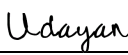


 TD-038 CapriAX Instructions for Use (IFU) Contents	Revision	02
	DCO No.	DCO24038
	Effective Date	25-Jun-2024
	Page	1 of 13

Roles	Name	Designation	Signature	Date
Author	Samantha Ng	RA Specialist		12-Jun-2024
Reviewer/ Approver	Udayan Patel	Global R&D Director		12-Jun-2024
Reviewer/Approver	Lawrence Kong	R&D Director		12-6-2024
Reviewer/Approver	John Wong	Management Representative		12-Jun-2024

Revision	DCO no.	Change Description	Author	Effective Date
01	DCO22165	Initial Release	Samantha Ng	03-Jan-2023
02	DCO24038	Removal of Stent Retrieval System from Cover page	Samantha Ng	25-Jun-2024



CapriAX™

Microcatheter

INSTRUCTIONS FOR USE

Hemo Bioengineering Pte Ltd

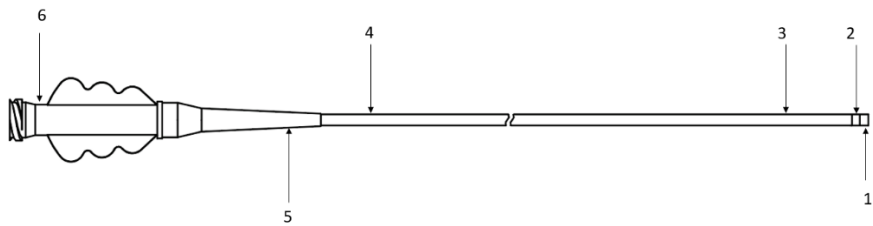
Product Name	CapriAX™
Name of Registrant, Manufacturer and After-sales Service Unit	HEMO Bioengineering Pte. Ltd.
Address of Registrant, Manufacturer and After-sales Service Unit	8 Kaki Bukit Avenue 1, #03-08 Singapore 417941
Address of Legal Manufacturer	8 Kaki Bukit Avenue 1, #03-08 Singapore 417941
Contact Information of Registrant and Manufacturer	Tel: +65 6980 6411 Email: enquire@hemocorp.com
Manufacturer License Number	UEN: 202038236G
Medical Device Registration Certificate / Product Technical Requirement Number	N.A.
Product Structure and Composition	This microcatheter is composed of a distal tip, distal tip marker band, distal catheter, proximal catheter, strain relief and hub. The microcatheter is EO sterilized and single use only.

1. DEVICE DESCRIPTION

CapriAX™ Microcatheter (herein referred to as CapriAX) is a single-lumen catheter that is designed to be introduced over a steerable guidewire into the target vasculature. It provides a platform for exchange of stent retriever and/or guidewires without losing position within the vasculature. The proximal end of the catheter is fixed with a luer connector hub for connection with other accessories. The proximal catheter is semi-rigid and the distal catheter is highly flexible, allowing the catheter ease to access the lesion site. There is a radiopaque distal tip marker band at the distal end of the catheter for identification via radiation. The outer surface of the catheter is coated with hydrophilic coating to assist in the microcatheter advancement.

CapriAX is composed of a distal tip, distal tip marker band, distal catheter, proximal catheter, strain relief and hub. (Refer to **Figure 1**)

Figure 1: CapriAX structure schematic diagram



1 – Distal tip, 2 – Distal tip marker band, 3 – Distal catheter,
4 – Proximal catheter, 5 – Strain relief, 6 – Hub

Table 1: CapriAX model and respective specifications

Model/ Specification	Proximal Inner Diameter (mm)	Proximal Outer Diameter (mm)	Distal Inner Diameter (mm)	Distal Outer Diameter (mm)	Effective Length (cm)	Recommended Guidewire Diameter (inch)
SC-021-150	0.53	0.89	0.53	0.79	150.0	0.014
SC-021-160	0.53	0.89	0.53	0.79	160.0	0.014
SC-027-150	0.68	0.99	0.68	0.92	150.0	0.018
SC-027-160	0.68	0.99	0.68	0.92	160.0	0.018
SC-031-150	0.79	1.14	0.79	1.02	150.0	0.018
SC-031-160	0.79	1.14	0.79	1.02	160.0	0.018

2. HOW SUPPLIED

CapriAX is provided sterile for single use only.

Sterile Sterilized using Ethylene Oxide. Non-pyrogenic.

Contents One (1) CapriAX

3. INDICATIONS FOR USE

CapriAX is intended to assist in the delivery of diagnostic agents (such as contrast media), therapeutic agents, and non-liquid interventional devices (such as stents) that are indicated for use in the neurovascular and peripheral blood vessels.

4. CONTRAINDICATIONS

CapriAX is not to be used on newborns.

5. WARNINGS

- CapriAX should only be used by physicians who have received appropriate training in interventional techniques.
- Do not attempt to use high-pressure perfusion to remove the obstruction when the flow of fluid through the CapriAX is obstructed. Withdraw CapriAX to analyze the cause of blockage or replace it with a new microcatheter. Excessive pressure can lead to the rupture of the CapriAX and cause injury to the patient.
- CapriAX is intended for single use only. Do not re-sterilize or reuse.
- Do not use CapriAX beyond the labeled shelf life under any circumstances.

6. PRECAUTIONS

- CapriAX 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.
- Prior to use, all accessories and reagents should be prepared according to the manufacturer's instructions.
- Prior to use, ensure that CapriAX is not blocked by injecting saline solution through the microcatheter.

- There is a hydrophilic coating on the outer surface of CapriAX, to maintain lubricity, hydrate the microcatheter with continuous flow of flush solution between CapriAX and the guide catheter.
- When CapriAX is in the body, it should be manipulated only under fluoroscopy for visualization. Do not attempt to move the catheter without observing the resultant tip response.
- When advanced through the guiding catheter distal end, carefully navigate CapriAX under fluoroscopy and repeatedly verify CapriAX did not advance into narrow, selective vasculature by slightly withdrawing the microcatheter. This ensures that CapriAX has not advanced too far as to impede its subsequent removal.

7. POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to:

- Distal embolism (air, foreign body, tissue or thrombus)
- Drug reactions caused by antiplatelet agents and / or contrast agents
- Hematoma
- Hemorrhage
- Infection
- Local ischemia
- Pain at insertion site
- Neurological deficit
- Vasospasm, dissection, perforation, rupture or injury

Adverse Event/Incident Reporting

Any serious adverse event/incident that has occurred in relation to the device should be reported to the manufacturer.

8. CLINICAL USE INFORMATION

Refer to IFU supplied with all accessories to be used with Intermediate catheter 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
- Support catheter
- Guide wire
- Micro guide wire
- Continuous flush

9. CLINICAL OPERATION PROCESS

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

Device Preparation

- 9.1. Select an appropriate size CapriAX from Table 1.
- 9.2. Open the packaging box. Using aseptic technique, open the primary packaging pouch and carefully transfer the content onto sterile field.
- 9.3. Gently remove CapriAX from the protective tube and put it on the tray.
- 9.4. Inspect CapriAX and its accessories for kinks or other damage. If any damage is found, do not use this device. Replace it with a new device.
- 9.5. Immerse CapriAX in heparinized saline to hydrate the hydrophilic coating on the outer surface of CapriAX.
- 9.6. CapriAX should remain hydrated throughout the operation.
- 9.7. Connect the syringe containing heparinized saline with CapriAX. Flush the lumen of CapriAX to check for any blockage, before inserting the micro-guidewire.
- 9.8. Select an appropriate micro-guidewire and guiding catheter according to the actual use needs.
- 9.9. CapriAX assembly: Gently insert a micro-guidewire into CapriAX, either directly or through the RHV, and advance the micro-guidewire into the lumen of CapriAX until the distal tip is near the distal end of CapriAX.

Directions for Use

- 9.10. Deploy a guiding catheter according to the guiding catheter IFU.
- 9.11. Loosen the guiding catheter RHV, and gently advance the CapriAX assembly into the lumen of the guiding catheter RHV. Advance CapriAX assembly to the distal end of the guiding catheter.
- 9.12. Tighten RHV connected CapriAX to prevent backflow. Do not over-tighten, as this will hinder the advancement of CapriAX.
- 9.13. Advance the micro-guidewire a short distance, then advance CapriAX over the micro-guidewire and repeat until the desired site is reached.

Delivery of Diagnostic and/or Therapeutic Agents

- 9.14. Before injecting diagnostic and/or therapeutic agents, withdraw the micro-guidewire completely from CapriAX. Connect a syringe for injection as needed.
- 9.15. After the operation, withdraw CapriAX through the guiding catheter according to standard operating procedure. Dispose CapriAX appropriately in accordance with institutional procedure.

Delivery of Non-liquid Interventional Devices

- 9.16. Where applicable, follow all accessory devices (such as stents) manufacturers' instructions.
- 9.17. After the operation, withdraw CapriAX through the guiding catheter according to standard operating procedure. Dispose CapriAX appropriately in accordance with institutional procedure.

10. DEVICE PACKAGE

- CapriAX is packed in a protective tube within a Tyvek primary packaging.
- The device is sterilized with ethylene oxide (EO).

11. TRANSPORTATION AND STORAGE

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

12. SYMBOL GLOSSARY

Symbol	Definition
	Model/Specification
	Manufacturer
	Date of Manufacture
	Use-by Date
	Lot Number
	Medical Device
	Refer to Instructions for Use
	Sterilized using Ethylene Oxide
	Non-pyrogenic
	Do not re-sterilize
	Do not re-use
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system with protective packaging inside
	Do not use if the package is damaged
	Keep dry
	Keep away from sunlight
	Caution

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