

SENTINEX® PRO Surgical Gown Spunlace, sterile

REF 19300 – 19304, 19310 – 19314

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1. Composition of the product

The SENTINEX® PRO Surgical Gowns Spunlace consist of:

Gown:	cellulose/polyester non woven
Cuffs:	polyester
Hook fastener:	polypropylene
Loop fastener:	polyamid
Transfer card:	cardboard

This product data sheet covers the following items:

REF	Product	Size
19300	Sentinex® PRO Standard Surgical Gown, sterile, with sterile wrapping	120 cm
19301	Sentinex® PRO Standard Surgical Gown, sterile, with sterile wrapping	130 cm
19302	Sentinex® PRO Standard Surgical Gown, sterile, with sterile wrapping	150 cm
19303	Sentinex® PRO Standard Surgical Gown, sterile, with sterile wrapping	170 cm
19304	Sentinex® PRO Standard Surgical Gown, sterile, with sterile wrapping	150cm large

REF	Product	Size
19310	Sentinex® PRO Special Surgical Gown, sterile, with sterile wrapping	120 cm
19311	Sentinex® PRO Special Surgical Gown, sterile, with sterile wrapping	130 cm
19312	Sentinex® PRO Special Surgical Gown, sterile, with sterile wrapping	150 cm
19313	Sentinex® PRO Special Surgical Gown, sterile, with sterile wrapping	170 cm
19314	Sentinex® PRO Special Surgical Gown, sterile, with sterile wrapping	150cm large

2. Packaging, structure, and composition

2.1 Unit container

- see 2.2

2.2 Shelf container

- deep draw bag of cellulose, polyamide, and polyethylene

2.3 Transit container

- polyethylene bag
- corrugated cardboard box

3. Manufacture

SENTINEX® PRO Surgical Gowns Spunlace are manufactured to specification under hygienic conditions and wrapped as described in their respective packaging specifications. They are sterilized by ethylene oxide in compliance with DIN EN ISO 11135-1.

4. Description

Turquoise colored disposable surgical gown, which is available in different sizes.

The surgical gowns Special contain additionally a sleeve- and a front reinforcement. The sleeve reinforcement consists of an adhesive laminated composite material of white polypropylene non woven and white polyethylene film. The front reinforcement consists of an adhesive laminated composite material of white polypropylene non woven and transparent polyethylene film.

Front- and sleeve reinforcement are bonded with the spunlace material by means of a Hotmelt glue. All other parts are sewn with the base material.

The wrapped gowns contain additionally two white towels consisting of drylaid tissue, the overwrap consists of white sterilization paper.

5. Properties

SENTINEX® PRO Surgical Gowns Spunlace are liquid-repellent disposable surgical gowns. They are abrasion resistant and low-linting.

6. Intended purpose / use

The SENTINEX® PRO Surgical Gowns Spunlace are intended for wearing during surgical procedures. They are to avoid transfer of infectious agents by direct contact from the operatinf wound of reverse

7. Medical device classification

SENTINEX® PRO Surgical Gowns Spunlace are medical devices of Class Is in terms of Rule 1.

(Annex IX, Council Directive 93/42/EEC concerning medical devices).

8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

The starting materials used in the manufacture of SENTINEX® PRO Surgical Gowns Spunlace are safe if the product is used appropriately and for the purposes intended.

The purpose of this documentation and the statements made herein is to show that there is no risk involved in the use of the medical device SENTINEX® PRO Surgical Gown Spunlace and that it is designed, manufactured, and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

9. Stability

Stored appropriately, SENTINEX® PRO Surgical Gowns Spunlace have a shelf life of 5 years.

10. Disposal

The user is advised to observe current legislation, norms, and guidelines regulating the disposal of medical waste.

Packaging materials must also be disposed of in compliance with applicable national requirements.

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Signed by

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