



Abdominal swabs

Compressas operatórias
Compresses abdominales
Bauchtuche
Buikkompres
Compressa addominale
Compresa de vientre
Bukduk

**WITH PRE-WASHED
EFFECT**

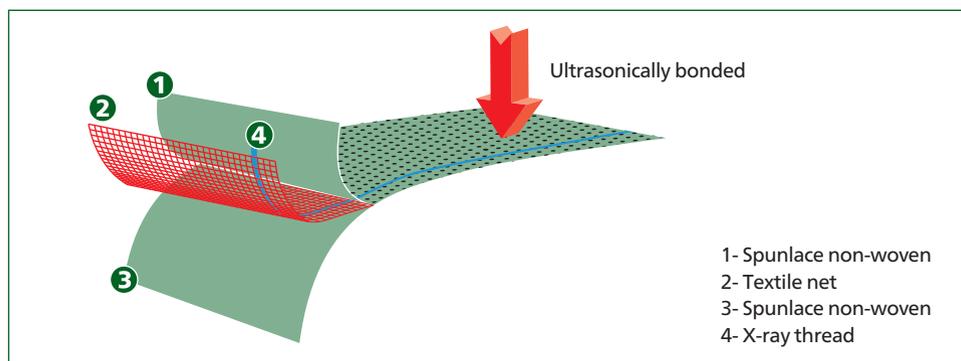


ABDOMINAL SWABS

Crepe like texture resembles the traditional pre-washed gauze but with higher absorption and minimum linting.

Texart 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 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.

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."

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

Disposability



Textart swabs as disposable products should be incinerated after use. This will permit the consequent energy recovery through 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 manufacture 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.





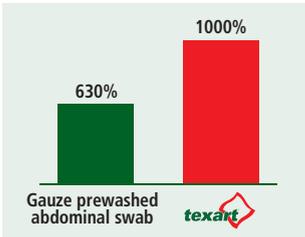
Highly absorbent



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

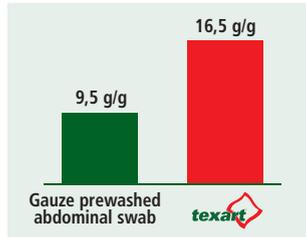
ABSORPTION CAPACITY

Acc. EN1644-1



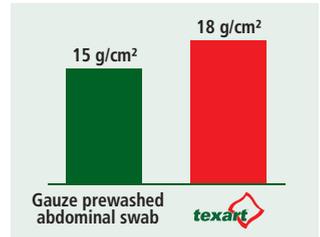
Evaluates the water absorption capacity by difference of mass before and after water immersion and draining without compression.

Acc. EN1644-2



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

Acc. EN13726-1



Evaluates the total absorptive capacity 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

Acc. EN1644-1 and ISO9073-10



Rapid wicking

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



Functional dry & wet strength

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



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.



Conformability

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



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



Low bioburden

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



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.



Chemical testing

-pH: neutral

-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 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		✓

Applicable standards and regulations

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 manufacture 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.

Presentations & sizes

REF	Size	Color	Tape	Sterile	Double pack + control tag	Pcs./ peel pack	Pcs./ Transp. carton
4395-001	30x45cm	White				-	210
4395-002	45x45cm	White				-	140
4395-003	45x70cm	White				-	90
4395-012	45x45cm	White	X			-	140
4396-001	30x45cm	Green				-	210
4396-002	45x45cm	Green				-	140
4396-003	45x70cm	Green				-	90
4396-012	45x45cm	Green	X			-	140
4395-501	30x45cm	White		X		5	360
4395-502	45x45cm	White		X		5	360
4395-503	45x70cm	White		X		1	150
4395-512	45x45cm	White	X	X		5	360
4396-501	30x45cm	Green		X		5	360
4396-502	45x45cm	Green		X		5	360
4396-503	45x70cm	Green		X		1	150
4396-512	45x45cm	Green	X	X		5	360
4395-801	30x45cm	White		X	X	5	360
4395-802	45x45cm	White		X	X	5	240
4395-803	45x70cm	White		X	X	1	100
4395-812	45x45cm	White	X	X	X	5	240
4396-801	30x45cm	Green		X	X	5	360
4396-802	45x45cm	Green		X	X	5	240
4396-803	45x70cm	Green		X	X	1	100
4396-812	45x45cm	Green	X	X	X	5	240

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.*