

# Technical Data Sheet

## Sorbact<sup>®</sup> Surgical Dressing



| General                    |                                                                                                                                                                   |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Product description</b> | Bacteria binding surgical dressing: acetate fabric with permanently bound dialkyl carbamoyl chloride (DACC) laminated to an absorbent wound pad of adhesive film. |
| <b>Ref no</b>              | <b>Size</b>                                                                                                                                                       |
| 98140                      | 5x7.2 cm                                                                                                                                                          |
| 98141                      | 8x10 cm                                                                                                                                                           |
| 98142                      | 8x15 cm                                                                                                                                                           |
| 98143                      | 10x20 cm                                                                                                                                                          |
| 98144                      | 10x25 cm                                                                                                                                                          |
| 98145                      | 10x30 cm                                                                                                                                                          |
| 98146                      | 10x35 cm                                                                                                                                                          |

| Material |                                                                                                        |                                                                                                                                                                                          |
|----------|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Layer 1  | <b>Protective liner, adhesive side</b><br>Colour                                                       | Monosiliconated paper<br>White                                                                                                                                                           |
| Layer 2  | <b>Adhesive backing film</b><br>Film<br>Adhesive<br>M.V.T.R. <sup>1</sup> (g/m <sup>2</sup> /24h/37°C) | Polyurethane film, clear Hypoallergenic acrylic polymer<br>>400                                                                                                                          |
| Layer 3  | <b>Protective liner, PU side</b>                                                                       | Plastics with blue line                                                                                                                                                                  |
| Layer 4  | <b>Absorbent pad</b><br><br>Absorbent layer<br><br>Inside layer<br><br>Adhesive binder                 | Absorbent + inside layers bound by adhesive<br><br>White viscose and polypropylene nonwoven<br><br>White hydro-entangled polyester nonwoven<br><br>Clear artificial thermoplastic rubber |
| Layer 5  | <b>Bacteria binding layer</b>                                                                          | A green acetate fabric with permanently bound dialkyl carbamoyl chloride (DACC)                                                                                                          |

<sup>1</sup> M.V.T.R. = Moisture Vapour Transmission Rate

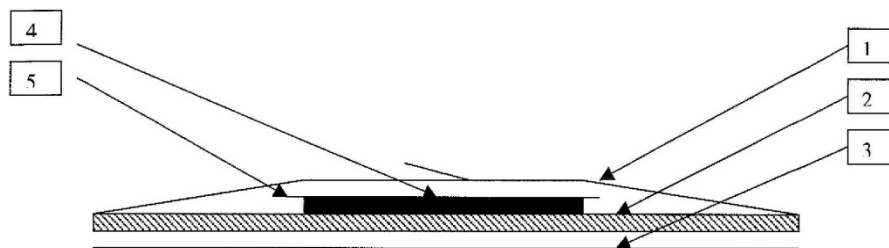
| Packaging           |                                   |
|---------------------|-----------------------------------|
| Primary packaging   | Individual hot sealed paper pouch |
| Secondary packaging | Cardboard box                     |
| Tertiary packaging  | Well transport box                |

| Manufacturing and regulatory                         |                                                            |
|------------------------------------------------------|------------------------------------------------------------|
| Sterilization method                                 | Gamma irradiation                                          |
| Shelf life                                           | 3 years                                                    |
| Storage conditions                                   | Keep dry and away from direct sunlight. Store at max 25°C. |
| Medical Device Class<br>acc to Annex IX of 93/42/EEC | IIb                                                        |
| Country of manufacture                               | Italy                                                      |
| Certification                                        | ISO 13485:2012<br>ISO 14001:2004<br>ISO 9001:2008          |

| Logistics                                          |                   |                   |                   |                   |                   |                   |                   |
|----------------------------------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Ref no                                             | 98140             | 98141             | 98142             | 98143             | 98144             | 98145             | 98146             |
| Weight, unit (kg)<br>(device in primary packaging) | 0.003             | 0.006             | 0.008             | 0.012             | 0.015             | 0.019             | 0.021             |
| Weight, secondary pack<br>(kg, with device)        | 0.353             | 0.163             | 0.218             | 0.307             | 0.376             | 0.465             | 0.511             |
| Weight, tertiary pack<br>(kg, with device)         | 3.9               | 2.1               | 2.0               | 4.0               | 4.1               | 3.9               | 4.5               |
| Units in secondary pack<br>(pcs)                   | 100               | 20                | 20                | 20                | 20                | 20                | 20                |
| Units in tertiary pack<br>(pcs)                    | 1200              | 240               | 160               | 240               | 200               | 160               | 160               |
| EAN code primary pack                              | 7392130<br>181401 | 7392130<br>181418 | 7392130<br>181425 | 7392130<br>181432 | 7392130<br>181449 | 7392130<br>181456 | 7392130<br>181463 |
| EAN code secondary pack                            | 7392130<br>981407 | 7392130<br>981414 | 7392130<br>981421 | 7392130<br>981438 | 7392130<br>981445 | 7392130<br>981452 | 7392130<br>981469 |
| EAN code tertiary pack                             | 7392130<br>800142 | 7392130<br>800159 | 7392130<br>800166 | 7392130<br>800173 | 7392130<br>800180 | 7392130<br>800197 | 7392130<br>800203 |

| Product specifics                                                    |              |
|----------------------------------------------------------------------|--------------|
| <b>Package material: bleach method</b><br>(chlorine, ECF, TCF)       | Non chlorine |
| <b>Package material: PVC or other halogen based plastic material</b> | No           |
| <b>Addition of antimicrobial substance</b>                           | No           |
| <b>Addition of antibiotics</b>                                       | No           |
| <b>Addition of allergens:</b>                                        |              |
| -Latex                                                               | No           |
| -Lanolin                                                             | No           |
| -Colophony and derivatives                                           | No           |
| -Phthalates (DEHP, DINP, DIDP, BBP, DBP)                             | No           |
| -Triclosan                                                           | No           |

### Cross section (all sizes)



1. Protective liner, adhesive side
2. Adhesive backing film
3. Protective liner, PU side, plastics with blue line
4. Absorbent pad
5. Bacteria binding layer