

**FORM 2**

**THE PATENTS ACT, 1970**

**(39 of 1970)**

**&**

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**THE PATENTS RULES, 2003**

**COMPLETE SPECIFICATION**

**(Section 10 and Rule 13)**

**1. TITLE OF THE INVENTION:**

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**EMBOLIZATION DEVICE**

**2. APPLICANT:**

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The following specification particularly describes the invention and the manner  
in which it is to be performed:

## **FIELD OF INVENTION**

[1] The present disclosure relates to a medical device. More particularly, the present disclosure relates to an embolization device.

## **BACKGROUND OF INVENTION**

5 [2] Percutaneous and non-invasive medical procedures are replacing the invasive exploratory surgeries. In percutaneous procedures, the medical tools/instruments are introduced within a patient's vasculature through a vascular access site, for example, a dermal puncture. After the medical procedure is completed, the vascular access site is closed to prevent bleeding  
10 and promote hemostasis.

[3] Manual compression is a standard hemostasis procedure that requires prolonged compression of the vascular access site. Alternatively, the vascular access site is closed by stitching it with one or more sutures.

15 [4] However, manual compression as well as suture-based stitching is very time consuming and prone to medical complications such as infections, premature bleeding before complete healing, etc.

[5] Due to these drawbacks, embolization devices became prevalent. Embolization is a procedure to block the blood flow through a blood vessel. In embolization, a surgeon makes an incision in a patient's body to access the  
20 target site through a guidewire. The guidewire guides the catheter to gain access to the target site inside a blood vessel. The catheter introduces the embolization device at the target site, which promotes thrombus formation and closure of the vascular access site. However, conventional devices heavily suffer from problems such as increased risk of blood clots, etc. which ultimately interrupt the flow of  
25 oxygen and blood to the brain. Other risks include damage to the blood vessel, bleeding at the puncture site, and infection. The embolic agent used in the procedure to check the blood flow through the blood vessel is stopped and may

lodge in the wrong place if the catheter is positioned incorrectly and deprive normal tissue of its oxygen supply.

[6] Thus, there arises a need for a device that overcomes the problems associated with the conventional solutions.

## 5 SUMMARY OF INVENTION

[7] Particular embodiments of the present disclosure are described herein below with reference to the accompanying drawings, however, it is to be understood that the disclosed embodiments are mere examples of the disclosure, which may be embodied in various forms. Well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present disclosure in virtually any appropriately detailed structure.

[8] The present disclosure relates to an embolization device. In an embodiment, the embolization device includes a frame, a bridge, a plurality of discs. The frame including a first portion at the proximal end and a second portion at the distal end. The first portion and the second portion include a hollow inner structure. The bridge is coupled to the first portion and the second portion. The plurality of discs is seated inside the hollow inner structure of the first portion and the second portion. Each disc includes a circumferential portion coupled to the frame and a sieve disposed centrally within the circumferential portion.

## 25 BRIEF DESCRIPTION OF DRAWINGS

[9] The summary above, as well as the following detailed description of illustrative embodiments, is better understood when read in conjunction with

the apportioned drawings. For the purpose of illustrating the present disclosure, exemplary constructions of the disclosure are shown in the drawings. However, the disclosure is not limited to specific methods and instrumentality disclosed herein. Moreover, those in the art will understand that the drawings are not to scale.

[10] Fig. 1 depicts a front view of an embolization device/ device 100 according to an embodiment of the present disclosure.

[11] Fig. 2 depicts a perspective view of the device 100, according to an embodiment of the present disclosure.

[12] Fig. 3 depicts a perspective view of a frame 110 of the device 100, according to an embodiment of the present disclosure.

[13] Fig. 4 depicts a membrane 120 of the device 100, according to an embodiment of the present disclosure.

[14] Fig. 5a depicts the plurality of discs 130 of the device 100, according to an embodiment of the present disclosure.

[15] Fig. 5b depicts a front perspective view of the disc 130 of the device 100, according to an embodiment of the present disclosure.

[16] Fig. 6a depicts a perspective view from a proximal end 100a of the device 100, according to an embodiment of the present disclosure.

[17] Fig. 6b depicts a perspective view from a distal end 100b of the device 100, according to an embodiment of the present disclosure.

[18] Fig. 7 depicts the device 100 inside the blood vessel, according to an embodiment of the present disclosure.

#### **DETAILED DESCRIPTION OF THE DRAWINGS**

[19] Prior to describing the invention in detail, definitions of certain words or phrases used throughout this patent document will be defined: the terms

"include" and "comprise", as well as derivatives thereof, mean inclusion without limitation; the term "or" is inclusive, meaning and/or; the phrases "coupled with" and "associated therewith", as well as derivatives thereof, may mean to include, be included within, interconnect with, contain, be contained within, connect to or with, couple to or with, be communicable with, cooperate with, interleave, juxtapose, be proximate to, be bound to or with, have a property of, or the like. Definitions of certain words and phrases are provided throughout this patent document, and those of ordinary skill in the art will understand that such definitions apply in many, if not most, instances to prior as well as future uses of such defined words and phrases.

[20] Reference throughout this specification to "one embodiment," "an embodiment," or similar language means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases "in one embodiment," "in an embodiment," and similar language throughout this specification may, but do not necessarily, all refer to the same embodiment, but mean "one or more but not all embodiments" unless expressly specified otherwise. The terms "including," "comprising," "having," and variations thereof mean "including but not limited to" unless expressly specified otherwise. An enumerated listing of items does not imply that any or all of the items are mutually exclusive and/or mutually inclusive, unless expressly specified otherwise. The terms "a," "an," and "the" also refer to "one or more" unless expressly specified otherwise.

[21] Although the operations of exemplary embodiments of the disclosed method may be described in a particular, sequential order for convenient presentation, it should be understood that the disclosed embodiments can encompass an order of operations other than the particular, sequential order disclosed. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Further, descriptions and disclosures provided in association with one particular embodiment are not limited to that

embodiment, and may be applied to any embodiment disclosed herein. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed system, method, and apparatus can be used in combination with other systems, methods, and apparatuses.

5 [22] Furthermore, the described features, advantages, and characteristics of the embodiments may be combined in any suitable manner. One skilled in the relevant art will recognize that the embodiments may be practiced without one or more of the specific features or advantages of a particular embodiment. In  
10 other instances, additional features and advantages may be recognized in certain embodiments that may not be present in all embodiments. These features and advantages of the embodiments will become more fully apparent from the following description and apportioned claims, or may be learned by the practice of embodiments as set forth hereinafter.

15 [23] The present disclosure relates to an embolization device (or device). The device may be used to provide thrombogenic barrier in, without limitation, a peripheral vascular intervention, an arterial occlusion, an endovascular surgery, etc. In a peripheral vascular intervention, the device is used for closing a vascular access site following a medical procedure like angioplasty, stenting, atherectomy, or thrombectomy. In an arterial occlusion, the device is used to  
20 occlude small to medium-sized arteries in peripheral vascular territories where precise closure is necessary to prevent bleeding and/or maintain hemostasis. In an endovascular surgery, the device is used in a medical procedure where minimally invasive technique(s) is employed to treat a condition such as a peripheral artery disease.

25 [24] The device provides precise and secure closure of a vascular access site (or implantation site), usually created prior to a non-invasive (or percutaneous) medical procedure. The device includes a frame made from a self-expandable material, such as nitinol. The self-expandable material facilitates easy

deployment of the device with precision. The device is radially expandable from a radially collapsed state at the time of implantation.

[25] The frame of the device is easily manufactured in different sizes for accommodating different sizes of vascular access sites and patient anatomies.

5 Thus, deployment of an appropriate device corresponding to the dimensions of the vascular access site provides a precise fit and ensures the device does not migrate post-implantation. In an embodiment, the frame is made by laser-cutting a tube. The use of laser cutting technology ensures precise and accurate fabrication of the device, leading to better performance.

10 [26] Primarily, the device provides improved occlusion and hemostasis with the help of a plurality of discs made of a fabric provided within the frame, thereby, reducing the risk of bleeding and other medical complication. Apart from the discs, the device is also provided with a membrane covering at least a portion of the frame that (along with the discs) promotes thrombogenesis (i.e.,  
15 thrombus formation). The thrombus formed by the device further helps in reducing the risk of bleeding and improving the success rates of the procedure. Further, the simple design of the device allows for easy manipulation and deployment, making it user-friendly for medical professionals performing procedures.

20 [27] The device of the present disclosure is provided with an adapter that operationally couples to a delivery system. The delivery system is used to constrain and maintain the device in the radially collapsed state to percutaneously position the device at the implantation site. Once positioned, the delivery system is actuated to easily deploy the device by allowing the device to  
25 self-expand at the implantation site. Post implantation, the delivery system is decoupled from the device and withdrawn from the implantation site, leaving the device implanted at the implantation site.

[28] Now referring to the figures, Fig. 1 and Fig. 2 depict a device 100

according to an exemplary embodiment of the present disclosure. While Fig. 1 depicts the front view of the device 100, Fig. 2 depicts the front perspective view of the device 100. The device 100 is used to provide occlusion and/or maintain hemostasis at an implantation site, for example a vascular access site. The device 100 extends between a proximal end 100a and a distal end 100b. The device 100 includes, without limitation, a frame 110, a membrane 120, and a plurality of discs 130. Each of the components of the device are explained below along with diagrams of each component provided individually.

[29] The proximal end 100a of the device 100 includes a closed configuration of the frame 110 while the distal end 100b of the device 100 includes an open configuration.

[30] The frame 110 (as shown in Fig. 3) includes at least two portions, namely, a first portion 111 and a second portion 113. The first portion 111 is disposed towards the proximal end 100a of the device 100. The second portion 113 is disposed towards the distal end 100b of the device 100. The first portion 111 and the second portion 113 include a hollow inner structure. The first portion 111 and the second portion 113 may be coupled to each other via a bridge 115 disposed between the first portion 111 and the second portion 113. The first portion 111, the second portion 113 and the bridge 115 may either be discrete portions of the device 100 or may form an integral structure of the device 100. In an exemplary embodiment, the first portion 111, the second portion 113, and the bridge 115 are integrally formed by laser cutting a tube (not shown).

[31] The frame 110 may be made of a self-expanding material including, but not limited to, nitinol, cobalt-chromium alloy, stainless steel, etc. In an exemplary embodiment, the frame 110 is made of nitinol. The first portion 111 and the second portion 113 of the frame 110 (and the device 100) are radially expandable from a radially collapsed state.

[32] The dimensions of the frame 110 may vary according to or based upon

size of the vascular access site and patient anatomy. The frame 110 has a pre-defined shape such as, without limitation, hour glass, dumbbell, infinity symbol, etc. In an exemplary embodiment, as shown in Fig. 3, the frame 110 has a hour glass shape.

5 [33] In the depicted embodiment, the first portion 111 and the second portion 113 include a plurality of axial struts 111a arranged circumferentially and equidistantly from each other. Alternately, the plurality of axial struts 111a may be arranged circumferentially as per a pre-defined pattern. The pre-defined pattern includes arrangements such as irregular spacing between two  
10 consecutive struts, two closely spaced struts followed by a distant one, etc. The axial struts 111a of the first portion 111 extend axially from the bridge 115 to the proximal end 100a of the device 100. Similarly, the axial struts 111a of the second portion 113 extend axially from the bridge 115 to the distal end 100b of the device 100.

15 [34] The number of axial struts 111a depends upon the dimensions of the frame 110 and/or the device 100. The number of axial struts 111a of the second portion 113 are one of, equal to, more than or less than the number of axial struts 111a of the first portion 111.

[35] Each axial strut 111a includes a curve. Hence, a cup shape is formed by  
20 the plurality of axial struts 111a when arranged together, as depicted. Both the first portion 111 and the second portion 113 include this cup shape. Towards the proximal end 100a or the distal end 100b, the axial struts 111a bulge compared to the portions of the struts near the bridge 115.

[36] In the depicted embodiment, as shown in Fig. 3, the plurality of axial  
25 struts 111a at the distal end 100b are free or unattached defining an open configuration of the second portion 113 of the distal end 100b of the device 100. Alternatively, the second portion 113 may include a closed configuration. The open configuration of the second portion 113 provides an initial grip on the

vessel wall, supporting deployment and embolization.

[37] The axial struts 111a may have a pre-defined thickness ranging from 100 microns to 500 microns. The axial struts 111a may have a width ranging from 50 microns to 500 microns. In an exemplary embodiment, the thickness and width  
5 of the axial struts 111a is 200 microns and 400 microns, respectively.

[38] The first portion 111 at the proximal end 100a further includes a plurality of radial struts 111b. The radial struts 111b extend radially from the proximal ends of the respective axial strut 111a to the center of the device 100. The radial struts 111b thus define the closed configuration of the device 100 at the  
10 proximal end 100a. The closed configuration of the first portion 111 provides a secure grip to the blood vessels during deployment of the device 100, thereby ensuring stable placement and effective performance.

[39] It is to be noted that the dimensions of the first portion 111 and the second portion 113 may be same or different. Depending upon the anatomical  
15 requirements, the dimensions can be selected.

[40] In an exemplary embodiment, at the center, the plurality of radial struts 111b and axial struts 111a converge inside a jacket 117 at the proximal end 100a. The jacket 117 (shown in Fig. 1 and Fig. 2) may be discrete or integrally formed with the frame 110. In an exemplary embodiment, the jacket 117 is a tubular  
20 extension of the loose ends of the axial struts 111a of the first portion 111 of the frame 110. Alternately, the jacket 117 may have a pre-defined shape including, but not limited to, barrel, bell-mouth, etc. The jacket 117 may either be hollow or solid. In an exemplary embodiment, the jacket 117 is a hollow tubular cylinder. The jacket 117 may have a pre-defined diameter ranging from 1 mm to  
25 8mm. The jacket 117 may have a pre-defined length ranging from 2 mm to 5mm. In an exemplary embodiment, the diameter and length of the jacket 117 is 4mm to 3mm, respectively.

[41] The jacket 117 or at least a portion thereof, may be provided with a

plurality of external threads and/or internal threads. In an exemplary embodiment, not shown, the jacket 117 is provided with a plurality of external threads. The plurality of external threads of the jacket 117 helps to couple the jacket 117 (and the device 100) to a delivery system (or delivery wire thereof). A distal end 100b of the delivery system is provided with complementing threads corresponding to the plurality of external threads of the jacket 117. The delivery system may be used to position and implant the device 100 at the implantation site. Post-implantation, the delivery system is decoupled from the device 100 and withdrawn from the implantation site leaving the device 100 at the implantation site. Although the coupling between the jacket 117 (and the frame 110) and the delivery system is described with the example of complementing threads, other functionally equivalent techniques/ mechanisms are within the scope of the teachings of the present disclosure.

[42] In an alternative embodiment, as shown in Figs. 1 and 2, the jacket 117 is provided with an adapter 140. The adapter 140 is an elongate tubular member. At least a portion of the adapter 140 is fixedly coupled to the jacket 117. An outer surface of the adapter 140 is provided with a plurality of external threads. The plurality of external threads of the adapter 140 helps to couple the jacket 117 (and the device 100) to a delivery system (or delivery wire thereof).

[43] The bridge 115 (as shown in Fig. 3) fixedly couples the first portion 111 to the second portion 113 of the frame 110. The bridge 115 may have a pre-defined shape including, but not limited to, cylindrical, etc. In an exemplary embodiment, as shown in Fig. 1, the bridge 115 is cylindrical. The bridge 115 may have a pre-defined length ranging from 1mm to 4mm. The bridge 115 may have a pre-defined diameter ranging from 1mm to 8mm. In an exemplary embodiment, the length and diameter of the bridge 115 is 3mm and 4mm, respectively. The bridge 115 may be hollow or solid.

[44] The membrane 120 (as shown in Fig. 4) is at least partially disposed on at

least one of an inner surface or an outer surface of the frame 110. In an exemplary embodiment, the membrane 120 is disposed over the inner surface of the frame 110. The membrane 120 may extend over at least a portion of the first portion 111, the second portion 113 and/or the bridge 115. In an exemplary embodiment, the membrane 120 extends from the jacket 117 at the proximal end 100a to the ends of the axial struts 111a of the second portion 113 at the distal end 100b. The membrane 120 may be made of one or more materials including, but not limited to, polyethylene terephthalate (PET), polypropylene (olefin), polyethylene (PE), nylon, silicon fabric, polytetrafluoroethylene, etc. In an exemplary embodiment, the membrane 120 is made of polyethylene terephthalate PET. The membrane 120 may be of around 15 GSM in the range of 70 to 90%, that is, 70 to 90 % of the fabric volume consists of open space. The membrane 120 provides a stable framework that integrates well with body tissues, facilitating effective occlusion.

[45] The membrane 120 may be coupled to the frame 110 (as shown in Fig. 6a and Fig. 6b) via at least one of suturing, serger, surgical stapling, etc. In an exemplary embodiment, the membrane 120 is sutured to axial struts 111a, and radial struts 11b of the frame 110.

[46] The one or more discs 130 (also shown in Fig. 5a) are disposed inside at least one of the first portion 111 and the second portion 113 of the frame 110. In an exemplary embodiment, as shown in Fig. 6 and Fig. 6b, the first portion 111 includes two disc 130 and the second portion 113 includes two disc 130. The incorporation of two discs 130 in each of the first portion 111 and the second portion 113, provides a more secure and stable occlusion of the vascular access site, reducing the risk of complications and improving patient outcomes.

[47] The disc 130 is made of one or more materials including, but not limited to, PET, polypropylene (olefin), polyethylene (PE), nylon, silicon fabric, polytetrafluoroethylene, etc. In an exemplary embodiment, the discs 130 are

made by laser-cutting a PET fabric.

[48] Fig. 5b depicts the disc 130 of the device 100. The disc 130 includes at least one sieve 130a at the center provided with a circumferential portion 130b at the edge of the sieve 130a. Thus, the sieve 130a of the disc 130 is radially disposed. And at least a circumferential portion 130b of the disc 130 circumferentially extends either proximally or distally over a portion of the inner surface of the frame 110. The circumferential portion 130b of the disc 130 is coupled to the membrane 120 via at least one of suturing, serger, surgical stapling, etc. In an exemplary embodiment, the circumferential portion 130b of the discs 130 disposed in the hollow inner structure of first portion 111 and the second portion 113 is sutured to the membrane 120. Alternatively, the disc 130 can be directly coupled to the axial struts 111a of the frame 110 in case the membrane 120 is absent. The discs 130 provides protection during complete occlusion.

[49] For implanting the device 100, the device 100 is coupled to a catheter. Specifically, the adapter 140 of the device 100 is coupled to the catheter. A sheath is used to cover the device 100 to prevent it from expanding and easy introduction in a vascular access site. The device 100 is introduced in a human body in a radially collapsed state via the catheter. Once the catheter is positioned at the desired location, the second portion 113 is pushed outside the catheter and therefore the sheath. Due to this, the second portion 113 of the device 100 immediately expands upon removal of constraining force of the sheath. Upon further push force, the first portion 111 of the device 100 is also exposed or uncovered from the sheath. The device 100 self-expands to the radially expanded state from the radially collapsed state. The device 100 is disengaged from the catheter, specifically the adapter 140 and the catheter are disengaged. The catheter is withdrawn from the body lumen. The device 100 is implanted in the vascular site, an artery or a vein to embolize the vascular site (as shown in Fig. 7).

[50] The scope of the invention is only limited by the appended patent claims. More generally, those skilled in the art will readily appreciate that all parameters, dimensions, materials, and configurations described herein are meant to be exemplary and that the actual parameters, dimensions, materials, and/or configurations will depend upon the specific application or applications for which the teachings of the present invention is/are used.

**WE CLAIM:**

1. An embolization device (100) including a proximal end (100a) and a distal end (100b), the device (100) comprising:

a. a frame (110) having a first portion (111) at the proximal end (100a) and a second portion (113) at the distal end (100b), the first portion (111) and the second portion (113) including a hollow inner structure;

b. a bridge (115) coupling the first portion (111) and the second portion (113); and

c. a plurality of discs (130) seated inside each of the hollow inner structure of the first portion (111) and the second portion (113),

wherein each disc (130) includes a circumferential portion (130b) coupled to the frame (110),

wherein each disc (130) includes a sieve (130a) disposed centrally within the circumferential portion (130b).

2. The device (100) as claimed in claim 1, wherein at the proximal end (100a) of the frame (110), the first portion (111) includes a closed configuration and at the distal end (100b) of the frame (110), the second portion (113) includes an open configuration or a closed configuration.

3. The device (100) as claimed in claim 1, wherein the first portion (111), and the second portion (113), of the frame (110) are radially expandable.

4. The device (100) as claimed in claim 1, wherein the frame (110) includes one of an hour glass, a dumbbell, or an infinity symbol, shape.

5. The device (100) as claimed in claim 1, wherein the frame (110) is made of one or more materials, including nitinol, cobalt-chromium alloy, and stainless steel.

6. The device (100) as claimed in claim 1, wherein the frame (110) is formed by laser cutting a tube.
7. The device (100) as claimed in claim 1, wherein the first portion (111) and the second portion (113) include a plurality of axial struts (111a) arranged circumferentially and equidistantly from each other.
8. The device (100) as claimed in claim 1, wherein the plurality of axial struts (111a) of the first portion (111) converge in a jacket (117) at the proximal end (100a).
9. The device (100) as claimed in claim 1, wherein the device (100) includes a membrane (120) extending at least partially on an inner surface of the frame (110).
10. The device (100) as claimed in claim 1 and 9, wherein at least one of the membrane (120) and the disc (130) is made of one or more materials including polyethylene terephthalate (PET), polypropylene (olefin), polyethylene (PE), nylon, and silicon fabric.
11. The device (100) as claimed in claim 9, wherein the membrane (120) is coupled to the frame (110) via at least one of suturing, serger, surgical stapling.
12. The device (100) as claimed in claim 9, wherein the circumferential portion (130b) of the disc (130) is coupled to the membrane (120) via at least one of suturing, serger, or surgical stapling.
13. The device (100) as claimed in claim 1, wherein the number of axial struts (111a) of the second portion (113) are one of, equal to, more than or less than the number of axial struts (111a) of the first portion (111).
14. The device (100) as claimed in claim 1, wherein the jacket (117) includes a pre-defined shape including, barrel, or bell-mouth.

Dated this 4<sup>th</sup> day of September, 2024



Shuchi Agarwal  
(IN/PA-1007)

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of SS Intellectual Property Neeti Consultancy LLP  
Agents for the Applicant

To  
The Controller of Patents,  
The Patent Office,  
At Mumbai

## ABSTRACT

### TITLE OF INVENTION : EMBOLIZATION DEVICE

The present disclosure relates to an embolization device (100). In an embodiment, the embolization device (100) includes a frame (110), a bridge (115), a plurality of discs (130). The frame (110) including a first portion (111) at the proximal end (100a) and a second portion (113) at the distal end (100b). The first portion (111) and the second portion (113) include a hollow inner structure. The bridge (115) is coupled to the first portion (111) and the second portion (113). The plurality of discs (130) is seated inside the hollow inner structure of the first portion (111) and the second portion (113). Each disc (130) includes a circumferential portion (130b) coupled to the frame (110) and a sieve (130a) disposed centrally within the circumferential portion (130b).

### FIG. 1

Dated this 4<sup>th</sup> day of September, 2024



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To  
The Controller of Patents,  
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