

PROTECTION SET

Single-use sterile set for the preparation of the sterile operating field for oral surgical procedures.

DEVICE CLASSIFICATION

Class Is	Disposable	STERILE
CND: T0202 - SURGICAL KITS (National classification of medical devices IT)		
GMDN: Not applicable		

PACK: 35 Kits

CODE: 270107

Kit composition:

PIECES	DESCRIPTION	MEASURES
2	NON-WOVEN TWO LAYERS SURGICAL ISOLATION DRAPE	50x75 CM
1	NON-WOVEN TWO LAYERS ISOLATION DRAPE	75x90 CM
1	NON-WOVEN TWO LAYERS PATIENT ISOLATION DRAPE WITH NON-ADHESIVE U-CUT 11x30 CM	100x150 CM
2	WHITE POLYETHYLENE INSTRUMENT-COVERING SHEATH WITH ADHESIVE	120x7 CM

APPLICABLE STANDARDS

EN ISO 13485; UNI-EN ISO 14644-1

PRODUCTION ENVIRONMENT

The set is manufactured and packaged in designated controlled clean room. Class ISO 8.

STERILIZATION

The set is sterilized with ethylene oxide.

PACKAGING

Sterile article, with individually folded components wrapped in bags for peel-open sterilisation, made with plastic film and medical grade paper. The sets, individually packaged, are packed in cardboard boxes, internally protected with a polyethylene sheath. The unopened package is guaranteed resistant to direct and indirect light sources.

Device equipped with double removable adhesive labeling to facilitate traceability.

Each peel-open bag is provided with a removable adhesive label to facilitate operators in the operations related to the traceability of the devices used during surgeries.

The removable adhesive label can be detached from the bag and stuck to the medical record or to any other document which, according to the procedures used, is used for traceability.

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.

LABELING

Each individual set is provided with an internal label visible through the transparent casing; this label is complete with all the information needed to identify the product:

- product trade name
- product code number
- manufacturer name
- sterilisation method
- production batch number
- expiry date
- sterile symbol
- single-use symbol
- place of production
- CE marking and number of the Notified body
- warnings



GENERAL PRECAUTIONS AND WARNINGS

This product should only be used by qualified and trained personnel. Always read the label.
Storage is in the original cardboard boxes, indoors and in a clean environment away from sunlight

PRODUCT DISPOSAL

The devices listed in this document must be disposed of as hospital waste and cannot be sent to the incinerator.

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 can cause allergies or any kind of skin rash.



DETAILED TECHNICAL FEATURES OF SET COMPONENTS

SINGLE-USE NON-WOVEN ISOLATION DRAPE			
Single-Use Isolation Drapes made with Impermeable Non-Woven Fabric. This insulated material provides a total bacteriological barrier, both wet and dry; it is composed of 2 layers:			
<ul style="list-style-type: none"> • Uniform blue high absorbency layer • Uniform blue impermeable polyethylene layer 			
TECHNICAL CHARACTERISTICS: (Dimensional tolerance \pm 5%)			
PIECES	DESCRIPTION	MEASURES	
2	NON-WOVEN SURGICAL ISOLATION DRAPE	50x75 CM	
1	NON-WOVEN SURGICAL ISOLATION DRAPE	75x90 CM	
1	NON-WOVEN PATIENT ISOLATION DRAPE WITH NON-ADHESIVE U-CUT 11x30 CM	100x150 CM	
TECHNICAL CHARACTERISTICS OF THE MATERIALS			
IMPERMEABLE ABSORBENT ISOLATED NON-WOVEN FABRIC			
Absorbent non-woven fabric coupled to an impermeable layer, hot-laminated across the entire width with polyolefin			
Weight		g/m ²	54
Colour		Light blue	
TEST EN 13795	UNIT OF MEASURE	VALUE	METHOD
TENSILE STRENGTH – DRY	N/50 mm	45.00	EN 29073-3
TENSILE STRENGTH – WET	N/50 mm	30.00	EN 29073-3
MICROBIAL CLEANING	Log (10) cfu/dm ²	1.18	EN 1174
RESISTANCE TO MICROBIAL PENETRATION – DRY	Log (10) cfu	< 1	ISO 22612
RESISTANCE TO MICROBIAL PENETRATION – WET	BI	6.00	ISO 22610
RESISTANCE TO LIQUID PENETRATION	Cm H ₂ O	160.00	EN 20811
BURSTING PRESSURE – DRY	KPa	108.00	EN 13938-1
BURSTING PRESSURE – WET	KPa	95.00	EN 13938-1
LINTING	Log (10)	3.20	ISO 9073-10

INSTRUMENT-COVERING SHEATH WITH ADHESIVE		
White low density transparent polythene instrument-covering sheath with adhesive for fastening		
PIECES	DESCRIPTION	MEASURES
2	POLYETHYLENE INSTRUMENT-COVERING SHEATH WITH ADHESIVE	120x7 CM

