



SELEFA[®] Optimia Nonwoven round sponges

REF: 223021, 223022, 223023

SELEFA[®] Optimia Nonwoven round sponges have a wide area of use: pre-operative skin cleansing, wound and abrasion cleansing, wiping, absorption, protection etc. They are also intended to stop bleeding or to apply topical medications. Their high softness insure lenient contact with wound and skin as the material is less adherent and less linting than gauze devices.

Key Features

- ▶ High quality viscose/polyester nonwoven material
- ▶ High softness and low linting
- ▶ Effective in liquid and exudate absorption
- ▶ Less adherent to the wound than woven gauze devices
- ▶ Can be sterilized using EO



REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
223021	Optimia Nonwoven round sponges, non-sterile, White	Ø 30 mm	200 / 3600
223022	Optimia Nonwoven round sponges, non-sterile, White	Ø 40 mm	150 / 2700
223023	Optimia Nonwoven round sponges, non-sterile, White	Ø 50 mm	100 / 1800

Sales Unit: Transport Carton

Regulations

The product complies with legal requirements for medical devices.



REACH regulation:	The products covered by this data sheet do not contain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA).
Biological evaluation:	EN ISO 10993-5 EN ISO 10993-10
Compliance with legal requirements:	Medical Device Regulation (EU) 2017/745, MDR class I
Compliance with product standards:	EN 29073, EN 1644-1,-2
Quality standards:	EN ISO 13485
Label information and packaging compliance:	EN ISO 15223-1, EN ISO 20417

Material

Product Part	Raw Material & Characteristics
Main material	Nonwoven, 70% viscose and 30% polyester, white
Elastic ring	SEBS block copolymer, white, latex-free

Warnings & Recommendations

Warnings	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.
Storage Recommendation	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone.
Disposal Recommendation	Dispose in accordance with local regulations.
Shelf Life	5 years

Packing Information

Package	Material	Size (L x W x H) mm
Single Pack	N/A	N/A
Dispenser Pack	PE bag, Transparent	223021: 270 x 390 x 104 223022: 270 x 390 223023: 270 x 390
Transport Carton	Carton, TCF or ECF quality	223021: 395 x 290 x 420 223022: 395 x 290 x 420 223023: 395 x 290 x 540
Packing Tape	PVC-free, Transparent	N/A

Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
223021	N/A	06438129354126	06438129554120
223022	N/A	06438129354133	06438129554137
223023	N/A	06438129354140	06438129554144

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