United States Patent Application Publication	20250255632
Kind Code	A1
Publication Date	August 14, 2025
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CATHETER ASSEMBLIES HAVING A DILATABLE RETRIEVAL BASKET AND METHODS OF USE

Abstract

A catheter assembly for performing a thrombectomy and methods of use, the catheter assembly including a catheter sheath and a dilation and capture assembly slidably positioned within the catheter sheath. The dilation and capture assembly includes a catheter having a balloon portion at a distal end of the catheter, and a retrieval basket. The balloon portion is selectively inflatable and deflatable between respectively a maceration orientation and a delivery orientation. The retrieval basket is deployable from a delivery configuration mounted to the balloon portion and a retrieving configuration axially displaced from the distal end of the catheter.

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Appl. No.: **18/857008**

Filed (or PCT Filed): **June 08, 2022**

PCT No.: **PCT/US2022/032660**

Publication Classification

Int. Cl.: **A61B17/221** (20060101); **A61B17/00** (20060101); **A61B17/22** (20060101); **A61M25/00** (20060101); **A61M25/10** (20130101)

U.S. Cl.:

CPC **A61B17/221** (20130101); **A61B17/00234** (20130101); **A61M25/0043** (20130101); **A61M25/10** (20130101); A61B2017/00238 (20130101); A61B2017/00305 (20130101); A61B2017/00367 (20130101); A61B2017/00477 (20130101); A61B2017/00836 (20130101); A61B2017/00862 (20130101); A61B2017/00867 (20130101); A61B2017/22065 (20130101); A61B2017/2212 (20130101); A61M2025/0004 (20130101); A61M2210/12 (20130101)

Background/Summary

TECHNICAL FIELD

[0001] The present specification generally relates to catheter assemblies for performing a thrombectomy and an angioplasty and, more specifically, catheter assemblies having a dilatable retrieval basket and methods of use.

BACKGROUND

[0002] A thrombectomy is performed to reduce the size of or completely dislodge a thrombus in a body vessel of a patient, while an angioplasty is performed to dilate a restricted vessel. The dislodged thrombus may be carried by blood flow in the body vessel to another location of a body of the patient, where the thrombus may cause further health complications. For example, the thrombus may become lodged in the body vessel, thereby reducing or completely restricting blood flow along the body vessel. This may result in health complications such as a stroke. A need for improved catheter assemblies for performing a thrombectomy and an angioplasty in an efficient and effective manner exists.

SUMMARY

[0003] In one embodiment, a catheter assembly for performing an angioplasty, the catheter assembly includes a catheter sheath and a dilation and capture assembly slidably positioned within the catheter sheath. The dilation and capture assembly includes a catheter having a balloon portion at a distal end of the catheter, and a retrieval basket. The balloon portion is selectively inflatable and deflatable between respectively a maceration orientation and a delivery orientation. The retrieval basket is deployable from a delivery configuration mounted to the balloon portion and a retrieving configuration axially displaced from the distal end of the catheter.

[0004] In another embodiment, a catheter assembly for performing an angioplasty, the catheter assembly includes a catheter sheath and a dilation and capture assembly slidably positioned within the catheter sheath. The dilation and capture assembly includes a catheter including a proximal portion and a balloon portion at a distal end of the proximal portion, a retrieval basket, and one or more attachment wires. The balloon portion is selectively inflatable and deflatable between respectively a maceration orientation and a delivery orientation. The retrieval basket is deployable from a delivery configuration mounted to the balloon portion and a retrieving configuration axially displaced from the balloon portion. The one or more attachment wires are configured to position the retrieval basket relative to the catheter sheath.

[0005] In yet another embodiment, a method of performing an angioplasty, the method includes inserting a catheter assembly into a body vessel, translating a balloon portion and a retrieval basket relative to a catheter sheath past a treatment site; and inflating the balloon portion, thereby dilating the retrieval basket. The catheter assembly includes a catheter sheath and a dilation and capture assembly slidably positioned within the catheter sheath. The dilation and capture assembly includes a catheter including a balloon portion at a distal end of the catheter, and a retrieval basket. The balloon portion is selectively inflatable and deflatable between respectively a maceration orientation and a delivery orientation. The retrieval basket is deployable from a delivery configuration mounted to the balloon portion and a retrieving configuration axially displaced from

the distal end of the catheter.
[0006] These and additional features provided by the embodiments described herein will be more fully understood in view of the following detailed description, in conjunction with the drawings.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0007] The embodiments set forth in the drawings are illustrative and exemplary in nature and not intended to limit the subject matter defined by the claims. The following detailed description of the illustrative embodiments can be understood when read in conjunction with the following drawings, where like structure is indicated with like reference numerals and in which:
[0008] FIG. **1** schematically depicts a side view of a catheter assembly for performing an angioplasty disposed in a body vessel and advanced to a thrombus site in a thrombus site position, according to one or more embodiments shown and described herein;
[0009] FIG. **2** schematically depicts a side view of a catheter of the catheter assembly of FIG. **1**, a balloon portion of the catheter shown in an inflated position, according to one or more embodiments shown and described herein;
[0010] FIG. **3** schematically depicts a side view of a retrieval basket of the catheter assembly of FIG. **1** shown in a deployed position, according to one or more embodiments shown and described herein;
[0011] FIG. **4** schematically depicts a cross sectional front view of the catheter assembly of FIG. **1** taken along line **4-4**, according to one or more embodiments shown and described herein;
[0012] FIG. **5** schematically depicts another cross sectional front view of the catheter assembly of FIG. **1** taken along line **5-5**, according to one or more embodiments shown and described herein;
[0013] FIG. **6** schematically depicts a side view of the catheter assembly of FIG. **1** in a delivery configuration past the thrombus site in a past thrombus position, with the balloon portion deflated and the retrieval basket not deployed, according to one or more embodiments shown and described herein;
[0014] FIG. **7** schematically depicts a side view of the catheter assembly of FIG. **6** in the delivery configuration in the past thrombus position, with the balloon portion inflated and the retrieval basket deployed, according to one or more embodiments shown and described herein;
[0015] FIG. **8** schematically depicts a side view of the catheter assembly of FIG. **7** in a separated position in the past thrombus position, with the balloon portion deflated and the retrieval basket deployed, according to one or more embodiments shown and described herein;
[0016] FIG. **9** schematically depicts a side view of the retrieval basket of FIG. **8** in a retrieving configuration in the past thrombus position with the balloon portion proximally displaced to be at the thrombus site position, according to one or more embodiments shown and described herein;
[0017] FIG. **10** schematically depicts a side view of the catheter of FIG. **9** in a deflated delivery orientation after being in an inflated maceration orientation to break thrombus, and the retrieval basket of FIG. **9** in the retrieving configuration, according to one or more embodiments shown and described herein;
[0018] FIG. **11** schematically depicts the catheter of FIG. **10** in a balloon removal position in which the balloon portion is proximally advanced from the thrombus site position, according to one or more embodiments shown and described herein;
[0019] FIG. **12** schematically depicts the retrieval basket of FIG. **10** in a retrieval basket removal position and retrieving configuration to retrieve thrombus when proximally being advanced back past the thrombus site including broken thrombus, according to one or more embodiments shown and described herein; and
[0020] FIG. **13** depicts the catheter assembly of FIG. **12** in an assembly extraction position,

according to one or more embodiments shown and described herein.

DETAILED DESCRIPTION

[0021] FIG. **1** generally depicts an embodiment of a catheter assembly **10** for performing a thrombectomy disposed in a body vessel **102** and advanced to a thrombus site position **100** at a thrombus **112** as a treatment site of a patient. The catheter assembly **10** may simultaneously perform an angioplasty by using a balloon catheter for both the thrombectomy and the angioplasty, as will be described in further detail herein. An angioplasty, as used herein, is a procedure for dilating a restricted blood vessel. It is contemplated that the "patient" described herein may be a human or an animal. The catheter assembly **10** of FIG. **1** includes a catheter sheath **12** and a dilation and capture assembly **14** slidably positioned within the catheter sheath **12** to allow the dilation and capture assembly **14** to move relative to the catheter sheath **12**. The dilation and capture assembly **14** includes a catheter **16** including a balloon portion **18** configured to be inflatable and deflatable between respectively a maceration orientation **59** (FIG. **10**) and a delivery orientation **49** (FIG. **10**) to macerate the thrombus **112** at a treatment site. The dilation and capture assembly **14** further includes a retrieval basket **20** that is movable relative to the balloon portion **18** so that the retrieval basket **20** is positionable downstream of the balloon portion **18** to be distally and axially displaced from the balloon portion **18** in a retrieving configuration **80** (FIG. **10**), as described in greater detail further below. The retrieval basket **20** is configured to collect particulate removed from the thrombus **112** as broken thrombus **113** during a maceration operation of the balloon portion **18** as described herein. Various embodiments of the catheter assembly and the operation of the catheter assembly will be described in more detail herein.

[0022] The catheter assembly **10** of FIG. **1** may be distally moved in the direction of arrow A to perforate a body **104** of the patient and be inserted and move distally into the body vessel **102**. The catheter assembly **10** may include an introducer sheath **110**, the catheter sheath **12**, and the dilation and capture assembly **14** slidably positioned within the catheter sheath **12** so that the dilation and capture assembly **14** may move relative to the catheter sheath **12**. The introducer sheath **110** may define a receiving lumen extending therethrough that is configured to receive the catheter sheath **12** and the dilation and capture assembly **14**. Each of the catheter sheath **12** and the dilation and capture assembly **14** may be positioned within the receiving lumen of the introducer sheath **110** and including portions configured to extend distally from the introducer sheath **110** and be proximally retracted into the introducer sheath **110**. Proximal portions of the catheter sheath **12** and the dilation and capture assembly **14** may extend proximally from the introducer sheath **110** to be positioned in an extracorporeal area **106** external to the body **104**, and be physically manipulatable by a user. Distal portions of the catheter sheath **12** and the dilation and capture assembly **14** may extend distally from the introducer sheath **110** to be positioned within the body vessel **102** in an intracorporeal area **108** within the body **104** when a distal portion of the introducer sheath **110** is inserted into the body **104** of the patient. The introducer sheath **110** may be used to grip the catheter assembly **10** and perforate the body **104** of the patient so that the catheter sheath **12** and dilation and capture assembly **14** may be inserted into the body vessel **102**. The introducer sheath **110** may first be inserted into the body **104** of the patient to create an access point for entry of the catheter sheath **12** and the dilation and capture assembly **14** into the body **104**. While the depicted catheter assembly **10** includes the introducer sheath **110** for introducing the dilation and capture assembly **14** into the body **104** of the patient, it is contemplated and possible that the catheter assembly **10** does not include an introducer sheath, where the catheter sheath **12** and the dilation and capture assembly **14** may be inserted into the body **104** in combination or in another manner through other insertion devices.

[0023] Referring to FIG. **1**, the dilation and capture assembly **14** may include a catheter **16**, a retrieval basket **20**, and an actuator **42** (FIG. **12**). As shown in FIG. **2**, the catheter **16** may include a catheter wall **11**, a hub **101**, a proximal portion **32**, a distal portion **33** positioned distal to the proximal portion **32**, and a balloon portion **18** at the distal portion **33** and including a distal end **17**

of the catheter **16**. In FIG. **2**, the balloon portion **18** is shown in an inflated position **58**. The balloon portion **18** may be coupled to the catheter wall **11** at a distal end of and a position distal to the catheter wall **11**. The catheter wall **11** may be an elongated, cylindrical body that extends between the hub **101** and the balloon portion **18** to connect the balloon portion **18** with the hub **101**. The proximal portion **32** of the catheter **16** may include a proximal end **37** and an opposite distal end **36**, and the balloon portion **18** of the distal portion **33** of the catheter **16** may include a proximal end **34** and a distal end **35** opposite the proximal end **34** of the balloon portion **18**.

[0024] The balloon portion **18** may thus be positioned in the distal portion **33** distal to the proximal portion **32** with the distal end **36** of the proximal portion **32** of the catheter **16** being coupled to the proximal end **34** of the balloon portion **18** at the distal portion **33** of the catheter **16**. The balloon portion **18** of the distal portion **33** may extend distally from the distal end **36** of the proximal portion **32**. The hub **101** may be positioned proximal to the proximal portion **32** of the catheter **16** and coupled to the proximal end **37** of the proximal portion **32**. When the dilation and capture assembly **14** is positioned within the body **104** of the patient, the hub **101** may extend proximally from the introducer sheath **110** so that the hub **101** may be physically manipulated by a user. The proximal portion **32** of the catheter **16** may be sized and shaped to be positioned and received within the catheter wall **11** of the catheter sheath **12**.

[0025] The balloon portion **18** may be tapered at the distal end **35** and the proximal end **34** thereof. The balloon portion **18** may include an atraumatic tip at the distal end **35** to reduce damage and perforation to the body vessels **102** as the balloon portion **18** traverses the body vessels **102**. In embodiments, the balloon portion **18** may be formed of a deformable material, such as polyurethane or silicone, to allow the balloon portion **18** to deform to maneuver through the body vessels **102**.

[0026] Referring to FIG. **4**, the catheter wall **11** of the catheter **16** may define an inflation lumen **38** and a guidewire lumen **40** extending therethrough. Particularly, the inflation lumen **38** and the guidewire lumen **40** may be defined within the catheter wall **11** at the proximal portion **32** of the catheter **16** and extend in parallel with one another. The inflation lumen **38** may be fluidly connected to the balloon portion **18** disposed at the distal end **17** of the catheter **16** and may be configured for inflating and deflating the balloon portion **18**. The guidewire lumen **40** may extend from the proximal end **37** of the proximal portion **32** of the catheter **16** to the distal end **35** of the balloon portion **18** of the catheter **16** so that a guidewire (not shown) may be positioned within the catheter **16** and extend distally therefrom at the distal end **17**. The guidewire lumen **40** may be configured to receive a guidewire for guiding the balloon portion **18**, along with the rest of the dilation and capture assembly **14**, through the body vessels **102**. The balloon portion **18** may be a balloon on a balloon catheter, such as, for example, a Dorado™ PTA balloon catheter. In embodiments, the catheter **16** may include any other expansion device for performing a thrombectomy or an angioplasty instead of the balloon portion **18**, such as, for example, an expandable cage, a stent, a stent graft, or other similar device configured for radial expansion.

[0027] Referring to FIG. **3**, the retrieval basket **20** is shown in a deployed position **60**. The retrieval basket **20** may include a retrieval side **28**, a closed side **30** distally opposite the retrieval side **28**, one or more attachment wire lumens **27** (FIG. **5**), and one or more attachment wires **22** connecting the retrieval basket **20** to attachment wire lumens **26** (FIG. **4**) of the catheter sheath **12**. The one or more attachment wires **22** may be configured to position the retrieval basket **20** relative to the catheter sheath **12**. The one or more attachment wires **22** may extend into the one or more attachment wire lumens **27** in the retrieval basket **20** to fixedly couple the one or more attachment wires **22** to the retrieval basket **20**.

[0028] Referring to FIG. **4**, the catheter sheath **12** may include a sheath wall **24** and one or more attachment wire lumens **26** defined by the sheath wall **24**. The sheath wall **24** may be a hollow cylindrical wall configured to receive a portion of the dilation and capture assembly **14** within the sheath wall **24**. However, the sheath wall **24** may be any operable shape capable of having the

dilation and capture assembly **14** be positioned therein, such as, for example, a square or an oval. The one or more attachment wire lumens **26** may extend along a length of the sheath wall **24** and be configured to receive the attachment wires **22**.

[0029] Referring to FIG. **5**, the retrieval basket **20** may be formed of a mesh **31** configured to allow blood flow through the closed side **30** of the retrieval basket **20**. The mesh **31** may be formed of any biocompatible material, such as, for example, nitinol. The mesh **31** may be sized so that particulate in the body vessel **102** from the thrombectomy may be collected by the retrieval basket **20**. The retrieval side **28** of the retrieval basket **20** may be open so that particulate may enter and flow through the retrieval basket **20** to the closed side **30**. The closed side **30** may be configured to retain particulate within the retrieval basket **20**. The closed side **30** may be tapered or contoured to complement the tapering of the balloon portion **18**. The closed side **30** may be deformable similar to the atraumatic tip of the balloon portion **18** to reduce damage to the body vessel **102** as the retrieval basket **20** is maneuvered through the body vessel **102**. Referring to FIG. **5**, in a delivery configuration **70**, the retrieval basket **20** may be sized to be positioned around the balloon portion **18**, with the balloon portion **18** at least partially positioned within the retrieval basket **20**.

[0030] Referring to FIGS. **1-5**, each of the attachment wires **22** may be slidably positioned within the one or more attachment wire lumens **26** to extend both proximally and distally from the catheter sheath **12**. Referring to FIG. **3**, each of the attachment wires **22** may extend distally from the attachment wire lumens **26** (FIG. **4**) in the catheter sheath **12** to connect to attachment wire lumens **27** in the retrieval side **28** of the retrieval basket **20** and thus to connect the retrieval basket **20** to the catheter sheath **12**. The retrieval basket **20** is configured to be moved between a delivery configuration **70** (FIGS. **1** and **5**) to a retrieving configuration **80** (FIG. **9**) as described in greater detail herein. The attachment wires **22** are fixedly coupled to the retrieval basket **20** and movably positioned within the attachment wire lumens **26** in the catheter sheath **12** so that the retrieval basket **20** is movable relative to the catheter sheath **12**. The retrieval basket **20** is additionally movable relative to the balloon portion **18** so that the balloon portion **18** may move proximal to the retrieval basket **20**. The retrieval basket **20** may be spaced apart from the catheter sheath **12** a distance that is greater than a length of the balloon portion **18** so that the balloon portion **18** may be moved to be positioned proximal to the retrieval basket **20** and distal to the catheter sheath **12**.

[0031] The one or more attachment wires **22** may extend through the attachment wire lumens **27** to be connected to the closed side **30** of the retrieval basket **20**. However, it is contemplated and possible that the attachment wires **22** are connected to the retrieval basket **20** at any position along the retrieval basket **20**, such as a position at the retrieval side **28**. The one or more attachment wires **22** may be formed of any biocompatible material capable of moving and retaining the retrieval basket **20** relative to the catheter sheath **12**, such as, for example, nitinol.

[0032] FIG. **6** depicts the catheter assembly **10** in the delivery configuration **70** past the thrombus site in a past thrombus position as a distally past thrombus site position **200** with the balloon portion **18** deflated and the retrieval basket **20** not deployed. FIG. **7** depicts the catheter assembly **10** in the distally past thrombus site position **200** with the balloon portion **18** inflated and the retrieval basket **20** deployed. In FIG. **7**, the retrieval basket **20** of the catheter assembly **10** is in a delivery configuration **70**. With reference to FIGS. **6** and **7**, the balloon portion **18** may thus be selectively inflatable and deflatable between a deflated position **48** (FIG. **6**) and an inflated position **58** (FIG. **7**), respectively. The balloon portion **18** may be inflated and deflated via a fluid flowing through the inflation lumen **38**. The fluid may be a saline and contrast mixture, such as used in an angiography. However, it is contemplated and possible that the fluid may be any fluid for inflating and deflating a balloon catheter, such as, for example, saline, water, air, a gas, or the like. The inflation lumen **38** may be in fluid connection with an fluid source (not shown) that controls fluid flow through the inflation lumen **38** and provides fluid to the balloon portion **18** through the inflation lumen **38** to inflate the balloon portion **18** to the inflated position **58**, and draws fluid from the balloon portion **18** through the inflation lumen **38** to deflate the balloon portion **18** to the

deflated position **48**. The radius of the balloon portion **18** may be smaller in the deflated position **48** than the radius in the inflated position **58**. The radius of the balloon portion **18** may be about the same as the radius of the body vessel **102** when in the inflated position **58**. Referring to FIG. **6**, in the deflated position **48**, the balloon portion **18** may have a radius that is less than a radius of the catheter sheath **12** so that the balloon portion **18** may pass through the catheter sheath **12**.

[0033] Further, the retrieval basket **20** may be movable between a collapsed position **50** (FIG. **6**) and a deployed position **60** (FIG. **7**). The retrieval basket **20** may be expanded from the collapsed position **50** to the deployed position **60** when the balloon portion **18** is inflated from the deflated position **48** to the inflated position **58** (FIG. **7**). Particularly, the inflation of the balloon portion **18** from the deflated position **48** toward the inflated position **58** exerts pressure on the retrieval basket **20** to expand the retrieval basket **20** radially outward from the collapsed position **50** to the deployed position **60**.

[0034] Referring to FIG. **10**, the balloon portion **18** of the catheter **16** of the dilation and capture assembly **14** may be selectively inflatable and deflatable between a maceration orientation **59** and a delivery orientation **49**. In the delivery orientation **49**, the balloon portion **18** is deflated and the dilation and capture assembly **14** is configured to be inserted into a body vessel **102** of the body **104** of the patient. Particularly, in the delivery orientation **49**, the balloon portion **18** is in the deflated position **48**, and the retrieval basket **20** may be in the collapsed position **50**. Referring again to FIG. **6**, in the delivery configuration **70**, the retrieval basket **20** may extend around the entirety of the balloon portion **18** that is in the deflated position **48** and be conformed to the shape of the balloon portion **18** so that the balloon portion **18** is in contact with the retrieval basket **20** along a length of the retrieval basket **20** between the closed side **30** and the retrieval side **28**. With the retrieval basket **20** conforming to the shape of the balloon portion **18** in the deflated position **48**, the dilation and capture assembly **14** is sized to be insertable within the body vessel **102** of the patient.

[0035] FIG. **8** depicts the catheter assembly **10** in a separated balloon and basket position **300** separating the balloon portion **18** and the retrieval basket **20** in the distally past thrombus site position **200** with the balloon portion **18** deflated in the deflated position **48** and the retrieval basket **20** deployed in the deployed position **60**. FIG. **9** depicts the retrieval basket **20** in a retrieving configuration **80** in the distally past thrombus site position **200** with the balloon portion **18** proximally displaced to be at the thrombus **112**. Referring again to FIGS. **6**-**9**, the retrieval basket **20** may be deployable from the delivery configuration **70** (FIGS. **6**-**8**) mounted to the balloon portion **18** to the retrieving configuration **80** (FIG. **9**) axially displaced from the distal end **17** of the catheter **16**.

[0036] Referring again to FIG. **6**, in the delivery orientation **49** (FIG. **10**), the balloon portion **18** is in the deflated position **48** to be sized so that the balloon portion **18** may be positioned within the retrieval basket **20** and move through the introducer sheath **110**. With the retrieval basket **20** in the delivery configuration **70**, the dilation and capture assembly **14** may be moved from the extracorporeal area **106** through the introducer sheath **110** and into the intracorporeal area **108** within the body vessel **102**. Once the dilation and capture assembly **14** is positioned within the body vessel **102**, the balloon portion **18** and retrieval basket **20** may be advanced in the direction of arrow A along the body vessel **102** to the distally past thrombus site position **200** positioned distal to the treatment site at the thrombus site position **100** where the thrombus **112** is located. The dilation and capture assembly **14** may be inserted so that the retrieval basket **20** is positioned distal to the thrombus **112** in the direction of blood flow so when the retrieval basket **20** is expanded to the deployed position **60**, particulate removed from the thrombus **112** (such as via the balloon portion **18** as described herein to form the broken thrombus **113** as shown in FIG. **10**) flows toward and into and/or may be captured by the retrieval side **28** of the retrieval basket **20** as described herein.

[0037] The balloon portion **18** may be expanded from the deflated position **48** (FIG. **6**) to the

inflated position **58** (FIG. **7**) to have a radius that is approximately the size of the radius of the body vessel **102**. As the balloon portion **18** expands from the deflated position **48** to the inflated position **58**, the balloon portion **18** contacts the retrieval basket **20** to expand the retrieval basket **20** with the balloon portion **18** from the collapsed position **50** (FIG. **6**) to the deployed position **60** (FIG. **7**). When the retrieval basket **20** is in the deployed position **60**, the retrieval basket **20** is expanded to the size of the body vessel **102** along with the balloon portion **18** so that any particulate later removed from the thrombus **112** as described herein by the balloon portion **18** flows into or is otherwise captured by the retrieval side **28** of the retrieval basket **20** when the balloon portion **18** is axially displaced from the retrieval basket **20**. Once the retrieval basket **20** is dilated by the balloon portion **18**, the mesh **31** is configured to maintain the size of the retrieval basket **20** so that the retrieval basket **20** does not reduce in size with the balloon portion **18** when the balloon portion **18** moves from the inflated position **58** to the deflated position **48** as shown in FIG. **8**.

[0038] Referring to FIG. **8**, once the retrieval basket **20** is in the deployed position **60** and dilated to the size of the body vessel **102**, the dilation and capture assembly **14** may be moved to the separated balloon and basket position **300**, where the balloon portion **18** is deflated from the inflated position **58** (FIG. **7**) to the deflated position **48** (FIG. **8**) with the retrieval basket **20** in the deployed position **60** so that the balloon portion **18** is separated, or spaced apart, from the retrieval basket **20**.

[0039] Referring to FIG. **9**, in the separated balloon and basket position **300** with the balloon portion **18** in the deflated position **48** and the retrieval basket **20** in the deployed position **60**, the balloon portion **18** of the catheter **16** is further movable relative to the retrieval basket **20** such that the retrieval basket **20** changes to the retrieving configuration **80** axially displaced from the distal end **17** of the catheter **16**. The hub **101** of the catheter **16** may be physically manipulated by a user to move the balloon portion **18** proximal to the retrieval basket **20** in the direction of arrow B so that the retrieval basket **20** is in the retrieving configuration **80**. In the retrieving configuration **80**, the retrieval basket **20** is positioned distal to the thrombus **112** with the balloon portion **18** positioned at the treatment site (e.g., the thrombus site position **100**) between the catheter sheath **12** and the retrieval basket **20**.

[0040] Referring to FIG. **10**, the catheter **16** is shown with the balloon portion **18** in the deflated position **48** associated with the delivery orientation **49** after being in the inflated position **58** associated with the maceration orientation **59** to macerate and break the thrombus **112** to create the broken thrombus **113** (such as through multiple inflation/deflation of the balloon portion **18**). Thus, when the balloon portion **18** is at the thrombus site position **100**, the balloon portion **18** may be inflated to the inflated position **58** to contact the thrombus **112**. Accordingly, when the retrieval basket **20** is in the retrieving configuration **80**, the balloon portion **18** may be inflated from the delivery orientation **49** to a maceration orientation **59**. When in the maceration orientation **59**, the balloon portion **18** may interact and macerate the thrombus **112**. In the maceration orientation **59**, the balloon portion **18** may be repeatedly inflated and deflated between the inflated position **58** and the deflated position **48** to macerate the thrombus **112**. The inflation of the balloon portion **18** may act to additionally perform an angioplasty by contacting and expanding the walls of the blood vessel **102**, thereby dilating the blood vessel **102**.

[0041] By moving between the deflated position **48** and the inflated position **58**, the balloon portion **18** expands to contact and deform the thrombus **112**, thereby breaking apart the thrombus **112** into broken thrombus **113** and dislodging the thrombus **112** from the body vessel **102**. The balloon portion **18** may repeatedly move between the deflated position **48** and the inflated position **58** to reduce the size of or entirely remove the thrombus **112** from the body vessel **102**. As the thrombus **112** breaks apart, particulate as broken thrombus **113** breaks apart from the thrombus **112** and flows through the body vessel **102** with the blood flow toward the retrieval basket **20**. The broken thrombus **113** and the blood flowing through the body vessel **102** may enter the retrieval basket **20** at the retrieval side **28** and flow toward the closed side **30**. As discussed above, the

closed side **30** is sized to allow blood to flow through the closed side **30**, while restricting movement of the broken thrombus **113**. Accordingly, the closed side **30** of the retrieval basket **20** filters out particulate of the broken thrombus **113** from the blood, trapping the particulate of the broken thrombus **113** within the retrieval basket **20**. The closed side **30** of the retrieval basket **20** may be shaped to prevent the collected particulate of the broken thrombus **113** from entirely restricting blood flow through the closed side **30**. For example, the closed side **30** may be shaped as a conc.

[0042] Referring to FIG. **11**, the dilation and capture assembly **14** is depicted in a balloon removal position **400** in which the balloon portion **18** is proximally advanced from the thrombus site position **100** (previously including thrombus **112** at a treatment site). In the balloon removal position **400**, the balloon portion **18** may be retracted in the direction of arrow B out of the body vessel **102**. The balloon portion **18** is in the deflated position **48** so that the balloon portion **18** may be retracted through the catheter sheath **12** and the introducer sheath **110** from the intracorporeal area **108** to the extracorporeal area **106** to be removed from the body vessel **102**. The hub **101** may be physically manipulated by a user to move the catheter **16** in the direction of arrow B. As the hub **101** is retracted in the direction of arrow B, the balloon portion **18** may pass through the introducer sheath **110** and the sheath wall **24** of the catheter sheath **12** without intervening with the attachment wires **22**.

[0043] Referring to FIG. **12**, the dilation and capture assembly **14** is depicted with the retrieval basket **20** in a retrieval basket removal position **500** and the retrieving configuration **80** to retrieve broken thrombus **113** when proximally being advanced back past the thrombus site including broken thrombus **113**. The retrieval basket **20** is moved so that the retrieval side **28** of the retrieval basket **20** is proximally directed toward the catheter sheath **12**. While moving toward the catheter sheath **12**, the retrieval basket **20** may collect particulate of the broken thrombus **113** that is positioned between the retrieval basket **20** and the catheter sheath **12**.

[0044] The retrieval basket **20** may be moved through the body vessel **102** toward the introducer sheath **110** in the direction of arrow B by operation of the actuator **42**. Particularly, the actuator **42** may be operatively coupled to the attachment wires **22** where actuation of the actuator **42** pulls the attachment wires **22** through the attachment wire lumens **26** in the catheter sheath **12** in the direction of arrow B, thereby moving the retrieval basket **20** in the direction of arrow B. Actuation of the actuator **42** may include moving the actuator **42** in the direction of arrow C, where movement of the actuator **42** moves the attachment wires **22** along the attachment wire lumens **26**, thereby pulling the retrieval basket **20** in the direction of arrow B toward the catheter sheath **12**. The pulling of the retrieval basket **20** via the attachment wires **22** may cause the retrieval basket **20** to collapse from the deployed position **60** to the collapsed position **50**.

[0045] As depicted, the actuator **42** may be a mechanical actuator, such as a tab, that the user may physically manipulate to move the retrieval basket **20**. The actuator **42** may be positioned on the proximal portion **32** of the catheter **16** (FIG. **2**) extending out of the introducer sheath **110** when the catheter **16** is positioned in the body vessel **102** so that the user can physically manipulate the actuator **42**. However, it is contemplated and possible that the actuator **42** may be any actuator capable of moving the retrieval basket **20**, such as, for example, a linear actuator, a rotary actuator, a pneumatic or hydraulic actuator, or the like. In such embodiments, the actuator **42** may include a motor to be automatically operated to move the attachment wires **22**.

[0046] Referring to FIG. **13**, the dilation and capture assembly **14** is depicted in an assembly extraction position **600**. In the assembly extraction position **600**, the retrieval basket **20** may be formed back into the collapsed position **50** so that the retrieval basket **20** is sized to be movable through the introducer sheath **110**. Additionally, the contact between the catheter sheath **12** and the retrieval side **28** of the retrieval basket **20** while in the collapsed position **50** prevents particulate of the broken thrombus **113** trapped within the retrieval basket **20** from exiting the retrieval basket **20** through the retrieval side **28**. In the assembly extraction position **600**, the retrieval basket **20** may

be moved, along with the particulate collected from maceration of the thrombus **112** and contained within the retrieval basket **20**, in the direction of arrow B so that the catheter sheath **12** and the retrieval basket **20** may move from the intracorporeal area **108** through the introducer sheath **110** and out of the body vessel **102** to the extracorporeal area **106**. The removal of the retrieval basket **20** from the body vessel **102** thereby removes the particulate of the broken thrombus **113** collected by the retrieval basket **20**.

[0047] Thus a method of performing a thrombectomy as described herein may include inserting the catheter assembly **10** into the body vessel **102**, as depicted in FIG. **1**. As described above, the catheter assembly **10** may be inserted into the body vessel **102** through the introducer sheath **110** that extends from the extracorporeal area **106** into the intracorporeal area **108**. The method further includes translating the balloon portion **18** and the retrieval basket **20** relative to the catheter sheath **12** in the direction of arrow A past the treatment site (e.g., the thrombus site position **100**) so that the retrieval basket **20** is disposed distal to the thrombus **112**, as depicted in FIG. **6**.

[0048] As shown in FIG. **7**, the method includes inflating the balloon portion **18** to the inflated position **58** as described herein, thereby dilating the retrieval basket **20** to the deployed position **60**, as depicted in FIG. **7**. As shown in FIG. **8**, the balloon portion **18** may be deflated to the deflated position **48** so that the retrieval basket **20** is spaced apart from the balloon portion **18**, and the balloon portion **18** is movable relative to the retrieval basket **20**. As shown in FIG. **9**, the balloon portion **18** may be translated in the direction of arrow B away from the retrieval basket **20** and toward the treatment site (e.g., the thrombus site position **100**), so that the retrieval basket **20** is in the deployed position **60** and the balloon portion **18** is configured to contact the thrombus **112** when in the inflated position **58**. As show in FIG. **10**, once the balloon portion **18** is positioned at the treatment site (e.g., the thrombus site position **100**), the balloon portion **18** is configured to be selectively and repeatedly inflatable and deflatable between respectively the maceration orientation **59** and the delivery orientation **49** to macerate the thrombus **112** and form the broken thrombus **113**. The retrieval basket **20** in the retrieving configuration **80** is configured to collect the particulate of the broken thrombus **113** removed from the thrombus **112** during inflation and deflation of the balloon portion **18** at the treatment site (e.g., the thrombus site position **100**).

[0049] As shown in FIG. **11**, the balloon portion **18** may be deflated to the deflated position **48**, so that the balloon portion **18** is sized to fit within the catheter sheath **12**. As shown in FIG. **12**, the balloon portion **18** may be retracted into the catheter sheath **12**. The retrieval basket **20** may further be retracted proximally toward the treatment site (e.g., the thrombus site position **100**) to collect the particulate of the broken thrombus **113** with the retrieval basket **20**. The retrieval basket **20** may be retracted using the actuator **42**, where actuation of the actuator **42** is configured to pull the attachment wires **22** and the retrieval basket **20** toward the treatment site. As shown in FIG. **13**, the catheter assembly **10** may be retracted out of the body vessel **102** such as through the introducer sheath **110** thereby removing the particulate as the broken thrombus **113** from the body vessel **102**.

[0050] Embodiments may be further described with reference to the following numbered clauses:

[0051] 1. A catheter assembly for performing a thrombectomy, the catheter assembly including: a catheter sheath; and a dilation and capture assembly slidably positioned within the catheter sheath, the dilation and capture assembly including: a catheter including a balloon portion at a distal end of the catheter, the balloon portion being selectively inflatable and deflatable between respectively a maceration orientation and a delivery orientation; and a retrieval basket deployable from a delivery configuration mounted to the balloon portion and a retrieving configuration axially displaced from the distal end of the catheter.

[0052] 2. The catheter assembly according to clause 1, wherein the retrieval basket comprises one or more attachment wires connecting the retrieval basket to the catheter sheath throughout movement of the retrieval basket from the delivery configuration to the retrieving configuration.

[0053] 3. The catheter assembly according to clause 2, wherein: the catheter sheath comprises a sheath wall and one or more attachment wire lumens formed within the sheath wall; and the one or

more attachment wires are slidably positioned within the one or more attachment wire lumens.
[0054] 4. The catheter assembly according to any of clause 1 to clause 4, wherein: the retrieval basket comprises a retrieval side configured to receive particulate removed during the thrombectomy, and a closed side opposite the retrieval side configured to retain the particulate in the retrieval basket, and the retrieval basket is at least partially formed of a mesh configured to allow blood flow through the closed side of the retrieval basket.
[0055] 5. The catheter assembly according to clause 4, wherein: the retrieval basket comprises one or more attachment wires connecting the retrieval side of the retrieval basket to the catheter sheath throughout movement of the retrieval basket from the delivery configuration to the retrieving configuration.
[0056] 6. The catheter assembly according to clause 5, wherein: the catheter sheath comprises a sheath wall and one or more attachment wire lumens formed within the sheath wall; and the one or more attachment wires are slidably positioned within the one or more attachment wire lumens.
[0057] 7. The catheter assembly according to any of clause 5 or clause 6, wherein the one or more attachment wires are formed of nitinol.
[0058] 8. The catheter assembly according to any of clause 4 to clause 7, wherein: the catheter comprises a proximal portion coupled to a proximal end of the balloon portion, the catheter defining an inflation lumen for inflating and deflating the balloon portion and a guidewire lumen.
[0059] 9. The catheter assembly according to any of clause 1 to clause 8, further including: an actuator operatively coupled to the retrieval basket, the actuator being configured to axially translate the retrieval basket.
[0060] 10. A catheter assembly for performing an thrombectomy, the catheter assembly including: a catheter sheath; a dilation and capture assembly slidably positioned within the catheter sheath, the dilation and capture assembly including: a catheter including a proximal portion and a balloon portion at a distal end of the proximal portion, the balloon portion being selectively inflatable and deflatable between respectively a maceration orientation and a delivery orientation; a retrieval basket deployable from a delivery configuration mounted to the balloon portion and a retrieving configuration axially displaced from the balloon portion; and one or more attachment wires configured to position the retrieval basket relative to the catheter sheath.
[0061] 11. The catheter assembly according to clause 10, wherein: the catheter sheath comprises a sheath wall and one or more attachment wire lumens formed within the sheath wall; and the one or more attachment wires are slidably positioned within the one or more attachment wire lumens.
[0062] 12. The catheter assembly according to any of clause 10 or clause 11, wherein: the retrieval basket comprises a retrieval side configured to receive particulate removed during the thrombectomy, and a closed side opposite the retrieval side configured to retain the particulate in the retrieval basket, and the retrieval basket is at least partially formed of a mesh configured to allow blood flow through the closed side of the retrieval basket.
[0063] 13. The catheter assembly according to clause 12, wherein: the one or more attachment wires connect the retrieval side of the retrieval basket to the catheter sheath throughout movement of the retrieval basket from the delivery configuration to the retrieving configuration.
[0064] 14. The catheter assembly according to any of clause 12 or clause 13, wherein: the catheter defines an inflation lumen for inflating and deflating the balloon portion and a guidewire lumen.
[0065] 15. The catheter assembly according to any of clause 10 to clause 14, further including an actuator operatively coupled to the retrieval basket, the actuator being configured to axially translate the retrieval basket.
[0066] 16. A method of performing a thrombectomy, the method including: inserting a catheter assembly into a body vessel, the catheter assembly including: a catheter sheath; and a dilation and capture assembly slidably positioned within the catheter sheath, the dilation and capture assembly including: a catheter including a balloon portion at a distal end of the catheter, the balloon portion being selectively inflatable and deflatable between respectively a maceration orientation and a

delivery orientation; and a retrieval basket deployable from a delivery configuration mounted to the balloon portion and a retrieving configuration axially displaced from the distal end of the catheter; translating the balloon portion and the retrieval basket relative to the catheter sheath past a treatment site; and inflating the balloon portion, thereby dilating the retrieval basket.
[0067] 17. The method according to clause 16, further including: deflating the balloon portion; translating the balloon portion toward the treatment site; repeatedly inflating and deflating the balloon portion at the treatment site.
[0068] 18. The method according to clause 17, wherein the retrieval basket collects particulate removed during inflation and deflation of the balloon portion at the treatment site.
[0069] 19. The method according to clause 18, further including: deflating the balloon portion; and retracting the balloon portion into the catheter sheath.
[0070] 20. The method according to clause 19, further including: retracting the retrieval basket toward the treatment site to collect the particulate with the retrieval basket; and retracting the catheter assembly out of the body vessel.
[0071] It is noted that the terms “substantially” and “about” may be utilized herein to represent the inherent degree of uncertainty that may be attributed to any quantitative comparison, value, measurement, or other representation. These terms are also utilized herein to represent the degree by which a quantitative representation may vary from a stated reference without resulting in a change in the basic function of the subject matter at issue.
[0072] While particular embodiments have been illustrated and described herein, it should be understood that various other changes and modifications may be made without departing from the spirit and scope of the claimed subject matter. Moreover, although various aspects of the claimed subject matter have been described herein, such aspects need not be utilized in combination. It is therefore intended that the appended claims cover all such changes and modifications that are within the scope of the claimed subject matter.

Claims

1. A catheter assembly for performing a thrombectomy, the catheter assembly comprising: a catheter sheath; and a dilation and capture assembly slidably positioned within the catheter sheath, the dilation and capture assembly comprising: a catheter comprising a balloon portion at a distal end of the catheter, the balloon portion being selectively inflatable and deflatable between respectively a maceration orientation and a delivery orientation; and a retrieval basket deployable from a delivery configuration mounted to the balloon portion and a retrieving configuration axially displaced from the distal end of the catheter.
2. The catheter assembly of claim 1, wherein the retrieval basket comprises one or more attachment wires connecting the retrieval basket to the catheter sheath throughout movement of the retrieval basket from the delivery configuration to the retrieving configuration.
3. The catheter assembly of claim 2, wherein: the catheter sheath comprises a sheath wall and one or more attachment wire lumens formed within the sheath wall; and the one or more attachment wires are slidably positioned within the one or more attachment wire lumens.
4. The catheter assembly of claim 1, wherein: the retrieval basket comprises a retrieval side configured to receive particulate removed during the thrombectomy, and a closed side opposite the retrieval side configured to retain the particulate in the retrieval basket, and the retrieval basket is at least partially formed of a mesh configured to allow blood flow through the closed side of the retrieval basket.
5. The catheter assembly of claim 4, wherein: the retrieval basket comprises one or more attachment wires connecting the retrieval side of the retrieval basket to the catheter sheath throughout movement of the retrieval basket from the delivery configuration to the retrieving configuration.

6. The catheter assembly of claim 5, wherein: the catheter sheath comprises a sheath wall and one or more attachment wire lumens formed within the sheath wall; and the one or more attachment wires are slidably positioned within the one or more attachment wire lumens.
7. The catheter assembly of claim 5, wherein the one or more attachment wires are formed of nitinol.
8. The catheter assembly of claim 4, wherein: the catheter comprises a proximal portion coupled to a proximal end of the balloon portion, the catheter defining an inflation lumen for inflating and deflating the balloon portion and a guidewire lumen.
9. The catheter assembly of claim 1, further comprising: an actuator operatively coupled to the retrieval basket, the actuator being configured to axially translate the retrieval basket.
10. A catheter assembly for performing a thrombectomy, the catheter assembly comprising: a catheter sheath; and a dilation and capture assembly slidably positioned within the catheter sheath, the dilation and capture assembly comprising: a catheter comprising a proximal portion and a balloon portion at a distal end of the proximal portion, the balloon portion being selectively inflatable and deflatable between respectively a maceration orientation and a delivery orientation; a retrieval basket deployable from a delivery configuration mounted to the balloon portion and a retrieving configuration axially displaced from the balloon portion; and one or more attachment wires configured to position the retrieval basket relative to the catheter sheath.
11. The catheter assembly of claim 10, wherein: the catheter sheath comprises a sheath wall and one or more attachment wire lumens formed within the sheath wall; and the one or more attachment wires are slidably positioned within the one or more attachment wire lumens.
12. The catheter assembly of claim 10, wherein: the retrieval basket comprises a retrieval side configured to receive particulate removed during the thrombectomy, and a closed side opposite the retrieval side configured to retain the particulate in the retrieval basket, and the retrieval basket is at least partially formed of a mesh configured to allow blood flow through the closed side of the retrieval basket.
13. The catheter assembly of claim 12, wherein: the one or more attachment wires connect the retrieval side of the retrieval basket to the catheter sheath throughout movement of the retrieval basket from the delivery configuration to the retrieving configuration.
14. The catheter assembly of claim 12, wherein: the catheter defines an inflation lumen for inflating and deflating the balloon portion and a guidewire lumen.
15. The catheter assembly of claim 10, further comprising an actuator operatively coupled to the retrieval basket, the actuator being configured to axially translate the retrieval basket.
16. A method of performing a thrombectomy, the method comprising: inserting a catheter assembly into a body vessel, the catheter assembly comprising: a catheter sheath; and a dilation and capture assembly slidably positioned within the catheter sheath, the dilation and capture assembly comprising: a catheter comprising a balloon portion at a distal end of the catheter, the balloon portion being selectively inflatable and deflatable between respectively a maceration orientation and a delivery orientation; and a retrieval basket deployable from a delivery configuration mounted to the balloon portion and a retrieving configuration axially displaced from the distal end of the catheter; translating the balloon portion and the retrieval basket relative to the catheter sheath past a treatment site; and inflating the balloon portion, thereby dilating the retrieval basket.
17. The method of claim 16, further comprising: deflating the balloon portion; translating the balloon portion toward the treatment site; and repeatedly inflating and deflating the balloon portion at the treatment site.
18. The method of claim 17, wherein the retrieval basket collects particulate removed during inflation and deflation of the balloon portion at the treatment site.
19. The method of claim 18, further comprising: deflating the balloon portion; and retracting the balloon portion into the catheter sheath.
20. The method of claim 19, further comprising: retracting the retrieval basket toward the treatment

site to collect the particulate with the retrieval basket; and retracting the catheter assembly out of the body vessel.