INSTRUCTIONS FOR USE Sterile Visibility Background Material

Description:

Silicone strip with a grid on one side and plain on the reverse side, available in blue, green and yellow colours.

Application/Intended Use/Performance:

For use in Micro Surgical Anastomosis of Micro Vessels, under a microscope to allow the surgeon to better visualise the detail of the vessels being closed.

The Visibility Material can be used with the grid side up, or the reverse plain side can also be used.

The material has a non-reflective surface eliminating distractions from theatre lighting and has a non-tacky finish to aid mobilisation of the vessel.

The silicone material selected is suitable for transient use within the body. A barium mix is used to provide x-ray opaque quality to the material.

Intended User:

Qualified clinicians with the required specialist knowledge to perform Anastomosis procedures.

Patient Population:

No restriction on patient age or population.

Packing & Sterilisation:

Visibility Background Material is supplied sterile for single use only. Packed individually in a box of 12, sterilised by Gamma Irradiation in accordance with EN 11137.

Precautions:

- · The material is LATEX FREE.
- · Must only be used for its intended purpose.
- Not for implantation Must be removed from the wound before closure.
- · Not to be used for longer than 60 minutes continuously.
- This device is supplied sterile, intended for single use ONLY.
- · Not to be re-sterilised once opened.
- Do not use if the packaging is damaged or open. Dispose of immediately if packaging is found to breached in any way.
- Re-use of single use devices present a risk of infection to the patient.

Storage:

- · To be stored under normal ambient conditions.
- · Keep away from direct sunlight and keep dry.
- Life of the product is limited to the expiry date on the label.

Disposal:

Can be disposed of without any special instructions and poses no danger if standard medical waste disposal regulations are observed.





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