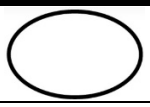
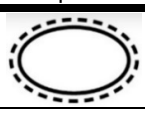
Instructions for use in all languages are available by scanning this code

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

Kimal Vessel Dilators are intended for use with adult patients in procedures requiring the insertion of a device into the vascular system and are placed over a guidewire to enlarge the entry site of a vessel to ease the insertion of a device into a vessel. Kimal Vessel Dilators are single use for up to one hour.

2. DEVICE DESCRIPTION

The dilator is a tubular polypropylene device with a colour-coded hub, supplied in different French sizes enabling percutaneous vascular access using up to a 0.038" guidewire. The dilator is latex free and is sterilised by Ethylene Oxide gas.

3. CLINICAL BENEFITS

Vessel dilators contain a radio-opaque strip made of Barium Sulphate which aids X-ray detectability during clinical use, have a tapered distal tip to allow for entry into vessel, and are available in various sizes to accommodate the patient anatomical requirements, his therapeutic needs, the size of the guidewire and of the catheter.

4. POTENTIAL COMPLICATIONS

Anytime a procedure using a Kimal Vessel Dilator is performed the possibility exists, but is not limited to one of the following to occur:

- Embolism
- Pneumothorax
- Thrombosis
- Haematoma
- Haemothorax
- Vessel erosion
- Vessel trauma
- Plaque dislodgement

The incidence of thrombus formation is higher when a guidewire is used in conjunction with a dilator and therefore careful selection of the appropriate dilator and guidewire size is recommended.

5. PRECAUTIONS

- Ensure the appropriate size Kimal Vessel Dilators is used for the procedure. The French size of each dilator is indicated on the hub and is also identified by the colour of the hub. The table below indicates the colour and corresponding French size, along with the guidewire that each French size accepts.

French size	Colour	Accepts guidewire
4 French	Red	0.035" (0.89MM)

French size	Colour	Accepts guidewire
5 French	Grey	
6 French	Green	0.038” (0.97MM)
7 French	Orange	
8 French	Light blue	
9 French	White	
10 French	Purple	
11 French	Grey	
12 French	Dark Blue	
14 French	Pink	

- Observe sterile technique when handling the dilator.
- To avoid damage and crimping of dilators during removal from package, gently grip hub of dilator and pull to remove.
- Avoid use of alcohol, antiseptic solutions, or other solvents directly on the vessel dilator as they may adversely affect the device.
- Do not manually re-shape the tip of the vessel dilator by applying external force intended to bend or affect the shape of the dilator.

6. WARNINGS

Percutaneous insertion procedures should only be undertaken by experienced and trained clinicians.

- Aseptic technique should be used when handling the Vessel Dilator to prevent transfer of pathogens.
- If resistance is encountered at any point in procedure, investigate cause and do not use force to advance or remove dilator.

7. INSTRUCTIONS FOR USE

- Peel open package and place contents on sterile field.
- Prep skin and drape in area of anticipated puncture site as desired.
- Inspect the system contents for any signs of damage; do not use if any damage is present.
- Follow standard hospital practice for placement or removal of dilator.

8. DISPOSAL OF DILATOR

Single-use devices should be disposed of according to best practices in the region.

9. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

The Summary of Safety and Clinical Performance (SSCP) can be referenced on the Eudamed public website (https://ec.europa.eu/tools/eudamed) or can be requested directly from Kimal (regulatory_department@kimal.co.uk)

10. BASIC UDI

The basic UDI for the Kimal Vessel Dilators is 5032932KSP-049JU.

11. 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.

12. OBTAINING A PAPER IFU

A paper copy of the IFU can be obtained upon request.

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