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: Post-Op Bra, Anna		**Article no:** 3270	**Article version**: 6X
APPROVED BY TYTEX BLH	**APPROVED BY CUSTOMER**	**VALID FROM** 28. October 2021	**VERSION NO.** 1.4

1. SCOPE

Medical Device, class I, Non-sterile textile products for the weeks following breast surgery / radiotherapy and for the recovery period, when the skin is still tender and sensitive.

2. INTENDED USE

Fixation of a bandage or another medical device for post-surgical use and for comfortable wear for a maximum of wound and scar protection.

Single Patient - multiple use

3. PICTURE



4. MATERIAL COMPOSITION

Main fabric: 91% Polyamide, 9% 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

5. RECOMMENDED CARE

Washing up to 40º C / 104º F in washing bag followed by gentle tumble drying.
Close zipper before washing/drying.

Recommended symbols (EN 3758):



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

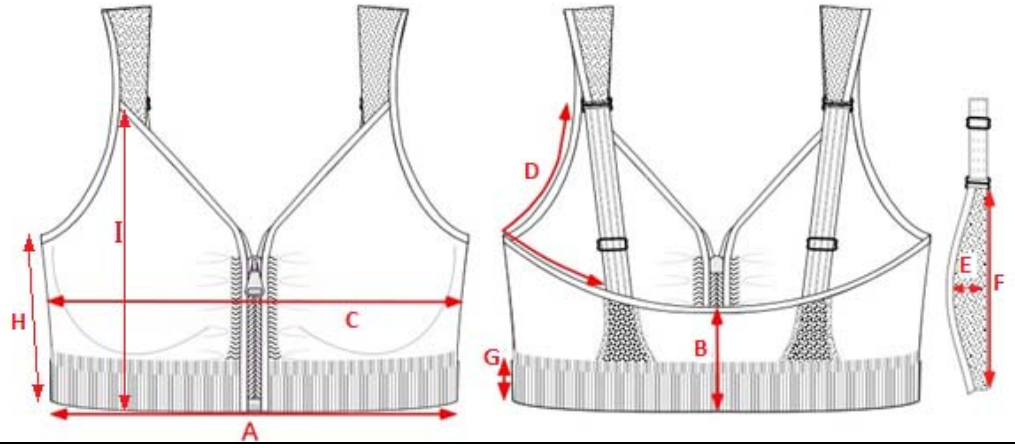
Products are Medical Devices Class I, None Sterile

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

GMDN Code:	10481
FDA Code and Listing	HEF E434962

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: Post-Op Bra, Anna		**Article no:** 3270	**Article version**: 6X
APPROVED BY TYTEX BLH	**APPROVED BY CUSTOMER**	**VALID FROM** 28. October 2021	**VERSION NO.** 1.4

9. METHOD OF MEASUREMENT



10. SIZE

Parameter	Size Code	Size	Size colour	
Size	01 03 05 07 09	S M L XL 2XL	White	

11. TECHNICAL SPECIFICATIONS

Parameter	Size	Unit	Target	Tolerance	Measurement method
A. Under bust, loose,	01 03 05 07 09	cm	26,0 28,0 30,0 32,0 34,5	± 1,5 ± 1,5 ± 1,5 ± 1,5 ± 1,5	Ruler
B. Height mid Back,	01 03 05 07 09	cm	8,0 8,5 9,0 9,5 10,0	± 1,0 ± 1,0 ± 1,0 ± 1,0 ± 1,0	Ruler
C. Body width	01 03 05 07 09	cm	25,0 27,0 29,0 31,5 34,0	± 2,0 ± 2,0 ± 2,0 ± 2,0 ± 2,0	Ruler
D. Arm opening	01 03 05 07 09	cm	20,0 20,5 21,0 22,0 23,0	± 2,0 ± 2,0 ± 2,0 ± 2,0 ± 2,0	Ruler

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: Post-Op Bra, Anna		**Article no:** 3270	**Article version**: 6X
APPROVED BY TYTEX BLH	**APPROVED BY CUSTOMER**	**VALID FROM** 28. October 2021	**VERSION NO.** 1.4

11. TECHNICAL SPECIFICATIONS

Parameter	Size	Unit	Target	Tolerance	Measurement method
Weight	01	g	46,0	± 4,0	Scale
	03		49,0	± 4,0	
	05		53,0	± 4,0	
	07		56,0	± 4,0	
	09		61,0	± 4,0	

12. TECHNICAL SPECIFICATIONS – Colours

Parameter	Size	Shade			Tolerance	Test method
Colour		White	Black	Tan		
Version		60	61	62		
Fastness to washing						
Staining	all	5	4-5	4-5	Min	ISO 105 C06
Change		5	5	5		
Fastness to rubbing						
Dry	all	5	5	5	Min	ISO 105- X12
Wet		5	5	5		
Fastness to light	all	N/A	5	5	Min	ISO 105-B02
Fastness to perspiration						
Change	all	5	5	5	Min	ISO 105-E04
Staining		4-5	5	5		

13. DESIGN PARAMETERS (not part of daily inspections and tests)

Parameter	Size	Unit	Target	Tolerance	Measurement method
E. Strap width	All	cm	3,0	± 0,5	Ruler
F. Strap loose	All	cm	16,5	± 1,5	Ruler
G. Under bust band height	All	cm	3,0	± 0,5	Ruler
H. Side height	01	cm	9,0	± 1,0	Ruler
	03		9,5	± 1,0	
	05		10,0	± 1,0	
	07		10,5	± 1,0	
	09		11,0	± 1,0	
I. Cup height	01	cm	18,0	± 1,0	Ruler
	03		19,0	± 1,0	
	05		20,5	± 1,0	
	07		22,0	± 1,0	
	09		23,0	± 1,0	
A. Under bust, 2200g	01	cm	39,5	± 2,0	Frame
	03		42,0	± 2,0	
	05		44,5	± 2,0	
	07		47,0	± 2,0	
	09		49,5	± 2,0	

13. DESIGN PARAMETERS (not part of daily inspections and tests)

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: Post-Op Bra, Anna		**Article no:** 3270	**Article version**: 6X
APPROVED BY TYTEX BLH	**APPROVED BY CUSTOMER**	**VALID FROM** 28. October 2021	**VERSION NO.** 1.4

Parameter	Size	Unit	Target	Tolerance	Measurement method
Shrinkage after 1st washing*	All	%	5	± 2	Domestic washing (40°C)
Durability*	All	washes	80	± 5	Domestic washing (40°C)
Bursting Strength	All	N	325	± 20	ASTM D 3787

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