

IFU of Central Venous Catheter Kit

Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description:

The Central Venous Catheter Kit is a sterile, single-use medical device designed to provide long-term access to the central venous system. The catheter is made of biocompatible polyurethane and is available in single and multi-lumen configurations. The radiopaque tip allows visibility under X-ray for proper placement, and depth markings support accurate positioning.

Product Name: Central Venous Catheter Kit

Variants:

- 1.Single Lumen
- 2.Double Lumen
- 3.Triple Lumen

Sizes:

Single Lumen– 16G x (13, 16, 20)cm, 20G x (8, 13)cm, 22G x (4, 6, 8, 13)cm.
Double Lumen– 4FR x (6, 8)cm, 5FR x (8, 10)cm & 7FR x (13, 16, 20)cm.
Triple Lumen– 4.5FR x (6, 8)cm, 5.5FR x (8, 10)cm, 7FR x (13, 16, 20)cm & 8.5FR x (13, 16, 20)cm.

Intended Use:

The device is intended to provide long-term access to the central venous system for the administration of fluids, medications, blood products, and parenteral nutrition. It is also used for central venous pressure monitoring and for obtaining venous blood samples in patients who require central venous access.

Material of construction:

Sr. No.	Components	Material
1.	Central Venous Catheter	TPU+PU+PE+PP+ABS/POM+PC
2.	Guide wire with advancer	Nitinol + PP
3.	Introducer Needle	SS304+ABS+PP
4.	Dilator	HDPE+PP
5.	Injection Syringe 5ml	PP+SS304
6.	Injection Stopper	PC/ABS + Latex
7.	Scalpel Blade-11#	SS304+PP
8.	Fixation Device	PE + PP
9.	Transparent Adhesive Dressing	PU
10.	Three Way Stop Cock	PC + HDPE
11.	Surgical Suture	SS304

Indications for use:

- Central venous pressure monitoring.
- Administration of intravenous fluids, medications, or chemotherapy.
- Frequent blood sampling or blood transfusion.

Contra-indications:

- Known bleeding disorders.
- Severe vascular damage.
- Known hypersensitivity to any materials used in the catheter.

Intended Patient Population:

Adults, Pediatrics and Neonatal Patients.

Intended User:

Nephrologists & Other Healthcare Professionals.

Use environment:

Proper Healthcare Setup.

Instruction for use:

- Clean and disinfect the insertion area using an approved antiseptic solution. Drape the area in a sterile manner.
- Administer local anesthetic to the puncture site according to hospital protocol.
- Flush all catheter lumens with sterile saline to ensure patency. Clamp the extension lines or attach injection caps. Leave one lumen open for guidewire insertion.
- Insert the introducer needle into the vein and confirm venous blood return. Do not rely on blood color alone to confirm venous access.
- Advance the J-tip guidewire gently through the needle into the vein to the required depth. Do not apply force. Hold the guidewire securely at all times.
- Remove the needle and pass the vessel dilator over the guidewire to enlarge the puncture site. Remove the dilator after dilation.
- Thread the catheter over the guidewire and advance it into the vein using a gentle twisting motion. Use the depth markings on the catheter to achieve the correct position.
- Hold the catheter in place and carefully remove the guidewire.
- Confirm the catheter tip position using X-ray or other approved imaging methods.
- Secure the catheter using fixation devices or sutures (do not suture directly through the catheter). Apply a sterile dressing over the insertion site.
- Flush unused lumens, clamp extension lines when not in use, and monitor the patient for any signs of complications.
- Dispose of the set after single use as per hospital protocol.

Intended Clinical Benefits to the patients:

- Provides reliable central venous access for renal therapies such as hemodialysis and medication delivery
- Enables safe administration of fluids, blood products, and parenteral nutrition in renal patients

- Supports accurate central venous pressure monitoring when clinically required
- Reduces the need for repeated peripheral venous punctures
- Allows multiple therapies to be delivered simultaneously through multi-lumen configurations.

Clinical Safety:

- Device Design and Material Safety.
- Biocompatible products.
- Our device is a single use device.
- Our product is non-toxic, sterile & non-pyrogenic.

Performance characteristics:

- The catheter provides stable and continuous central venous access for renal therapy and intravenous treatment.
- The radiopaque tip allows clear visualization under imaging to support accurate placement.
- Multiple lumen options enable simultaneous administration of fluids, medications, and blood sampling without interruption.

Accessories which can be used with the device:

Introducer needle, Guidewire with J-tip, Vessel dilator, Syringe & Extension lines with clamps.

Warnings:

- The product should not be reprocessed.
 - Improper transport and handling may cause structural and/or functional damage to device or packaging.
 - Do not clean or resterilize.
 - Do not expose to heat or direct sunlight.
 - The product should be used immediately after opening the packaging.
- MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.

Cautions:

- Do not use if package is damaged.
- Discard after single use.

Limitations:

- Used by only trained healthcare professionals.
- High Pressure Injections.

Potential Side Effects:

- Bleeding or bruising at the insertion site.
- Infection at the catheter site or in the bloodstream.
- Formation of blood clots.

Disposable instructions:

Used Devices may be contaminated with infectious and/or other hazardous materials. Unused expired devices should be disposed of as per local regulations.

Duration of use:

Long-term duration (more than 30 days)

Storage Conditions:

Store in Cool & Dry Place. Keep away from direct sunlight.

Shelf life:

5 Years.

Type of Sterilization:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened unused devices.

Notice to Users and/ or Patients:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Date of manufacture (Indicates the date when the medical device was manufactured)
	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)
	Single sterile barrier system (Indicates a single sterile barrier system)		Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Non-pyrogenic (Indicates a medical device that is non-pyrogenic)		Keep dry (Indicates a medical device that needs to be protected from moisture)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website: www.maisindia.com
	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Medical device (Indicates the item is a medical device)
	Country of manufacture (To identify the country of manufacture of products)		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
	This way up		

ISO & CE Certified Company

Manufactured by:

Mais India Medical Devices Pvt. Ltd.

525-P, Sector-37, Pace City-II,

Gurgaon, Haryana-122001 (INDIA)

Mfg. Lic. No.: MFG/MD/2019/000037