



## Swabs / Abdominal swabs

Compressas / Compressas operatórias Compresses / Compresses abdominales Kompresse / Bauchtuche Kompres / Buikkompres Compressa / Compressa addominale Compresa / Compresa de vientre Tork / Bukduk



Textart is essentially a reinforced non-woven swab, that combines woven and non-woven technologies in a single product.

It consists in two layers of Spunlace nonwoven, widely used on the medical market, and a textile net in between. The three layers are sealed together by ultrasonics.



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

Texart is a medical fabric that combines the best of woven and non-woven 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. (2015)

## Composition



Spunlace non-woven 70% viscose and 30% polyester.

Polyamide/Polyester textile net.

X-ray contrast thread made of polypropylene and polyester with 60% Barium Sulphate content.

### Known raw materials



Spunlace is a technology used in the production of non wovens involving the use of very high pressure water jets without the use of any binders or any other chemicals. The textile net is done with fibers used for long time in many other medical devices, but specialy approved for this specific products.

# Consistent quality



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

## Sterilizable



Sterilizable by steam or ethylene oxide.

### Presentations & sizes



Available in different sizes and presentations: -Sterile.

-Sterile with double pack

-Non sterile.

### Safety requirements



Meets all safety and toxicological requirements. Free of:

- -Latex -PVC
- -PVC -Alternative plasticizers (e.g. phthalates, trimellitates) -Colophony and colophony derivatives
- -Chlorine -Bisphenol A (BPA) -Heavy metals -Raw materials of animal origin -Toxic substances.

## Disposability



Texart swabs as disposable products should be incinerated after use. This will permit the consequent energy recovery throught heat generation.

## Single-use



For complete patient safety.

#### ACCORDING WITH UE 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.
- -Tested according EN 1644-1: Test methods for non-woven compresses for medical use:
  - -Part 1 Non-wovens used in the manufature of compresses. 1997 (CEN)
  - -Part 2: Finished compresses. 2000. (CEN).
- -EC Certificate of Conformity under 93/42/EEC.

-Compliance with Registration, Evaluation, Authorization and Restriction of Chemicals-REACH Regulation.



## **Highly absorbent**

Spunlace non-woven is known for its absorption capacity. This is further enhanced by the shrinking effect produced by the textile net. Texart swabs and abdominal swabs present higher absorption values when compared with gauze swabs.

#### **ABSORPTION CAPACITY**



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



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

Acc. EN13726-1



after 30 minutes of immersion at 37°C without any compression.

## 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.

#### **RELEASE OF PARTICLES - DRY LINTING**



### Rapid wicking



Spunlace non-woven is known for rapid absorbency. In less than 2 seconds Texart swabs/abdominal swab stay completely wet. (EN1644-2)

## Soft



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

## No loose threads



Non-woven means no threads and increased safety.

Cotton gauze may expose threads with consequent danger of loose threads being left in the body.

Unlike swabs/abdominal swabs in cotton gauze, Texart swabs/abdominal swabs do not use sewing line, commonly contaminated with optical brightener.

## X-Ray thread



X-Ray thread is phthalate free and for complete safety is knitted into the textile net and ultrasonically bonded together with the non-woven.

# Functional dry & wet strength



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

## Conformability



Texart has an excellent malleability and conformability.It is easy to fold and unfold in dry or wet state

## Low bioburden



Production process from roll form to finished/folded swab is fully automated without handling. Production takes place in a controled area. The finished products has therefore a much lower bioburden than the equivalent cotton swabs/abdominal swabs sewn one by one.



pri. neutrai

-Colour will not bleed: Stability testing has been performed in green swabs.

-Other chemical analysis (see chart next page): Tests done accordingly to EN 1644 observing the limits of the EN 14079 for cotton gauze swabs.

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

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

# Applicable standards and regulations

EU Regulations	Product standard	Does TEXAI No	RT comply? Yes
EC Certificate	Directive 93/42/EEC		$\checkmark$
Clinical evaluation of medical devices	MEDDEV 2.7.1.		$\checkmark$
Risk Management of medical devices	EN ISO 14971:2012		$\checkmark$
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		$\checkmark$
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		$\checkmark$
Charilization Velidation	Due and a standard	Does TEXA	RT comply?

Sterilization Validation	Process standard	Does TEXAF No	T comply? 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 TEXAI No	RT comply? Yes
Quality management systems – Requirements	EN ISO 9001:2008		$\checkmark$
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) EN 1644-2 Test methods for non-woven compresses for medical use - Part 2: Finished compresses. 2000. (CEN) Thomas, 5. Observations upon a new family of surgical absorbents. July 2015.

## **Presentations & sizes**

REF	Size	Color	Таре	Sterile	Double pack + control tag	Pcs./ peel pack	Pcs./ Bag	Pcs./ Sh. box	Pcs./ Transp. carton
4398-502	10x10cm	White		Х		5	-	900	3.600
4398 <del>-</del> 802	10x10cm	White		Х	Х	5	-	540	2.160
4398-002	10x10cm	White				-	200	-	2.000
4398 <b>-</b> 503	10x20cm	White		Х		5	-	450	1.800
4398-803	10x20cm	White		Х	Х	5	-	300	1.200
4398-003	10x20cm	White				-	100	-	1.000
4398 <b>-</b> 504	10x40cm	White		Х		5	-	240	960
4398-804	10x40cm	White		Х	Х	5	-	300	600
4398 <b>-</b> 004	10x40cm	White				-	100	-	1.000
4398-501	10x60cm	White		Х		5	-	140	560
4398 <del>-</del> 801	10x60cm	White		Х	Х	5	-	120	480
4398-001	10x60cm	White				-	100	-	800
4398-505	20x40cm	White		Х		5	-	300	600
4398 <b>-</b> 805	20x40cm	White		Х	Х	5	-	240	480
4398-005	20x40cm	White				-	75	-	600
4398-506	30x45cm	White		Х		5	-	180	360
4398-806	30x45cm	White		Х	Х	5	-	150	300
4398-006	30x45cm	White				-	165	-	165
4398-507	45x45cm	White		Х		5	-	90	180
4398-807	45x45cm	White		Х	Х	5	-	90	180
4398-007	45x45cm	White					110		110
4398-508	45x45cm	White	Х	Х		5	-	90	180
4398-808	45x45cm	White	Х	Х	Х	5	-	90	180
4398-008	45x45cm	White	Х			-	110	-	110
4398-509	45x70cm	White		Х		2	-	60	120
4398-809	45x70cm	White		Х	Х	2		50	100
4398-009	45x70cm	White				-	75	-	75
4398-606	30x45cm	Green		Х		5	-	180	360
4398-906	30x45cm	Green		Х	Х	5		150	300
4398-106	30x45cm	Green				-	165	-	165
4398-607	45x45cm	Green		Х		5		90	180
4398-907	45x45cm	Green		Х	Х	5	-	90	180
4398-107	45x45cm	Green				-	110	-	110
4398-608	45x45cm	Green	Х	Х		5	-	90	180
4398-908	45x45cm	Green	Х	Х	Х	5	-	90	180
4398-108	45x45cm	Green	Х			-	110	-	110
4398-609	45x70cm	Green		X		2	-	60	120
4398-909	45x70cm	Green		X	X	2	-	50	100
4398-109	45x70cm	Green				-	75	-	75

All REFs with X-Ray contrast thread.

# Meets all requirements for optimal abdominal swabs

- ✓ 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.

