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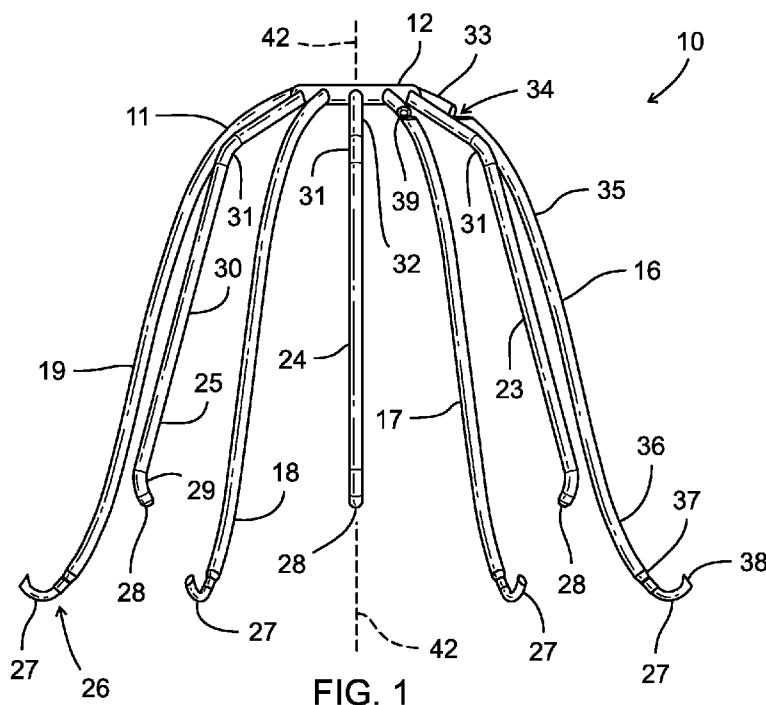
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(54) Title: VASCULAR IMPLANT



(57) Abstract: A vascular implant, comprising a polymeric filter body having a central longitudinal axis and configured to be placed in a patient's blood conveying vessel portion. The filter body has a head and an outer periphery. Multiple filter legs extend both radially and longitudinally from said head. Each leg tapes between the axis and said outer periphery. Each leg has a proximal end portion next to the head and a distal portion with an anchor for engaging a vessel wall. A weakened break point is on one or more of the legs. The filter body and legs are 3D printed of a bioresorbable polymer.

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PATENT APPLICATION

TITLE OF THE INVENTION

VASCULAR IMPLANT

5

10 CROSS-REFERENCE TO RELATED APPLICATIONS

N/A

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR
DEVELOPMENT

Not applicable

15 REFERENCE TO A "MICROFICHE APPENDIX"

Not applicable

BACKGROUND OF THE INVENTION

1. Field of the Invention

20 The present invention relates to bioresorbable vascular implants such as filters (e.g., vena cava filters) and occlusion devices. More particularly, the present invention relates to an improved vascular implant that bioresorbs into a patient's vascular system (e.g., inferior vena cava, iliofemoral vein, ovarian vein, splenic artery, uterine artery, hepatic artery or other vein/artery vessel). For example, the present invention bioresorbs into a patient's vascular system (e.g. inferior vena cava or iliofemoral vein) after
25 transient risk of pulmonary embolism (PE) has subsided. The entire implant structure could be made of bioresorbable material so that no implant or implant remnant/element would ultimately be left behind as the entire implant could resorb into vascular tissue. In one or more embodiments, the implant is specially configured and 3D printable. Break points have a controlled break (or breaks) at selected locations.

30 2. General Background of the Invention

Vascular implants include various devices that are placed at a selected locale in a patient's blood vessel. One example is a vena cava filter. Another example is an

occlusion device. Various patents have issued for vascular implants. Patents have also issued that relate in general to 3D printing of implants. Examples (each incorporated herein by reference) are listed in the following Table 1.

TABLE 1

PATENT OR PUBLICATION NO.	DESCRIPTION	ISSUE DATE (DD/MM/YYYY)
8,092,484	EMBOLUS BLOOD CLOT FILTER WITH POST DELIVERY ACTUATION	10/01/2012
8,092,485	RECOVERABLE INFERIOR VENA CAVA FILTER	10/01/2012
8,317,818	REMOVABLE BLOOD CLOT FILTER WITH EDGE FOR CUTTING THROUGH THE ENDOTHELIUM	27/11/2012
8,420,113	BIODEGRADABLE MEDICAL DEVICES WITH ENHANCED MECHANICAL STRENGTH AND PHARMACOLOGICAL FUNCTIONS	16/04/2013
8,518,072	JUGULAR FEMORAL VENA CAVA FILTER SYSTEM	27/08/2013
8,562,638	EMBOLUS BLOOD CLOT FILTER WITH FLOATING FILTER BASKET	22/10/2013
8,734,479	EMBOLUS BLOOD CLOT FILTER DELIVERY SYSTEM	27/05/2014
8,777,975	EMBOLUS BLOOD CLOT FILTER WITH BIO-RESORBABLE COATED FILTER MEMBERS	15/07/2014
8,795,351	MIGRATION RESISTANT EMBOLIC FILTER	05/08/2014
8,870,943	STENT STRUCTURE FOR IMPLANTABLE MEDICAL DEVICE	28/10/2014
8,992,562	FILTER DELIVERY SYSTEM	31/03/2015
9,220,588	SYSTEMS, METHODS AND DEVICE FOR EMBOLIC PROTECTION	29/12/2015
9,393,095	JUGULAR FEMORAL VENA CAVA FILTER SYSTEM	19/07/2016
9,421,081	EMBOLUS BLOOD CLOT FILTER DELIVERY SYSTEM	23/08/2016
9,445,895	INTRACARDIAC CAGE AND METHOD OF DELIVERING SAME	25/09/2016
9,456,888	REVERSIBLE VASCULAR FILTER DEVICES AND METHODS	04/10/2016
9,468,513	EMBOLUS BLOOD CLOT FILTER WITH BIO-RESORBABLE COATED FILTER	18/10/2016

PATENT OR PUBLICATION NO.	DESCRIPTION	ISSUE DATE (DD/MM/YYYY)
	MEMBERS	
9,561,094	DEVICES AND METHODS FOR TREATING VENOUS DISEASES	07/02/2017
9,597,435	MEDICAL DEVICES HAVING A BIORESORBABLE COATING LAYER WITH A PRE-DETERMINED PATTERN FOR FRAGMENTATION	21/03/2017
9,693,851	FILTER DELIVERY SYSTEM	14/07/2017
9,730,781	EMBOLUS BLOOD CLOT FILTER REMOVAL SYSTEM AND METHOD	15/08/2017
9,949,816	IVE FILTER RETRIEVAL SYSTEMS WITH MULTIPLE CAPTURE MODES	24/04/2018
9,980,804	VENA CAVA FILTER WITH FILAMENT	29/05/2018
10,105,206	INFERIOR VENA CAVA FILTER WITH STABILITY FEATURES	23/10/2018
10,188,496	VENA CAVA FILTER FORMED FROM A SHEET	29/01/2019
10,188,498	EMBOLUS BLOOD CLOT FILTER DELIVERY SYSTEM	29/01/2019
10,226,322	JUGULAR FEMORAL VENA CAVA FILTER SYSTEM	12/03/2019
10,258,454	VISUAL STABILIZER ON ANCHOR LEGS OF VENA CAVA FILTER	16/04/2019
10,279,078	CROSSLINKABLE 3D PRINTED BIOMATERIAL-BASED IMPLANTS AND METHODS OF MANUFACTURE THEREOF	07/05/2019
10,299,906	EMBOLUS BLOOD CLOT FILTER UTILIZABLE WITH SINGLE DELIVERY SYSTEM OR A SINGLE RETRIEVAL SYSTEM IN ONE OF A FEMORAL OR JUGULAR ACCESS	28/05/2019
10,342,654	IVC FILTER WITH TRANSLATING HOOKS	09/07/2019
10,368,972	EMBOLUS BLOOD CLOT FILTER WITH BIO-RESORBABLE COATED FILTER MEMBERS	06/08/2019
10,390,925	MIGRATION RESISTANT EMBOLIC FILTER	27/08/2019
10,441,689	METHODS AND DEVICES FOR THREE-DIMENSIONAL PRINTING OR ADDITIVE MANUFACTURING OF	15/10/2019

PATENT OR PUBLICATION NO.	DESCRIPTION	ISSUE DATE (DD/MM/YYYY)
	BIOACTIVE MEDICAL DEVICES	
10,470,865	VASCULAR FILTER DEVICE	12/11/2019
10,492,898	EMBOLUS BLOOD CLOT FILTER AND DELIVERY SYSTEM	03/12/2019
10,512,531	FILTER DELIVERY SYSTEM	24/12/2019
10,531,942	ABSORBABLE VASCULAR FILTER	14/01/2020
10,579,755	METHOD FOR 3-DAY PRINTING A CUSTOM BONE GRAFT	03/03/2020
10,624,731	VASCULAR FILTER SYSTEM	21/04/2020
10,729,527	REMOVABLE EMBOLUS BLOOD CLOT FILTER	04/08/2020
10,813,738	TUBULAR FILTER	27/10/2020
10,842,608	VENA CAVA FILTER WITH FILAMENT	24/11/2020
2007/064731	TRANSMISSION APPARATUS WITH FUNCTION OF MULTI-STEP BANDWIDTH ASSIGNMENT TO OTHER COMMUNICATION APPARATUSES	22/03/2007
2010/0074934	MEDICAL IMPLANTS WITH A COMBINATION OF COMPOUNDS	25/03/2010
2016/0166371	ENDOLUMINAL FILTER DESIGN VARIATIONS	16/06/2016
2016/0175085	ENHANCED FLUOROGENIC ENDOLUMINAL FILTER STRUCTURE	23/06/2016
2017/0105830	BIODEGRADABLE VASCULAR FILTER	20/04/2017
2017/0218228	THREE DIMENSIONAL PRINTING OF BIO-INK COMPOSITIONS	03/08/2017
2017/0249440	3D PRINTING SURGICAL REPAIR SYSTEMS	31/08/2017
2017/0340429	VASCULAR FILTER SYSTEM	30/11/2017
2018/0168811	NOVEL BIODEGRADABLE AND NON-BIODEGRADABLE 3D PRINTED IMPLANTS AS A DRUG DELIVERY SYSTEM	21/06/2018
2018/0296343	3-D PRINTING OF POROUS IMPLANTS	18/10/2018
2018/0303616	3-D PRINTING OF BONE GRAFTS	25/10/2018
2018/0311028	VENA CAVA FILTER WITH FILAMENT	01/11/2018
2019/0110880	MEDICAL DEVICES AND ANCHORS THEREFOR	18/04/2020

PATENT OR PUBLICATION NO.	DESCRIPTION	ISSUE DATE (DD/MM/YYYY)
2020/0001540	ADDITIVE MANUFACTURING ON UNCONSTRAINED FREEDOM SURFACES	02/01/2020
2020/0197150	VASCULAR FILTER SYSTEM	25/06/2020
WO2007064731	HELICAL VENA CAVA FILTER	07/06/2007
WO2011079287	REVERSIBLE VASCULAR FILTER DEVCIES AND METHODS FOR USING SAME	30/06/2011
WO2016154148	ARTIFICIAL TYMPANIC MEMBRANE DEVICES AND USES	29/09/2016
WO2018117907	SHAPE MEMORY POLYMER COMPOSITE FOR 3D PRINTING OF MEDICAL ITEMS	28/06/2018
WO2018218085	THREE-DIMENSIONAL PRINTED ORGANS, DEVICES, AND MATRICES	29/11/2018
WO2019178086	ELECTROHYDRODYNAMIC BIOPRINTER SYSTEM AND METHOD	19/09/2019
WO2020123945	FABRIC MATERIAL FOR MEDICAL DEVICES	18/06/2020
EP2363156	METHOD OF FABRICATING BIODEGRADABLE MEDICAL DEVICES WITH ENHANCED MECHANICAL STRENGTH AND PHARMACOLGOICAL FUNCTIONS	07/09/2011

BRIEF SUMMARY OF THE INVENTION

One embodiment of the present invention includes a vascular implant, having a polymeric filter body and a central longitudinal axis, configured to be placed in a patient's blood conveying vessel portion.

The filter body preferably has a head and an outer periphery. The head can be circular, oval, rounded, polygonal or other shape that enables attachment of filter legs thereto.

Multiple filter legs preferably extend both radially and longitudinally from the head.

Each leg can preferably be tapering between the central longitudinal axis and the outer periphery.

Each leg preferably has a proximal end portion next to the head and a distal

portion with an anchor for engaging a vessel wall.

Preferably, there is a weakened break point on one or more of the legs.

In one or more embodiments, the filter body and legs are 3D printed.

5 In one or more embodiments, the body and legs are 3D printed of a bioresorbable material.

In one or more embodiments, the head is positioned at the central longitudinal axis.

10 In one or more embodiments, each leg tapers. Preferably, the thickness of each leg is encompassed in a range of a minimum thickness of about 0.2 mm to a maximum thickness of about 4.0 mm.

In one or more embodiments, the weakened break point is an indentation.

In one or more embodiments, the weakened break point is a score.

In one or more embodiments, the polymeric body is too soft to be machined.

15 In one or more embodiments, the polymeric body has a durometer reading of between 35 Shore A and 75 Shore D.

In one or more embodiments, the head has a ring, annular shape, oval or rounded or polygonal shape.

In one or more embodiments, the filter body and legs define a vena cava filter.

In one or more embodiments, the filter body and legs define an occlusion device.

20 In one or more embodiments, a vascular implant has a filter body having a central longitudinal axis and configured to be placed in a patient's blood conveying vessel portion. The filter body has a head and an outer periphery. Multiple filter legs preferably extend both radially and longitudinally from the head. Each leg has a proximal end portion next to said head and a distal portion with anchor for engaging a vessel wall.

25 There is a weakened break point on one or more of said legs.

In one or more embodiments, the filter body is of a material that is too soft to be machined.

In one or more embodiments, the head is in the form of a ring.

30 In one or more embodiments, the body and legs are 3D printed of a bioresorbable material, such as a bioresorbable polymer.

In one or more embodiments, the polymeric body is too soft to be machined, being of a material having a durometer reading below approximately 20 Shore D.

In one or more embodiments, at least some of said anchors are hook shaped.

The diameter of the present invention can vary depending on location as would be recognized and known to one of ordinary skill in the art. For inferior vena cava (IVC) pulmonary embolism prevention the diameter can be between about 15-30 mm. For iliofemoral pulmonary embolism prevention the diameter can be between about 6 and 20 mm. For other smaller vessels for occlusion, the diameter can be between about 2 and 8 mm. Lengths can be between about 5-50 mm.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

For a further understanding of the nature, objects, and advantages of the present invention, reference should be had to the following detailed description, read in conjunction with the following drawings, wherein like reference numerals denote like elements and wherein:

Figure 1 is an elevation view of a preferred embodiment of the apparatus of the present invention;

Figure 2 is a top view of a preferred embodiment of the apparatus of the present invention;

Figure 3 is a fragmentary view of a preferred embodiment of the apparatus of the present invention; and

Figure 4 is a fragmentary view of a preferred embodiment of the apparatus of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Figures 1-4 show a preferred embodiment of the apparatus of the present invention, designated generally by the numeral 10. Vascular implant 10 has a body 11 with central longitudinal axis 42. Body 11 can be polymeric and can be of a bioresorbable material such as a bioresorbable polymeric material. When of a bioresorbable material, the bioresorption starts as soon as the implant is exposed to the blood and like many of the standard polymers degrades over time via polymer breakdown and absorption of the byproducts. This bioresorption can be tuned as needed to ensure the implant maintains structural filtering integrity until transient risk of pulmonary embolism has subsided. Body 11 includes a head in the form of a ring, also referred to as an annular member 12 and has an outer periphery. In this example, the outer periphery lies in the longitudinal at a distance from the head, and the implant is to

be placed in the vessel with the head upstream, in a direction of bloodflow, from the outer periphery. The body 11 is open at the bottom, and seen in radial direction, the bottom is wider than the head, more specifically in this embodiment the outer periphery is located at the bottom of the body 11. The body 11 has a frusto-conical shape with an open base, with the head 12 forming the top and the outer periphery the base of the conus. In this embodiment, the frusto-conical shape has a bell-shaped form, where at the top the conus is curved inwards, towards the central axis and at the bottom curved outwards.

The body 11 comprises multiple appendages, also referred to as legs 14-19, which extend both radially and longitudinally from the head, towards the outer periphery, in this embodiment up to the outer periphery. The part of the appendages 14-19 which in radial direction is most distant from the longitudinal axis of the body 11 may form the outer periphery. Each of the legs 14-19 has a proximal end portion next to the head and a distal portion with an anchor for engaging a vessel wall. In the shown embodiment, appendages 14-19 are affixed at attachment 43 to ring 12 (see Figure 3) (with appendages or legs 20-25 affixed to ring 12 with attachment 44) (see Figure 4). In this embodiment, the distal portion forms a free-end of the respective appendage 14-19. The appendages may form an open cell filter or a closed cell filter, for instance.

When the vascular implant is placed in the vessel, blood will flow, substantially in the longitudinal direction of the body 11, in the direction from the outer periphery towards the head and pass through the body 11 to be filtered. The blood will flow through the space between the legs 14-25, as well as in this embodiment through the opening 13 of the ring 12, and blood clots that cannot pass through this space and, if present, the opening are blocked from passing through.

Hood, ring or annular member 12 can have central opening 13 (see Figure 2). This can reduce the fluid resistivity of the filter body. In one or more embodiments, body 11 is manufactured (e.g., in one piece) with a 3D printer. Body 11 can be of a soft material that is too soft to be machined. A durometer reading of body 11 can be between about 35 Shore A and 75 Shore D.

The implant 10 may comprise mutually differing appendages. For example, the implant 10 may comprise two or more sets of appendages, where between the sets the appendages differ but in each set the appendages are similar. In the shown embodiment,

for instance the implant 10 comprises appendages 14-19 with anchors and appendages 20-25 without anchors. Additionally, or alternatively, the sets may differ in other aspects. In the shown embodiment, for instance, appendages 14-19 (see Figure 3) are a first set of appendages that can be longer than appendages 20-25 (see Figure 1) of a second set. Appendages 14-19 each have a distal end or distal end portion 26 having an anchor 27 such as a hook shaped anchor 27. Anchor 27 can have a sharp tip 38 (see Figure 3) for enabling penetration of anchor 27 into a patient's vascular tissue 40 (e.g., inferior vena cava or iliofemoral vein). In Figure 2, reference numeral 41 represents the penetrating portion of anchor 27 that penetrates vascular tissue 40. The penetration allows to anchor the implant in the respective vessel and to hold the implant in position.

As illustrated in the shown embodiment, one or more of the appendages may be provided with a weakened break point, also referred to as a weakened portion 39. Due to the breakpoint, the appendage will break away from the body a certain period in time after having been placed in the vessel, without intervention of a medical practitioner. Thereby, the attachment of the body to the vessel via that appendage is released. The need for a retrieval procedure on the patient to retrieve the implant can be obviated thereby. For example, some or all of the appendages that anchor in the vessel may be provided with weakened break points and upon breaking of a respective breakpoint the filter may fall towards the opposite side of the vessel and to e.g. be resorbed in the vessel. In one or more embodiments, one or more of the appendages 14-19 has a recess, notch, or score 34 that is next to a weakened portion 39 (see Figure 3). The weakened portion 39 is made of a material that breaks down over time, e.g. by dissolving or resorbing. The depth of the cut of recess, notch or score 34 determines the time to failure. In Figures 1 and 3, the notch is shown cut at the deep end of the range (though the notch need not be cut at the deep end of the range). Weakened portion 39 can be on an appendage that has an anchor. As weakened portion 39 dissolves or resorbs, the appendage portion distally of recess, notch, or score 34 will break away from the remainder of body 11. The appendage portion distally of recess, notch, or score 34 may then e.g. breakdown, e.g. dissolve or resorb into vascular tissue 40. The body 11 may be implemented such that all of body 11 will also resorb into the vascular tissue 40. When an appendage breaks at the weakened area 39 next to notch 34, it is a controlled failure. The leg would resorb into the wall/vascular tissue and the remaining portion of the filter would fall to the

other/opposing side of the vessel and resorb into the wall/vascular tissue. This configuration provides a way to bias the filter to resorb where desired (desired location).

Figures 3-4 show appendages 14-19 (Figure 3) and 20-25 (Figure 4) in more detail. Appendages 14-19 each have upper section 33, lower section 36 and middle section 35. Upper 33 and lower 36 sections can be curved (all or part of sections 33, 36 can be curved). Anchor 27 extends from or attaches to lower section 36 at tapered section 37 (see Figure 3).

In Figure 4, appendages 20-25 each have distal end 28. Each appendage 20-25 has a curved section or bend 29 that curves toward body 11 central longitudinal axis 42 (see Figure 1). Thus, appendages 20-25 will not anchor into the vessel. Each appendage 20-25 can have straight section 30, curved section or bend 31, and straight section 32. Straight section 32 affixes to annular member, ring or head 12 at attachment 44. Appendages 20-25 can be shorter than appendages 14-19. For example, as seen in FIG. 2, appendages 20-25 can be, seen in radial direction, be inside the perimeter defined by the distal ends 27 of the appendages 14-19 and when the implant is placed not touch the vessel.

The implant 10 could be deployed with either a femoral or jugular approach. Such a deployment could employ a pusher or pusher apparatus/mechanism such as one specified in one or more of the patents listed in Table 1. An example is U.S. Patent No. 8,518,072 naming Jonathan Miller as inventor and assigned to C.R. Bard, Inc. Implant 10 could also be a balloon-mounted implant that is then expanded with balloon dilation, as seen, for example, in balloon expandable stents.

The vascular implant can thus be characterized by comprising a filter body comprising a central longitudinal axis and configured to be placed in a patient's blood conveying vessel portion, said filter body comprising a head and an outer periphery. The body comprising multiple filter legs extending both radially and longitudinally from said head, each of said legs comprising a proximal end portion next to said head and a distal portion with anchor for engaging a vessel wall and a weakened break point on one or more of said legs. Without limitation, the implant may further be characterized by one or more of the following statements.

Statement 1. A vascular implant, comprising:

a) a polymeric filter body comprising a central longitudinal axis and

configured to be placed in a patient's blood conveying vessel portion;

- b) said filter body comprising a head and an outer periphery;
- c) multiple filter legs extending both radially and longitudinally from said head;
- 5 d) each said leg tapering between said axis and said outer periphery;
- e) each leg comprising a proximal end portion next to said head and a distal portion with an anchor for engaging a vessel wall; and
- f) a weakened break point on one or more of said legs.

Statement 2. The vascular implant of statement 1 wherein said filter body and
10 legs are 3D printed.

Statement 3. The vascular implant of statement 2 wherein the body and legs are 3D printed of a bioresorbable material.

Statement 4. The vascular implant of any of the preceding statements wherein the head is positioned at said central longitudinal axis.

15 Statement 5. The vascular implant of any of the preceding statements wherein each said leg tapers from a minimum thickness to a maximum thickness.

Statement 6. The vascular implant of any of the preceding statements wherein said weakened break point is an indentation.

20 Statement 7. The vascular implant of any of the preceding statements wherein said weakened break point is a score.

Statement 8. The vascular implant of any of the preceding statements wherein said polymeric body is too soft to be machined.

Statement 9. The vascular implant of statement 8 wherein the polymeric body has a durometer reading of between 35 Shore A and 75 Shore D.

25 Statement 10. The vascular implant of any of the preceding statements wherein said head is ring shaped.

Statement 11. The vascular implant of any of the preceding statements wherein the filter body and legs define a vena cava filter.

30 Statement 12. The vascular implant of any of the preceding statements wherein the filter body and legs define an occlusion device.

Statement 13. A vascular implant, comprising:

- a) a filter body comprising a central longitudinal axis and configured to be

placed in a patient's blood conveying vessel portion;

- b) said filter body comprising a head and an outer periphery;
- c) multiple filter legs extending both radially and longitudinally from said head;
- 5 d) each leg comprising a proximal end portion next to said head and a distal portion with anchor for engaging a vessel wall;
- e) a weakened break point on one or more of said legs; and
- f) wherein the filter body is of a material that is too soft to be machined.

Statement 14. The vascular implant of any of the preceding statements wherein
10 the head is in the form of a ring.

Statement 15. The vascular implant of statement 13 or 14 wherein said filter body and legs are 3D printed.

Statement 16. The vascular implant of statement 15 wherein the body and legs are 3D printed of a bioresorbable material.

15 Statement The vascular implant of statement 16 wherein said body is too soft to be machined.

Statement 18. The vascular implant of any of the preceding statements wherein at least some of said anchors are hook shaped.

Statement 19. The vascular implant of any of statements 13-18 wherein at least
20 some of said anchors are hook shaped.

Statement 20. A vascular implant, comprising:

- a) a filter body comprising a central longitudinal axis and configured to be placed in a patient's blood conveying vessel portion;
- b) said filter body comprising a head in the form of an annular member with
25 a central opening and an outer periphery;
- c) multiple filter legs extending both radially and longitudinally from said head;
- d) each leg comprising a proximal end portion that connects said annular member and a distal end portion;
- 30 e) a weakened break point on one or more of said legs; and
- f) wherein the filter body is of a material that is too soft to be machined.

The following is a list of parts and materials suitable for use in the present

invention.

PARTS LIST

	<u>Part Number</u>	<u>Description</u>
5	10	vascular implant
	11	body
	12	annular member/ring/head
	13	central opening
	14	appendage/leg
10	15	appendage/leg
	16	appendage/leg
	17	appendage/leg
	18	appendage/leg
	19	appendage/leg
15	20	appendage/leg
	21	appendage/leg
	22	appendage/leg
	23	appendage/leg
	24	appendage/leg
20	25	appendage/leg
	26	distal end portion
	27	anchor/hook shaped distal end
	28	distal end
	29	curved section/bend
25	30	straight section
	31	curved section/bend
	32	straight section
	33	upper section
	34	recess/notch/score
30	35	middle section
	36	lower section
	37	tapered section

	38	sharp tip
	39	weakened portion
	40	vascular tissue
	41	penetrating portion
5	42	central longitudinal axis
	43	attachment
	44	attachment

All measurements disclosed herein are at standard temperature and pressure, at
10 sea level on Earth, unless indicated otherwise. All materials used or intended to be used
in a human being are biocompatible, unless indicated otherwise.

The foregoing embodiments are presented by way of example only; the scope of
the present invention is to be limited only by the following claims.

CLAIMS

1. A vascular implant, comprising:
 - a) a polymeric filter body having a central longitudinal axis and configured to be placed in a patient's blood conveying vessel portion;
 - 5 b) said filter body having a head and an outer periphery;
 - c) multiple filter legs extending both radially and longitudinally from said head;
 - d) each said leg tapering between said axis and said outer periphery;
 - e) each leg having a proximal end portion next to said head and a distal
 - 10 portion with an anchor for engaging a vessel wall; and
 - f) a weakened break point on one or more of said legs.
2. The vascular implant of claim 1 wherein said filter body and legs are 3D printed.
3. The vascular implant of claim 2 wherein the body and legs are 3D printed
- 15 of a bioresorbable material.
4. The vascular implant of claim 1 wherein the head is positioned at said central longitudinal axis.
5. The vascular implant of claim 1 wherein each said leg tapers from a minimum thickness to a maximum thickness.
- 20 6. The vascular implant of claim 1 wherein said weakened break point is an indentation.
7. The vascular implant of claim 1 wherein said weakened break point is a score.
8. The vascular implant of claim 1 wherein said polymeric body is too soft
- 25 to be machined.
9. The vascular implant of claim 8 wherein the polymeric body has a durometer reading of between 35 Shore A and 75 Shore D.
10. The vascular implant of claim 1 wherein said head is ring shaped.
11. The vascular implant of claim 1 wherein the filter body and legs define a
- 30 vena cava filter.
12. The vascular implant of claim 1 wherein the filter body and legs define an occlusion device.

13. A vascular implant, comprising:
- a) a filter body having a central longitudinal axis and configured to be placed in a patient's blood conveying vessel portion;
- b) said filter body having a head and an outer periphery;
- 5 c) multiple filter legs extending both radially and longitudinally from said head;
- d) each leg having a proximal end portion next to said head and a distal portion with anchor for engaging a vessel wall;
- e) a weakened break point on one or more of said legs; and
- 10 f) wherein the filter body is of a material that is too soft to be machined.
14. The vascular implant of claim 1 wherein the head is in the form of a ring.
15. The vascular implant of claim 13 wherein said filter body and legs are 3D printed.
16. The vascular implant of claim 15 wherein the body and legs are 3D
- 15 printed of a bioresorbable material.
17. The vascular implant of claim 16 wherein said body is too soft to be machined.
18. The vascular implant of claim 1 wherein at least some of said anchors are hook shaped.
- 20 19. The vascular implant of claim 13 wherein at least some of said anchors are hook shaped.
20. A vascular implant, comprising:
- a) a filter body having a central longitudinal axis and configured to be placed in a patient's blood conveying vessel portion;
- 25 b) said filter body having a head in the form of an annular member with a central opening and an outer periphery;
- c) multiple filter legs extending both radially and longitudinally from said head;
- d) each leg having a proximal end portion that connects said annular
- 30 member and a distal end portion;
- e) a weakened break point on one or more of said legs; and
- f) wherein the filter body is of a material that is too soft to be machined.

21. The inventions substantially as shown and/or described herein.

AMENDED CLAIMS
received by the International Bureau on
26 April 2023 (26.04.23)

Claims

- [Claim 1] [Amended] A vascular implant, comprising:
a) a polymeric filter body having a central longitudinal axis and configured to be placed in a patient's blood conveying vessel portion;
b) said filter body having a head and an outer periphery;
c) multiple filter legs extending both radially and longitudinally from said head;
d) each said leg tapering between said axis and said outer periphery;
e) each leg having a proximal end portion next to said head and a distal portion with an anchor for engaging a vessel wall;
f) a weakened break point on one or more of said legs; and
g) wherein a majority of the length of each said leg is in between the weakened break point and the anchor.
- [Claim 2] The vascular implant of claim 1 wherein said filter body and legs are 3D printed.
- [Claim 3] The vascular implant of claim 2 wherein the body and legs are 3D printed of a bioresorbable material.
- [Claim 4] The vascular implant of claim 1 wherein the head is positioned at said central longitudinal axis.
- [Claim 5] The vascular implant of claim 1 wherein each said leg tapers from a minimum thickness to a maximum thickness.
- [Claim 6] The vascular implant of claim 1 wherein said weakened break point is an indentation.
- [Claim 7] The vascular implant of claim 1 wherein said weakened break point is a score.
- [Claim 8] The vascular implant of claim 1 wherein said polymeric body is too soft to be machined.
- [Claim 9] The vascular implant of claim 8 wherein the polymeric body has a durometer reading of between 35 Shore A and 75 Shore D.
- [Claim 10] The vascular implant of claim 1 wherein said head is ring shaped.
- [Claim 11] The vascular implant of claim 1 wherein the filter body and legs define a vena cava filter.
- [Claim 12] The vascular implant of claim 1 wherein the filter body and legs define an occlusion device.
- [Claim 13] [Amended] A vascular implant, comprising:
a) a filter body having a central longitudinal axis and configured to be placed in a patient's blood conveying vessel portion;

- b) said filter body having a head and an outer periphery;
- c) multiple filter legs extending both radially and longitudinally from said head;
- d) each leg having a proximal end portion next to said head and a distal portion with an anchor for engaging a vessel wall;
- e) a weakened break point on one or more of said legs that is closer to the head than to the anchor; and
- f) wherein the filter body is of a material that is too soft to be machined.

[Claim 14] The vascular implant of claim 1 wherein the head is in the form of a ring.

[Claim 15] The vascular implant of claim 13 wherein said filter body and legs are 3D printed.

[Claim 16] The vascular implant of claim 15 wherein the body and legs are 3D printed of a bioresorbable material.

[Claim 17] The vascular implant of claim 16 wherein said body is too soft to be machined.

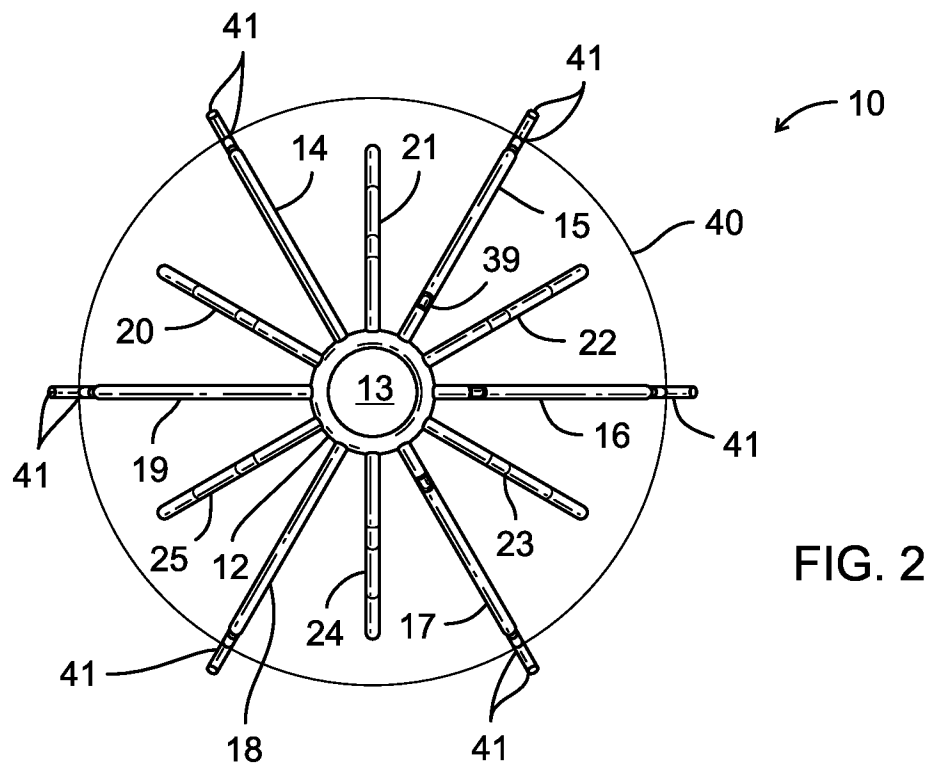
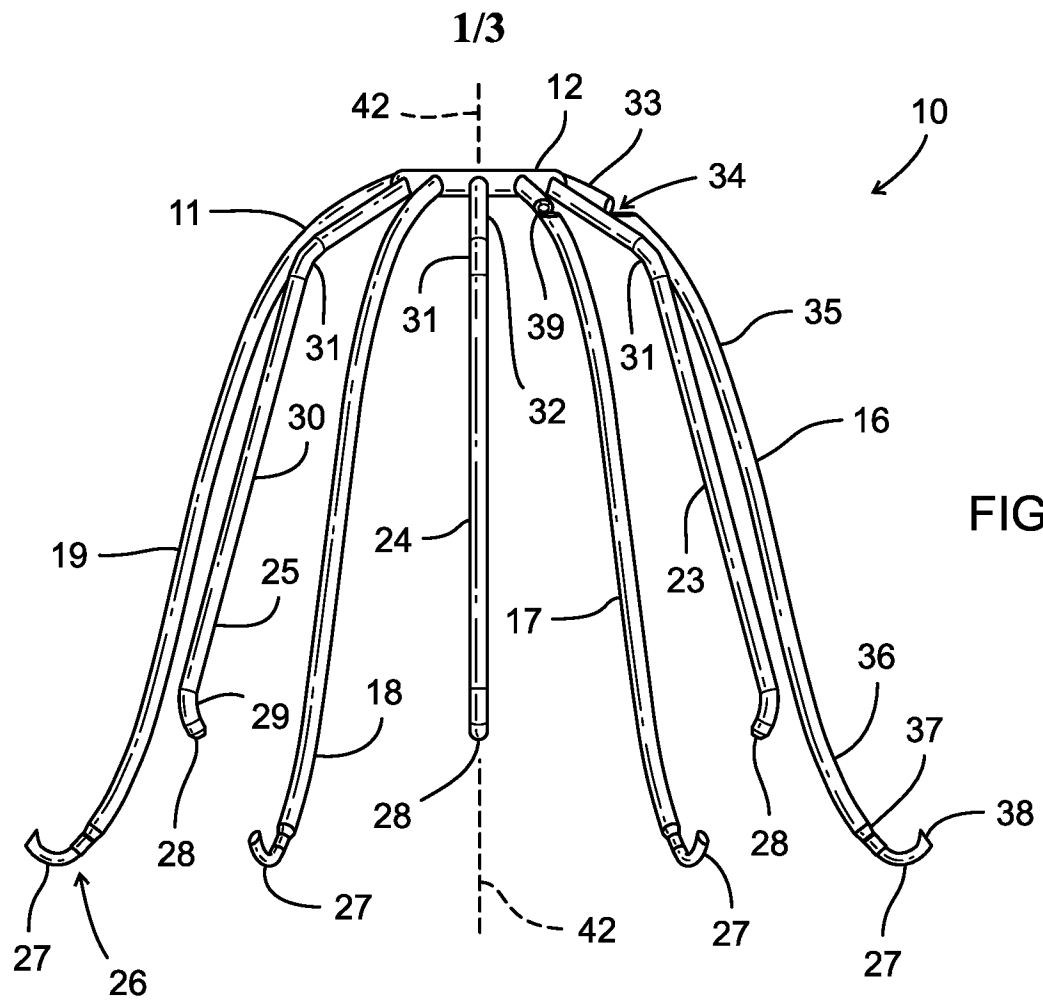
[Claim 18] The vascular implant of claim 1 wherein at least some of said anchors are hook shaped.

[Claim 19] The vascular implant of claim 13 wherein at least some of said anchors are hook shaped.

[Claim 20] [Amended] A vascular implant, comprising:

- a) a filter body having a central longitudinal axis and configured to be placed in a patient's blood conveying vessel portion;
- b) said filter body having a head in the form of an annular member with a central opening and an outer periphery;
- c) multiple filter legs extending both radially and longitudinally from said head;
- d) each leg having a proximal end portion that connects said annular member, and a distal end portion;
- e) a weakened break point on the proximal end portion of one or more of said legs; and
- f) wherein the filter body is of a material that is too soft to be machined.

[Claim 21] [Cancelled]



2/3

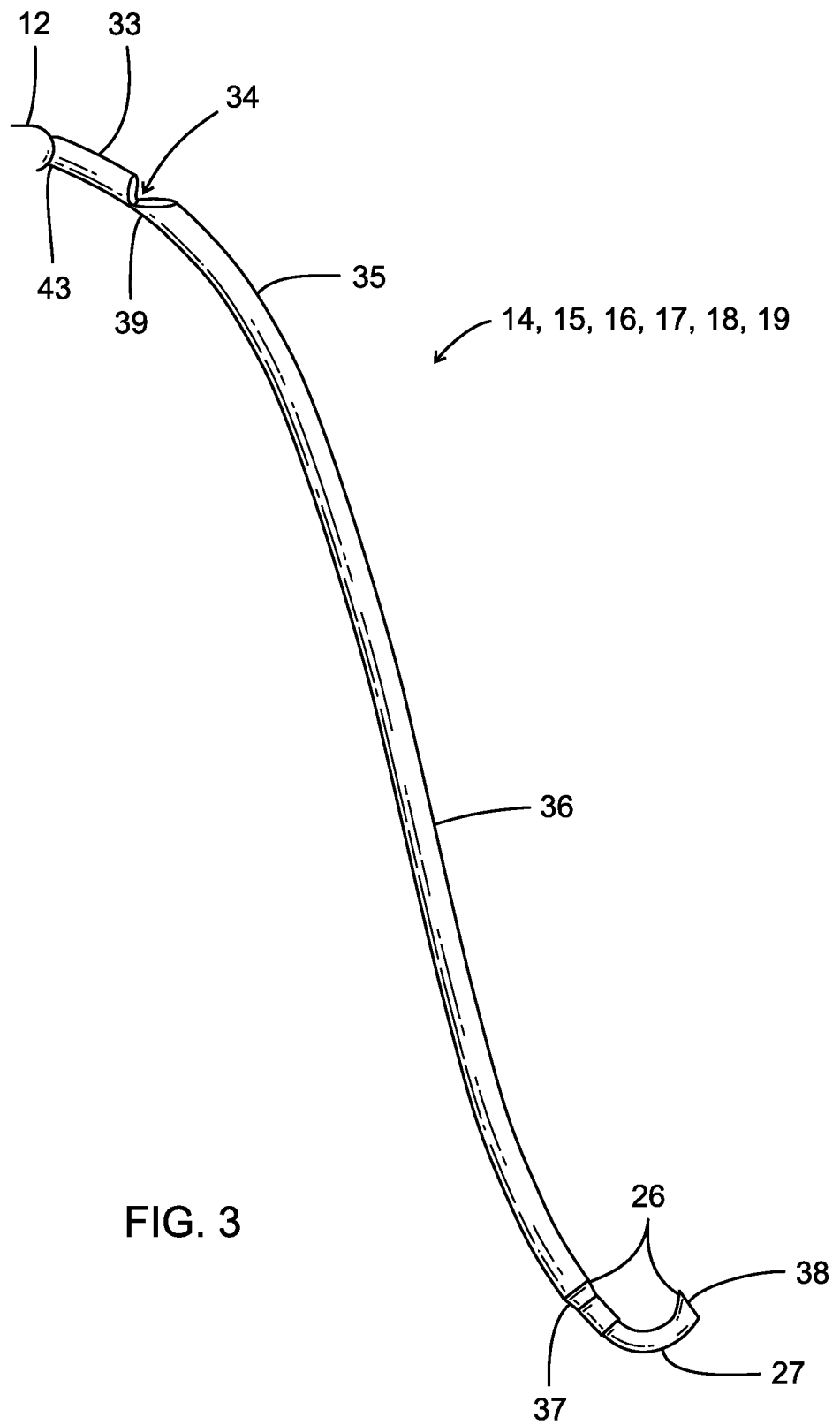


FIG. 3

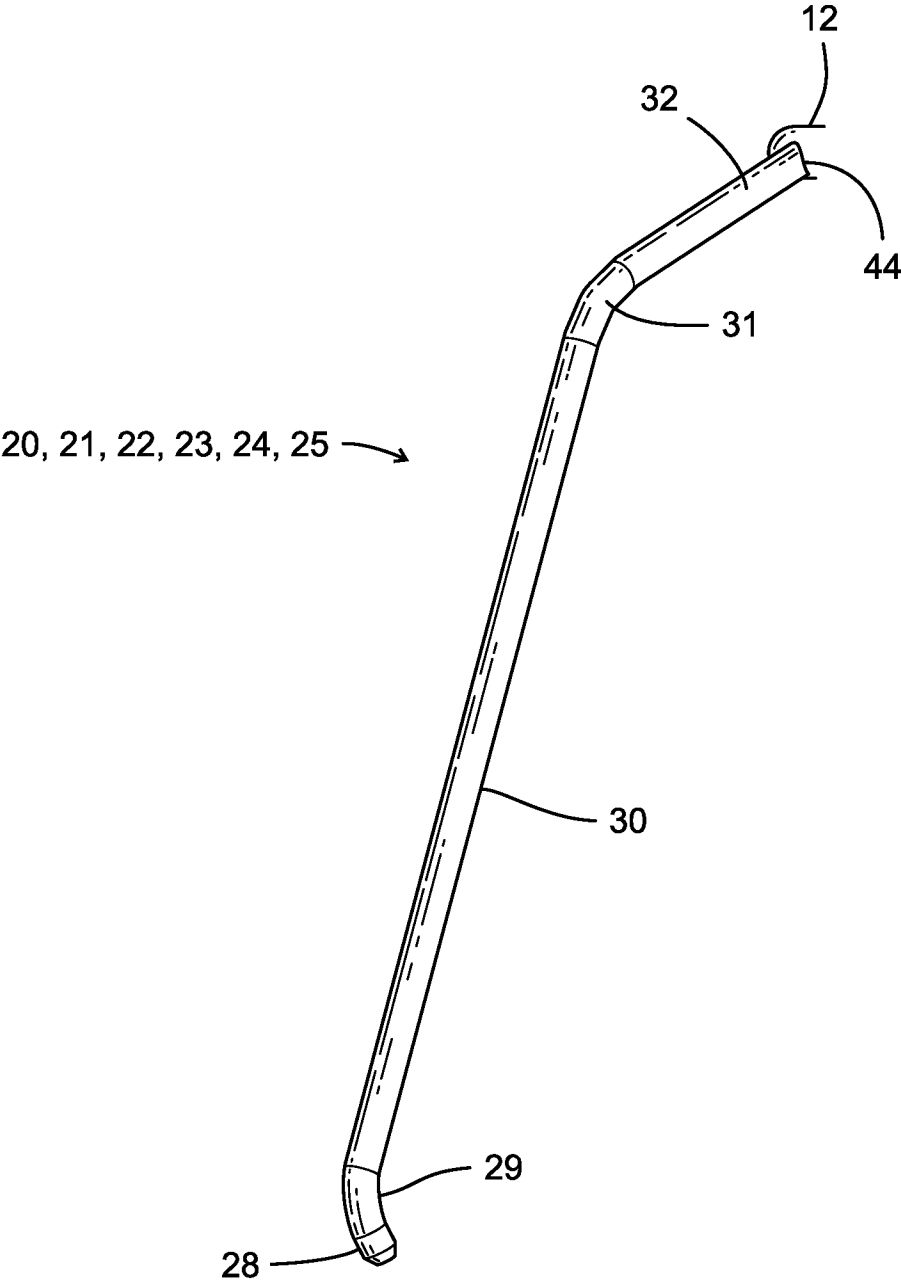


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2021/073175

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/01

ADD.

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)

A61F B33Y A61B

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2007/106378 A2 (BARD INC C R [US]; CARR ROBERT M JR [US]; CHANDUSZKO ANDRZEJ J [US]) 20 September 2007 (2007-09-20) paragraphs [0022] - [0025], [0028], [0029], [0033] - [0040]; figures 3A-4, 6, 7 -----	1-12

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

12 September 2022

Date of mailing of the international search report

20/09/2022

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Geuer, Melanie

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2021/073175

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: **13-21**
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 13-21

1 The present application contains 21 claims of which 4 are independent. It contains 4 independent claims concerning a vascular implant. There is no clear distinction between the independent claims within one group because of overlapping scope. There are so many claims, and they are drafted and ordered in such a way that the claims as a whole are not in compliance with the provisions of clarity and conciseness of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought.

2 There is a multitude of equally likely permutations of features providing as many fall-back positions, making it impossible to foresee to which subject-matter from the claims and the description are most likely to provide the basis for prosecution of the application.

3 Some of the most serious clarity issues are detailed further below:

3.1 Although entity claims 1, 13, 20 and 21 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

3.2 The claims and description are formulated to provide a multitude of permutations of features, providing as many equally likely fall-back positions, making it impossible to foresee to which subject-matter from the description and the claims are most likely to provide a basis for prosecution of the application.

4 The applicant has been informally invited to provide a clarification of the subject-matter which should be searched. The invention defined in the device claim and the invention defined in the method claim should meet the requirement of unity of invention under Rule 13 PCT.

5 Due to failure to provide a clarification, the search is limited to the subject-matter of claims 1-12 which represent the broadest claims, for the reasons mentioned above.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2),

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

should the problems which led to the Article 17(2) PCT declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2021/073175

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007106378	A2	20-09-2007	NONE
