

Tamponadebinde® (sterile)

General Product Description/Intended Purpose

The sterile tamponing bandage is manufactured from 100% cotton. Its fast selvedges ensures the use for tamponing of natural body cavities and wounds. It allows the absorption of exudate.

Application/Indication

The tamponing bandage is a single-use, sterile medical device used on humans by instructed lay persons and healthcare professionals for tamponing of wounds or natural body cavities. Application in combination with externas.

Reference Numbers

REF	name	size	bandage per plastic box	plastic box per peel pouch
3708001	Tamponadebinde® (sterile)	1 cm x 5 m	1	1
2880190	Tamponadebinde® (sterile)	2 cm x 5 m	1	1



Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

Not known

Sterile Device

The sterile packaging is in accordance with DIN EN ISO 11607.

Sterilization with ethylenoxide according to DIN EN ISO 11135 or steam according to DIN EN ISO 17665 with validated process.

Instruction	Symbol acc. to EN ISO 15223-1
Do not use if package is damaged	
Do not resterilize	

Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Tamponadebinde® should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

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Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Product Performance Characteristics

Tamponadebinde® (sterile)	
property	value
Sinking time	< 10 sec
Number of threads*	Warp $\geq 117/100$ mm Weft (double weft) $74 \text{ cm} \pm 2/100$ mm
Area weight*	$52 \pm 3 \text{ g/m}^2$
Tensile strength dry*	$\geq 60 \text{ N/50 mm}$
Optical brighteners	none

* different to EN 14079, due to the double weft thread and the resulting higher area weight

Material Characteristics

Gauze
100% chlorine free bleached cotton, chemical properties according EN 14079

Labelling

Lot-No. with 9-digit code

e.g.:



9

999

01

00

1

explanation [9 = 2019]

[999-000]

definition

year

serial production order

for internal purposes only

Manufacturing date

e.g.:



2019
year

04
month

01
day

Expiry date

e.g.:



2024
year

04
month

01
day

Shelf Life: 5 years

Medical Device



Unique Device Identification (UDI)



Sterile Barrier System with Protective Packaging Inside



Single sterile barrier system
with protective packaging inside

Latest Date of Revision: 2020-04-14