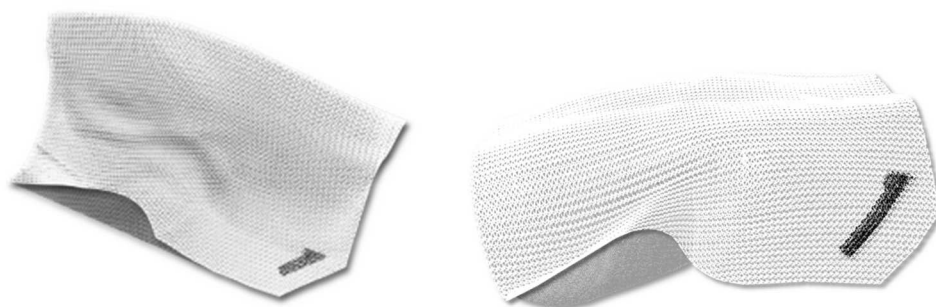






3D IMPLANTS® TECHNICAL DATASHEET

Synthetic mesh for inguinal hernia by laparoscopy



1. Administrative information about MICROVAL

	<p>MICROVAL ZA CHAMP DE BERRE, 43240 SAINT JUST MALMONT, France Tel: +33 4 77 35 03 03 Fax: +33 4 77 35 03 19 E-mail: info@microval.fr Website: www.microval.fr</p>	
	<p>Medical device vigilance contact: Olivier CUILLERON Tel : +33 4 77 35 03 03 Fax : +33 4 77 35 03 19 E-mail : info@microval.fr</p>	

2. Device information

2.1	Common name: Synthetic permanent implant for abdominal wall reinforcement
2.2	Commercial name: 3D implant®
2.3	Nomenclature code: GMDN 60300 EMDN P900202
2.4	<p>Class of medical device: IIb according to European Directive 93/42/CEE (2007/47/CE) Notified Body number: 1639 Date of first sale: 1998 Manufacturer: MICROVAL Basic UDI-DI : 37004584DT010-DIG-COEV8</p>



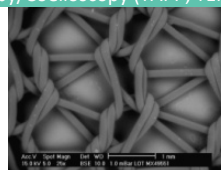
Certificate No. : FR19-81843429

2.5 Device's description:

- ❖ These patented implants are macroporous, monofilament, medical grade polypropylene meshes with a shape memory that helps surgeon to deploy the device internally.
- ❖ Their anatomical shape perfectly fits the anatomical region which reduces the migration phenomenon.
- ❖ These permanent implants and their very high burst test resistance allow a durable inguinal reinforcement.
- ❖ A medical black ink marker allows the surgeon to easily identify the internal inferior edge in order to ease the implant's placement.
- ❖ These implants can be implanted with all coelioscopic/laparoscopic available techniques including robotic surgery (TAPP, TEP, eTEP, etc.), with or without fixation.

Characteristics	Value*
Mesh type	Knitted monofilament polypropylene – lock stitch
Thickness ¹	0.56 mm
Weight ²	90 g/m ²
Max pore size ³	1.31 mm
Porosity ⁴	≥77%
Burst resistance ⁵ (max in vivo value ≈ 170mmHg ^a)	≥ 6135mmHg
Strain at Ultimate Tensile Test ⁶	102% (longitudinal) 111% (transverse)
Durability	Permanent
Additional fixation	With or without
Surgical technique	Laparoscopy/Coelioscopy (TAPP, TEP, eTEP, etc.)














Microscopic view of the mesh



*Average values given as an indication

¹ NF EN ISO 5084 (1996); ² ISO 3801 (1977) method 5
³ NF S94-801(2007) method B; ⁴ NF S94-801(2007) method A
⁵ NF EN ISO 13938-1(2019) ; ⁶ NF EN ISO 13934-1 (2013)

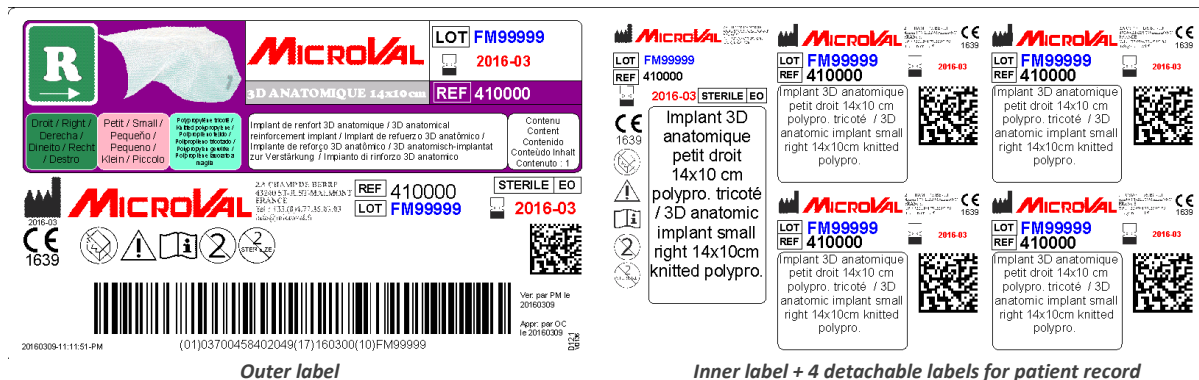
^a Pott et al. 2012, « Mechanical Properties of Mesh Materials Used for Hernia Repair and Soft Tissue Augmentation », PLoS ONE 7(10): e46978. doi:10.1371/journal.pone.0046978

2.6	<p><u>References:</u></p> <table border="1"> <tr> <td rowspan="2">3D®10x14 cm</td><td></td><td>right</td><td>410 000</td></tr> <tr> <td></td><td>left</td><td>410 001</td></tr> <tr> <td rowspan="2">3D® 11x16 cm</td><td></td><td>right</td><td>410 010</td></tr> <tr> <td></td><td>left</td><td>410 011</td></tr> </table> <p>The choice of the size is made according to the morphology of the patient and the importance of the hernia. The choice of a left or right implant is made according to the laterality of the pathology.</p>	3D®10x14 cm		right	410 000		left	410 001	3D® 11x16 cm		right	410 010		left	410 011
3D®10x14 cm			right	410 000											
		left	410 001												
3D® 11x16 cm		right	410 010												
		left	410 011												
2.7	<p><u>Device composition:</u> 100% polypropylene + biocompatible implantable silicon ink for marking.</p> <p>✓ No latex ✓ No phthalates ✓ No products of animal or organic origin</p>														
2.8	<p><u>Field of use – Indications:</u> Reinforcement of abdominal wall. Treatment of inguinal hernias by laparoscopy.</p>														
3. Sterilization															
3.1	<p><u>Sterilized:</u> <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</p>														
3.2	<p><u>Sterilization process:</u> Ethylene oxide according to NF EN ISO11135:2014 and NF EN ISO10993-7:2008 (A1:2019)</p>														
4. Storage conditions															
	<p><u>Packaging:</u> 1 implant packed in simple PETG blister with protective cover AND filmed cardboard box 224mm x 152mm x 63mm (non-contractual photograph)</p> <div style="text-align: center;">  </div> <p><u>Expiration:</u> 5 years after sterilization <u>Storage:</u> no particular conditions, store at ambient temperature, please read D121 IFU</p>														
5. Safety															
	<p>Please read Instructions for Use D121</p>														
6. Usage															
6.1	<p><u>IFU:</u> D121</p>														
6.2	<p><u>Indication:</u> Abdominal wall reinforcement. Inguinal hernia repair through laparoscopic approach.</p>														
6.3	<p><u>Precautions of use:</u> Before operation, please check that all specific instruments for the operation are available and functional. Avoid any contact with objects which could damage the device. The damaged devices and/or that have been in contact with a patient must be isolated and disinfected before cleaning and possible back forwarding.</p>														
6.4	<p><u>Contra-indications:</u> Children during their growth, intensive and/or violent physical activities; Allergic reaction. Serious illness inducing a risk of dangerous post-operative complication. Infection and septicemia are absolute contra-indications.</p>														
7. Additional information concerning the product															
	<p>Bibliography, test reports: specific data for Microval 3D</p> <ul style="list-style-type: none"> ❖ [Ref0507] "Laparoscopic totally extraperitoneal hernioplasty with nonfixation of three-dimensional mesh: Dulucq's technique", A L MEYER, J L DULUCQ, A MAHAJNA, Brazilian archives of digestive surgery 2013, 26(1):59-61 ❖ [Ref0033] "Laparoscopic Totally Extraperitoneal Inguinal Hernia Repair: Nonfixation of Three-Dimensional Mesh", A L MEYER, D M BELLANDI, F DELACOSTE, J ATGER, E BERGER, M A A RANOYA, O MONTEIRO, P A ALONSO, L M V GUIMARAES, Bras. J. Video-Sur. 2010, 3(1): 019-023 ❖ [Ref0030] "Laparoscopic totally extraperitoneal inguinal hernia repair: lessons learned from 3100 hernia repairs over 15 years", J L DULUCQ, P WINTRINUGER, A MAHAJNA, Surg Endosc. 2009 Mar;23(3):482-6. doi: 10.1007/s00464-008-0118-3 ❖ [Ref0028] "Laparoscopic totally extraperitoneal inguinal hernioplasty: The use of a contoured three-dimensional mesh", P W Y CHIU, S-F HON, P B-S LAI, E K-W NG, Surgical Practice. 2005: 9 p25-27 ❖ [Ref0020] "Etude rétrospective et analytique du traitement des hernies inguinales de l'adulte sur 130 patients de 1996 à 1997.", DULUCQ and P WINTRINUGER, étude PMCF Microval 1998 														

8. Appendices

8.1 IFU: D121

8.2 Labelling example:



8.3 Symbols used in IFU and/or labels:



Please check D121 IFU



Do not use if packing has been damaged



Sterilized with Ethylene oxide



5 years after sterilization



Single use



Do not re-sterilize