PROL Synthetic mesh fo	AFIX TECHNICAL DATASHEET or Pelvic Organ Prolapse (POP) – Abdominal approach

	MICROVAL							
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2	2. Device information							
2.1	Common name: Implant for Pelvic I	Floor reinforc	ement					
2.2	<u>Commercial name:</u> PROLAFIX impla	int						
2.3	Nomenclature code: GMDN 60842							
	EMDN P90020	)2 (polypropy	lene) / EMDN	P900205 (pol	yester)			
2.4	Class of medical device: IIb accordin	ng to Europea	n Directive 93	3/42/CEE (200	7/47/CE)			
	Notified Body number: 1639							E
	Date of first sale: 2004							
	Manufacturer: MICROVAL							
	Basic UDI-DI : 37004584DT004-PROLA62 Certificate No. : FR19-8184342							
		102						
2.5	<ul> <li><u>Device's description:</u></li> <li>These implants are macro</li> <li>Available in multiple size multifilament polyester).</li> </ul>	oporous mesh es and mater	nes to mechan ials (macropo	ically reinforc rous monofila	e native tissue iment polypro	es. opylene –star	ndard or light	meshes-
2.5	<ul> <li><u>Device's description:</u></li> <li>These implants are macro</li> <li>Available in multiple size multifilament polyester).</li> <li>Especially designed for all</li> </ul>	pporous mesh es and materi odominal surg	nes to mechan ials (macropo gery of prolaps	ically reinforc rous monofila se (sacrocolpo	e native tissue iment polypro pexy) in coelio	es. opylene –star oscopy or lapa	ndard or light arotomy.	meshes-
2.5	<ul> <li><u>Device's description:</u></li> <li>These implants are macro</li> <li>Available in multiple size multifilament polyester).</li> <li>Especially designed for all</li> <li>Characteristics</li> </ul>	pporous mesh es and materi odominal surg	nes to mechan ials (macropo gery of prolaps Val	ically reinforc rous monofila se (sacrocolpo ue* according t	e native tissue iment polypro pexy) in coelie o NF \$94-801:2	es. opylene –star oscopy or lapa 2007	ndard or light arotomy.	meshes-
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2.5	Device's description:         ◆       These implants are macro         ◆       Available in multiple size         multifilament polyester).       ◆         Especially designed for all         Characteristics         Mesh type         Construction         Thickness <sup>1</sup> Fiber diameter         Weight <sup>2</sup> Max pore size <sup>3</sup> Mean porosity <sup>4</sup>	poporous mesh es and materi odominal surg Knitted mo polypropylen Star 0.56 0.15 90 g 1.31 ≥7 <i>longitudinal</i> 324N/5cm	nes to mechan ials (macropo gery of prolaps Val poofilament de – lock stitch idard 5 mm g/m <sup>2</sup> 1 mm 7% transverse 289N/5cm	ically reinforc rous monofila se (sacrocolpo ue* according t Knitted mo polypropylen Lightv 0.52 0.15 60g 1.70 ≥& <i>longitudinal</i> 227N/5cm	e native tissue iment polypro pexy) in coelie o NF S94-801:2 nofilament e – lock stitch weight mm /m <sup>2</sup> mm 4% <i>transverse</i> 367N/5cm	es. opylene –star oscopy or lapa 2007 Knitted mi polyester - 2D v 0.50 Ø 76 o 100 1.29 ≥8 <i>longitudinal</i> 342N/5cm	ndard or light arotomy. ultifilament – lock stitch veave 0 mm 0 Tex 22 g/m <sup>2</sup> 5 mm 30% <u>transverse</u> 570N/5cm	L (1977) method 5 F 594-801(2007) method A
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2.5	Device's description: <ul> <li>These implants are macro</li> <li>Available in multiple size multifilament polyester).</li> <li>Especially designed for ab</li> </ul> <li>Characteristics         <ul> <li>Mesh type</li> <li>Construction             <ul> <li>Thickness<sup>1</sup></li> <li>Fiber diameter</li> <li>Weight<sup>2</sup></li> <li>Max pore size<sup>3</sup></li> <li>Mean porosity<sup>4</sup></li> <li>Ultimate Tensile Test<sup>5</sup></li> <li>Strain at Ultimate Tensile Test<sup>5</sup></li> <li>Durability</li> </ul> </li> </ul> </li>	pporous mesh es and materi odominal surg Knitted mo polypropylen Star 0.56 0.15 90 { 1.31 ≥7 <i>longitudinal</i> 324N/5cm 102% 4%	nes to mechan ials (macropo gery of prolaps Val ponofilament ne – lock stitch ndard 5 mm 5 mm 5 mm 5 mm 7% 289N/5cm 111% 5%	ically reinforc rous monofila se (sacrocolpo ue* according t Knitted mo polypropylen Lightw 0.52 0.15 60g 1.70 ≥8 longitulinal 227N/5cm 104% 17% Perm	e native tissue iment polypro pexy) in coelie o NF S94-801:2 nofilament e – lock stitch weight mm /m <sup>2</sup> mm /m <sup>2</sup> mm	es. opylene –star oscopy or lapa 2007 Knitted mi polyester - 2D v 0.5C Ø 76 c 100 1.25 ≥8 <i>longitudinal</i> 342N/5cm 33% 1.1%	ndard or light arotomy. ultifilament – lock stitch veave 0 mm dTex 22 g/m <sup>2</sup> 5 mm 00% <i>transverse</i> 570N/5cm 52% 1.1%	5); <sup>2</sup> ISO 3801 (1977) method 5 ethod B; <sup>4</sup> NF S94-801(2007) method A 013)
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2.5	Device's description: <ul> <li>These implants are macro</li> <li>Available in multiple size multifilament polyester).</li> <li>Especially designed for all</li> </ul> <li>Characteristics         <ul> <li>Mesh type</li> <li>Construction</li> <li>Thickness<sup>1</sup></li> <li>Fiber diameter</li> <li>Weight<sup>2</sup></li> <li>Max pore size<sup>3</sup></li> <li>Mean porosity<sup>4</sup></li> </ul> </li> <li>Ultimate Tensile Test<sup>5</sup></li> <li>Strain at Ultimate Tensile Test<sup>5</sup></li> <li>Durability</li> <li>Surgical technique</li> <li>Microscopic view of the mesh</li>	poporous mesh es and materi odominal surg Knitted mo polypropylen Star 0.56 0.15 90 { 1.31 ≥7 <i>longitudinal</i> 324N/5cm 102% 4%	nes to mechan ials (macropo gery of prolaps Val ponofilament ne – lock stitch ndard 5 mm 5 mm 5 mm 5 mm 5 mm 5 mm 289N/5cm 111% 5% Sacroco	ically reinforc rous monofila se (sacrocolpo ue* according t Knitted mo polypropylen Lightw 0.52 0.15 60g 1.70 ≥8 longitudinal 227N/5cm 104% 17% Perm Ipopexy by lapa	e native tissue iment polypro pexy) in coelie o NF S94-801:2 nofilament e – lock stitch weight mm /m <sup>2</sup> mm /m <sup>2</sup> mm 4% <i>transverse</i> 367N/5cm 74% 9% anent roscopy or lap	es. opylene –star oscopy or lapa 2007 Knitted mi polyester - 2D v 0.50 Ø 76 o 100 1.25 ≥8 <i>longitudinal</i> 342N/5cm 33% 1.1% arotomy	ndard or light arotomy. ultifilament – lock stitch veave 0 mm fTex 22 g/m <sup>2</sup> 5 mm 30% <i>transverse</i> 570N/5cm 52% 1.1%	NF EN ISO 5084 (1996); <sup>2</sup> ISO 3801 (1977) method 5 NF 594-801 (2007) method B; <sup>4</sup> NF 594-801(2007) method A NF EN ISO 13934-1 (2013)
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2.6	References:									
		Name	Shape	Size	Standard Polypropylene	Lightweight Polypropylene	2D weave Polyester			
		K3 - kit		2.5/8 x 19 cm 2.5 x 18 cm 2.5/3.5 x 18 cm	413 803	414 803	416 803			
		K3+- kit		2.5/8 x 24 cm 2.5 x 18 cm 2.5/3.5 x 18 cm	-	414 813	416 813			
		A4 - anterior		4.5 x 18 cm	-	-	416 881			
		P4 - posterior		4.5/8 x 20 cm	-	-	416 891			
	Kits are available with two anterior implants so that the surgeon can choose the one that fits the best the patient. The choice of the size and shape is made according to the morphology of the patient. The choice of material is made regarding the mechanical properties and the handling that best fits the surgeon. Polyester is hydrophilic and degrades more than polypropylene which is hydrophobic. A higher porosity and/or a larger pore size leads to a faster tissue integration. A monofilament leads to less infection potentially.									
2.7	<ul> <li>7 <u>Device composition:</u> 100% polypropylene or 100% polyester</li> <li>✓ No latex</li> <li>✓ No phthalates</li> </ul>									
2.8	<ul> <li>✓ No products of animal or organic origin</li> <li>2.8 <u>Field of use – Indications:</u> PROLAFIX implants are indicated for women with advanced apical pelvic organ prolapse (POP-Q ≥ stage 2) in abdominal surgery. These implants can be used in women with or without uterus and concomitant surgical proceedures can be performed if processary at the discretion of the surgeon.</li> </ul>									
3	B. Steri	lization		,						
3.1	<u>Steriliz</u>	<u>ed:</u> ⊠YES □N	0							
3.2	3.2 <u>Sterilization process:</u> Polyester: gamma ray radiation according to ISO 11137:2019 Polypropylene: Ethylene Oxide according to NE EN ISO11135:2014 and NE EN ISO10993-7:2019									
4	I. Stora	age conditions	5	-						
	Packaging: 1 to 3 implants packed in sealed double Tyvek bags AND filmed cardboard box 240mm x 220mm x 20mm (non contractual photo)									
	Expiration: 5 years after sterilization									
	Storage	<u>e:</u> no particular c <b>tv</b>	onditions, sto	ore at ambient ten	perature, please read	D134 IFU				
3	Description       Please read Instructions for Use D134									
6	5. Usag	e								
6.1	<u>IFU:</u> D1	, 134								
6.2	<ul> <li>.2 <u>Indication:</u> PROLAFIX implants are indicated for women with advanced apical pelvic organ prolapse (POP-Q ≥ stage 2) in abdominal surgery. These implants can be used in women with or without uterus and concomitant surgical procedures can be performed if necessary at the discretion of the surgeon.</li> </ul>									
6.3	<ul> <li>Precautions or use: Before the operation, check that the instruments specific to the installation of the device are available and functional. Avoid contact with objects that may damage the device. Damaged devices and/or devices that have been in contact with a patient must be isolated and decontaminated before cleaning and possible reshipment.</li> <li>Warning: a defect in the fixing, positioning or assembly of the device may induce abnormal stresses and/or reduce the service life of the device. In women with increased risk of complications related to a synthetic implant (chronic steroid use, smoking, etc.), other surgeries should be considered. For patients with medical co-morbidities that prevent them from undergoing more invasive and longer surgery (heart disease, chronic obstructive pulmonary disease or thromboembolic disease), a vaginal approach (with a different implant) should be considered. The placement of a preventive posterior implant in the context of primary surgery should not be systematic.</li> <li><u>Contra-indications:</u> Pregnant woman or those considering a future pregnancy. Child during their growth. Intense physical activities. Allergic reactions. Serious illness containing a risk of dangerous post-operative complications. Infection and sepsis are absolute contraindications.</li> </ul>									
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