Vesalio NeVa Mechanical Thrombectomy System Instructions for Use
enVast Coronary Thrombectomy System

Caution: This device is restricted to use by or on the order of a physician.

DEVICE DESCRIPTION

The Vesalio enVast Mechanical Thrombectomy System is temporarily inserted into the coronary vasculature under angiographic visualization to restore blood flow and remove thrombus in vessels blocked by thrombo-embolic material.

The system is available in various sizes and configurations.

The enVast Mechanical Thrombectomy System has two (2) components within the primary package, including one (1) enVast Mechanical Thrombectomy device and one (1) Introducer Sheath.

INTENDED PURPOSE

The enVast Mechanical Thrombectomy System variants are intended to restore blood flow and remove thrombus in vessels occluded by thrombo-embolic material while experiencing symptoms of thrombosis in the coronary vasculature. The Vesalio enVast Mechanical Thrombectomy System variants are positioned across the embolus or blood clot and is used to facilitate the restoration of blood flow and removal of the clot obstruction.

INDICATIONS FOR USE

The Vesalio enVast Mechanical Thrombectomy System is indicated for endovascular temporary use to restore blood flow in patients who are experiencing symptoms of thrombosis in the coronary vasculature.

INTENDED USER

Only physicians trained in endovascular cardio intervention should utilize the Vesalio enVast Coronary Thrombectomy System. As with any medical treatment, it is the responsibility of the surgeon/physician to use his or her judgment in utilizing the procedures best suited to the needs of the patient.

INTENDED PATIENT POPULATION

The intended population of patients consists of persons from that have been diagnosed with an acute ischemic stroke from a thromboembolic event and patients who are experiencing symptoms of thrombosis in the coronary vasculature.

CONTRAINDICATIONS

- Delivery of pharmacological agents not routinely used to treat thrombosis in the coronary vasculature
- Patient presents with nickel allergy
- Patients with suspected or known allergies to contrast media
- Pregnancy
- Excessive vessel tortuosity that prevents the placement of the device
- Known hemorrhagic diathesis, coagulation factor deficiency or oral anticoagulant therapy with INR>3.0
- Patient has baseline platelets <30,000
- Patient has severe sustained hypertension

WARNINGS AND PRECAUTIONS

- The Vesalio enVast Mechanical Thrombectomy System should only be used by physicians who have received appropriate training in interventional cardiology.
- Select a device size and configuration to engage the clot and to maintain sufficient vessel coverage on each side of the embolus along the parent vessel. An incorrectly sized device may result in no blood flow restoration and/or embolus migration.
- The Vesalio enVast Mechanical Thrombectomy System family of products, as noted in the Recommended Sizing Guideline Table, is designed for use in vessels ≥ 2mm and ≤ 6mm in diameter. Use of the device in vessel diameters outside the recommendation can produce excessive resistance forces on the vessel and device components. If excessive resistance is encountered during the use of the device or any of its components at any time during the procedure, discontinue use. Movement of the device against resistance may result in damage to the vessel or a device component.
- The device is provided STERILE for single use only. Reusing the device could result in compromised device performance, cross-infection and other safety related hazards.
- Store in a cool, dry place.
- Do not re-sterilize. After use, dispose in accordance with hospital, administrative and/or local government policy.
- Use the device prior to the 'Use Before' date printed on the package.
- Carefully inspect the sterile package and device prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components.
- The Vesalio enVast Mechanical Thrombectomy System has not been shown to be MRI compatible.
- The device should not be removed or repositioned without recapturing within the introducer Microcatheter unless thrombectomy is being attempted.
- Exercise caution when crossing the deployed device with adjunctive devices (e.g., micro catheter).
- Tighten the Rotating Hemostasis Valves sufficiently to create an adequate hemostasis seal without crushing the introducer microcatheter and Vesalio enVast Mechanical Thrombectomy System shaft. Inadequately tightening the Rotating Hemostasis Valves may lead to premature deployment of the device.
- After deployment, the distal tip of the device may foreshorten.
- Do not steam shape or use pre-shaped microcatheters for the Vesalio enVast Mechanical Thrombectomy System introducer microcatheter because it could damage the device.
- The Vesalio enVast Mechanical Thrombectomy System is delivered to and positioned in the occluded vasculature, unsheathed, and then retrieved in order to capture and remove clot and restore flow. Should the first attempt at flow restoration fail, the device can be recaptured into its introducer sheath, and redeployed as described earlier.. The system can be used in conjunction with any proximal flow control strategy preferred by the physician (examples: manual aspiration, pump aspiration, flow arrest with balloon guide catheter).

EXPECTED CLINICAL BENEFITS

The benefits of the Vesalio enVast Coronary Thrombectomy System include the following:

- Restoration of blood flow to previously occluded vessel segments.
- Minimizing time to recanalization.

RISKS AND UNDESIRABLE SIDE EFFECTS

Evaluate the risks associated with clot removal in the coronary vasculature (see complications below) and the possible benefits of immediate flow restoration prior to use of the Vesalio enVast Mechanical Thrombectomy System.

Possible complications of the use of the Vesalio enVast Mechanical Thrombectomy System include but are not limited to:

- Acute occlusion
- Adverse reaction to device materials
- Clot formation
- Perforation or dissection of the vessel
- Air embolism
- Arterial perforation with guidewire
- Pericardial effusion and myocardial tamponade due to vessel perforation from guidewire placement or device microcatheter placement
- Vascular spasm or vascular occlusion
- Distal embolization including to a previously uninvolved territory
- False/Pseudo aneurysm formation

Complications of routine endovascular revascularization include:

- Arterial injury (dissection, perforation) associated with arterial catheter insertion
- Myocardial ischemia
- Coagulopathy
- Death
- Embolic stroke/myocardial infarction
- Hematoma, pain, and/or infection at access site
- Pericardial hemorrhage
- Infection
- Post-procedure bleeding
- Pseudoaneurysm formation
- Renal failure
- Vessel thrombosis
- Vessel and soft tissue damage

PROCEDURE

The **Vesalio enVast Mechanical Thrombectomy System** is delivered endovascularly under fluoroscopic guidance in a manner consistent with other cardiovascular catheter-based devices.

Antiplatelet and anticoagulation regimen used for interventional cardiovascular procedures is recommended at the discretion of the treating physician.

Procedure Steps:

Angiographic Assessment of Occluded Vessel and Device Selection

1. Using standard interventional procedures, access the vessel/artery and insert a guide catheter. The guide catheter should have an inner diameter (ID) large enough to allow for contrast injection while the microcatheter is in place. This will allow for fluoroscopic road mapping during the procedure. The enVast Coronary Thrombectomy system can be used in conjunction with any proximal flow control strategy preferred by the physician (examples: manual aspiration, pump aspiration, flow arrest with balloon guide catheter if appropriate).
2. Using angiography, determine the location of the occluded vessel.
3. Select and place the appropriately sized microcatheter into the target vessel (Refer to Table 1, page 43). Position the microcatheter tip distal to thrombus (or embolus) using standard techniques. At this point, the status of the anatomy distal to the embolus can be confirmed by infusing 0.25 – 0.50 mL of contrast through the microcatheter.
4. Based upon customary clinical accepted practice for cardiovascular procedures, select a Vesalio enVast Mechanical Thrombectomy System based on the diameter and shape of the vasculature at the occlusion site, and anticipated clot length and morphology (Table 1, page 43). **No more than 4 device interventions per vessel should be attempted.**
5. Flush the Rotating Hemostasis Valve and connect to the proximal hub of the microcatheter.

Vesalio enVast Mechanical Thrombectomy System *Preparation and Procedure*

Preparation

1. Administer anti-coagulation and anti-platelet medications per standard institutional guidelines.
2. Aided by angiographic radiography, determine the location and size of the area to be revascularized.
3. Select a Vesalio enVast Mechanical Thrombectomy System per Table 1 (page 43).
4. To achieve optimal performance of the Vesalio enVast Mechanical Thrombectomy System and to reduce the risk of thromboembolic complications, maintain continuous flushing action between all access devices and the Vesalio enVast Mechanical Thrombectomy System. Check all connections to make sure that during the continuous flush that no air enters the guide catheter or the microcatheter.
5. Position a suitable guide catheter as close to thrombus site as possible employing a standard method. The guide catheter should be appropriately sized to retrieve clot in subsequent steps. Connect a RHV to the fitting of the guide catheter, and then connect a tube to the continuous flush.
6. With the aid of Table 1 (page 43), select a microcatheter suitable for advancing the Vesalio enVast Mechanical Thrombectomy System.
7. Connect a second RHV to the fitting of the microcatheter and then connect a tube to the continuous flush.
8. Set the flush rate per standard institutional guidelines.
9. With the aid of a suitable guide wire, advance the microcatheter until the end of the microcatheter is positioned sufficiently distal to the thrombus such that the usable length portion of the Vesalio enVast Mechanical Thrombectomy System will extend past the thrombus in the vessel/artery when fully deployed. Tighten the RHV around the microcatheter.

Delivering the Vesalio enVast Mechanical Thrombectomy System

10. Flushing: Insert the distal end of the introducer sheath partially into the RHV connected to the microcatheter. Tighten the RHV and verify that fluid exits the proximal end of the introducer sheath.
11. Loosen the RHV and advance the introducer sheath until it is firmly seated in the hub of the microcatheter. Tighten the RHV around the introducer sheath to prevent back flow of blood, but not so tight as to damage the Vesalio enVast Mechanical Thrombectomy System during its introduction into the microcatheter. Confirm that there are no air bubbles trapped anywhere in the system.
12. Transfer the Vesalio enVast Mechanical Thrombectomy System into the microcatheter by advancing the push wire in a smooth, continuous manner. Once the flexible portion of the push wire has entered the microcatheter shaft, loosen the RHV and remove the introducer sheath over the proximal end of the push wire. Once completed, tighten the RHV around the push wire. Leaving the introducer sheath in place will interrupt normal infusion of flushing solution and allow back flow of blood into the microcatheter.
13. Visually verify that the flushing solution is infusing normally. Once confirmed, loosen the RHV to advance the push wire.
14. A marker band is present approximately 130 cm from the distal tip of the device to guide the user as to when to start fluoroscopic monitoring. With the aid of fluoroscopic monitoring, carefully advance the Vesalio enVast Mechanical Thrombectomy System until the visible distal tip of the NeVa basket lines up with the distal marker of the microcatheter. The Vesalio enVast Mechanical Thrombectomy System should be positioned such that when the device is fully deployed, its usable (active) portion extends past the thrombus in the artery/vessel.

WARNING: IF EXCESSIVE RESISTANCE IS ENCOUNTERED DURING THE DELIVERY OF THE VESALIO ENVAST MECHANICAL THROMBECTOMY SYSTEM, DISCONTINUE THE DELIVERY AND IDENTIFY THE CAUSE OF THE RESISTANCE. ADVANCEMENT OF THE VESALIO ENVAST MECHANICAL THROMBECTOMY SYSTEM AGAINST RESISTANCE MAY RESULT IN DEVICE DAMAGE AND/OR PATIENT INJURY.

Deploying the Vesalio enVast Mechanical Thrombectomy System

15. Loosen the RHV around the microcatheter. To deploy the Vesalio enVast Mechanical Thrombectomy System, fix the pusher wire to maintain the position of the device while carefully withdrawing the microcatheter in the proximal direction.
16. Retract the microcatheter until it is just proximal to the proximal marker of the Vesalio enVast Mechanical Thrombectomy System. If a guide catheter or aspiration catheter is in place the microcatheter may be withdrawn. Tighten the RHV to prevent any movement of the pusher wire. The usable length of the deployed device should extend past the thrombus for best result.

17. Tighten the RHV around the microcatheter.

Revascularization Device Recovery

18. If using balloon guide catheter, inflate guide catheter balloon to occlude the vessel/artery as specified in Balloon Guide Catheter labeling.
19. To retrieve thrombus, **slowly** withdraw the microcatheter and Vesalio enVast Mechanical Thrombectomy System as a unit towards the guide catheter tip while applying aspiration to the guide catheter with a 60cc syringe. Never advance the deployed Vesalio enVast Mechanical Thrombectomy System distally. Note: Ensure microcatheter covers the enVast proximal marker.
20. Apply vigorous aspiration to the guide catheter using syringe and recover Vesalio enVast Mechanical Thrombectomy System and microcatheter inside guide catheter. Continue aspirating guide catheter until Vesalio enVast Mechanical Thrombectomy System and microcatheter are nearly withdrawn from the guide catheter. NOTE: If withdrawal into the guide catheter is difficult, deflate balloon (if using balloon guide catheter) and then simultaneously withdraw guide catheter, microcatheter and Vesalio enVast Mechanical Thrombectomy System as a unit through the sheath while maintaining aspiration. Remove sheath if necessary.

WARNING: IF EXCESSIVE RESISTANCE IS ENCOUNTERED DURING RECOVERY OF THE VESALIO ENVAST MECHANICAL THROMBECTOMY SYSTEM, DISCONTINUE THE RECOVERY AND IDENTIFY THE CAUSE OF THE RESISTANCE. DO NOT PERFORM MORE THAN THREE RECOVERY ATTEMPTS IN THE SAME VESSEL USING A VESALIO ENVAST MECHANICAL THROMBECTOMY SYSTEM.

21. Open the guide catheter RHV to allow the microcatheter and the Vesalio enVast System to exit without resistance. Use care to avoid interaction with the site of the intervention and to prevent air from entering the system.
22. Aspirate the guide catheter to ensure the guide catheter is clear of any thrombus material.
23. Deflate guide catheter balloon if using balloon guide catheter.
24. Angiographically assess the revascularization status of the treated vessel.
25. If additional flow restoration attempts are desired with:
    a new Vesalio enVast Mechanical Thrombectomy System, then repeat the steps described above starting with the "Preparation" section.
    the same Vesalio enVast Mechanical Thrombectomy System, then:
    a. Clean the device with saline solution. **Do not use solvents or autoclave.**
    b. Carefully inspect the device for damage. If there is any damage, do not use the device and use a new Vesalio enVast Mechanical Thrombectomy System for subsequent flow restoration attempts following the steps described above starting with the "Preparation" section. Use of a damaged device could result in additional device damage or patient injury.

WARNING: DO NOT USE EACH VESALIO ENVAST MECHANICAL THROMBECTOMY SYSTEM FOR MORE THAN THREE FLOW RESTORATION RECOVERIES.

Vesalio enVast Mechanical Thrombectomy System Re-Sheathing

If resheathing of the Vesalio enVast Mechanical Thrombectomy System is necessary (e.g. for repositioning), follow these steps:

WARNING: ADVANCING THE MICROCATHETER WHILE THE DEVICE IS ENGAGED IN CLOT MAY LEAD TO EMBOLIZATION OF DEBRIS. DO NOT ADVANCE THE MICROCATHETER AGAINST ANY RESISTANCE. DO NOT REPOSITION MORE THAN THREE TIMES.

1. Loosen the RHV around the microcatheter and around the push wire. With the aid of fluoroscopic monitoring, hold the pusher wire firmly in its position to prevent the Vesalio enVast Mechanical Thrombectomy System from moving.
2. Carefully re-sheath the Vesalio enVast Mechanical Thrombectomy System by advancing the microcatheter over the Vesalio enVast Mechanical Thrombectomy System until the distal markers of the Vesalio enVast Mechanical Thrombectomy System line up at the end of the microcatheter. **If significant resistance is encountered during the re-sheathing process**, **stop immediately** and proceed to the section above entitled "Revascularization Device Recovery".

HOW SUPPLIED

Each **Vesalio enVast Mechanical Thrombectomy System** contains one device positioned in an introducer sheath. All are supplied STERILE (Ethylene Oxide) and **FOR SINGLE USE ONLY**. All components should be handled carefully to avoid damaging the device.

The Vesalio enVast Mechanical Thrombectomy System contains no latex or natural rubber materials.

STORAGE AND HANDLING

Handle with care. Packages should be stored in a manner that protects the integrity of the package; packages should be stored at a controlled room temperature in a dry place.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The summary of safety and clinical performance (SSCP) is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of the Vesalio enVast Mechanical Thrombectomy System. The SSCP is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI.

Eudamed Website Link	Basic UDI-DI for Vesalio enVast Mechanical Thrombectomy System
https://ec.europa.eu/tools/eudamed	0851279008NEVA2J

SERIOUS INCIDENT REPORTING

In the event of patient/user facing a serious incident involving the Vesalio enVast Mechanical Thrombectomy System, report the incident to Vesalio at info@vesalio.com, and the Competent Authority of the country where the user/patient resides.

WARRANTY AND LIMITATION OF WARRANTY

Vesalio LLC warrants that reasonable care was used in the design and manufacture of this product. Because **Vesalio LLC** has no control over the conditions of use, patient selection or handling of the device after it leaves its possession, **Vesalio LLC** does not warrant either a good effect or against an ill effect following its use. **Vesalio LLC.** shall not be directly or indirectly responsible for any incidental or consequential loss, damage or expenses directly or indirectly arising from the use of this product. **Vesalio LLC** sole responsibility in the event **Vesalio LLC** determines the product was defective when shipped by **Vesalio LLC,** shall be the replacement of the product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including but not limited to any implied warranties of merchantability or fitness for use.

Table 1: Vesalio enVast Mechanical Thrombectomy System – Basic UDI-DI: 0851279008NEVA2J

Product Name Numbers and Recommend Sizing Guidelines for enVAST Mechanical Thrombectomy System variants

Product Number	Product Name	Labeled Device Diameter (mm)	Labeled Device Length (mm)	Self Expanded Device Diameter (mm)	Recommended Vessel Diameter (mm)	Pusher Length	Introducer Microcatheter Minimum Inner Diameter	UDI-DI
EV-4030-F2RR	enVast 4.0 x 30 mm	4.0	30	4.0	≥ 2.0 - ≤ 3.5	200 cm	.021"	00851279008699
EV-4038-F3RR	enVast 4.0 x 38 mm	4.0	38	4.0	≥ 2.0 - ≤ 3.5	200 cm	.021"	00851279008705
EV-4537-F2RR	enVast 4.5 x 37 mm	4.5	37	4.5	≥ 2.0 - ≤ 4.5	200 cm	.021"	00851279008712
EV-4546-F3RR	enVast 4.5 x 46 mm	4.5	46	4.5	≥ 2.0 - ≤ 4.5	200 cm	.021"	00851279008729
EV-6035-F2RR	enVast 6.0 x 35 mm	6.0	35	6.0	≥ 3.5 - ≤ 6.0	200 cm	.027"	00851279008736
EV-6044-F3RR	enVast 6.0 x 44 mm	6.0	44	6.0	≥ 3.5 - ≤ 6.0	200 cm	.027"	00851279008743

Symbol Glossary			
	Use-by date		Keep Away from Sunlight
	Manufacturer		Keep Dry
	Date of Manufacture		Do not use if package is damaged
STERILE EO	Sterilized using ethylene oxide		Caution
	Non-pyrogenic		Do not resterilize
	Do not re-use	EC REP	Authorized representative in the European Community
REF	Catalogue number	MD	Medical Device
LOT	Batch code		Single sterile barrier system with protective packaging inside
	Consult Instructions for Use		Translation
Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	CE 0297	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union Acts
Medtronic Global BV	Importer		

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