Abstract: Devices and methods for accessing and treating bodily vessels and cavities are disclosed. The devices can have evert-ing balloon catheters that can deliver heating or cooling to biological vessels.
APPARATUS AND METHODS FOR ACCESSING AND TREATING BODILY VESSELS AND CAVITIES

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CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Application No. 62/175,534, filed 15 June 2015, which is incorporated by reference herein in its entirety.

BACKGROUND

1. Technical field

[0002] An everting catheter is disclosed that can be used for accessing and treating vessels, as examples, the fallopian tubes for contraception, the uterine cavity for the treatment of excessive menorrhagia, the arterial system for the treatment of plaque, the venous system for the treatment of valve disorders, sinus passageways for the treatment of sinusitis, and additional passageways in the mammalian body including the urethra, ureters, bile ducts, mammary ducts, gastrointestinal tract for the treatment of disorders or tissue therapy.

[0003] An everting catheter is disclosed for accessing and treating vessels and cavities in combination with other instruments, media, therapeutic agents, and devices which can be equally delivered or placed for treatment or therapy.

2. Related art

[0004] For physicians and medical professionals, accessing systems for vessels and bodily cavities in patients have typically used various guidewire and catheter technologies. In the techniques described above, the methods involved pushing an object, guidewire, mandrel, or device itself through the vessel to gain access to a desired region in the body. The result of pushing an object, mandrel, or device creates shear forces on the lumen wall. In some cases the shear forces can result in trauma, pain for the patient, or perforation. In additions, the tortuosity and attributes of the physical anatomy may make access to the desired therapeutic site difficult and challenging.
In contrast, another access technology is referred to as an evert ing catheter. Evert ing  
catheters utilize a traversing action in which a balloon is inverted and with the influence of  
hydraulic pressure, created by a compressible or incompressible fluid or medium inside of the  
balloon, rolls inside out or everts with a propulsion force through the vessel. Evert ing  
balloons, or linear, evert ing catheters as seen in U.S. Patent Nos. 5,364,345, 5,372,247,  
h, 5,458,573, 5,472,419, 5,630,797, 5,902,286, 5,993,427, 6,039,721, 3,421,509, and 3,911,927,  
categorized as evert ing balloons and due to their property of traversing vessels, cavities, tubes,  
or ducts in a frictionless manner.

In other words, an evert ing balloon can traverse a tube without imparting any shear  
of forces on the wall being traversed. Because of this action and lack of shear forces, resultant  
trauma can be reduced and the risk of perforation reduced. In addition, as a result of the  
mechanism of travel, through a vessel, material and substances in the proximal portion of the  
tube or vessel are not pushed or advanced forward to a more distal portion of the tube or  
vasculature. Furthermore, as the evert ing catheter deploys inside, out, uncontaminated or untouched  
vasculature, it maintains the uncontaminated state, the balloon material is placed inside the vessel wall.

In the inverted or undeployed state, the balloon is housed inside the catheter body and  
does not come into direct contact with the patient or physician. As the balloon is pressurized  
and everted, the balloon material rolls, inside out without contacting any element outside of the  
body. The method of access for an evert ing balloon can be more comfortable for the patient  
and the patient, the catheter being housed in the vessel without imparting any shear forces.  
Since the hydraulic forces “pull” the balloon, membrane through the vessel, or duct as opposed  
to “push” the balloon, membrane through the vessel, the balloon can be deployed in a standard  
method that needs to be “pushed” into and through the vessel or duct opposed  
Due to its ability to navigate tortuous anatomy and gain access to difficult regions of  
the body, the evert ing balloon can be a useful tool for physicians to provide therapeutic tools  
to these regions. In another respect, the evert ing balloon can be adapted to become the  
therapeutic tool or device once in the desired location in the body.

One form of therapy in thermal or ablative treatments, Hyper-therapy, by way of  
heated thermal energy, causes cellular necrosis or a wound-healing response that can promote  
a desired therapeutic effect. As an example, heated balloons applied in the uterine cavity for  
the treatment for menorrhagia. Conversely, hypo-therapy, or the cooling of tissue, can  
for the treatment for menorrhagia. Conversely, hypo-therapy, or the cooling of tissue, can
promote cellular necrosis and disruption. As an example, cellular disruption of the venous valves can have a positive aesthetic effect in the treatment of varicose veins.

SUMMARY OF THE INVENTION

[0010] Devices and methods for accessing and treating bodily vessels and cavities are disclosed. The devices can have everting balloon catheters that can deliver heating or cooling to biological vessels.

[0011] For both hyper- or hypo-therapy, the therapeutic effect can be administered to the everting balloon once access to the desired location has been established by filling the balloon with either heated or cooled media. Alternatively the second catheter can provide the element for heating or cooling the balloon media. The element can be an electrode or an electrically coupled instrument for direct heating. RF, or microwave energy, as an electrode or by placing the balloon surface with flexible electrodes. As an electrode, the balloon can provide radiofrequency, bipolar or monopolar, capacitive coupling, or microwave energy. As an example, the electrodes can be placed onto or within the balloon material.

Alternatively the second catheter can provide the electrode, or microwave antenna as an example, that provides the energy through the balloon material and onto the target tissue once the eversion process, or access, has been achieved. Alternatively the second catheter can deliver the electrode that energizes the balloon material to affect the target tissue.

[0012] Another example can utilize the everting balloon to provide laser energy at a specific wave length that can be absorbed specifically by chromophores within the desired tissue. The everting balloon would deliver the laser within the second catheter and once energized, the provide light energy at a specific wave length for the desired therapeutic tissue.

[0014] The above examples utilize the ability of the everting balloon to reach a target site and supply a therapeutic effect. The following examples provide further details for site specific applications.

Accessing and treating the fallopian tube

[0015] The everting catheter can access the fallopian tube with either a hysteroscope or under ultrasound or radiographic guidance. Once everted into the fallopian tube, the media within the everting balloon can be heated, cooled, radiated, or laser treated.
the everting balloon can be placed by heated or cooled media for tissue necrosis depending
upon the amount of time in contact with the target tissue. Representative samples of internal
heating of the fallopian tube include U.S. Publication No. 2010/0217250 and U.S. Publication
No. 2013/0123613, both of which are incorporated by reference herein in their entirities.

Internal fallopian tube heating can include depositing a tubal occlusion member after internally
heating the fallopian tube to induce tissue response.

[E0218] Evertng catheters can have a handle for controlling instruments within an everting
catheter, as shown for example in U.S. Patent No. 5,346,498 which is incorporated by
reference herein in its entirety. The handles and instruments can be used to place electrodes
within the everting catheter or controlling both the everting balloon and an electrode

within the everting catheter or controlling both the everting balloon and an electrode

for example, in the cervix. The cervical canal is a single lumen vessel that can stretch or dilate. To cross
the cervical canal, the everting catheter can have an outer catheter, an inner catheter, an
everting balloon membrane, and a handle advancement and pressurization system.

The device can have an adapter, such as a Tuohy-Borst adapter and/or Y-connector, to
connect an inner catheter to the balloon membrane. The adapter can allow the inner catheter to
advance and retract, for example, through the Y-connector, without losing pressure. The inner
catheter can have an internal lumen or be configured as a flexible solid rod or mandrel. The
inner catheter can withstand both hydraulic pressures and advancement and retraction tensile
crowns, and compression forces without deformation. Movement of an advancement button on a,
hand or device can induce hydraulic pressures and advancement and retraction while
a handle can move the inner catheter within the Y-connector and through the outer catheter, for
example rolling out the everting balloon to traverse the cervical canal. The advancement
button can be attached to an advancing ratchet or a roller wheel geared into or with the inner
catheter to allow for incrementally stepped and/or one-way translation of the inner catheter.

[0020] The everting balloon membrane can be constructed with varying outer diameters
depending upon the application. For applications in the cervical canal, the most proximal
portion of the everting balloon outer diameter can have a smaller outer diameter than the
remainder of the everting balloon membrane. The everting balloon can be made from an
Arkema in Colombes, France), or combinations thereof,
irradiated polyurethane such as polyether block amides (e.g., Pebax from
frictionless manner without shear forces. Once everted, the balloon membrane can be filled
with heated or cooled media for tissue necrosis. The balloon membrane, or inner catheter can
be configured with electrodes for heating, RF, microwave, and other energy sources as
be computed and configured for heating RF, microwave, and other energy sources as
the everting balloon could be configured with an outer diameter of from about 3 mm to about 6
from the 3 mm diameter can be scaled down to as small as 1 mm. An everting balloon can have an inside diameter of about 6
about 10 mm to about 20 mm, for example when used in the urethra to create a seal in the
about 10 mm to about 20 mm, for example when used in the urethra to create the
The everting balloon can access and cross a stenosis in an arterial or venous blood
vessel. Once identified in the proper location, the balloon membrane can be configured to
apply energy to the arterial plaque. The balloon membrane can be used to deliver energy to

valves in the venous vessels for the treatment of varicose veins. The device can be
delivered to the bile ducts, ureters, urethra, GI tract, sinus passageways, esophagus, mammary
ducts, or combinations thereof to deliver energy,

the exterior surface of the everting balloon membrane can have electrode wires,
materials or material within the polymer to transmit electrical energy for heating, for example to
treat tissue in contact with or adjacent to the membrane.
plaque, a lesion within the vessel wall, or radiation energy for heating, for example to
tissue in contact with or adjacent to the membrane.

The everting balloon membrane can be used to deliver an inner catheter that houses
electrodes that are connected to an electrical generator for the transmission of RF, microwave,
or direct heating. The inner catheter can deliver a microwave antenna for the transmission of
or direct heating. The inner catheter can deliver a microwave antenna for the transmission of
microwave energy. The inner catheter can also house a laser to emit laser energy to targeted tissue.

**[0026]** During and after eversion of the balloon, the hydraulic pressure in the evverting balloon can be from about 2 atm to about 5 atm of media pressure. The balloon membrane can have more than 5 atm of media pressure, for example, to further distend the bodily cavity, lumen or vessel. This additional distension and space created in vivo can, for example, allow for an additional electrode within or on the surface of the balloon membrane to expand. The distension forces can create a more uniform shape within the bodily cavity or vessel. By stretching the biological vessel walls under distension, application of thermal therapy can be applied by the balloon membrane throughout the entire surface of the tissue. Everters-balloon catheters can be constructed with an inner catheter with an internal lumen or through-lumen (also spelled "thru-lumen"). The through-lumen can be used for the passage of instruments, media, materials, therapeutic agents, endoscope, guidewires, or other instruments. Everters catheters with through-lumens are known in the art, such as disclosed in U.S. Patent Nos. 5,374,247 and 5,458,573, both of which are incorporated by reference herein in their entireties. U.S. Patent Nos. 5,374,247 and 5,458,573, both of which are incorporated by reference herein. As an example, the evverting balloon catheter can be used to access the fallopian tube or the uterine cavity via the cervix. As the evverting balloon unrolls through the cervix, the through-lumen or inner catheter can act as a passage for additional instruments or catheters.

**[0027]** Once the evverting balloon is pressurized, the inner catheter can be advanced by hand or with a one-handed control system.

**[0028]** As described previously, the movement of the inner catheter can be controlled by use of a handle. The handle can allow the physician to hold the entire catheter system and manipulate the pressurization, movement of components, and de-pressurization of the balloon membrane with one hand. This single-handed control can allow the physician to utilize the techniques, or depositing materials within the through-lumen by use of another syringe or delivery device mechanism.

**[0029]** As described above, a controller can be attached to the outer catheter. The controller can control the advancement and movement of the evverting balloon and inner catheter. Once fully deployed, the inner catheter can be positioned (e.g., housed) at least partially or fully deployed, the inner catheter can be positioned (e.g., housed) at least partially
completely within the controller to allow for easy insertion of other devices into the inner
catheter and into the target site (e.g., uterine cavity). The evert ing balloon can be used to provide
direct heating to target tissue. The evert ing balloon can be used to access the mammary ducts to provide direct
treatment of other diseases (e.g., breast cavity).

The evert ing balloon can be used to access the mammary ducts to provide direct
treatment of other diseases (e.g., breast cavity).

The evert ing balloon can navigate the tortuous anatomy of the GI tract. Once at the
desired location, the balloon can be configured to deliver treatment.

In addition, for all of the applications mentioned, it may be useful to combine the
therapy with additional therapeutic agents or drugs. The evert ing balloon can be a conduit for
the delivery of therapeutic instruments, endoscopes for internal visualization, and other instruments for
diagnosis (e.g., intraoperative ultrasound imaging and/or histology). The evert ing balloon can be used for
biopsies, tissue sampling, aspiration, or combinations thereof.

In one example, the evert ing balloon can house an endoscope to confirm the
target location of the GI tract. The evert ing balloon can be constructed with a through-lumen for
providing aspiration for tissue, fluid, or cellular sampling. The evert ing balloon can then be
employed to evacuate any tissue sloughing or
byproducts of excessive heating during or after the treatment.

A thermal treatment system is disclosed. The system can have a radially outward catheter,
radially inner catheter slidably translatable inside the outer catheter, an evert ing balloon, a
heater, and a first fluid media heated above 55°C. The evert ing balloon can be attached at a
first end to the outer catheter and a second end to the inner catheter. The first fluid media
heater, and a fluid media heated above 55°C, can be attached to the balloon. The fluid media can be exposed to the heater and inside of the evert ing balloon. The system can have a pump
configured to pressurize the fluid media. The fluid media can be heated above 80°C.

The system can provide heat to target tissue. The fluid media can be heated above 60°C.

Part of the heater can be attached to the inner catheter. At least part of the heater can be
located inside of the evert ing balloon.

The heater can have or be an electrode. The electrode can be or have a coil. At least
part of the heater can be attached to the inner catheter. At least part of the heater can be
configured to radially expand outward when in a radially expanded configuration.

The evert ing balloon can have an evert ing balloon membrane. At least part of the
heater can be embedded in or otherwise attached to the evert ing balloon membrane.
The system can have a cooler. The fluid media can be cooled below 10°C, below 5°C, or below 0°C.

A method for thermal treatment of biological tissue is disclosed. The method can include positioning a device in a target site. The device can have an outer catheter, an inner catheter slidably translatable inside of the outer catheter, and an everting balloon. A first end of the everting balloon can be attached to the outer catheter, and a second end of the everting balloon can be attached to the inner catheter. The method can include delivering a media to the target site. The method can include heating the media to or above 55°C.

The heating can include heating the media before and/or after the delivery of the media to the everting balloon. The heating can be performed with an electrode inside of the everting balloon. The method can include heating the media when the media is in the everting balloon.

The everting balloon can be performed with an electrode in the balloon, when the balloon is at the target site.

The target site can be a fallopian tube.

The target site can be a fallopian tube.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic drawing of a variation of the thermal delivery system.

Figures 2a and 2b are cross-sectional views of a variation for deploying the device in a target site.

Figure 3a is a cross-sectional view of variations of the distal end of the device in an everted configuration.

Figures 4a and 4b are cross-sectional views of a variation of the distal end of the device in an everted configuration.

Figures 5a and 5b are cross-sectional views of a variation of the distal end of the device in an everted configuration.

Figures 6a through 6c are cross-sectional views of variations of the distal end of the device in an everted configuration.
DETAILED DESCRIPTION

[0050] Figure 1 illustrates that an energy delivery system can have a media reservoir in fluid communication with a heater. The heater can be in fluid communication with a pump. The pump can be in fluid communication with a media pressure valve. The media pressue valve can be in fluid communication with the energy delivery device. The heater, pump, and media pressure valve can be in fluid communication with the energy delivery device. The media reservoir, pump, and media pressure valve can be placed in orders other than shown in Figure 1 (e.g., the media reservoir can connect directly to the pump, the pump can then connect downstream directly to the heater, and then the heater can connect downstream to the media pressure valve). The media reservoir, heater, pump, media pressure valve, or combinations thereof can be combined into a single element (e.g., the reservoir can be a pressurized heater with an integrated pump and an insulation jacket, the pressure valve). The media can be a pressurized heater with an integrated pump and storage tank heater. The media can be saline solution, sterile water, glycerine, oil, gels, or combinations thereof. The media can be a storage tank heater, heat pump heater, or a tankless on-demand heater. The heater can be integrated into the device, such as an on-demand heater in the balloon or inner catheter (e.g., an electrode heater). The heater can heat the media from about 55°C to about 100°C, more narrowly from about 65°C to about 90°C. The media can be thermally insulated so the media temperature in the balloon can be substantially equal to the media temperature in the heater. The surface of the balloon membrane can be substantially equal to the media temperature. Tissue being treated can also be changed to substantially the same temperature as the media. Tissue being treated can also be changed to substantially the same temperature as the media.

[0053] The heater can be an electrode heater, for example, an electrode heater, instead of a heated balloon. The media can be gas, gas media, fluid, or fluid media. The media can be gas and/or fluid. The media can be gas, gas media, fluid, or fluid media. The media can be a combination of gas and fluid. The media can be gas or fluid. The media can be a combination of gas and fluid. The media can be gas, gas media, fluid, or fluid media. The media can be gas, gas media, fluid, or fluid media. The media can be a combination of gas and fluid. The media can be gas or fluid. The media can be a combination of gas and fluid. The media can be gas, gas media, fluid, or fluid media. The media can be gas, gas media, fluid, or fluid media. The media can be a combination of gas and fluid. The media can be gas or fluid. The media can be a combination of gas and fluid. The media can be gas, gas media, fluid, or fluid media. The media can be gas, gas media, fluid, or fluid media. The media can be a combination of gas and fluid. The media can be gas or fluid. The media can be a combination of gas and fluid. The media can be gas, gas media, fluid, or fluid media.
more narrowly from about -5°C to about 5°C. The cooler can cool the media, for example, to about -40°C, -5°C, 0°C, or 5°C. The cooler can cool the media between about -5°C and about 5°C. The cooler can cool the media between about -5°C and about 5°C, or between about -10°C and about 0°C. The cooler can cool the media to about -40°C, 0°C, or 5°C. The cooler can cool the media below -40°C, -5°C, 0°C, or 5°C.

[0054] The media can be cooled between a heater and a cooler, for example delivering hot media to the balloon for a fixed time and then delivering cool media for a fixed time. The hot and cold cycling can be repeated (e.g., hot media for a fixed time, then cold media for a fixed time, e.g., for a hot time, then cool time, then hot again for a fixed time, then cold again for a fixed time) The temperature of the media can be controlled by the operator, for example with a temperature control on a handle of the device.

[0055] The media pressure valve can be a gate, globe, ball, butterfly, diaphragm, check, or relief valve. The valve can be integrated into the device. The valve can be attached to control pressure levels in the balloon. The valve can be attached to control pressure levels in the balloon. The valve and/or pump can be attached to control pressure levels in the balloon. The valve and/or pump can be attached to control pressure levels in the balloon. The valve and/or pump can be attached to control pressure levels in the balloon. The valve and/or pump can be attached to control pressure levels in the balloon.

[0056] The device can have an outer catheter, an inner catheter, an evertable balloon having a distal proximal end of the radially inner portion of the balloon. The radially outer portion of the balloon can be attached to the proximal end of the radially inner portion of the balloon. The radially outer portion of the balloon can be attached to the outer balloon. The distal end of the balloon can be attached to the outer balloon. The distal end of the balloon can be attached to the outer balloon. The distal end of the balloon can be attached to the outer balloon.

[0057] Figure 2a illustrates that the distal end of the device can be positioned in a biological lumen at the proximal end of a target site having target tissue. The target tissue can partially or completely obstruct the biological lumen. The balloon can be inflated with fluid communication with the remaining of the system. The inner lumen or through-lumen of the inner catheter can be accessed through the adapter. The adapter can be a Tuohy-Borst adapter and/or Y-connector. The adapter can be a Tuohy-Borst adapter and/or Y-connector. The adapter can be a Tuohy-Borst adapter and/or Y-connector. The adapter can be a Tuohy-Borst adapter and/or Y-connector. The adapter can be a Tuohy-Borst adapter and/or Y-connector. The adapter can be a Tuohy-Borst adapter and/or Y-connector.

[0058] Figure 2b illustrates that the pressurized media can flow, as shown by arrows, into the balloon, inflating the balloon membrane. For example, the media pressure valve can be opened and/or the pump can be turned on to pressurize the media, pushing the media into the balloon, inflating the balloon membrane. For example, the media pressure valve can be opened and/or the pump can be turned on to pressurize the media, pushing the media into the balloon. The outer balloon can be inflated and/or the media pressure can cause the balloon to evert and unroll (e.g., from a hydraulic propulsion). The unrolling of the balloon can extend the length of the balloon distal to the outer catheter. The pressurized balloon membrane can expand or of the balloon distal to the outer catheter. The pressurized balloon membrane can expand or
distend, as shown by arrows, the radially inner surface of the target tissue. The balloon
membrane can be in contact with or adjacent to the surface of the target tissue. The pressure
can be sufficient to close a possible radially inner lumen of the balloon. As shown in Figure 3,
the radially inner lumen of the balloon can be open and patent, for example, allowing easier
passage of agents (e.g., fluid therapeutic or diagnostic agents) or instruments through the
lumen of the inner catheter and balloon. Force can be applied to push agents and
instruments through the closed lumen of the balloon shown in Figure 2b and into or distal to
the target site.

[0060] The heated or cooled media can fill the balloon, heating and/or cooling the balloon
membrane. The balloon membrane can then heat and/or cool the target tissue. The media can
be heated and/or cooled by the heater and/or cooler in the remainder of the system outside of
the balloon. For example, the balloon can be heated with an open circuit heater and cooling
fluid can be provided to the outer catheter and balloon. Force can be applied to push agents and
instruments through the closed lumen of the balloon shown in Figure 2b and into or distal to
the target site.

[0061] Figure 3a illustrates that the outer catheter can thermally insulate the media from
affecting unintended areas of the patient’s body, e.g., not at the target site. The balloon
membrane can reduce thermal energy transfer to unintended areas of the patient’s body by
altering unintended areas of the patient’s body, e.g., not at the target site.

[0062] The membrane thickness can be tapered, as shown in Figure 3a, or discretely stepped, as
shown in Figure 3b. The balloon membrane can be coiled with insulating material in the areas
of desired thermal protection. The thermal insulation and/or coating can be flexible and
expandable, enough to evert with the balloon membrane. The balloon outer diameter can be
made with smaller diameter sections (i.e., waists) to provide less or no tissue contact in certain
circumstances. Tampered or waisted balloon areas can allow therapeutic agents or insulation to be
areas for thermal protection.

[0063] One or more thermometers, such as thermocouples, can be attached to the external
surface of, embedded in, and/or attached to the internal surface of the balloon membrane. The
thermometers can be used to determine the temperature of the surface of the target tissue. The
thermometers can be located spread angularly and/or longitudinally about the balloon membrane.
For example, the thermometers can be evenly spaced apart longitudinally along a length of the
balloon membrane and angularly evenly spaced around the balloon membrane.

[0064] The desired location or locations of the target tissue reach the desired
temperatures for the desired amounts of time (the physician may wish to make the target tissue
for the desired amounts of time (the physician may wish to make the target tissue
a particular temperature merely instantaneously or for an extended time period), the pump
and/or valve be reversed and/or the pump can be turned off to reduce the media pressure in the
balloon. The heater (e.g., heater external to the device and/or electrode or other heater internal
to the device) and/or cooler can be turned off. The inner catheter can be proximally translated
and/or retracted to frictionlessly invert the balloon into the outer catheter. The outer catheter can
be withdrawn from the target site. Illustrated in Figure 3a, terminate longitudinally
the inner catheter. An electric lead or wire (not shown) extending along the surface of or in
the wall of the inner catheter can deliver power to the electrode. The electrode can be powered
by an electrical power source in the system inside or outside of the device.

If the balloon is in an everted configuration, the electrode can be positioned along
all or part of the length of the balloon. The electrode can extend past the distal end of
the balloon, or be longitudinally coincidental or, as shown in Figure 3a, terminate longitudinally
proximal to the terminal distal end of the balloon.

When the balloon is everted and positioned in contact or adjacent to the target tissue,
the electrode can be activated by an electrical power source or generator in the system. The
electrode can then provide RF, microwave, or direct current heating to the media. In RF and
microwave applications, for example, the thermal energy can also travel beyond the media and
into tissue. Bipolar and monopolar energy can be employed, for example, with the electrode
attached or adjacent to the inner catheter. RF and microwave energy, for example, can traverse
layers of tissue to provide direct heating and thermal treatment deeper than the surface of the
target tissue. Different wave forms can be used during a single treatment.

The inner catheter can have or be attached to a laser that can deliver laser energy
through the balloon membrane to the target tissue. The laser can deliver collimated laser light
to the inner catheter at various angles for optimal tissue effect. The media can have
chromophores. The laser can heat the media, for example by being directed into the media
that has chromophores.

Figure 3b illustrates that the electrode can be in the wall of or attached to the surface of
the inner catheter, and not longitudinally extend past the distal terminal end of the inner
catheter. The inner catheter can longitudinally extend past the distal terminal end of the outer catheter. The inner catheter can longitudinally extend past the distal terminal end of the outer balloon. The electrode can be located in the through-lumen of the inner catheter and/or balloon. The electrode can be located in the through-lumen of the inner catheter and/or balloon. The electrode can be located in the through-lumen of the inner catheter and/or balloon. The electrode can be located in the through-lumen of the inner catheter and/or balloon. The electrode can be located in the through-lumen of the inner catheter and/or balloon. The electrode can be located in the through-lumen of the inner catheter and/or balloon.

Figure 4a illustrates that the electrode can be radially expandable and in a radially contracted, unexpanded, unbiased, or relaxed configuration. The electrode can change shape after the balloon is inflated. The electrode can change shape when the radial expanding electrode can push the balloon membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue.

For example, the radially expanding electrode can push the membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue. For example, the radially expanding electrode can push the membrane and the target tissue.
balloon membrane radially outward to dilate the biological lumen (e.g., an obstructed blood
vessel) in which the device is located.

[0076] The electrode can have multiple members. The multiple members can be configured to
deliver bipolar RF energy with alternative members being connected to the electrosurgical
generator as positive or negative for the delivery of energy.

[0077] Once the vessel is dilated, the tissue wall can become stretched or more uniform before
delivery of thermal energy. The device can be used to dilate and deliver thermal energy to the
walls of the esophagus, GI tract, urethra, other bodily vessels and cavities, and combinations
thereof. The device can be used to dilate and deliver thermal energy to the

[0078] Figure 5a illustrates that the radially expandable electrode can be attached to the
radially everted outer surface of the inner catheter. The distal terminal end of the radially
expandable electrode can be equal or proximal to the longitudinal location of the distal
terminal end of the inner catheter.

[0079] Figure 5b illustrates that the inner catheter can have two parts longitudinally slidable
with respect to each other. A first part of the inner catheter can be attached to the distal end of
the electrode. A second part of the inner catheter can be attached to the proximal end of the
inner catheter. The first part of the inner catheter can be longitudinally retracted, as shown by
the arrows, while the second part of the inner catheter is held in a longitudinally constant position
with respect to the remainder of the device. The retraction of the distal part of the inner

catheter radially expandable electrode can bow out or radially expand, as shown by arrows, the
everything radially expandable body. The retracted distal end of the inner
electrode. The retraction of the inner catheter can be used to radially expand the catheter in
combination with any of the other methods described herein.

[0080] Figure 6a illustrates that the electrode can be attached to the radially inner surface of
evorted balloon membrane. Figure 6b illustrates that the electrode can be attached to the
radially outer surface of the evorted balloon membrane. Figure 6c illustrates the electrode is
embedded in the balloon membrane.

[0081] The balloon membrane can have an integrated electrically conductive material. For
example, a conductive (e.g., metal) plating or wire can be attached to the surface of the balloon
membrane. Also, for example, the balloon membrane can be painted or coated with a
conductive (e.g., silver) coating that can be electrically connected to the balloon
membrane. For example, a conductive material can be integrated within the balloon
membrane to act as the electrode.
The electrode can be connected to a generator to provide direct heating, RF, or microwave energy. The electrode can be configured to deliver energy in only certain areas of the balloon, and angular locations around the balloon.

The electrode, for example, when the balloon membrane acts as the electrode, can deliver uniform heat throughout the entire radially internal surface of the target tissue of a vessel or cavity, for example with varying morphology or curvature. This can provide an electrode that fits the available space and is formed in place inside the vessel or cavity with the media pressure.

The pressure of the media can be increased during use to further inflate the balloon, increasing the balloon outer diameter. The distension pressure (i.e., media pressure) can be increased to increase the rigidity of the balloon and decrease the flexibility of the balloon. The distension pressure can be reduced to decrease the rigidity and increase the flexibility of the balloon. For example, before repositioning the balloon in the target site, the media pressure can be reduced. After repositioning the balloon, the media pressure can be increased.

The balloon electrode can be configured as a monopolar electrode with a return pad attached to the patient. As a bipolar electrode, the return electrode can be placed on the outer catheter near the distal end of the outer catheter. As a unipolar electrode, the return electrode can be placed on the outer catheter.

The term thermal energy and thermal treatment are used herein to refer to the application of heat and/or cold.

It is apparent to one skilled in the art that various changes and modifications can be made to this disclosure, and equivalents employed, without departing from the spirit and scope of the invention. Elements of systems, devices and methods shown with any embodiment are exemplary for the specific embodiment and can be used in combination or otherwise on other embodiments within this disclosure. Furthermore, unless specified otherwise, the elements of methods described can be performed in various orders, not just the disclosed order.
I claim:

1. A thermal treatment system comprising:
   a radially outer catheter;
   a radially inner catheter slidably translatable inside the outer catheter;
   an everting balloon attached at a first end to the outer catheter and at a second end to
   a first fluid media heated above 55°C, wherein the first fluid media is exposed to the
   heater and inside of the everting balloon; and
   a pump configured to pressurize the fluid media.

2. The system of claim 1, wherein the fluid media is heated above 80°C.

3. The system of claim 1, wherein the heater comprises an electrode

4. The system of claim 3, wherein the electrode comprises a coil

5. The system of claim 1, wherein at least part of the heater is attached to the inner catheter.

6. The system of claim 1, wherein at least part of the heater is located inside of the everting balloon.

7. The system of claim 1, wherein the heater is radially expandable.

8. The system of claim 7, wherein the heater is configured to radially bow outward when in a
   radially expanded configuration.

9. The system of claim 1, wherein the everting balloon has an everting balloon membrane, and
   wherein at least part of the heater is embedded in the everting balloon membrane.

10. The system of claim 1, wherein the everting balloon has an everting balloon membrane, and
    wherein at least part of the heater is embedded in the everting balloon membrane.
10. The system of claim 1, further comprising a cooler, and a second fluid media, wherein the second fluid media is cooled below 10°C.

11. A thermal treatment device comprising:
   a radially outer catheter;
   a radially inner catheter comprising:
   an everting balloon attached at a first end to the outer catheter and at a second end to the inner catheter;
   a fluid media cooled below 10°C, wherein the fluid media is exposed to the heater and inside of the everting balloon; and
   a pump configured to pressurize the fluid media.

12. The system of claim 11, wherein the fluid media is cooled below 5°C.

13. The system of claim 11, wherein the fluid media is cooled below 0°C.

14. A method for thermal treatment of biological tissue comprising:
   positioning a device in a target site, wherein the device comprises an outer catheter, an inner catheter slidably translatable inside of the outer catheter, and an everting balloon, wherein a first end of the everting balloon is attached to the outer catheter, and wherein a second end of the everting balloon is attached to the inner catheter, wherein the everting balloon is exposed to a heater and wherein a delivering a media under pressure to the everting balloon; everting the everting balloon at the target site; and heating the media to or above 55°C.

15. The method of claim 14, wherein the heating comprises heating the media before the delivering the media.

16. The method of claim 14, wherein the heating comprises heating the media after the delivering the media.

17. The method of claim 14, wherein the heating comprises heating the media after the delivering the media.
17. The method of claim 16, wherein the heating comprises heating the media with an electrode inside of the everting balloon.

18. The method of claim 16, wherein the heating of the media is when the media is in the everting balloon.

19. The method of claim 14, further comprising dilating the target site.

20. The method of claim 19, wherein dilating comprises expanding the everting balloon at the target site.

21. The method of claim 19, wherein dilating comprises expanding an electrode in the balloon when the balloon is at the target site.

22. The method of claim 14, wherein the target site comprises a fallopian tube.

22. The method of claim 14, wherein the target site comprises a fallopian tube.
INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/37715

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8): A61F 7/12 (2016.01)
CPC: A61F 7/123, A61F 2007/126, A61F 7/12, A61M 25/10, A61M 29/02, A61M 29/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A61F 7/12
CPC: A61F 7/123, A61F 2007/126, A61F 7/12, A61M 25/10, A61M 29/02, A61M 29/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8): A61M 29/02, A61M 29/00, A61M 25/10 (2016.01)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google (Web); Scholar; Patents
Search terms: evertimg thermal balloon catheter treatment inner outer heater heated fluid media tubes cooled heating cooling cooled electrode within wall fallopian tube pressure pump contact target tissue expand folding vessel

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 6,645,233 B1 (AYERS et al.); 11 November 2003 (11.11.2003); entire document, especially Fig. 8, 11; col. 5, In 57-62; col. 8, In 29-31; col. 10, In 20-36; col. 11, In 43-54; col. 13, In 36-46; col. 13, In 58-65; col. 14, In 28-32</td>
<td>1-2, 10-16, 18-20</td>
</tr>
<tr>
<td>Y</td>
<td>US 2008/0172050 A1 (SATAKE); 17 July 2008 (17.07.2008); entire document, especially Fig. 1.</td>
<td>3-9, 17, 21-22</td>
</tr>
<tr>
<td>Y</td>
<td>US 2003/0065371 A1 (SATAKE); 3 April 2003 (03.04.2003); entire document, especially Abstract, Figs. 4a, 4b.</td>
<td>7-9, 21</td>
</tr>
<tr>
<td>Y</td>
<td>US 2009/0157069 A1 (TOM et al.); 18 June 2009 (18.06.2009); entire document, especially Fig. 9A, para. [0088].</td>
<td>22</td>
</tr>
<tr>
<td>A</td>
<td>US 7,144,407 B1 (LASERSONH); 5 December 2006 (05.12.2006); entire document.</td>
<td>1-22</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C.

| "A" | Special categories of cited documents: |
| "E" | earlier application or patent but published on or after the international filing date |
| "L" | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) |
| "O" | document referring to an oral disclosure, use, exhibition or other means |
| "P" | document published prior to the international filing date but later than the priority date claimed |

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

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

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

"&" | document member of the same patent family |

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