	Gmd Group Medikal San. Ve Tic. A.Ş		Ref No.	DX-06
			Rev No.	06
	Damadioxanone	PDO (Absorbable)	Issue Date	21.07.2023

1.Product Information

1.1. General Product Name:

Sterile Single Use Absorbable Polydioxanone Surgical Suture

Product Name:

Damadioxanone and PDO

1.2.Product Images



1.3.Code:


16584- Suture, polydioxanone DESCRIPTION: It is a sterile thread made of polydioxanone used to suture the edges of a wound or incision together.

CATEGORIES:

03-Dental devices 10-Disposable devices

1.4.Intended use of the product:

- ✓ Polydioxanone monofilament synthetic absorbable sutures are indicated for use in all types of soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. Polydioxanone suture is not indicated in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.
- ✓ **Contraindications:**
These sutures, being absorbable, are not to be used where prolonged (beyond six weeks) approximation of tissues under stress is required and are not to be used in conjunction with prosthetic devices, i.e., heart valves or synthetic grafts.
- ✓ **Warnings:**
The safety and effectiveness of Polydioxanone sutures have not been established in neural tissue, adult cardiovascular tissue or for use in microsurgery. Under certain circumstances,

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notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon. Do not re-sterilize.

✓ **Precautions:**

Polydioxanone suture knots must be properly placed to be secure. As with other synthetic sutures, knot security requires the standard surgical technique of flat and square ties with additional throws if indicated by surgical circumstance and the experience of the operator. As with any suture, care should be taken to avoid damage when handling. Avoid the crushing or crimping application of surgical instruments, such as needle holders and forceps, to the strand except when grasping the free end of the suture during an instrument tie. Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be removed as indicated. Subcuticular sutures should be placed as deeply as possible in order to minimize the erythema and induration normally associated with absorption. Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.

Adverse reactions:

Adverse effects associated with the use of synthetic absorbable sutures include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood borne pathogens.

✓ **Sterility:**

Polydioxanone sutures are sterilized by ethylene oxide. Do not re – sterilize! Do not use if package is opened or damaged! Discard opened unused sutures.


✓ **Storage:**

Recommended storage condition below 25 °C, away from moisture and direct heat. Do not use after expiry date.

➤ **FEATURES**

Polydioxanone suture is a synthetic, monofilament absorbable suture.

- **Polydioxanone sutures** are available from U.S.P. size 2 to size 6-0. Sutures are available in violet colour.
- **Polydioxanone sutures** are composed of polymers made from 100% homopolymer of polydioxanone.
- **Polydioxanone sutures** absorb by simple hydrolytic mechanism and absorption is predictable.

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- **Polydioxanone sutures** retain about 70% of the initial tensile strength after 2 weeks, 65% of the initial tensile strength after 4 weeks and 25% after 6 weeks of implantation and the suture is essentially absorbed within 180-240 days.

➤ ADVANTAGES

- **PDO** sutures pass through tissue easily causing very little trauma.
- **PDO** sutures have good knot security and it has easy knot placement.
- **PDO** sutures have the highest tensile strength compared to any other synthetic absorbable sutures and it is absorbed over a longer period of time hence can be used where long term tissue approximation is required.
- **PDO** sutures are available with needles made from 300 series alloy steel for superior strength, sharpness and performance.

Damadioxanone and PDO suture is coloured using Beige(undyed) colored multifilament braided, multifibers according to the size of the strands that meets all the requirements of the European Pharmacopoeia (EP) for Synthetic Absorbable Multifilament Sutures and the requirements of United States Pharmacopoeia (USP) Absorbable Sutures except for a slight oversize in diameter.


1.5. Mechanism of Action

PDO sutures elicit a minimal acute inflammatory reaction in tissue and ingrowth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of PDO suture occurs by means of hydrolysis, gradually and decreases the strength in the body. The absorption process begins a loss of tensile strength followed by a loss of mass. Implantation studies indicate that PDO suture retains approximately 75% of the original tensile strength at 2 weeks and in excess of 50%-60% at 4 weeks post implantation. Absorption of PDO suture is essentially complete between 180 to 240 days.

1.6. Components and Raw Materials of product: Surgical Suture

Surgical Needle

Manufacturer/Supplier	Material
METABIOMED	Polydioxanone (PDO), purple or beige (undyed)
Sima Ambalaj	Shrinking Cover
Quality Needles Pvt	Stainless Steel Surgical Needle
Kurşun Ambalaj FTM Ambalaj	First packing (aluminum foil) Second packing (medical paper)
Endüstri Matbaa	Boxes

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1.5.Accessories Information+

There is no accessories.

Name:

Poly(P-dioxanone)

Content of residues:

Monomers ≤ 1.0 w/w %

Catalysts ≤ 100 ppm Heavy

metals ≤ 10 ppm Solvents ≤ 500

ppm **Additives:**

Stabilizing agent : none Antioxidizing

agent : none **Dyestuffs**

Undyed braids : none


Coating

None

Physical Specification

Damadioxanone and PDO braids 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.

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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.)	Individual (in N) (Min.)
	0.1	11-0	0.007	0.005	0.069	0.049
	0.2	10-0	0.014	0.010	0.137	0.098
0.4	0.3	9-0	0.021	0.015	0.206	0.147
0.5	0.4	8-0	0.050	0.025	0.490	0.245
0.7	0.5	7-0	0.080	0.040	0.784	0.392
1	0.7	6-0	0.17	0.08	1.67	0.784
1.5	1	5-0	0.23	0.11	2.25	1.08
2	1.5	4-0	0.45	0.23	4.41	2.25
3	2	3-0	0.68	0.34	6.67	3.33
3.5	3	2-0	1.10	0.45	10.8	4.41
4	3.5	0	1.50	0.45	14.7	4.41
5	4	1	1.80	0.60	17.6	5.88
6 and larger	5 and larger	2 and larger	1.80	0.70	17.6	6.86

Moisture content : ≤ 400 ppm


Retention ratio of tensile strength

retain about 70% of the initial tensile strength after 2 weeks, 50% of the initial tensile strength after 4 weeks and 25% after 6 weeks of implantation and the suture is essentially absorbed within 180 days.


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Product codes and Description:


ORIGINAL PRODUCT BARCODE	CODE DESCRIPTION	PRODUCT REFERENCE CODE	BRAND NAME	GMDN CODE	CLASS	SHELF LIFE (MONTHES)
8681677074079	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (VIOLET) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DX02M40	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677073379	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX0K40	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677072006	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DX0M40	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677072013	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 0 (VIOLET) 40mm 1/2 CIRCLE TAPER POINT NEEDLE (LOOPED ON)	DX0ML40-150	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677073386	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 40mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX1K40	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677072020	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DX1M40	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677075625	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 50mm 1/2 CIRCLE TAPER POINT NEEDLE	DX1M50	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36

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8681677072037	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 1 (VIOLET) 40mm 1/2 CIRCLE TAPER POINT NEEDLE (LOOPED ON)	DX1ML40-150	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677071337	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX2K26	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677071382	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DX2M26	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677073898	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (VIOLET) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DX2M26-90	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677074420	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 26mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DX2M26-D	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677071986	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DX2M30	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677071375	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX3K26	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681665009120	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DX3M22	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677073881	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 120cm USP SIZE 3-0 (VIOLET) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DX3M22-120	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36

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8681677070460	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DX3M26	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677071955	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 26mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DX3M26-D	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677073256	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX4K20	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677072181	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DX4M16	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677072792	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DX4M20	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677075533	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 13mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX5K13	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677072266	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX5K16	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677072204	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DX5M13	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677072303	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DX5M16	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36

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8681677073393	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DX5M20	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677072273	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (VIOLET) 13mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX6K13	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677072259	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (VIOLET) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DX6M13	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677076394	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX4K16	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677076622	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DX4M26	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677076851	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 1 (VIOLET) 50mm 1/2 CIRCLE TAPER POINT NEEDLE (LOOPED ON)	DX1ML50-150	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677077827	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 25mm 1/2 CIRCLE TAPER POINT NEEDLE	DX0M25	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677077834	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DX3M30	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677077858	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 3-0 (VIOLET) 25mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX3K25-45	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36

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8681677078367	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DX2M22	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677078497	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 26mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX5K26	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677078848	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 60mm STRAIGHT NORMAL CUTTING NEEDLE	DX4GC60	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677079104	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DX3HR17	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8681677079111	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DX4HR17	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154200084	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 1 (VIOLET) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DX01HR40-150	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154200091	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 17mm 3/8 CIRCLE TAPER POINT NEEDLE	DX50DR17	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154200107	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DX50HR17	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154200114	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 45cm USP SIZE 6-0 (VIOLET) 13mm 1/2 CIRCLE TAPER POINT NEEDLE	DX60HR13-45	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36

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8684154200329	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DX30HR20	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154200398	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX20DS18	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154200404	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX30DS18	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154200411	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 18mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX40DS18	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154200756	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 12mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX50DS12	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154201012	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX40DS24	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154201616	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX50DS20	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154202651	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (VIOLET) 12mm 1/2 CIRCLE TAPER POINT NEEDLE	DX60HR12	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154202682	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2 (VIOLET) 50mm 1/2 CIRCLE TAPER POINT NEEDLE	DX02HR50-90	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36

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8684154202699	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 31mm 1/2 CIRCLE TAPER POINT NEEDLE	DX01HR31	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154202705	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DX20HR40	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154202712	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 150cm USP SIZE 2-0 (VIOLET) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DX20HR40-150	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154202729	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 0 (VIOLET) 40mm 1/2 CIRCLE TAPER POINT NEEDLE	DX00HR40-100	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154202835	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX01DS30	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154202842	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX20DS24	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154202859	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 20mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX30DS20	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154204273	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2 (VIOLET) 37mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX02DS37	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206246	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 36mm 1/2 CIRCLE TAPER POINT NEEDLE	DX01HR36	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36

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8684154206253	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 30mm 1/2 CIRCLE TAPER POINT NEEDLE	DX00HR30	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206260	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 24mm 1/2 CIRCLE TAPER POINT NEEDLE	DX30HR24	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206277	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 19mm 1/2 CIRCLE TAPER POINT NEEDLE	DX50HR19	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206284	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (VIOLET) 16mm 1/2 CIRCLE TAPER POINT NEEDLE	DX60HR16	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206291	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX01DS36	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206307	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX00DS30	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206314	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 30mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX20DS30	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206321	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 24mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX30DS24	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206338	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX40DS19	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36

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8684154206345	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX50DS19	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206352	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 6-0 (VIOLET) 16mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX60DS16	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206789	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 1 (VIOLET) 22mm 1/2 CIRCLE TAPER POINT NEEDLE	DX01HR22	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206796	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 0 (VIOLET) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DX00HR26-90	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154206802	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 22mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DX30HR22-D	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154207083	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DX30HR18	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154207915	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 3-0 (VIOLET) 19mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX30DS19	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154207922	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 5-0 (VIOLET) 13mm 3/8 CIRCLE TAPER POINT NEEDLE	DX50DR13	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154208066	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 0 (VIOLET) 36mm 1/2 CIRCLE TAPER POINT NEEDLE	DX00HR36	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36

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8684154208073	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 4-0 (VIOLET) 19mm 1/2 CIRCLE TAPER POINT NEEDLE	DX40HR19	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154208080	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 36mm 3/8 CIRCLE REVERSE CUTTING NEEDLE	DX20DS36	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154208110	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (VIOLET) 20mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DX40HR20-D-90	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154208431	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (VIOLET) 17mm 1/2 CIRCLE TAPER POINT NEEDLE	DX40HR17-90	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154208448	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 3-0 (VIOLET) 26mm 1/2 CIRCLE TAPER POINT NEEDLE	DX30HR26-90	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154208455	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 2-0 (VIOLET) 18mm 1/2 CIRCLE TAPER POINT NEEDLE	DX20HR18-90	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154208462	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (VIOLET) 20mm 1/2 CIRCLE TAPER POINT NEEDLE	DX40HR20-90	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154208561	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (VIOLET) 48mm 1/2 CIRCLE TAPER POINT NEEDLE	DX01HR48-90	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154208578	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 75cm USP SIZE 2-0 (VIOLET) 25mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DX20HR25-D	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36

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8684154208967	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 100cm USP SIZE 2-0 (VIOLET) 26mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DX20HR26-D-100	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154208974	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 1 (VIOLET) 36mm 1/2 CIRCLE REVERSE CUTTING NEEDLE	DX01HS36-90	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36
8684154208110	DAMADIOXANONE: PDO MONOFILAMENT ABSORBABLE SUTURE 1PCS X 90cm USP SIZE 4-0 (VIOLET) 20mm 1/2 CIRCLE TAPER POINT DOUBLE NEEDLE	DX40HR20-D-90	DAMADIAXANONE	16584 - Suture, polydioxanone	Class III	36

1.9.2.NEEDLE:

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

For Analysis Certificates see: Test Reports

1.9.3. Specification of primary and secondary packaging material

Primary packaging material is made of Aluminum foil.


Secondary packaging material is made from a pouch made of medical paper.

1.9. Patient Populations

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 gastrointestinal, obstetric and gynecologic and urologic surgery.

1.10. Intended User

The device should used by physician and/or surgeons.

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1.11. Repeat 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 occurred and/or the wound would open. There is not any restriction as to the number or duration of reapplications.

1.12. Single Use / Reusable


The device is only single-used.

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 Damadioxanone and PDO.(TF13 Clinical and Biological Evaluation)

1.13. Biocompatibility Tests of the Raw Materials for Medical Device Damadioxanone and PDO (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)


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Biocompatibility Test Matrix

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

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:

Product	Classification	Required Tests
Damadioxanone and PDO	Implant Devices Tissue/Bone C-Permanent	<ul style="list-style-type: none"> • Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Subchronic Toxicity • Genotoxicity • Implantation

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The following evaluation is taken by NAMSA, CA. U.S.A.

- ☐Cytotoxicity study using the ISO elution method
- ☐In vitro hemolysis study
- ☐ISO sensitization study in the guinea pig
- ☐ISO acute systemic toxicity study in the mouse
- ☐ISO acute intracutaneous reactivity study in the rabbit
- ☐ISO rabbit pyrogen study
- ☐ISO muscle implantation study in the rabbit (4 weeks)
- ☐ISO muscle implantation study in the rabbit (26 weeks)

Genotoxicity:bacterial reverse mutation study.

The results of the biocompatibility tests on the PDO absorbable braid demonstrate the excellent biocompatibility of the PDO material and also demonstrate that the ETO sterilization does not have any negative effects on the polymer material.

Based on the clinical experiences with the product PDO, 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 PDO can be regarded as biocompatible and suitable for a clinical application.

All related test reports, supplier data and related documentation with this section are given on Test Reports of this technical file.


1.14. Biodegradation for Medical Device Damadioxanone and PDO.

Using the and PDO properties as a starting point, it is possible to copolymerize the two monomers to extend the range of homopolymer properties. Copolymers of glycolide with both L-lactide and DL-lactide have been developed for both device and drug delivery applications.

Sterility test and absorbability study in rats by Korea Testing &Research Institute

This study was performed to evaluate sterility and absorbability in rat.

absorbable PDO Braid Violet, Coated was absorbed between 180 days with recovery from inflammatory response.

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1.15. 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 manually insertion of the thread into the needles. After testing products are wound in a paper, are packed into aluminum paper, then packed again 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 an aluminum foil inner envelope (primary packaging) and labeled in ISO 8 Clean Room, but not sealed at this stage.
- This inner aluminum envelope is then placed in an outer envelope (secondary packaging), which is sealed.


One package unit of Damadioxanone and PDO contains 12 single pouches.

Sterilization

Damadioxanone and PDO (PDO) sutures are sterilized in-house by ETO. 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 minimum 30 °C 30% Humidity with a gas injection period of 5 hours.

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

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Drying

Damadioxanone and PDO sutures are dried after ETO sterilization. They are vacuum-dried using a vacuum oven (3 hours, 50°C) Than with Nitrogen washing for 12 hours and a final vacuum 5 hours and drying for another 3 hours. At the end of the drying process the aluminum packages are sealed under controlled conditions. The sutures are then boxed, 12 per box and boxes are wrapped by shrinking cover.

Packaging into cartons

Twelve sutures pouches are packed into a carton and labelled. Each carton is poliolefin wrapped. Hundred 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.

he residual test is carried out according to EN 10993-7 and the results are shown in Test Reports.

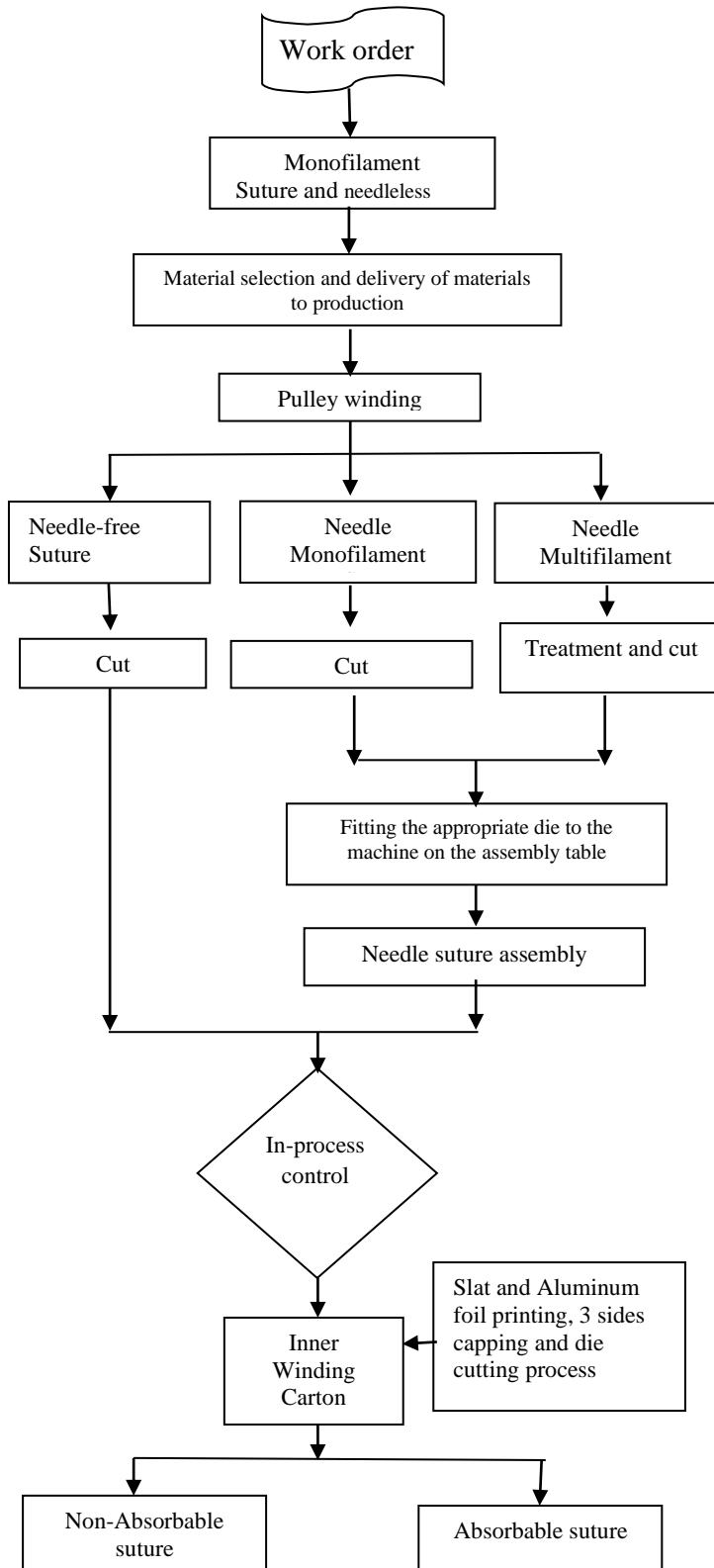
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Manufacturing Flow Chart

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

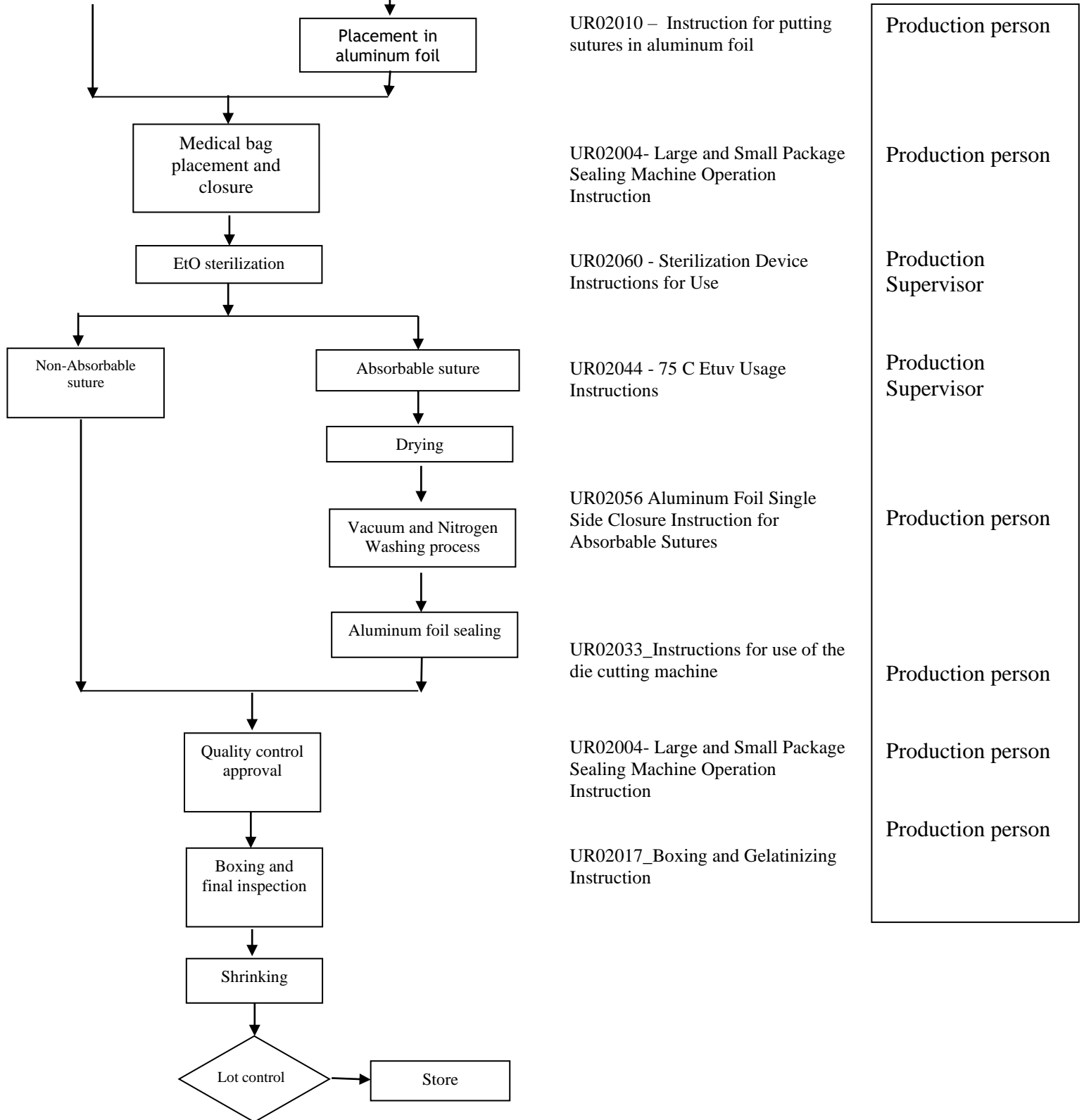
QA Manager


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

1.16. Product and Test Specifications:


The Damadioxanone and PDO ® range of sutures started to successfully produced and extensively used in 2016(June)

The following tests are specified as final batch release controls according to USP 0:

Table: Test specifications and Lot results

Pilot Production

Test Parameter	Method	Lot 23C01X067 DX00DS30	
		Limit	Result
Needle Attachment	USP 0	15,0	60,4
Sterility Test	USP 0	Sterile	Sterile
Water content (moisture)		0.25	0.13


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Validation1

Test Parameter	Method	Lot 16C01 DX1M30	
		Limit	Result
Needle Attachment	USP 1	18,0	56,13
Sterility Test	USP 1	Sterile	Sterile
Water content(moisture)		0.25	0.15

Validation 2

Parameter	Method	Lot 16C01 DX0M30	
		Limit	Result
Needle Attachment	USP 0	15,0	68,27
Sterility Test	USP 0	Sterile	Sterile
Water content(moisture)		0.25	0.13

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Sterility Test	USP 0	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile
Water content(moist ure)		0.25	0.15	0.25	0.15	0.25	0.15

The test reports of PDO lots given on the above table are given on Test reports

1.17. Stability/Aging Test and Product Life Time :

The relevant tests and reports are given on Test Reports.

1.18. Product Tests (Performance) :

The relevant tests and reports are given on Test Reports.


1.19. The Product Classification

According to annex IX, rule no. 8 of EC-Directive 93/42/EEC the product category Damadioxanone and PDO is classified as Medical Devices class III. The product is a synthetic 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 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.

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1.20. Clinical Evaluation :

For the clinical evaluation of GMD literature route of MEDDEV 2.7.1Rev.4 has been selected. Clinical Evaluation is given TF13 of this technical file.

1.21. Declaration of Conformity

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

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

1.22. 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. MB.2016.106.7035 of UDEM dated 25.10.2016 issued by UDEM TECHNICAL INSPECTION & CERTIFICATION.

1.23. 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 this technical file.


1.24. 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 this technical file.

1.25. 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”.













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1.26. 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.

Symbols used on the labels:

ÜRÜN ÜZERİNDEKİ SEMBOLLER SYMBOLS USED ON THE PRODUCT	SYMBOLY POUŽITÉ NA PRODUKTU ИСПОЛЬЗУЕМЫЕ ОБОЗНАЧЕНИЯ الرموز المستخدمة على المنتج
 <p>Üretim Tarihi Date Of Manufacture Datum Výroby Сроки Изготовления تاريخ التصنيع</p>	 <p>Paket Açılmış yada Zarar Görmüş ise Kullanmayınız Do Not Use If Pack Is Opened or Damaged Nepoužívejte, Pokud Je Balení Otevřené Nebo Poškozené Не Применять При Повреждении Упаковки لا تستخدمها إذا كان الغلاف مفتوح أو متضرر</p>
 <p>Son Kullanma Tarihi Date Of Expiry Datum Spotřeba Использовать До تاريخ نهاية الصلاحية</p>	 <p>Tekrar Kullanmayınız Do-Not Reuse Nepoužívejte Opakovaně Не Использовать Повторно لا تعيد استخدامها</p>
 <p>Sıcaklık Limiti Storage Temperature Limits Teplotní Omezení Ограничение Температуры حدود درجة حرارة التخزين</p>	 <p>Etilen Oksit ile Sterilize Edilmiştir Ethylene Oxide Sterilized Product Produkt Sterilizovaný Ethylenoxidem Простерилизовано Оксидом Этилена منتج معقم بأكسيد الإيثان</p>
 <p>Lot Numarası Batch Number Číslo Sarže Код Партии رقم الدفعة</p>	 <p>Tekrar Sterilize Edilmez Do-Not Re-Sterilize Nesterilizujte Znovu Повторно Не Стерилизовать لا تقم بإعادة التعقيم</p>
 <p>Nemden Uzak Tutunuz Avoid Moisture Vyvarujte Se Vlhkosti Беречь От Влага تجنب الرطوبة</p>	 <p>Kullanmadan Önce Kullanım Kılavuzunu Okuyunuz Consult Instructions For Use Viz Návod K Použití Обратитесь К Инструкции По Применению راجع التعليمات للاستخدام</p>
 <p>Güneş Işığına Maruz Bırakmayınız Avoid Direct Sunlight Chraňte Před Přímým Slunečním Zářením Избегать Прямых Солнечных Лучей تجنب أشعة الشمس المباشرة</p>	 <p>Üretici Firma Manufacturer Výrobce Производитель الشركة المصنعة</p>

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1.27. Conformity Assessment Procedure:

Damadioxanone and PDO 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.

1.28. Regulatory Requirements for the Product:

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

1.29. Planned Design Change


Any design change is not planned. If a change is required, it should be carried out in accordance with GE01021 Change Management Procedure

1.30. Sale Information for DAMADIOXANONE ech& PDO

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;

DAMADIOXANONE : PDO 0 75CM NEEDLE 40MM ROUND	BOX	750
DAMADIOXANONE : PDO 0 Violet 75cm Needle T.P. 1/2 40mm	BOX	961
DAMADIOXANONE : PDO 0 loop Violet 150cm Needle T.P. 1/2 40mm	BOX	342
DAMADIOXANONE : PDO 1 Violet 75cm Needle T.P. 1/2 40mm	BOX	272
DAMADIOXANONE : PDO 1 loop Violet 150cm Needle T.P. 1/2 40mm	BOX	725
DAMADIOXANONE : PDO 2-0 Violet 75cm Needle Rev.C 3/8 26mm	BOX	760
DAMADIOXANONE : PDO 2-0 Violet 75cm Needle T.P. 1/2 26mm	BOX	860
DAMADIOXANONE : PDO 3-0 Violet 75cm Needle Rev.C 3/8 26mm	BOX	775
DAMADIOXANONE : PDO 3-0 Violet 75cm Needle T.P. 1/2 26mm	BOX	932
DAMADIOXANONE : PDO 4-0 75CM NEEDLE 20MM CUTTING	BOX	10
DAMADIOXANONE : PDO 4-0 Violet 75cm Needle T.P. 1/2 16mm	BOX	129
DAMADIOXANONE : PDO 5-0 Violet 75cm Needle Rev.C 3/8 16mm	BOX	70
DAMADIOXANONE : PDO 5-0 Violet 75cm Needle T.P. 1/2	BOX	189

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13mm		
DAMADIOXANONE : PDO 6-0 Violet 75cm Needle Rev.C 3/8 13mm	BOX	74
DAMADIOXANONE : PDO 6-0 Violet 75cm Needle T.P. 1/2 13mm	BOX	11
DAMADIOXANONE: PDO 1 75CM NEEDLE 40MM CUTTING	BOX	1500
DAMADIOXANONE: PDO 4-0 75CM NEEDLE 20MM ROUND	BOX	15
DAMADIOXANONE: PDO 5-0 75CM NEEDLE 20MM ROUND	BOX	257
TOPLAM		8632

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 22.05.2018	Added "PDO"
Rev.04 25.10.2018	İtems: Intended use of the product,1Intended user, Patient Population, Design Change, Sale Information have been changed and mentioned in the document by highlight.
Rev.5 17.06.2019	Title Update
Rev .6. 04.07.2019	Model list added

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