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

1 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 some or all of the of the following components:

- Introducer Needle
- Guidewire
- Introducer Sheath
- Tubing set for tumescent pump

2 INTENDED USE

The procedure packs are sterile, single use kits that contain a combination of products packaged together; to provide tumescent anaesthesia to perform radiofrequency segmental thermal venous ablation.

3 INTENDED USERS

The packs are typically opened and set up by nurses or technicians and the products within are used by radiologists, anaesthesiologists, neurologists, and vascular surgeons.

The packs are for use by trained clinicians only.

4 CLINICAL BENEFITS

The packs provide indirect clinical benefits as it is designed to support set up for a procedure and to create a sterile field, using an aseptic technique. Majority of the supportive components needed for tumescent anaesthesia and thermal ablation are contained in one pack. The clinical benefit being the aseptic technique and components helping reduce the risk of infection, during a surgical intervention. Also, improving the time between procedure set up by having many of the required components all in one pack, therefore reducing the need for the user to get standalone parts off the shelf.

5 PERFORMANCE CHARACTERISTICS

The pack facilitates the creation of a sterile field and provides components to complete the procedure. The individual components within the packs differ but commonly they can contain the following:

Component	Intended purpose
Introducer needle	To gain access to a blood vessel using the needle to create a puncture for other devices like a guidewire to then advance in
Guidewire	To advance through the introducer needle to further gain initial access to the vein to perform the Seldinger technique

Component	Intended purpose
Introducer Sheath	Advance over the guidewire to perform the Seldinger technique and gain access to the vein for the duration of the procedure, so other devices can be advance through the sheath
Tubing set for tumescent pump	Tubing that supports the flow of fluids to perform tumescent anaesthesia

6 HOW SUPPLIED

All contents are supplied STERILE and non-pyrogenic in unopened and undamaged packaging. The devices are sterilised by ethylene oxide. Do not use any unit if sterile package has been damaged or opened. DO NOT RE-USE OR RE-STERILISE the device.

Do not re-sterilise, reprocess, or reuse. Reuse, reprocessing or re-sterilisation may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or re-sterilisation may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Storage

Protect from direct sunlight, any source of heat, and moisture. Store at room temperature and do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that devices are used prior to expiration date on package label.

7 CONTRA-INDICATIONS

There are no specific contra-indications related to the procedure pack. However, radiofrequency segmental thermal venous ablation is not appropriate for patients with thrombus in the vein segment to be treated.

8 INSTRUCTIONS FOR USE

⚠ **WARNING**: Aseptic technique should be implemented when using a Procedure Pack and its components.

8.1 Introducer Sheath

The introducer assembly consists of a dilator and an outer sheath body that permits entry of a catheter/guidewire once the inner dilator is removed. The sheath body and dilator have a proximal female luer attachment to allow syringe connection and guidewire entry. The Introducer valve is haemostatic and includes a sidearm with stopcock for fluid administration and a suture ring for securement.

⚠ **WARNING: Use aseptic technique**

- Peel open package and place contents on sterile field.
- Inspect all component for defects. Do not use any defective devices.
- Flush the Introducer needle, dilator, introducer sheath and side port with normal heparinised saline solution.
- Prepare skin and drape in area of anticipated puncture site as desired.
- Insert introducer needle into the blood vessel. The angle of the needle should be adjusted depending on the patients build: shallow in a thin person, deeper in a heavyset person.

- Aspirate the puncture needle using a syringe. The needle position should be verified by aspirating and observing blood return.

8.2 Guidewire use

A stainless steel guidewire is provided with the procedure pack and it is inserted and advanced through the patient's vein to the required location to act as a track for a sheath.

- Remove the syringe used for aspiration, and insert the soft tip of the guidewire through the introducer needle into the vessel. Advance guidewire to required depth. Leave an appropriate amount of guidewire exposed.

⚠ **WARNING: At no time should the guidewire be advanced or withdrawn when resistance is met.** Determine the cause of resistance before proceeding. Fluoroscopic verification of the guidewire location is suggested.

1. Hold guidewire in place and remove introducer needle.

⚠ **WARNING: Do not withdraw the guidewire back into the introducer needle as this may result in separation of the guidewire. The introducer needle should be removed first. Do not allow Guidewire to advance totally into patient.**

- Assemble the introducer set by carefully inserting the dilator completely into sheath introducer. Firmly thread the dilator to the sheath valve cap.
- When using an introducer with a sideport, follow standard hospital practice/procedural needs for flushing, aspiration or administration of other solutions.
- While holding the introducer close to the skin, advance the dilator and sheath together over the guidewire and into the vessel. Fluoroscopic observation may be advisable. Attaching a clamp or haemostat to the proximal end of the guidewire will prevent inadvertently advancing the guidewire entirely into the patient.
- To detach the dilator from the sheath cap, unwind the dilator hub from the sheath valve cap until it becomes detached. Remove the vessel dilator and guidewire, leaving the sheath as a conduit into the vessel.
- Introduce the selected catheter into the sheath using the instructions provided by the manufacturer of the catheter or other device, and standard hospital practice.

⚠ **WARNING: When removing the catheter, aspirate via the sideport extension to collect fibrin that may have been deposited at the tip of the sheath.**

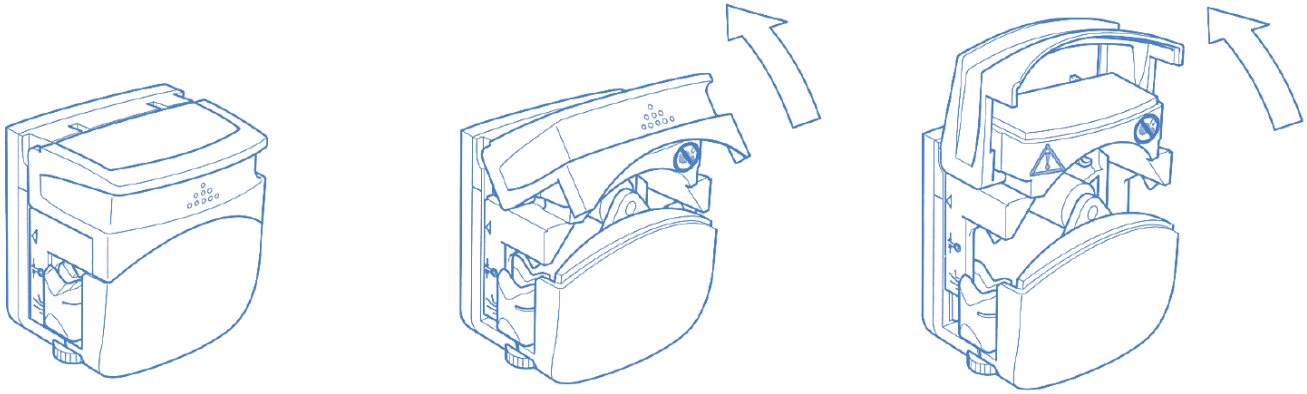
8.3 Introducer Sheath, insertion, and withdrawal:

- For occlusion of sheath, use dilator of same size as sheath.
- For flushing and infusion, use the side port attached to the sheath.
- Attach a flushing line/syringe to the sheath sideport extension and flush.
- While holding the sheath in place, place thumb and index finger between the sheath and dilator hubs, squeeze firmly and withdraw dilator.

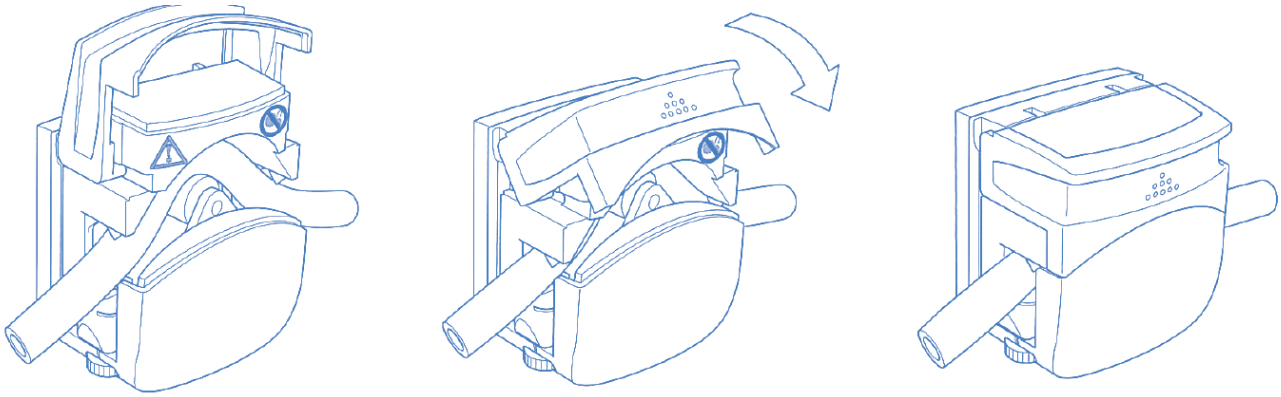
8.4 Tubing Set

The Procedure pack contains a tumescent tubing set intended for administering saline with the pump system DP 20 4m. The following steps should be used:

- Open the pump head and insert the tubing set (note flow of direction)



- Close the pump head – the pump is ready for operation



9 POTENTIAL COMPLICATIONS

The procedure pack contains components intended to provide a sterile solution for the surgical procedure and as such does not have potential complications, however the surgeon should consider the potential complications associated with the procedure and each individual component.

Radiofrequency segmental thermal venous ablation potential complications include, but are not limited to, the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, infection, adjacent nerve injury, skin burn, hematoma or discoloration.

10 DEVICE DISPOSAL

All component and packaging should be disposed of in compliance with hospital and hazardous waste protocols.

11 SERIOUS ADVERSE EVENTS

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

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and

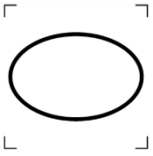
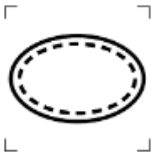
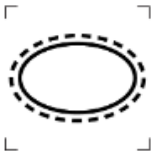
to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:

https://health.ec.europa.eu/system/files/2023-02/md_vigilance_contact_points.pdf.

12 BASIC UDI-DI

The basic UDI for the Surgical Procedure Pack is 5032932KSP-107D-3UE

13 SYMBOL GLOSSARY

				
Keep away from sunlight	**Medical device**	**Fragile, handle with care**	**Do not reuse**	**Do not resterilize**
				
Keep dry	**Single sterile barrier system**	**Single sterile barrier system with protective packaging inside**	**Single sterile barrier system with protective packaging outside**	**Sterilized using ethylene oxide**
				
Catalogue number	**Batch code**	**Use-by date**	**Manufacturer**	**Caution**
				
Do not use if package is damaged and consult instructions for use	**This way up (To indicate correct upright position of the transport package)**	**Consult instructions for use or consult electronic instructions for use**	**Contains or presence of phthalate**	**CE marking of conformity with European notified body identification number**
				
Unique Device Identifier				

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