

1 **DEFLECTABLE ANCHOR BALLOON CATHETER FOR VASCULAR PROCEDURES**

2 **CROSS REFERENCE TO RELATED APPLICATIONS**

3 This application claims the priority of U.S. Provisional Application Serial No. 62/977,993,
4 filed on February 18, 2020, which is hereby incorporated herein by reference in its entirety.

5 **FIELD OF THE INVENTION**

6 The present invention relates to catheters and catheter based procedures. More particularly,
7 the present invention relates to catheters and procedures for percutaneous interventions, local
8 vascular drug delivery and vascular embolization procedures to treat peripheral vascular disease
9 (PVD), peripheral artery disease (PAD), and deep venous thrombosis (DVT).

10 **BACKGROUND**

11 In medicine, peripheral artery occlusive disease, also known as peripheral vascular disease
12 (PVD) and peripheral artery disease (PAD), refers to diseases caused by the obstruction of large
13 peripheral arteries, which can result from atherosclerosis, inflammatory processes leading to
14 stenosis, an embolism or thrombus formation. It causes either acute or chronic ischemia.

15 Mild PAD may be asymptomatic or cause intermittent claudication; severe PAD may cause
16 rest pain with skin atrophy, hair loss, cyanosis, ischemic ulcers, and gangrene. Diagnosis is by
17 history, physical examination, and measurement of the ankle-brachial index. Severe PAD usually
18 requires angioplasty or surgical bypass and may require amputation. Prognosis is generally good
19 with treatment, although mortality rate is relatively high.

20 Typically, PAD causes intermittent claudication, which is a painful, aching, cramping,
21 uncomfortable, or tired feeling in the legs that occurs during walking and is relieved by rest.
22 Claudication usually occurs in the calves but can occur in the feet, thighs, hips, buttocks, or, rarely,
23 arms. Claudication is a manifestation of exercise-induced reversible ischemia, similar to angina
24 pectoris. As PAD progresses, the distance that can be walked without symptoms may decrease,
25 and patients with severe PAD may experience pain during rest, reflecting irreversible ischemia.
26 Rest pain is usually worse distally, is aggravated by leg elevation (often causing pain at night), and
27 lessens when the leg is below heart level. The pain may feel like burning, although this finding is
28 nonspecific. About 20% of patients with PAD are asymptomatic, sometimes because they are not

1 active enough to trigger leg ischemia. Some patients have atypical symptoms (e.g., nonspecific
2 exercise intolerance, hip or other joint pain).

3 As ischemia worsens, ulcers may appear (typically on the toes or heel, occasionally on the
4 leg or foot), especially after local trauma. The ulcers tend to be surrounded by black, necrotic tissue
5 (dry gangrene). They are usually painful, but people with peripheral neuropathy due to diabetes or
6 alcoholism may not feel them. Infection of ischemic ulcers (wet gangrene) occurs readily,
7 producing rapidly progressive cellulitis.

8 The level of arterial occlusion influences location of symptoms. Aortoiliac PAD may cause
9 buttock, thigh, or calf claudication; hip pain; and, in men, erectile dysfunction. In femoropopliteal
10 PAD, claudication typically occurs in the calf; pulses below the femoral artery are weak or absent.
11 In PAD of more distal arteries, femoropopliteal pulses may be present, but foot pulses are absent.

12 Dependent on the severity of the disease, a spectrum of treatment options are available.
13 Angioplasty, cryotherapy, or stents (PTA or percutaneous transluminal angioplasty) can be done
14 on lesions in all leg arteries. Plaque excision, in which the plaque is scraped, or undergoes laser
15 removal, off of the inside of the vessel wall. Occasionally, bypass grafting is needed to circumvent
16 a seriously stenosed area of the arterial vasculature. Generally, the saphenous vein is used,
17 although artificial material is often used for large tracts when the veins are of lesser quality. When
18 gangrene of toes has set in, amputation is often a last resort to stop infected dying tissues from
19 causing septicemia. Arterial thrombosis or embolism has a dismal prognosis, but is occasionally
20 treated successfully with thrombolysis.

21 Revascularization (e.g., femoropopliteal bypass grafting) uses synthetic or natural
22 materials (often the saphenous or another vein) to bypass occlusive lesions. Revascularization
23 helps prevent limb amputation and relieve claudication. Amputation is a procedure of last resort,
24 indicated for uncontrolled infection, unrelenting rest pain, and progressive gangrene.

25 Routing a therapeutic catheter to a damaged artery can be difficult in patients suffering
26 from PAD or other arterial diseases. Entering directly into an affected femoral artery, for instance
27 routing a catheter from directly above the area and working a device straight down the affected
28 femoral artery is quite difficult, requiring great skill on the part of the surgeon and significant time.
29 Moreover, there is a significant risk of further damaging already damaged arteries and
30 complications approach fifty percent (50%). A better method using therapeutic catheters is to enter
31 through a healthy artery that is distant from the damaged arteries to be treated. An alternative

1 method would require entering through the arm and working a catheter downwards through the
2 aorta and into the iliac artery and then into the affected femoral artery. This long route through the
3 aorta can cause a great deal of discomfort for patients, and also entails relatively high complication
4 rates, and frequently the therapeutic catheters are not long enough.

5 For example, in endovascular procedures to repair damage to a femoral artery damaged by
6 PAD, the most preferred method would be to enter through a healthy femoral artery in the opposite
7 leg from the procedure, advancing the catheter upwards into the iliac artery of the near leg (*i.e.*,
8 the leg not being repaired), make the U-turn through the lower aorta/common iliac artery and into
9 the opposite side iliac artery, and then proceed down into the affected femoral artery for surgery.
10 However, until now several problems can prevent this method from being used. First, therapeutic
11 catheters are not flexible enough to make the bend from the near iliac artery into the opposite iliac
12 artery and down into the femoral artery—referred to as the “U-turn”. This bend essentially entails
13 a nearly 180 degree turn—impossible for currently available large-bore catheters. Second, flexible
14 catheters, can make the turn, but they cannot hold themselves in the opposite femoral artery when
15 attempting to route a stiff guide wire through, which stiff guide wire could then be used to guide a
16 therapeutic catheter. As an operator attempts to route a stiff guide wire through the flexible catheter,
17 the flexible catheter displaces out of the femoral and iliac arteries when the stiff wire reaches the
18 U-turn, and moves up into the aorta. At that point the stiff guide wire is not flexible enough to re-
19 route the flexible catheter back into the iliac and femoral arteries. This same difficulty applies in
20 other procedures where a therapeutic catheter must be routed to a location through a tortuous
21 vascular path to support a stiff guide wire for therapeutic catheter routing. Therefore, until now
22 PAD procedures on patients with difficult anatomy requiring entry from an opposite extremity
23 could not be performed reliably, and the patients have been left with the option of no treatment or
24 procedures with greater risks of complications.

25 To date most attempts at solving the problem have focused on increasing the flexibility of
26 the tips of larger therapeutic catheters and stiff guide wires. This results in more expensive and
27 complicated devices, as well as greater skill on the part of the operator to effectively use the devices.
28 The difficulty of using the devices also increases the time required for a surgeon to complete a
29 procedure, which both increases the costs and increases the potential for complications.

30 Deep venous thrombosis (DVT) is a condition that occurs when a blood clot forms in a
31 patient's vein deep in the body, usually in the patient's legs or the feet. The clot can block proper

1 blood flow and may lead to severe injury or death if the clot breaks off and travels through the
2 bloodstream to other areas of the body, such as the brain or lungs. Venous thromboembolism (VTE)
3 is the third leading vascular disease after acute myocardial infarction and stroke. VTE, which
4 encompasses deep vein thrombosis DVT and pulmonary embolism (PE), contributes to a yearly
5 economic burden of 7 to 10 billion dollars in the USA.

6 A thrombus is typically classified as acute if it has formed within 2 to 4 weeks of diagnosis.
7 Duplex ultrasound characteristic of acute DVT include a smooth homogenous thrombus
8 appearance, soft or spongy texture, hypoechogenicity, poor wall attachment or free floating,
9 surrounding dilated vessel size and absence of collaterals with no flow noted in the vein on spectral
10 Doppler. Approximately 25–50% of patients with lower extremity DVT develop post-thrombotic
11 syndrome (PTS), despite anticoagulation therapy. Symptoms of PTS include swelling, pain,
12 heaviness, and venous claudication which can worsen with dependency of the leg. The primary
13 goal of catheter directed interventions for acute DVT is to prevent or reduce the likelihood of
14 developing PTS and VTE. Catheter-directed pharmacologic thrombolysis (CDPT), mechanical
15 and pharmacomechanical thrombectomy, aspiration thrombectomy are being used more
16 commonly to prevent PTS and VTE. The most relevant major complications identified in a pooled
17 analysis of more than 1,000 patients included major hemorrhage (8.3%), symptomatic PE (0.9%),
18 death (0.3%), and intracranial hemorrhage (0.2%) .

19 SUMMARY

20 Embodiments of the disclosed invention provides a multidirectional balloon tipped catheter
21 system to seek a solution through simplified components and a simple multi-step methodology
22 that has not been used prior.

23 These advantages and others are achieved, for example, by a multidirectional balloon
24 tipped catheter system for conducting vascular procedures upon arteries in an extremity from an
25 entry point or other branch point opposite to the extremity in the arterial system. The catheter
26 system includes a multidirectional catheter body having a proximal end and a distal end. The
27 multidirectional catheter body includes a plurality of curls and flexion points for multidirectional
28 deflections. The catheter body includes a plurality of lumens which include at least one wire lumen
29 including an exit port at the distal end and at least one balloon lumen including a balloon port near
30 the distal end. The catheter system further includes an anchor balloon mounted to near the distal
31 end of the catheter body and a guide wire placed in the wire lumen. The anchor balloon is in fluid

1 communication with the balloon port and overhangs the distal end of the catheter body by a
2 predetermined distance when the anchor balloon is inflated. The guide wire is configured to
3 protrude beyond the distal end of the catheter body when the guide wire is in use.

4 The anchor balloon may be inflated with a fluid including air, saline, or contrast, and may
5 be configured to be inflated in various sizes. The anchor balloon may overhang the distal end of
6 the catheter body by two to three millimeters when the anchor balloon is inflated. A diameter of
7 the anchor balloon may be configured to occlude a vascular channel at a selected location. A
8 diameter of the wire lumen may be equal to or greater than 0.91 mm. A distance of a distal end of
9 the anchor balloon from the distal end of the catheter body may be in a range of 10 mm to 20 mm
10 when the anchor balloon is deflated. The catheter body may be configured to be insertable into a
11 femoral artery or other vascular access. The plurality of lumens may further include one or more
12 additional lumens for delivery of pharmaceuticals, chemotherapeutics and embolization products
13 to a selected location.

14 These advantages and others are achieved, for example, by a method for conducting
15 vascular procedures upon arteries in an extremity from an entry point opposite to the extremity
16 with a multidirectional balloon tipped catheter system. The method includes processes of inserting
17 the multidirectional balloon tipped catheter system into the entry point in a near femoral artery or
18 other vascular access, advancing the catheter system toward a branch point that is connected to the
19 extremity, inflating the anchor balloon at a first size, navigating the catheter system to an ostium
20 of the extremity, inflating the anchor balloon at a second size that is larger than the first size,
21 anchoring the catheter system at the ostial and proximal segment of the extremity by using the
22 anchor balloon inflated at the second size where the extremity is occluded by the anchor balloon,
23 advancing the guide wire into a distal segment of the extremity for diagnostic or therapeutic
24 procedures, and deflating the anchor balloon to free the occlusion in the extremity.

25 The method may further include inserting an entry sheath into the entry point into which
26 the catheter system is inserted through the entry sheath. The method may further include
27 performing the diagnostic or therapeutic procedures while the catheter system is anchored at the
28 ostial and proximal segment of the extremity. The method may further include further advancing
29 the catheter system into the distal segment of the extremity for further diagnostic or therapeutic
30 procedures. The method may further include administering pharmaceutical and chemotherapeutic
31 agents to local vasculature of the extremity using the catheter system while the anchor balloon is

1 inflated. The method may further include removing the catheter body with deflated anchor balloon
2 while leaving the guide wire in place, and withdrawing the entry sheath over the guide wire while
3 leaving the guide wire in place. The guide wire may be then available to insert a long sheath or
4 therapeutic catheter for therapeutic procedures. The method may further include occluding blood
5 vessels with embolization coils, glues, plugs and other occluder devices using the catheter system
6 while the anchor balloon is inflated.

7 These advantages and others are achieved, for example, by a multidirectional balloon
8 tipped catheter system for conducting closed loop perfusion and reperfusion for treatment of deep
9 venous thrombosis. The catheter system includes a multidirectional catheter body having a
10 proximal end and a distal end and including a plurality of curls and flexion points for
11 multidirectional deflections. The catheter body includes a plurality of lumens which include a main
12 lumen including an exit port at the distal end and at least one balloon lumen including a balloon
13 port near the distal end. The catheter system further includes an anchor balloon mounted to near
14 the distal end of the catheter body and an inner catheter device disposed in the main lumen. The
15 anchor balloon is in fluid communication with the balloon port and overhangs the distal end of the
16 catheter body by a predetermined distance when the anchor balloon is inflated. The inner catheter
17 device includes a flexible inner catheter body including a center lumen, at least one balloon lumen,
18 and a plurality of additional lumens. The inner catheter body is configured to advance beyond the
19 distal end of the multidirectional catheter body. The additional lumens include exit ports open to
20 outside of the inner catheter body. The inner catheter device further includes an anchor balloon
21 mounted to near the distal end of the inner catheter body. The anchor balloon is in fluid
22 communication with the balloon lumen and overhangs the distal end of the inner catheter body by
23 a predetermined distance when the anchor balloon is inflated.

24 The anchor balloon and the anchor balloon of the inner catheter device may be inflated
25 with a fluid including air, saline, or contrast, and may be configured to be inflated in various sizes.
26 The exit ports of the additional lumens of the inner catheter device may be formed at proximal side
27 from the anchor balloon of the inner catheter device. The multidirectional catheter body may
28 include channels that are connected to the main lumen and are open to outside of the
29 multidirectional catheter body. The inner catheter body may include channels that are connected
30 to the center lumen and are open to outside of the inner catheter body. The channels of the
31 multidirectional catheter body may be configured to be substantially aligned with the channels of

1 the inner catheter body to form open fluid paths, when the inner catheter device advances by a
2 predetermined distance. The exit ports of the additional lumens of the inner catheter device may
3 be configured to be exposed outside the main lumen for delivery of pharmaceuticals,
4 chemotherapeutics and embolization products to a selected location, when the inner catheter device
5 advances by the predetermined distance.

6 BRIEF DESCRIPTION OF THE DRAWINGS

7 The preferred embodiments described herein and illustrated by the drawings hereinafter be
8 to illustrate and not to limit the invention, where like designations denote like elements.

9 FIGS. 1A-1D show exemplary illustrations which show multidirectional balloon tipped
10 catheter system for conducting vascular procedures upon arteries in an extremity from an opposite
11 entry point or other branch point in the arterial system.

12 FIGS. 2A-2C show an embodiment of multidirectional balloon tipped catheter system of
13 the disclosed invention for conducting vascular procedures upon arteries in an extremity from an
14 opposite entry point or other branch point in the arterial system.

15 FIGS. 3A-3C show longitudinal side views of the distal end portion of the multidirectional
16 balloon tipped catheter system.

17 FIG. 3D shows a transverse cross-sectional view of the section A-A' of the distal end
18 portion of the multidirectional balloon tipped catheter system shown in FIG. 2C.

19 FIG. 4 shows an exemplary embodiment of a mechanical deflection mechanism that can
20 be employed at the proximal end portion of the catheter body to control deflections of the catheter
21 system.

22 FIG. 5 shows a workflow diagram for a method for conducting vascular procedures upon
23 arteries in an extremity from an entry point opposite to the extremity using a multidirectional
24 balloon tipped catheter system.

25 FIG. 6A shows a longitudinal cross-sectional side view of a distal end portion of another
26 embodiment of the multidirectional balloon tipped catheter system.

27 FIG. 6B shows a transverse cross-sectional view of the distal end portion of the
28 multidirectional balloon tipped catheter system.

29 FIGS. 7A-7B show exemplary illustrations of single catheter system and dual catheter
30 system conducting closed loop perfusion for treatment of DVT or other diseases in blood vessels.

FIGS. 8A-8B show exemplary illustrations of single catheter system and dual catheter system conducting closed loop reperfusion for treatment of DVT or other diseases in blood vessels.

DETAILED DESCRIPTION

The following detailed description is merely exemplary in nature and is not intended to limit the described embodiments or the application and uses of the described embodiments. As used herein, the word “exemplary” or “illustrative” means “serving as an example, instance, or illustration.” Any implementation described herein as “exemplary or “illustrative” is not necessarily to be construed as preferred or advantageous over other implementations. All of the implementations described below are exemplary implementations provided to enable persons skilled in the art to make or use the embodiments of the disclosure and are not intended to limit the scope of the disclosure, which is defined by the claims. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the inventive concepts defined in the appended claims. Hence, specific dimensions and other physical characteristics relating to the embodiments disclosed herein are not to be considered as limiting, unless the claims expressly state otherwise.

Embodiments of the disclosed invention seek a solution through simplified components and a simple multi-step methodology that has not been used prior. Embodiments include a method and apparatus which will allow an operator performing endovascular procedures, such as on a femoral artery, to anchor a flexible catheter in an upstream location in an artery so that a stiff guide wire can then be routed through the flexible catheter, which stiff guide wire can subsequently be used to route a medium or large catheter or sheath to conduct the actual therapeutic surgery, whether that involves an angioplasty balloon catheter, or inserting a stent, or some other sort of device or surgical procedure.

Currently, none of the procedures for treating PAD through the use of a catheter are able to cross from one extremity to the other through the arteries of a patient with difficult anatomy. Currently available balloon catheters are not useful for this purpose either. In this regard, “difficult anatomy” is the inability to pass a catheter from a proximal entry point to a location in an opposite side artery requiring a therapeutic procedure. This difficulty may be due, for example, to tortuous

1 vessels with marked curvature, narrow iliac bifurcation with angles less than 45 degrees (*i.e.*, a U-
2 turn of nearly 180 degrees for femoral artery procedures), or due to previous endovascular
3 intervention. None of the existing devices and procedures allow introduction into the femoral
4 artery of the near leg of a patient with difficult anatomy, and progression of a therapeutic catheter
5 to the femoral artery of the opposite leg.

6 Therefore, in order to get a catheter with therapeutic devices to a selected location in an
7 artery for catheter based procedures to treat PAD, in patients with difficult anatomy, an operator
8 must first pass a stiff wire from the near leg to the opposite leg via the common iliac artery and
9 pass the therapeutic catheter over the stiff wire, or alternatively pass a sheath over the stiff wire
10 through which a therapeutic catheter device may be passed.

11 To date most attempts are being made for local drug delivery for treating malignancies etc.
12 The difficulty in such therapeutics is the vascular site selectiveness such that normal tissue may
13 remain unharmed. Solving the problem have focused on increasing the flexibility of the tips of
14 larger therapeutic catheters and stiff guide wires. This results in more expensive and complicated
15 devices, as well as greater skill on the part of the operator to effectively use the devices. The
16 difficulty of using the devices also increases the time required for an operator to complete a
17 procedure, which both increases the costs and increases the potential for complications.

18 The problem therefore, is how to get such a stiff guide wire and a catheter which is
19 occlusive such as to deliver pharmaceuticals, chemotherapeutics and embolization products to the
20 selected location. Embodiments provide a solution through a multidirectional balloon tipped
21 catheter that has not been used prior and solves this problem.

22 With reference to FIGS. **1A-1D**, shown are exemplary illustrations which show
23 multidirectional balloon tipped catheter system **100** for conducting vascular procedures upon
24 arteries in an extremity from an opposite entry point or other branch point in the arterial system.
25 For illustration purpose, FIGS. **1A-1D** show aorta artery **200** splitting to become paired iliac
26 arteries **201**, **202** in which the vascular procedures with the multidirectional balloon tipped catheter
27 system **100** is conducted. As shown in FIG. **1A**, the catheter system **100** is inserted in the left iliac
28 artery **201** through an entry sheath **150**, and proceeds to the right iliac artery **202** through a branch
29 **203** between the left iliac artery **201** and the right iliac artery **202**. When the catheter system **100**
30 passes through the branch **203**, it needs to make the U-turn through the branch **203** (lower
31 aorta/common iliac artery) to proceed into the right iliac artery **202**, and then to proceed down into

1 the affected femoral artery for surgery. These processes will be described later in detail.
2 Embodiments of the disclosed invention provide multidirectional balloon tipped catheter **100** that
3 enables vascular procedures upon arteries in an extremity from an opposite entry point or other
4 branch point in the arterial system, overcoming the problems discussed above.

5 With reference to FIGS. **2A-2C** shown are an embodiment of multidirectional balloon
6 tipped catheter system **100** of the disclosed invention for conducting vascular procedures upon
7 arteries in an extremity from an opposite entry point or other branch point in the arterial system.
8 With reference to FIGS. **3A-3C** shown are longitudinal cross-sectional side views of the distal end
9 portion of the multidirectional balloon tipped catheter system **100**. With reference to FIG. **3D**,
10 shown is a transverse cross-sectional view of the section A-A' of the distal end portion of the
11 multidirectional balloon tipped catheter system **100** shown in FIG. **2C**.

12 The multidirectional balloon tipped catheter system **100** includes a multidirectional or
13 deflectable flexible catheter body **110** that includes a proximal end **101** and a distal end **102**. The
14 catheter body **110** is French sizes, and includes curls and flexion points to be multidirectional or
15 deflectable. For example, the catheter body **110** may include a plurality of flexion points **103**, **104**
16 to facilitate the multidirectional deflections or bending. The catheter body **110** has a length
17 sufficient to reach a selected location in a patient's opposite extremity or other branch point in the
18 arterial system. The catheter body **110** is configured to be insertable into a femoral artery or other
19 vascular access as illustrated in FIG. **1A**. The catheter body **110** includes a plurality of lumens.
20 The plurality of lumens includes at least one wire lumen **111** including a wire access port (not
21 shown) accessible to an operator at said catheter proximal end **101** and a wire exit port **111a** at the
22 flexible catheter distal end **102**, and a balloon lumen **114** for inflating and deflating at least one
23 anchor balloon **115**. The balloon lumen **114** includes a balloon control port (not shown) for
24 connecting to a balloon control device accessible to an operator at the catheter proximal end **101**
25 and a balloon port **114a** connected to the balloon **115** near the multidirectional catheter distal end
26 **102**.

27 The plurality of lumens may include one or more additional lumens for delivery of
28 pharmaceuticals, chemotherapeutics and embolization products to the selected locations or areas.
29 FIG. **3D** exemplarily shows two additional lumens **125**, **126**. However, the number of the
30 additional lumens is not limited to two. The additional lumens **125**, **126** may be used for local drug
31 delivery for treating malignancies, for local vascular drug delivery and vascular embolization

1 procedures, and for flushing and aspirating, *etc.* The additional lumens **125**, **126** have access ports
2 at the proximal end **101** of the catheter body **110**, and external devices, such as drug delivery
3 devices, may be connected to the access ports of the additional lumens **125**, **126**.

4 The multidirectional balloon tipped catheter system **100** includes compliant or non-
5 compliant anchor balloon **115** that is mounted on the multidirectional catheter body **110** near the
6 distal end **102** of the catheter body **110**. FIGS. **2A** and **2B** show deflated anchor balloon **115**, and
7 FIGS. **2B** and **3B** show inflated anchor balloon **115** at the distal end **102** portion of catheter body
8 **110**. The anchor balloon **115** is connected to the balloon port **114a** of the catheter lumen **114**, and
9 is in fluid communication through the balloon lumen **114**. Fluid, which is injected or removed at
10 the balloon control port at the proximal end **101**, inflates or deflates the anchor balloon **115** through
11 the balloon lumen **114**.

12 The anchor balloon **115** may be inflated with air, saline, contrast and other solutions, and
13 may be inflated to various sizes. The anchor balloon **115** is placed at a selected distance from the
14 distal end **102** of the catheter body **110**. For example, when the anchor balloon **115** is deflated, the
15 distance **L1** of a distal end of the anchor balloon **115** from a distal end **102** of the catheter body
16 **110** may be in the range 10 mm (0.4 inches) to 20 mm (0.8 inches). When the anchor balloon **115**
17 is inflated, the anchor balloon **115** may overhang the distal end **102** of the catheter body **110** by a
18 distance **L2** which may be two to three millimeters.

19 The multidirectional balloon tipped catheter system **100** includes stiff guide wire **112**
20 disposed in the wire lumen **111**. The catheter body **110** includes pacing lead lumen **111** that
21 includes a cord access port (not shown) accessible to an operating device at the proximal end **101**
22 and exit port **111a** at the distal end **102** of the catheter body **110**. The wire lumen **111** may be
23 positioned at a center of the cross-section of the catheter **110** as shown in FIG. **3D**. The diameter
24 of the pacing lead lumen **111** may be equal to or greater than 0.91 mm (0.035 inches). The guide
25 wire **112** may be placed inside the wire lumen **111** while the catheter system **100** advances toward
26 a proper position.

27 The diameter **D** of the anchor balloon **115**, when fully inflated, is such as to occlude the
28 artery or the vascular channel at the selected location, thereby the inflated anchor balloon **115**
29 stabilizes the catheter system **100** to allow the stiff guide wire **112** to pass through the distal end
30 **102** of the catheter body **110**. When the catheter system **100** is stabilized, the guide wire **112** may
31 advance out of the wire lumen **111** beyond the distal end **102** of the catheter body **110** to perform

1 diagnostic or therapeutic procedures. FIGS. 2C and 3C show the guide wire **112** advancing out of
2 the distal end **102** of the catheter body **110**.

3 With reference now to FIG. 4, shown is an exemplary embodiment of a mechanical
4 deflection mechanism **130** that can be employed at the proximal end **101** portion of the catheter
5 body **110** to control deflections of the distal end portion of the catheter system **100**. Mechanical
6 deflection mechanism may enable distal end of catheter body **110** to be deflected or angulated to
7 various angles with respect to a longitudinal axis (from the proximal end **101** to the distal end **102**)
8 of the catheter system **100**. Mechanical deflection mechanism or device **130** may include a pull
9 wire anchor **131** affixed to the catheter body **110** and pull wire actuator **132** connected to pull wire
10 anchor **131** with pull wire (not shown). Rotation of pull wire actuator **132**, as shown, may exert
11 force on pull wire anchor **131** that deflects or angulates distal end of the catheter body **110**. Pull
12 wire actuator **132** may be rotated by handle connected thereto (not shown). The deflection
13 mechanism **130** together with the flexion points and curls formed in the catheter body **110** enables
14 the distal end of the catheter body **110** to deflect at a stiff angle such as more than 135 degrees to
15 make the U-turn through the branch **203** to proceed, for example, into the right iliac artery **202**
16 from the left iliac artery **201**. U.S. Patent Application Serial No. 17/061,761 filed on October 2,
17 2020 by the same inventor discloses an improved handle that can be employed in the catheter
18 system of the disclosed invention to provide deflections.

19 With reference to FIG. 5, shown is a workflow diagram for a method **300** for conducting
20 vascular procedures upon arteries in an extremity from an entry point opposite to the extremity
21 using a multidirectional balloon tipped catheter system **100** including a multidirectional catheter
22 body **110**. The catheter system **100** is inserted into the entry point **151** in a near femoral artery or
23 other vascular access, block **310**. In the exemplary illustrations shown in FIGS. 1A-1D, the
24 catheter system **100** is inserted through the entry point **151** at left iliac/femoral artery **201** which
25 is located opposite to the extremity (right iliac/femoral artery **202**). The catheter system **100** is
26 advanced toward branch point **203** that is connected to the extremity (right iliac/femoral artery
27 **202**), block **311**. The anchor balloon **115** is inflated at a first size, block **312**, while the catheter
28 system **100** navigates toward the branch point **203**. The catheter system **100** is navigated to an
29 ostium of the extremity **202**, block **313**, as shown in FIG. 1B. The anchor balloon **115** is inflated
30 at a second size that is larger than the first size, block **314**. The distal end **102** of the catheter system
31 **100** is anchored at the ostial and proximal segment of the extremity **202** by using the anchor

1 balloon **115** inflated at the second size. The extremity **202** may be occluded by the anchor balloon
2 **115** inflated at the second size, block **315**, as shown in FIG. **1C**. The guide wire **112** is advanced
3 into a distal segment of the extremity **202** for diagnostic or therapeutic procedures, block **316**, as
4 shown in FIG. **1D**. Then, the anchor balloon **115** may be deflated to free the occlusion in the
5 extremity **202**.

6 In order to insert the catheter system **100** into the entry point **151** in a near femoral artery
7 or other vascular access, a short entry sheath **150** may be inserted into the entry point **151**. The
8 catheter system **100** is inserted into the entry point **151** through the entry sheath **150**. Diagnostic
9 or therapeutic procedures may be performed while the catheter system **100** is anchored at the ostial
10 and proximal segment of the extremity **202**. The catheter system **100** may be further advanced into
11 the distal segment of the extremity **202** for further diagnostic or therapeutic procedures. While the
12 anchor balloon **115** is inflated and the catheter system **100** is anchored, pharmaceutical and
13 chemotherapeutic agents may be administered to local vasculature of the extremity **202** using the
14 catheter system **100**.

15 The catheter body **110** with deflated anchor balloon **115** may be removed while leaving the
16 guide wire **112** in place. The entry sheath **150** over the guide wire **112** may be withdrawn while
17 leaving the guide wire **112** in place. In this stage, the guide wire **112** is then available for inserting
18 a long sheath or therapeutic catheter for therapeutic procedures. The guide wire **112** may guide the
19 long sheath or therapeutic catheter into a selected point in the extremity **202**. The blood vessels in
20 the extremity **202** may be occluded with embolization coils, glues, plugs and other occluder
21 devices using the catheter system while the anchor balloon is inflated.

22 With reference to FIG. **6A**, shown is a longitudinal cross-sectional side view of a distal end
23 portion of another embodiment of the multidirectional balloon tipped catheter system **400**. With
24 reference to FIG. **6B**, shown is a transverse cross-sectional view of the distal end portion of the
25 multidirectional balloon tipped catheter system **400**. The catheter system **400** has a similar
26 structure to the catheter system **100** shown in FIGS. **2A-3D**, except that the guide wire **112** of the
27 catheter system **100** is replaced with an inner catheter system **400a** that includes deflectable or
28 flexible catheter body **410** and anchor balloon **415** mounted to a distal end of the catheter body
29 **410**. The inner catheter system **400a** is movably disposed in the lumen **111** of outer catheter system
30 **400b**. The inner catheter system **400a** protrudes beyond the distal end of the outer catheter system

1 **400b** when in use. The structures and features of the outer catheter system **400b**, except the guide
2 wire **112**, are substantially the same as the catheter system **100**.

3 The outer catheter system **400b** includes multidirectional outer catheter body **110'** that is
4 French sizes and includes curls and flexion points to be multidirectional or deflectable. For
5 example, the catheter body **110'** may include a plurality of flexion points **103**, **104** (shown in FIG.
6 **2A**) to facilitate the multidirectional deflections or bending. Unlike the catheter body **110** of the
7 catheter system **100**, the outer catheter body **110'** of the catheter system **400b** is configured to have
8 channels **118** for fluid communication to outside of the catheter system **400**. Anchor balloon **115**
9 is mounted to the distal end of the catheter body **110'**.

10 The flexile balloon tipped inner catheter system **400a** includes a deflectable flexible inner
11 catheter body **410** that includes a proximal end (not shown) and a distal end **402**. The catheter body
12 **410** is French sizes and flexible. The inner catheter body **410** has a length sufficient to reach a
13 selected location in a patient's opposite extremity or other branch point in the venous or arterial
14 system. The inner catheter body **410**, together with the outer catheter body **110'**, is configured to
15 be insertable into a femoral artery or vein or other vascular access as illustrated in FIG. **1A**. The
16 catheter body **410** includes a plurality of lumens. The plurality of lumens includes at least one
17 main lumen **411** including an exit port **411a** at the distal end **402**, and a balloon lumen **414** for
18 inflating and deflating at least one inner anchor balloon **415**. The balloon lumen **414** includes a
19 balloon control port (not shown) for connecting to a balloon control device accessible to an
20 operator at the catheter proximal end and a balloon port **414a** connected to the anchor balloon **415**
21 near the multidirectional catheter distal end **402**.

22 The plurality of lumens include one or more additional lumens **416** for delivery of drugs,
23 pharmaceuticals, chemotherapeutics and embolization products to the selected locations or areas.
24 The additional lumens **416** have exit ports **417** to discharge the pharmaceuticals into the selected
25 locations or areas. As shown in FIG. **6A**, the exit ports **417** are formed at longitudinal side surface
26 of the inner catheter body **410** at proximal side from the anchor balloon **415**. When the inner
27 catheter system **400a** advances by a predetermined distance **L3**, the exit ports **417** may be
28 positioned between the two anchor balloons **115** and **415**, and may be exposed to the outside of
29 the catheter body **410**. For illustration purpose, FIG. **6A** exemplarily shows the additional lumens
30 **416** and the exit ports **417** on the upper side of the catheter body **410** and FIG. **6B** exemplarily
31 shows four additional lumens **416**. However, the number of the additional lumens is not limited to

four. The additional lumens **416** have access ports at the proximal end of the catheter body **410**, and external devices, such as drug delivery devices, may be connected to the access ports of the additional lumens **416**.

As shown in FIGS. **6A-6B**, the inner catheter body **410** has channels **418** that are formed at proximal side of the catheter body **410** from the anchor balloon **415** and are connected to the main lumen **411**. The channels **418** form open fluid paths to the outside of the inner catheter body **410**. The outer catheter body **110'** has channels **118** that are configured to be substantially aligned with the channels **418** of the inner catheter body **410**, when the inner catheter system **400a** advances by a predetermined distance **L3** from the distal end of the outer catheter system **400b**. The channels **118** of the outer catheter body **110'** form open fluid paths to the outside of outer the catheter body **110'**. Consequently, the main lumen **411** of the inner catheter system **400a** has open fluid paths to outside of the catheter system **400** through the channels **418** and **118**. These channels **418** and **118** are formed at a proximal side from the anchor balloon **115** of the outer catheter body **110'** as shown in FIG. **6A**. Therefore, while the area between two anchor balloons **115** and **415** may be blocked and isolated, the area at the distal end **402** of the inner catheter system **400a** may be open to the proximal outside area after the anchor balloon **115** through the lumen **411** and channels **418** and **118**, as illustrated in FIG. **7A**. FIGS. **6A-6B** exemplarily show the channels **118**, **418** at a bottom side of the catheter bodies, but the locations and numbers of the channels **118**, **418** are not limited to these locations and numbers.

The multidirectional balloon tipped catheter systems **100** and **400** of the disclosed invention can be used in the venous system proximal and distal to the deep venous thrombosis (DVT). The anchor balloons are occlusive on the vein. This would allow for localized thrombolysis without any systemic complications from the thrombolytic. It may additionally also prevent pulmonary embolism (PE) because of embolization during catheter directed therapeutic procedures. It may allow for a more complete thrombectomy and therefore less PTS.

With reference to FIGS. **7A-7B**, shown are exemplary illustrations which show multidirectional balloon tipped catheter systems **100**, **400** for conducting closed loop perfusion for treatment of DVT or other diseases in blood vessels. For illustration purpose, FIGS. **7A-7B** show vein **210** with area **211** that requires treatment such as removing blood clots. FIG. **7A** shows the treatment procedure with the multidirectional balloon tipped catheter **400**, which may be referred

1 to as a single catheter system, and FIG. 7B shows the treatment procedure with two
2 multidirectional balloon tipped catheters **100**, **100'**, which is referred to as a dual catheter system.

3 Referring to FIG. 7A, the catheter system **400** may be inserted into an entry point in a near
4 femoral vein or other vascular access. For example, the catheter system **400** may be inserted
5 through an entry point at left iliac/femoral vein (not shown) which is located opposite to the
6 extremity (for example, right femoral vein **210**). However, in the embodiment, the entry point is
7 not limited to the opposite to extremity. The entry point may be in the extremity side. The catheter
8 system **400** advances toward the area **211** that requires treatment. The anchor balloon **115** is
9 inflated to anchor the outer catheter system **400b** at a proper location (first location) near the
10 treatment area **211**, blocking blood flow through the first location. The inner catheter system **400a**
11 further advances passing the area **211** while the outer catheter **400b** is anchored at the first location.
12 At a proper location after passing the treatment area **211**, the anchor balloon **415** is inflated to
13 anchor the inner catheter system **400a** at a second location. The inflated anchor balloon **415** blocks
14 blood flow through the second location. With the anchor balloons **115**, **415**, the treatment area **211**
15 is isolated for treatment. Blood flowing in the outer area **210a** bypasses the treatment area **211** and
16 flows into opposite outer area **210b** through the open path formed by lumen **411** and channels **418**
17 and **118**. Pharmaceuticals are delivered to the treatment area **211** through the lumens **416** and the
18 exit ports **417** connected to the lumens **416** of the inner catheter body **410**.

19 In the dual catheter system shown in FIG. 7B, first catheter **100** may be inserted into an
20 entry point in a near femoral vein or other vascular access, and advances toward the treatment area
21 **211**. The second catheter **100'** is inserted into another entry point that is located at an opposite side
22 of the treatment area **211**, and advances toward the treatment area **211**. The first catheter system
23 **100** may be inserted in an entry point located opposite to the extremity while the second catheter
24 system **100'** may be inserted in an entry point at the extremity. The catheter systems **100**, **100'** are
25 anchored at proper locations near the treatment area **211** by inflating anchor balloons **115**, **115'**,
26 respectively. The inflated balloons **115**, **115'** block blood flow through the anchored locations, and
27 consequently, the treatment area **211** is isolated by the two anchor balloons **115**, **115'**.
28 Pharmaceuticals are delivered to the treatment area **211** through one or more of the lumens **111**,
29 **125**, **126** (shown in FIG. 3D) of the first catheter system **100** and/or the second catheter system
30 **100'**.

1 With reference to FIGS. **8A-8B**, shown are exemplary illustrations which show
2 multidirectional balloon tipped catheter systems **100, 400'** for conducting closed loop reperfusion
3 for treatment of DVT or other diseases in blood vessels. Referring to FIG. **8A**, catheter system **400'**
4 is inserted into the vein **210**. The outer catheter system **400b'**, which includes catheter body **110**,
5 is anchored at a location of the vein **210** by the inflated anchor balloon **115**, blocking blood flow
6 through the location. The inner catheter system **400a** advances further to perform reperfusion. The
7 balloon **415** of the inner catheter system **400a** may not be fully inflated, allowing blood flow.
8 Pharmaceuticals are delivered into the vein **210** through the lumens **416** and exit ports **417** formed
9 on the catheter body **410**. Referring to FIG. **8B**, first catheter system **100** is inserted into the vein
10 **210** through an entry point and second catheter system **100'** is inserted into the vein **210** through
11 another entry point. The first catheter system **100** is anchored at a location of the vein **210** by the
12 inflated anchor balloon **115**, blocking blood flow through the location. The second catheter system
13 **100'** is positioned at another location in the vein **210** to perform reperfusion. The balloon **115'** of
14 the second catheter system **100'** may not be fully inflated, allowing blood flow. Pharmaceuticals
15 are delivered into the vein **210** through the lumens **111** formed on the catheter body **110'**.

16 Since many modifications, variations, and changes in detail can be made to the described
17 preferred embodiments of the invention, it is intended that all matters in the foregoing description
18 and shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense.
19 Consequently, the scope of the invention should be determined by the appended claims and their
20 legal equivalents.

1 **WHAT IS CLAIMED IS:**

2 1. A multidirectional balloon tipped catheter system for conducting vascular procedures upon
3 arteries in an extremity from an entry point or other branch point opposite to the extremity in the
4 arterial system, comprising:

5 a multidirectional catheter body having a proximal end and a distal end and including a
6 plurality of curls and flexion points for multidirectional deflections, wherein the catheter body
7 includes a plurality of lumens comprising:

8 at least one wire lumen including an exit port at the distal end; and

9 at least one balloon lumen including a balloon port near the distal end;

10 an anchor balloon mounted to near the distal end of the catheter body, wherein the anchor
11 balloon is in fluid communication with the balloon port and wherein the anchor balloon overhangs
12 the distal end of the catheter body by a predetermined distance when the anchor balloon is inflated;
13 and

14 a guide wire placed in the wire lumen, wherein the guide wire is configured to protrude
15 beyond the distal end of the catheter body when the guide wire is in use.

16 2. The multidirectional balloon tipped catheter system of claim 1 wherein the anchor balloon
17 is inflated with a fluid including air, saline, or contrast, and is configured to be inflated in various
18 sizes.

19 3. The multidirectional balloon tipped catheter system of claim 1 wherein the anchor balloon
20 overhangs the distal end of the catheter body by two to three millimeters when the anchor balloon
21 is inflated

22 4. The multidirectional balloon tipped catheter system of claim 1 wherein a diameter of the
23 anchor balloon is configured to occlude a vascular channel at a selected location.

24 5. The multidirectional balloon tipped catheter system of claim 1 wherein a diameter of the
25 wire lumen is equal to or greater than 0.91 mm.

26 6. The multidirectional balloon tipped catheter system of claim 1 wherein a distance of a distal
27 end of the anchor balloon from the distal end of the catheter body is in a range of 10 mm to 20 mm
28 when the anchor balloon is deflated.

29 7. The multidirectional balloon tipped catheter system of claim 1 wherein the catheter body
30 is configured to be insertable into a femoral artery or other vascular access.

1 8. The multidirectional balloon tipped catheter system of claim 1 wherein the plurality of
2 lumens further comprises one or more additional lumens for delivery of pharmaceuticals,
3 chemotherapeutics and embolization products to a selected location.

4 9. A method for conducting vascular procedures upon arteries in an extremity from an entry
5 point opposite to the extremity with a multidirectional balloon tipped catheter system, comprising:

6 inserting the multidirectional balloon tipped catheter system into the entry point in a near
7 femoral artery or other vascular access, wherein the catheter system includes a catheter body, at
8 least one anchor balloon mounted to near the distal end of the catheter body, and a guide wire
9 disposed inside the catheter body;

10 advancing the catheter system toward a branch point that is connected to the extremity;

11 inflating the anchor balloon at a first size;

12 navigating the catheter system to an ostium of the extremity;

13 inflating the anchor balloon at a second size, wherein the second size is larger than the first
14 size;

15 anchoring the catheter system at the ostial and proximal segment of the extremity by using
16 the anchor balloon inflated at the second size, wherein the extremity is occluded by the anchor
17 balloon;

18 advancing the guide wire into a distal segment of the extremity for diagnostic or therapeutic
19 procedures; and

20 deflating the anchor balloon to free the occlusion in the extremity.

21 10. The method of claim 9 further comprising inserting an entry sheath into the entry point,
22 wherein the catheter system is inserted into the entry point through the entry sheath.

23 11. The method of claim 9 further comprising performing the diagnostic or therapeutic
24 procedures while the catheter system is anchored at the ostial and proximal segment of the
25 extremity.

26 12. The method of claim 9 further comprising further advancing the catheter system into the
27 distal segment of the extremity for further diagnostic or therapeutic procedures.

28 13. The method of claim 9 further comprising administering pharmaceutical and
29 chemotherapeutic agents to local vasculature of the extremity using the catheter system while the
30 anchor balloon is inflated.

31 14. The method of claim 9 further comprising:

1 removing the catheter body with deflated anchor balloon while leaving the guide wire in
2 place; and

3 withdrawing the entry sheath over the guide wire while leaving the guide wire in place,
4 wherein the guide wire is then available to insert a long sheath or therapeutic catheter for
5 therapeutic procedures.

6 15. The method of claim 9 further comprising occluding blood vessels with embolization coils,
7 glues, plugs and other occluder devices using the catheter system while the anchor balloon is
8 inflated.

9 16. The method of claim 9 wherein the anchor balloon is inflated with a fluid including air,
10 saline, or contrast, and is configured to be inflated in various sizes.

11 17. The method of claim 9 wherein the catheter body include a plurality of curls and flexion
12 points for multidirectional deflections.

13 18. A multidirectional balloon tipped catheter system for conducting closed loop perfusion and
14 reperfusion for treatment of deep venous thrombosis, comprising:

15 a multidirectional catheter body having a proximal end and a distal end and including a
16 plurality of curls and flexion points for multidirectional deflections, wherein the catheter body
17 includes a plurality of lumens comprising:

18 a main lumen including an exit port at the distal end; and

19 at least one balloon lumen including a balloon port near the distal end;

20 an anchor balloon mounted to near the distal end of the catheter body, wherein the anchor
21 balloon is in fluid communication with the balloon port and wherein the anchor balloon overhangs
22 the distal end of the catheter body by a predetermined distance when the anchor balloon is inflated;
23 and

24 an inner catheter device disposed in the main lumen, wherein the inner catheter device
25 comprises:

26 a flexible inner catheter body including a center lumen, at least one balloon lumen,
27 and a plurality of additional lumens, wherein the inner catheter body is configured to
28 advance beyond the distal end of the multidirectional catheter body, and wherein the
29 additional lumens include exit ports open to outside of the inner catheter body; and

30 an anchor balloon mounted to near the distal end of the inner catheter body, wherein
31 the anchor balloon is in fluid communication with the balloon lumen and wherein the

1 anchor balloon overhangs the distal end of the inner catheter body by a predetermined
2 distance when the anchor balloon is inflated.

3 19. The multidirectional balloon tipped catheter system of claim 18 wherein the anchor balloon
4 and the anchor balloon of the inner catheter device are inflated with a fluid including air, saline,
5 or contrast, and are configured to be inflated in various sizes.

6 20. The multidirectional balloon tipped catheter system of claim 18 wherein the exit ports of
7 the additional lumens of the inner catheter device are formed at proximal side from the anchor
8 balloon of the inner catheter device.

9 21. The multidirectional balloon tipped catheter system of claim 18 wherein:

10 the multidirectional catheter body includes channels that are connected to the main lumen
11 and are open to outside of the multidirectional catheter body;

12 the inner catheter body includes channels that are connected to the center lumen and are
13 open to outside of the inner catheter body; and

14 the channels of the multidirectional catheter body are configured to be substantially aligned
15 with the channels of the inner catheter body to form open fluid paths, when the inner catheter
16 device advances by a predetermined distance.

17 22. The multidirectional balloon tipped catheter system of claim 21 wherein the exit ports of
18 the additional lumens of the inner catheter device are configured to be exposed outside the main
19 lumen for delivery of pharmaceuticals, chemotherapeutics and embolization products to a selected
20 location, when the inner catheter device advances by the predetermined distance.

21 23. The multidirectional balloon tipped catheter system of claim 18 wherein the
22 multidirectional catheter body is configured to be insertable into a femoral vein or other vascular
23 access.