


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: LeggyFix		Article no: 0915	Article version: 54
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 28. November 2019
		VERSION NO. 1.9	

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



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: LeggyFix		Article no: 0915	Article version: 54
APPROVED BY TYTEX 	APPROVED BY CUSTOMER	VALID FROM 28. November 2019	VERSION NO. 1.9

<p>4. MATERIAL COMPOSITION 63 % Polyester, 37 % Elastane</p> <p>Products do not contain latex or natural rubber or pose any harmful human impact associated with its intended use.</p> <p>Products do not contain human or animal tissue or extracts, prohibited azo-dye pigments, medical substances or phthalates.</p> <p>Products do not pose any harmful impact associated with its intended use or application.</p> <p>The products are in compliance with REACH.</p> <p>No chemicals added during treatment/finishing. Products may contain softening and antistatic agents up to 1.5 %.</p> <p>The products are covered by Oeko-Tex Standard 100, class II</p>	  
<p>5. RECOMMENDED CARE Washing up to 60° C / 140° F in washing bag followed by gentle tumble drying.</p> <p>Recommended symbols (EN 3758):</p>  <p>Use of chlorine based bleach or chlorine based disinfection will decrease durability</p>	
<p>6. EXPIRATION Products have an expiry date of five years from the date of manufacturing.</p>	
<p>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.</p> <p>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.</p> <p>Waste: Products may be disposed with regular household waste</p>	 

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: LeggyFix		Article no: 0915	Article version: 54
APPROVED BY TYTEX	<i>Jhe</i>	APPROVED BY CUSTOMER	VALID FROM 28. November 2019
		VERSION NO. 1.9	

8. CLASSIFICATION

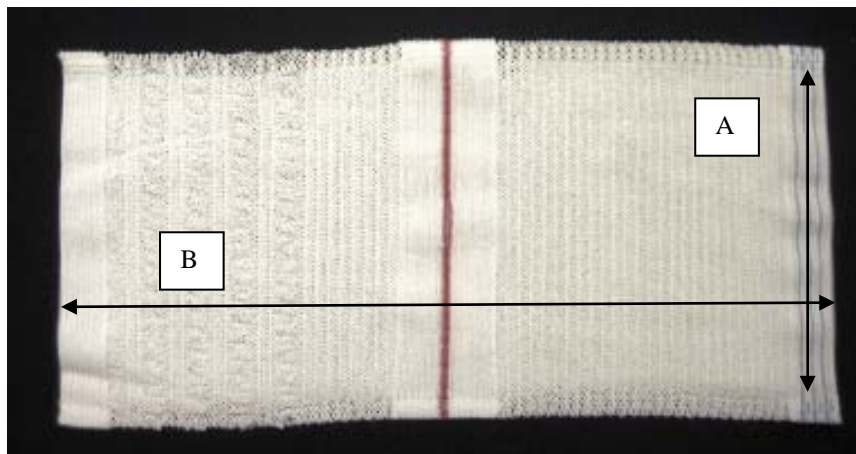
Products are Medical Devices Class I, None Sterile

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



10. SIZE

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

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: LeggyFix		Article no: 0915	Article version: 54
APPROVED BY TYTEX	APPROVED BY CUSTOMER	VALID FROM 28. November 2019	VERSION NO. 1.9

11. TECHNICAL SPECIFICATIONS					
Parameter	Size	Unit	Target	Tolerance	Test method
A. Leg relaxed	01	cm	10,0	± 2,0	Ruler
	02		13,5	± 2,0	
	03		17,0	± 2,0	
	05		20,0	± 2,0	
	07		24,5	± 2,0	
B. Height relaxed	01	cm	36,0	± 2,0	Ruler
	02		36,0	± 2,0	
	03		36,0	± 2,0	
	05		36,0	± 2,0	
	07		36,0	± 2,0	
Weight	01	g	12,8	± 2,0	Scale
	02		16,4	± 2,0	
	03		20,4	± 2,0	
	05		24,3	± 2,0	
	07		28,5	± 2,0	
A.Leg, 1800 g load	01	cm	24,0	± 2,0	Frame
	02		32,5	± 2,0	
	03		40,0	± 2,0	
	05		45,0	± 2,0	
	07		52,0	± 2,0	

12. TECHNICAL SPECIFICATIONS (not part of daily inspections and tests)					
Parameter	Size	Unit	Target	Tolerance	Test method
A. Leg, 800 g load	01	cm	16,5	± 2,0	Frame
	02		22,5	± 2,0	
	03		28,0	± 2,0	
	05		31,5	± 2,0	
	07		38,0	± 2,0	
Hole, 1000 g load	All	cm	8,5	± 1,0	Frame
Shrinkage after 1st washing*	All	%	10	± 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	25 - 33	Inches	10 - 13
	02		33 - 40		13 - 15½
	03		40 - 50		15½ - 19½
	05		50 - 60		19½ - 23½
	07		60 - 70		23½ - 27½