



## Swabs/Abdominal swabs

#### Compressas/Compressas operatórias

- B Kompressen/Bauchtuche
- tompres/Buikkompres
- Compressa/Compressa addominale
- Compresa/Compresa de vientre
- SV Kompress/Bukduk
- Пампони/Коремни тампони
- IR Vatice/Upijajuće vatice
- Brišní roušky
- Servietter/Abdominalservietter

- Tampoonid/Kõhutampoonid
   Harsotaitokset/Vatsan sideharso
   Τολύπια/Κοιλιακά τολύπια
- Törlők/Hasi törlők
- Salvetes/Vēdera dobuma salvetes
- Tamponai/Tamponai pilvui
- PL Kompresy/Kompresy do jamy brzusznej
- Ro Tampoane/Tampoane abdominale
- S Tampóny/Abdominálne tampóny
- SD Zloženci/Trebušne komprese



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.



## SWABS / ABDOMINAL SWABS

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 greately 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% polvester.

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.

#### **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.

#### Disposability

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

#### **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.

## **Sterilizable**



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

#### Safetv requirements

Absence of

-Toxic substances

Sinale-use

- -Alternative plasticizers
- (e.g. phthalates, trimellitates) -Chlorine
- -Colophony and derivatives -Animal origin substances
- -Heavy metals

Sterilizable by ethylene oxide.



#### **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 difference of mass before and after water immersion and draining with compression.

#### Acc. EN13726-1



Evaluates the total absorptive capacity after 30 minutes of immersion at 37°C (without any compression).



-Bisphenol A

(BPA)

#### Conformability

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

#### 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.

#### **Rapid wicking**



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

#### Low lint and no fraying

### Resistant



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

#### Low bioburden



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

## **Chemical testing**



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

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



Product requirements	Group standard	TEXART No	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		<ul> <li>Image: A second s</li></ul>
	Conformability	EN1644-2		$\checkmark$
	Liquid Absorbency time	EN1644-1 / ISO9073-6		$\checkmark$
NO	Liquid Absorptive capacity	EN1644-1 / ISO9073-6		$\checkmark$
ORPT	Absorbent capacity	EN1644-2		$\checkmark$
ABS	Rate of absorption	EN1644-2		$\checkmark$
	Free Swell Absorption Capacity	EN13726-1		$\checkmark$
	Dry Constructional Strength	EN1644-2		$\checkmark$
	Wet Constructional Strength	EN1644-2		$\checkmark$
ESISTANCE	Dry bursting strength	EN1644-2		$\checkmark$
	Wet bursting strength	EN1644-2		$\checkmark$
	Dry Tensile strength	ISO 9073-3		$\checkmark$
œ	Dry Extension at break	ISO 9073-3		$\checkmark$
	Wet Tensile strength	ISO 9073-3		$\checkmark$
	Wet Extension at break	ISO 9073-3		$\checkmark$
ĐNI.	Wet linting	EN1644-2		$\checkmark$
LINT	Dry linting	EN1644-2 / ISO9073-10		$\checkmark$
	Water soluble substances	EN1644-1		$\checkmark$
CHEMICAL	Fluorescence	EN1644-1		$\checkmark$
	Acidity/Alkalinity aqueous extract	EN1644-1		$\checkmark$
	Non-polar soluble substances (Ether)	EN1644-1		$\checkmark$
	Surface-active substances	EN1644-1		$\checkmark$

# Standards and regulations

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

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		$\checkmark$	
Cleanrooms-Classification for air cleanliness by particle concentration	ISO 14644-1:2015		~	
Cleanrooms and associated controlled environments — Part 5: Operations	ISO 14644-5:2004		$\checkmark$	
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	Description	Таре	Sterile	Double pack + control tag	Pcs./ peel pack	Pcs./ Bag	Pcs./ Sh. box	Pcs./ Transp. carton
4398-002	10x10cm	White	Swab					200		2.000
4398-502	10x10cm	White	Swab		Х		5		900	3.600
4398-802	10x10cm	White	Swab		Х	Х	5		540	2.160
4398-003	10x20cm	White	Swab					100		1.000
4398-503	10x20cm	White	Swab		Х		5		450	1.800
4398-803	10x20cm	White	Swab		Х	Х	5		300	1.200
4398-004	10x40cm	White	Abd. swab					100		1.000
4398-504	10x40cm	White	Abd. swab		Х		5		240	960
4398-804	10x40cm	White	Abd. swab		Х	Х	5		300	600
4398-001	10x60cm	White	Abd. swab					100		800
4398-501	10x60cm	White	Abd. swab		Х		5		140	560
4398-801	10x60cm	White	Abd. swab		Х	Х	5		120	480
4398-016	20x15cm	White	Abd. swab					100		1.000
4398-516	20x15cm	White	Abd. swab		Х		5		300	600
4398-005	20x40cm	White	Abd. swab					75		600
4398-505	20x40cm	White	Abd. swab		Х		5		270	540
4398-515	20x40cm	White	Abd. swab	Х	Х		5		300	600
4398-805	20x40cm	White	Abd. swab		Х	Х	5		225	450
4398-006	30x45cm	White	Abd. swab					165		165
4398-106	30x45cm	Green	Abd. swab					165		165
4398-506	30x45cm	White	Abd. swab		Х		5		180	360
4398-606	30x45cm	Green	Abd. swab		Х		5		180	360
4398-806	30x45cm	White	Abd. swab		Х	Х	5		150	300
4398-906	30x45cm	Green	Abd. swab		Х	Х	5		150	300
4398-007	45x45cm	White	Abd. swab					110		110
4398-107	45x45cm	Green	Abd. swab					110		110
4398-108	45x45cm	Green	Abd. swab	Х				110		110
4398-910	45x45cm	Green	Abd. swab		Х	Х	2		56	112
4398-008	45x45cm	White	Abd. swab	Х				110		110
4398-507	45x45cm	White	Abd. swab		Х		5		90	180
4398-607	45x45cm	Green	Abd, swab		Х		5		90	180
4398-807	45x45cm	White	Abd. swab		X	Х	5		90	180
4398-907	45x45cm	Green	Abd, swab		Х	Х	5		90	180
4398-508	45x45cm	White	Abd. swab	Х	X		5		90	180
4398-608	45x45cm	Green	Abd. swab	X	X		5		90	180
4398-808	45x45cm	White	Abd. swab	X	X	Х	5		90	180
4398-908	45x45cm	Green	Abd, swab	Х	Х	Х	5		90	180
4398-009	45x70cm	White	Abd. swab					75		75
4398-010	45x70cm	White	Abd. swab	Х				75		75
4398-109	45x70cm	Green	Abd swab					75		75
4398-512	45x70cm	White	Abd. swab	X	Х		2		60	120
4398-810	45x70cm	White	Abd. swab	X _	X _	Х	2		50	100
4398-509	45x70cm	White	Abd. swab		X		2		60	120
4398-609	45x70cm	Green	Abd swab		X		2		60	120
4398-809	45x70cm	White	Abd. swab		X	Х	2		50	100
4398-909	45x70cm	Green	Abd. swab		X	X	2		50	100

All REFs with X-Ray contrast thread.

# Meets all requirements for optimal swabs/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 ethylene oxide.

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