

SHEATH WITH INSERTER AND ELASTICS FOR FASTENING

Sterile single-use sheath for combined coverage of dentist and/or doctor's offices with cardboard inserter and 2 elastics for fastening. Single-use sheath with specific inserter prepared so as to considerably allow the operator to easily and quickly cover the instrument, thereby considerably reducing the risk of cross-contamination.

- Sheath made with transparent anti-reflex Polythene tube with 0.05 mm thickness.
- Sheath with truncated cone featuring a 3 cm hole at the end.
- 2 elastics to secure the ends
- Sheath folded on a convenient white cardboard inserter
- Cardboard size: 7x20 cm

TECHNICAL FEATURES: Dimensional tolerance $\pm 5\%$

PRODUCTION:

The product is produced and packaged in a special **clean room with a controlled environment**

CLEAN ROOM WITH CONTROLLED ENVIRONMENT:

Class ISO 8 – Standard UNI-EN ISO 14644-1.

Environment with constant temperature and humidity; by means of special ventilation and filtering systems, the presence of the bacterial load is kept controlled and at low levels.

PACKAGING:

Individually-folded sterilisation sleeve in a pouch/blister made from medical paper with plastic film overlay and peel-open system indicating the sterilisation batch. Packed in cardboard boxes.

STERILIZATION:

Sterilization is carried out with ethylene oxide; the sterilization process is regularly validated and kept under constant control by routine analysis; and the residue of the sterilizing gas is kept within the limits established by the current legislation. Sterilization is performed by a specialized laboratory.

EXPIRY:

This product is valid for 59 months from the sterilisation date (MONTH-YEAR). The expiry date indicated refers to the product in its unopened and correctly preserved packaging.

QUALITY CONTROL:

The quality system adopted by ALLE complies with the following regulations:

- **EN ISO 13485**

Controls are carried out at all stages of production: entry, production, packaging, sterilization.

GENERAL PRECAUTIONS AND WARNINGS :

This product should only be used by qualified and trained personnel. Always read the label.

STORAGE:

- The items are stored in the original cardboard boxes, in a closed and clean environment protected from sunlight
- The integral sales package is guaranteed impermeable to direct and indirect light sources.

PRODUCT DISPOSAL:

The device listed in this document can be disposed of as non-hazardous waste in authorized plants, including incineration, in accordance with current regulations.

However, if the device used during surgical procedures in the operating room is exposed to contact with the patient's biological fluids, it must be treated and disposed of as hospital waste.

LATEX AND PHTHALATE-FREE:

- The device does not contain natural rubber latex (Latex free)
- The device does not contain phthalates (PVC free)
- The device does not contain elements (adhesives, chemicals, etc.) that could cause allergies or any skin reaction.

CND: T030102 - INSTRUMENT COVER SLEEVES (National classification of medical devices IT)

GMDN: Not applicable

PRODUCT CLASSIFICATION: CLASS IS Medical Device

SIZE	WEIGHT	PACKAGING	CODE
120x7 CM	Gr/sqm 47	10 PIECES	270310

