

Description: Nonwoven ball

Final dimensions:	25 cm x24 cm
Composition:	Silicone ring, Viscose/Polyester Nonwoven.
Size variation:	±10 %
Diameter:	65mm
Construction:	Nonwoven 30 gsm
Weight/sqm:	> 30,00g/m2
Weight/piece:	> 0,6873g
XR Specifications:	NON PVC X-RAY thread
Latex:	Free
PVC:	Free
Re use:	No
Counting Efficiency approx	99 % (see note below)
Round diameter:	55 mm
Sterilization method:	Moist heat
Shelf life:	60 months
Liq Retention Cap/pc	4,811g water
CFU/g	N.A.
Tensides (EN 1644-1)	Absence
Fluorescence	conform
pH (acidity or alkalinity)	conform
Rate of absorption	<10 s
Non-polar soluble subst.	<0,50 %
Water soluble substances	<0,50 %
Absorption EN 1644-1	>700 %
Absorption EN 1644-2	> 8 g/g
Wet Tensile strength MD	>30 N/5cm
Dry Tensile strength TD	>7 N/5 cm
Dry Tensile strength MD	>25 N/5cm
Wet Elongation break TD	<115 %
Wet Elongation break MD	<50 %
Wet Tensile strength TD	>7 N/5cm
Dry Elongation at breakTD	<170 %
Dry Elongation at breakMD	<60 %
Wet Linting	≤4000 Nr. particles
Dry Linting	<4,0 Log10
Dry bursting strength	>350 kPa
Wet bursting strength	>350 kPa
Size	5



Nr and Revision Date:	33 -- 2020/11/18
CE Class:	Ila
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC

Applicable norms:	EN ISO 13485:2016 ; EN 1041:2008+A1:2013 ; EN ISO 11607-1:2009 ; EN ISO 11607-2:2006 ; EN ISO11737-1:2006AC:2009 ; EN 1644-1:1997 ; EN 1644-2:2000 ; EN ISO 14971:2012 ; EN ISO 10993-5:2009 ; EN ISO 10993-10:2013 ; EN ISO 11737-1:2006/AC:2009 ; ISO 16142-1:2016 ; EN ISO 15 223-1:2016 ;
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Important Notes: 1st packing with units control stickers

Level	Type	Dimension	Stamp	Labels
1	5 INNER flexible peel-open pack	134x185mm	Quantity control label-TAG	
2	5 DOUBLE Flexible peel-open pack	200x290mm		
3	125 Carton box	312x213x247mm	stamped	labeled
4	750 Carton box	780x225x635mm		labeled

Important Notes:	The device is intended to be used on a single patient during one single procedure to prevent risks from contamination, including possible infections, and/or functional damage.
CountingEfficiency approx	Surgeons and nurses shall never assume that number of surgical sponges, in each pack, is exact at all times. The usual counting efficiency of BV products in double packing with control TAG or tied's is 99 % . The tracking of sponges is full responsibility of the healthcare professionals. In order to avoid retained surgical sponges following surgical operation, (1) follow rigorous manual counting protocols, (2) use sponges marked with a radiopaque marker, as well as, (3) careful examination of the abdomen by the operating surgeon before closure.
Storage instructions	Store in a dry place at room temperature and protect from sunlight. The product has a good stability and therefore, normal conditions of medical devices storage shall apply
Waste instructions	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Intended use	For cleansing and disinfection of the skin/wounds, absorption of exudates from body orifices, as well as for swabbing and absorbing blood and discharge during surgery.
<i>Any modification of the product as presented or any use out of its intended use are not of the manufacturer responsibility.</i>	

Non-harmonized symbols used in article labeling



diameter



Check the number of pieces



Nonwoven balls with x-ray thread



Medical Device

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	549
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ISSUED BY: Quality Management Department, 2021/05/14

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