


<b>PRODUCT SPECIFICATION</b>		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.	
<b>Product Name:</b> CarePocket		<b>Article no:</b> 0912	<b>Article version:</b> 50
<b>APPROVED BY TYTEX</b> 	<b>APPROVED BY CUSTOMER</b>	<b>VALID FROM</b> 21. February 2023	<b>VERSION NO.</b> 2.5

### 1. SCOPE

Product to be worn as part of a two-piece system for securely holding a urine bag in place for maximum security and support.

### 2. INTENDED USE

Medical device for fixating of a urine bag on a body part or limb of a human being.



Single Patient - multiple use

### 3. PICTURE



### 4. MATERIAL COMPOSITION

Main fabric: 80 % Polyester, 20 % 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



<b>PRODUCT SPECIFICATION</b>		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.	
<b>Product Name:</b> CarePocket		<b>Article no:</b> 0912	<b>Article version:</b> 50
<b>APPROVED BY TYTEX</b> 	<b>APPROVED BY CUSTOMER</b>	<b>VALID FROM</b> 21. February 2023	<b>VERSION NO.</b> 2.5

**5. RECOMMENDED CARE**

Washing up to 60° C / 140° F in washing bag followed by gentle tumble 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**

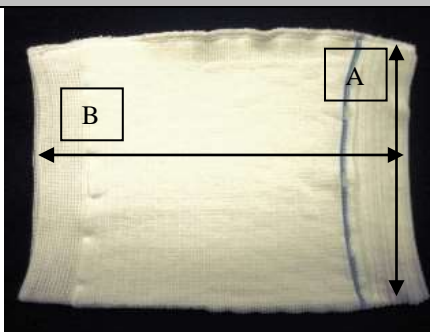
Products are Medical Devices Class I, None Sterile

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

GMDN Code: 37685

FDA Code and Listing: NNW E435024

**9. METHOD OF MEASUREMENT**



<b>PRODUCT SPECIFICATION</b>		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.	
<b>Product Name:</b> CarePocket		<b>Article no:</b> 0912	<b>Article version:</b> 50
APPROVED BY TYTEX	APPROVED BY CUSTOMER	VALID FROM	VERSION NO.
		21. February 2023	2.5

10. SIZE				
Parameter	Size	Unit	Size colour	
Size	01	S	Yellow	
	03	M	Blue	
	05	L	Brown	
	07	XL	Green	

11. TECHNICAL SPECIFICATIONS					
Parameter	Size	Unit	Target	Tolerance	Measurement method
A. Leg Relaxed	01	cm	9,0	± 2,5	Ruler
	03		13,0	± 2,5	
	05		15,5	± 2,5	
	07		17,5	± 2,5	
B. Height Relaxed	01	cm	21,0	± 2,0	Ruler
	03		21,0	± 2,0	
	05		21,0	± 2,0	
	07		21,0	± 2,0	
A. Leg 1200 g	01	cm	20,0	± 2,5	Frame
	03		27,0	± 2,5	
	05		32,0	± 2,5	
	07		36,5	± 2,5	
Weight	01	g	11,5	± 1,5	Scale
	03		16,5	± 1,5	
	05		20,0	± 1,5	
	07		22,5	± 1,5	

12. TECHNICAL SPECIFICATIONS (not part of daily inspections and tests)					
Parameter	Size	Unit	Target	Tolerance	Measurement method
A. Leg 200 g	01	cm	11,0	± 2,0	Frame
	03		16,0	± 2,0	
	05		19,0	± 2,0	
	07		21,5	± 2,0	
A. Leg 1800 g	01	cm	24,5	± 2,5	Frame
	03		33,0	± 2,5	
	05		37,5	± 2,5	
	07		42,5	± 2,5	
Shrinkage after 1st washing*	All	%	7	± 2	Domestic washing
Durability*	All	washes	25	± 5	Domestic washing

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

13. SIZE RECOMMENDATIONS <small>Size recommendations are to be used as a guide only.</small>					
Parameter	Size	Unit	Target	Unit	Target
Leg Circumference	01	cm	30-45	Inches	12,0-17,5
	03		45-65		17,5-25,5
	05		55-80		21,5-31,5
	07		65-90		25,5-35,5