

DOC NO : TF03/01 Rev. No. : 00

Rev Date: 19.07.2016

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INTRODUCTION

HERNIA PROSTHESIS

Hernia refers to swellings that develop as the internal layers of core muscles weaken or tear apart. The membrane around the abdominals cause sacs as it is pushed out of the weakened abdominal walls. Hernia is formed most commonly in: pubic channels, femoral channels, around the belly, and surgical lacerations. The patient feels pain as he lifts heavy loads, coughs incessantly for a long time, strains, sits down or remains standing for a long period of time. The pain can begin suddenly and be intensive or else it can increase during the day in a manner that its location cannot be determined for sure by the patient. Intestines come in and go out of those swellings most of the time. Hernia results in labor loss and affects the quality of life in a negative way. It constitutes one of the most important problems in surgery, as it is a common disease. The most significant treatment is surgical operation. Among surgical alternatives, reinforcement with prosthesis materials has an important role. When there is not sufficient healthy tissue or else the defect is large, prosthesis material application turns out to be the first alternative. Our product mesh is a prosthesis substituted for tissue reinforcement. It is made of polypropylene suitable for medical use. The product is manufactured in clean room with Class ISO7.



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PHOTOGRAPHS



PLUG MESH:

The groin region (area between the abdomen and the thigh) is part of the main abdominal wall. The abdominal wall is made up of several layers of tough connective tissue (similar to that of tendons and ligaments), muscle, fat and skin. Usually, a hernia starts out as a small tear in this connective tissue and expands. It is called "inguinal" because the intestines push through a weak spot in the inguinal canal, located in the connective tissue between layers of abdominal muscle. You can be born with a weakness in this connective tissue or it can be caused through repetitive lifting or straining. This stretching and tearing of tissue can be very painful. The mesh plug is inserted into the hole and secured in place. Operating and recovery times are reduced with this method.

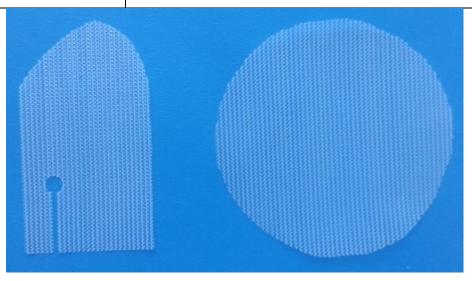
The innovative shape simply conforms to the defect, stays in place, sutures easily, and will not collapse or "pop out" during the procedure.

It is used for recovery of femoral hernia and paraumblical hernia other than Inhuinal hernia. The only difference from normal duzey Polypropylene mesh is shape difference. Normal mesh is generally square and rectangle but plug mesh generally 2 parts. First part is round and the second part is like Vshape.



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PRODUCT SIZES/MODELS

SIZES/ MODELS	
PRODUCT	BARCODE NO
POLYPROPYLENE MESH 5X5 CM	8680081330016
POLYPROPYLENE MESH 5X10 CM	8680081330023
POLYPROPYLENE MESH 6X11 CM	8680081330030
POLYPROPYLENE MESH 6X14 CM	8680081330047
POLYPROPYLENE MESH 7.5X15 CM	8680081330054
POLYPROPYLENE MESH 8X13 CM	8680081330061
POLYPROPYLENE MESH 10X15 CM	8680081330078
POLYPROPYLENE MESH 12,5X15 CM	8680081330085
POLYPROPYLENE MESH 15X15 CM	8680081330092
POLYPROPYLENE MESH 15X20 CM	8680081330108
POLYPROPYLENE MESH 15X30 CM	8680081330115
POLYPROPYLENE MESH 30X40 CM	8680081330122
POLYPROPYLENE MESH 20X30 CM	8680081330139
POLYPROPYLENE MESH 30X30 CM	8680081330146
PLUG MESH Q 7 CM	8680081330153
PLUG MESH Q 9 CM	8680081330160
PLUG MESH Q 11 CM	8680081330177
	PRODUCT POLYPROPYLENE MESH 5X5 CM POLYPROPYLENE MESH 5X10 CM POLYPROPYLENE MESH 6X11 CM POLYPROPYLENE MESH 6X14 CM POLYPROPYLENE MESH 7.5X15 CM POLYPROPYLENE MESH 8X13 CM POLYPROPYLENE MESH 10X15 CM POLYPROPYLENE MESH 12,5X15 CM POLYPROPYLENE MESH 15X15 CM POLYPROPYLENE MESH 15X20 CM POLYPROPYLENE MESH 15X30 CM POLYPROPYLENE MESH 30X40 CM POLYPROPYLENE MESH 20X30 CM POLYPROPYLENE MESH 30X30 CM POLYPROPYLENE MESH 30X30 CM PULYPROPYLENE MESH 30X30 CM PULYPROPYLENE MESH 30X30 CM PLUG MESH Q 7 CM PLUG MESH Q 9 CM



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SPECIFICATIONS

MATERIALS

Non-absobable & Monofilament Polypropylene

Mesh is constructed of knitted filaments of extruded polypropylene

TECHNICAL DETAILS

Duzey Mesh:

Raw Material : Polypropylene

Bursting Strenght: 700 kPa
Thickness: 0,50 mm
Weight: 55 gr/m²
Porosity: 1.3*1.0
Thread diameter: 0.15
Indicate that it is: woven

Elasticity :bidirectional shelf life :5 years

CLASSIFICATION/RULE

Our product is an implantable product. It is aimed to stay in the body for so long time.

For this reason, according ot the rule 8 of MDD/93/42/EEC written below, the class of our product is CLASS IIB.

2.4. Rule 8

All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:



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- to be placed in the teeth, in which case they are in Class IIa,
- $\boldsymbol{-}$ to be used in direct contact with the heart, the central circulatory system
- or the central nervous system, in which case they are in Class III,
- to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,
- or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.

SHELF LIFE

Our product's shelf life is determined as 5 years as results of the all tests made according to ASTM F1980 standards.