

## IMPLANTOLOGY SET

Disposable sterile set for oral implantology surgery. Device used for preparing the sterile field and for covering the dentist, assistants and the patient.

## DEVICE CLASSIFICATION

**Class Is**

**Disposable**

**STERILE**

**CND:** T0202 - SURGICAL KITS (National classification of medical devices IT)

**GMDN:** Not applicable

**PACKAGING:** 15 Kit

**CODE:** 270105

Kit composition:

UNITS	DESCRIPTION	MEASURES
N. 3	BLUE NON-WOVEN FABRIC GOWNS WITH CUFFS	115x135 CM
N. 1	BLUE NON-WOVEN FABRIC SURGICAL CAP WITH FIXED LACES	
N. 2	BLUE NON-WOVEN FABRIC ROUND CAPS	Ø 53 CM
N. 2	CELLULOSE DRY PAPER TOWELS	30x40 CM
N. 3	THREELAYERS NONWOVEN FABRIC MASKS WITH ELASTICS	
N. 1	TWOLAYERS DRAPE (TISSUE PE) WITH HOLE ø 6 CM	50x75 CM
N. 1	TWOLAYERS DRAPE (TISSUE PE)	75x90 CM
N. 2	TWOLAYERS DRAPE (TISSUE PE)	50x50 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 set, whose components are individually folded and wrapped in the medical grade paper that acts as a wrapper. The set is packaged in peel-open bags made of a plastic film and medical paper. The single sets are packed in cardboard boxes, internally protected by 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:

- trade name of the product
- product code number
- name of the manufacturer
- sterilization method
- production batch number
- Expiration date
- sterile symbol
- disposable symbol
- production place



- 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.

## 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 skin manifestation.



**DETAILED TECHNICAL FEATURES OF SET COMPONENTS**

<b>BLUE NONWOVEN FABRIC GOWNS WITH CUFFS</b>		
Disposable gown made of blue Spunbond nonwoven fabric, suitable for short or ambulatory operations. It eliminates the risk of cross contamination. The gown has an excellent fit, allowing normal movements without causing tears to the fabric.		
<b>TECHNICAL FEATURES:</b> (Dimensional tolerance) $\pm 5\%$		
<ul style="list-style-type: none"> <li>Gown made of Spunbond non-woven fabric in light blue polypropylene</li> <li>Gown length: 115 cm</li> <li>Gown width: 135 cm</li> <li>Gown with adjustable belt in T.N.T. applied in the front</li> <li>Neck closure with back straps</li> <li>Gown with cuffs</li> </ul>		
UNITS	DESCRIPTION	MEASURES
N. 3	<b>BLUE NON-WOVEN FABRIC GOWNS WITH CUFFS</b>	115x135 CM
MATERIAL TECHNICAL FEATURES		
BLUE NONWOVEN FABRIC		
Non-woven fabric composed of 100% polypropylene fibers, made of tightly woven fibers that allow free air circulation. It is soft, drapable and has good dry and wet resistance.		
COLOR	Blue	
WEIGHT	30 g/m <sup>2</sup> $\pm 5$	

<b>BLUE NON-WOVEN FABRIC SURGICAL CAP WITH FIXED LACES</b>		
Disposable cap for surgeons with fixed laces made of non-woven fabric, shaped and sized such as to completely isolate the head and hair. Especially recommended in the operating room, even for long-term operations as the perforated absorbent non-woven fabric of which it is made allows excellent breathability. The non-woven fabric acts as a bacteriological barrier while allowing a high breathability of the skin and avoiding a rise in body temperature. It eliminates the risk of cross contamination.		
<b>TECHNICAL FEATURES:</b> (Dimensional tolerance) $\pm 5\%$		
The cap is made of 3 sewn parts: <ul style="list-style-type: none"> <li>An oval-shaped upper part 24.5x16 cm</li> <li>Two side bands 8x31 cm</li> <li>Two fixed rear laces 24.5 cm each</li> </ul>		
UNITS	DESCRIPTION	MEASURES
N. 1	<b>BLUE NONWOVEN FABRIC SURGICAL CAP WITH FIXED LACES</b>	
MATERIAL TECHNICAL FEATURES		
BLUE SPUNBOND NONWOVEN FABRIC		
Non-woven fabric made of of 100% polypropylene fibers. It is soft, drapable and has good dry and wet resistance.		
COLOR	Blue	
WEIGHT	35 g/m <sup>2</sup> $\pm 5$	

<b>BLUE NON-WOVEN FABRIC ROUND CAPS</b>		
Cap in blue Spunbond nonwoven fabric, particularly suitable for visitors, staff and operands. It eliminates the risk of cross contamination. The non-woven fabric used constitutes a bacteriological barrier while allowing a high breathability of the skin and avoiding a rise in body temperature. It is a soft, resistant, air permeable and highly extensible cap.		
<b>TECHNICAL FEATURES:</b> (Dimensional tolerance) $\pm 5\%$		
<ul style="list-style-type: none"> <li>Circular cap with a diameter of 53 cm</li> <li>Cap with hypoallergenic elastic on the whole diameter</li> <li>Cap of a shape and size such as to completely hold thick hair</li> </ul>		
UNITS	DESCRIPTION	MEASURES
N. 2	<b>ROUND CAPS</b>	Ø 53 CM
MATERIAL TECHNICAL FEATURES		
BLUE SPUNBOND NONWOVEN FABRIC		
Non-woven fabric made of of 100% polypropylene fibers that do not allow bacteria to penetrate but allow free air circulation. It is soft, drapable and has good dry and wet resistance.		



COLOR	Blue
WEIGHT	15 g/m <sup>2</sup> ± 5 (DIN 53854)

## CELLULOSE DRYPAPER HAND TOWELS

- Disposable towel wipes made of dry paper with high absorption power. It eliminates the risk of cross contamination
- Nonwoven cellulosic fiber wipe formed with dry air flow process
- Raw materials: 100% long fiber cellulose, bleached with a chlorine-free process
- Binders: ethylene-vinyl-acetate in emulsion
- Weight: 50 g/m<sup>2</sup>

UNITS	DESCRIPTION	MEASURES
N. 2	CELLULOSE DRYPAPER TOWELS	30x40 CM

## THREELAYERS NON-WOVEN FABRIC MASKS WITH ELASTICS

Mask with three layers of non-woven fabric: soft colored TNT, anti-particulate and antibacterial PFE and BFE filter, comfortable TNT inside.

Light blue mask with white elastic bands and built-in nose clip.

**TECHNICAL FEATURES:** (Dimensional tolerance) ± 5%

- **Filtering capacity: ≥ 99% (BFE)**
- Mask size: Height: folded 90 mm - Length: 175 mm

UNITS	DESCRIPTION
N. 3	THREE LAYERS NONWOVEN FABRIC MASKS WITH ELASTICS

## TWOLAYERS DISPOSABLE DRAPES

Disposable drapes made of absorbent waterproof double-layered light blue material.

The double-layered material allows a total bacteriological barrier both in wet and dry conditions; consists of 2 layers:

- Light blue tissue layer with absorbing power
- Waterproof layer in transparent polyethylene

**TECHNICAL FEATURES:** (Dimensional tolerance) ± 5%

UNITS	DESCRIPTION	MEASURES
N. 1	TWO LAYERS DRAPES	50x75 CM
N. 1	TWO LAYERS DRAPES	75x90 CM
N. 2	TWO LAYERS DRAPES	50x50 CM

## MATERIAL TECHNICAL FEATURES

### BI-COUPLED WATERPROOF AND ABSORBENT DRAPE

High absorbency material composed of 100% cellulose coupled with a waterproof PE layer.

- Absorbent layer in pure light blue cellulose (100%)
- Waterproof layer in transparent polyethylene (100%)

COLOR	g/m <sup>2</sup>		40
WEIGHT	Light blue		
<b>TEST EN 13795</b>	MEASUREMENT UNIT	VALUE	METHOD
RESISTANCE TO TRACTION - DRY	N/50 mm	147.00	EN 29073-3
RESISTANCE TO TRACTION - HUMID	N/50 mm	138.80	EN 29073-3
MICROBIAL CLEANING	Log (10) cfu/dm <sup>2</sup>	0	EN 1174
RESISTANCE TO MICROBIC - DRY PENETRATION	Log (10) cfu	0	ISO 22612
RESISTANCE TO MICROBIAL - HUMID PENETRATION	BI	6.00	ISO 20810
RESISTANCE TO PENETRATION OF LIQUIDS	Cm H <sub>2</sub> O	> 200.00	EN 20811
BURST PRESSURE - DRY	KPa	313.00	EN 13938-1
EXPLOSION PRESSURE - WET	KPa	301.00	EN 13938-1
RELEASE OF PARTICLES - LINTING	Log (10)	2.40	ISO 9073-10
SPECIAL CLEANING	IPM	2.30	ISO 9073-10

