



Instructions for use in all languages are available by scanning this code



Symbol Glossary: Symbols are in compliance with BS EN ISO 15223-1 and BS EN 15986
Some symbols may not apply to this product. Refer to product labelling for symbols that specifically apply to this product.

Medical device	Catalogue number	Lot number	Unique device identifier	Caution	Consult instructions for use	Temperature limit
Manufacturer	Date of manufacture	Use-by date	Keep away from sunlight	Keep dry	Do not re-use	Do not use if package is damaged
Sterilised using ethylene oxide	Do not resterilise	Fragile	Contains latex	Latex free	Authorised representative in the European Union	
Contains phthalates	Single sterile barrier system	Single sterile barrier system with protective packaging inside		Single sterile barrier system with protective packaging outside		

1. INDICATIONS

The Haemodialysis procedure pack is single use and contains a combination of products packaged together with the purpose of providing a draping platform to facilitate the connection then disconnection of dialysis lines to an arteriovenous fistula (AV fistula) or dialysis catheter. The device is for use by either a trained healthcare professional, or by a patient within the patient's own home, as determined by the patient's clinician.

2. DEVICE DESCRIPTION

The procedure pack provides the correct components to create a sterile field and complete the procedure.

Each procedure pack is unique to the end user but will commonly contain a combination of the following components.

Component	Intended purpose	Connection packs	Disconnection
Gloves	For the user to ensure no contamination occurs during the procedure	X	X
Drape / Tray wrap	To create a sterile field to containing all components	X	X
Syringes	To draw blood from and flush the fistula needles or the catheter lumens To administer fluid or drugs in the dialysis circuit. For priming the catheter with saline before administering fluids	X	
Hypodermic needle	To connect to the syringe to administer fluid or drugs in the dialysis circuit	X	
Swabs/Cotton balls	For cleaning the skin or to absorb any exudates	X	X
Caps	To apply to the lines after dialysis disconnection		X
Adhesive waste bag	To safely dispose of all waste	X	X
Dressings	May be required to stop bleeding after removal of AV fistula needles.		X
Bowls/Trays	Used to hold antiseptics required to clean the skin prior to cannulation.	X	
Accessories	Used in support of the overall usage of the dialysis procedure pack and serving an ancillary role to the devices listed above (these include tourniquet, paper rules, plastic forceps etc.)	X	X

The procedure pack may contain two wrapped parts labelled “On” pack, another labelled “Off-pack” and where applicable a priming set.

3. CLINICAL BENEFITS

The Procedure packs provide indirect clinical benefits as it is designed to support connection and disconnection of haemodialysis lines using an aseptic technique, the clinical benefit of which is prevention of infection. Accessing haemodialysis lines or catheters are a potential source of infection so the aseptic technique supported by this device ensures this risk is minimised.

All the components needed for a basic connection and disconnection of haemodialysis lines are contained in one pack. Therefore, the user does not need to get standalone parts from the shelf.

4. POTENTIAL COMPLICATIONS

If components are re-used and not discarded or sterile procedures not observed, infection may occur. Follow Instructions provided carefully.

5. WARNINGS

All components are provided sterile and are for single use only. Do not re-use any component provided as this may cause infection. Discard all components once used, as per the instructions provide. Do not use if any damage is visible. If any issues are encountered when using this device, contact a healthcare professional.

6. INSTRUCTIONS FOR USE

6.1 Connection steps

When the patient is ready for the connection procedure use the procedure pack as follows:

- Perform hand hygiene and put on new clean gloves.
- Open the pouch of the procedure pack by peeling in the direction indicated on the label until the pouch is fully open
TO OPEN PEEL IN THIS DIRECTION ►►►►►►►
- Remove the pouch labelled 'Off' that is in the procedure pack and put it aside to use for disconnection at the end of the dialysis session
- Take the wrap containing the 'connection' components out of the pack and place it on a clean surface for use
- Unfold the wrap ensuring the blue side faces down. Ensure the components remain on the drape.
- If a second drape is included, place this on the arm of the chair under the patient's arm to create a further sterile environment
- Open the pouch containing the syringes and drop the syringes onto the wrap with the other 'connection' component, ensuring they only come into contact either with a gloved hand or the sterile area created by the opened wrap.
- Use the swabs provided with appropriate disinfectants to disinfect all catheter hubs or the skin at and around the puncture site of the fistula.
- Syringes are provided in some procedure packs for flushing and priming of the catheter or the arterio-venous fistula lines, refer to the relevant catheter priming instructions.
- Follow the specific instructions provided with the Haemodialysis catheter for every specific patient.
- Discard any used items in the waste bag provided as per hospital/ clinical protocol.

6.2 Disconnection steps

When the procedure has been completed and the dialysis lines can be disconnected.

- Perform hand hygiene and put on new clean gloves.
- Open the pouch labelled "Off" pack (if relevant) by peeling in the direction indicated on the label until the pouch is fully open
TO OPEN PEEL IN THIS DIRECTION ►►►►►►►
- Remove the complete wrap containing "Disconnection" components from the procedure pack and place onto clean surface.
- Unfold the wrap ensuring the blue side faces down. Ensure the components remain on the drape.
- Use the swabs provided with appropriate disinfectants to disinfect all catheter hub and the skin.
- Follow the specific instructions provided with the Haemodialysis catheter for every specific patient to safely disconnect the haemodialysis fluids form the catheter.
- Where provided replace the catheter caps with the provided caps from the procedure pack
- Discard any used items in the waste bag provided as per hospital/ clinical protocol.

7. DISPOSAL OF PROCEDURE PACKS

For clinical users, dispose of in line with hospital protocol.

For home users, use a sharps bin to dispose of used needles or sharps. A sharps bin is a specially designed box with a lid that you can get on prescription (FP10 prescription form) from a GP or pharmacist. When full, the box may be collected for disposal by your local council. All other waste can be disposed of by placing used items into the included waste bag and placing into general waste.

8. BASIC UDI

The basic UDI for the Kimal Dialysis Procedure Packs is 5032932KSP-107EHE.

9. SERIOUS ADVERSE EVENT

If a serious adverse event occurs, please report it to Kimal at vigilance@kimal.co.uk and to your national competent authority.

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