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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/930,183	10/29/2024	David John Onushko	2001.3357101	3963

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EXAMINER	
RESTAINO, ANDREW PETER	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
05/18/2026	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

BSC.USPTO@stwiplaw.com

Office Action Summary	Application No. 18/930,183	Applicant(s) Onushko et al.	
	Examiner Andrew Restaino	Art Unit 3771	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 05/05/2026.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-18 and 20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-18 and 20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 05/05/2026 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Response to Amendment

2. This Office action is in response to the applicant's communication filed 05/05/2026.

Status of the claims:

Claims 1 – 18 and 20 are pending in the application.

Claims 1, 13, and 20 are amended.

Drawings

3. The objections to the drawings in the previous action dated 02/18/2026 have been withdrawn in light of the Applicant's amendments filed 05/05/2026. Specifically, the objection to the drawings, regarding the reference number "628" in Fig. 10, has been withdrawn as the appropriate corrections have been made.

Claim Objections

4. The objections to claims 1, 13, 19, and 20 in the previous action dated 02/18/2026 have been withdrawn in light of the Applicant's amendments filed 05/05/2026. Specifically, the objection to claims 1, 13, and 20 regarding the phrase "an occlusive implant", the objection to claim 13 regarding the phrase "having spacer

assembly", and the objection to claim 19 regarding the phrase "wherein spacer member" have all been withdrawn as the appropriate corrections have been made.

Claim Rejections - 35 USC § 112

5. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

> The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 10 and 11 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

7. Regarding claims 10 and 11, the phrase "one or more bead members" renders the claim indefinite because claim 1 defines "a plurality of bead members", and it is unclear if Applicant is intending for the "one or more bead members" of claims 10 and 11 to be bead members that are comprised within the "plurality of bead members" of claim 1 or if Applicant is intending for "the one or more bead members" of claims 10 and 11 to be separate bead members such that claims 10 and 11 require at least three bead members (i.e., a plurality plus one). For the purpose of examination the Examiner will read the claim to mean the former.

Claim Rejections - 35 USC § 102

8. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

10. **Claims 13 and 16 – 18 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Perszyk et al (US 2018/0235658 A1) *(previously cited)*.**

11. **Regarding claim 13**, Perszyk discloses a delivery device (introducer assembly 100 and delivery cable 200) for an occlusive implant (medical device 201) (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – 5), the delivery device comprising:

a. a delivery sheath (delivery sheath 203) having a proximal region, a distal tip region, and a lumen formed therein (paragraphs [0006 – 0007], [0024], [0030 – 0031], [0039 – 0040], and Fig. 2);

b. a core wire (delivery cable 200) slidably disposed in the lumen (paragraphs [0006 – 0007], [0032 – 0036], and Fig. 5) (Examiner's note:

paragraph [0007] recites “The method further includes advancing the delivery cable through the deployed delivery sheath”);

c. wherein the core wire (delivery cable 200) includes a central shaft (inner member 202), a first region (proximal section 206) having a first coil assembly (proximal outer member 210) disposed along the central shaft (inner member 202), a second region (distal section 204) with having spacer assembly (distal outer member 208) disposed along the central shaft, and a distal implant securing region (end screw 212) (paragraphs [0036 – 0040] and Fig. 5); and

d. an occlusive implant (implant 201) coupled to the distal implant securing region (paragraphs [0026], [0030], [0032], and Fig. 2);

e. wherein the spacer assembly (distal outer member 208) defines an outer diameter approximately equal to an inner diameter of the lumen (paragraphs [0028] and [0039]) (Examiner’s note: the term “approximately” is defined as very close to. With that said, as stated in paragraph [0040] the outer diameter of the distal outer member 208 (i.e., the spacer assembly) is greater than 98% of the inner diameter of the delivery sheath (i.e., the diameter of the lumen), and because the outer diameter of the distal outer member 208 (i.e., the spacer assembly) being within less than two percent of the inner diameter of the lumen of the delivery sheath the outer diameter of the distal outer member 208 (i.e., the spacer assembly) is considered to be approximately equal to the inner diameter of the lumen. Therefore, Perszyk discloses the device as claimed).

12. **Regarding claim 16**, Perszyk discloses wherein the spacer assembly (distal outer member 208) includes a spiral tube (distal outer member 208 is a coil, which is a spiral tube) disposed about the central shaft (inner member 202) (paragraphs [0036 – 0040] and Fig. 5).

13. **Regarding claim 17**, Perszyk discloses wherein the central shaft (inner member 202) includes stainless steel (paragraph [0034])

14. **Regarding claim 13**, *(alternate interpretation – changes italicized below)* Perszyk discloses a delivery device (introducer assembly 100 and delivery cable 200) for an occlusive implant (medical device 201) (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – *6*), the delivery device comprising:

f. a delivery sheath (delivery sheath 203) having a proximal region, a distal tip region, and a lumen formed therein (paragraphs [0006 – 0007], [0024], [0030 – 0031], [0039 – 0040], and Fig. 2);

g. a core wire (delivery cable 200) slidably disposed in the lumen (paragraphs [0006 – 0007], [0032 – 0036], and Fig. 5) (Examiner's note: paragraph [0007] recites "The method further includes advancing the delivery cable through the deployed delivery sheath");

h. wherein the core wire (delivery cable 200) includes a central shaft (inner member 202 with *core wire 406, first layer 404, and second layer 406*), a first region (proximal section 206) having a first coil assembly (proximal outer member 210) disposed along the central shaft (inner member 202), a second

region (distal section 204) with having spacer assembly (distal outer member 208) disposed along the central shaft, and a distal implant securing region (end screw 212) (paragraphs [0036 – 0040] and Fig. 5); and

i. an occlusive implant (implant 201) coupled to the distal implant securing region (paragraphs [0026], [0030], [0032], and Fig. 2);

j. wherein the spacer assembly (distal outer member 208) defines an outer diameter approximately equal to an inner diameter of the lumen (paragraphs [0028] and [0039]) (Examiner's note: the term "approximately" is defined as very close to. With that said, as stated in paragraph [0040] the outer diameter of the distal outer member 208 (i.e., the spacer assembly) is greater than 98% of the inner diameter of the delivery sheath (i.e., the diameter of the lumen), and because the outer diameter of the distal outer member 208 (i.e., the spacer assembly) being within less than two percent of the inner diameter of the lumen of the delivery sheath the outer diameter of the distal outer member 208 (i.e., the spacer assembly) is considered to be approximately equal to the inner diameter of the lumen. Therefore, Perszyk discloses the device as claimed).

15. **Regarding claim 18**, *(alternate interpretation)* Perszyk discloses wherein the central shaft (inner member 202) includes a stainless steel member (second layer 406) and a nickel-titanium alloy member (first layer 404) secured to the stainless steel member (paragraph [0047]).

Claim Rejections - 35 USC § 103

16. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

17. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly

owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

20. **Claims 1 – 5, 7 – 12, and 14 are rejected under 35 U.S.C. 103 as being unpatentable over Perszyk et al (US 2018/0235658 A1) *(previously cited)* and in view of Chin et al (US 2012/0191012 A1) *(previously cited)* and Douk et al (US 6,183,420 B1) *(previously cited)*.**

21. **Regarding claims 1, 10, and 11**, Perszyk discloses a delivery device (introducer assembly 100 and delivery cable 200) for an occlusive implant (medical device 201) (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – 5, 12), the delivery device comprising:

k. a delivery sheath (delivery sheath 203) having a proximal region, a distal tip region, and a lumen formed therein (paragraphs [0006 – 0007], [0024], [0030 – 0031], [0039 – 0040], and Fig. 2);

l. a core wire (delivery cable 200) slidably disposed in the lumen (paragraphs [0006 – 0007], [0032 – 0036], and Fig. 5,12);

m. wherein the core wire (delivery cable 200) includes a central shaft (inner member 202), a first region (proximal section 206) having a first coil assembly (proximal outer member 210) disposed along the central shaft (inner member 202), a second region (distal section 204) having a second coil assembly (distal outer member 208) disposed along the central shaft, and a distal implant

securing region (end screw 212) (paragraphs [0036 – 0040], [0055], and Fig. 12); and

n. an occlusive implant (implant 201) coupled to the distal implant securing region (paragraphs [0026], [0030], [0032], and Fig. 2);

o. wherein second coil assembly (distal outer member 208) defines an outer diameter approximately equal to an inner diameter of the lumen (paragraphs [0028] and [0039]) (Examiner's note: the term "approximately" is defined as very close to. With that said, as stated in paragraph [0040] the outer diameter of the distal outer member 208 (i.e., the spacer assembly) is greater than 98% of the inner diameter of the delivery sheath (i.e., the diameter of the lumen), and because the outer diameter of the distal outer member 208 (i.e., the spacer assembly) being within less than two percent of the inner diameter of the lumen of the delivery sheath the outer diameter of the distal outer member 208 (i.e., the spacer assembly) is considered to be approximately equal to the inner diameter of the lumen. Therefore, Perszyk discloses the device as claimed).

22. However, Perszyk is silent regarding **[claims 1, 10, and 11] (i)** a plurality of beads members disposed over the central shaft adjacent to the first region and/or disposed over the central shaft between the first region and the second region and **(ii)** wherein each of the plurality of beads members defines an outer diameter approximately equal to an inner diameter of the lumen.

23. **As to (i),** Chin teaches guidewire (which equates to the delivery wire 200 of Perszyk) for an implant delivery catheter a core wire with a central shaft (core wire 101; which equates to the inner member 202 of Perszyk) comprising one or more bead

members (beads 109) disposed along the length for the purpose of imparting a desired rigidity / controllable stiffness to the core wire (core wire 101) (abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B).

24. **Additionally,** Douk teaches an angioplasty guidewire with a core wire (core wire 162; which equates to the inner member 202 of Perszyk) comprising a central shaft (core wire 162) with a distal coil assembly (stiffening spring 168) or a plurality of beads (beads 175) (abstract, col. 8 lines 24 – 55, and Fig. 15). Therefore, Douk teaches coil assemblies and bead assemblies are functionally similar and are interchangeable.

25. It should be understood that Perszyk and Chin with the teachings of Douk are known references in the art that teach a delivery system comprising a core wire with stiffening elements (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – Perszyk ; abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B – Chin ; abstract, col. 8 lines 24 – 55, and Fig. 15 – Douk); and the Examiner contends that it would have been obvious to one of ordinary skill in the art before the effective filling date of the claimed invention to have substituted one known stiffening element for another (i.e., substituting *one of the* stiffening coils for a series of beads), and the results of the substitution would have been predictable and resulted in the modified delivery cable 200 of Perszyk being able to function as intended to properly push/pull the occluder/implant to the desired treatment site. The examiner notes the rejection above is based on KSR int'l Co. V. Teleflex inc., 550 U.S. 398, 415-421, 82 USPQ2d 1385, 1395-97 (2007), rational B, outlined in MPEP 2143. **Furthermore,** it has been held that choosing any solution from a finite number of solutions to obtain a predictable result is well within the purview of ordinary skill in the art. KSR International

Co. v. Teleflex Inc. (KSR), 550 U.S., 82 USPQ2d 1385 (2007). It can be seen that there are only a finite number of coils that can be substituted for a series of beads, it can be either: all of the outer member coils (proximal, intermediate, distal), only the proximal outer member coil, only the intermediate outer member coil, only the distal outer member coil, or some variation of the three outer coils. Therefore, it would have been obvious to one of ordinary skill in the art to modify the intermediate outer member 240 to be a series of beads since there are a limited number of possible coils to be substituted and having the ***intermediate outer member 240*** be a series beads would have yielded, with a reasonable expectation of success, a delivery cable with enough column strength to push / pull the occluder through the catheter and after/prior to deployment of the occluder. Therefore, the modification encompasses one or more beads in the intermediate region of the delivery cable adjacent to the first (proximal) region and in between the first (proximal) region and the second (distal) region.

26. **As to (ii)**, as stated above, Perszyk teaches wherein the outer diameter of the second coil assembly (distal outer member 208) approximates the inner diameter of the lumen (lumen of the delivery sheath) (paragraphs [0028] and [0039]). Perszyk, further teaches, in paragraph [0028], wherein having the outer diameter approximate the inner diameter of the lumen (inner diameter of the delivery catheter) reduces the amount of force necessary to advance the medical device through the lumen (lumen of the delivery sheath). Therefore, It would have been obvious to one of ordinary skill in the art, prior to the effective filing date of the claimed invention, to modify each of the plurality of beads of Persyzk in view of Chin and Douk such that the outer diameter of the plurality of beads approximates the inner diameter of the lumen of the delivery sheath for the

purpose of reducing the amount of force necessary to advance the medical device through the lumen (paragraph [0028] – Perszyk).

27. **Regarding claim 2**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Chin in view of Douk. Additionally, Perszyk discloses wherein the central shaft (inner member 202) includes stainless steel (paragraph [0034]).

28. **Regarding claim 3**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Chin in view of Douk. Additionally, Perszyk discloses wherein the central shaft (inner member 202) includes a nickel-titanium alloy (paragraph [0034]).

29. **Regarding claim 5**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Chin in view of Douk. Additionally, Perszyk discloses wherein the first region (proximal section 206) includes an outer jacket (heat shrink material 302) disposed over the first coil assembly (paragraph [0044] and Fig. 5).

30. **Regarding claim 7**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Chin in view of Douk. Additionally, Perszyk discloses wherein the first coil assembly (proximal outer member 210) includes a single coil (proximal outer member 210) (Fig. 5).

31. **Regarding claim 9**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Chin in view of Douk. Additionally, Perszyk discloses wherein the second coil assembly (distal outer member 208) includes two or more coils (Examiner's note: as stated in paragraph [0059] the distal outer member 208 is a double layer coil, thus comprising two coils).

32. **Regarding claim 12**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Chin in view of Douk. Additionally, Perszyk discloses wherein the first region (proximal section 206) has a first outer diameter and wherein the second region (distal section 204) has a second outer diameter different from the first outer diameter (Fig. 5).

33. **Regarding claim 1**, *(alternate interpretation – changes italicized below)* Perszyk discloses a delivery device (introducer assembly 100 and delivery cable 200) for an occlusive implant (medical device 201) (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – *6*), the delivery device comprising:

p. a delivery sheath (delivery sheath 203) having a proximal region, a distal tip region, and a lumen formed therein (paragraphs [0006 – 0007], [0024], [0030 – 0031], [0039 – 0040], and Fig. 2);

q. a core wire (delivery cable 200) slidably disposed in the lumen paragraphs [0006 – 0007], [0032 – 0036], and Fig. 5);

r. wherein the core wire (delivery cable 200) includes a central shaft (inner member 202 with *core wire 406, first layer 404, and second layer 406*), a first region (*distal section 204*) having a first coil assembly (*distal outer member 208*) disposed along the central shaft (inner member 202), a second region (*proximal section 206*) with having a second coil assembly (*proximal outer member 210*) disposed along the central shaft (inner member 202), and a distal implant securing region (end screw 212) (paragraphs [0036 – 0040], *[0046 – 0047], and Fig. 6*); and

s. an occlusive implant (implant 201) coupled to the distal implant securing region (paragraphs [0026], [0030], [0032], and Fig. 2);

t. wherein second coil assembly (distal outer member 208) defines an outer diameter approximately equal to an inner diameter of the lumen (paragraphs [0028] and [0039]) (Examiner's note: the term "approximately" is defined as very close to. With that said, as stated in paragraph [0040] the outer diameter of the distal outer member 208 (i.e., the spacer assembly) is greater than 98% of the inner diameter of the delivery sheath (i.e., the diameter of the lumen), and because the outer diameter of the distal outer member 208 (i.e., the spacer assembly) being within less than two percent of the inner diameter of the lumen of the delivery sheath the outer diameter of the distal outer member 208 (i.e., the spacer assembly) is considered to be approximately equal to the inner diameter of the lumen. Therefore, Perszyk discloses the device as claimed).

34. However, Perszyk is silent regarding **(i)** a plurality of beads members disposed over the central shaft adjacent to the first region and/or disposed over the central shaft

between the first region and the second region and **(ii)** wherein each of the plurality of beads members defines an outer diameter approximately equal to an inner diameter of the lumen.

35. **As to (i),** Chin teaches guidewire (which equates to the delivery wire 200 of Perszyk) for an implant delivery catheter a core wire with a central shaft (core wire 101; which equates to the inner member 202 of Perszyk) comprising one or more bead members (beads 109) disposed along the length for the purpose of imparting a desired rigidity / controllable stiffness to the core wire (core wire 101) (abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B).

36. **Additionally,** Douk teaches an angioplasty guidewire with a core wire (core wire 162; which equates to the inner member 202 of Perszyk) comprising a central shaft (core wire 162) with a distal coil assembly (stiffening spring 168) or a plurality of beads (beads 175) (abstract, col. 8 lines 24 – 55, and Fig. 15). Therefore, Douk teaches coil assemblies and bead assemblies are functionally similar and are interchangeable.

37. It should be understood that Perszyk and Chin with the teachings of Douk are known references in the art that teach a delivery system comprising a core wire with stiffening elements (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – Perszyk ; abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B – Chin ; abstract, col. 8 lines 24 – 55, and Fig. 15 – Douk); and the Examiner contends that it would have been obvious to one of ordinary skill in the art before the effective filling date of the claimed invention to have substituted one known stiffening element for another (i.e., substituting *one of the* stiffening coils for a series of beads), and the results of the substitution would have been predictable and resulted in the

modified delivery cable 200 of Perszyk being able to function as intended to properly push/pull the occluder/implant to the desired treatment site. The examiner notes the rejection above is based on KSR int'l Co. V. Teleflex inc., 550 U.S. 398, 415-421, 82 USPQ2d 1385, 1395-97 (2007), rational B, outlined in MPEP 2143. **Furthermore,** it has been held that choosing any solution from a finite number of solutions to obtain a predictable result is well within the purview of ordinary skill in the art. KSR International Co. v. Teleflex Inc. (KSR), 550 U.S., 82 USPQ2d 1385 (2007). It can be seen that there are only a finite number of coils that can be substituted for a series of beads, it can be either: all of the outer member coils (proximal, intermediate, distal), only the proximal outer member coil, only the intermediate outer member coil, only the distal outer member coil, or some variation of the three outer coils. Therefore, it would have been obvious to one of ordinary skill in the art to modify the intermediate outer member 240 to be a series of beads since there are a limited number of possible coils to be substituted and having the ***intermediate outer member 240*** be a series beads would have yielded, with a reasonable expectation of success, a delivery cable with enough column strength to push / pull the occluder through the catheter and after/prior to deployment of the occluder. Therefore, the modification encompasses one or more beads in the intermediate region of the delivery cable adjacent to the first (proximal) region and in between the first (proximal) region and the second (distal) region.

38. **As to (ii)**, as stated above, Perszyk teaches wherein the outer diameter of the second coil assembly (distal outer member 208) approximates the inner diameter of the lumen (lumen of the delivery sheath) (paragraphs [0028] and [0039]). Perszyk, further teaches, in paragraph [0028], wherein having the outer diameter approximate the inner

diameter of the lumen (inner diameter of the delivery catheter) reduces the amount of force necessary to advance the medical device through the lumen (lumen of the delivery sheath). Therefore, It would have been obvious to one of ordinary skill in the art, prior to the effective filing date of the claimed invention, to modify each of the plurality of beads of Persyzk in view of Chin and Douk such that the outer diameter of the plurality of beads approximates the inner diameter of the lumen of the delivery sheath for the purpose of reducing the amount of force necessary to advance the medical device through the lumen (paragraph [0028] – Perszyk).

39. **Regarding claim 2**, *(alternate interpretation)* as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Chin in view of Douk. Additionally, Perszyk discloses wherein the central shaft (inner member 202) includes stainless steel (paragraph [0034]).

40. **Regarding claim 3**, *(alternate interpretation)* as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Chin in view of Douk. Additionally, Perszyk discloses wherein the central shaft (inner member 202) includes a nickel-titanium alloy (paragraph [0034]).

41. **Regarding claim 4**, *(alternate interpretation)* as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Chin in view of Douk. Additionally, Perszyk discloses wherein the central shaft (inner member 202) includes a stainless steel member (second layer 406) and a nickel-

titanium alloy member (first layer 404) secured to the stainless steel member (paragraph [0047]).

42. **Regarding claim 8**, *(alternate interpretation)* as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Chin in view of Douk. Additionally, Perszyk discloses wherein the first coil assembly (*distal outer member 208*) includes two or more coils (Examiner's note: as stated in paragraph [0059] the distal outer member 208 is a double layer coil, thus comprising two coils).

43. **Regarding claim 14,** as discussed above, *(alternate interpretation)* Perszyk discloses the delivery device of claim 13.

44. However, Perszyk is silent regarding **(i)** wherein the spacer assembly includes one or more bead members.

45. **As to the above,** Chin teaches guidewire (which equates to the delivery wire 200 of Perszyk) for an implant delivery catheter a core wire with a central shaft (core wire 101; which equates to the inner member 202 of Perszyk) comprising one or more bead members (beads 109) disposed along the length for the purpose of imparting a desired rigidity / controllable stiffness to the core wire (core wire 1091) (abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B).

46. **Additionally,** Douk teaches an angioplasty guidewire with a core wire (core wire 162; which equates to the inner member 202 of Perszyk) comprising a central shaft (core wire 162) with a distal coil assembly (stiffening spring 168) or a plurality of beads

(beads 175) (abstract, col. 8 lines 24 – 55, and Fig. 15). Therefore, Douk teaches coil assemblies and bead assemblies are functionally similar and are interchangeable.

47. It should be understood that Perszyk and Chin with Douk are known references in the art that teach a delivery system comprising a core wire with stiffening elements (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – Perszyk ; abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B – Chin ; abstract, col. 8 lines 24 – 55, and Fig. 15 – Douk); and the Examiner contends that it would have been obvious to one of ordinary skill in the art before the effective filling date of the claimed invention to have substituted one known stiffening element for another (i.e., substituting *the distal outer member coil* of Perszyk for a series of beads), and the results of the substitution would have been predictable and resulted in the modified delivery cable 200 of Perszyk being able to function as intended to properly push/pull the occluder/implant to the desired treatment site. The examiner notes the rejection above is based on KSR int'l Co. V. Teleflex inc., 550 U.S. 398, 415-421, 82 USPQ2d 1385, 1395-97 (2007), rational B, outlined in MPEP 2143. Furthermore, as stated above, Perszyk teaches wherein the outer diameter of the spacer assembly (distal outer member 208) approximates the inner diameter of the lumen (lumen of the delivery sheath) (paragraphs [0028] and [0039]). Perszyk, further teaches, in paragraph [0028], wherein having the outer diameter approximate the inner diameter of the lumen (inner diameter of the delivery catheter) reduces the amount of force necessary to advance the medical device through the lumen (lumen of the delivery sheath). Therefore, It would have been obvious to one of ordinary skill in the art, prior to the effective filing date of the claimed invention, to modify each of the plurality of beads of

Persyzk in view of Chin and Douk such that the outer diameter of the plurality of beads approximates the inner diameter of the lumen of the delivery sheath for the purpose of reducing the amount of force necessary to advance the medical device through the lumen (paragraph [0028] – Perszyk).

48. **Claim 6 is rejected under 35 U.S.C. 103 as being unpatentable over Perszyk et al (US 2018/0235658 A1) *(previously cited)* in view of Chin et al (US 2012/0191012 A1) *(previously cited)* and Douk et al (US 6,183,420 B1) *(previously cited)*, as applied to claim 1 above, and further in view of Kajima (US 5,554,139) *(previously cited)*.**

49. **Regarding claim 6**, as discussed above, the combination of Perszyk, Chin, and Douk teaches the delivery device of claim 1.

50. However, the combination of Perszyk, Chin, and Douk is silent regarding **(i)** wherein the first region includes a braid coupled to the first coil assembly.

51. **As to the above**, Kajima teaches a medical device comprising a sheath (guiding catheter 9) and a core wire (catheter 1; which equates to the delivery cable 200 of Perszyk) extending through the sheath (abstract, col. 12 lines 50 – 63, col. 21 lines 10 – 25 and Figs. 1,3,8) comprising the core wire comprising a central shaft (inner layer 6; which equates to the inner member 202 of Perszyk), a first region (main body portion 2; which equates to the proximal region 206 of Perszyk) with a first coil assembly (coil 8; which equates to the proximal outer coil 210) and wherein the first region includes a braid (metal braid layer 30) for the purpose of restricting possible deformation of the coil (col. 7 lines 52 – 54 and col. 16 lines 53 – 65).

52. It would have been obvious to one of ordinary skill in the art, prior to the effective filing date of the claimed invention, based on the teachings of Kajima, to modify the first region of Perszyk in view of Chin and Douk to incorporate a braid attached to the first coil assembly for the purpose of restricting possible deformation of the coil (col. 7 lines 52 – 54 – Kajima).

53. **Claim 15 is rejected under 35 U.S.C. 103 as being unpatentable over Perszyk et al (US 2018/0235658 A1) *(previously cited)* as applied to claim 13 above, and further in view of Kajima (US 5,554,139) *(previously cited)*.**

54. **Regarding claim 15,** as discussed above, *(alternate interpretation)* Perszyk discloses the delivery device of claim 13.

55. However, Perszyk is silent regarding **(i)** wherein the spacer assembly includes a stent-like structure.

56. **As to the above**, Kajima teaches a medical device comprising a sheath (guiding catheter 9) and a core wire (catheter 1; which equates to the delivery cable 200 of Perszyk) extending through the sheath (abstract, col. 12 lines 50 – 63, col. 21 lines 10 – 25 and Figs. 1,2,3,8) comprising the core wire comprising a central shaft (inner layer 6; which equates to the inner member 202 of Perszyk), a second region (tip portion 4; which equates to the distal region 204 of Perszyk) with a spacer assembly (portion of coil 8 in the tip portion 4; which equates to the distal outer coil 208) and wherein the spacer assembly includes a stent like structure (metal braid layer 30) for the purpose of restricting possible deformation of the coil (col. 7 lines 52 – 54 and col. 16 lines 53 – 65).

57. It would have been obvious to one of ordinary skill in the art, prior to the effective filing date of the claimed invention, to modify the spacer assembly (i.e., the distal outer coil 208) of Perszyk to incorporate a braid (i.e., a stent-like structure), based on the teachings of Kajima, for the purpose of restricting possible deformation of the coil (col. 7 lines 52 – 54 – Kajima).

58. **Claim 20 is rejected under 35 U.S.C. 103 as being unpatentable over as Perszyk et al (US 2018/0235658 A1) *(previously cited)* and in view of Larsen et al (US 2014/0142617 A1) *(previously cited)*, Chin et al (US 2012/0191012 A1) *(previously cited)*, and Douk et al (US 6,183,420 B1) *(previously cited)*.**

59. **Regarding claim 20**, Perszyk discloses a method for implanting an occlusive implant (occluder / medical device 201) (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], [0050], and Figs. 1 – 5, 8, 12) *to a treatment site*, the method comprising:

u. advancing a delivery device (introducer assembly 100 and delivery cable 200) to a position adjacent to *a treatment site* (paragraphs [0024] and [0050]), the delivery device comprising:

i. a delivery sheath (delivery sheath 203) having a proximal region, a distal tip region, and a lumen formed therein (paragraphs [0006 – 0007], [0024], [0030 – 0031], [0039 – 0040], and Fig. 2);

ii. a core wire (delivery cable 200) slidably disposed in the lumen paragraphs [0006 – 0007], [0032 – 0036], and Fig. 5,12);

iii. wherein the core wire (delivery cable 200) includes a central shaft (inner member 202), a first region (proximal section 206) having a first coil assembly (proximal outer member 210) disposed along the central shaft (inner member 202), a second region (distal section 204) with having a *second coil assembly (distal outer member 208)* disposed along the central shaft, and a distal implant securing region (end screw 212) (paragraphs [0036 – 0040], [0055], and Fig. 12); and

iv. an occlusive implant (implant 201) coupled to the distal implant securing region (paragraphs [0026], [0030], [0032], and Fig. 2); and

v. advancing the core wire (delivery cable 200) such that the occlusive implant (implant 201) advances out from the distal tip region of the delivery sheath (paragraph [0050] and Fig. 8).

60. However, Perszyk is silent regarding **(i)** wherein the implant is a left atrial appendage occlusive implant, wherein the method is for implanting the occlusive implant into the left atrial appendage, **(ii)** wherein the second region comprises a plurality of beads members disposed over the central shaft adjacent to the first region and/or disposed over the central shaft between the first region and the second region and **(iii)** wherein each of the plurality of beads members defines an outer diameter approximately equal to an inner diameter of the lumen.

61. **As to (i)**, Larsen teaches, in the same field of endeavor, a method of implanting an occlusive implant (occlusive device 100) into a left atrial appendage comprising advancing a delivery device (delivery sheath 168 and delivery catheter 170) to a position adjacent to the left atrial appendage, the delivery device comprising a sheath

(sheath 168) and a core wire (delivery catheter 170; which equates to the delivery cable 200 of Perszyk), and advancing the core wire (delivery catheter 170) such that the occlusive implant (occlusive device 100) advances out from the delivery sheath (sheath 168) for the purpose of treating thrombus formation in the LAA of arrhythmic patients (abstract, paragraphs [0004], [0064], [0066 – 0067], and Figs. 1,6).

62. It would have been obvious to one of ordinary skill in the art, prior to the effective filing date of the claimed invention, to modify the system to include a LAA occlusive implant and modify the method of Perszyk to incorporate the step of placing the LAA occlusive implant to/into the LAA, as taught by Larsen, for purpose of treating thrombus formation in the LAA of arrhythmic patients (paragraph [0004] – Larsen).

63. **As to (ii),** Chin teaches guidewire (which equates to the delivery wire 200 of Perszyk) for an implant delivery catheter a core wire with a central shaft (core wire 101; which equates to the inner member 202 of Perszyk) comprising one or more bead members (beads 109) disposed along the length for the purpose of imparting a desired rigidity / controllable stiffness to the core wire (core wire 101) (abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B).

64. **Additionally,** Douk teaches an angioplasty guidewire with a core wire (core wire 162; which equates to the inner member 202 of Perszyk) comprising a central shaft (core wire 162) with a distal coil assembly (stiffening spring 168) or a plurality of beads (beads 175) (abstract, col. 8 lines 24 – 55, and Fig. 15). Therefore, Douk teaches coil assemblies and bead assemblies are functionally similar and are interchangeable.

65. It should be understood that Perszyk and Chin with Douk are known references in the art that teach a delivery system comprising a core wire with stiffening elements

(abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – Perszyk ; abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B – Chin ; abstract, col. 8 lines 24 – 55, and Fig. 15 – Douk); and the Examiner contends that it would have been obvious to one of ordinary skill in the art before the effective filling date of the claimed invention to have substituted one known stiffening element for another (i.e., substituting *the distal outer member coil* of Perszyk for a series of beads), and the results of the substitution would have been predictable and resulted in the modified delivery cable 200 of Perszyk being able to function as intended to properly push/pull the occluder/implant to the desired treatment site. The examiner notes the rejection above is based on KSR int'l Co. V. Teleflex inc., 550 U.S. 398, 415-421, 82 USPQ2d 1385, 1395-97 (2007), rational B, outlined in MPEP 2143. Furthermore, as stated above, Perszyk teaches wherein the outer diameter of the spacer assembly (distal outer member 208) approximates the inner diameter of the lumen (lumen of the delivery sheath) (paragraphs [0028] and [0039]).

66. **As to (iii)**, Perszyk, further teaches, in paragraph [0028], wherein having the outer diameter of the outer coil member 208 approximate the inner diameter of the lumen (inner diameter of the delivery catheter) reduces the amount of force necessary to advance the medical device through the lumen (lumen of the delivery sheath); and It would have been obvious to one of ordinary skill in the art, prior to the effective filing date of the claimed invention, to modify each of the plurality of beads of Persyzk in view of Larsen, Chin, and Douk such that the outer diameter of the plurality of beads approximates the inner diameter of the lumen of the delivery sheath for the purpose of reducing the amount of force necessary to advance the medical device through the

lumen (paragraph [0028] – Perszyk).Therefore, the combination of Perszyk, Larsen, Chin, and Douk encompasses the limitations substantially as claimed above.

Response to Arguments

67. Applicant's arguments, filed 05/05/2026, with respect to the rejection of claims under Barajas et al have been considered but are moot as the arguments are directed to Applicant's amendments, and the previous rejection of the claims has been withdrawn in light of said amendments. Specifically, the rejections were withdrawn because the Barajas et al does not teach wherein diameter of the bead members approximates the inner diameter of the lumen of the delivery sheath. It is noted that a new rejection of claims 1 and 20 has been made over Perszyk in view of Chin and Douk. The teachings of Perszyk, Chin, and Douk are relied upon for teaching the newly added limitations as discussed above.

68. Applicant's arguments, filed 05/05/2026 with respect to the newly added limitations of claims 1, 13, and 20 and with respect to the previously cited prior art Perszyk, Chin, and Douk, have been fully considered but they are not persuasive. More specially:

w. With respect to Applicant's argument that "*Independent claim 13 similarly requires that the spacer assembly has an outer diameter approximately equal to an inner diameter of the lumen that the core wire is slidably disposed in. Perszyk is silent regarding the size of the outer member 208 relative to the lumen of the introducer 100. Additionally, as illustrated in FIG. 2, the outer member 208 is shown to be significantly smaller than the introducer 100.*", as stated in

paragraph [0028] and [0039], the outer diameter of the outer member 208 is approximately equal to the inner diameter of the lumen of the delivery sheath. Additionally, as stated throughout the disclosure of Perszyk, and specifically in paragraphs [0006 – 0007], the delivery cable, which includes the outer member 208, is slid through the lumen of the delivery catheter; therefore, the core wire is disclosed as being slidably disposed within the delivery sheath. Therefore, Applicant's argument is not persuasive.

x. With respect to Applicant's argument that "*The reference to Chin is directed towards the positioning of a plurality of beads along a guidewire, but is silent regarding the size of the bead, or the size of the beads relative to a lumen they are advanced therethrough. The reference to Douk is directed towards a core wire 162 having either a stiffening spring 168 or a plurality of beads 175 disposed along a distal portion of the core wire 162. The beads provide a variable stiffness along the length of the guidewire, and Douk is silent regarding their size relative to a lumen the guidewire is advanced through. Additionally, the beads 175 are disposed within outer spring 170, and thus must necessarily be smaller than the inner diameter of any lumen the guidewire 160 is advanced therethrough*", the Examiner acknowledges that neither Chin nor Douk mentions the diameter or relative size of the beads, however, and as stated in the rejection above, Perszyk makes obvious having the outer diameter of the outer member (i.e., the beads) be approximate the inner diameter of the lumen. Therefore, the combination of Perszyk, Chin, and Douk teaches the device as claimed. Thus, Applicant's arguments are not persuasive.

Conclusion

69. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

70. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any nonprovisional extension fee (37 CFR 1.17(a)) pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

71. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Restaino whose telephone number is (571)272-4748. The examiner can normally be reached Mon - Fri 8:00 - 4:00 ET.

72. Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an

interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

73. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Elizabeth Houston can be reached at 571-272-7134. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

74. Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Restaino/
Primary Examiner, Art Unit 3771