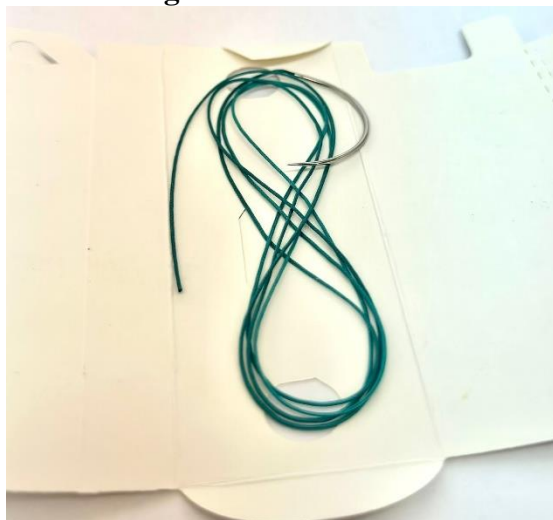
	Gmd Group Medikal San. ve Tic. A.Ş		Ref No.	DS-05
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	Damaester	Polyester (Non-Absorbable)	Issue Date	21.07.2023

1.Product Information

1.1. General Product Name:


Sterile, Single Use, Non-Absorbable, Synthetic, multifilament, Polyester Surgical Suture

1.2.Product Images




Product codes and Description:


ORIGINAL PRODUCT BARCODE	CODE DESCRIPTION	PRODUCT REFERENCE CODE	BRAND NAME	GMDN CODE	CLASS	SHELF LIFE (MONTHS)
8681677070828	DAMAESTER: PES BRAIDED NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (UNDYED) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DS02M40	DAMAESTER	13906 - Suture, polyester	Class III	60
8681665009137	DAMAESTER: PES BRAIDED NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (UNDYED) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DS0M30	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677070880	DAMAESTER: PES BRAIDED NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (UNDYED) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DS2M26	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677074734	DAMAESTER: PES BRAIDED NON- ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (UNDYED) 26mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DS2M26-D	DAMAESTER	13906 - Suture, polyester	Class III	60

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8681677072778	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (UNDYED) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DS4M20	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677074741	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (UNDYED) 20mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DS4M20-D	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677071184	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (UNDYED) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DS4M22	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677074758	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (UNDYED) 13mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DS6M13-D	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677076868	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (UNDYED) 26mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DS2M26-D-90	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677078237	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (UNDYED) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DS0M40	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677078244	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (UNDYED) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS02K40	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677079050	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DS4HR20G	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677079098	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (GREEN) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DS02HR40G	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677079173	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS40DS16G	DAMAESTER	13906 - Suture, polyester	Class III	60

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8681677079180	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN DYED) 18mm 1/2 CIRCLE TAPER CUT NEEDLE	DS40HRT18G	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677079395	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 3-0 (GREEN) 26mm 1/2 CIRCLE TAPER CUT NEEDLE	DS30HSY26G-90	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677079418	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 18mm 1/2 CIRCLE TAPER CUT NEEDLE	DS40HSY18G	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677079524	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 2 (UNDYED) WITHOUT NEEDLE	DS02-1X150	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677079531	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 6PCS X 45cm USP SIZE 2 (UNDYED) WITHOUT NEEDLE	DS02-6X45	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677079968	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (GREEN) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS30DS16G	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677079975	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (GREEN) 17mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS30DS17G	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677079982	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (GREEN) 18mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DS30HS18G	DAMAESTER	13906 - Suture, polyester	Class III	60
8681677079999	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 17mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS40DS17G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200039	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 18mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DS40HS18G	DAMAESTER	13906 - Suture, polyester	Class III	60

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8684154200046	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 13PCS X 60cm USP SIZE 0 (UNDYED) WITHOUT NEEDLE	DS00-13X60	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200053	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5 (UNDYED) 55mm 1/2 CIRCLE TAPER CUT NEEDLE	DS05HRT55	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200060	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 12PCS X 60cm USP SIZE 2-0 (UNDYED) WITHOUT NEEDLE	DS20-12X60	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200077	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (UNDYED) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DS30HR26	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200336	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (GREEN) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS50DS18G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200343	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (GREEN) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS30DS18G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200350	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS40DS18G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200367	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (GREEN) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS20DS18G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200497	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS40DS19G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200503	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 17mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DS40HS17G	DAMAESTER	13906 - Suture, polyester	Class III	60

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8684154200510	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 20mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DS40HS20G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200527	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DS40HR17G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200794	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 0 (UNDYED) WITHOUT NEEDLE	DS00-150	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200916	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (GREEN) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DS30HR20G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200923	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS40DS20G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200930	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DS40HR18G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200947	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (GREEN) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DS50HR18G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200985	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (GREEN) 16mm 1/2 CIRCLE TAPER CUT NEEDLE	DS30HRT16G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154200992	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (GREEN) 18mm 1/2 CIRCLE TAPER CUT NEEDLE	DS30HRT18G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154201005	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (GREEN) 16mm 1/2 CIRCLE TAPER CUT NEEDLE	DS40HRT16G	DAMAESTER	13906 - Suture, polyester	Class III	60

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8684154201142	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (GREEN) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DS30HR26G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154201159	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (GREEN) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DS50HR13G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154201166	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (UNDYED) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DS50HR13U	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154204501	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (GREEN) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DS01HR40G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154204518	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (GREEN) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS01DS40G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154204525	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (GREEN) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DS00HR40G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154204532	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (GREEN) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS00DS40G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154208226	DAMAESTER: POLYESTER TAPE (PES) COATED BRAIDED UNDYED NONABSORBABLE 1PC W: 5MM L: 50CM 1/2 CIRCLE ROUND BODY DOUBLE NEEDLE	DST5HR50-D-50	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154206925	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (GREEN) 17mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DS20HR17G-D	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154206932	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (UNDYED) 17mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DS20HR17U-D	DAMAESTER	13906 - Suture, polyester	Class III	60

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8684154208349	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (GREEN) 24mm 1/2 CIRCLE TAPER POINT NEEDLE	DS30HR24G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154208356	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (GREEN) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DS40HR16G-90	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154208363	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 60cm USP SIZE 5-0 (GREEN) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DS50HR16G-60	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154208370	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (GREEN) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DS50HR17G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154208783	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 3-0 (GREEN) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS30DS30G-90	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154208790	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (GREEN) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DS20DS30G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154208806	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 400cm USP SIZE 2 (GREEN) WITHOUT NEEDLE	DS02G-1X400	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154208813	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (GREEN) 48mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DS02HS48G	DAMAESTER	13906 - Suture, polyester	Class III	60
8684154214821	DAMAESTER: PES BRAIDED NON-ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 4-0 (GREEN) 16mm 3/8 CIRCLE NORMAL CUTTING NEEDLE	DS40DC16G-45	DAMAESTER	13906 - Suture, polyester	Class III	60

1.3.Gmdn Code:

13906- Suture, polyester DESCRIPTION: A sterile thread made of polyester used to stitch together the edges of a wound or incision. CATEGORIES: 03-Dental devices 10-Disposable devices

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1.4.Intended use of the product:

Surgical sutures are sterile threads that are attached to needle and are used for surgical procedures.

DAMAESTER sutures are indicated for use in soft tissue approximation and/or ligation, including ophthalmic procedures.

DAMAESTER sutures are also indicated for use in cardiovascular surgery.

If suture sold as a cardiovascular surgery, also it is called as the name of ' DAMAESTER ' and used by cardiologist. (only one difference between them)

DAMAESTER are green and undyed colour sterile, synthetic, multifilament, Polyester, non-absorbable sutures are not subject to degradation or weakening by tissue enzymes. They are extremely inert in tissue and have been found to retain tensile strength for periods of as long as two years in vivo. Polyester sutures cause minimal tissue reaction and hold knots better than most other synthetic multifilament materials.

DAMAESTER are sterile, synthetic, monofilament, non absorbable, Polyester sutures are not subject to degradation or weaking by tissue enzymes. They are extremely inert in tissue and have been found to retain tensile strenght for periods of as long as two years in vivo.Polyester sutures cause minimal tissue reaction and hold knots better than most other synthetic multifilament materials.

1.5. Intended User

The device should used by physician and/or surgeons.

1.6. Patient population

The patients are used for all people who are need to ligate, close and cover suturable wounds under sterile conditions by initially suturing the wound due to cardiovascular, ophthalmic, microsurgery and neurological surgery microsurgery and neurological surgery.

The target group of this device is patients who are need to ligate/close/cover the wounds due to cardiovascular, ophthalmic, microsurgery and neurological surgery microsurgery and neurological surgery.


1.7. Applications, Including Any Restrictions as to the Number or Duration of Reapplications

After surgery, the closing and covering can be repeated if an undesirable case would be occured and/or the wound would open. There is not any restriction as to the number or duration of reapplications.

Single Use / Reusable: The device is only single-used

Mechanism of Action

Damaster sutures elicit minimal acute inflammatory reaction in tissues, which is followed by

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gradual encapsulation of the suture by fibrous connective tissue.

DAMAESTER is available in a range of gauge sizes and lengths, non-needle or attached to stainless steel needles of varying types and sizes.

The product range of DAMAESTER varies as the diameter of sterile non absorbable surgical suture strands from 0,070 mm to 0,599 mm. The length of sterile non absorbable surgical suture strands varies from 45 cm to 180 cm. The length of needles varies from 13 mm to 55 mm. The shape of needles varies from 3/8 to 1/2 circle or straight. The different variants are listed in the PRODUCT LIST of DAMAESTER.

DAMAESTER sutures elicits minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Polyester multifilament surgical suture is not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.

Surgical suture is a medical device used to hold body tissues together after an injury or surgery.

It is used for closing and covering suturable wounds under sterile conditions by initially suturing and stapling the wound.

*According to the size of the strands that meets all the requirements of the European Pharmacopoeia (EP) for Synthetic Non-Absorbable Multifilament Sutures and the requirements of United States Pharmacopoeia (USP) Non Absorbable Sutures except for a slight oversize in diameter.

1.8. Components and Raw Materials of product: Surgical Suture Surgical Needle

Manufacturer/Supplier	Material
Shandong Kanglida Medical Products Co.	Polyester Silicon Coated Green and undyed
Quality Needles Pvt Co.	Stainless Steel 300 (Serial number)
FTM Ambalaj	packing (medical paper)
Endustri Matbaacılık	Paper (card)

1.9. Accessories Information

There is no accessories.

1.10. Suitability of Raw Material


Raw materials are supplied from the suppliers given in 1.4. Components of product. Raw materials analysis reports are given in Test Reports

1.11. Indication ,Contraindication and Adverse Reactions

1.12.

1.11.1. Indications:

sutures are indicated for use in Gastrointestinal Surgery, obstetric and gynecologic surgery and urological surgery, soft tissue approximation and/or ligation, including ophthalmic procedures.

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1.11.2.Contraindications:

DAMAESTER, being not absorbable should not be used where extended approximation of tissue under stress is required. There are not known any other contraindications of DAMAESTER Polyester multifilament sutures

1.11.3. Adverse Reactions

Adverse effects associated with the use of this device include wound dehiscence, failure to provide wound support in closure of the abdomen, chest, joints and other sites where expansion, stretching or distension occur. Failure to provide adequate wound support in elderly, malnourished or debilitated patients, or in patients suffering from cancer, anemia, obesity, diabetes, infected or other conditions which may delay wound healing, enhance bacterial infectivity, minimal acute inflammatory tissue reaction, localized irritation when skin closures are left in place for greater than seven days, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions, such as urine and bile occurs, and pain, edema and at the wound site.

*One package unit of DAMAESTER contains 12 single pouches.

1.13. Material Specifications:

The following components and compounds are used for the manufacturing of the surgical sutures:

1.12.1 Thread (Polyester,non absorbable,monofilament,green and undyed colour) The following specifications are met:

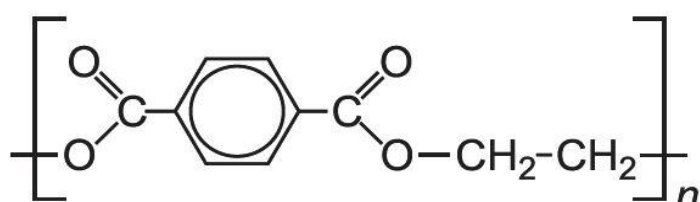
Appearance:


The Polyester non-absorbable suture is composed of synthetic multifilament materials for the intended size to meet current USP specifications. The Polyester has been dyed green and undyed. Green colored for easy identification during Surgery.

Name:

Polyester

Formula of Polyester polimer



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Additives:

The quantity of colour additive is not to exceed 0.5 % by weight of the suture

Dyestuffs

Green coloured threads

Chemical name: Phthalocyaninato (-2)) copper in accordance with FDA requirements Reference: Federal Register, title 21,74.3045

Coating

Coated with Silicon to provide for smoother and better handling.


Physical Specification

DAMAESTER meet all requirements established by the United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP) except for diameter.

The diameter could be slightly over the specification

Suture Biological Physical Properties: Polyester

EP SIZE	USP SIZE	DIA METER			Knot pull tensile strength		Suture-Needle tensile strength	
		A Dia meter average (mm)	B		C Average values (N)	D Min values (kgf (N))	A Average (kgf) (N)	B Min values (kgf) (N)
			Min values (mm)	Max values (mm)				
0.3	9-0	0.030-0.039	0.025	0.045	0.035	0.006	0.021	0.015
0.4	8-0	0.040-0.049	0.035	0.060	0.060	0.015	0.05	0.025
0.5	7-0	0.050-0.069	0.045	0.085	0.10	0.035	0.08	0.04
0.7	6-0	0.070-0.099	0.060	0.125	0.15	0.060	0.17	0.08
1	5-0	0.100-0.149	0.085	0.175	0.30	0.100	0.23	0.11
1.5	4-0	0.150-0.199	0.125	0.225	0.50	0.150	0.45	0.23
2	3-0	0.200-0.249	0.175	0.275	0.90	0.300	0.68	0.34
2.5	-	0.250-0.299	0.225	0.325	1.30	0.500	0.92	0.46
3	2-0	0.300-0.349	0.275	0.375	1.50	0.900	1.10	0.45
3.5	0	0.350-0.399	0.325	0.450	2.20	1.300	1.50	0.45
4	1	0.400-0.499	0.375	0.550	2.70	1.500	1.80	0.60
5	2	0.500-0.599	0.450	0.650	3.50	2.200	1.80	0.70
6	3	0.600-0.699	0.550	0.750	5.00	2.700	1.80	0.70
7	4	0.700-0.799	0.650	0.850	6.20	3.500	1.80	0.70

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Knot pull tensile strength linear pull tensile strength for non-sterile braid

USP 29 NF24 Page 2050

USP Size	Metric Size (gauge no.)	Limits on Average Diameter (mm)		Limits on Average Knot-Pull (except where otherwise specified) ^a Tensile Strength (in kgf) ^b			Limits on Average Knot-Pull (except where otherwise specified) ^a Tensile Strength (in N) ^b		
		Min.	Max.	Class I Min.	Class II Min.	Class III Min.	Class I Min.	Class II Min.	Class III Min.
12-0	0.01	0.001	0.009	0.001 ^a	—	0.002 ^a	0.01 ^a	—	0.02 ^a
11-0	0.1	0.010	0.019	0.006 ^a	0.005 ^a	0.02 ^a	0.06 ^a	0.05 ^a	0.20 ^a
10-0	0.2	0.020	0.029	0.019 ^a	0.014 ^a	0.06 ^a	0.194 ^a	0.14 ^a	0.59 ^a
9-0	0.3	0.030	0.039	0.043 ^a	0.029 ^a	0.07 ^a	0.424 ^a	0.28 ^a	0.68 ^a
8-0	0.4	0.040	0.049	0.06	0.04	0.11	0.59	0.39	1.08
7-0	0.5	0.050	0.069	0.11	0.06	0.16	1.08	0.59	1.57
6-0	0.7	0.070	0.099	0.20	0.11	0.27	1.96	1.08	2.65
5-0	1	0.10	0.149	0.40	0.23	0.54	3.92	2.26	5.30
4-0	1.5	0.15	0.199	0.60	0.46	0.82	5.88	4.51	8.04
3-0	2	0.20	0.249	0.96	0.66	1.36	9.41	6.47	13.3
2-0	3	0.30	0.339	1.44	1.02	1.80	14.1	10.0	17.6
0	3.5	0.35	0.399	2.16	1.45	3.40 ^a	21.2	14.2	33.3 ^a
1	4	0.40	0.499	2.72	1.81	4.76 ^a	26.7	17.8	46.7 ^a
2	5	0.50	0.599	3.52	2.54	5.90 ^a	34.5	24.9	57.8 ^a
3 and 4	6	0.60	0.699	4.88	3.68	9.11 ^a	47.8	36.1	89.3 ^a
5	7	0.70	0.799	6.16	—	11.4 ^a	60.4	—	112 ^a
6	8	0.80	0.899	7.28	—	13.6 ^a	71.4	—	133 ^a
7	9	0.90	0.999	9.04	—	15.9 ^a	88.6	—	156 ^a
8	10	1.00	1.099	—	—	18.2 ^a	—	—	178 ^a
9	11	1.100	1.199	—	—	20.5 ^a	—	—	201 ^a
10	12	1.200	1.299	—	—	22.8 ^a	—	—	224 ^a

^a The tensile strength of sizes smaller than USP size 8-0 (metric size 0.4) is measured by straight pull. The tensile strength of sizes larger than USP size 2-0 (metric size 3) of monofilament Class III (metallic) Nonabsorbable Surgical Suture is measured by straight pull.

Silver wire meets the tensile strength values of Class I Sutures but is tested in the same manner as Class III Sutures.

^b The limits on knot-pull tensile strength apply to Nonabsorbable Surgical Suture that has been sterilized. For nonsterile Sutures of Class I and Class II, the limits are 25% higher.

Table 1 Standard Needle Attachment for Absorbable and Nonabsorbable Sutures

Metric Size (Gauge No.)		Limits on Needle Attachment			
Absorbable Collagen Suture	Nonabsorbable and Synthetic Absorbable Sutures	USP Size	Average (in kgf) (Min.)	Individual (in kgf) (Min.)	Average (in N) (Min.)
	0.1	11-0	0.007	0.005	0.069
	0.2	10-0	0.014	0.010	0.137
	0.3	9-0	0.021	0.015	0.206
	0.4	8-0	0.050	0.025	0.490
	0.5	7-0	0.080	0.040	0.784
	0.7	6-0	0.17	0.08	1.67
	1	5-0	0.23	0.11	2.25
	1.5	4-0	0.45	0.23	4.41
	2	3-0	0.68	0.34	6.67
	3	2-0	1.10	0.45	10.8
	3.5	0	1.50	0.45	14.7
	4	1	1.80	0.60	17.6
6 and larger	5 and larger	2 and larger	1.80	0.70	17.6
					6.86

Retention ratio of tensile strength

Polyester multifilament surgical suture is not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.


1.13.2. NEEDLE:

Needle material is made from stainless steel and meets the internationally accepted specifications of surgically used metals

For Analysis Certificates see Test Reports

1.13.4 Specification of packaging material

packaging material is made from a pouch made of medical paper For Analysis Certificates see Test Reports

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1.14. Biological and Toxicological Evaluation

The following section contains information on the preclinical evaluation of the raw materials and the toxicological and biocompatibility tests on the sterile finished product DAMAESTER (C l i n i c a l and Biological Evaluation)

1.15. Biocompatibility Tests of the Raw Materials for Medical Device (ISO10993-1:2009)

Specific safety evaluation programs follow International Organization for Standardization (ISO) 10993 standards and Food and Drug Administration (FDA) guidance (May 1, 1995). The table below is based on ISO 10993-1 Evaluation and testing, 2009 edition. The crosses (X) indicate data endpoints that can be necessary for a biological safety evaluation per ISO 10993-1, based on a risk analysis. Where existing data are adequate, additional testing is not required. (Clinical and Biological Evaluation)


Biocompatibility Test Matrix

BODY CONTACT

A = Limited (< 24 hours)

CONTACT DURATION

DEVICE CATEGORIES			BIOLOGICAL EFFECT													
			Cytotoxicity	Sensitization	Irritation/Intracutaneous	Acute	Systemic Toxicity	Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental	Biodegradation	
SURFACE DEVICES	Skin	A	x	x												
		B	x	x												
		C	x	x												
	Mucosal Membrane	A	x	x												
		B	x	x												
		C	x	x		x	x									
	Breached or Compromised Surfaces	A	x	x												
		B	x	x												
		C	x	x		x	x									
EXTERNALLY COMMUNICATING DEVICES	Blood Path, Indirect	A	x	x		x				x						
		B	x	x		x				x						
		C	x			x	x	x		x						
	Tissue/Bone/Dentin Communicating	A	x	x												
		B	x	x		x	x	x	x							
		C	x	x		x	x	x	x							
	Circulating Blood	A	x	x		x				x						
		B	x	x		x	x	x	x	x						
		C	x	x		x	x	x	x	x						
IMPLANT DEVICES	Tissue/Bone	A	x	x												
		B	x	x		x	x	x	x							
		C	x	x		x	x	x	x							
	Blood	A	x	x		x	x			x	x					
		B	x	x		x	x	x	x	x						
		C	x	x		x	x	x	x	x						

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In compliance with the standard EN ISO 10993-1, Table 1, the biocompatibility classification of our product and the tests required in accordance are determined as below:

The results of the biocompatibility tests on Sterile, Single Use, Non-Absorbable, Synthetic, Monofilament, Polyester Surgical suture demonstrate the excellent biocompatibility of the material and also demonstrate that the ETO sterilization does not have any negative effects on the material.

Based on the clinical experiences with the product DAMAESTER, the material documentation as well as the biocompatibility test results on the end product, the material used for the manufacturing of the surgical suture and the final product can be regarded as biocompatible and suitable for a clinical application.

1.16. Biodegradation for Medical Device DAMAESTER

Sterile, Single Use, Non-Absorbable, Synthetic, Monofilament, Polyester Surgical Suture is not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of the sutures tensile strength over time.

1.17. Manufacturing Process:

Manufacturing is performed at the İkitelli OSB, İsdök Sosyal Tesis 2 sk. B Blok 1 B 7 Başakşehir/İstanbul, Turkey. The manufacturing is made under clean room conditions. The productions consist of manual insertion of the thread into the needles. After testing products are wound in a paper, then packed in a medical paper and the products are ETO sterilized in-house.

The following major manufacturing steps are used:


Manufacturing Methods

- Threads are applied with tipping solution
- Threads are cut to the required length.
- Threads are manually attached to needles using purpose made attaching machines in ISO 8 Clean Room.

Packaging Procedures

- After attaching, the suture is reverse wound into a retaining pouch leaving the needle accessible for easy withdrawal of the thread.
- The wound sutures are packed in a medical pouch envelope and labeled in ISO 8 Clean Room.
- This inner aluminum envelope is then placed in an outer envelope (secondary packaging), which is sealed.

One package unit of DAMAESTER contains 12 single pouches.

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Sterilization

DAMAESTER sutures are sterilized in-house by EO. They are then vacuum-dried, sealed and packed.

Sterilization process is verified by chemical indicators and biological indicators are also used routinely to challenge the procedure. The sterilization process is validated according to EN ISO 11135-1:2014. Main routine sterilization parameters are 55 °C %30 Humidity with a gas injection period of 6 hours.

As regards the manufacturing / assembly area, environmental conditions are monitored at regular intervals using standard microbiological methods (i.e. culture plates)

Packaging into cartons

Twelve sutures pouches are packed into a carton and labelled. Each carton is cellophane wrapped. Sixty cartons are packed in a shipper, which is sealed. Each shipper is allocated a unique sequential identification number and labelled with the contents and their batch numbers.

Production Hygiene:

Production (Assembly) is performed under ISO 8 clean room conditions. Bioburden is checked on a routinely basis and controlled by responsible persons.

ETO-Residual Tests

ISO 10993-7:2008 provides limits for sterilization residuals based on product application.

ETO residuals are tested according to the requirements of ISO 10993-7:2008 by using gas chromatography.


EN 10993-7 Article 4.3.3 Prolonged exposure devices

The average daily dose of EO to patient shall not exceed 2 mg/d. In addition, the maximum EO dose shall not exceed:

– 4 mg in the first 24 h.

– 60 mg in the first 30 d.

The residual test is carried out according to EN 10993-7 and the results are shown in

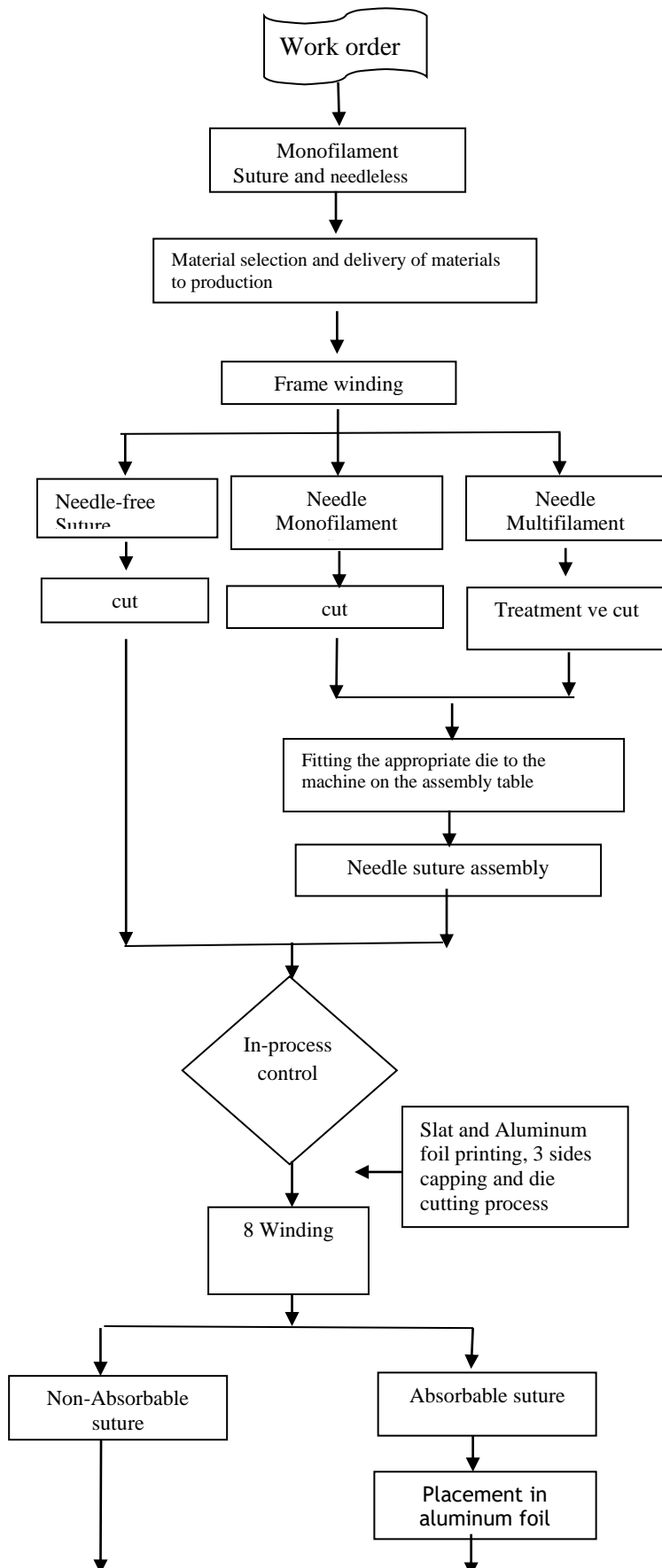
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Manufacturing Flow Chart

WORKFLOW

RELATED DOCUMENT

SUPERVISOR



UR02001- Work Order
Opening Instruction

UR02002-Work Order
Compliant Material
Selection Instruction

DP02007-Material to the
warehouse Material
Introduction and Production
Exit Instruction

UR02003-Pulley Winding,
Cutting and Machine
Operation Instruction

UR02006-Installing Die
Pull-Tester Adjustment
Instruction

KG02021-In-Process
Control
Instruction

UR02007- Needle and
Suture Installation
Instruction

KG02021-In-process
Control
Instruction

KG02002-Suture Length
Control and The Separation
of the Needle from the
Thread Strength Test

UR02014_inner winding
cardboard,
Aluminum Foil Preparation
and Labeling Instruction

UR02009-Winding of
sutures Inner winding carton
on the table
Instruction on hugging

Production

Production
Supervisor

Store and shipping
supervisor

Production
Supervisor and
Production Person

Production
Supervisor

QA Manager


Production person

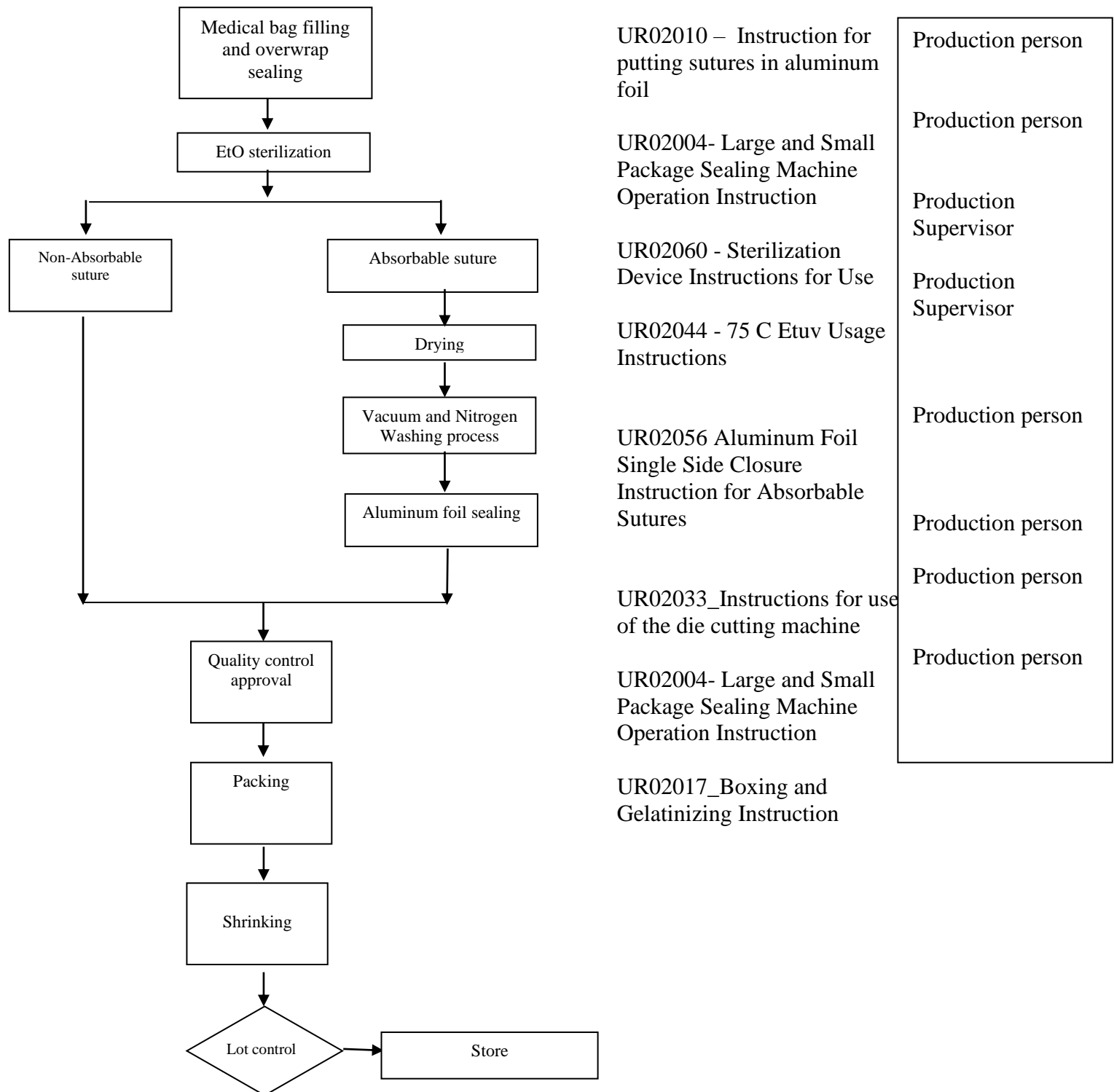
QA Manager

QA Manager

Production
personnel

Production
personnel


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From material entrance into the production to Temporary warehouse (carrantina area) all processes are carried out in GMD Clean room

1.18. Product and Test Specifications:

The DAMAESTER range of sutures started to successfully produced and extensively used in 2016.

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The following tests are specified as final batch release controls according to USP 29: Table: Test specifications and Lot results

Test Parameter	Method	Lot: 23B01S015		Lot: 23D01S045	
		Code: DS40HRT18G		Code: DS30HR26G	
		Limit	result	limit	result
Needle Attachment	USP 25	4,5	12,1	6,8	15,8
Sterility Test	USP 25	sterile	sterile	sterile	sterile

The test reports of DAMAESTER

lots given on the above table are given on Test reports.

1.19. Stability/Aging Test and Product Lifetime:

Stability Testing were performed as accelerated tests and real time tests according to ICH Guideline CPMP QWP 556/96

The product's shelf life was identified as 5 years according to the test results.

1.20. Product Tests (Performance):

The relevant tests and reports are given on Test Reports

1.21. The Product Classification

DAMAESTER According to annex IX, rule no. 8 of EC-Directive 93/42/EEC the product category DAMAESTER is classified as Medical Devices class III. The product is a non-absorbable medical device (surgical suture) for surgically invasive long-term implantation applications.


Rule 8:

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

- to be placed in the teeth, in which case they are in Class IIa,
- 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.

Damaester

According to annex IX, rule no. 8 of EC-Directive 93/42/EEC the product category Damaster

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is classified as Medical Devices **class III**. The product is a non-absorbable medical device (surgical suture) for surgically invasive long-term implantation applications. It is used in cardiovascular area.

Rule 8:

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

- to be placed in the teeth, in which case they are in Class IIa,
- 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.

1.22. Clinical Evaluation :

For the clinical evaluation of literature route of MEDDEV 2.7.1Rev.4 has been selected. Clinical Evaluation is given of this technical file.

1.23. Declaration of Conformity

Declaration of Conformity for GMD has been prepared according to EC Directive 93/42/EEC and approved by the General Manager of the company.

The copy of the declaration of Conformity is given on this technical file.


1.24. Notified Body Information

UDEM-TECHNICAL INSPECTION & CERTIFICATION (2292) has been selected as the notified body and certification body.

During CE marking of these products the above declaration of conformity is made on the basis of the Quality Assurance Certificate No. MD.2016.106.7035 of UDEM dated 25.10.2016 issued by UDEM TECHNICAL INSPECTION & CERTIFICATION.

1.25. Essential Requirements:

The evidence of the fulfilment of Essential requirements given on Annex I of EC Directive 93/42/EEC, detailed on the Essential Requirements Checklist given on TF08 of this technical file.

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1.26. List of Applicable Standards:

The applicable standards used in compliance with the Essential requirements given on Annex I of EC Directive 93/42/EEC, (detailed on the Essential Requirements Checklist given on this technical file) are mainly ISO and EN standards which are harmonised by European Commission for the MDD 93/42/EEC.

The list of applicable standards used in design, manufacturing and testing are given on TF04 of this technical file.

1.27. Risk Analyses

Risk Analyses process of GMD is designed according to EN ISO 14971:2012 and covers all life- cycle process of the product. The Risk Management Activities of GMD are performed according to “Risk Management Instruction”.

1.28. Labels and Instruction for Use

All information required for use of GMD safely is given on the product label and IFU. The device is intended for professional use only and all the applicable information required according to article 13 of Annex I , 93/42/EEC are given on the label and IFU.

The symbols are selected according to EN ISO 15223:2012 The sample layout of IFU and the product label are given on this technical file.

1.29. Conformity Assessment Procedure:

DAMAESTER manufactured by GMD are CE marked according to Annex II, Article 4 of EC Directive 93/42/EEC . The certification is based on quality management system of GMD, which is certificated according to ISO 13485:2012.

1.30. Regulatory Requirements for the Product:

EC directive 93/42/EEC is the applicable regulatory requirement for GMD.

1.31. Planned Design Changes


Any design change is not planned. If a change is required, it should be carried out in accordance with GE01021 Değişiklik Yönetimi Prosedürü

1.32. Sale Information

Sale Information for DAMASTER

The product has been in market since 2016. CE marked has been provided from UDEM (2292)

The product has been in the Turkey and European Markets. For 2022 sale informations has been presented below;

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Product Name	Package	Quantity
DAMAESTER: 4-0 75CM NEEDLE 20MM ROUND	BOX	52

Revision history

Rev.00	15.04.2016	Initial Publish
Rev.01	25.04.2016	General changes
Rev.02	22.08.2017	General changes according to Meddev 2.7.1 Rev.04
Rev.03	23.10.2018	İtems: Product images, Intended use of the product, Intended user, Patient Population, mechasim of action Design Change, Sale Information have been changed.
Rev 04	20.06.2019	Title Updated

Quality Assurance Manager

Aylin KAYA


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