



TD-006

AsprAX IFU

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Roles	Name	Designation	Signature	Date
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02	DCO23115	Update to align manufacturer's name	Thng Kun Hong	18-Oct-2023
03	DCO23127	Removed basilar and vertebral arteries from intended use	Thng Kun Hong	02-Nov-2023
04	DCO24002	Added warning for tip shaping	Chen Yuning	17-Jan-2024
05	DCO25006	Add CE mark	Jeff Tee	27-May-2025

AsprAX™

Aspiration Catheter

Intracranial Thrombectomy Device

INSTRUCTIONS FOR USE

Hemo Bioengineering Pte. Ltd.

1. DEVICE DESCRIPTION

AsprAX™ Aspiration Catheter Intracranial Thrombectomy Device (hereinafter referred to as AsprAX) is a single lumen, braid and coil reinforced, variable stiffness catheter, of which the distal end bears a radiopaque mark to track the position of the catheter, and the proximal end bears a catheter hub to facilitate connection with other devices. AsprAX dimensions can be found on the label of each device. AsprAX is compatible with 0.014" - 0.035" guidewires and other interventional devices. Additional support catheters can also be used to assist access to the target vascular system. AsprAX will be used in conjunction with an aspiration pump/syringe to aspirate thrombi.

Models and specifications are detailed in Table 1.

Table 1 – Product model and respective specifications

Model and specification	Proximal diameter in mm (F)		Distal diameter in mm (F)		Catheter length (cm)	Recommended diameter of target vessel (mm)
	Inner diameter	Outer diameter	Inner diameter	Outer diameter		
088-100	2.24 (6.7)	2.74 (8.2)	2.24 (6.7)	2.67 (8.0)	100	> 4.0
088-110	2.24 (6.7)	2.74 (8.2)	2.24 (6.7)	2.67 (8.0)	110	
071-117	1.80 (5.4)	2.11 (6.3)	1.80 (5.4)	2.11 (6.3)	117	
071-127	1.80 (5.4)	2.11 (6.3)	1.80 (5.4)	2.11 (6.3)	127	
071-137	1.80 (5.4)	2.11 (6.3)	1.80 (5.4)	2.11 (6.3)	137	
065-127	1.65 (5.0)	1.98 (5.9)	1.65 (5.0)	1.98 (5.9)	127	
065-137	1.65 (5.0)	1.98 (5.9)	1.65 (5.0)	1.98 (5.9)	137	3.0-4.0
055-127	1.70 (5.1)	2.03 (6.1)	1.40 (4.2)	1.75 (5.3)	127	
055-137	1.70 (5.1)	2.03 (6.1)	1.40 (4.2)	1.75 (5.3)	137	2.0-3.0
045-134	1.63 (4.9)	2.03 (6.1)	1.14 (3.4)	1.52 (4.6)	134	
045-144	1.63 (4.9)	2.03 (6.1)	1.14 (3.4)	1.52 (4.6)	144	
035-143	1.19 (3.6)	1.52 (4.6)	0.89 (2.7)	1.30 (3.9)	143	
035-158	1.19 (3.6)	1.52 (4.6)	0.89 (2.7)	1.30 (3.9)	158	

AsprAX is supplied with a Rotating Hemostasis Valve (RHV) as an accessory. RHV is used to connect to the luer connector of the catheter hub at the proximal end of AsprAX, so as to sustain hemostasis during use with other devices.

Additionally, SRRC-088 AsprAX includes a catheter introducer as an accessory, to facilitate the insertion of SRRC-088 AsprAX into an 8F introducer sheath.

2. HOW SUPPLIED

AsprAX is provided sterile for single use only.

Sterile Sterilised using Ethylene Oxide. Non-pyrogenic.

Contents One (1) AsprAX
One (1) Rotating Hemostasis Valve (RHV)
One (1) Catheter Introducer (For SRRC-088 models only)

3. INDICATIONS FOR USE

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

4. CLINICAL BENEFIT

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

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

5. CONTRAINDICATIONS

There are no known contraindications.

6. WARNINGS

- AsprAX is intended for single use only. Do not re-sterilise or reuse. Reprocessing and re-sterilization may increase the risk for infection in patients and may compromise device performance.
- Exercise extreme caution when advancing AsprAX near or through any aneurysm or other vascular malformations.
- AsprAX is not intended for tip shaping. Do not attempt to shape the distal tip, which may result in damage to the device.
- Do not advance or withdraw any accessories through AsprAX against resistance until the cause of the resistance is determined by fluoroscopy. If the cause cannot be determined, withdraw AsprAX and its accessories as a whole. Operating or torquing the device against resistance may cause damage to the vascular system or the device.
- Do not use an automated high-pressure contrast injection device with AsprAX as this may result in device damage. When a contrast medium is injected, the injection pressure should not exceed 5 atm.

7. PRECAUTIONS

Precautions before Use

- AsprAX should only be used by physicians who have been trained in neurointerventional techniques and AsprAX.
- Verify that AsprAX is compatible with any devices previously implanted in the patient.
- Do not use AsprAX after the 'use-by' date printed on the product label under any circumstances.
- AsprAX 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.

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- Do not use device that is kinked or damaged.
- Verify that the maximum outer diameter of AsprAX is compatible with the minimum inner diameter of any auxiliary catheter or accessories when AsprAX is intended to be introduced through.
- Verify that the maximum outer diameter of any auxiliary catheter or device intended to be inserted into AsprAX is compatible with the minimum inner diameter of AsprAX.
- It is essential to use a catheter introducer while advancing SRRC-088 AsprAX through the introducer sheath into patient, to avoid kinking and other damage to the device.

Precautions during Use

- Use AsprAX with fluoroscopy for visualization.
- Carefully navigate AsprAX through tortuous anatomy.
- Continually infuse an appropriate flush solution. Otherwise, flush AsprAX regularly with an appropriate flush solution to minimise thrombosis.
- If heparinised 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.
- If flow through AsprAX becomes restricted, do not attempt to clear its lumen by infusion. Remove and replace the device.
- RHV should be used appropriately throughout surgery to minimise blood loss. Intraoperative blood loss should also be monitored throughout surgery to ensure that appropriate intervention can be performed when necessary.
- When AsprAX is used, the standard techniques for guiding catheters, microcatheters and guidewires should be applied.
- If AsprAX needs to be repositioned during surgery, standard microcatheters and guidewires techniques should be applied.
- AsprAX has been verified compatible with aspiration pump and aspiration tubing or syringe. During use, the minimum lumen diameter of aspiration tubing is 0.110". Different aspiration pumps that cannot provide the same vacuum pressure or different aspiration tubing with smaller diameters should be used with caution.
- It is recommended to use a surgical aspiration pump that can reach a vacuum pressure of -635 mmHg (-85 kPa) and a pumping rate not less than 25 L/min. The maximum pressure recommended for aspiration with the aspiration pump is -508 mmHg (-68 kPa).
- If using an aspiration pump, refer to the manufacturer's IFU for installation and usage.
- During aspiration, ensure that the valve of the aspiration tubing is opened for the minimum time required to remove thrombus. Excessive aspiration or failure to close the valve of the aspiration tubing may cause serious injury to the patient.

Precautions after Use

- Dispose AsprAX in accordance with institutional procedure.
- The administration of anticoagulants and antiplatelet drugs should be suspended until 24 hours after treatment. Medical management and post-acute stroke care should be carried out in accordance with the institutional guidelines for the endovascular treatment of acute ischemic stroke. 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:

- Acute myocardial infarction
- Acute occlusion
- Air embolism
- Arrhythmia (including ventricular fibrillation)
- Arteriovenous fistula
- Cerebral edema
- Cerebral infarction/necrosis
- Clotting disorder
- Death
- Device failure
- Distal embolism
- Embolus
- Failure to completely remove thrombus
- Fever
- Hypotension
- Infection, sepsis
- Hypertension
- Intracranial haemorrhage
- Local ischemia
- Neurological defects (including stroke)
- Pseudoaneurysm formation
- Puncture site hematoma or haemorrhage
- Reaction/allergic reaction to a contrast medium
- Renal insufficiency/kidney failure caused by contrast medium
- Thrombosis
- Unstable angina
- Vascular injury (i.e., dissection, perforation, rupture)
- Vasospasm

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 with AsprAX 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:

- Introducer sheath
- Guiding catheter
- Guidewire
- Microcatheter
- Micro-guidewire
- Aspiration pump and aspiration tubing
- Syringe
- Continuous flush

10. CLINICAL OPERATION PROCESS

Formal training in the use of aspiration catheters 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 length of the intervention path to the target lesion, select an appropriately sized AsprAX (see Table 1).
Note: The triaxial use of a compatible inner microcatheter can facilitate access to the occlusion site.
- 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 AsprAX from the protective tube and RHV from the holder.
- 10.4. Inspect AsprAX and its accessories for kinks or other damage. If any damage is found, do not use this device. Replace it with a new device.
- 10.5. Connect RHV to the proximal luer connector of the catheter hub.
- 10.6. Hydrate the outer surface of AsprAX and flush the lumen of the catheter and RHV with heparinised saline.

Preparation of AsprAX Assembly

Using guidewire (Steps 10.7 and 10.8)

- 10.7. Depending on the size of AsprAX, a 0.014"-0.035" guidewire can be used.
- 10.8. Open RHV and advance the guidewire into AsprAX until the distal tip of the guidewire slightly protrudes through the distal tip of AsprAX. Tighten the RHV to fix the guidewire in place (hereinafter referred to as AsprAX assembly).

Using support catheter and guidewire (Steps 10.9 and 10.10)

- 10.9. Depending on the size of the support catheter, a 0.014"-0.035" guidewire can be inserted into the support catheter and advanced until its distal tip is aligned with the distal tip of the support catheter.
- 10.10. Open RHV and advance the support catheter and guidewire into AsprAX until the distal tip of the support catheter slightly protrudes through the distal tip of AsprAX. Tighten the RHV to fix the support catheter in place (hereinafter referred to as AsprAX assembly). Do not over-tighten RHV, otherwise it may deform the lumen of the support catheter and prevent the passage of guidewire.

Deployment Procedure

For SRRC-088 AsprAX (Steps 10.11 to 10.14)

- 10.11. Carefully slide the catheter introducer down AsprAX from its initial position (seated over the strain relief) until the tip slightly protrudes beyond the distal tip of AsprAX.
- 10.12. Gently insert the catheter introducer into an introducer sheath.
- 10.13. Under fluoroscopy, advance AsprAX assembly through the catheter introducer into the introducer sheath and into the patient's vascular system.
- 10.14. Once the distal tip of AsprAX has been advanced past the distal tip of the introducer sheath, slide the catheter introducer back to its initial position. Continue to Step 10.17.

For all other AsprAX models (Steps 10.15 and 10.16)

- 10.15. Insert a guiding/intermediate catheter (that is compatible with the outer diameter of AsprAX) into the access site through the introducer sheath. Under fluoroscopy, advance the guiding/intermediate catheter as close to the embolism site as possible while ensuring safety.
Note: Refer to the manufacturer's Instructions for Use for the guiding catheter/ intermediate catheter.
- 10.16. Gently advance the AsprAX assembly into the guiding/intermediate catheter until the distal tip of AsprAX slightly protrudes through the distal tip of the guiding/intermediate catheter. Continue to Step 10.17.
- 10.17. Using conventional catheterization techniques under fluoroscopy, advance the support catheter and/or guidewire into the target vessel.
Note: If contrast medium is injected through the support catheter, withdraw the guidewire, and aspirate the support catheter's lumen before injection. If contrast medium is injected through AsprAX, withdraw the support catheter and/or guidewire and aspirate AsprAX's lumen before injection.
- 10.18. After gaining access with the support catheter and/or guidewire, advance AsprAX to the target vessel over the support catheter or guidewire.

Thrombectomy using AsprAX

- 10.19. Position AsprAX to the proximal end of thrombus. Remove the support catheter and/or guidewire. Tighten the RHV on AsprAX.

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Using an aspiration pump for aspiration (Steps 10.20-10.23)

- 10.20. Ensure that the valve on the aspiration tubing is closed, connect the aspiration tubing to the aspiration pump, and turn on the aspiration pump. Stabilise the aspiration pump for at least 1 minute at a pressure value not exceeding -508 mmHg (-68 kPa) before use.
- 10.21. Connect aspiration tubing to the side port of RHV.
- 10.22. To begin aspiration, open the valve on the aspiration tubing. To stop aspiration, close the valve on the aspiration tubing and switch off the aspiration pump.
- 10.23. Disconnect the aspiration tubing before using a 5cc or 10cc syringe to draw about 5cc of blood from AsprAX, to remove any residual thrombus in AsprAX. Continue to Step 10.26.

Using a syringe for aspiration (Steps 10.24 – 10.25)

- 10.24. Connect a 50cc or larger syringe to the side port of RHV.
- 10.25. Carry out negative pressure aspiration. Continue to Step 10.26.
- 10.26. Inject contrast medium through AsprAX to obtain an angiogram after thrombectomy to verify that thrombus has been completely removed.

WARNING

Ensure that the pressure of any liquid injected through AsprAX does not exceed 5atm. Exceeding this value may cause serious vascular injury.

- 10.27. If further distal access is required, AsprAX can be used as a support catheter for other interventional and diagnostic devices.
- 10.28. After surgery is completed, withdraw AsprAX through the introducer sheath according to the standard operation procedure.
Important: While removing AsprAX, perform aspiration through its lumen to collect any fibrin that may be deposited in or at the tip of the catheter.
- 10.29. Dispose AsprAX appropriately in accordance with institutional procedure.

This device's European Summary of Safety and Clinical Performance (SSCP) is available in European database on medical devices (EUDAMED), searchable via device based on the basic UDI-DI.

EUDAMED: <https://ec.europa.eu/tools/eudamed>,

Basic UDI-DI: 888501905001KJ

11. STORAGE

Store the product at room temperature.

Keep dry and away from sunlight.

12. Symbol Glossary

Symbol	Definition
	Catalogue number
	Authorised Representative in the European Community
	Manufacturer
	Date of manufacture
	Use-by date
	Lot number
	Medical device
	Consult instructions for use
	Sterilised using ethylene oxide
	Non-pyrogenic
	Do not resterilise
	Do not re-use
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system with protective packaging inside
	Do not use if package is damaged (or opened) and consult instructions for use

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Symbol	Definition
	Keep dry
	Keep away from sunlight
	CE Mark
	Caution

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