texart® T

O.R. towels

Toalha de bloco operatório
Champ de bordure
Op-handtuch
Ok handdoek
Tovagliette assorbenti
Toalla para bloque operatório
Operationshandduk

Introducing texart

Texart is a product that gathers some of the best technologies used in the medical area. It consists of spunlace non-woven 70% viscose and 30% polyester widely used in medical swabs and a textile net bonded together by ultrasonic. This combination results in a very low lint product with functional resistance in both dry and wet state, excellent softness and enhanced absorption properties.

Sizes and presentation

- 45x60cm.
- White, blue and green colour.
- Sterilizable by steam or ethylene oxide.

Composition

- Non-woven spunlace 70% viscose and 30% polyester.
- Textile net made of polyamide and polyester.
- X-Ray thread made of polypropylene and polyester with 60% barium sulphate.

Medically known raw materials

- Texart is made from spunlace non-woven, commonly used in non-woven swabs, and textile fibres also used in many other medical devices. Spunlace is a non-woven technology involving water jets. No chemicals or binders are used on the manufacturing process of Texart.

Consistent quality made in europe

- Texart is 100 % manufactured in the E.U.

According with EU regulations and international standard

- Biological Evaluation of medical devices according with ISO 10993.
- Risk Management of medical devices according with EN ISO 14971.
- Clinical evaluation of medical devices according with MEDDEV 2.7.1.
- Related product specifications (see Table, last page).
- EC Certificate of Conformity under 93/42/EEC.
- Compliance with Registration, Evaluation, Authorization and Restriction of Chemicals – REACH Regulation.

Main features

Characteristics

- Non-woven Spunlace: low lint product, without any binder and according with EN1644.
- Textile net: produces a shrinking effect that increases very much resistance and absorption capacity of the product. It becomes very soft and comfortable, keeping the spongy feeling even when completely wet.

X-ray thread

- Although the vast majority of OR-Towels/Procedure Towels available in the market do not have radiopaque element, all Texart OR-Towels have x-ray thread for extra security in the OR-Theatre.
- X-Ray thread is phthalate free and for complete safety is knitted into the textile net and ultrasonically bonded together with the non-woven.

Meet safety and toxicological requirements

- Latex Free.
- PVC Free.
- Phthalates Free.
- Colophony and colophony derivatives Free.
- Raw materials of animal or human origin Free.
- Chlorinated polymers Free.
- Bisphenol A (BPA) Free.
- Alternative plasticizers, such as terephthalates or trimellitates Free.
- Heavy metals Free.
- Antimicrobial additives Free.
- No toxic substances.

Environmentally friendly & Disposability

- Non-woven is environmental friendly and protects valuable natural resources.
- In contrast cotton production involves significant quantities of water, a scarce natural resource and big quantities of harmful environmental substances such as fertilizers and pesticides.
- After use Texart should be incinerated with a consequent energy recovery through heat generation.

Single-use

- Single-use guarantee patient safety since the devices are used for only one patient during one surgery, avoiding cross-contamination and risk of hospital acquired infections.
- Furthermore there are no hidden costs such as re-sterilizing and re-packaging.

Technical specifications

We have adopted applicable test methods of European Norm 1644 "Test methods for non-woven compresses for medical use"

Highly absorbent

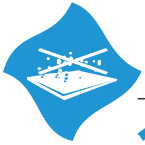
- Spunlace non-woven is known for its high absorption capacity. This is further enhanced by the shrinking effect produced by the textile net. Texart OR-Towel presents much higher values when compared with standard textile OR-Towel.

COMPARISON OF TEXART OR-TOWEL WITH TEXTILE OR-TOWEL.

	Test method	Textart OR-towel	OR-towel (standard/textile)
Absorbent capacity	EN1644-2 (Evaluates the water retention capacity by difference of mass before and after water immersion, draining with compression).	11 g/g	4 g/g
Liquid Absorptive capacity	EN1644-1 and ISO 9073-6 (Evaluates the water absorption capacity by difference of mass before and after water immersion and draining without compression).	980%	320%

Rapid wicking

- Spunlace non-woven is known for rapid absorbency. In less than 2 seconds Texart OR-Towel stays completely wet.

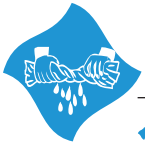


Low lint and no fraying

- Linting is defined as the release of fibre fragments and other particles during handling and use. This test counts all particles with a size range considered to be capable of carrying microorganisms. Low linting is clearly one of the biggest advantages of using non-woven spunlace materials when comparing to cotton gauze.

COMPARISON OF TEXART OR-TOWEL WITH TEXTILE OR-TOWEL

	Test method	Textart OR-towel	OR-towel (standard/textile)
Dry linting	EN1644-2 and ISO9073-10.	0-5.000 particles	> 60.000 particles



Functional dry and wet strength

- Texart presents high wet strength which is not damaged by wringing.

Excellent conformability and malleability

- Conformable.
- Ease of folding and unfolding.

Safe and very comfortable

- Soft.
- Non-woven construction. Absence of loose threads.
- No sewing line (commonly contaminated with optical brightener).

Chemical testing

- pH: neutral.
- Colour will not bleed: Stability testing has been performed in green and blue OR-Towel.
- Other chemical analysis (e.g. ether and water soluble substances): As EN1644 does not refer to any limits, internally we adapt applicable requirements adopted in the EN 14079 for cotton gauze swabs which are historically used and accepted by healthcare market.

Low bioburden

- Manufacturing process is automatic with no handling.
- Furthermore these are controlled environments with regular microbiology control.

References
EN 1644-1 Test methods for non-woven compresses for medical use - Part 1 Non-wovens used in the manufature of compresses. 1997 (CEN)
EN 1644-2 Test methods for non-woven compresses for medical use - Part 2: Finished compresses. 2000. (CEN)
Thomas, S. Observations upon a new family of surgical absorbents. July 2015.

Applicable standards and regulations

Performance Requirements	Product standard	Does TEXART comply? No	Yes
Weight	ISO 9073-1		✓
Liquid Absorbency time	EN1644-1 / ISO9073-6		✓
Liquid Absorptive capacity	EN1644-1 / ISO9073-6		✓
Water soluble substances	EN1644-1		✓
Fluorescence	EN1644-1		✓
Acidity/Alkalinity aqueous extract	EN1644-1		✓
Non-polar soluble substances	EN1644-1		✓
Surface-active substances	EN1644-1		✓
Absorbent capacity	EN1644-2		✓
Rate of absorption	EN1644-2		✓
Dry Constructional Strength	EN1644-2		✓
Wet Constructional Strength	EN1644-2		✓
Dry bursting strength	EN1644-2		✓
Wet bursting strength	EN1644-2		✓
Conformability	EN1644-2		✓
Wet linting	EN1644-2		✓
Dry linting	EN1644-2 / ISO9073-10		✓
Free Swell Absorption Capacity	EN13726-1		✓
Dry Tensile strength	ISO 9073-3		✓
Dry Extension at break	ISO 9073-3		✓
Wet Tensile strength	ISO 9073-3		✓
Wet Extension at break	ISO 9073-3		✓

Performance Requirements	Group standard	Does TEXART comply? No	Yes
Cytotoxicity	ISO10993-5		✓
Chemical characterization of materials: Quantification of leachable and identification of extractable substances	ISO10993-18		✓
Biological evaluation within a risk management process	ISO10993-1		✓

EU Regulations	Product standard	Does TEXART comply? No	Yes
EC Certificate	Directive 93/42/EEC		✓
Clinical evaluation of medical devices	MEDDEV 2.7.1.		✓
Risk Management of medical devices	EN ISO 14971:2012		✓
Information supplied by the manufacturer of medical devices	EN 1041:2008 + A1:2013		✓
Symbols for use in the labelling of medical devices	EN 980:2008		✓
Symbols to be used with medical device labels, labelling and information to be supplied	ISO 15223-1:2012		✓
Medical devices – Recognized essential principles of safety and performance of medical devices-Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards	ISO 16142-1:2016		✓
REACH Regulation	(EC) 1907/2006		✓

Sterilization Validation	Process standard	Does TEXART comply? No	Yes
Sterilization of medical devices- Microbiological methods-Part 1: Determination of a population of microorganisms on products	EN ISO11737-1:2006/AC:2009		✓
Sterilization of health-care products- Ethylene oxide- Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO 11135:2014		✓
Sterilization of health care products- Moist heat- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO 17665-1:2006		✓

Quality management systems	Basic standard	Does TEXART comply? No	Yes
Quality management systems – Requirements	EN ISO 9001:2008		✓
Medical devices – Requirements for regulatory purposes	EN ISO 13485:2012		✓

REFERENCES
EN 1644-1 Test methods for non-woven compresses for medical use - Part 1 Non-wovens used in the manufature of compresses. 1997 (CEN)
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Presentations & sizes

REF	Size	Color	Sterile	Double pack + control tag	Pcs./ peel pack	Pcs./ Transp. carton
4465-001	45x60cm	White			-	90
4466-001	45x60cm	Green			-	90
4465-502	45x60cm	White	X		2	240
4466-502	45x60cm	Green	X		2	240
4465-802	45x60cm	White	X	X	2	160
4466-802	45x60cm	Green	X	X	2	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.*

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