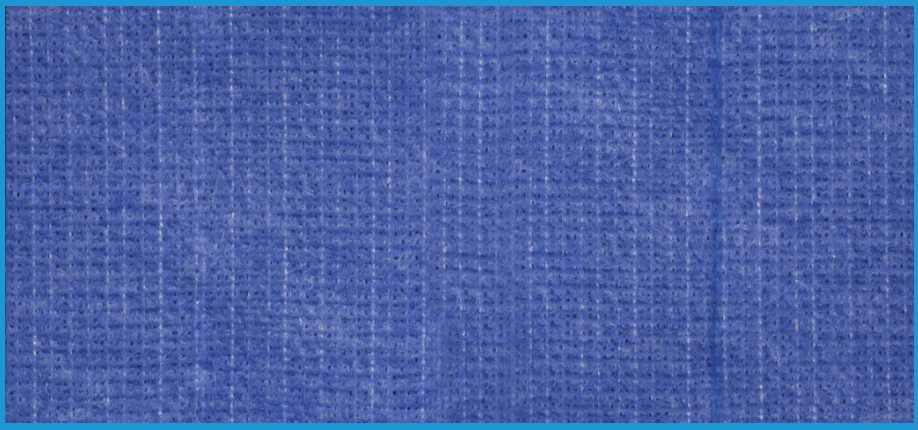
texart® T



O.R. Towel

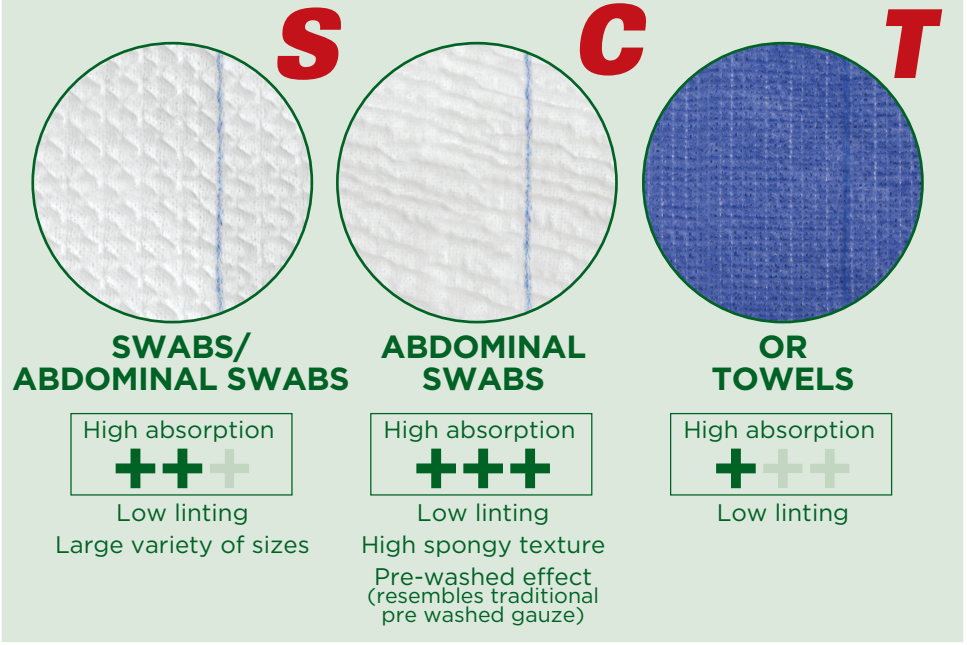
Toalha de bloco operatório

FR Champ de bordure
DE OP-Handtuch
NL OK handdoek
IT Tovagliette assorbenti
ES Toalla para bloque operatorio
SV Operationshandduk
BG Операционна зала Кърпа
HR Ručnik za kirurško dvoranu
CS Absorpční rouška
DA OP-serviet
ET Operatsioonirätik
FI Leikkaussalipyyhe
EL Πετσέτα χειρουργείου
HU Műtéti törölköző
LV Operāciju zāles dvielis
LT Operacinės rankšluostis
PL Ręczniki operacyjne
RO Prosop sală operație
SK Uterák pre operačnú sálu
SL Brisača za v operacijsko sobo

Texart is a patented medical fabric that combines the best of woven and nonwoven technologies used in the medical area. It was developed in order to meet the definition of the ideal swabs:

> "It should be highly absorbent and should not shed significant quantities of fibres or particles during use. The fabric from which it is constructed should contain no toxic substances and the swab should have a high wet strength so that it is not damaged by wringing. The material should be soft and conforming both wet and dry, and should not form lumps when wet. If the material is to be introduced into the human body during any form of surgical procedure it should have a radiographically detectable thread/patch which must be firmly incorporated into the structure."
>
> Thomas, S. Observations upon a new family of surgical absorbents. July 2015.

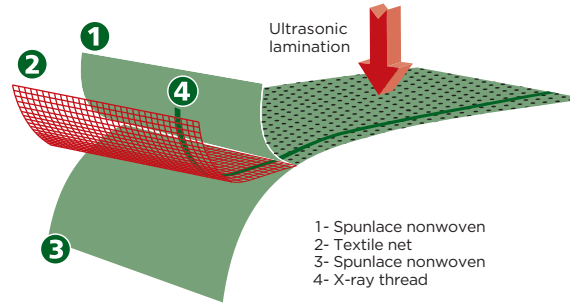
What's the difference between all texart range?



OR TOWELS

Texart is essentially a reinforced nonwoven swab, that consists in two layers of spunlace nonwoven and a textile net in between. The three layers are ultrasonically sealed together with X-ray detectable thread resulting in a spongy texture.

The wrinkled surface of the swab **increases very much the absorption capacity**, whilst the interior textile net greatly increases the resistance. The final product becomes compact, but very soft, with a **spongy feeling** in dry or wet state and **very low linting**.



Sponge feeling

The wrinkled surface of the swab produces a very soft and sponge like feeling which is incomparable with other equivalent products in the market.

Composition

Nonwoven spunlace 70%viscose/30% polyester.

Textile polyamide/polyester net.

X-ray contrast polypropylene/polyester thread (with at least 60% barium sulphate).

X-Ray thread

X-ray is phthalate free and is ultrasonically bonded together with low linting spunlace nonwoven material, widely used on the medical market.

Automatic production

Fully automatic process includes unwinding of the three layers, ultrasonic lamination, cut, fold and stacking resulting in minimal contamination by handling.

Consistent quality

All raw materials and all production are 100 % Made in Europe.

Single-use

For complete patient safety. To be used on a single patient during one single procedure.

Known raw materials

Nonwoven spunlace production involves the use of very high pressure water jets without the use of any binders and any other chemicals.
The textile net consists of fibers used for a long time in medical devices, but specially approved for this product.

Safety requirements

Absence of:
-Toxic substances.
-Alternative plasticizers (e.g. phthalates, trimellitates)
-Colophony and derivatives
-Animal origin substances
-Heavy metals
-Latex
-PVC
-Chlorine
-Bisphenol A (BPA)

Disposability

Texart swabs are generally disposable through incineration. This will permit the consequent energy recovery throught heat generation.

Sterilizable

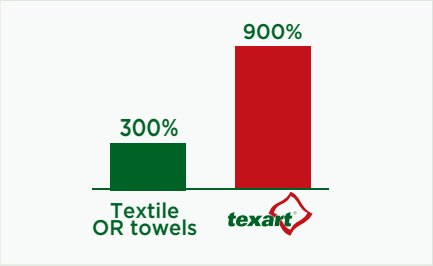
Sterilizable by steam and ethylene oxide.

Highly absorbent

Spunlace nonwoven presents high absorption capacity which is enhanced by the shrinking effect of the textile net. Texart presents higher absorption values when compared with gauze swabs.

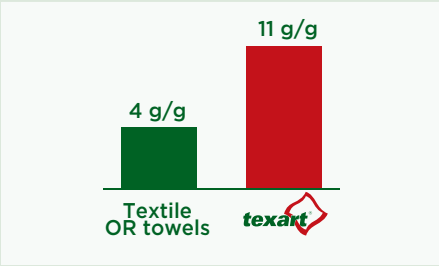
ABSORPTION CAPACITY

Acc. EN1644-1



Evaluates the water absorption capacity by difference of mass before and after water immersion and draining without compression.

Acc. EN1644-2



Evaluates the water retention capacity by difference of mass before and after water immersion and draining with compression.

Conformability

Excellent malleability and conformability. Easy to fold and unfold in dry or wet state.

Resistant

Functional dry and wet high strength, which is not damaged by wringing.

No loose threads

Nonwoven means no threads and increased safety.
Cotton gauze may expose threads with consequent danger of loose threads being left in the body.

Low bioburden

Automatic production process in a controlled area results in a much lower bioburden product. Textile towels includes manual handling, namely sewing one by one with thread commonly contaminated with optical brightener.

Rapid wicking

Spunlace nonwoven materials present rapid absorbency.
In less than 2 seconds Texart is completely wet.

Chemical testing

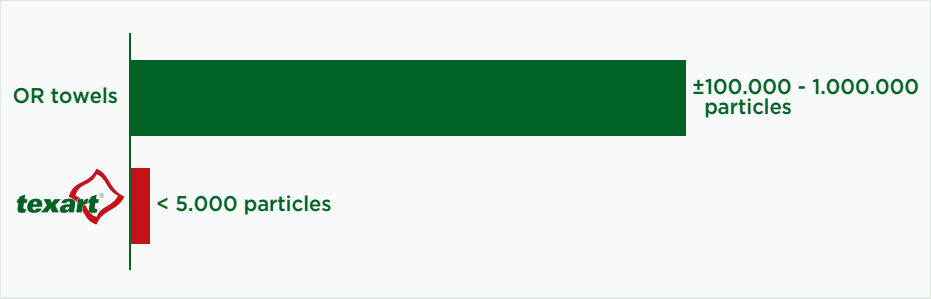
Neutral pH.
Stability colour testing performed in green and blue OR towels.
Water and non polar substances extraction testing control.

Low lint and no fraying

Linting consists on the release of fibre fragments and particles during use.
This test counts all particles capable of carrying microorganisms.
Texart presents much lower linting when compared with gauze swabs.

RELEASE OF PARTICLES - DRY LINTING

Acc. EN1644-1 and ISO9073-10



Product requirements	Group standard	TEXART comply? No	Yes
Test methods for nonwoven compresses for medical use - Part 1 Nonwovens used in the manufature of compresses.	EN 1644-1:1997		✓
Test methods for nonwoven compresses for medical use - Part 2: Finished compresses.	EN 1644-2:2000		✓

	Performance requirements	Product standard	TEXART comply? No	Yes
	Weight	ISO 9073-1		✓
	Conformability	EN1644-2		✓
ABSORPTION	Liquid Absorbency time	EN1644-1 / ISO9073-6		✓
ABSORPTION	Liquid Absorptive capacity	EN1644-1 / ISO9073-6		✓
ABSORPTION	Absorbent capacity	EN1644-2		✓
ABSORPTION	Rate of absorption	EN1644-2		✓
RESISTANCE	Dry Constructional Strength	EN1644-2		✓
RESISTANCE	Wet Constructional Strength	EN1644-2		✓
RESISTANCE	Dry bursting strength	EN1644-2		✓
RESISTANCE	Wet bursting strength	EN1644-2		✓
RESISTANCE	Dry Tensile strength	ISO 9073-3		✓
RESISTANCE	Dry Extension at break	ISO 9073-3		✓
RESISTANCE	Wet Tensile strength	ISO 9073-3		✓
RESISTANCE	Wet Extension at break	ISO 9073-3		✓
LINTING	Wet linting	EN1644-2		✓
LINTING	Dry linting	EN1644-2 / ISO9073-10		✓
CHEMICAL	Water soluble substances	EN1644-1		✓
CHEMICAL	Fluorescence	EN1644-1		✓
CHEMICAL	Acidity/Alkalinity aqueous extract	EN1644-1		✓
CHEMICAL	Non-polar soluble substances (Ether)	EN1644-1		✓
CHEMICAL	Surface-active substances	EN1644-1		✓

Standards and regulations

Medical devices and general requirements	Product standard	TEXART comply? No	Yes
Clinical evaluation of medical devices	MEDDEV 2.7.1.		✓
Risk management of medical devices	EN ISO 14971:2019		✓
Information supplied by the manufacturer of medical devices	EN 1041:2008 + A1:2013		✓
Symbols to be used with medical device labels, labelling and information to be supplied	ISO 15223-1:2016		✓
REACH Regulation	(EC) 1907/2006		✓

Biological Safety requirements	Group standard	TEXART comply? No	Yes
Biological evaluation within a risk management process	EN ISO10993-1:2020		✓
Chemical characterization of materials: Quantification of leachable and identification of extractable substances	EN ISO10993-18:2020		✓

Sterilization Validation	Process standard	TEXART comply? No	Yes
Sterilization of medical devices- Microbiological methods-Part 1: Determination of a population of microorganisms on products	EN ISO11737-1:2018		✓
Sterilization of health-care products- Ethylene oxide- Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 11135:2014/A1:2019		✓
Cleanrooms – Biocontamination control	EN ISO 14698-1:2003		✓
Cleanrooms–Classification for air cleanliness by particle concentration	ISO 14644-1:2015		✓
Cleanrooms and associated controlled environments — Part 5: Operations	ISO 14644-5:2004		✓
Standard Guide fo accelerated aging of sterile barrier systems for medical devices	ASTM F1980-16		✓

Quality management systems	Basic standard	TEXART comply? No	Yes
Medical devices – Requirements for regulatory purposes	EN ISO 13485:2016		✓

Presentations & sizes

REF	Size	Color	Sterile	Double pack + control tag	Pcs./ peel pack	Pcs./ Bag	Pcs./ Sh. box	Pcs./ Transp. carton
4467-002	45 x 45 cm	Blue / Azul				140		140
4465-001	45 x 60 cm	White / Branco				90		90
4466-001	45 x 60 cm	Green / Verde				90		90
4467-001	45 x 60 cm	Blue / Azul				90		90
4465-502	45 x 60 cm	White / Branco	X		2		120	240
4466-502	45 x 60 cm	Green / Verde	X		2		120	240
4467-502	45 x 60 cm	Blue / Azul	X		2		120	240
4465-802	45 x 60cm	White/Branco	X	X	2		80	160
4466-802	45 x 60cm	Green/Verde	X	X	2		80	160
4467-802	45 x 60cm	Blue/Azul	X	X	2		80	160

All REFs with X-Ray contrast thread.

Meets all requirements for optimal OR-Towel/Procedure towel

- ✓ *Highly absorbent.*
- ✓ *Rapid wicking.*
- ✓ *Very low lint - Does not shed significant quantities of fibers or particles during use.*
- ✓ *No loose threads.*
- ✓ *No toxic substances.*
- ✓ *Functional dry and wet strength.*
- ✓ *High wet strength, that it is not damaged by wringing.*
- ✓ *Soft and conformable both wet and dry.*
- ✓ *X-Ray detectable.*
- ✓ *Ease of folding and unfolding.*
- ✓ *Sterilizable by steam and ethylene oxide.*

Bastos Viegas,s.a.

Av. da Fábrica, 298. 4560-164 Guilhufe, Penafiel - Portugal - Tel.: 255 729 500 - geral@bastosviegas.com - www.bastosviegas.com

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