

Embra® Surgical cap Tristan

REF: 279103

Embra® Headwears are designed to help prevent foreign particles such as hair or skin scales falling from medical personnel into the wound during surgical interventions. Our surgical caps are suitable for most interventions and situations and are available in a wide range of colors and designs. Embra® surgical cap Tristan is a popular design in the USA. Its smaller design does not fully cover ears and long hair. Made in a soft and breathable viscose nonwoven material. The top of the cap is made of thinner nonwoven material (white) for better breathability. The tie band in the back allows for individual fit.

Key Features

- ▶ Universal size
- ▶ Top of cap in thinner nonwoven material for better breathability
- ▶ Tie band in the back allows for secure fit
- ▶ 80% viscose, 20% polyester meaning most of the materials are from renewable resources
- ▶ Viscose from sustainable forests (FSC-certified)
- ▶ Production moved from Asia to Europe to further reduce emissions
- ▶ High-performance headwear protects from falling skin cells or stray hairs
- ▶ Breathable and comfortable headwear
- ▶ Drapes easily
- ▶ Suitable for long shifts in the most intense surgical environments
- ▶ Tested for skin irritation, skin sensitisation and in vitro cytotoxicity according to EN ISO 10993

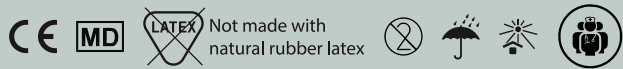


REF	DESCRIPTION	SIZE	PACK COUNT dispenser/carton
279103	Surgical cap Tristan, Green	Universal	100 / 600

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

Quality standards:

EN ISO 13485

Label information and packaging compliance:

EN ISO 20417, EN ISO 15223-1

Material

Product Part	Raw Material & Characteristics
Body	Viscose nonwoven, green
Cap	Spunbond PP nonwoven, white
Tie bands	Spunbond PP nonwoven, white
Sewing thread	Nylon and polyester, white

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

Packaging Information

Package	Material	Size (L x W x H) mm
Single Pack	N/A	N/A
Dispenser Pack	TCF or ECF quality	185 x 300 x 145
Transport Carton	TCF or ECF quality	310 x 385 x 455
Packing Tape	Transparent, PVC-free	N/A

Barcodes / UDI-DI

REF	Single Pack	Dispenser Pack	Transport Carton
279103	N/A	06438129370157	06438129570151

Embra's mission is to develop responsible healthcare solutions focused on lowering the environmental impact while heightening quality for patients and caregivers. Together we can make a positive difference, so thank you for choosing Embra.