# IFU of 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 Set (with Needle Free Connector)

**Brand Names:** MaiSafe Extn™ & MAISAFE EXT PRO™

**Variants:**

**Neutral & Negative Pressure:**
Mono, Duo, Trio & Quadro.

**Sizes:**
Mono - 10cm, 15cm, 18cm & 26cm
Duo - 10cm, 15cm, 18cm & 26cm
Trio - 10cm, 15cm, 18cm & 26cm
Quadro - 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 | DEHP Free PVC |
| 2. | Multi-lumen Connector | Polycarbonate |
| 3. | Slide Clamp for extension tube | ABS |
| 4. | White Cap | HDPE/PP |
| 5. | Rotator | PC/ABS |
| 6. | Needle Free Connector | Lipid Resistant + 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:**
- Verify package integrity, expiry date and device configuration before use.
- Inspect the device for visible damage and ensure connections are secure.
- Perform hand hygiene and follow the applicable aseptic technique.
- Disinfect the needle-free connector's access surface using a compatible antiseptic and allow it to dry according to the validated procedure and antiseptic instructions.
- Connect compatible devices securely without overtightening.
- Monitor for leakage, obstruction, disconnection or other signs of malfunction during use.
- Discard the device after single use in accordance with applicable healthcare waste procedures.

**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 The devices provide a secure fluid pathway for the administration of IV fluids and medications during infusion therapy.
- The devices are designed to maintain secure connections with compatible IV sets, syringes, and catheters to minimize the risk of leakage and disconnection during clinical use.
- The needle-free connectors are available in Neutral Pressure and Negative Pressure variants, with pressure-displacement characteristics corresponding to the respective connector design.
- The multi-lumen extension sets provide separate fluid pathways, allowing the administration of different fluids or medications through compatible lumens.
- The devices provide fluid transfer performance suitable for their intended use, as established through applicable performance verification.

**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

**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) |
|  | Do not re-sterilize (Indicates a medical device that is not to be re-sterilized) |  | 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 Mark (CE Marking with Notified Body Number) |
|  | Single sterile barrier system (Indicates a single sterile barrier system) |  | 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) |  | 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 85275899990 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) |
|  | Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified) |  | Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.) |
|  | 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) |
|  | Non-pyrogenic (Indicates a medical device that is non- pyrogenic) |  | This way up |

CE 0123

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

**REV.:** 04_24.10.2026