**LOHMANN & RAUSCHER**

# SETPACK® Gauze Balls, X-ray detectable, sterile

## REF 22800 - 22810

August 2013

Translation: PAGRA
Revision: MI / C. Zorn

### 1.    Composition of the product

SETPACK® Gauze Balls, X-ray detectable, sterile, consist of
- absorbent cotton gauze (20-thread) in accordance with DIN EN 14079
- an X-ray detectable thread (polypropylene filaments spun with polyester yarn.
  This thread is dyed blue and contains barium sulphate)
- safety ring made of silicone

The raw materials used are all **free of natural latex**.

This Product Data Sheet applies to the following items:

| REF 22801 | SETPACK® Gauze Balls, X-ray detectable, sterile | Size 2 | 10 pcs./pack |
|---|---|---|---|
| REF 22802 | SETPACK® Gauze Balls, X-ray detectable, sterile | Size 3 | 10 pcs./pack |
| REF 22805 | SETPACK® Gauze Balls, X-ray detectable, sterile | Size 3 | 15 pcs./pack |
| REF 22808 | SETPACK® Gauze Balls, X-ray detectable, sterile | Size 3 | 20 pcs./pack |
| REF 22803 | SETPACK® Gauze Balls, X-ray detectable, sterile | Size 4 | 10 pcs./pack |
| REF 22806 | SETPACK® Gauze Balls, X-ray detectable, sterile | Size 4 | 15 pcs./pack |
| REF 22809 | SETPACK® Gauze Balls, X-ray detectable, sterile | Size 4 | 20 pcs./pack |
| REF 22804 | SETPACK® Gauze Balls, X-ray detectable, sterile | Size 6 | 10 pcs./pack |
| REF 22807 | SETPACK® Gauze Balls, X-ray detectable, sterile | Size 6 | 15 pcs./pack |
| REF 22810 | SETPACK® Gauze Balls, X-ray detectable, sterile | Size 6 | 20 pcs./pack |
| REF 22800 | SETPACK® Gauze Balls, X-ray detectable, sterile | Size 7 | 5 pcs./pack |

### 2.    Packaging, structure and composition

### 2.1.    Unit container

- double-sterile packaging (deep-draw pouch) consisting of
  cellulose, polyamide, and polyethylene

**2.2    Shelf container**

- cellulose folding box


**2.3    Transit container**

- corrugated cardboard carton (cellulose)


**3.    Manufacture**

SETPACK® Gauze Balls, X-ray detectable, are manufactured to specification under hygienic conditions, and wrapped in accordance with applicable packaging specifications.
They are sterilized by ethylene oxide in compliance with DIN EN ISO 11135-1.


**4.    Description**

Ready-to-use, white to yellowish-white, highly absorbent gauze balls with a blue X-ray detectable thread, in double-sterile deep-draw pouches.


**5.    Properties**

Highly absorbent gauze balls made of 20-thread cotton gaze according to EN 14079.


**6.    Intended purpose**

SETPACK® Gauze Balls, X-ray detectable, are intended for the usage in the operating room. The product is used for absorbing blood and exudates during surgical procedures.


**7.    Medical device classification**

SETPACK® Gauze Balls, X-ray detectable, are a medical device of Class IIa in terms of Rule 6 (Medical Device Directive 93/42/EEC, Annex IX)


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

The starting materials used in the manufacture of SETPACK® Gauze Balls, X-ray detectable, are safe when the product is used for its intended purposes.


The purpose of this documentation and of the statements made therein is to show that the medical device "SETPACK® Gauze Balls, X-ray detectable" is designed, manufactured, and packaged in such a manner that its use presents no hazard or risk to the patients' clinical condition or safety, nor to the safety and health of the user or any third parties involved, provided that the SETPACK® Gauze Balls, X-ray-detectable, are used under the conditions and for the purposes intended.

**9.      Stability**

Stored appropriately, SETPACK® Gauze Balls, X-ray detectable, 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 refuse.
Packaging materials must also be disposed of in compliance with applicable national requirements.

Lohmann & Rauscher GmbH & Co. KG
D- 56579 Rengsdorf
signed by
Dr. Martin Abel
(Medical & Regulatory Affairs)