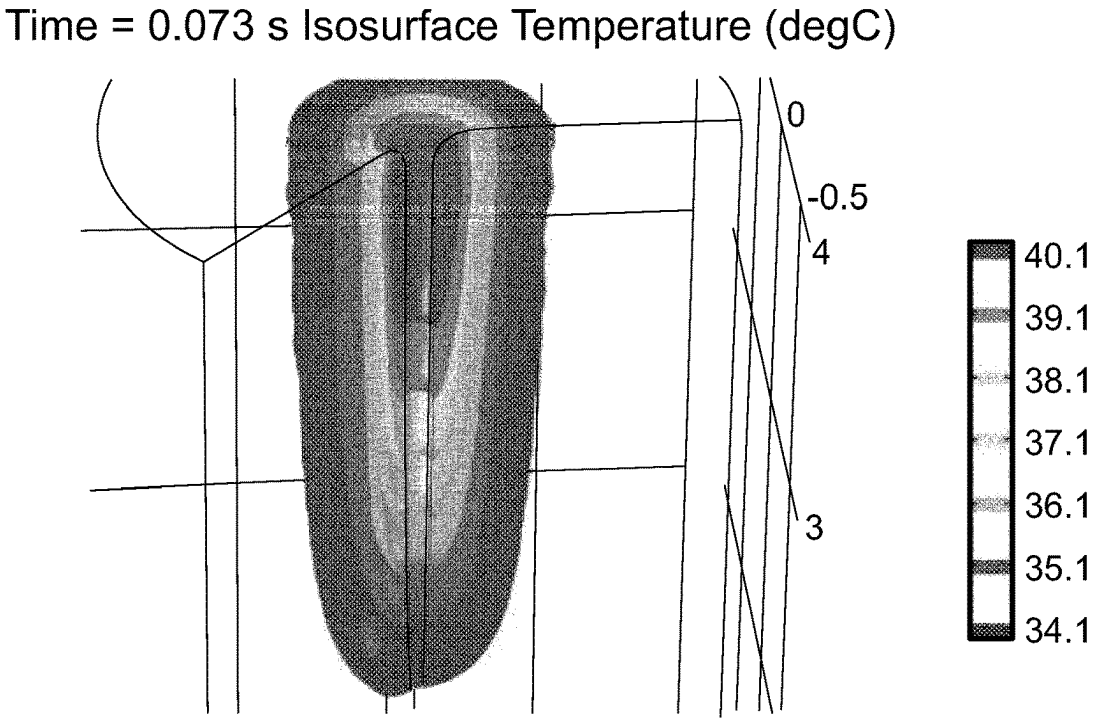
Time = 0.073 s Isosurface Temperature (degC)
0
-0.5
4
3
40.1
39.1
38.1
37.1
36.1
35.1
34.1

FIG. 56

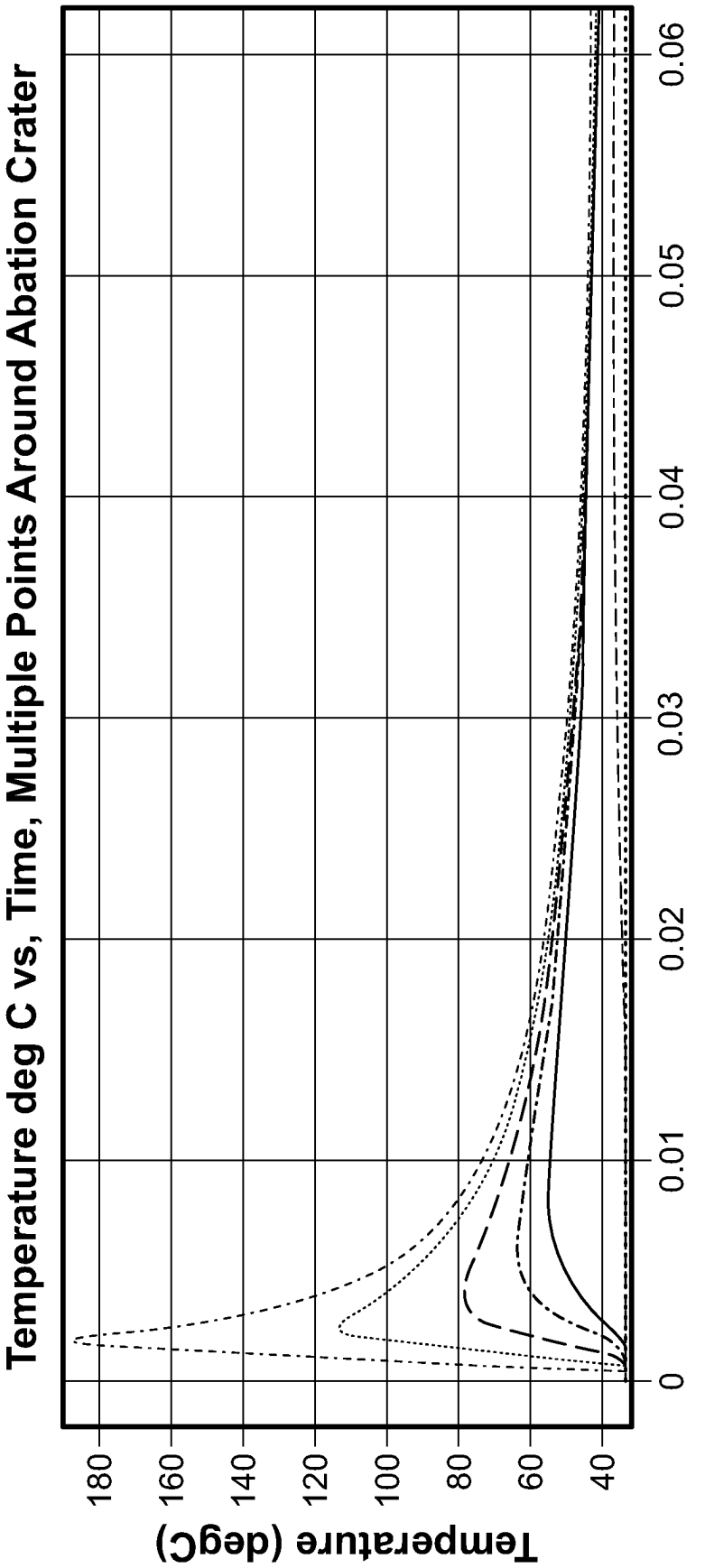
Temperature deg C vs, Time, Multiple Points Around Abation Crater
Temperature (degC)
180
160
140
120
100
80
60
40
0
0.01
0.02
0.03
0.04
0.05
0.06
Time (sec)

Fig. 57

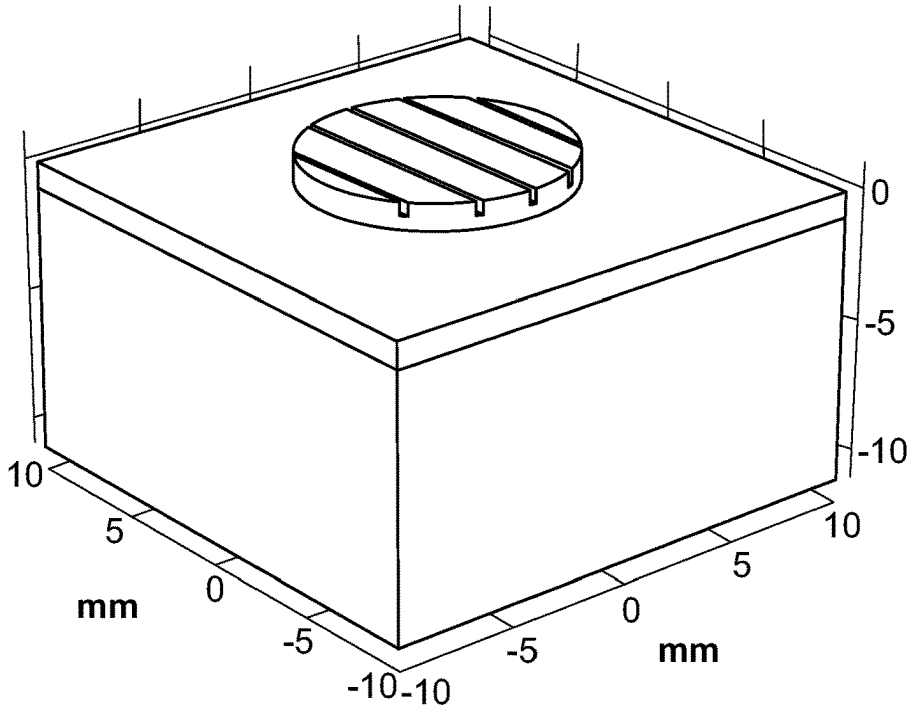
0
-5
-10
10
5
0
-5
-10
mm
10
5
0
-5
-10
mm

FIG. 58

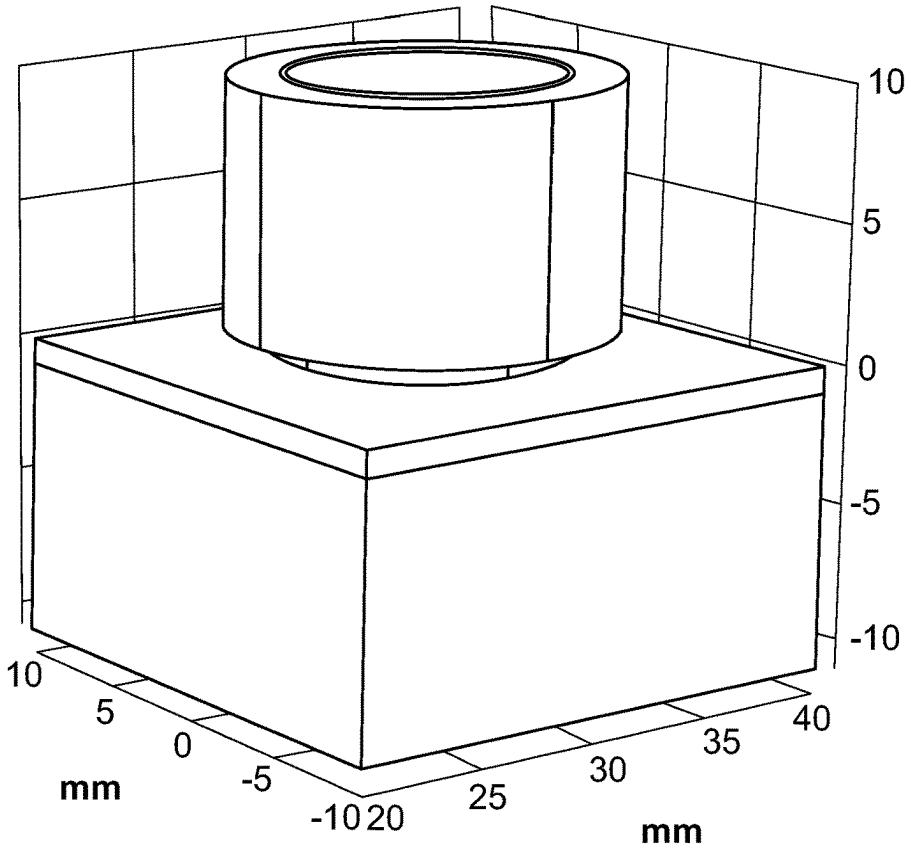
10
5
0
-5
-10
10
5
0
-5
-10
mm
20
25
30
35
40
mm

FIG. 59

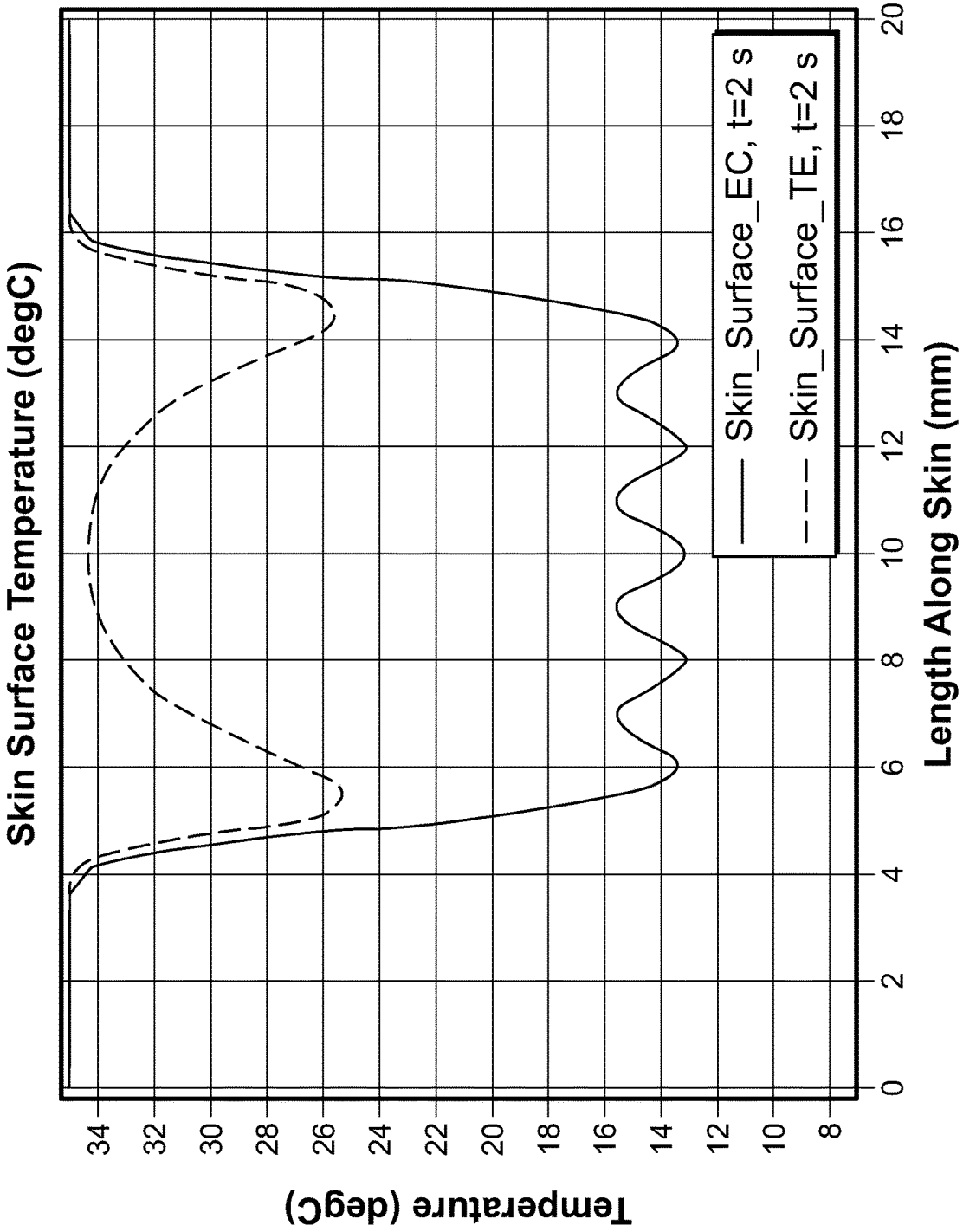
Skin Surface Temperature (degC)
Temperature (degC)
Length Along Skin (mm)
Skin_Surface_EC, t=2 s
Skin_Surface_TE, t=2 s
34
32
30
28
26
24
22
20
18
16
14
12
10
8
0
2
4
6
8
10
12
14
16
18
20

FIG. 60

SYSTEMS AND METHODS FOR THERMAL TREATMENT OF TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a U.S. National Phase of PCT Application No. PCT/US2017/049850 filed on Sep. 1, 2017, which is based on, claims priority to, and incorporates herein by reference in their entirety, U.S. Provisional Patent Application No. 62/447,997, filed on Jan. 19, 2017, Unites States Provisional Patent Application No. 62/482,027, filed on Apr. 5, 2017, U.S. Provisional Patent Application No. 62/500,047, filed on May 2, 2017, U.S. Patent Application No. 62/511,837, filed on May 26, 2017, U.S. Provisional Patent Application No. 62/523,492, filed on Jun. 22, 2017, U.S. Provisional Patent Application No. 62/532,343, filed on Jul. 13, 2017, and U.S. Provisional Patent Application No. 62/541,650, filed on Aug. 4, 2017.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable.

BACKGROUND

In some medical applications, cooling may be selectively applied to a tissue region to perform a desired medical procedure (e.g., cryolipolysis). Alternatively, cooling may be implemented to protect non-target tissue during a heat treatment procedure performed on a target tissue region (e.g., laser ablation). Conventional cooling systems implemented in these medical applications suffer from insufficient cooling capacity and require various moving components and external power supplies.

BRIEF SUMMARY

The present disclosure provides systems and methods for a medical device configured to provide cooling and/or heating to a tissue region. The medical device leverages two-phase heat transfer to provide an extremely high cooling capacity when compared to conventional state-of-the-art cooling mechanisms (e.g., single-phase cooling, thermoelectric cooling, Joule-Thompson cooling, spray cooling, etc.). The medical device may be configured to noninvasively or invasively cool the tissue region to a predetermined temperature. In some non-limiting examples, the two-phase heat transfer leveraged by the medical device to provide cooling may be combined with a heating element to enable the medical device to selective switch between providing heating and cooling to a tissue region.

In one aspect, the present disclosure provides a medical device configured to provide cooling to a tissue region. The medical device includes a base and an evaporative structure arranged on the base and configured to receive a working fluid. The evaporative structure is designed to promote evaporation of the working fluid to cool the base to a predetermined operating temperature.

In one aspect, the present disclosure provides a noninvasive medical device configured to provide cooling to a tissue region. The noninvasive medical device includes a base having a treatment surface arranged thereon, and a porous substrate in engagement with at least a portion of the base and configured to receive a working fluid. The porous substrate is designed to promote evaporation of the working fluid to cool the treatment surface to a predetermined operating temperature.

In one aspect, the present disclosure provides an invasive medical device configured to provide cooling to a tissue region. The invasive medical device includes an outer wall, and an inner wall having at least one channel thereon and that extends axially therealong. The at least one channel is designed to promote evaporation of a working fluid arranged therein to cool the outer surface to a predetermined operating temperature.

In one aspect, the present disclosure provides a noninvasive medical device configured to provide cooling to a tissue region subjected to a fractional treatment pattern. The noninvasive medical device includes a base defining a plurality of openings arranged therein to accommodate the fractional treatment pattern, and a plurality of channels arranged on the base and configured to receive a working fluid. The plurality of channels are designed to promote evaporation of the working fluid to cool the base to a predetermined operating temperature.

In one aspect, the present disclosure provides a noninvasive medical device configured to provide cooling to a tissue region. The noninvasive medical device includes a top plate, a bottom plate including a contact surface, and an evaporative structure arranged between the top plate and the bottom plate configured to receive a working fluid. The evaporative structure is configured to promote evaporation of the working fluid to cool the contact surface. The noninvasive medical device includes an opening extending through the top plate, the bottom plate, and the evaporative structure.

In one aspect, the present disclosure provides a noninvasive medical device configured to provide cooling to a tissue region. The noninvasive medical device includes a transparent top plate including an inlet port and an outlet port, and a transparent bottom plate including a bottom surface configured to engage the tissue region and an evaporative structure in fluid communication with the inlet port and the outlet port. The inlet port is configured to receive a working fluid and the evaporative structure is configured to promote evaporation of the working fluid to cool the desired tissue region to a predetermine temperature.

In one aspect, the present disclosure provides a noninvasive medical device configured to provide cooling to a tissue region. The noninvasive medical device includes a base having a condensing plate with a treatment surface arranged thereon and an inlet port and an outlet port, and a evaporative plate having an evaporative structure arranged therein. The condensing plate includes a flow path extending between the inlet port and the outlet port and is configured to receive a cooling fluid, and wherein the evaporative structure is configured receive a working fluid and to promote evaporation of the working fluid to cool the treatment surface to a predetermined operating temperature.

In one aspect, the present disclosure provides a method for control a medical device configured to thermally treat a tissue region. The method includes engaging a medical device with a tissue region, measuring a temperature at one or more locations along a surface of the tissue region, determining a temperature profile at one or more depths within the tissue region based on the measured temperature at the one or more locations along the surface of the tissue region, and adjusting an operational parameter of the medical device based on the determined temperature profiled at the one or more depths within the tissue region.

The foregoing and other aspects and advantages of the invention will appear from the following description. In the

description, reference is made to the accompanying drawings which form a part hereof, and in which there is shown by way of illustration a preferred embodiment of the invention. Such embodiment does not necessarily represent the full scope of the invention, however, and reference is made therefore to the claims and herein for interpreting the scope of the invention.

BRIEF DESCRIPTION OF DRAWINGS

The invention will be better understood and features, aspects and advantages other than those set forth above will become apparent when consideration is given to the following detailed description thereof. Such detailed description makes reference to the following drawings.

FIG. **1** is a schematic illustration of a medical device according to one aspect of the present disclosure.

FIG. **2** is a schematic illustration of a medical device in communication with a heat source according to one aspect of the present disclosure.

FIG. **3** is a schematic illustration of a medical device in communication with a fluid source according to one aspect of the present disclosure.

FIG. **4** is a schematic illustration of a medical device in communication with a fluid source and a fluid control device according to one aspect of the present disclosure.

FIG. **5** is a schematic illustration of a medical device in communication with a fluid source and a condenser according to one aspect of the present disclosure.

FIG. **6** is a schematic illustration of a medical device in communication with a fluid source, a fluid control device, and a condenser according to one aspect of the present disclosure.

FIG. **7** is a schematic illustration of a medical device in communication with a fluid source, a reservoir, and a condenser according to one aspect of the present disclosure.

FIG. **8** is a schematic illustration of a medical device having a patterned evaporative structure according to one aspect of the present disclosure.

FIG. **9** is a schematic illustration of a tiled medical device according to one aspect of the present disclosure.

FIG. **10** is a schematic illustration of a medical device including a plurality of channels according to one aspect of the present disclosure.

FIG. **11** is a schematic illustration of a medical device include a porous substrate according to one aspect of the present disclosure.

FIG. **12** is a top, front, right isometric view of a noninvasive medical device with an open circuit according to one aspect of the present disclosure.

FIG. **13** is a bottom, back, left isometric view of the noninvasive medical device of FIG. **12**.

FIG. **14**A is a top view of a condenser side of a noninvasive medical device with a closed circuit according to one aspect of the present disclosure.

FIG. **14**B is a bottom view of the condenser side of the noninvasive medical device of FIG. **14**A.

FIG. **15** is a top, front view of an evaporative side of the noninvasive medical device of FIG. **14**A.

FIG. **16** is a top view of the noninvasive medical device of FIG. **14**A, when assembled.

FIG. **17** is a bottom view of the noninvasive medical device of FIG. **14**A, when assembled.

FIG. **18** is a schematic illustration of a non-invasive medical device with an evaporator applied to a tissue region that draws fluid from a liquid storage tank.

FIG. **19** is a schematic illustration of the non-invasive medical device of FIG. **18** with a flexible cover and a vacuum.

FIG. **20** is a schematic illustration of the non-invasive medical device of FIG. **18** with an adhesive layer, an anti-freeze layer, and a removable sheet applied between the device and a tissue surface.

FIG. **21** is a schematic illustration of the non-invasive medical device of FIG. **18** with an adhesive layer, an anti-freeze layer, and a removable sheet applied between the device and a tissue surface where a heater is integrated into the removable sheet.

FIG. **22** is a schematic illustration of the non-invasive medical device of FIG. **18** with an adhesive layer, an anti-freeze layer, and a removable sheet applied between the device and a tissue surface where a heater is integrated between the adhesive layer and the anti-freeze layer.

FIG. **23** is a schematic illustration of a concave treatment surface of a noninvasive medical device according to one aspect of the present disclosure.

FIG. **24** is a schematic illustration of a treatment surface of a noninvasive medical device having a plurality of peaks and valleys according to one aspect of the present disclosure.

FIG. **25** is a schematic illustration of a treatment surface of a noninvasive medical device having a plurality of protrusions according to one aspect of the present disclosure.

FIG. **26** is a schematic illustration of a horseshoe-shaped treatment surface of a noninvasive medical device according to one aspect of the present disclosure.

FIG. **27** is a schematic illustration of a crescent moon-shaped treatment surface of a noninvasive medical device according to one aspect of the present disclosure.

FIG. **28** is a schematic illustration of an annular-shaped treatment surface of a noninvasive medical device according to one aspect of the present disclosure.

FIG. **29** is a schematic illustration of a noninvasive medical device treating a tissue region having a recess according to one aspect of the present disclosure.

FIG. **30** is a schematic illustration of a noninvasive medical device treating a tissue region having a protrusion according to one aspect of the present disclosure.

FIG. **31** is a schematic illustration of an invasive medical device according to one aspect of the present disclosure.

FIG. **32** is an enlarged view of section A-A of the invasive medical device of FIG. **31**.

FIG. **33** is a cross-section view of the invasive medical device of FIG. **31** taken along line **33-33**.

FIG. **34** is a cross-section view of the invasive medical device of FIG. **31** taken along line **34-34**.

FIG. **35** is a cross-section view of the invasive medical device of FIG. **31** taken along line **35-35**.

FIG. **36** is a schematic illustration of a noninvasive medical device array for use in fractional medical applications according to one aspect of the present disclosure.

FIG. **37** is a side view of the noninvasive medical device array of FIG. **36**.

FIG. **38** is a top, front, right isometric view of another noninvasive medical device array for use in fractional medical applications according to one aspect of the present disclosure.

FIG. **39** is a side view of the noninvasive medical device array of FIG. **38**.

FIG. **40** is a top, front, right isometric view of a transparent noninvasive medical device according to one aspect of the present disclosure.

FIG. **41** is a schematic illustration of the transparent noninvasive medical device of FIG. **40** assembled and treating a tissue region according to one aspect of the present disclosure.

FIG. **42** is a graph illustrating an initial temperature of a cooling device arranged on a tissue region.

FIG. **43** is a graph illustrating isothermal layers within the tissue region while cooling is being applied by the cooling device.

FIG. **44** is a schematic illustration of a non-invasive temperature monitoring and control system according to one aspect of the present disclosure.

FIG. **45** is a graph illustrating temperature as a function of time at locations **1** and **5** in FIG. **44**.

FIG. **46** is a graph illustrating temperature as a function of time at locations **2** and **6** in FIG. **44**.

FIG. **47** is a graph illustrating temperature as a function of time at locations **3** and **7** in FIG. **44**.

FIG. **48** is a graph illustrating temperature as a function of time at locations **4** and **8** in FIG. **44**.

FIG. **49** is a graph illustrating an interpolation of the temperature of locations **5-8** in FIG. **44**.

FIG. **50** is a graph illustrating an interpolation of the temperature of locations **1-4** in FIG. **44**.

FIG. **51** is a graph illustrating x, y pairs for a 0° C. isotherm based on the interpolation date in FIGS. **49** and **50**.

FIG. **52** is a graph illustrating x, y, pairs of a 10° C. isotherm and the can also be determined and are plotted with the 0° C. isotherm 0° C. isotherm based on the interpolation date in FIGS. **49** and **50**.

FIG. **53** is a schematic illustration of a test setup used to measure a temperature as a function of time at varying depths into a simulated tissue region that was noninvasively cooled using two-phase cooling.

FIG. **54** is a graph illustrating the temperature as a function of time at varying depths within the simulated tissue setup of FIG. **53** for thermoelectric cooling and two-phase cooling.

FIG. **55** is a graph illustrating a three-dimensional temperature profile after 0.059 seconds within a tissue region being subjected to a laser treatment and being cooled by a non-invasive medical device according to the present disclosure.

FIG. **56** is a graph illustrating a three-dimensional temperature profile after 0.073 seconds within a tissue region being subjected to a laser treatment and being cooled by a non-invasive medical device according to the present disclosure.

FIG. **57** is a graph illustrating temperature as a function of time for varying distances radially from the laser beam for the cooling treatment illustrated in FIGS. **55** and **56**.

FIG. **58** illustrates a setup used to model the cooling performance of a transparent noninvasive medical device during a laser-based medical treatment.

FIG. **59** illustrates a setup used to model the cooling performance of a conventional cooling device during a laser-based medical treatment

FIG. **60** is a graph illustrating a temperature at the skin surface two seconds after the cooling was initiated during a laser-based medical treatment for the noninvasive medical device of FIG. **58** and the conventional cooling device of FIG. **59**.

DETAILED DESCRIPTION

The use of the terms "upstream" and "downstream" herein indicates a direction relative to the flow of fluid. The term "downstream" corresponds to the direction of fluid flow, while the term "upstream" refers to the direction opposite or against the direction of fluid flow.

FIG. **1** illustrates one non-limiting example of a medical device **100** according to one aspect of the present disclosure. The medical device **100** may be configured to provide cooling to a tissue region, or an array of tissue regions, either noninvasively (e.g., at a surface of the tissue region) or invasively (e.g., at a predetermined depth into the tissue region). The medical device **100** includes a base **102** and an evaporative structure **104**. The base **102** is configured to contact a tissue region to facilitate the removal of heat from the tissue region, thereby cooling the tissue region to a predetermined temperature. In some non-limiting examples, the medical device **100** may be configured to cool the tissue region to a desired temperature profile as a function of time.

In some non-limiting examples, the base **102** may be a noninvasive implement designed to continuously contact a surface of a tissue region to cool the tissue region at the surface and/or to a predetermined depth into the tissue region. In some non-limiting examples, the base **102** may be a noninvasive implement designed to discretely contact a surface of a tissue region in a desired fractional pattern to provide fractional cooling over the tissue region and/or to a predetermined depth into the tissue region. In some non-limiting examples, the base **102** may be a noninvasive implement designed to provide thermal management (i.e., cooling) adjacent to or around a fractional heating pattern to minimize damage to non-target tissue between the fractional heating areas. In some non-limiting examples, the base **102** may be an invasive implement configured to penetrate into a tissue region, or an array of tissue regions, to provide cooling to the tissue region(s) at a predetermined depth, or a range of depths.

In some non-limiting examples, the evaporative structure **104** may be in contact with or integrated into the base **102**. The evaporative structure **104** is configured to receive a working fluid to facilitate cooling of a tissue region via a two-phase heat transfer process. The evaporative structure **104** is designed to include one or more of cavities and/or one or more flow paths formed therein, each configured to be filled with the working fluid. Once filled with the working fluid, liquid menisci are formed within each of the cavities or paths due to the combined effect of capillary and short range forces. The liquid menisci act as evaporation sites that provide significant heat removal potential from the evaporative structure **104** and the base **102** due to the large enthalpy of vaporization of liquids. Thus, the medical device **100** is operable to provide cooling to a tissue region via a two-phase heat transfer process, which provides a heat removal capacity as high as several orders of magnitude greater than conventional medical cooling technologies (e.g., single-phase cooling, thermoelectric cooling, Joule-Thompson cooling, etc.).

In the illustrated non-limiting example, the evaporative structure **104** may not be required to receive a continuous flow of fluid. Rather, the evaporative structure **104** may be filled or charged with a predetermined quantity of the working fluid. Alternatively or additionally, the evaporative structure **104** may be initially brought into fluid communication with a source of the working fluid, and the capillary forces provided by the design of the evaporative structure **104** cause the working fluid to flow into the evaporative structure **104** without the requirement of an externally induced pressure differential (e.g., a pump). In some non-limiting examples, the evaporative structure **104** may be coated with a material that possesses a high surface tension

(e.g., a single layer of graphite, or graphene). Once filled, the evaporative structure **104** may be removed from fluid communication with the source of working fluid. The evaporative structure **104** may be designed to initiate and maintain evaporation of the working fluid, once the base **102** is brought into contact with a tissue region. That is, heat transferred from the tissue region through the base **102** and to the evaporative structure **104** is sufficient to initiate and maintain the evaporation of the working fluid and, thereby, the cooling of the tissue region. Thus, the medical device **100** is operable to provide cooling to a tissue region without the requirement of an external power supply, or heat source, to facilitate the evaporation of the working fluid therein. In some non-limiting examples, this enables the medical device **100** to operate as a passive device (i.e., does not require an external source of energy to operate) and to possess increased mobility over conventional medical cooling system, which require wires, power supplies, etc., to operate. Alternatively or additionally, the evaporative structure **104** may be designed such that the capillary forces maintain the working fluid within the evaporative structure **104** regardless of the orientation of the medical device **100**. That is, the capillary forces within the evaporative structure **104**, once filled, may be greater than the force of gravity enabling the medical device **100** to be used in any orientation without the threat of leakage of the working fluid or partially dry areas in the evaporative structure **104**.

Due to the thermodynamic operation of the of the medical device **100**, an amount of working fluid needed to cool a tissue region to a desired temperature for a desired amount of time is known. That is, the rate of evaporation of the working fluid from the evaporative structure **104** may be known based on the heat input from the tissue region. In this way, the medical device **100** may be tailored to provide a desired amount of cooling for a desired amount of time. Alternatively or additionally, the known amount of time for a given mass of working fluid to evaporate may be utilized to determine when the working fluid needs to be re-filled and/or when a different working fluid may be communicated to the evaporative structure **104** to control the temperature of the tissue region.

The medical device **100** may be operable with a variety of different working fluids. For example, water, a liquid hydrocarbon or alcohol, halogenated hydrocarbons, ammonia, carbon dioxide, to name a few. In some non-limiting examples, the working fluid may be chosen based on a specific medical application, desired heat exchange rate, and/or range of operating temperatures. Since evaporative processes are substantially isothermal, the desired temperature range and heat transfer characteristics may be governed by the thermophysical properties of the working fluid. That is, the boiling point of the working fluid is known for a given pressure and temperature and, thus, an equilibrium temperature achieved by the medical device **100** may be determined based at least in part by the chemical composition of the working fluid. Table 1 below provides various non-limiting examples of the properties and operational characteristics of the medical device **100**.

TABLE 1

Properties and Operating Characteristics of the Medical Device 100	
Operating Range	−220° C. to 200° C.
Operating Pressure	0.01 bar to 10 bar
Working Fluids	Hydrocarbons, Hydrofluorocarbons, Hydrofluoroolefins, Alcohols, Water, Aqueous Solution, Nobel Gases, Binary Mixtures, Nanoparticle laden Fluids, Cryogenic Fluids: N_2, O_2, etc.
Substrate Material	Metals, Polymers, Composite Materials, Non-metallic elements E.G., Copper, Aluminum, Graphite, etc.
Evaporative Structure	Microgrooved, Fractional Pattern Microchannels, Nano-spheres E.G., Aluminum, Copper, Carbon, Steel, etc.
Evaporative Pore Size	100 nm-2000 μm
Coatings	Wetting or non-wetting coating, Gold, Teflon, Anodized Nano-Layers, Nano-structured coatings
Fluid Flow Control	Thermo-capillary, Piezo-electric, Expansion Valve, Capillary Tube, Electroosmotic Driven Flow, Electromotive Force
Temperature Control	Thermocouple, RTD, Embedded Contact Micro-wires

When implementing the medical cooling device **100** to cool a desired tissue region, the thermal characteristics of the desired tissue region combined with its structural-mechanics response to change in temperature may play a role in energy-based medical applications. For example, in the case of cryolipolysis, water and fat containing tissues may undergo a phase change as their temperature drops below the melting point for water and/or fat. This phase change (i.e., crystallization) is accompanied with two events in the thermal characteristics of the tissue as well as the energy balance during the cooling process. First, the thermal conductivity for the solid phase is higher than the liquid phase, therefore, the conduction heat transfer may be improved significantly as the frozen front moves into the non-frozen section of the desired tissue region. For example, water possesses a thermal conductivity of approximately four times higher in the solid phase (i.e., ice) when compared to liquid water. This increase in thermal conductivity may induce a cascade of accelerating affects as long as the heat removal capacity is not exceeded and while the distance from the cold surface is not imposing a large resistance on the heat flow. Second, the latent heat of the phase change released at the interface between the frozen and non-frozen sections of tissue may add a significant load to the total heat that should be removed from the desired tissue region. If the cooling capacity is limited, the cooling process is slowed down to match the maximum heat flow that could be dissipated.

These dynamic characteristics of the tissue, explained above, may only be noticed in circumstances where the heat flow from the desired tissue region to the cold surface is not limited by the capacity of the mechanism employed to provide the cooling effect. The two-phase cooling leveraged by the medical device **100** provides superior cooling performance and significantly increased cooling capacity when compared to conventional cooling mechanism (e.g., single-phase cooling, thermoelectric cooling, Joule-Thompson cooling, spray cooling, etc.). The extremely high cooling capacity of the medical device **100** turns the dynamic thermal behavior of the desired tissue region into an advantage to accelerate the progression of the frozen front, enhance the effectiveness of the thermal damage to the desired tissue region by increasing the energy removed from the unit volume of tissue per unit time, reduce the duration of a desired medical procedure, shrink the footprint of the overall medical device **100** and significantly reduce the total weight thereof, reduce the risk of undesired damage to

neighboring/non-target tissue, improve the reliability of the medical device **100** due to passive operation, increase the effective range (distance from the cold surface) that can be cooled, and improve the temporal and spatial accuracy in controlling and maintaining the temperature levels.

In some non-limiting examples, the medical device **100** may be configured to provide a step-wise, cyclic, or predetermined temperature profile as a function of time cooling approach by inducing cooling waves into the desired tissue region. For example, if a tissue region is required to be cooled to −10° C., the medical device **100** may be configured to start at an operating temperature of −5° C. and stay there for a first predetermined amount of time. After the first predetermined amount of time, the medical device **100** may be configured to transition to an operating temperature of −15° C. for a second predetermined amount of time. The operating temperature transition between −5° C. and −15° C. may be facilitated, for example, by changing the operating pressure of system and/or changing the working fluid and/or the flow rate of the working fluid, to name a few. Once the second predetermined amount of time has passed, the medical device **100** may be configured to transition back to an operating temperature of −5° C. for a third predetermined amount of time. In some non-limiting examples, the medical device **100** may cyclically continue to transition between −5° C., −15° C., and −5° C. operating temperatures until a total time for a given procedure is reached. The step-wise, or cyclic, transitions in operating temperature may enable the medical device **100** to more efficiently cool the tissue region to the desired −10° C. and reach the desired −10° C. temperature in less time, when compared to providing cooling at a constant −10° C.

In accordance with a non-limiting configuration, the use or method of use of the medical device **100** does not include a step of treatment of a human or animal body by surgery or therapy. It is noted that the skills of a person using a device as described herein, may not have the skills of a physician, and that the intended treatment may not be motivated due to illness of the treated person, rather for aesthetic reasons.

In some non-limiting examples, a suction device may be implemented to adhere the tissue region to the base **102**. The suction device may be in the form of a vacuum pump, or another device capable of generating a pressure lower than atmospheric pressure, to suction the tissue region onto the base **102**.

FIG. **2** illustrates another non-limiting example of the medical device **100** according to one aspect of the present disclosure. As illustrated in FIG. **2**, the medical device **100** may include a heat source **106**. In some non-limiting examples, the heat source **106** may be a resistive heater, a thin, transparent heater arranged between the base **102** and the tissue region, a thermoelectric heater, a microwave heater, an electromagnetic heater (e.g., infrared), an ultrasound heater, a radio frequency heater etc. In some non-limiting examples, the heat source **106** may leverage waste heat from another component (e.g., a laser) located externally from the base **102**.

The heat source **106** may be configured to selectively apply heat to the base **102** and/or a tissue region. In some non-limiting examples, the heat source **106** may be integrated into the base **102** to facilitate the selective heating of the base **102**. In some non-limiting examples, the heat source **106** may be located remotely from the base **102** and in thermal communication with the base **102** and/or a tissue region. In operation, the medical device **100** may be used to cool a tissue region for a given medical application, and the heat source **106** may subsequently heat the tissue region and/or an adjacent tissue region back to approximately room temperature. In some non-limiting application, the medical device **100** may freeze at least a portion of the tissue region (e.g., the surface of the tissue region) and the heat source **106** may be used to prevent sticking between the base **102** and the surface of the tissue region. For example, a thin, transparent heat source **106** may be arranged between the base **102** and the surface of the tissue region to facilitate quick removal of the medical device **100** from the surface of the tissue region after the desired cooling has been applied thereto.

FIG. **3** illustrates another non-limiting example of the medical device **100** according to one aspect of the present disclosure. As illustrated in FIG. **3**, the evaporative structure **104** may be in fluid communication with a fluid source **108**. The fluid source **108** may include a supply of working fluid that may be furnished to the evaporative structure **104**. In some non-limiting examples, the fluid source **108** may be a non-pressurized source (i.e., at approximately atmospheric pressure) of working fluid. In these non-limiting example, fluid contact of between the fluid source **108** and the evaporative structure **104** may be sufficient induce capillary forces that supply the evaporative structure **104** with the working fluid. In some non-limiting examples, the fluid source **108** may be configured to induce a pressure drop between the fluid source **108** and the evaporative structure **104** to furnish the working fluid into the evaporative structure **104**. In these non-limiting examples, the fluid source **108** may be configured to selectively furnish the working fluid into the evaporative structure **104** (e.g., when it is determined that the evaporative structure **104** requires more working fluid).

FIG. **4** illustrates another non-limiting example of the medical device **100** according to one aspect of the present disclosure. As illustrated in FIG. **4**, the medical device **100** may include a fluid control device **110** in communication with the fluid source **108** and/or the evaporative structure **104**. In some non-limiting examples, the fluid control device **110** may be configured to control a direction of the fluid flow between the fluid source **108** and the evaporative structure **104**, or the flow rate of the working fluid. For example, the fluid control device **110** may be in the form of a check valve configured to only allow fluid to flow from the fluid source **108** to the evaporative structure **104**.

In some non-limiting examples, the fluid control device **110** may be configured to control a pressure of the working fluid provided from the fluid source **108** to the evaporative structure **104**. For example, the fluid control device **110** may be in the form of a disposable charged cartridge that is configured to selectively increase the pressure of the working fluid flowing to the evaporative structure **104**. In this way, the fluid control device **110** may be utilized to control a cooling temperature output by the medical device **100** by varying the pressure of the working fluid within the evaporative structure **104**. Alternatively or additionally, the fluid control device **110** may include a pressure regulator configured to increase or decrease the pressure of the working fluid, as desired.

In some non-limiting examples, the fluid control device **110** may be configured to selectively provide fluid communication between the fluid source **108** and the evaporative structure **104**. For example, the fluid control device **110** may be in the form of an on/off valve configured to selectively provide fluid communication between the fluid source **108** and the evaporative structure **104** to activate and deactivate the cooling of a tissue region. It should be appreciated that the various forms of the fluid control device **100** described

herein may be combined, and the medical device **100** is not limited to the use of only one of the described functionalities.

FIG. **5** illustrates another non-limiting example of the medical device **100** according to one aspect of the present disclosure. As illustrated in FIG. **5**, the medical device **100** may include a condenser **112** in fluid communication with the evaporative structure **104**. The condenser **112** may be configured to facilitate the condensation of evaporated working fluid that flows from the evaporative structure **104**. In some non-limiting examples, the condenser **112** may be configured to provide a sufficient amount of heat removal or dissipation to the working fluid to effectuate the condensation thereof. The condenser **112** may be in fluid communication with the fluid source **108** to recapture the working fluid and provide it to the fluid source **108**. In other non-limiting examples, the condenser **112** may be configured to communicate the condensed working fluid to a reservoir, as will be described.

FIG. **6** illustrates another non-limiting example of the medical device **100** according to one non-limiting example of the present disclosure. As illustrated in FIG. **6**, the fluid control device **110** may be remotely in fluid communication (i.e., not arranged in-line with the fluid source **108**) with the working fluid downstream of the fluid source **108** and downstream of the evaporative structure **104**. This configuration may enable the fluid control device **110** to selectively control a pressure of the working fluid flowing into the evaporative section **104** (e.g., to control a cooling temperature provided by the medical device **100**) and/or control a pressure of the evaporated working fluid leaving the evaporative structure **104** (e.g., to control the condensing of the evaporated working fluid).

FIG. **7** illustrates another non-limiting example of the medical device **100** according to one aspect of the present disclosure. As illustrated in FIG. **7**, the evaporative structure **104** may be in fluid communication with the fluid source **108**, the condenser **112**, and a reservoir **114**. In some non-limiting examples, the reservoir **114** may be a tank or vessel at approximately atmospheric pressure that contains working fluid. In some non-limiting examples, the reservoir **114** may be tank or vessel either above or below atmospheric pressure that contains working fluid. The fluid source **108** may be configured to furnish the working fluid from the reservoir **114** to the evaporative structure **104** at a predetermined pressure and flow rate. In some non-limiting examples, the working fluid may flow continually from the fluid source **108** to the evaporative structure **104** through the condenser **112** and back to the reservoir **114**. In some non-limiting examples, the working fluid may be selectively provided to the evaporative structure **104**, as needed.

The thermal and thermodynamic characteristics of the medical device **100** enable the medical device **100** to be self-adapting, or self-regulating based on the heat input applied thereto. That is, the amount of working fluid evaporated within the evaporative structure **104** and subsequently condensed by the condenser **112** may be proportional to the heat input to the medical device **100** from the tissue. In this way, the medical device **100** may self-regulate the amount of evaporation and subsequent condensing of the working fluid to provide sufficient liquid working fluid to the reservoir **114** and fluid source **108**.

FIG. **8** illustrates another non-limiting example of the medical device **100** according to one aspect of the present disclosure. As illustrated in FIG. **8**, the evaporative structure **104** may be the form of a patterned evaporative structure **118**. The patterned evaporative structure **118** may be configured to provide a cooling pattern with varied heat flux to a tissue region. In some non-limiting examples, the mechanical structure of the patterned evaporative structure **118** may be tailored to spatially vary the heat dissipation flux provided by the medical device **100**. For example, a porosity of the patterned evaporative structure **118** may be designed to spatially vary the heat removal flux or capacity across the medical device **100**. Alternatively or additionally, a material of the base **102**, a coating of the base **102** or the patterned evaporative structure **118**, and/or an external coating applied between the base **102** and the tissue region may be designed to spatially vary the heat dissipation flux or profile of the medical device **100** to define a cooling pattern. In one non-limiting example, an antifreeze coating, or material, may be applied between the base **102** and the tissue region to protect certain areas within the tissue region from the cooling effect of the medical device **100** (e.g., to provide protection against freezing).

In some non-limiting examples, the medical device **100** may be configured to operate with a spatially varying operating temperature along the base **102**. For example, the base **102** may define a symmetrical operating temperature profile that increases in temperature from a centerline of the base **102** to first and second edges of the base **102**. In some non-limiting examples, the base **102** may define a symmetrical operating temperature profile that decreases in temperature from a centerline of the base **102** to first and second edges of the base **102**. In some non-limiting examples, the base **102** may define a varied operating temperature profile that conforms to any functional form, as desired.

FIG. **9** illustrates a non-limiting example of a tiled medical device **200** according to one aspect of the present disclosure. As illustrated in FIG. **9**, the tiled medical device **200** may include a plurality of the medical devices **100** arranged in an array, or tiled, pattern. It should be appreciated that the medical devices **100** may be arranged in any pattern as desired. In some non-limiting examples, the medical devices **100** may be linked via a mesh-like structure. In other non-limiting examples, the medical devices **100** may be individually mounted to an external structure. In any case, the medical devices **100** may be moveable to enable the tiled medical device **200** to conform to any anatomical region and/or to match any anatomical features, as desired. In some non-limiting examples, the medical devices **100** may be individually controlled within the tiled medical device **200** to enable the tiled medical device **200** to provide a predetermined cooling pattern. For example, the medical devices **100** may be provided with various working fluids to define different operating temperatures. Alternatively or additionally, the evaporative structures **104** within the medical devices **100** may be designed to provide different heat transfer properties. Alternatively or additionally, the bases **102** of the medical devices **100** may be coated and/or insulated to control the output temperature thereof. In some non-limiting examples, selective groups of the medical devices **100** within the tiled medical device **200** may be controlled to enable the tiled medical device **200** to provide a predetermined cooling pattern. For example, selective groups of the medical devices **100** within the tiled medical device **200** may be connected to different working fluid circuits, which enable the selective groups of the medical devices **100** to operate at different cooling temperatures.

It should be appreciated that the various non-limiting examples of the medical device **100** described herein are not necessarily separate in nature, and the medical device **100**

may be adapted to include any combination of the various non-limiting components and configurations described herein.

FIG. **10** illustrates one non-limiting example of the evaporative structure **104** according to one aspect of the present disclosure. In the non-limiting example of FIG. **10**, the evaporative structure **104** is integrated into the base **102**. The base **102** includes a plurality of fins **400** that extend from a first surface **402** of the base **102** to form a plurality of channels **404** therebetween. The channels **404** are configured to receive the working fluid and are dimensioned to ensure that liquid menisci are formed therein. During operation, for example, a second surface **406** of the base **102** may be brought into engagement with a tissue region. Heat energy from the tissue region may travel through the base **102** and the fins **400** to the liquid menisci formed in the channels **404** where the working fluid is evaporated. The integral effect of evaporation from all the menisci in the evaporative structure **104** provides the substantial heat removal capacity of the medical device **100**. The properties of the evaporative structure **104** may affect the rate of evaporation and thereby the overall heat removal capacity of the medical device **100**. For example, the number of channels **404**, the channel width W, the material of the base **102**, a coating applied to the base **102**, and a material applied to the exterior of the base **102** (i.e., between the base **102** and the tissue region) may all affect the overall cooling performance of the medical device **100**.

FIG. **11** illustrates another non-limiting example of the evaporative structure **104** according to the present disclosure. As shown in FIG. **11**, the evaporative structure **104** may be formed by a porous substrate **500**. In some non-limiting examples, the porous substrate **500** may be attached to, or removably positioned, on the first surface **402** of the base **102**. In some non-limiting examples, the porous substrate **500** may be attached to the first surface **402** of the base **102**. In any case, the porous substrate **500** includes a plurality of pores **502** that each act as sites to form menisci, once filled with the working fluid. During operation, for example, the second surface **406** of the base **102** may be brought into engagement with a tissue region. Heat energy from the tissue region may travel through the base **102** and the porous substrate **500** to the liquid menisci where the working fluid is evaporated. The properties of the porous substrate **500** may affect the rate of evaporation and thereby the overall heat removal capacity of the medical device **100**. For example, the number of pores **502**, the size of the pores **502**, the material of the porous substrate **500**, the material of the base **102**, a material applied to the exterior of the base **102** (i.e., between the base **102** and the tissue region), and a coating applied to the base **102** may all affect the overall cooling performance of the medical device **100**.

As described above, the medical device **100** may be in the form of a noninvasive medical device. FIGS. **12** and **13** illustrate one non-limiting example of a noninvasive medical device **600** configured to cool a tissue region via a two-phase heat transfer process in accordance with the systems and methods described herein. The noninvasive medical device **600** includes a base **602** having a first surface **604**, a treatment surface **606** arranged opposite to the first surface **604**, and a cooling cavity **608** formed in the base **602**. In some non-limiting examples, the base **602** may be fabricated from a metal material (e.g., aluminum, copper, brass, etc.). In some non-limiting examples, the base **602** may be fabricated from a graphite or woven material (e.g., carbon fiber).

In the illustrated non-limiting example, the base **602** includes two cooling cavities **608**. In other non-limiting examples, the base **602** may include more or less than two cooling cavities **608**. The cooling cavities **608** are formed by recesses that extend into the first surface **604** toward the treatment surface **606**. In the illustrated non-limiting example, the cooling cavities **608** define a generally rectangular shape. In other non-limiting examples, the cooling cavities **608** may define another shape (e.g., round, polygonal, etc.), as desired.

The cooling cavities **608** are configured to receive a porous substrate **610** therein. In some non-limiting examples, the porous substrate **610** may be fabricated from a metal (e.g., aluminum or copper), carbon fiber mesh material, or metal foam material. The porous substrates **610** includes a plurality of pores that each act as sites to form menisci, once filled with the working fluid. As described herein, the menisci may act as sites for the working fluid to evaporate from, in response to heat input from the desired tissue region in contact with the treatment surface **606**.

The geometric properties of the porous substrates **610** (e.g., a size of the pores) may be designed such that, once filled with working fluid, capillary forces maintain the working fluid therein regardless of the orientation of the noninvasive medical device **600**. That is, the capillary forces within the porous substrates **610**, once filled, may be greater than the force of gravity enabling the noninvasive medical device **600** to be used in any orientation without the threat of leakage of the working fluid.

The porous substrates **610** may be in engagement with at least a portion of the base **602**. In the illustrated non-limiting example, one or more posts **611** protrude upward from the bottom surface of the cooling cavities **608** to enhance contact between the base **602** and the porous substrates **610**. The posts **611** may be arranged throughout the cooling cavities **608** to aid the conductive heat transfer between the porous substrates **610** and the base **602**. In the illustrated non-limiting example, each of the cooling cavities **608** include six posts **611** staggered therealong. In other non-limiting examples, each of the cooling cavities **608** may include more or less than six posts **611** arranged in any pattern, as desired.

In the illustrated non-limiting example, the porous substrates **610** may be exposed to the surroundings (i.e., the noninvasive medical device **600** defines an open circuit with respect to the working fluid). This may allow the working fluid arranged within the porous substrates **610** to evaporate to the surroundings. In these non-limiting examples, the working fluid may be chosen to be chemically inert and/or safe for inhalation by the patient and/or the user. In some non-limiting examples, the porous substrates **610** may be pre-loaded with the working fluid. In some non-limiting examples, the porous substrates **610** may be quasi-open where porous substrates **610** are covered by a structure, which is exposed to the surroundings. The evaporated working fluid may travel along the structure and subsequently condense therein to enable at least a portion of the working fluid to be collected and recirculated, as desired. In some non-limiting examples, the porous substrates **610** may be sealed from the surroundings to provide a closed circuit for the working fluid. That is, the working fluid may be provided to the noninvasive medical device **600** from a sealed reservoir, and the evaporated working fluid may be captured from the sealed cooling cavities **608** and subsequently condensed either actively (e.g., via a condenser) or passively (e.g., via heat transfer with the surroundings). The condensed working fluid may be fluidly communicated back to the sealed

reservoir. Thus, in the closed circuit, the working fluid may not be exposed to the surroundings thereby enabling the use of chemically active working fluids that may be potentially harmful in an open circuit.

The cooling cavities **608** and thereby the porous substrates **610** are connected to a port **612** via first and second channels **614** and **616**. The port **612** and the first and second channels **614** and **616** are recessed into the first surface **604**. During operation, the port **612** may be configured to be connected to a supply of working fluid. The working fluid may flow from the port **612** along the channels **614** and **616** to the cooling cavities **608** and into the porous substrates **610**.

In some non-limiting examples, a disposable charged cartridge (not shown) may be provided to control a pressure of the working fluid within the noninvasive medical device **600**. For example, the charged cartridge may be in fluid communication with the working fluid upstream of the cooling cavities **608**, and configured to selectively increase a pressure of the working fluid flowing into the cooling cavities **608**. Alternatively or additionally, the charged cartridge may be in fluid communication with the noninvasive medical device **600** downstream of the cooling cavities **608**, for example, to effectuate condensation of the working fluid.

During operation of the closed circuit configuration of the noninvasive medical device **600**, for example, a working fluid may be supplied to the noninvasive medical device **600** to fill the porous cavities **608**. In some non-limiting examples, the capillary forces provided by the design of the porous substrates **610** may cause the working fluid to flow therein without the requirement of an externally induced pressure differential. Thus, working fluid may be supplied to the port **612** and the working fluid may be naturally (i.e., without external forces) drawn into the porous substrates **610**.

Once the porous substrates **610** are filled with the working fluid, the noninvasive medical device **600** may be positioned such that the treatment surface **606** engages a desired tissue region of a patient. The engagement of the treatment surface **606** with the desired tissue region initiates heat transfer between the noninvasive medical device **600** and the desired tissue region. Specifically, heat from the desired tissue region transfers through the treatment surface **606** and to a bottom surface of the cooling cavities **608**. From the bottom surface of the cooling cavities **608**, the heat transfers through the porous substrates **610** to the liquid menisci where evaporation of the working fluid due to the heat input from the tissue region. The integral effect of evaporation from all the menisci in the porous substrates **610** provides the noninvasive medical device **600** with substantial heat removal capacity (i.e., heat flux capacity) when compared to conventional medical cooling technologies.

As described above, in some non-limiting examples, the noninvasive medical device **600** may define a closed circuit with respect to the working fluid. FIGS. **14**A-**15** illustrate a illustrate non-limiting example of the noninvasive medical device **600** that implements a closed circuit with respect to the working fluid. As illustrated in FIGS. **14**A and **14**B, the noninvasive medical device **600** may include a condensing plate **629** and defines a flow path **618** on one side thereof and a condensing structure **631** on another side thereof. The flow plat **618** extends from an inlet port **620** to an outlet port **622**. The flow path **618** may be recessed into one side of the condenser plate **629** and define a shape that covers a desired amount of the surface area of the base **602**. In the illustrated non-limiting example of FIG. **14**A, the flow path **618** extends from the inlet port **620** in a generally straight path toward an opposing end of the condensing plate **629** and, adjacent to the opposing end of the condensing plate **629**, the flow path **618** curves in a direction toward a center of the condensing plate **629**. The flow path **618** then extends in a direction back toward the end of the condensing plate **629** on which the inlet port **620** is arranged in a generally swirl-like pattern. That is, the flow path **618** curves back and forth as it extends toward the inlet end of the base **602**. Once the swirl section of the flow path **618** reaches the inlet end of the condensing plate **629**, the flow path **618** curves in a curves in a direction away from the inlet port **620** and extends in a generally straight path to the outlet port **622**.

It is to be appreciated that the illustrated flow path **618** is but one non-limiting example and that the flow path **618** may be shaped to cover a desired amount of the condensing plate, as desired. For example, the flow path **618** may be shaped to uniformly cover a substantial amount of the total surface area of the condensing plate **629**. In other non-limiting examples, the flow path **618** may be shaped to cover a selected section of the surface area of the condensing plate **629** where cooling is desired.

As illustrated in FIG. **14**B, the other side of the condensing plate **629** include the condensing structure **631**. In the illustrated non-limiting example, the condensing structure **631** includes a plurality of ridges **633** arranged along a recessed surface **635**. The plurality of ridges **633** protrude outwardly from the recessed surface **635** and extend in a lateral direction between first and second ends **637** and **639** of the condensing plate **629**. In some non-limiting example, the plurality of ridges **633** may act as fins to promote addition heat transfer from the fluid flowing through the flow path **618**, which acts to aid in condensing of evaporated working fluid, as will be described.

FIG. **15** illustrates a evaporative plate **641** of the noninvasive medical device **600** with a closed circuit. As illustrated in FIG. **15**, the evaporative plate **641** includes an evaporative structure **624** arranged on a side thereof opposite to the treatment surface **606**. In the illustrated non-limiting example, the evaporative structure **624** may include a plurality of ridges **626** that protrude outwardly from a recessed surface **643** in a direction away from the treatment surface **606**. The plurality of ridges **626** may extend in a lateral direction between first and second ends **628** and **630** of the recessed surface **624**, and may be arranged along the recessed surface **624** between the inlet port **620** and the outlet port **622**. In some non-limiting examples, the plurality of ridges **626** may extend varying lateral distances between the first and second ends **628** and **630**. For example, the plurality of ridges **626** may alternate between a first ridge **632** and a second ridge **634** between the inlet port **620** and the outlet port **622**. The first ridge **632** may extend from a center of the recessed surface **624** to a location between the center and each of the first and second ends **628** and **630** (i.e., the first ridge **632** does not extend completely between the first and second ends **628** and **630**). The second ridge **634** may extend completely between the first and second ends **628** and **630**. In some non-limiting examples, a distance between adjacent ridges **632** and **634** may ensure that capillary forces maintain the working fluid therebetween. Therefore, the different lateral extensions between the first ridge **632** and the second ridge **634** may maintain the working fluid along a centerline of the evaporative plate **641**. In other non-limiting examples, the design of the evaporative structure **641** may be altered to accommodate any desired cooling pattern, for example, by manipulating the arrangement and orientation of the ridges **632**, **634**. In some non-limiting examples, the evaporative structure **641** may be

in the form of a porous structure, as described herein. In some non-limiting examples, the evaporative structure **641** may be in the form of one or more microchannels that extend along the recessed surface **624**.

Both of the condenser plate **629** and the evaporative plate **641** may include a recessed notch **636** that extends therein and surrounds the flow path **618**, the condensing structure **631**, and the evaporative structure **624**. The recessed notches **636** may be configured to receive a seal (e.g., an o-ring or gasket) therein to facilitate forming a seal between a cover plate attached to the each of the sides of the condenser plate **629** and the non-treatment side of the evaporative plate **641**.

As illustrated in FIGS. **16** and **17**, the noninvasive medical device **600** may, when assembled, include an insulated layer **640** arranged around a periphery thereof. In some non-limiting examples, the insulated layer **640** may aid in inhibiting heat from dissipating from the noninvasive medical device **600** to the atmosphere, and may provide protection for a user manipulating the noninvasive medical device **600**. Additionally, the noninvasive medical device **600** may include a charging port that enables the working fluid to be charged into the device (i.e., flow into the area between the evaporative structure **641** and the condensing structure **631**. When assembled, the condenser plate **629** may be attached to the condenser plate **641** such that the evaporative structure **624** faces the condensing structure **631**. Thus, when assembled, one side of the device includes the treatment surface **606**, which is thermally coupled to the evaporative structure **624**, and a cover plate may be arranged on the other side, which covers the flow path **618**.

During operation of the closed circuit configuration of the noninvasive medical device **600**, for example, working fluid may be charged into a cavity formed between the evaporative structure **624** and the condensing structure **631**. Once charged, this cavity may be sealed off, thereby closing the working fluid off from the surroundings. When the treatment surface **606** is placed in contact with a desired tissue region, heat transfer initiates between the desired tissue region and the evaporative structure **624**. Specifically, heat from the desired tissue region transfers through the treatment surface **606** and to the working fluid flowing within the evaporative structure **624**. The heat input from the desired tissue region facilitates the evaporation of the working fluid which can come into contact with the condensing structure **631**. Evaporation of the working fluid flowing within the evaporative structure **624** enables the noninvasive medical device **600** to leverage the advantages of two-phase heat transfer processes described herein. Thus, the noninvasive medical device **600** provides substantial heat removal capacity (i.e., heat flux capacity) when compared to conventional medical cooling technologies.

During operation of the device, cooling fluid may be flown through the flow path **618**, which is isolated from the working fluid. Thus, as the evaporated working fluid builds up around the condensing structure **631**, the cooling provided by the fluid flowing through the flow path **618** may provide the necessary heat removal to facilitate condensing of the evaporated working fluid and result in the condensed working fluid "raining down" onto the evaporative structure **624**.

FIG. **18** another non-limiting example of the noninvasive medical device **600** implemented in a thermal treatment application. As illustrated in FIG. **18**, the noninvasive medical device **600** may define an open system with respect to the working fluid (i.e., the working fluid is provided to the device and recovered from the device) and the device does not include a condensing stage within the base **602** (i.e., the condensing stage happens remotely from the base **602**, which is in contact with the tissue region). The noninvasive medical device **600** may be configured to receive working fluid from a tank **603**. A inlet line **613** extends between the tank **603** and an inlet to the evaporative structure **610**, **624** to provide fluid communication therebetween. A flow control device **110**, **605** may be arranged on the inlet line **613** between the tank **603** and the inlet to the evaporative structure **610**, **624** In some non-limiting examples, the flow control device **110**, **605** may be configured to control a direction of fluid flow, a pressure of fluid flow, and/or a flow rate. From the inlet to the evaporative structure **610**, **624**, the working fluid can flow along the evaporative structure **624** and remove heat from the tissue region, which results in evaporation of the working fluid. Thus, the noninvasive medical device **600** provides substantial heat removal capacity (i.e., heat flux capacity) when compared to conventional medical cooling technologies.

The evaporated working fluid may flow through an outlet to the evaporative structure **610**, **624** and into an outlet line **615**. From the outlet line **615**, the evaporated working fluid may be condensed in a condenser **609** and subsequently stored in a tank **611**.

In the illustrated non-limiting example, a controller **607** is in communication with one or more temperature sensors arranged to measure temperature adjacent to or on a surface of the desired tissue region. The controller **607** may instruct the flow control device **110**, **605** to adjust the operating parameters of the noninvasive medical device **600** based at least in part on the measurement of the temperature sensors. Several parameters may be used to control the thermal output parameters of the noninvasive cooling **600**, as described herein.

In some non-limiting examples, the noninvasive medical deice **600** may be utilized with a flexible blanket **645** that is convers and seals around the noninvasive device **600**. A space between the flexible blanket **645** and the noninvasive medical device **600** may be in communication with a vacuum **647** that is configured to reduce a pressure within this space. Due to the form factor of the noninvasive medical device **600** (e.g., thin), the connection to the vacuum **647** may maintain thermal contact between the tissue surface and the treatment surface **606**, prevent thermal disturbance from the surroundings (i.e., insulation), suppress blood flow in the tissue region, and accelerate cooling or heating of the target tissue.

In some non-limiting examples, as illustrated in FIG. **20**, the noninvasive medical device **600** may be provided with an adhesive layer **621** that is adhesively attached to the treatment surface **606**. An anti-freeze **623** layer may be provided between the adhesive layer **621** and a removable sheet **625**. The anti-freeze layer **623**. The removable sheet **625** may be a disposable component that is applied to a desired tissue region and disposed of after a desired medical treatment is performed. In this way, the sterility of the noninvasive medical device **600** may be maintained.

In some non-limiting examples, as illustrated in FIG. **21**, a thin heater **627** may be integrated into the removable sheet **625** to melt any frozen sticking between the treatment surface **606** and the tissue surface **606** and enable the detachment of the noninvasive medical device **600** from the tissue surface. In some non-limiting examples, as illustrated in FIG. **22**, the thin heater **627** may be not be a disposable component and may be arranged between the adhesive layer **621** and the anti-freeze layer **623**.

In all of the configurations of the noninvasive medical device **600**, the treatment surface **606** may be configured to

conform to a specific tissue region on a patient. In some non-limiting examples, the treatment surface **606** may be coated with a coating. The coating applied to the treatment surface **606** may fabricated from a material configured to correspond with the thermophysical properties of the base **602** and/or the working fluid within the porous substrates **610**. In the non-limiting example of FIG. **13**, the treatment surface **606** defines a generally arcuate or curved surface with a generally rectangular profile. In the non-limiting example of FIG. **17**, the treatment surface **606** defines a generally flat surface with a generally rectangular profile. In other non-limiting examples, the treatment surface **606** may define a generally convex shape, as shown in FIG. **23**. In some non-limiting examples, the treatment surface **606** may define a generally smooth, or uninterrupted profile. In some non-limiting examples, the treatment surface **606** may define a rough, or interrupted, profile. For example, the treatment surface **606** may include a structural pattern arranged thereon to increase a surface area thereof. FIG. **24** illustrates one non-limiting example of a structural pattern of the treatment surface **606** that includes a plurality of alternating peaks and valleys. FIG. **25** illustrates one non-limiting example of the treatment surface **606** including a plurality of protrusions, or pins, **642** extending therefrom.

In some non-limiting examples, the base **602** or treatment surface **606** may define a generally horseshoe shape, as shown in FIG. **26**. In some non-limiting, examples, the base **602** or treatment surface **606** may define a generally banana, or crescent moon, shape, as shown in FIG. **27**. In some non-limiting examples, the base **602** or treatment surface **606** may define a generally annular shape, as shown in FIG. **28**. In these non-limiting examples, a suction device may be configured to draw a tissue region into a central aperture defined by the base **602**.

In some non-limiting examples, the noninvasive medical device **600** may be operable to provide cooling to an uneven, or non-uniform, tissue surface. For example, as shown in FIG. **29**, a tissue surface **644** may include one or more recesses **646** arranged thereon. In these non-limiting examples, a material (e.g., a gel or foam) **648** may be applied to the tissue surface within the recess **646** to fill the recesses **646**. The material may be configured to selectively protect, or insulate, the tissue recesses **646**. In some non-limiting examples, the material **648** may define a thermal conductivity that is less than or equal to a thermal conductivity defined by the tissue surface **644** (e.g., skin). By applying the material, for example, to the skin to fill, and insulate, the recesses **646**, the treatment surface **606** of the noninvasive medical device **600** may only provide cooling to the areas between, or around, the recesses **646**, which contact the treatment surface **606**.

In some non-limiting examples, as shown in FIG. **30**, a tissue surface **650** may include one or more protrusions **652** arranged thereon. The material (e.g., a gel or foam) **648** may be applied in a pool around the protrusion **652** to selectively protect, or insulate, the tissue surface **650** adjacent to the protrusion **652**. By applying the material **648** in a pool around the protrusion **652**, the treatment surface **606** of the noninvasive medical device **600** may only provide cooling to the protrusion **652**.

In accordance with a non-limiting configuration, the use or method of use of the noninvasive medical device **600** does not include a step of treatment of a human or animal body by surgery or therapy. It is noted that the skills of a person using a device as described herein, may not have the skills of a physician, and that the intended treatment may not be motivated due to illness of the treated person, rather for aesthetic reasons.

Various parameters of the noninvasive medical device **600** may be altered to control the heat removal capacity and operating temperature range based on the application. For example, the material of the base **602**, the material of the porous substrates **610**, the size of the pores, porosity in the porous substrates **610**, the geometry of the fluid path **618**, the thermophysical properties of the working fluid, the geometric properties of the cooling cavities **608**, etc. Table 2 below provides various non-limiting examples of the properties and operational characteristics of the noninvasive medical device **600**.

TABLE 2

Properties and Operating Characteristics of the Noninvasive Medical Device 600

Operating Range	−200° C. to 200° C.
Operating Pressure	0.01 bar to 10 bar
Working Fluids	Hydrocarbons, Hydrofluorocarbons, Alcohols, Water, Aqueous Solution, Nobel Gases, Binary Mixtures, Nanoparticle laden Fluids
Substrate Material	Metals, Polymers, Composite Materials
Porous Substrate Material	Examples: Copper, Aluminum, Graphite Aluminum, Copper, Carbon, Steel
Porous Substrate Pore Size	100 nm-2000 μm
Coatings	Wetting or non-wetting coating, Gold, Teflon, Anodized Nano-Layers, Nano-structured coatings
Fluid Flow Control	Thermo-capillary, Piezo-electric, Expansion Valve, Capillary Tube
Temperature Control	Thermocouple, RTD, Embedded Contact Micro-wires

As described above, the medical device **100** may be in the form of an invasive medical device. FIG. **31** illustrates one non-limiting example of an invasive medical device **700** configured to cool or heat a tissue region via a two-phase heat transfer process in accordance with the systems and methods described herein. In the illustrated non-limiting example, the invasive medical device **700** may be in the form a needle or an arrangement of needles (either fixed or expandable), which may include an introducer (not shown) to control a penetration depth of the invasive medical device **700**. In other non-limiting examples, the invasive medical device **700** may be in the form of a catheter based device.

The invasive medical device **700** includes a proximal end **702**, a distal end **704**, an inner surface **706**, and an outer surface **708**. The proximal end **702** may be coupled to the introducer (not shown). The distal end **704** includes a needle tip **710** to facilitate penetration into a desired tissue region of a patient. The inner surface **706** includes one or more channels **712** formed therein. In some non-limiting examples, the inner surface **706** may be coated with a material (e.g., a single layer of graphite, or graphene) that possesses a desired surface characteristics such as wetting properties, high surface tension, etc.

The invasive medical device **700** may define an insulated length L_I that may include, for example, an insulated coating to inhibit heat transfer to and from surrounding tissue. The insulated length L_I may be defined at any axial length along the outer surface **708**, as desired. In some non-limiting examples, the insulated length L_I may extend axially from

the proximal end **702** to a location between the proximal end **702** and the distal end **704** to insulate tissue adjacent to a surface of the desired tissue region.

The invasive medical device **700** may define a thermally active length L_T that is configured to be exposed to the desired tissue region at a desired depth within the tissue region to facilitate cooling of the desired tissue region at the desired depth. The thermally active length L_T may define any length along the outer surface **708**, as desired. In some non-limiting examples, the thermally active length may extend axially from the distal end **704** to a location between the distal end **704** and the proximal end **702** to cool tissue below a surface of the desired tissue region.

With specific reference to FIGS. **32-35**, the channels **712** are recessed radially into the inner surface **706** and extend axially along the inner surface **706** between the proximal end **702** and the distal end **704**. The inner surface **706** defines a generally hollow cavity **714** configured to receive a working fluid therein. During operation, for example, the hollow cavity **714** of the invasive medical device **700** may be filled with a working fluid. The invasive medical device **700** may then be inserted into a desired tissue region to a desired depth within the tissue region. In some non-limiting examples, the axial arrangements of the insulated length L_I and the thermally active length L_T may determine a treatment depth to which the cooling extends within the desired tissue region.

Once the outer surface **708** is brought into contact with and/or inserted into the desired tissue region, the working fluid within the cavity **714** starts to evaporate thereby initiating the cooling of the desired tissue region to a target temperature. As the working fluid evaporates, vapor V flows out of the cavity **714** while working fluid flow L is maintained within the channels **712** to facilitate the continuous cooling of the desired tissue region. The design of the channels **712** within the inner surface **706** is configured to maintain working fluid flow within at least a portion of the channels **712** toward the distal end **704**, and prevent dry-out, against the friction to fluid flow within the channels **712**. The driving force to induce working fluid to flow into the channels **712** is maintained by the gradient in liquid pressure along the channels **712** as they extend axially along the inner surface **706**. The pressure gradient is induced by the change in capillary pressure that results from the change in the structure of the channels **712** as they extend axially along the inner surface **706** toward the distal end **704**. Specifically, as shown in FIGS. **33-35**, the average radius for liquid meniscus within the channels **712** decreases step-wise as the channels **712** extend axially along the inner surface **706** toward the distal end **704**. In the illustrated non-limiting example, the decrease in the meniscus radius within the channels **712** may be facilitated by an increase in the circumferential distribution of the channels **712** as the channels **712** extend axially along the inner surface **706**. That is, the number of channels **712** arranged circumferentially around the inner surface **706** may increase step-wise as the channels **712** extend axially toward the distal end **704**. Thus, the design of the invasive cooling device **700** ensures that working fluid flow is maintained within at least a portion of the channels **712** along the inner surface **706** to provide evaporative cooling to the desired tissue region throughout the cooling process.

In some non-limiting examples, the channels **712** may define a continuous flow path as they increase in circumferential disbursement axially along the invasive medical device **700**. That is, the channels **712** adjacent to the proximal end **702** (FIG. **33**) may branch into the channels **712** in between the proximal and distal ends **702** and **704** (FIG. **34**), which may then branch into the channels **712** adjacent to the distal end **704** (FIG. **35**). In some non-limiting examples, the channels **712** may be at least partially discontinuous as they increase in circumferential disbursement axially along the invasive medical device **700**.

In some non-limiting examples, the invasive medical device **700** may, instead of the channels **712**, include a plurality of microspheres arranged within an inner cavity defined by the inner surface. The microspheres with varying diameters may be arranged at different locations axially along the inner cavity. For example, microspheres with the smallest diameter may be provide axially along a portion of the inner cavity adjacent to the needle tip **710**, microspheres with the largest diameter may be provided axially along a portion of the inner cavity adjacent to the proximal end **702**, and microspheres with a medium diameter may be provided between the smallest diameter and largest diameter microspheres. In this way, the varying diameters may draw the working fluid into the inner cavity by capillary forces and enable the evaporation of the working fluid therein.

In some non-limiting examples, the invasive medical device **700** may be combined with a heating to provide varying thermal characteristics axially therealong. For example, the a top portion of the invasive medical device **700** may be provided with one of the various evaporative structures described herein and a bottom portion of the invasive medical device may be provided with a heat source (e.g., RF heating) to provide a combined heating a cooling effect. For example, the cooling effect may mitigate pain associated with the heating effect.

In some non-limiting examples, the invasive medical device **700** may be arranged into an array to, for example, to be implemented in a fractional medical treatment.

In accordance with a non-limiting configuration, the use or method of use of the invasive medical device **700** does not include a step of treatment of a human or animal body by surgery or therapy. It is noted that the skills of a person using a device as described herein, may not have the skills of a physician, and that the intended treatment may not be motivated due to illness of the treated person, rather for aesthetic reasons.

Various parameters of the invasive medical device **700** may be varied to control the heat removal capacity and operating temperature range based on the application. For example, the pattern of the channels **712** on the inner surface **706**, the thermophysical properties of the working fluid, the material of the noninvasive medical device **700**, and the coatings on the inner surface **706** and the outer surface **708**. It should be appreciated that the control of the cooling capacity of the invasive medical device **700** may be more constrained than the noninvasive medical devices described herein. That is, the significantly increased cooling capacities provided by the two-phase heat transfer process leveraged by the systems and methods described herein may require specific attention to the cooling capacity of the invasive medical device **700** to prevent tissue damage. Table 3 below provides various non-limiting examples of the properties and operational characteristics of the invasive medical device **700**.

TABLE 3

Properties and Operating Characteristics of the Invasive Medical Device 700

Operating Range	−220° C. to 200° C.
Operating Pressure	0.1 bar to 10 bar
Working Fluids	Hydrocarbons, Hydrofluorocarbons, Hydrofluoroolefins, Water, Aqueous Solution, Binary Mixtures, Cryogenic Fluids: N_2, O_2
Needle Material	Metals, Non-metallic elements, Composite Materials Examples: Copper, Aluminum, Graphite
Needle-Wall-Internal Structure	Microgrooved, Fractional Pattern Microchannels, Nano-Spheres
Porous Substrate Pore Size	100 nm-20 μm
Needle Internal Wall Coatings	Wetting or non-wetting coating, Gold, Anodized Nano-Layers
Fluid Flow Control	Electroosmotic Driven Flow, EMF, Piezo-electric, Capillary Tube
Fluid Injection	Direct Heat Exchange, Micro-nozzles for enhanced mixing
Temperature Control	Thermocouple, RTD, Embedded Contact Microwires

As described above, the medical device **100** may be in the form of a noninvasive medical device. FIGS. **36** and **37** illustrate another non-limiting example of a noninvasive medical device array **900** configured to cool a tissue region via a two-phase heat transfer process in accordance with the systems and methods described herein. In the illustrated non-limiting example, the noninvasive medical device array **900** may be implemented to provide cooling adjacent to locations subjected to a fractional damage or injury pattern. In some non-limiting examples, the fractional damage or injury pattern may be created through the use of electromagnetic energy (e.g., a laser), radiofrequency needle, coring need, or other device that causes tissue damage either through heating, mechanical disruption, ultrasound or other methods of causing tissue damage. The noninvasive medical device array **900** may be comprised of a base **901** having a plurality of openings **912** arranged therein to accommodate a fractional treatment pattern. In the illustrated non-limiting example, the base **901** includes a plurality of array tiles **902**. Each of the array tiles **902** includes a plurality of array units **904** that are configured to provide cooling to a tissue region adjacent to the fractionally heated tissue.

The array units **904** include a proximal end **906**, a distal end **908**, and a plurality of channels **910** arranged thereon. The proximal end **906** is configured to be arranged adjacent to the fractionally heated tissue. When assembled, the proximal ends **906** are configured to combine to create an opening **912** through which the fractional treatment may be performed. That is, the openings **912** formed by the assembled proximal ends **906** of the array units **904** provides access to the tissue region in a desired fractional pattern. The number of openings **912** and orientation of the openings **912** formed by the noninvasive medical device array **900** is not meant to be limiting in any way, and the array tiles **902** may be modularly arranged to create any fractional pattern, as desired.

The distal ends **908** may be in fluid communication with a fluid source **914**. In the illustrated non-limiting example, the fluid source **914** may be an accumulation, or pool, of working fluid. The working fluid may be naturally drawn into the channels **910** and flow therethrough based on the capillary pressure induced by the design of the channels **910**. The channels **910** may extend varying lengths along the array unit **904** from the proximal end **906** to a location between the proximal end **906** and the distal end **908**. In this way, number of channels **910** for the working fluid to flow through increases as the fluid is drawn from the distal end **908** to the proximal end **906** on each of the array units **904**. Since the array units **904** define a fixed width, as the number of channels **910** for the working fluid to flow through increases, a channel width experienced by the fluid flowing through the channels **910** along the array units **904** may decrease. This decrease in channel width may induce the capillary pressure necessary to draw the working fluid from the fluid sources **914** to the proximal ends **906**, thereby filling the channels **910** of each array unit **904** with working fluid. Once filled with working fluid, each of the channels **910** within array units **904** may form menisci to facilitate the evaporation of the working fluid. The evaporation of the working fluid from the channels **910** may remove heat conductively from the array units **904**.

In operation, the noninvasive medical device array **900** may be placed in contact with a tissue region that will be subjected to a fractional medical treatment that will result in heating of the tissue in a fractional pattern. The noninvasive medical device array **900** is modularly constructed to enable the array tiles **902** to be arranged in any fraction pattern to conform to the desired medical treatment. Once constructed in the desired fraction pattern, the fluid source **914** may be placed in fluid communication with the distal ends **908** of the array units **904** to fill the channels **910** with working fluid. The working fluid within each of the channels **910** can form menisci along the channels **910** to promote the evaporation of the working fluid within the channels **910**. Heat may be absorbed from the tissue region and transferred through the array units **904** to the working fluid within the channels **910** where the heat input may facilitate the evaporation of the working fluid at the menisci formed therein. The heat absorbed from the tissue region may cool the tissue region in the areas where the array units **904** contact the tissue region. The openings **912** formed by the array tiles **902** enable the fractional medical or cosmetic treatment (e.g., incident laser light) to be performed on the tissue region, while the tissue adjacent to, or around, the openings **912** are cooled by the noninvasive medical device array **900**. As is known in the art, it is imperative to ensure that tissue between regions of fractional treatment remain undamaged to promote healing. Furthermore, the cooling provided by the noninvasive medical device array **900** may provide an anesthetic effect. Thus, the noninvasive medical device array **900** may add to the efficacy, safety, comfort, and/or tolerability of fractional medical treatments.

FIGS. **38** and **39** illustrate another non-limiting example of the noninvasive medical device array **900** that may be implemented to provide cooling adjacent to locations subjected to a fractional damage or injury pattern using a two-phase heat transfer process in accordance with the systems and methods described herein. As illustrated in FIGS. **38** and **39**, the noninvasive medical device array **900** includes the plurality of openings **912** arranged in a desired fractional pattern. The plurality of openings **912** may be dimensioned to enable, for example, a laser beam **916** to propagate therethrough and subject a tissue region **918** to a fractional treatment (e.g., ablation).

In general, the individual areas on the surface of the tissue region **918** subjected to the laser beam **916** may be very small. In addition, the laser beam **916** may deliver large amounts of energy in short bursts of time. Thus, the neigh-

boring areas of the tissue region **918** not subjected to the laser beam **916** require large amounts of heat to be dissipated in a short amount of time to prevent the formation of hot spots, which may undesirably damage the neighboring tissue. Due to the two-phase heat transfer process leveraged by the noninvasive medical device array **900**, any growing temperature gradients forming in the tissue neighboring the plurality of openings **912** may be decayed rapidly by localized high flux evaporation of a working fluid within the noninvasive medical device array **900**.

In the illustrated non-limiting example, the noninvasive device array **900** may include a top plate **920**, a bottom plate **922**, and an evaporative structure **924** arranged between the top plate **920** and the bottom plate **922**. The top plate **920** and the bottom plate **922** may be fabricated from a metal material (e.g., aluminum) and may provide a seal around the plurality of openings **912**. In some non-limiting examples, the evaporative structure **924** may be open to the atmosphere along the sides thereof to facilitate the introduction of the working fluid therein. In some non-limiting examples, the evaporative structure **924** may comprise a plurality of microchannels or a porous substrate (e.g., a metal foam). In any case, the evaporative structure **924** is configured to be filled with a working fluid (e.g., by placing the working fluid in fluid communication with the evaporative structure **924** and allowing capillary forces to draw the working fluid into the evaporative structure **924**). Once filled with the working fluid, the evaporative structure **924** may be in its thermodynamic equilibrium with its own pure vapor.

During a fractional ablation procedure, for example, a high flux is introduced by the laser beam **916** at the onset of ablation. As the laser beam **916** drills deeper into the tissue region **918**, the high temperature area on the surface of the tissue region **918** begins to spread radially through the tissue region **918** at each of the fractional sites (i.e., adjacent to each of the plurality of openings **912**). This heat spread continues to propagate through the tissue region **918** at each of the fractional sites long after the laser beam **916** has been removed. Without sufficient cooling applied to the areas neighboring the fractional sites, the thermal damage area may grow quickly into the neighboring areas, as an undesirable side effect.

The noninvasive medical device array **900** illustrated in FIGS. **38** and **39** provides a heat transfer path with an extremely small resistance compared to the alternative path (i.e., through the tissue). Therefore, heat is conducted to from the tissue region **918** to the bottom plate **922** and into the evaporative structure **924**. The heat in the desired tissue region **918** in contact with the bottom plate **922** is rapidly removed and spread by the immediate evaporation of the working fluid within the evaporative structure. The evaporative structure **924** may maintain the working fluid in liquid form over the entire surface of the bottom plate **922** to ensure uniform evaporative cooling capacity as the laser beam **916** encounters the surface of the tissue region **918**. For example, evaporated working fluid may condense once it contacts the top plate **920** and the condensed working fluid may fall back into the evaporative structure **924**. In the illustrated non-limiting example, the noninvasive medical device array **900** may operate passively and may not include any moving parts, which provides an advantage over conventional medical cooling technologies.

Various parameters of the noninvasive medical device array **900** may be altered to control the heat removal capacity and operating temperature range based on the application. For example, the material of the array units **904**, the number and arrangement of the array units **904**, the width of the channels **910**, the thermophysical properties of the working fluid, etc. It should be appreciated that the properties and operating characteristics of the noninvasive medical device **600** in Table 2 may apply to the noninvasive medical device array **900**.

In accordance with a non-limiting configuration, the use or method of use of the noninvasive medical device array **900** does not include a step of treatment of a human or animal body by surgery or therapy. It is noted that the skills of a person using a device as described herein, may not have the skills of a physician, and that the intended treatment may not be motivated due to illness of the treated person, rather for aesthetic reasons.

In some non-limiting examples, the design and properties of the noninvasive medical device array **900** provide several advantages in addition to the significantly increased cooling capacity described herein. For example, the noninvasive medical device array **900** may be fabricated from an opaque mesh structure that protects tissue oriented under the mesh structure from being subjected to the electromagnet energy. While the mesh is opaque to the electromagnetic energy, the openings within the mesh do not create any losses in the transmission of the electromagnetic energy to the surface of the tissue region, which is not true when sprays or sapphire cooling systems are used. In some non-limiting examples, the noninvasive medical device array **900** provides a framework for delivering a distributed but localized pressure to the surface of the tissue region. This substantially increases the pressure applied to a given location subjected to the mesh. To this end, the framework may provide constriction of blood flow due to the pressure applied, and constriction of nerve signals from tissue oriented distally from the brain with the framework located more proximally.

In addition to the non-limiting examples of the noninvasive medical device array **900** described herein, the noninvasive medical device array **900** may be formed of tubes that facilitate evaporative cooling with the tubes extending to form a mesh across the surface of the tissue region. In this case, the diameter and distribution of the tubes may be selected to create a mesh having parameters in ratios that are selected to optimize parameters, such as cooling, pressure, protected tissue surface area, amount of time dedicated to pre-cooling of the tissue before laser application, and the like.

In some non-limiting applications, the noninvasive medical device array **900** may be used with other therapeutic systems, such as needles or surgical devices (e.g., biopsy systems and the like). Cooling, tissue protection, and pressure application to constrain blood flow, or nerve signal conduction may be used in conjunction with needle application through the openings in the mesh or surgical devices extended through the openings in the mesh, such as biopsy devices extended through the device or the like.

Regardless of the particular clinical application being performed, the noninvasive medical device array **900** may be utilized with negative pressure or suction/vacuum systems, where the tissue arranged in the opening of the array may be subjected to a negative pressure as part of a larger therapeutic procedure.

FIGS. **40** and **41** illustrate a non-limiting example of a noninvasive medical device **1000** that may be implemented to provide cooling adjacent to locations subjected to a fractional damage or injury pattern using a two-phase heat transfer process in accordance with the systems and methods described herein. The noninvasive medical device **1000** may

also be implemented in other medical cooling applications other than fractional treatments (e.g., photo-dynamic treatments and tumor ablation).

As illustrated in FIG. **40**, the noninvasive medical device **1000** includes a top plate **1002** and a bottom plate **1004**. The top plate **1002** and the bottom plate **1004** may be fabricated from a transparent, or optically transmissive, material. The material that the top plate **1002** and bottom plate **1004** are fabricated from may be chosen to provide desired optical characteristics. For example, the noninvasive medical device **1000** may be used to cool non-target tissue in applications where electromagnetic energy is delivered to a tissue region. Thus, the material for the top plate **1002** and the bottom plate **1004** may be chosen to be transparent in the wavelength range that corresponds with a given electromagnetic treatment.

The top plate **1002** may include an inlet port **1006** and an outlet port **1008** that both extend through the top plate **1002**. When assembled, the inlet port **1006** is configured to align with an inlet reservoir **1010** formed in the bottom plate **1004** and the outlet port **1008** is configured to align with an outlet reservoir **1012** formed in the bottom plate **1004**. The bottom plate **1004** includes a plurality of microchannels **1014** that extend between the inlet reservoir **1010** and the outlet reservoir **1012**. In some non-limiting examples, a porous substrate may be arranged between the top plate **1002** and the bottom plate **1004**. Each of the inlet reservoir **1010**, the outlet reservoir **1012**, and the plurality of microchannels **1014** are recessed into the bottom plate **1004**.

In some non-limiting examples, a ratio of the projected area used by the plurality of microchannels **1014** to the total contact surface area (i.e., the bottom surface **1011** of the bottom plate **1004**) may be less than 10%. In some non-limiting examples, a ratio of the projected area used by the plurality of microchannels **1014** to the total contact surface area (i.e., the bottom surface **1011** of the bottom plate **1004**) may be less than 5%. In any case, the projected area occupied by the plurality of microchannels **1014** is very small relative to the contact surface area. Thus, the substantial majority of the bottom plate **1004** may be uninterrupted by the plurality of microchannels **1014**, which leaves significant space for the electromagnetic energy to pass through the noninvasive medical device **1000** without interruption.

In the illustrated non-limiting example, each of the plurality of microchannels **1014** defines a generally constant width, rectangular cross-section. In other non-limiting examples, the plurality of microchannels **1014** may define an alternative shape and/or pattern on the bottom plate **1004**. For example, the spacing between the microchannels **1014** and shape of the path traversed by the microchannels **1014** between the inlet reservoir **1010** and the outlet reservoir **1012** may be designed to prevent interference with any incoming electromagnetic energy (e.g., a fractional laser patter, a single laser beam, etc.). In some non-limiting examples, the spacing between the microchannels **1014**, the pattern of the microchannels, **1014**, and/or the geometry of the cross-section defined by the microchannels **1014** may be tuned to provide a fast cooling response and steady cooling, while avoiding interference with incoming electromagnetic energy. In some non-limiting examples, the inner surface of the microchannels **1014** may be covered with a coating, or patterned to enhance fluid flow and lower friction losses.

In the illustrated non-limiting example, the noninvasive medical device **1000** defines a generally round shape. In other non-limiting examples, the noninvasive medical device **1000** may define another shape (e.g., curved, polygonal, etc.). For example, the contact surface **1011** of the bottom plate **1004** and/or the noninvasive medical device **1000** may take any of the various geometries described herein with reference to the base **602** and the treatment surface **606** of the noninvasive medical device **600**.

With reference to FIGS. **40** and **41**, during operation of the noninvasive medical device **1000**, for example, the contact surface **1011** of the bottom plate **1004** may be brought into contact with the surface of a desired tissue region **1016** to be subjected to an electromagnetic-based treatment. The working fluid may be drawn from an external reservoir **1018** and enter the inlet reservoir **1010** of the bottom plate **1004** through the inlet port **1006** of the top plate **1002**. The working fluid may be distributed over the plurality of microchannels **1014** passively by surface tension and intermolecular forces (e.g., capillary forces).

Electromagnetic energy may be transmitted through the noninvasive medical device **1000**, without interference, in a desired treatment pattern. The working fluid flowing through the plurality of microchannels **1014** may absorb incoming thermal energy from the tissue region **1016** and evaporate. The evaporation of the working fluid as is flows along the plurality of microchannels **1014** toward the outlet reservoir **1012** induces a direct and uniformly distributed cooling effect over the entire contact area of the contact surface **1011**. The working fluid may exit through the outlet port **1008** in the gas phase (e.g., vapor), and the vapor leaving the outlet port **1008** may be collected, condensed in a condenser **1021**, and returned to the reservoir **1018**.

As illustrated in FIG. **41**, the cooling effect provided by the noninvasive medical device **1000** may protect a non-target tissue region **1020** from heat generated by the incoming electromagnetic energy, and ensure that a target tissue region **1022** is subjected to the desired medical treatment provided by the electromagnetic energy. Flow of the working fluid to the noninvasive medical device **1000** may be controlled via one or more feedback signals acquired from the tissue region **1016** and/or the noninvasive medical device **1000**. For example, the temperature at one or more locations along the bottom plate **1004**, a contact force between the contact surface **1011** and the surface of the tissue region **1016**, and/or a temperature at one or more locations at the interface between the contact surface **1011** and the surface of the tissue region **1016**.

Various parameters of the noninvasive medical device **1000** may be altered to control the heat removal capacity and operating temperature range based on the application. For example, the material of the top plate **1002** and the bottom plate **1004**, the number and arrangement of the plurality of microchannels **1014**, the geometry and pattern of the channels **1014**, the thermophysical properties of the working fluid, etc. It should be appreciated that the properties and operating characteristics of the noninvasive medical device **600** in Table 2 may apply to the noninvasive medical device **1000**.

In accordance with a non-limiting configuration, the use or method of use of the noninvasive medical device **1000** does not include a step of treatment of a human or animal body by surgery or therapy. It is noted that the skills of a person using a device as described herein, may not have the skills of a physician, and that the intended treatment may not be motivated due to illness of the treated person, rather for aesthetic reasons.

As described herein, the present disclosure provides various non-limiting examples of noninvasive medical devices **100**, **600**, **900**, and **1000**, which may be implemented to selectively cool a tissue region in medical applications. Due to the noninvasive nature of these devices, it may be

desirable to acquire the feedback signals, which may be used to control these devices, noninvasively. Some of the feedback signals that may be used to control the noninvasive medical devices **100**, **600**, **900**, and **1000** disclosed herein are the temperature within the tissue region are various locations and depths within the tissue region. Additionally, in some medical applications, it is desired to determine the temporal and spatial distribution of temperature within a tissue region to ensure that a target tissue region is treated, while other tissue regions remain untreated. For example, it may be necessary to track a cold front penetrating into a tissue region and to control a medical cooling device based on a desired location or depth of this cold front. Clearly, obtaining temperature information within a tissue region would require an invasive technique. Thus, the present disclosure provides an approach to noninvasively determine a spatial and temporal temperature distribution at various depths within a tissue region, for example, based on a temperature distribution measured at the surface of the tissue region.

FIGS. **42** and **43** are a graphs depicting one non-limiting example of a progression of isothermal surfaces that illustrate penetration of a cold front in a medium (e.g., tissue). By measuring the temperature at any point and direction of the isothermal surfaces, the temperature distribution in other points and directions may be extracted. The present disclosure provides an approach to determine the temperature distribution within this tissue region based on information gathered from the surface of the tissue region. In some non-limiting examples, a plurality of temperature measurements gathered at the surface of a tissue region may be related to the actual existing temperature profiles within the tissue region (e.g., in the fat layer) at different depths at a given time.

FIG. **44** illustrates one non-limiting example of a test setup utilized to develop the noninvasive temperature determination approach according to the systems and methods of the present disclosure. In the illustrated non-limiting example, the test was performed on a cubic sample of pig tissue with a skin layer **1100** and a fat later **1102**. The pig skin was at an initial temperature of 24° C. and a flat cooling applicator **1104** with an initial temperature of −15° C., which covered half of the skin. Four thermocouples (numbered **1-4** in FIG. **44**) were placed are varying depths Y1, Y2, Y3, an Y4 within the tissue sample under the cooling applicator **1104**. In addition, four thermocouples (numbered **5-8** in FIG. **44**) were placed along the surface of the skin at different locations X1, X2, X3, and X4 next to the cooling applicator **1104**. By interpolating between these four data points (i.e., X,Y pairs) at a given time, a function that describes the temperature at any given point on the skin for that given time may be calculated. This information may provide the temperature profile distribution for the surface of the skin in that specific time. Thus, the temperature at any given point inside the fat or on the surface of the skin may be a function of its coordinates and time (i.e., $T(t)=f(x, y, t)$, where T is temperature, x is the distance along the skin surface from an origin, and y is the depth into the tissue from the origin, and t is time).

FIGS. **45-48** are graphs illustrating the temperature as a function of time for the eight thermocouples depicted in FIG. **44** for one thousand seconds after the cooling applicator was brought into contact with the skin. The interpolation of the temperature of the four horizontal thermocouples for each fifty second interval from the start till the end of the one thousand second experiment verses the horizontal distance from the origin are illustrated in the graph of FIG. **49**. By equating each of the extracted equations to a desired temperature, the location of the points with that temperature can be extracted. For example, a thermocouple on the surface of the skin can be represented by $T(t)=f(x, 0, t)$. By solving this equation for 0° C., the equation becomes: $f(x, 0, t)=0$. Then for t=1:50:1000, the corresponding values for x(t) can be extracted from the extracted equations.

The interpolation of the temperature of the four vertical (depth) thermocouples for each fifty second interval from the start till the end of the one thousand second experiment versus the depth relative to the skin surface are illustrated in the graph of FIG. **49**. This data gives a second function $T(t)=f(0, y, t)$. By solving this equation for 0° C., the equation becomes $f(0, y, t)=0$. Then for t=1:50:1000, the corresponding values for y(t) can be extracted.

With the gathered information, now x and y pairs are known at the same time for T=0° C. For example, at the time that the temperature at a location five millimeters from the origin is going to be 0° C., the corresponding depth into the tissue region that the temperature is also 0° C. can be determined. Thus, the pairs for identical temperatures at difference depths into the tissue region can be determined. For example, for any isotherms at 0° C., an equation $y=f(x)$ can be developed to determine the temperature at various depths into the tissue region when the option to invasively measure the temperature within the tissue is unavailable or undesirable to implement. By placing the X coordinate at its corresponding temperature equation, a corresponding depth for that temperature can be determined within the tissue region. Eventually, a function can be developed that equates the depth within the tissue region to a length on the surface of the skin for the exact same temperature.

FIG. **51** is a graph illustrating the x, y pairs for the 0° C. isotherm in the experiment described above. Using the above-described approach, the x, y, pairs of the 10° C. isotherm can also be determined and are plotted with the 0° C. isotherm in FIG. **52**. As illustrated, the x, y pairs for any temperature isotherm can be determined based on a corresponding temperature at the surface of the tissue region. Thus, the present disclosure provides an approach to noninvasively determine a spatial and temporal temperature profile within a tissue region based on a temperature at a surface of the tissue region. In real world applications, the option of providing the thermocouples at various depths within the tissue region may not be practical, however, the equations described above have already been developed, which may act as virtually having the thermocouples within the tissue region. Thus, the need to invasively measure a temperature at depth within a region may be eliminated and the approach described herein may act to relate the temperature at the surface of a tissue region to the temperature at depth.

In some non-limiting applications, one or more temperatures may be measured on a tissue surface adjacent to a medical device configured to provide a thermal effect to a tissue region. For example, one or more temperatures may be measured at a predetermined intervals to the side or adjacent to a medical device configured to provide a thermal effect to a tissue region. In this way, the temperature profile at the tissue surface may be determined and, using the approach described herein, correlate this profile at the surface to a profile within, or at depth into, the tissue region. It should be appreciated that the approach for noninvasively measuring a temperature profile within a tissue region may be equally applicable to medical cooling technologies and medical heating technologies.

The various medical devices **100**, **600**, **700**, **900**, and **1000** described herein that may be implemented to cool a tissue region described herein may be controlled by varying one or more control parameters. For example, fluid flow into the devices **100**, **600**, **700**, **900**, and **1000** can be adjusted to control the temperature and cooling rates applied to the tissue region. The fluid flow rates may be controlled either passively or actively. For passive control, fluid flow is controlled by the pressure in the device **100**, **600**, **700**, **900**, and **1000** and, if present, the condenser (e.g., the condenser **112**, **1022**). The pressure in the device **100**, **600**, **700**, **900**, and **1000** and, if present, the condenser may be determined by the incoming heat flux, heat loss, and the geometry and orientation of the device **100**, **600**, **700**, **900**, and **1000** and, if present, condenser as well as the liquid and vapor transport lines between them. Some advantages of passive fluid flow control are the simplicity of the system, straight forward integration, and higher reliability.

For active control, a control valve, flow control device, or a capillary tube may control the fluid flow to the device **100**, **600**, **700**, **900**, and **1000** and/or the vapor pressure in the condenser, if present. The control system response may be tuned based on the feedback parameters obtained by a monitoring system. Some advantages of the active fluid flow control are the flexibility in responding to sharp temperature fluctuations and user defined cooling/heating procedures.

As described herein, another control parameter to adjust the operating characteristics of the devices **100**, **600**, **700**, **900**, and **1000** may be the thermo-physical properties of the working fluid used. The thermophysical properties may determine the performance, operating ranges for temperature, pressure, and cooling rates, and the geometrical parameters of the device **100**, **600**, **700**, **900**, and **1000** and, if present, the condenser. Several substances can be employed as working fluid for each particular application. Each fluid determines its own operating condition and design parameters based on its equilibrium pressures, latent heat of evaporation, density, etc. Therefore, selection of the cooling fluid(s) is essential in the design, operation, and specifically optimization and control of a phase-change heating/cooling system.

In addition to flow control and working fluid selection, the temperature of the treatment/contact surface for the devices **100**, **600**, **700**, **900**, and **1000** described herein may be controlled directly using electrical heating, and/or convective heating/cooling. Each of these methods can be integrated into the phase-change system as an auxiliary system for ultra-fast response or reversing the temperature change direction quickly, if needed.

In some non-limiting examples, the temperature and cooling/heating rates of a the devices **100**, **600**, **700**, **900**, and **1000** described herein may also be controlled using two or more substances employed as working fluid. For example, in a two-fluid system, Fluid A may be introduced to lower the temperature quickly from initial tissue temperature to an intermediate temperature. The thermos-physical properties of the fluid determine/assure a fixed minimum temperature for the step **1** of the cooling. The system can then switch to using Fluid B to cool the target tissue to the final temperature. This process may be reversed to then bring the tissue back to the intermediate temperature, if desired. The multi-fluid process may be expanded to implement more than two working fluids to define as many temperature "steps" as desired.

In some non-limiting examples, the quality of the thermal/mechanical contact between the tissue and the devices **100**, **600**, **700**, **900**, and **1000** described herein may be important in controlling the heat exchange rates across the cooling/heating interface. The local normal force, the presence and thickness of interfacial materials such gels, pastes, etc. and an applied vacuum level are among crucial factors affecting the thermal resistance and thermal contact quality. Each of these parameters can be used to adjust and control the heat flow and cooling rates across the tissue/hot/cold plate interfaces.

EXAMPLES

The following examples set forth, in detail, ways in which the various medical devices described herein that leverage a two-phase heat transfer process to cool a tissue region may be used or implemented, and will enable one of skill in the art to more readily understand the principles thereof. The following examples are presented by way of illustration and are not meant to be limiting in any way.

FIG. **53** illustrates a test setup utilized to test the two-phase heat transfer process leveraged for cooling a tissue region according to the systems and methods described herein. A porous substrate was arranged within a metal applicator that includes a contact surface. The metal applicator was fabricated from 6061 aluminum and includes a contact surface of 15 millimeters (mm), a wall thickness of 4 mm, and an outer diameter (of the portion receiving the porous substrate) of 24 mm. The porous substrate was fabricated from aluminum and included a variable pore size that decreased as the porous substrate progressed toward the contact surface. The decreasing pore size enabled a working fluid to be naturally drawn into the porous substrate due to capillary forces in accordance with the systems and methods described herein. The working fluid for the test was iso-butane (C_4H_{10}), and the working pressure was 1 bar. The boiling point of iso-butane is −11.7° C. at 1 bar. The tissue sample tested included an average skin thickness of 2.5 mm and a fat thickness of 20 mm. For the test, the tissue sample was inserted into a plastic enclosure with dimensions slightly larger than the sample itself to reduce heat exchange between the tissue sample and the surroundings. The enclosure covered all but the top surface (i.e., the skin surface) of the tissue sample where it was in contact with the contact surface of the applicator. The tissue sample tested was porcine.

Initially, all of the components including the tissue sample, the enclosure, and the applicator were at thermal equilibrium with the ambient air. The contact surface was brought into engagement with the surface of the tissue sample and the liquid iso-butane was injected into the applicator. The temperature was measured as a function of time at varying depths into the tissue for both the illustrated two-phase device and thermoelectric cooling. The temperature was measured using Omega Hypodermic Type-E thermocouples HYP-1.

As illustrated in FIG. **54**, once the iso-butane was injected into the porous substrate of the applicator, the two-phase cooling penetrated more rapidly into the simulated tissue. For example, after 200 seconds (s) the thermoelectric cooling had only cooled from approximately 24° C. to approximately 20° C. at a depth of 5.5 mm into the tissue sample, while the two-phase cooling cooled the tissue sample to approximately 13° C. in the same time. In addition, the two-phase cooling device maintained the surface of the tissue sample at a higher temperature when compared to the thermoelectric cooling, while simultaneously maintaining a colder temperature at a depth of 5.5 mm into the tissue sample. Thus, the two-phase cooling, when compared to

thermoelectric cooling, provides more rapid cooling that can penetrate to greater depths within the tissue and maintain the surface of the tissue at warmer temperatures.

FIGS. **55-57** illustrates a model of a tissue region after being subjected to a laser pulse during an ablation procedure. The noninvasive medical device array **900** is placed in contact with the tissue surrounding the laser beam. As illustrated in FIGS. **55** and **56**, the heat input from the laser is rapidly dissipated by the noninvasive medical device array **900**. FIG. **57** illustrates the temperature as a function of time at various locations radially outward from the laser beam. After the delivery of the laser energy (i.e., the peaks illustrated in the graph), the noninvasive medical device array **900** almost instantaneously (e.g., less than 0.2 seconds) decreases the temperature in the regions radially outward from the laser beam to a non-damaging temperature.

FIG. **58** illustrates a setup used to model the cooling performance of the noninvasive medical device **1000** against the cooling performance of a conventional cooling device, which was modeled using the setup of FIG. **59**. FIG. **60** is a graph illustrating the temperature a temperature at the skin surface two seconds after the cooling was initiated. As illustrated in FIG. **60**, the conventional cooling system provided an extremely uneven temperature profiles and failed to uniformly cool the tissue. Conversely, the two-phase heat transfer leveraged by the noninvasive medical device **1000** provides significantly increased cooling capacity and was able to uniformly reduce the temperature of the skin to a temperature well below the conventional cooling device.

Thus, while the invention has been described above in connection with particular embodiments and examples, the invention is not necessarily so limited, and that numerous other embodiments, examples, uses, modifications and departures from the embodiments, examples and uses are intended to be encompassed by the claims attached hereto. The entire disclosure of each patent and publication cited herein is incorporated by reference, as if each such patent or publication were individually incorporated by reference herein.

We claim:

1. A noninvasive medical device configured to provide cooling to a tissue region, the noninvasive medical device comprising:

a top plate;

a bottom plate including a contact surface;

an evaporative structure arranged between the top plate and the bottom plate configured to receive a working fluid, wherein the evaporative structure is configured to promote evaporation of the working fluid to cool the contact surface; and

an opening extending through the top plate, the bottom plate, and the evaporative structure, wherein the opening enables fractional heat treatment to be performed on the tissue region via the opening.

2. The noninvasive medical device of claim **1**, wherein further comprising a plurality of openings arranged in a fractional pattern of the fractional medical treatment.

3. The noninvasive medical device of claim **1**, wherein the top plate, the bottom plate, and the evaporative structure is included in a base that includes a plurality of array tiles each including a plurality of array units, wherein the plurality of array units each include a proximal end, a distal end, and a portion of a plurality of channels arranged thereon.

4. The noninvasive medical device of claim **1**, wherein the evaporative structure is in the form of a porous substrate.

5. The noninvasive medical device of claim **1**, wherein the evaporative structure is in the form of a metal foam.

6. The noninvasive medical device of claim **1**, wherein the evaporative structure is in the form of a plurality of channels extending from the opening.

7. The noninvasive medical device of claim **1**, wherein the contact surface defines at least one of a concave shape, a convex shape, or a plurality of peaks and valleys.

8. The noninvasive medical device of claim **1**, wherein the contact surface includes a plurality of protrusions extending therefrom.

9. The noninvasive medical device of claim **1**, wherein the bottom plate defines at least one of a horseshoe shape, a banana shape, or an annular shape.

10. The noninvasive medical device of claim **1**, wherein the opening is sealed between the top first plate and the bottom plate.

11. The noninvasive medical device of claim **1**, wherein the working fluid is supplied to the evaporative structure from a fluid source.

12. The noninvasive medical device of claim **1**, wherein the working fluid is at least one of a hydrocarbon, a hydrofluorocarbon, an alcohol, or water.

13. A medical device configured to provide cooling to a tissue region, the medical device comprising:

an evaporative structure including:

a plurality of channels each configured to receive a working fluid; and

a plurality of apertures extending through the evaporative structure, the plurality of apertures to enable fractional heat treatment to be performed on the tissue region via the plurality of apertures; and

a contact surface in engagement with the evaporative structure, wherein the plurality of apertures extend through the contact surface, and

wherein heat from the contact surface is transferred to the evaporative structure to evaporate the working fluid in the plurality of channels and provide cooling to the contact surface adjacent to the plurality of apertures.

14. The medical device of claim **13**, wherein the working fluid is supplied to the plurality of channels from a fluid source.

15. The medical device of claim **13**, wherein the working fluid is at least one of a hydrocarbon, a hydrofluorocarbon, an alcohol, or water.

16. The medical device of claim **13**, wherein the contact surface defines at least one of a concave shape, a convex shape, or a plurality of peaks and valleys.

17. The medical device of claim **13**, wherein the contact surface includes a plurality of protrusions extending therefrom.

18. The medical device of claim **13**, wherein a bottom plate of the medical device defines at least one of a horseshoe shape, a banana shape, or an annular shape.

19. The medical device of claim **13**, wherein the evaporative structure is sealed between a top plate and a bottom plate, and wherein the contact surface is formed on the bottom plate.

20. The medical device of claim **19**, wherein the plurality of apertures extend through the top plate and the bottom plate.

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