Roles	Name	Designation	Signature	Date
Author	Jeff Tee	QA/RA Senior Specialist		03/07/2025
Reviewer/Approver	Lawrence Kong	R&D Director		03/07/2025
Reviewer/Approver	John Wong	Management Representative		03/03/2025

Revision	DCO no.	Change Description	Author	Effective Date
01	DCO23066	Initial release	Nicholas Yeo	27-Jun-2023
02	DCO24057	Adding Contraindications - Pregnant women and children (Not clinically evaluated)	Jeff Tee	10-Dec-2024
03	DCO25003	Add CE mark	Jeff Tee	10-Mar-2025

CerebrAX™

Stent Retriever

Intracranial Thrombectomy Device

INSTRUCTIONS FOR USE

Hemo Bioengineering Pte Ltd

1. DEVICE DESCRIPTION

CerebrAX™ Stent Retriever Intracranial Thrombectomy Device (hereinafter referred to as CerebrAX) is used for patients with acute ischemic stroke due to intracranial large vessel occlusion. CerebrAX is used in a minimally invasive interventional procedure where under fluoroscopy, the self-expanding stent is delivered to target lesion site along a microcatheter. At the site, the crossings of the stent's struts are embedded within the thrombus. The thrombus is removed from the body by withdrawing CerebrAX. This procedure recanalizes the blood vessel, allowing for reperfusion of ischemic sites.

CerebrAX is designed for use in the neurovascular system, such as the internal carotid artery, M1 and M2 segments of the middle cerebral artery.

Models and specifications are detailed in Table 1.

Figure 1: CerebrAX Sheathed

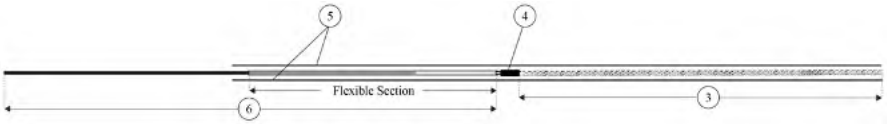
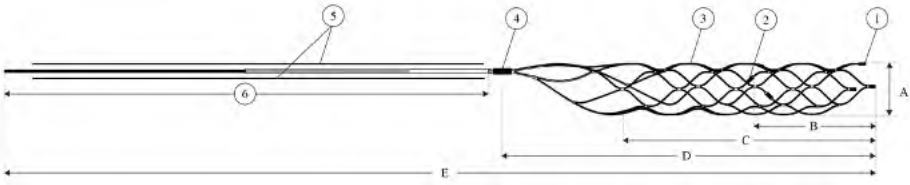


Figure 2: CerebrAX Unsheathed



①	Distal marker	**A**:	Stent diameter
②	Body marker	**B**:	Length from the body marker to the distal marker
③	Self-expanding stent	**C**:	Effective length of the self-expanding stent
④	Proximal marker	**D**:	Length from the proximal marker to the distal marker
⑤	Introducer sheath	**E**:	Total length of the device

⑥ Push wire

Table 1 – Product Model and Respective Specifications

Model and specification	Stent diameter, A (mm)	Recommended vessel diameter (mm)	Recommended minimum microcatheter inner diameter (mm/inch)
SARD-3-10	3	2.0-3.0	0.53/0.021
SARD-3-20	3	2.0-3.0	0.53/0.021
SARD-4-20	4	2.5-4.0	0.53/0.021
SARD-4-40	4	2.5-4.0	0.53/0.021
SARD-5-20	5	3.5-4.5	0.69/0.027
SARD-5-30	5	3.5-4.5	0.69/0.027
SARD-6-20	6	4.0-5.5	0.69/0.027
SARD-6-30	6	4.0-5.5	0.69/0.027

Model and specification	Effective length of the stent, C (mm)	B (mm)	D (mm)	E (mm)	Number of markers		
					Proximal	Body	Distal
SARD-3-10	10	8	20	1850	1	2	2
SARD-3-20	20	10	30	1850	1	2	2
SARD-4-20	20	10	33	1850	1	3	3
SARD-4-40	40	19	53	1850	1	3	3
SARD-5-20	20	11	36	1850	1	3	4
SARD-5-30	30	16	46	1850	1	3	4
SARD-6-20	20	13	36	1850	1	3	4
SARD-6-30	30	18	46	1850	1	3	4

2. HOW SUPPLIED

CerebrAX is provided sterile for single use only.
Sterile Sterilized using Ethylene Oxide. Non-pyrogenic.
Contents One (1) CerebrAX

3. INDICATIONS FOR USE

CerebrAX is intended for use within 8 hours after symptoms onset for revascularisation in patients with acute ischemic stroke due to intracranial large vessel occlusion (internal carotid artery, M1 and M2 segments of the middle cerebral artery).

CerebrAX is also intended for use in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA therapy.

4. CLINICAL BENEFIT

CerebrAX may provide the following benefit during intervention in patients with acute ischemic stroke due to intracranial large vessel occlusion:

- Revascularisation in target vessel (mTICI 2b-3)

5. CONTRAINDICATIONS

The use of CerebrAX is contraindicated in patients with these circumstances:

- Known to be allergic to nickel-titanium alloys
- Stenosis proximal to the thrombus site
- Carotid dissection confirmed by angiography
- Pregnant women and children (Not clinically evaluated)

6. WARNINGS

- Do not torque CerebrAX.
- For vascular safety, do not use CerebrAX for more than three revascularisation attempts in the same target blood vessel.
- For device safety, do not use the same CerebrAX for more than three revascularisation attempts.
- Inspect CerebrAX before each revascularisation attempt.
- For each new CerebrAX, a new microcatheter should be used in conjunction with it.
- To prevent device separation,
  - Do not use an overly large device.
  - Do not retract (i.e. pull back) the device when excessive resistance is encountered. Resheath the device with a microcatheter and remove the entire system under aspiration. If resistance is encountered during resheathing, stop the operation and remove the entire system under aspiration.
- Do not advance or retract CerebrAX or any accessories by force against resistance until the cause of the resistance is determined by fluoroscopy. If the cause cannot be determined, CerebrAX and its accessories can be withdrawn as a whole. Operating or torquing the device against resistance may cause

damage to the vascular system or the device.

7. PRECAUTIONS

Precautions Before Use

- CerebrAX should only be used by physicians who have been trained in neurointerventional radiology, ischemic stroke treatment and CerebrAX.
- Do not use CerebrAX after the 'use-by' date printed on the product label under any circumstances.
- CerebrAX and its sterile package should be carefully inspected before use.
  - Do not use the device if its label is incomplete or illegible.
  - Do not use the device if its package has been opened or damaged.
  - Do not use device that is kinked or damaged.
- CerebrAX is intended for single use only. Do not re-sterilize or reuse. Reprocessing and re-sterilization may increase the risk for infection in patients and may compromise device performance.
- Verify that CerebrAX is compatible with any devices previously implanted in the patient.
- Select an appropriate CerebrAX according to the diameter of the target vessel and full length of the thrombus.
- Verify that the maximum outer diameter of CerebrAX is compatible with the minimum inner diameter of any auxiliary catheter or accessory that CerebrAX is intended to be inserted into.

Precaution During Use

- The introducer sheath helps to prevent CerebrAX from expanding until it is ready for transfer into the microcatheter. It is not meant to enter the body, and it will be removed once a sufficient length of CerebrAX is inserted into the microcatheter. The introducer sheath must be used to transfer CerebrAX into microcatheter lumen. Attempting to transfer CerebrAX into the microcatheter without using the introducer sheath may damage the device. Refer to steps in "**Transferring CerebrAX into microcatheter**".
- Use CerebrAX with fluoroscopy for visualization.
- Carefully navigate CerebrAX through tortuous anatomy.
- Continually infuse an appropriate flush solution. If heparinized flush solution is used, care should be taken to account for the additional heparin given through the flush solution, so as to prevent clotting disorders and excessive

bleeding at the access site.

- Rotating Hemostasis Valves (RHV) should be used appropriately throughout surgery to minimize blood loss. Intraoperative blood loss should also be monitored throughout surgery to ensure that appropriate intervention can be performed when necessary.
- If CerebrAX needs to be repositioned during surgery, standard microcatheters and guidewires techniques should be applied.
- Do not use an automated high-pressure contrast injection device with CerebrAX as this may result in device damage.

Precaution After Use

- Dispose CerebrAX in accordance with institutional procedure.
- Medical management and post-acute stroke care should be carried out in accordance with institutional guidelines. Appropriate antiplatelet and anticoagulant therapy should be implemented in accordance with standard medical practice. According to the best practices for hospitals, any neurological deterioration should be evaluated through emergency CT scans and other evaluation methods.

8. POTENTIAL COMPLICATIONS

Potential complications include but are not limited to:

- Adverse reaction to antiplatelet/ anticoagulation agents or contrast media
- Air embolism
- Allergic reaction
- Arteriovenous fistula
- Artery dissection
- Brain herniation
- Cerebral edema
- Distal embolization including to a previously uninvolved territory
- Infection
- Intracranial hemorrhage
- Ischemia
- Postoperative hemorrhage
- Pseudoaneurysm formation
- Puncture site hematoma and hemorrhage
- Sepsis
- Target vessel reocclusion
- Thrombosis (acute and subacute)
- Vasospasm
- Vessel perforation

Adverse Event/Incident Reporting

In the EU, any serious adverse event/incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable member state.

For all other countries, any serious adverse event/incident that has occurred in relation to the device should be reported to the manufacturer.

9. CLINICIAN USE INFORMATION

Refer to IFU supplied with all accessories to be used in conjunction with CerebrAX for their intended uses, contraindications and potential complications.

Other accessories for performing a procedure and NOT supplied; to be selected based on the physician's experience and preferences:

- Guiding/intermediate catheter
- Balloon guide catheter
- Microcatheter
- Guidewire
- Aspiration device (50 ml syringe)
- Continuous flush
- RHV
- Femoral arterial sheath

10. CLINICAL OPERATION PROCESS

Formal training in the use of stent retrievers is necessary. The following instructions are not intended as substitute for the physician's experience and judgment during treatment.

Device Preparation

10.1. According to the diameter of the blood vessel and the approximate length of the thrombus, select an appropriately sized CerebrAX (see Table 1).

10.2. Open the packaging box. Using aseptic technique, open the primary packaging pouch and carefully transfer the content onto a sterile field.

10.3. Gently remove CerebrAX from the protective tube.

10.4. Inspect CerebrAX for kinks or other damage. If any damage is found, do not use this device. Replace it with a new device.

Deployment Procedure

10.5. After angiography is completed, use a 0.035" guidewire to advance a 6-8F intermediate catheter as much as possible into the target blood vessel to enhance support. If the path is poor, consider adding another intermediate catheter.

Note: A proximal balloon guiding catheter, or a large-diameter distal access catheter can also be used instead of a conventional guiding catheter to deliver CerebrAX during thrombectomy.

10.6. After the catheter is in place, withdraw the guidewire. Under fluoroscopy, use a 0.014" micro guidewire and an appropriately sized microcatheter to pass through the thrombus. Withdraw micro guidewire.

Transferring CerebrAX into microcatheter

10.7. Align the distal end of introducer sheath to the distal end of CerebrAX.

10.8. Loosen the RHV attached to the microcatheter and partially insert the introducer sheath into the RHV. Advance the introducer sheath into the microcatheter's hub until resistance is felt against the proximal end of the microcatheter.

10.9. Tighten the RHV around the introducer sheath to prevent back flow of blood. Ensure that the introducer sheath remains flushed against the proximal end of the microcatheter and securely in place. Do not over-tighten RHV such that CerebrAX is damaged. Ensure that there are no trapped air bubbles in the system.

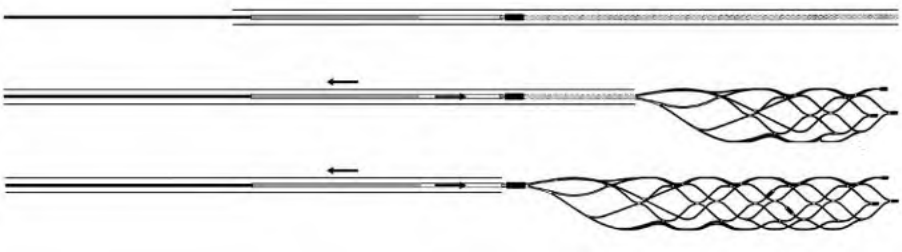
10.10. Under fluoroscopy, smoothly advance CerebrAX. Loosen the microcatheter RHV and remove the introducer sheath over the proximal end of the push wire once the flexible section of the push wire (refer to Figure 1) has entered the microcatheter.

10.11. After removing the introducer sheath, continue advancing CerebrAX until the distal marker of the stent is aligned with the distal end of the microcatheter. CerebrAX should be positioned such that the stent's effective length will cover the total length of the thrombus when the stent is fully expanded.

Thrombectomy using CerebrAX

10.12. Loosen the microcatheter RHV. Slowly withdraw the microcatheter until it reaches the proximal marker of the stent so that the stent can fully expand. Withdraw the microcatheter while exerting a pushing or resistance force on the push wire to ensure the position of the stent remains unchanged.

Figure 3: CerebrAX Deployment



10.13. Perform angiography to observe and evaluate recanalization of the target vessel and distal reperfusion through the occlusion site. Regardless of whether reperfusion reaches mTICI grade 2b or above, the stent should be retained in the target blood vessel for **at least 5 minutes** so that the crossings of the stent's struts can be fully embedded within the thrombus.

10.14. Ensure that CerebrAX and the microcatheter are secured together before withdrawing them as a unit. Loosen the RHV of the guiding catheter to withdraw CerebrAX together with the microcatheter from the body. During the withdrawal, use a 50 ml syringe to draw about 20 ml of blood from the guiding catheter RHV. NOTE: Under some circumstances, a single revascularisation attempt using stent retriever may not completely remove the occlusion. Most patient may have residual thrombus in-situ or reocclusion.

WARNING
For vascular safety, do not use CerebrAX for more than three revascularisation attempts in the same target blood vessel.
For device safety, do not use the same CerebrAX for more than three revascularisation attempts.
Inspect CerebrAX carefully before each revascularisation attempt.

10.15. After recanalization is completed, refrain from removing guiding catheter and auxiliary accessories immediately. Make an angiographic observation through the guiding catheter for 10-15 minutes to re-evaluate the mTICI score. If the outcome is satisfactory, withdraw the guiding catheter and auxiliary accessories.

10.16. After the surgery is completed, dispose CerebrAX appropriately in accordance with institutional procedure.

For a copy of this device's current European summary of safety and clinical performance (SSCP) please go to the European database on medical devices (Eudamed), where it is linked to the basic UDI-DI.
https://ec.europa.eu/tools/eudamed.

Basic UDI-DI: 888501905002KL

11. STORAGE

Store the product at room temperature. Keep dry and away from sunlight.

12. SYMBOL GLOSSARY

Symbol	Definition
	Manufacturer
	CE mark
	Authorized Representative in the European Community
	Date of Manufacture
	Use-by Date
	Lot Number
	Catalogue Number
	Sterilized using Ethylene Oxide
	Do not resterilize
	Do not use if package is damaged (or opened) and consult Instruction For Use
	Keep away from sunlight
	Keep dry
	Do not re-use
	Consult instructions for use
	Caution
	Non-pyrogenic
	Medical Device
	Single sterile barrier system with protective packaging inside

Symbol	Definition
	Single sterile barrier system with protective packaging outside

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EC REP

MedNet EC-REP III GmbH
Borkstrasse 10
48163 Münster
Germany

Hemo Bioengineering Pte Ltd
8 Kaki Bukit Avenue 1
#03-08
Singapore 417941

CE 2797