IFU of MaiSafe Extn™

Extension Sets with Needle Free Connector

Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description:
The Extension Sets with Needle Free Connector is intended for injection (medication) during infusion therapy. Multi lumen provides separate and simultaneous fluid pathways, allowing administration of different drugs or fluids.

Product Name:
1. Extension Sets with Needle Free Connector

Brand Names: MaiSafe Extn™

Variants:
Extension Sets with Needle Free Connector:
Mono, Duo & Trio

Sizes:
Mono - 10cm, 15cm, 18cm & 26cm
Duo - 10cm, 15cm, 18cm & 26cm
Trio - 10cm, 15cm, 18cm & 26cm

Intended Use:
Extension Sets with Needle Free Connector:
The extension sets with needle free connectors are used for the administration of medications to an IV line using Injection without hypodermic needle reducing the needle stick injury. The multi-lumen extension lines provide separate and simultaneous fluid pathways and comfort to the patients.

Material of construction:

Sr. No.	Components	Material
1.	Tube	PVC
2.	1-way/2-way/3-way Connector	Polycarbonate
3.	Slide Clamp for extension tube	ABS
4.	White Cap	HDPE
5.	Rotator	ABS
6.	Needle Free Connector	Polycarbonate + Silicon

Indications for use:

- Multiple IV administration or medication.
- Repeated access to IV line.

Contra-indications:

- Do not use this device if there is a confirmed catheter-related bloodstream infection (CRBSI) or active infection at the proposed vascular access site.
- Hypersensitivity/Allergic reaction to device materials.

Intended Patient Population:
All patient population

Intended User:
Healthcare Professionals

Use environment:
Proper Healthcare Setup

Instruction for use:

- Open the blister pack and take out the device.
- Disinfect the access surface with an appropriate antiseptic swab and allow drying completely.
- Attach the Injection Stopper to the luer lock connector of the catheter, extension set, or IV line by twisting clockwise until secure.
- Do not over tighten.
- Administer medication.
- Disconnect the syringe or device by twisting anti clockwise.
- After disconnection, disinfect the accessed area again before next use.
- Dispose of the device after single use, in accordance with hospital policy and local regulations for bio hazardous waste.
- Do not re-sterilize or reuse.

Intended Clinical Benefits to the patients:

- Provides secure, needle-free access to IV lines for infusion and blood sampling.
- Maintains a closed system to reduce infection and leakage risks.
- Enhances treatment efficiency and patient comfort with optional multi-lumen access.

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 devices provide a secure channel for the administration of IV fluids, medications, and blood sampling, during Infusion therapy.
- The devices maintain tight and secure connections to prevent leakage and disconnection during clinical use.
- The injection stoppers and needle free connectors are compatible with standard IV sets, syringes, and catheters, ensuring smoother process in infusion therapy.
- The multi-lumen extension lines provide separate and simultaneous fluid pathways, allowing administration of different drugs or fluids during Infusion therapy.
- The devices ensure adequate fluid transfer rates to support effective IV therapy.

Accessories which can be used with the device:
I.V. Sets, Injection Syringes & other compatible infusion devices.

Warnings:

- The product should not be reprocessed.
- Improper transport and handling may cause structural and/or functional damage to device or packaging.
- Avoid excessive bending, twisting, or pulling of the extension tubing.
- Do not use sharp objects, such as scissors around the tubing.
- Protect the device and connections from moisture exposure.

MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.

Cautions:

- Do not use if package is damaged.
- Discard after single use.
- Do not clean or re-sterilize.
- Do not expose to heat or direct sunlight.
- The product should be used immediately after opening the packaging.

Limitations:

- Single-use only.
- Material/Chemical Compatibility.
- Flow/Pressure Limitations

Potential Side Effects:

- Infection at the IV site.
- Redness.
- Allergy respect to material.
- Blood reflux.

Disposable instructions:
Devices should be disposed of as per local regulations.

Duration of use:
Short Term (Normally intended for less than 30 days).

Storage Conditions:
Store in Cool & Dry Place.
Keep away from sunlight.
Temperature: 10° C to 40° C
Humidity: 50 ± 10%.

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 Single sterile barrier system (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)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)	LOT	Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)	CE 0123	CE Mark (CE Marking with Notified Body Number)
	Non-pyrogenic (Indicates a medical device that is non- pyrogenic)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	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)	EU REP	Authorized representative in the European Community / European Union (Indicates the authorized representative in the European Community / European Union) OBELIS S.A. Boulevard Général Wahis 53, 1030 Brussels, Belgium Contact Number: +32(2)73 25 954 Email ID: regulatory@obelis.net Website: www.obelis.net

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Keep dry (Indicates a medical device that needs to be protected from moisture)		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
UDI	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)	MD	Medical device (Indicates the item is a medical device)
	Humidity limitation (Indicates the range of humidity to which the medical device can be safely exposed.		Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.
REF	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
	Country of manufacture (To identify the country of manufacture of products)		This way up

EU REP **Obelis S.A.**
Boulevard Général Wahis 53, 1030 Brussels, Belgium.

Manufactured by:
Mais India Medical Devices Pvt. Ltd.
525-P, Sector-37, Pace City-II,
Gurgaon, Haryana-122001 (INDIA)

REV.: 01_05.12.2025