EmerAX™

Intermediate Catheter

INSTRUCTIONS FOR USE

Hemo Bioengineering Pte Ltd

1. DEVICE DESCRIPTION

EmerAX Intermediate Catheter (hereinafter referred to as EmerAX) is a single lumen, braid and coil reinforced catheter with variable stiffness, 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. EmerAX dimensions can be found on the label of each device. Additional support catheters can also be used to assist access to the target vascular system.

Model specifications are shown in **Table 1**.

Table 1 – Product model and respective specifications

Model and specification	**Proximal diameter in mm**		**Distal diameter in mm**		**Catheter length (cm)**
SRAC-	**Inner diameter**	**Outer diameter**	**Inner diameter**	**Outer diameter**	
088-80	⩾2.16	2.75	⩾2.16	2.70	80
088-90	⩾2.16	2.75	⩾2.16	2.70	90
088-100	⩾2.16	2.75	⩾2.16	2.70	100
071-95	⩾1.70	2.10	⩾1.70	2.10	95
071-105	⩾1.70	2.10	⩾1.70	2.10	105
071-115	⩾1.70	2.10	⩾1.70	2.10	115
071-125	⩾1.70	2.10	⩾1.70	2.10	125
071-130	⩾1.70	2.10	⩾1.70	2.10	130
065-117	⩾1.55	1.98	⩾1.55	1.98	117
065-127	⩾1.55	1.98	⩾1.55	1.98	127
065-132	⩾1.55	1.98	⩾1.55	1.98	132
060-117	⩾1.45	1.90	⩾1.45	1.90	117
060-127	⩾1.45	1.90	⩾1.45	1.90	127
060-132	⩾1.45	1.90	⩾1.45	1.90	132
055-117	⩾1.30	1.75	⩾1.30	1.75	117
055-127	⩾1.30	1.75	⩾1.30	1.75	125
055-132	⩾1.30	1.75	⩾1.30	1.75	132
045-144	⩾1.10	1.52	⩾1.10	1.52	144
035-143	⩾0.80	1.30	⩾0.80	1.30	143
035-158	⩾0.80	1.30	⩾0.80	1.30	158

SRAC-088 and SRAC-071 EmerAX catheter includes a catheter introducer as an accessory to facilitate the insertion of SRAC-088 and SRAC-071 catheter into an introducer sheath.

2. HOW SUPPLIED

EmerAX is provided sterile for one time use only.

Sterile	Sterilized using Ethylene Oxide. Non-pyrogenic.
Contents	One (1) EmerAX One (1) Catheter Introducer (For SRAC-088 and SRAC-071 models only)

3. INDICATIONS FOR USE

EmerAX is indicated for the introduction of interventional or diagnostic devices into the neuro vasculature.

4. CONTRAINDICATIONS

There are no known contraindications.

5. WARNINGS

- EmerAX should only be used by physicians who have received appropriate training in interventional techniques.
- Exercise extreme caution when advancing EmerAX near or through any aneurysm or other vascular malformations.
- EmerAX is intended for single use only. Do not re-sterilize or reuse. Dispose EmerAX after use in accordance with the hospital and/or local government policy.
- Do not use EmerAX beyond the labeled shelf life under any circumstances.
- Do not advance or withdraw any accessories through EmerAX against resistance until the cause of the resistance is determined by fluoroscopy. If the cause cannot be determined, withdraw EmerAX and its accessories as a whole. Operating or torquing the device against resistance may cause damage to the vascular system or the device.

6. PRECAUTIONS

- EmerAX and its sterile package should be carefully inspected before use.

  - Do not use the device if its package has been opened or damaged.
  - Do not use device that is kinked or damaged.
  - Do not use the device if its label is incomplete or illegible.
- Verify that EmerAX is compatible with any devices previously implanted in the patient.
- Select the optimal specification of EmerAX according to the target vessel diameter.
- Verify that the maximum outer diameter of EmerAX is compatible with the minimum inner diameter of any support catheter or accessories when EmerAX is intended to be introduced through.
- Verify that the maximum outer diameter of any support catheter or device intended to be inserted into EmerAX is compatible with the minimum inner diameter of EmerAX.
- It is essential to use a catheter introducer while advancing SRAC-088 or SRAC-071 EmerAX through the introducer sheath into patient, to avoid kinking and other damage to the device.
- Rotating Hemostasis Valve (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.
- When EmerAX is used, the standard techniques for guiding catheters, microcatheters and guide wires should be applied.
- Use EmerAX with fluoroscopy for visualization.
- Carefully navigate EmerAX through tortuous anatomy.
- Measures should be taken to prevent or reduce coagulation when using any catheter in a vascular catheter. Consider the use of systemic heparinized and heparinized sterile solutions.
- 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.
- If flow through EmerAX becomes restricted, do not attempt to clear its lumen by infusion. Remove and replace the device.
- Do not use automated high-pressure contrast injection devices on the EmerAX as it may damage the catheter.

7. POTENTIAL COMPLICATIONS

Potential complications include but are not limited to:

- Acute myocardial infarction
- Acute occlusion
- Amputation
- Arrhythmia (including ventricular fibrillation)
- Cerebral edema
- Cerebral infarction/necrosis
- Clotting disorder
- Death
- Distal embolism
- Embolus
- Fever
- Hypertension
- Hypotension
- Infection, sepsis
- Intracranial hemorrhage
- Local ischemia
- Neurological defects (including stroke)
- Pseudoaneurysm formation
- Puncture site hematoma or hemorrhage
- 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

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 country.

8. CLINICIAN USE INFORMATION

Refer to IFU supplied with all accessories to be used with EmerAX 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:

- Rotating Hemostasis Valve (RHV)
- Introducer sheath
- Support catheter
- Guide wire
- Microcatheter
- Micro guide wire
- Continuous flush

9. CLINICAL OPERATION PROCESS

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

Device Preparation

9.1. According to the diameter of the blood vessel and the length of the intervention path to the target lesion, select an appropriately sized EmerAX (see **Table 1**).

9.2. If SRAC-071 EmerAX or a smaller catheter is used, it is recommended to use the SRAC-088 EmerAX as the guiding catheter for the smaller catheter.

9.3. Select a suitable support catheter, if necessary, based on the size of EmerAX used, the target vessel and the anatomical structure to assist the introduction of EmerAX.

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

9.5. Gently remove EmerAX from the protective tube.

9.6. Inspect EmerAX and its accessories for kinks or other damage. If any damage is found, do not use this device. Replace it with a new device.

Preparation of EmerAX Assembly

9.7. Connect RHV to the proximal luer connector of the catheter.

9.8. Hydrate the outer surface of EmerAX and flush the inner lumen of the

catheter and RHV with heparinized saline.

9.9. If a support catheter is used, continue with step 9.10. Else, proceed to step 9.11.

9.10. Open RHV and advance the guide wire with support catheter into EmerAX lumen until the distal tip of the support catheter just passes through the distal tip of EmerAX, then tighten RHV to fix the support catheter in place.

Note: Do not over-tighten RHV, otherwise it may deform the lumen of the support catheter and prevent the passage of guide wire.

9.11. Depending on the size of the support catheter or EmerAX, a 0.014"-0.038" guide wire can be inserted into the support catheter or EmerAX and advanced until its distal tip is aligned with the distal tip of the EmerAX.

Operating Procedure

9.12. Insert an introducer sheath (that is compatible with the outer diameter of EmerAX selected) into the access site. Refer to IFU supplied with the introducer sheath for this step.

9.13. **If using a SRAC-088 or SRAC-071 EmerAX**,

a. Carefully slide the catheter introducer down EmerAX from its initial position(seated over the strain relief) to slightly past the distal tip of EmerAX.

Note: Use a catheter introducer while advancing SRAC-088 and SRAC-071 EmerAX through the introducer sheath into patient, to avoid kinking and other damage to the device.

b. Gently insert the catheter introducer, EmerAX, support catheter *(if used)* and guide wire (hereinafter referred to as EmerAX assembly) into an introducer sheath.

c. Under fluoroscopy, advance EmerAX assembly through the catheter introducer into the introducer sheath and into the patient's vascular system.

d. Slide the catheter introducer back to its initial position once the distal tip of EmerAX has been advanced past the distal tip of the introducer sheath.

9.14. **If NOT using a SRAC-088 or SRAC-071 EmerAX**,

a. Gently insert the EmerAX, support catheter *(if used)* and guide wire (hereinafter referred to as EmerAX assembly) into an introducer sheath.

b. Under fluoroscopy, advance EmerAX assembly into the introducer sheath and into the patient's vascular system.

9.15. Under fluoroscopy, advance EmerAX assembly into the target vessel.
Note: If contrast medium is injected through the support catheter, withdraw the guide wire, and aspirate the support catheter's lumen before injection. If contrast medium is injected through EmerAX, withdraw the support catheter and/or guide wire and aspirate EmerAX's lumen before injection.

9.16. During the introduction of EmerAX, use support catheter or guide wire to navigate to the target vessel. Then, advance EmerAX to the target vessel over the support catheter or guide wire.

9.17. Continue to step 9.18 if target vessel can be reached using the EmerAX selected. Else,
   a. Withdraw the guide wire and support catheter *(if used)*.
   b. Prepare a smaller catheter, according to steps 9.3-9.11.
   c. Advance the smaller catheter into the target vessel through the lumen of the previously introduced EmerAX according to the standard techniques for guiding catheters, microcatheters and guidewires.

9.18. After positioning, EmerAX can be used to introduce interventional or diagnostic devices into the target vessel.
Note: Ensure that the maximum outer diameter of any ancillary catheter or device is compatible with the inner diameter of the selected specification of EmerAX.

9.19. After surgery is completed, withdraw EmerAX through the introducer sheath according to the standard operation procedure.

9.20. Dispose EmerAX appropriately in accordance with institutional procedure.

10. PACKAGING

The catheter is placed in a protective tube and then mounted, along with any accessories, onto a packaging card. The packaging card is inserted into a Tyvek® pouch which is then sealed to maintain sterility.
The device is sterilized with ethylene oxide (EO).

11. STORAGE

Avoid exposure to water, sunlight, extreme temperatures, and high humidity during storage. Store in a cool, dry place at room temperature.

12. Symbol Glossary

Symbol	Definition
	Catalogue Number
	Manufacturer
	Date of Manufacture
	Use-by Date
	Lot Number
	Medical Device
	Consult instructions for use
	Sterilized using Ethylene Oxide
	Non-pyrogenic
	Do not resterilize
	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
	Keep dry
	Keep away from sunlight
	Caution

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