

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: CarePocket Premium		Article no: 5080	Article version: 50
APPROVED BY TYTEX <i>Jhu</i>	APPROVED BY CUSTOMER	VALID FROM 08. February 2020	VERSION NO. 1.2

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



4. MATERIAL COMPOSITION
77% Polyester, 23% 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



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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

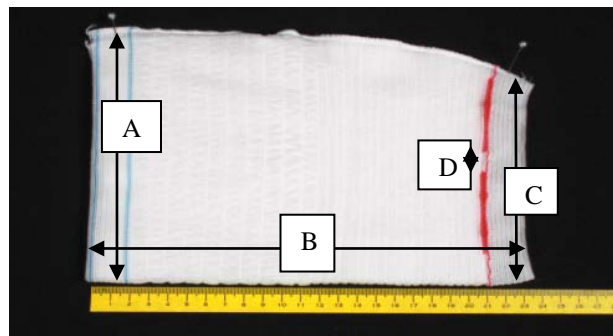
Products are Medical Devices Class I, None Sterile

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



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10. SIZE				
Parameter	Size Code	Size	Size colour	
Size	01	S	Yellow	
	02	S/M	Red	
	03	M	Blue	
	05	L	Brown	
	07	XL	Green	

11. TECHNICAL SPECIFICATIONS					
Parameter	Size	Unit	Target	Tolerance	Measurement method
A. Leg top relaxed	01	cm	12,0	± 1,5	Ruler
	02		15,0	± 1,5	
	03		17,0	± 1,5	
	05		20,0	± 1,5	
	07		23,0	± 1,5	
B. Height relaxed	01	cm	23,0	± 2,0	Ruler
	02		23,0	± 2,0	
	03		23,0	± 2,0	
	05		23,0	± 2,0	
	07		23,0	± 2,0	
A. Leg top 1800 g load	01	cm	18,0	± 2,0	Frame
	02		23,0	± 2,0	
	03		27,0	± 2,0	
	05		31,0	± 2,0	
	07		35,0	± 2,0	
Weight	01	g	10,5	± 2,0	Scale
	02		13,0	± 2,0	
	03		15,5	± 2,0	
	05		17,5	± 2,0	
	07		19,5	± 2,0	

12. DESIGN PARAMETERS (not part of daily inspections and tests)					
Parameter	Size	Unit	Target	Tolerance	Measurement method
A Leg top, 800 g load	01	cm	14,0	± 2,0	Frame
	02		18,0	± 2,0	
	03		21,0	± 2,0	
	05		25,0	± 2,0	
	07		29,0	± 2,0	
C Leg bottom, relaxed	01	cm	9,0	± 1,5	Scale
	02		12,0	± 1,5	
	03		14,0	± 1,5	
	05		16,0	± 1,5	
	07		19,0	± 1,5	

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

Parameter	Size	Unit	Target	Tolerance	Measurement method
C Leg bottom, 1200 g load	01	cm	18,0	± 2,0	Frame
	02		22,0	± 2,0	
	03		25,0	± 2,0	
	05		29,0	± 2,0	
	07		33,0	± 2,0	
D Hole 1000 g	All	cm	5,0	± 1,0	Frame
Shrinkage after 1st washing*	All	%	10	± 2	Domestic washing
Bursting Strength	All	N	225	± 20	ASTM D 3787
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

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

	Leg top Circumference		
Size	Cm		
01	25 – 33		
02	33 – 40		
03	40 – 50		
05	50 – 60		
07	60 – 70		