

PRODUCT SPECIFICATION		This document is the property of Tytex. The contents must not be disclosed to third parties without the expressed written consent from Tytex. Infringements in the above will result in prosecution.	
Product Name: Soft Support		Article no: 3246	Article version: 50
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 12. January 2020
		VERSION NO. 1.7	

1. SCOPE

Product to be worn as part of a two-piece reusable or disposable absorbent incontinence solution.

2. INTENDED USE

Textile fixation devices for fixating of i.e. a bandage or a pad, worn as normal underwear pants for alleviation of continence diseases or handi-cap.



Single Patient - multiple use

3. PICTURE



4. MATERIAL COMPOSITION

97 % Polyester, 3 % Elastane.

Products do not contain latex or natural rubber or pose any harmful human impact associated with its intended use.

Products do not contain human or animal tissue or extracts, prohibited azo-dye pigments, medical substances or phthalates.

The products are in compliance with REACH.

No chemicals added during treatment/finishing. Products may contain softening and antistatic agents up to 1.5 %.

The products are covered by Oeko-Tex Standard 100, class II



PRODUCT SPECIFICATION		This document is the property of Tytex. The contents must not be disclosed to third parties without the expressed written consent from Tytex. Infringements in the above will result in prosecution.	
Product Name: Soft Support		Article no: 3246	Article version: 50
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 12. January 2020
		VERSION NO. 1.7	

5. RECOMMENDED CARE

Washing at 60° C/ 140° F. in washing bag followed by gentle tumble-drying. Recommended symbols (EN 3758):



Best durability achieved at 60° C / 140° F washing.

Use of chlorine based bleach or chlorine based disinfection will decrease durability

6. EXPIRATION

Products have an expiry date of five years from the date of manufacturing



7. TRANSPORTATION, STORAGE AND WASTE HANDLING

Transportation and Storage:

No special requirements to temperature or humidity.

Preferable transport in sealed boxes on pallets with stretch wrapping.

Do not stack pallets on top of each other unless previously agreed.

Keep the products in a dry, well ventilated place and not exposed to direct sunlight, especially when original stretch wrapping has been removed from packaging.



Waste:

Products may be disposed with regular household waste



8. CLASSIFICATION

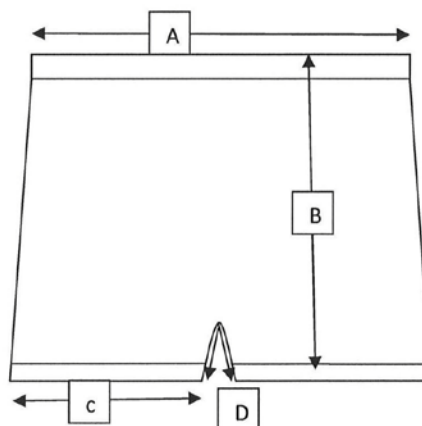
Products are Medical Devices Class I, None Sterile

Design and manufacturing in accordance with Medical Device Regulation 2017/745 and FDA requirements.

GMDN Code: 35120

FDA Code and Listing: EYQ E434956

9. METTHOD AF MEASURMENT



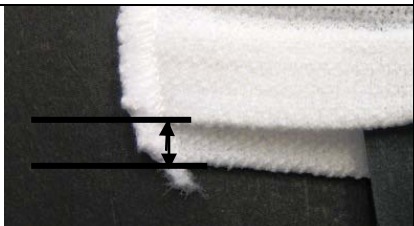
PRODUCT SPECIFICATION		This document is the property of Tytex. The contents must not be disclosed to third parties without the expressed written consent from Tytex. Infringements in the above will result in prosecution.	
Product Name: Soft Support		Article no: 3246	Article version: 50
APPROVED BY TYTEX	APPROVED BY CUSTOMER	VALID FROM 12. January 2020	VERSION NO. 1.7

10. SIZE				
Parameter	Size		Size Colour	
Size	01	S	Yellow	
	03	M	Blue	
	05	L	Brown	
	07	XL	Green	
	09	XXL	Orange	
	11	XXXL	Grey	

11. TECHNICAL SPECIFICATIONS					
Parameter	Size	Unit	Target	Tolerance	Measurement Method
A Waist, relaxed	01	cm	23,5	± 1,5	Ruler
	03		25,5	± 1,5	
	05		26,5	± 1,5	
	07		27,5	± 1,5	
	09		29,0	± 1,5	
	11		31,0	± 2,0	
B Height, relaxed	01	cm	21,0	± 1,5	Ruler
	03		22,0	± 1,5	
	05		23,5	± 1,5	
	07		25,5	± 1,5	
	09		27,0	± 1,5	
	11		29,0	± 1,5	
D Crotch width	01	cm	7,0	± 2,0	Ruler
	03		8,0	± 2,0	
	05		8,5	± 2,0	
	07		9,5	± 2,0	
	09		10,5	± 2,0	
	11		11,5	± 2,0	
A Waist, 1800 g load	01	cm	51,0	± 2,5	Frame
	03		52,5	± 2,5	
	05		56,0	± 2,5	
	07		59,0	± 2,5	
	09		69,0	± 2,5	
	11		78,0	± 3,0	
C Leg, 1000 g load	01	cm	28,5	± 2,0	Frame
	03		30,0	± 2,0	
	05		32,5	± 2,0	
	07		34,5	± 2,0	
	09		38,5	± 2,0	
	11		43,5	± 2,5	

PRODUCT SPECIFICATION			This document is the property of Tytex. The contents must not be disclosed to third parties without the expressed written consent from Tytex. Infringements in the above will result in prosecution.	
Product Name: Soft Support			Article no: 3246	Article version: 50
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 12. January 2020	VERSION NO. 1.7

11. TECHNICAL SPECIFICATIONS					
Parameter	Size	Unit	Target	Tolerance	Measurement Method
Weight	01	g	16,5	± 3,5	Scale
	03		17,5	± 3,5	
	05		18,5	± 3,5	
	07		19,0	± 3,5	
	09		23,0	± 3,5	
	11		26,0	± 3,5	

12. DESIGN PARAMETERS Not part of daily sampling routine for inspection and test.					
Parameter	Size	Unit	Target	Tolerance	Test method
A Waist, 500 g load	01	cm	33,5	± 1,5	On frame
	03		35,0	± 1,5	
	05		36,5	± 1,5	
	07		38,0	± 1,5	
	09		42,2	± 1,5	
	11		46,5	± 1,5	
C Leg, 200 g load	01	cm	19,0	± 1,5	On frame
	03		19,0	± 1,5	
	05		20,5	± 1,5	
	07		22,0	± 1,5	
	09		25,5	± 1,5	
	11		29,0	± 1,5	
Height, waistband	All	cm	1,7	± 0,5	Ruler
Leg displacement In crotch area. (Sewing)	All	cm	Max 0,5		
Bursting Strength	All	N	200	± 30	ASTM D 3787
Shrinkage after 1st washing*	All	%	5	± 2	Domestic washing
* Durability	All	Washes	50	± 20	Domestic washing

* Assuming proper washing temperature, chemicals and cycle times. (The test does not include the wear and tear of the product)

PRODUCT SPECIFICATION			This document is the property of Tytex. The contents must not be disclosed to third parties without the expressed written consent from Tytex. Infringements in the above will result in prosecution.	
Product Name: Soft Support			Article no: 3246	Article version: 50
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 12. January 2020	VERSION NO. 1.7

13. SIZE RECOMMENDATIONS

Size recommendations are to be used as a guide only. Other size parameters on product packaging may be used at customer discretion.

Size	Waist Measurement		Leg Circumference		Hip Measurement		Body weight	
	cm	Inches	cm / max	Inches	cm	Inches	Kg	Lbs.
01	60 - 90	23½ - 35½	40 - 55	15½ - 21½	75 - 95	29½ - 37½		
03	75 - 100	29½ - 39½	45 - 60	17½ - 23½	85 - 105	33½ - 41½		
05	85 - 110	33½ - 43½	50 - 65	19½ - 25½	90 - 110	35½ - 43½		
07	95 - 120	37½ - 47	55 - 70	21½ - 27½	100 - 120	39½ - 47		
09	105 - 140	41½ - 55	60 - 80	23½ - 31½	110 - 140	43½ - 55		
11	120 - 160		70 - 90		130 - 170			

14. Waist Band

Outside	Colour Stripe
Inside	Notning