

Instructions for Use (IFU)

Device Identification	
Device Name or Trade Name	Aseptic Medical Devices (AMD) Sterile Transfer Sets & Accessories
Intended Purpose	
Intended Purpose (inc. intended use environment)	Aseptic Medical Device (AMD) Sterile Transfer Sets & Accessories are sterile, single-use devices, intended for the preparation of medicinal products within aseptic pharmacy or clinical compounding environments. Once prepared, the capped AMD Syringe is taken to the patient, and the medicinal product is manually administered. As such, the capped AMD Syringe is indirectly in contact with the patient through the medicinal product, and there is no direct contact between the capped AMD Syringe and the patient. The capped syringe containing the medicinal product is not intended as a storage device. The intended patient population for these devices ranges from neonates to end-of-life patients. They are intended to be used by trained healthcare professionals such as pharmacy technicians, Parenteral drug manufacturers & clinicians. They are not intended to be used by lay persons.
Indications	Aseptic Medical Devices (AMD) Sterile Transfer Sets & Accessories are indicated for use by trained healthcare professionals in aseptic pharmacy and clinical compounding environments for the preparation and transfer of sterile medicinal products. Once prepared, the capped AMD syringe is taken to the patient, and the medicinal product within the AMD syringe is manually administered to the patient.
Intended Users	Aseptic Medical Devices (AMD) Sterile Transfer Sets & Accessories are intended to be used by qualified or trained pharmacy technicians, parenteral drug manufacturers and clinicians. They are not intended to be used by laypersons.
Intended Patient Population	The intended patient population of the AMD Sterile Transfer Set & Accessories ranges from neonates to end-of-life patients.
Instructions for use	
The Aseptic Medical Devices (AMD) Sterile Transfer Sets & Accessories are supplied in a multi-layer sterile packaging system designed to support aseptic transfer through progressively cleaner or controlled environments such as Pharmacy Compounding Units areas: 1. The outer layer pouch packaging layer can be disinfected using a suitable disinfectant (e.g. 70% IPA) in accordance with the pharmacy compounding disinfection/decontamination protocol.	

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1. Multi-layer pouch packaging is removed sequentially as the AMD Sterile Transfer Set/Kit progresses through the facility's aseptic transfer process (progressively cleaner or controlled environments. There is no requirement to disinfect each layer.
2. The sterile barrier shall remain intact until the product has reached the designated Sterile Pharmacy Compounding Facility Area where preparation of medicinal product(s) commences (e.g. ISO 5 Primary Engineering Controls - PEC (Laminar Air Flow Hood, Biological Safety Cabinet, Compounding Aseptic Isolator or Isolator))
3. Open the sterile barrier aseptically and present the sterile component(s) for preparation of compounded sterile preparations (CSPs) to commence. There is no requirement to disinfect the components, as they are sterile.

Warnings

- Do not use if the current date exceeds the label expiry.
- Do not reuse the device (single use only)
- Do not use if the device or packaging is broken or damaged.
- Accessories (including needles, vial access devices) are intended for use within aseptic pharmacy or clinical compounding environments only and must not be taken to the patient. Only the capped AMD Syringe is intended to leave the aseptic environment and be taken to the patient for manual administration.
- The AMD Sterile Transfer Sets & Accessories must be used only within the scope of the intended use as described in the Specification.
- **The capped syringe containing the medicinal product is not intended as a storage device.**

Precautions/Cautions

- Compatibility with specific medicinal products has not been evaluated by Riverside Medical. It is the responsibility of the customer or end-user to ensure compatibility with the intended medicinal product.
- Silicone-lubricated syringes have been associated with intraocular events such as "floaters" and endophthalmitis (inflammation of the interior of the eye). Components containing silicone are identified in the 'materials' section of the relevant specification.

Storage Conditions

- Keep dry
- Protect from sunlight
- Store at room temperature, avoid high temperatures and moisture

Sterility Information

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Aseptic Medical Devices (AMD) Sterile Transfer Sets & Accessories are supplied sterile – Sterilisation by Gamma Irradiation.

Shelf Life

Please see this product's labelling for the expiration date.

Disposal Instructions

Aseptic Medical Devices (AMD) Sterile Transfer Sets & Accessories are single-use and should be discarded following facility protocols.

Incident Reporting Information (Serious Adverse Events)

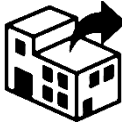
If a serious adverse event occurs, please report it to Riverside Medical at quality@riversidemedical.co.uk and to your federal authority.

This document may be updated periodically. Please ensure that all printed copies of this IFU are identical to the version available at: www.asepticmedical.com/eIFU

Symbols Glossary

Reference number and graphic	Title	Description
5.1.1 (ISO 15233) 	Manufacturer	Indicates the medical device manufacturer
5.1.3 (ISO 15233) 	Date of Manufacture	Indicates the date when the medical device was manufactured
5.1.4 (ISO 15233) 	Use-by date	Indicates the date after which the medical device is not to be used
5.1.5 (ISO 15233) 	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified

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5.1.6 (ISO 15233)		Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
5.1.8 (ISO 15233)		Importer	Indicates the entity importing the medical device into the locale
5.1.9 (ISO 15233)		Distributor	Indicates the entity distributing the medical device into the locale
5.2.6 (ISO 15233)		Do not resterilise	Indicates a medical device that is not to be resterilised
5.2.8 (ISO 15233)		Do not use if package is damaged and consult instructions for use	Indicates that a medical device should not be used if the package has been damaged or opened, and that the user should consult the instructions for use for additional information
5.2.11 & 5.2.4 (ISO 15233)		Single sterile barrier system & Sterilized using irradiation	Indicates a single sterile barrier system & Indicates a medical device that has been sterilised using irradiation
5.2.14 (ISO 15233)		Sterile barrier with protective outer packaging	Indicates a sterile barrier with protective outer packaging

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5.3.2 (ISO 15233)		Keep away from sunlight	Indicates a medical device that needs protection from light sources
5.3.4 (ISO 15233)		Keep dry	Indicates a medical device that needs to be protected from moisture
5.4.2 (ISO 15233)		Do not re-use	Indicates a medical device that is intended for single use only
5.4.3 (ISO 15233)		Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
5.4.4 (ISO 15233)		Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator action in order to avoid undesirable consequences
5.7.7 (ISO 15233)		Medical device	Indicates the item is a medical device
21 CFR 801.109(b)(1)		Rx Only	Caution: Federal Law restricts this device to sale by or on the order of a Physician