CLNICAL EVALUATION REPORT

STERILE POLYDIOXANONE SUTURE WITH NEEDLE

Approval of the Clinical evaluation report is performed in accordance with the responsibility of the following functional area representatives

The following product applies ClassⅢ according to Council Directive 93/42/EEC amended by 2007/47/EEC AnnexⅨ Rule8.

Product name	STERILE POLYDIOXANONE SUTURE WITH NEEDLE
Brand name	Re:Jur
Model codes	165 Model codes including YRN25-01

Revision history

Rev. No	Rev. Date	Modified contents	Remark
0	Jan. 13, 2014	Firstly prepared	-
1	Feb. 15, 2015	Update of clinical evaluation report	-
2	Jun. 15, 2016	Addition of brand name / Deletion of brand name	

Functional area representatives

Division	Department	Name	Date	Signature
Authored by	Quality assurance team	Lee Min Woo	Jun. 15, 2016	
Reviewed by	President	Yahng Hae June	Jun. 15, 2016	
Approved by	Medical Doctor of clinical evaluation	Kang Kyoung Jin	Jun. 15, 2016	

Kang Kyoung Jin CV
- MD & PhD
- Ex-Professor of Catholic University of Daegu, Medical School, South Korea
- Founder & 1st president of Korean College of Cosmetic Surgery

1. INSTURCTION

The objectives of this clinical evaluations are :

- To verify that, normal conditions of use, the characteristic and the performance of the below device to those referred to in Section 1 and 3 of Annex Ⅰ of Council Directive 93/42/EEC amended by MDD 07/47/EEC of the European Parliament and of the Council of 5 September 2007 concerning medical devices, and
- To determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device.

2. SCOPE

The following product was applied.

Product name	Sterile Polydioxanone Suture with Needle
Brand name	Re:Jur
Model	165 Model codes including YRN25-01

3. REFERENCE STANDARDS

3.1 Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007

3.2 EN ISO14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

3.3 Evaluation of clinical data: A guide for manufacturers and notified bodies (MEDDEV.2.7.1)

4. TERMS AND DEFINITIONS

4.1 Medical device

Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used on human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap;
- Evaluation, replacement or modification of the anatomy or of a physiological process;
- Control of conception

And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

4.2 Device; device intended for clinical evaluation

Any MEDICAL DEVICE intended for use by an appropriately qualified practitioner when conducting CLINICAL EVALUATIONS in an adequate clinical environment.

4.3 Clinical evaluation

Any systematic study in human SUBJECTS, undertaken to verify the safety and PERFORMANCE of a specific MEDICAL DEVICE, under normal conditions of use

4.4 Clinical evaluation plan; protocol

A document which includes detailed information on the rationale, aims and objectives, design and proposed analyses, methodology, and conduct of the CLINICAL EVALUATION.

4.5 Clinical investigator

The investigator responsible for the conduct of a CLINICAL EVALUATION and who takes the clinical responsibility for the well-being of the SUBJECTS involved.

4.6 Performance of the device

The action of a specific MEDICAL DEVICE with reference to its intended use when correctly applied to applied to appropriate SUBJECTS.

4.7 Ethics committee, research ethics committee, institutional review board and properly constituted body of medical professionals and non-medical members, appointed in accordance with current practice, whose responsibility is to ensure that the safety, well-being and human right of the SUBJECTS participating in a particular CLINICAL EVALUATION are protected.

4.8 Final report of clinical evaluation
A comprehensive description of the CLINICAL EVALUATION on completion.

4.9 Sponsor; promoter
An individual or an organization which takes responsibility for the initiation and/or implementation of a CLINICAL EVALUATION.

4.10 Subject
A human being, either a patient or a non-patient volunteer, participating in a CLINICAL EVALUATION.

4.11 Informed consent; consent
The voluntary confirmation and documentation of a SUBJECT's willingness (or his legal guardian or representative's permission) to participate in a particular evaluation, after information has been given to the SUBJECT on the nature of the CLINICAL EVALUATION.

4.12 Monitor
A person appointed by the SPONSOR and responsible to him for monitoring and reporting on the progress of the CLINICAL EVALUATION.

4.13 Adverse event
Any undesirable clinical occurrence in a SUBJECT whether it is considered to be DEVICE related or not.
4.14 Adverse device effect; undesirable side effect
A DEVICE related ADVERSE EVENT.

4.15 Multicentre evaluation
A CLINICAL EVALUATION, conducted according to a single CLINICAL EVALUATION PLAN, which takes place at different evaluational sites.

4.16 Principal clinical investigator
A CLINICAL EVALUATION INVESTIGATOR appointed by the SPONSOR to coordinate the work in a MULTICENTRE CLINICAL EVALUATION or that of several CLINICAL EVALUATION INVESTIGATORS at one site.

4.17 Case report form
A set of documents, designed for complete recording of all relevant patient- and device-related data, as required by the CLINICAL EVALUATION PLAN,

4.18 Clinical evaluation investigator's brochure
A collection of relevant information known prior to the onset of a CLINICAL EVALUATION.

5. DESCRIPTION OF THE DEVICE

5.1 Overview

This device is 'Sterile Polydioxanone Suture with Needle' to insert PDO into the hypodermic to use needle. And this device consist of suture, sponge, cannula, hub, protect cap

5.2 Device Name: Sterile Polydioxanone Suture with Needle

5.3 Model code :165 model codes including YRN25-01

5.3.1 Polydioxanone suture with general needle

A. Traditional general needle

1) General PDO suture with general needle (53 models)

(1) Normal (18 models)

YRN25-01	YRN26-01	YRN27-01	YRN29-01	YRN30-01
YRN25-02	YRN26-02	YRN27-02	YRN29-02	YRN30-02
YRN25-03	YRN26-03	YRN27-03	YRN29-03	
YRN25-05	YRN26-05	YRN27-05	YRN29-04	

(2) Pair Spiral (8 models)

YRT25-01	YRT26-01
YRT25-02	YRT26-02
YRT25-03	YRT26-03
YRT25-05	YRT26-05

(3) Normal Spiral (12 models)

YRS25-03	YRS26-01	YRS27-01	YRS29-02	YRS30-02
	YRS26-02	YRS27-02	YRS29-03	
	YRS26-03	YRS27-03	YRS29-04	
		YRS27-05		

(4) Duo Normal Spiral (7models)

YRDS25-01	YRDS26-01
YRDS25-02	YRDS26-02
YRDS25-03	YRDS26-03
	YRDS26-05

(5) Pair-Normal Spiral (8 models)

YRTS25-01	YRTS26-01
YRTS25-02	YRTS26-02
YRTS25-03	YRTS26-03
YRTS25-05	YRTS26-05

2) Cog PDO suture with general needle (37 models)

(1) AB type (6 models)

YRPN-23-07	YRPN-25-07
YRPN-23-08	YRPN-25-08
YRPN-23-10	YRPN-25-10

(2) BC type (6 models)

YRPN-23-27	YRPN-25-27
YRPN-23-28	YRPN-25-28
YRPN-23-30	YRPN-25-30

(3) BP type (3 models)

YRPN-19-42	YRPN-21-35	YRPN-23-35

(4) BSP type (3 models)

YRPN-27-06
YRPN-27-08
YRPN-27-10

(5) CA type (5 models)

YRPN-19-46	YRPN21-40	YRPN-23-38
YRPN-19-48		YRPN-23-40

(6) DSP type (2 models)

YRPN-25-111
YRPN-25-113

(7) FA type (1 models)

YRPN-21-58

(8) FC type (3 models)

YRPN-19-84	YRPN-21-70	YRPN-23-70

(9) FD type (3 models)

YRPN-19-90	YRPN-21-75	YRPN-23-75

(10) FE type (3 models)

YRPN-19-96	YRPN-21-80	YRPN-23-80

(11) FG type (2 models)

YRPN-19-103
YRPN-19-104

5.3.2 Polydioxanone suture with blunt needle

A. General “W” blunt needle

1) General PDO suture with General “W” blunt needle (1 models)

(1) Normal (1 models)

YRN30-01-W

2) Cog PDO suture with general “W” blunt needle (37 models)

(1) AB type (6 models)

YRPN-23-07-W	YRPN-25-07-W
YRPN-23-08-W	YRPN-25-08-W
YRPN-23-10-W	YRPN-25-10-W

(2) BC type (6 models)

YRPN-23-27-W	YRPN-25-27-W
YRPN-23-28-W	YRPN-25-28-W

YRPN-23-30-W	YRPN-25-30-W

(3) BP type (3 models)

YRPN-19-42-W	YRPN-21-35-W	YRPN-23-35-W

(4) BSP type (3 models)

YRPN-27-06-W
YRPN-27-08-W
YRPN-27-10-W

(5) CA type (5 models)

YRPN-19-46-W	YRPN21-40-W	YRPN-23-38-W
YRPN-19-48-W		YRPN-23-40-W

(6) DSP type (2 models)

YRPN-25-111-W
YRPN-25-113-W

(7) FA type (1 models)

YRPN-21-58-W

(8) FC type (3 models)

YRPN-19-84-W	YRPN-21-70-W	YRPN-23-70-W

(9) FD type (3 models)

YRPN-19-90-W	YRPN-21-75-W	YRPN-23-75-W

(10) FE type (3 models)

YRPN-19-96-W	YRPN-21-80-W	YRPN-23-80-W

(11) FG type (2 models)

YRPN-19-103-W
YRPN-19-104-W

B. General “L” blunt needle

1) Cog PDO suture with general “L” blunt needle (37 models)

(1) AB type (6 models)

YRPN-23-07-L	YRPN-25-07-L
YRPN-23-08-L	YRPN-25-08-L
YRPN-23-10-L	YRPN-25-10-L

(2) BC type (6 models)

YRPN-23-27-L	YRPN-25-27-L
YRPN-23-28-L	YRPN-25-28-L
YRPN-23-30-L	YRPN-25-30-L

(3) BP type (3 models)

YRPN-19-42-L	YRPN-21-35-L	YRPN-23-35-L

(4) BSP type (3 models)

YRPN-27-06-L
YRPN-27-08-L
YRPN-27-10-L

(5) CA type (5 models)

YRPN-19-46-L	YRPN21-40-L	YRPN-23-38-L
YRPN-19-48-L		YRPN-23-40-L

(6) DSP type (2 models)

YRPN-25-111-L
YRPN-25-113-L

(7) FA type (1 models)

YRPN-21-58-L

(8) FC type (3 models)

YRPN-19-84-L	YRPN-21-70-L	YRPN-23-70-L

(9) FD type (3 models)

YRPN-19-90-L	YRPN-21-75-L	YRPN-23-75-L

(10) FE type (3 models)

YRPN-19-96-L	YRPN-21-80-L	YRPN-23-80-L

(11) FG type (2 models)

YRPN-19-103-L
YRPN-19-104-L

5.4 Intended use :

This device is intended to fixate sub dermal tissue in an elevated position in plastic and reconstructive surgery. Polydioxanone suture provides wound support for longer period as compared to other synthetic absorbable suture. It also prolongs the stimulation time that increases the treatment effect on the body.

5.5 Classification applied

1) ‘Sterile Polydioxanone Suture with Needle’ has been classified as **ClassⅢ** according to MDD93/42/EEC amended by 2007/47/EEC AnnexIX, Rule8.

5.6. Characteristic

1) Ethylene oxide gas be sterilized by Yurim Medical Co., Ltd.
- Sterilization parameter
① Sterilizing agent : 20 : 80(E.O : CO_2)
② Sterilization assurance level[SAL] : 10^{-6}

2) Packing method & material
① Blister heat sealing
② Polyethylene Terephthalate(PET) +Linear low density polyethylene and sterile paper

3) This device should be used for Single-use.

4) Shelf-life : 2years

5.7 Usage method

5.7.1 Preparation before use
1) Confirm the model codes in accordance with dimensions
2) Check the validity period and packaging damaged.
3) Know how to use the product.

5.7.2 How to operate and how to use
1) Determine the length of the needle in accordance with the position to operate
2) Sterilize the affected part to operate
3) Push the needle in until the end of the suture is inserted into the cortex of the affected part completely
4) Pull the needle out and paste the band on the affected part

5.7.3 How to store and manage after use.
1) Keep it in normal temperature
2) Avoid direct sunlight and where to be high temperature and humidity.
3) Discard the product if it is opened once even if it does not used
4) Don't reuse because of single use product.

5.8 Attention

1) Do not use the product that the validity period is passed.
2) Do not use the product that the package is damaged.
3) Do not use this product for other purpose besides the intended use.
4) This product should be used only by professional medical personnel.
5) Do not use if there is inflammation or concerned about infection in the position to operate

6. RAW MATERIAL OF THE DEVICE

No	Part name	Material	Standard	Cas no.	Manufacturer	Remark
1	suture	Poly(1.4-dioxanone-2-one)	- Strand length : ≥98% of labeled length - Diameter : 0.095~0.125 - Knot-pull tensile strength :Initial ≥ 0.35 kgf - Retention test : Initial ≥ 0.45 kgf, 2Weeks ≥ 75.0 % - Extractable color : Should not be darker than MS. - Water content : ≤ 500ppm - Residual monomer : ≤ 1% - Heavy metal : ≤ 10ppm	Cas 29223-92-5	Samyang biopharmaceuticals Corp.	Contact (tissue)
	color	D&C Violet No.2	21CFR 74.3602	Cas81-48-1	Samyang biopharmaceuticals Corp.	Contact (tissue)
2	sponge	Polyethylene	-Appearance: white -Odor: Essentially odorless pellet. -PH: Not applicable -Solubility: (In water)Insoluble (Other solvent): soluble in toluene, xylene, trichloroethane etc. -Melt point: 126~ 136℃ -Specific gravity(H20=1): 0.940~0.970 -Molecular weight:>10.000	Cas 9002-88-4	Lotte chemical Corp.	Non-contact
3	cannula	Stainless	KS D3698 (STS 304)	Cas7439-89-6	Ace medical industry	Contact

		Steel(STS 304)			Co.,Ltd.	(tissue)
4	HUB	Polypropylene	- Appearance: white solid - Smell: odorless - Melting point / freezing point: <165 ℃ - Solubility in water: insoluble - Relative density (water = 1): 0.9 - Spontaneous ignition temperature: 375 ~ 400 ℃ - Molecular weight:> 40,000	Cas 9003-07-0	GS Caltex	Non-contact
5	protect cap	Polypropylene	- Appearance: white solid - Smell: odorless - Melting point / freezing point: <165 ℃ - Solubility in water: insoluble - Relative density (water = 1): 0.9 - Spontaneous ignition temperature: 375 ~ 400 ℃ - Molecular weight:> 40,000	Cas 9003-07-0	GS Caltex	Non-contact

7. NEED TO PERFORM CLINICAL EVALUATION

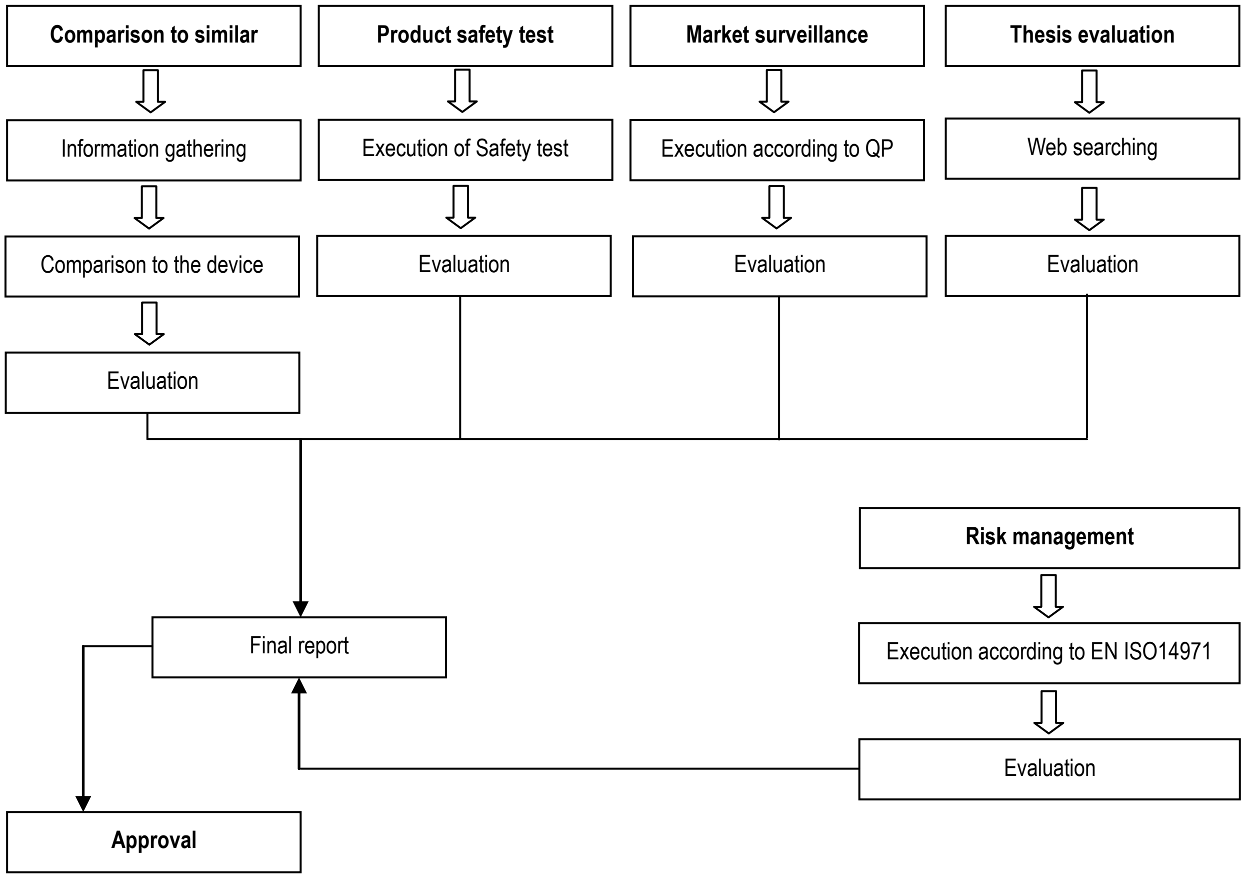
Since ‘Sterile Polydioxanone Suture with Needle’ is developed for 11 years, we have been manufactured the device since 2013 and have sold in Korea,

The raw material used for our products are not the ones that have been newly developed or the ones that have not been ever used till now. The raw material have been used in medical field for a long time. The raw materials of our product, polydioxanone suture, needle is well known of its biological safety, so that they does not need to be tested of its bio-compatibility.

However, we decided to conduct clinical evaluation for comparison to similar, product safety test, market surveillance, thesis evaluation as shown in section 8

8. OVERVIEW OF THE CLINICAL EVALUATION

8.1 Process flow for the clinical evaluation performance



9. RESPONSIBILITY AND AUTHORITY

9.1 Responsibility and authority

No	Step	Authored by	Reviewed by	Approved by
1	Comparison to similar	Lee Min Woo	Lee Min Woo	Yahng Hae June
2	Product safety test			
3	Market surveillance			
4	Thesis searching			
5	Final report			
6	Risk management	According to the risk management procedure		
7	Human part	Kim Jun Woo (Medical doctor)		

9.2 Qualification of the person who intervene on Clinical evaluation

1) Lee Min Woo

2013	11	28	Quality management leader of Yurim Medical Co., Ltd.

2) Yahng Hae June

No	Period	Education or Career
1	2013. 01 ~	President of Yurim Medical Co., Ltd.

3) Kang Kyoung Jin (Medical doctor)
- MD & PhD
- Ex-Professor of Catholic University of Daegu, Medical School, South Korea
- Founder & 1st president of Korean College of Cosmetic Surgery

10. EVALUATION_PRODUCT SAFETY TEST

10.1 Contamination test results in manufacture process

No	Testing item	Standard	TEST LAB	ISSUE DATE	Test result
1	Particles	ISO14644 Series	KTR (Korea testing & researching institute)	Nov.04,2014, Aug.12,2014, Aug.12,2014,	Pass
2	Airborne microbial counts	ISO14644 Series	KTR (Korea testing & researching institute)	Nov.04,2014, Aug.12,2014, Aug.12,2014,	Pass
3	Setting plates counts	ISO14644 Series	KTR (Korea testing & researching institute)	Nov.04,2014, Aug.12,2014, Aug.12,2014,	Pass
4	Contact plates counts	ISO14644 Series	KTR (Korea testing & researching institute)	Nov.04,2014, Aug.12,2014, Aug.12,2014,	Pass

10.2 Product test

Ⅰ. Needle

1. PRODUCT TEST RESULTS

All our products were performed by laboratories acquired ISO17025. Test samples to be used in this test were from manufacture line.

1.1 Biocompatibility test

- Test Client : **Ace Medical Industry Co., Ltd.**
- Test Laboratory : KCL
- The date of issue : Aug.19,2013

No	Test item	Test method / Test criteria	Test result	TEST LAB	ISSUE DATE	REP NO
1	Test for in vitro cytotoxicity	EN ISO 10993-5(2009) Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity Non-cytotoxic	Qualitative result (Grade) of test on extracts was 0.0. (Pass)	KCL	Aug.19, 2013	MT13-00158-A1
2	Acute systemic toxicity test	EN ISO 10993-11(2009) Biological evaluation of medical devices - Part 11: Tests for systemic toxicity Non-toxic	None of animals on study were observed with abnormal clinical signs (Pass)	KCL	Aug.19, 2013	
	Pyrogen Test	Korea Pharmacopoeia 9th General testing method <9>-Test for pyrogen ISO (material mediated) Rabbit Pyrogens Test - *in vivo* Non-pyrogenic	the test substance extract was judged as non-pyrogenic (Pass)	KCL	Aug.19, 2013	
4	Intracutaneous reactivity test	EN ISO 10993-10(2013) Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization if the final test sample score is 1.0 or less.	The test substance meets the ISO requirement (Pass)	KCL	Aug.19, 2013	
5	Skin sensitization test	EN ISO 10993-10(2013) Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization No- skin hypersensitivity reactions.	extraction solution for the test sample was not considered to be Skin hypersensitivity reactions. (pass)	KCL	Aug.19, 2013	
6	Hemolysis test	EN ISO10993-4(2009) Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood Non-hemolytic	The test sample extraction solution was nonhemolytic. (Pass)	KCL	Aug.19, 2013	

1.2 Chemical test

- Test Client : Ace Medical Industry Co., Ltd.
- Test Laboratory : KCL
- The date of issue : Aug.19,2013

No	Test item		Test method		
			Test criteria	Test result	Test record
1	Extraction Test	PH	Korea Pharmacopoeia 9th General testing method <56>-Extract testing Extract testing for plastic container of medicinal drug [Difference of PH]		
			Difference of PH ≤ 1.0	0.56 (Pass)	MT13-00158-A1
		Potassium permanganate reducing substances	Korea Pharmacopoeia 9th General testing method <56>-Extract testing Extract testing for plastic container of medicinal drug [KMnO4 Consumption]		
			Difference in titres ≤ 2.0ml	0.8 (Pass)	MT13-00158-A1
		Residue after evaporation	Korea Pharmacopoeia 9th General testing method <56>-Extract testing Extract testing for plastic container of medicinal drug [Evaporation residue]		
			Difference in extractales ≤ 1.0mg	0.2	MT13-00158-A1

				(Pass)	
		Heavy metals	Korea Pharmacopoeia 9th General testing method <53>-Heavy metal test [Atomic absorption spectrophotometry]		
			Not greater than a comined total of the Sn, Pb, Zn and Fe Shall be less than 0.1mg/L of Cd	Conform (Pass)	MT13-00158-A1

1.3 Performance test
- Test Client : Ace Medical Industry Co., Ltd.
- Test Laboratory : KCL
- The date of issue : Aug.19,2013

No	Test item	Test method		
		Test criteria	Test result	
1	Inner/ Outside and Structure	ISO7864:1993 Sterile hypodermic needles for single use –Section 4.5		
		See the test report	Pass	MT13-00158-A1
2	Dimension	ISO9626: 1991/Amd1:2001 Stainless steel needle tubing for the manufacture of medical devices–Section 8		
		See the test report	Pass	MT13-00158-A1
3	Draw Test	ISO7864:1993 Sterile hypodermic needles for single use –Section 13.1		
		See the test report	Pass	MT13-00158-A1
4	Elasticity Test	ISO7864:1993 Sterile hypodermic needles for single use –Section 4.5		
		See the test report	Pass	*MT13-00158-A1*
5	Flexual Rigidity	ISO7864:1993 Sterile hypodermic needles for single use –Section 4.5		
		See the test report	Pass	*MT13-00158-A1*

Ⅱ. Suture

1. PRODUC TEST RESULTS

All our products were performed by laboratories acquired ISO17025. Test samples to be used in this test were from manufacture line.

1.1 **Biocompatibility test**
- Test Client : Yurim Medical Co.,Ltd.
- Test Laboratory : KTC (korea test certificate)
- The date of issue : Sep. 4, 2015

No	Test item	Test method		
		Test criteria	Test result	Test record
1	Cytotoxicity test	ISO10993-5 (2009) Biological evaluation of medical devices. Part 5: Tests for in vitroCytotoxicity, 8.2 test on extracts		
		The biological response is less than or equal to grade 2(mild) in reactivity grades for elution test	None cell lysis or toxicity (evaluation grade:0) (Pass)	T-2015-03856
2	Guniea pig maximization test	ISO10993-10 (2010) Biological evaluation of medical devices Part 10: Teat for Irritation and skin sensitization, 7.5 Guniea pig maximization test		

		Clinical observations : normal Body weight : no significant change	No evidence of causing delayed dermal contact sensitization (Pass)	T-2015-03856
3	Animal intracutaneous (intradermal) reactivity test	ISO10993-10 (2010) Biological evaluation of medical devices Part 10: Teat for Irritation and skin sensitization 6.4 Animal intracutaneous (intradermal) reactivity test		
		Clinical observations : normal Body weight : no significant change	No evidence of significant irritation (Pass)	T-2015-03856
4	Acute systemic toxicity	ISO10993-11 (2006) Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, 5. Acute systemic toxicity		
		No mortality, Clinically normal	No mortality or evidence of acute systemic toxicity (Pass)	T-2015-03856
5	Pyrogen test	ISO10993-11 (2006) Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, Annex F Information on material-mediated pyrogens		
		No single animal shows increase more than 0.5℃	Non-pyrogenic (Pass)	T-2015-03856
6	Genotoxicity test (Bacterial Reverse Mutation test)	ISO 10993-3 (2014) Biological evaluation of medical devices - Part 3: Test for genotoxicity, Carcinogenicity and Reproductive Toxicity, 5. Genotoxicity tests		
		See the attached test report	Was not mutagenic for any tester strain (Pass)	T-2015-03856
7	Genotoxicity test (Mammalian Erythrocyte Micronucleus test)	ISO 10993-3 (2014) Biological evaluation of medical devices - Part 3: Test for genotoxicity, Carcinogenicity and Reproductive Toxicity, 5. Genotoxicity tests		
		See the attached Test report	No evidence of causing micronucleus in the immature erythrocytes (Pass)	T-2015-03856
8	Implantation test (12 weeks)	ISO10993-6 (2007) Biological evaluation of medical devices - Part 6: Tests for local effects after implantation, Annex C Test methods for implantation in muscle		
		See the attached Test report	Non-irritant (Pass)	T-2015-03856

1.2 Bio-stability
- Test Client : Samyang Corporation
- Test Laboratory(institute) : R&D center, Samyang Corporation
- The date of issue : March ~ December, 2000

No	Product name (Manufacturer)	USP Size	Absorption area (cm²) [(ratio %)] of absorbable sutures					
			10th days	80th days	120th days	180th days	220th days	260th days
1	Monosorb (Samyang)	2	9.89(100)	9.94(100.5)	9.64(97.5)	1.33(13.4)	Disappear	Disappear
		3/0	2.90(100)	2.93(101.1)	2.32(79.8)	1.00(34.5)	Disappear	Disappear
2	PDS II (Ethicon)	2	9.15(100)	9.51(104.0)	9.81(407.2)	2.57(28.1)	.15(1.6)	Disappear
		3/0	2.94(100)	2.62(89.2)	2.23(75.6)	0.57(19.3)	Disappear	Disappear

- The test method : Monosorb and PDS II were implanted to the same rat. Using optic microscope, area of the samples in the tissue was measured at 10, 80, 120, 180, 220, 260 days after implantation

- The test result : Absorption time of Monosorb was 180~220days. This result was similar with other suture products, PDS II. No significant difference between Monosorb and PDS II was observed.

1.3 Safety test
- Test Client : Yurim Medical Co.,Ltd.
- Test Laboratory : KCL(Korea Conformity Laboratories)
- The date of issue : Jan.08,2014

No	Test item	Test method		
		Test criteria	Test result	Test record
1	Sterility test	Korea Pharmacopoeia 9th General testing method <9>-Sterility testing		
		All sample should be the negative reaction.	Pass	MT13-00325
2	Ethylene oxide gas residual test	ISO10993-7:2008 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals		
		ETO≤ 25PPM, ECH≤ 25PPM, EG≤ 250PPM	Pass	MT13-00325

1.4 Performance test
- Test Client : Yurim Medical Co.,Ltd.
- Test Laboratory : KCL(Korea Conformity Laboratories)
- The date of issue : Jan.08,2014

No	Test item	Test method		
		Test criteria	Test result	Test record
1	Suture diameter	(USP) Synthetic Absorbable Monofilament Sutures-Diameter		
		See the attached testing report	Pass	MT13-00325
2	Suture length	(USP) Synthetic Absorbable Monofilament Sutures-length		
		See the attached testing report	Pass	MT13-00325
3	Appearance test	(USP) Synthetic Absorbable Monofilament Sutures-visual test		
		See the attached testing report	Pass	MT13-00325

Ⅲ. Suture with needle

1 Safety test

1) Shelf life and packaging qualification
- Test Client : Yurim Medical Co.,Ltd.
- Test Laboratory : MENG Co.
- The date of issue : May 28, 2014

No	Test item	Test method		
		Test criteria	Test result	Test record
1	Shelf-life test for 2 years	ASTM F1980:2002 Standard Guide for Accelerated Aging of Sterile medical device packages		

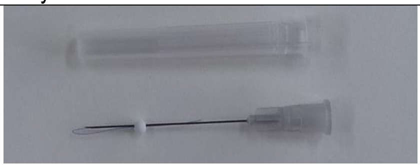
		See the attached shelf-life test report	Pass	MEN-SL14024

1.2 Safety test
- Test Client : Yurim Medical Co.,Ltd.
- Test Laboratory : MENG Co.
- The date of issue : Mar. 20, 2015

No	Test item	Test method		
		Test criteria	Test result	Test record
1	Ethylene Oxide Sterilization Validation Test	EN ISO 11135(2014) Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices		
		See the attached Ethylene Oxide Sterilization Validation Test	Pass	YR-SVR-1501

10.3.3 Evaluation : we confirmed that our device has no problems about performance and biocompatibility.

11. EVALUATION_COMPARISON TO SIMILAR DEVICE
1) Needle part

No	Division	Yurim Medical Co., Ltd.	JEIL TECH Co.,Ltd	Substantial Equivalence Discussion
		Sterile Absorbable Polydioxanone Suture with Needle	STERILE SINGLE USE POLYDIOXANONE SUTURE WITH NEEDLE	
1	Intended for use	This device is intended to fixate sub dermal tissue in an elevated position in plastic and reconstructive surgery. Polydioxanone suture provides wound support for longer period as compared to other synthetic absorbable suture. It also prolongs the stimulation time that increases the treatment effect on the body.	To insert PDO into the hypodermic to use needle..	similar
2	Shape			similar
4	Needle Diameter	(1.020-1.100), (0.800-0.830), (0.600~0.673) (0.500~0.530), (0.440~0.470), (0.400~0.420) (0.324~0.351), (0.298~0.320)mm	0.298~0.320mm, 0.324~0.351mm, 0.400~0.420mm 0.440~0.470mm, 0.500~0.530mm, 0.550~0.580mm 0.600~0.673mm	similar
5	Needle Length	25,38,50,60,70,90 100mm	13,25,38,50,60,70,90 mm	similar
	Lubricant	Silicon	Silicon	Equivalence
6	Needle gauge	19G, 21G, 23G, 25G, 26G, 27G, 29G, 30G	23G,24G,25G,26G,27G,29G,30G	similar
7	Sterilization method	EO Gas	EO Gas	Equivalence

8	Needle point shape	Bevel Sharp	Bevel Sharp	Equivalence

2) Suture part

No	Division	Yurim Medical Co., Ltd. Sterile Absorbable Polydioxanone Suture with Needle	JEIL TECH Co.,Ltd STERILE SINGLE USE POLYDIOXANONE SUTURE WITH NEEDLE	Substantial Equivalence Discussion
1	Intended for use	This device is intended to fixate sub dermal tissue in an elevated position in plastic and reconstructive surgery. Polydioxanone suture provides wound support for longer period as compared to other synthetic absorbable suture. It also prolongs the stimulation time that increases the treatment effect on the body.	To insert PDO into the hypodermic to use needle	similar
2	Shape	Absorbable sutures	Absorbable sutures	Equivalence
4	Suture Diameter	(0.400~0.499)mm, (0.340~0.399)mm (0.250~0.339)mm, (0.200~0.249)mm (0.150~0.199)mm, (0.095~0.149)mm (0.050~0.094)mm,	0.05~0.094mm , 0.095~0.149mm 0.15~0.199mm , 0.20-0.249mm	similar
5	Suture Length	30,60,80,100,120,160,180 mm	30,50,70,90,110,150 mm	similar
6	Material	Polydioxanone(PDO)	Polydioxanone(PDO)	Equivalence
7	Sterilization method	EO Gas	EO Gas	Equivalence
8	CE number		44121/101/1/2012/CE	Difference
9	Usage method	1. How to operate and how to use 1) Determine the length of the needle in accordance with the position to operate 2) Sterilize the affected part to operate 3) Push the needle in until the end of the suture is inserted into the cortex of the affected part completely 4) Pull the needle out and paste the band on the affected part	1) Open the package and removed the protect cap safely when use it. 2) After Insert suture in the skin and pull needle out 3) Dispose it into the safety box after recovering protect cap	similar

3) Evaluation for section

① Evaluation for Intended for use
The Intended use of the product is all similar (Yurim Medical Co., Ltd, JEIL TECH Co.,Ltd)

② Evaluation for Shape
The shape of the all product (Yurim Medical Co., Ltd., JEIL TECH Co.,Ltd) is designed in accordance with EN ISO 7864.and structure as per manufacturer

③ Evaluation for Point
The point geometry of the all product (Yurim Medical Co., Ltd, JEIL TECH Co.,Ltd) is designed in accordance with EN ISO 7864.

④ Evaluation for Needle Diameter
The Needle diameter of the product (Yurim Medical Co., Ltd, JEIL TECH Co.,Ltd)is designed in accordance with EN ISO 7864.

⑤ Evaluation for Needle Length
The Needle length of the product (Yurim Medical Co., Ltd, JEIL TECH Co.,Ltd) is designed in accordance with EN ISO 7864.

⑥ Evaluation for Material
The product (Yurim Medical Co., Ltd., JEIL TECH Co.,Ltd) uses the safety material that is proved about biological safety.

⑦ Evaluation for Sterilization method
The product (Yurim Medical Co., Ltd., JEIL TECH Co.,Ltd) is sterilized by Ethylene oxide gas according to EN ISO11135.

⑧ Evaluation for Structure
The sterile needle of Yurim Medical Co., Ltd. is similar as disposable needle with JEIL TECH Co.,Ltd

11.4 Evaluation
When our device is compared to similar device, we confirmed that the structure, material, intended use, usage method, sterilization method of our device are equal similar device. Therefore, our device is not new development medical device.

12. EVALUATION_MARKET SURVEILLANCE

12.1 Market experience

1) This products has been sold since the first distribution in 2013. The distributed quantity of products from Jan. 2015 to Dec. 2015 was about 300, 000 pieces. They have been released on the market in Korea

12.2 Distribution of products

Year	Area	Quantity distributed
Jan. 2015 ~ Dec. 2015	Domestic	300,000
	Overseas	0
Total		300,000

12.3 Customer complaints analysis

No.	Items of side-effects	No. of incident	Complaints Received	Corrective action
1	Bio-contamination	0	0	0
2	Toxicity	0	0	0
3	Pyrogenicity	0	0	0
4	Inadequate labeling	0	0	0

5	Instruction for use	0	0	0
6	Ingress of substance into device	0	0	0
7	Inadequacy of performance Characteristics for the intended use	0	0	0
8	Inadequate packing	0	0	0
9	Other misuse	0	0	0
10	Packing damage	0	0	0
11	Q'ty shortage	0	0	0
12	Damage of delivery	0	0	0
	Total	0	0	0

12.4 Reported hazards and action for hazards

No.	Reported hazards and action for hazards	No. of incident	Complaints Received	Corrective action
1	In-coming inspection data	0	0	0
2	in-process inspection data	0	0	0
3	Final inspection data	0	0	0
4	Hazards and actions after produce.	0	0	0
	Total	0	0	0

12.5 Others

No.	Items	No. of incident	Complaints Received	Corrective action
1	Feedback from customers	0	0	0
2	Emergency of new information on safety or performance	0	0	0
3	Verification of safety and performance of device	0	0	0
4	Interaction with other medical products or treatments	0	0	0
5	Significant changes to the products or to its intended use	0	0	0
6	The results of the analysis and control during production	0	1	1

12.6 Recalls and side effect case in website
12.6.1 U.S.A : FDA
1) Searching date : Oct. 5th, 2015
2) Knot tensile strength requirement

We could find the recall case for knot tensile strength of suture in FDA site. The manufacturer reason for recall was that product does not meet minimum knot tensile strength requirements. The recall is as follow

Class 2 Recall
Monodek

See Related Information

Date Posted	April 25, 2014
Recall Status[1]	Open
Recall Number	Z-1509-2014
Recall Event ID	67972
Premarket Notification 510(K) Number	K030212
Product Classification	Suture, Surgical, Absorbable, Polydioxanone - **Product Code** NEW
Product	Monodek Violet Synthetic Absorbable Surgical Sutures, MF 0 TC43/HR26 48
Code Information	Product Code: 833-137, Batch: 02H1103434, 02H1200349, and 02K1201354.
Recalling Firm/ Manufacturer	Teleflex Medical 2917 Weck Dr. Research Triangle Park, North Carolina 27709
For Additional Information Contact	Michael T. Taggart 919-433-4940
Manufacturer Reason for Recall	Product does not meet minimum knot tensile strength requirements.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Consignees were notified by an Urgent Medical Device Recall Notification letter, dated 3/11/2014. The letter identified the affected product and the reason for recall. Customers were instructed to immediately discontinue use of and quarantine any affected product in stock. The affected product is to be returned; and the Recall Acknowledgement Form should be completed and faxed to the number provided regardless of whether customers have affected product in stock. Questions should be directed to a local sales rep or Customer Service at 1-866-246-6990.
Quantity in Commerce	3,072 ea.
Distribution	Worldwide Distribution -- USA, including the state of MA, and the country of Germany
Total Product Life Cycle	TPLC Device Report

3) The seal integrity of the outer product pouch

We could find the recall case for the seal integrity of the outer product pouch in FDA site. The manufacturer reason for recall was that the seal integrity of the outer product pouch may be compromised due to partial determination of the two layers that make up part of the pouch. The recall is as follow

Class 2 Recall
MonoDox Synthetic Absorbable Suture

See Related Information

Date Posted	November 19, 2011
Recall Status[1]	Terminated on December 13, 2011
Recall Number	Z-0259-2012
Recall Event ID	60173
Premarket Notification 510(K) Number	K013274
Product Classification	Suture, Surgical, Absorbable, Polydioxanone - **Product Code** NEW
Product	Product is a synthetic absorbable suture with needle and labeled as sterile. The product is sealed inside an inner foil pouch with an outside Tyvek pouch. The outer sterile barrier seal is intact. The product is boxed and shrink wrapped for protection against contamination. The product is a Violet, monofilament synthetic absorbable suture with needle, size 4/0 (1.5 Metric), NFS-2 Needle (Product code M397-Polydioxanone) or size 3/0 (2.0 Metric) (Product code M398 {Butler code 029254}). Product is labeled in part: "***POLYDIOANONE Violet (PDO) Monofilament Absorbable Suture***". Intended for use in general soft tissue approximation and/or ligation including use in pediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. The suture is not recommended for adult cardiac tissue, microsurgery or neural tissue. The absorbable sutures are useful where extended wound support is desirable.
Code Information	M397, M398 (Butler code 029254)
Recalling Firm/ Manufacturer	C P Medical Inc. 803 NE 25th Avenue Portland, Oregon 97232-2304
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Barbara Keller Horton 503-232-1555
Manufacturer Reason for Recall	The seal integrity of the outer product pouch may be compromised due to partial delamination of the two layers that make up part of the pouch.
FDA Determined Cause [2]	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
Action	CP Medical, Inc. sent a "RECALL NOTICE" letter dated January 5, 2009 to all affected customers.The letter describes the product, problem, and the actions to be taken by the customers. Customers are instructed to identify affected product and to return the product to the firm. Customers should call 1-503-232-1555 for a return goods authorization number and shipping account number. Contact your customer service representative at 1-800-950-2763 for questions concerning this recall.
Quantity in Commerce	13632 sutures
Distribution	Nationwide Distribution
Total Product Life Cycle	TPLC Device Report

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55

12.6.2 U.K : MHRA (Medical and Healthcare Products Regulatory Agency)
We tried to search recall case and side effect for polydioxanone suture and PDO suture with needle in the website, MHRA (www.gov.uk/governent/organization/). However, we couldn't find any recall case and side effect for polydioxanone suture and polydioxanone suture with needle

12.6.3 Korea : MFDS (Ministry of Food and Drug Safety)
We also tried to search recall case and side effect for polydioxanone suture and polydioxanone suture with needle in the website, (www.mfds.go.kr). However, we couldn't find any recall case and side effect for polydioxanone suture with needle

12.7 Taken action to prevent the recalls and side effect case searched in website
12.7.1 Taken action for the 1st recall case (tensile strength) above that was identified in FDA website.
1) Purchase of vacuum dehumidification
Recall case above was identified in FDA website. Humidity has relationship with tensile strength of suture. Our Yurim Medical Co.,Ltd. has no the problem for the tensile strength of suture now. We have a drying

machine and drying manufacturing process now. However, we bought a new vacuum dehumidification machine additionally to prevent the problem of tensile strength for suture. If the product is not dried enough to below of 500ppm, the tensile strength of suture may be weak and the quality of performance may be degraded. By using of a vacuum dehumidification machine, the dry effectiveness of the product can be increased and it is possible to maintain effectively the tension of suture.

2) Reflection in manufacturing process
Update of manufacturing process : In the drying process of product, we decided to use not only general drying machine, but also a vacuum dehumidification machine.

No	Process	Description	Applicable Documents	Remark
1	Purchasing of Raw material	Needle, Polydioxanone suture	Inspection standard & Inspection method(YR-QP-803)	
2	Incoming inspection of parts	Needle appearance PDO spec and labeling	Inspection standard & Inspection method (YR-QP-803)(YR-QI(M)-01)	
3	Assembly Process	Assemble with the Cannula / stylet, with the Cap& the Hub. And PDO	1. Process Control Procedure (YR-QP-706) 2. Working Instrument (YR-WI-01) 3. Inspection Standard & Inspection method (YR-QP-803)	Cleanroom
4	In-process Inspection	Inspector check all device	Inspection standard & Inspection method(YR-QP-803)(YR-QI(M)-01)	
5	Packaging	Packaging in clean room Blister packing	Process Control Procedure (YR-QP-706) (YR-QP-803)	
6	Sterilization	E.O Gas Sterilization	Process Control Procedure (YR-QP-706)	
7	Drying process	Drying / vacuum dehumidification	Process Control Procedure(YR-QP-706)	
8	Final inspection	Packaging and display according to the guide	Exam tests regulations (YR-QP-803) Product standard file	
9	Storage of products	Store only pass inspection	Import, storage, shipment management regulations (YR-QP-708)	
10	Release of products	Release for acceptable product	Import, storage, shipment management regulations (YR-QP-708)	

3) Reflection in risk management assessment
Please See. (13. Evaluation_ Risk management)

12.7.2 Taken action for the 2nd recall case (partial delamination of the two layers that make up part of the pouch) above that was identified in FDA website.
1) There is no additional reflection of risk management about the above 2nd recall case, because the recall case is already reflected in risk management report.
2) We reinforced the income inspection for packaging material and revised the product standards document.

13. EVALUATION_RISK MANAGEMENT

1) Severity
The severity of harm consists of five stages;

level	Severity	Definition
5	Ctastrophic	Is going to die soon
4	Critical	life-threatening injuries
3	Serious	occur injury or disability
2	Minor	Temporary disability or injury
1	Negligible	Discomfort or dissatisfaction

2) Frequency
The frequency of harm consists of five stages;

level	Possibility of Risk	Rating
5	Frequent	>1
4	Probable	10^{-2} to 1
3	Occasional	10^{-2} to 10^{-4}
2	Remote	10^{-4} to 10^{-6}
1	Improbable	$<10^{-6}$

3) Acceptability of risk

Frequent (5)					
Probable(4)					
Occasional(3)					
Remote(2)					
Improbable(1)					
	Negligible(1)	Mimor(2)	Serious(3)	Critical(4)	Catastrophic(5)

	Unacceptable risk
	Invastigation further risk reduction
	Insignificant risk

4) Residual risk analysis is as follow
(1) Dehumidication suture below 500ppm
- Identification of possible : function
- Example of hazards : Loss or deterioration function
- Risk control : Dehumidication suture below 500ppm
- Risk control & perform : Final inspection report
- In risk analysis, we estimated residual risk to severity 2, frequency 2.

(2) No resterilization
- Identification of possible : Bio compatibility
- Example of hazards : pyrogenicity
- Risk control : No resterilization
- Risk control & perform : IFU
- In risk analysis, we estimated residual risk to severity 3, frequency 2.

(3) Expiration date
- Identification of possible : Biological
- Example of hazards : viruses
- Risk control : Expiration date
- Risk control & perform : IFU
- In risk analysis, we estimated residual risk to severity 3, frequency 2.

(S : Severity, F: Frequency)

Identification of Possible hazards	Examples of hazards	Possible Situation	S	F	Result	ID No.
Biological	Bacteria	If the device is non-sterile It will cause patient's infection	4	2	Non-accept	ID-1
		If the device is damaged packaging It will cause patient's infection	4	2	Non-accept	ID-2
	Viruses	If the device is non-sterile It will cause patient's infection	4	2	Non-accept	ID-3
		If the device is damaged packaging It will cause patient's infection	4	2	Non-accept	ID-4
		If the product that the expiration date is ended is used, it will cause patient's infection	3	2	accept	ID-25
	Re-or cross-infection	If the device is re-used It will cause patient's infection	3	2	accept	ID-5
Chemical	Residues	If there is residues, it will cause the problem of immune system.	3	2	accept	ID-6
	Degradation products	If there is degradation products, it will cause the problem of immune system.	3	2	accept	ID-7
Bio compatibility	Toxicity of chemical constituents, e.g.	If the device is use of inappropriate materials, It will cause patient's infection	3	2	accept	ID-8
	allergenicity / irritancy	If the device is cleanliness problem, It will cause patient's infection	3	2	accept	ID-9
	Pyrogenicity	If the device is sterilization process problem, It will cause patient's infection	3	2	accept	ID-10
		If the device is damaged packaging, It will cause patient's infection	3	2	accept	ID-11
		If the device is re-sterilized, It will cause patient's infection	3	2	accept	ID-24
Function	Loss or deterioration of function	Due to loss or deterioration of function, It will cause dysfunction of device	3	2	accept	ID-12
		If there is loss or deterioration of tensile strength of suture, It will cause dysfunction of device	2	2	accept	ID-23
Use error	Attention failure	Due to the incorrect use, It will cause patient's infection	3	2	accept	ID-13
	Rule-based failure	Due to the incorrectly use It will cause contaminates	2	3	accept	ID-14
Labeling	Incomplete instructions for use	If the device is removed label, It will cause patient's infection	2	3	accept	ID-15
	Inadequate description of performance characteristics	Due to Use of expired products, It Will cause patient's infection	2	3	accept	ID-16
	Inadequate specification of intended use	If the device is removed label, It will cause patient's infection	2	3	accept	ID-17
	Inadequate disclosure of limitations	If the device is removed label, It will cause patient's infection	2	3	accept	ID-18
Operating Instructions	Inadequate specification of accessories to be used with the medical device	Due to the lack of pre-use checks in user's manual, It will cause dysfunction of device	2	2	accept	ID-19

	Inadequate specification of pres-use checks	Due to the lack of pre-use checks in user's manual, It will cause dysfunction of device	2	3	accept	ID-20
Warnings	Of side effects	If you have used for other purposes, It will cause patient's infection	2	3	accept	ID-21
	Of hazards likely with re-use of single-use medical devices	If you have used with carelessness, It will cause patient's infection	2	3	accept	ID-22

4) Evaluation result of identification of possible hazards.

Frequent (5)					
Probable(4)					
Occasional(3)		8 cases			
Remote(2)		2 case	11 cases	4 cases	
Improbable(1)					
	Negligible (1)	Mimor(2)	Serious(3)	Critical(4)	Catastrophic(5)

5) Hazard control for residual risk analysis is as follow

From Identification of Possible hazards, to reduce hazards until acceptable level, risk control is performed by modified design, precaution in process and information of safety.
Risk control should be evaluated by the Residual risk. Related data is as following

Identification of Possible hazards	**Examples of hazards**	**Risk Control**	**Risk Control & Perform**	**Residual risk**			**Result**	**Risk/ Benefit**	**Other generated hazards**	**Completion of control**	**ID No.**
				S	**F**	**Risk**					
Biological	Bacteria	Sterilization	IFU	4	1	4	accept	Benefit	No	Yes	ID-1
		Sterilization	IFU	4	1	4	accept	Benefit	No	Yes	ID-2
	Viruses	Sterilization	IFU	4	1	4	accept	Benefit	No	Yes	ID-3
		Sterilization	IFU	4	1	4	accept	Benefit	No	Yes	ID-4
		Expiration date	IFU	3	1	3	accept	Benefit	No	Yes	ID-25
	Re-or cross-infection	Sterilization	IFU	3	1	3	accept	Benefit	No	Yes	ID-5
Chemical	Residues	Raw material	Chemical test	3	1	3	accept	Benefit	No	Yes	ID-6
	Degradation products	Raw material	Chemical test	3	1	3	accept	Benefit	No	Yes	ID-7
Bio compatibility	Toxicity of chemical constituents, e.g.	Sterilization/ Raw material	Sterilization& Packing Validation / Biological evaluation report/ QC inspection / Label warning	3	1	3	accept	Benefit	No	Yes	ID-8

	allergenicity / irritancy	Sterilization/ Raw material	Sterilization& Packing Validation / Biological evaluation report/ QC inspection / IFU	3	1	3	accept	Benefit	No	Yes	ID-9
	Pyrogenicity	Sterilization/ Raw material	Sterilization& Packing Validation / Biological evaluation report/ QC inspection / IFU	3	1	3	accept	Benefit	No	Yes	ID-10
		Sterilization/ Raw material	Sterilization& Packing Validation / Biological evaluation report/ QC inspection / IFU	3	1	3	accept	Benefit	No	Yes	ID-11
		No resterilization	IFU	3	1	3	accept	Benefit	No	Yes	ID-24
Function	Loss or deterioration of function	Labeling & User's manual	Write function of device clearly in IFU	3	1	3	accept	Benefit	No	Yes	ID-12
		Dehumidication of suture below 500ppm	Final inspection report	2	1	2	accept	Benefit	No	Yes	ID-23
Use error	Attention failure	Labeling & User's manual	Write attention' clearly in I IFU	3	1	3	accept	Benefit	No	Yes	ID-13
	Rule-based failure	Labeling & User's manual	Write rule clearly in I IFU	2	2	4	accept	Benefit	No	Yes	ID-14
Labeling	Incomplete instructions for use	Labeling & User's manual	Write instructions for use clearly in IFU	2	2	4	accept	Benefit	No	Yes	ID-15
	Inadequate description of performance characteristics	Labeling & User's manual	Write performance characteristics clearly in IFU	2	2	4	accept	Benefit	No	Yes	ID-16
	Inadequate specification of intended use	Labeling & User's manual	Write intended use clearly in IFU	2	2	4	accept	Benefit	No	Yes	ID-17

	Inadequate disclosure of limitations	Labeling & User's manual	Write limitation clearly in IFU	2	2	4	accept	Benefit	No	Yes	ID-18
Operating Instructions	Inadequate specification of accessories to be used with the medical device	Labeling & User's manual	Write specification of accessories clearly in IFU	2	2	4	accept	Benefit	No	Yes	ID-19
	Inadequate specification Of pre-use checks	Labeling & User's manual	Write pre-use checks clearly in IFU	2	2	4	accept	Benefit	No	Yes	ID-20
Warnings	Of side effects	Labeling & User's manual	Write side effects clearly in IFU	2	2	4	accept	Benefit	No	Yes	ID-21
	Of hazards likely with re-use of single-use medical devices	Labeling & User's manual	Write single use clearly in IFU	2	2	4	accept	Benefit	No	Yes	ID-22

Risk control result of identification of possible hazards.

Frequent (5)					
Probable(4)					
Occasional(3)					
Remote(2)		9 case			
Improbable(1)		1case	11 cases	4 cases	
	Negligible (1)	Mimor(2)	Serious(3)	Critical(4)	Catastrophic(5)

6) Risk re-control

Risk control should be controlled again to decrease to AFAP. Related data is as following

Identification of Possible hazards	Examples of hazards	Risk Control	Risk Control & Perform	Residual risk			Result	Risk/ Benefit	Other generated hazards	Completion of control	ID No.
				S	F	Risk					
Biological	Bacteria	Sterilization	IFU	4	1	4	accept	Benefit	No	Yes	ID-1
		Sterilization	IFU	4	1	4	accept	Benefit	No	Yes	ID-2
	Viruses	Sterilization	IFU	4	1	4	accept	Benefit	No	Yes	ID-3
		Sterilization	IFU	4	1	4	accept	Benefit	No	Yes	ID-4
		Expiration date	IFU	3	1	3	accept	Benefit	No	Yes	ID-25
	Re-or cross-	Sterilization	IFU	3	1	3	accept	Benefit	No	Yes	ID-5

	infection										
Chemical	Residues	Raw material	Chemical test	3	1	3	accept	Benefit	No	Yes	ID-6
	Degradation products	Raw material	Chemical test	3	1	3	accept	Benefit	No	Yes	ID-7
Bio compatibility	Toxicity of chemical constituents , e.g.	Sterilization/ Raw material	Sterilization& Packing Validation / Biological evaluation report/ QC inspection / IFU	3	1	3	accept	Benefit	No	Yes	ID-8
	allergenicity / irritancy	Sterilization/ Raw material	Sterilization& Packing Validation / Biological evaluation report/ QC inspection / IFU	3	1	3	accept	Benefit	No	Yes	ID-9
	Pyrogenicity	Sterilization/ Raw material	Sterilization& Packing Validation / Biological evaluation report/ QC inspection / IFU	3	1	3	accept	Benefit	No	Yes	ID-10
		Sterilization/ Raw material	Sterilization& Packing Validation / Biological evaluation report/ QC inspection / IFU	3	1	3	accept	Benefit	No	Yes	ID-11
		No resterilization	IFU	3	1	3	accept	Benefit	No	Yes	ID-24
Function	Loss or deterioration of function	Labeling & User's manual	Write function of device clearly in IFU	3	1	3	accept	Benefit	No	Yes	ID-12
		Dehumidication of suture below 500ppm	Final inspection report	2	1	2	accept	Benefit	No	Yes	ID-23
Use error	Attention failure	Labeling & User's manual	Write attention' clearly in IFU	3	1	3	accept	Benefit	No	Yes	ID-13
	Rule-based failure	Labeling & User's manual	Write rule clearly in IFU	2	1	2	accept	Benefit	No	Yes	ID-14
Labeling	Incomplete instructions for use	Labeling & User's manual	Write instructions for use clearly in IFU	2	1	2	accept	Benefit	No	Yes	ID-15

	Inadequate description of performance characteristics	Labeling & User's manual	Write performance characteristics clearly in IFU	2	1	2	accept	Benefit	No	Yes	ID-16
	Inadequate specification of intended use	Labeling & User's manual	Write intended use clearly in IFU	2	1	2	accept	Benefit	No	Yes	ID-17
	Inadequate disclosure of limitations	Labeling & User's manual	Write limitation clearly in IFU	2	1	2	accept	Benefit	No	Yes	ID-18
Operating Instructions	Inadequate specification of accessories to be used with the medical device	Labeling & User's manual	Write specification of accessories clearly in IFU	2	1	2	accept	Benefit	No	Yes	ID-19
	Inadequate specification Of pre-use checks	Labeling & User's manual	Write pre-use checks clearly in IFU	2	1	2	accept	Benefit	No	Yes	ID-20
Warnings	Of side effects	Labeling & User's manual	Write side effects clearly in IFU	2	1	2	accept	Benefit	No	Yes	ID-21
	Of hazards likely with re-use of single-use medical devices	Labeling & User's manual	Write single use clearly in IFU	2	1	2	accept	Benefit	No	Yes	ID-22

(1) Risk control result of identification of possible hazards.

Frequent (5)					
Probable(4)					
Occasional(3)					
Remote(2)					
Improbable(1)		10case	11 cases	4 cases	
	Negligible (1)	Mimor(2)	Serious(3)	Critical(4)	Catastrophic(5)

7) Risk/benefit Analysis

The residual risk has been reduced or removed through the control of residual risk.

The result of risk management has accepted the Risk /benefit analysis. We could find there were benefits of the device overweigh the risks of the product

8) Conclusion

(1) As long as users use our product in accordance with user's manual in the normal situation, there will be low risk to users. However, there are potential risks in the aspects of Biological and Bio compatibility, Operational Hazards and Information Hazards, Etc. of the medical device to the use of the medical device.
(2) The risk management report comprises the analyses and actions to potential risks of the produced Product in accordance with ISO 14971(2012) standard.
(3) We have a risk management and taken an action against risks. The evaluation mark of this analysis and action-taking is in the range of acceptable zone. It is verified that this risk level is safe for use of the relevant product.

14. ANALYSIS AND EVALUTION FOR POST LITERATURE SEARCHING

14.1 Objective

- The objective of this literature searching is to verify that the product can be able to sell safely and to search other side effects.

14.2 Methodology

1) A protocol is developed to identify, select and collate relevant publications to address these questions. This should be developed and executed by persons with expertise in information retrieval, having due regard to the scope of the clinical evaluation set out by Yurim Medical Co., Ltd.

2) The literature search protocol should include.
   - The sources of data that will be used and a justification for their choice;
   - The extent of any searches of scientific literature databases (the database search strategy);
   - The selection/criteria to be applied to published literature and justification for their choice; and
   - Strategies for addressing the potential for duplication of data across multiple publications;

3) Once the literature search has been executed, a report should be compiled to present the results of the search.
   A copy of the protocol should be included and any deviations noted. A possible format for the literature search report is located at the literature search protocol.

4) The following documentation should be used in the clinical evaluation by the clinical evaluator
   - The literature search protocol;
   - The literature search report; and
   - Published articles and other references identified as being relevant to the device in question and suitable for evaluation.

14.3 Literature search protocol

1) This should be developed and executed by persons with expertise in information retrieval

- Lee Min Woo : QA manager

No	Period	Career

1	2013. 11 ~	Quality management leader of Yurim Medical Co., Ltd.

■ Academic ability
- University graduation
- Major : Chemical / industrial engineering

■ Main task
- PDO with needle development
- Material analysis / Information searching / statistical analysis

2) The sources of data that will be used and a justification for their choice

- EMBASE- Excerpta Medica published by Elsevier
- CENTRAL- The Cochrane Central Register of Controlled Trials
- IRIS- The TGA"s medical device Incident Report Investigation Scheme
- MAUDE- US FDA"s Manufacturer And User Facility Device Experience database
- MEDION- Database that indexes literature on diagnostic tests
- MEDLINE- Published by US National Library of Medicine-
- JAMA & Archives
- ScicenceDirect
- Google

3) The extent of any searches of scientific literature databases

- Scientific databases – bibliographic
- Specialized databases
- Systematic review databases
- **C**linical trial registers
- Adverse event report databases
- Reference texts

4) Literature search index

(1) The words used to search the literature must be selected with consideration of our products and the searching must be done by using the words as follows.

- Polydioxanone suture
- Polydioxanone thread
- Aptos methods
- Facial lifting suture thread
- Barbed threads facial rejuvenation
- Polydioxanone suture biocompatibility

(2) Criteria of useful literature
- The most recent thesis published to be selected

- The thesis with conclusions both on ‘clinical safety’ and ‘performance’ to be selected
- The thesis with conclusions either on ‘clinical safety’ or ‘performance’ to be selected
- Period covered by search : 2000 ~ 2014

5) **Possible methodology for documenting the screening and selection of literature within a literature search report**

Potentially relevant literature identified through the search (copy of all citations)

Literature excluded, with reasons

Literature retrieved for more detailed assessment

Literature excluded from clinical evaluation, with reasons

Literature with relevant useable data included in the clinical evaluation, by outcome
- Device performance
- Device safety
- Device comparability (if applicable)

6) Common criteria of literature selection

(1) The common criteria for selecting literatures are as follows :

* Literatures that have to be included
- polydioxanone suture/ polydioxanone thread+ aptos methods / facial lifting suture thread
- polydioxanone suture/polydioxanone thread + biocompatibility / safety / performance
- polydioxanone suture/polydioxanone thread + effect / effectiveness / efficacy

* Literatures that are not included
- Literatures about beauty,cosmetic

(2) Firstly, titles were investigated to select proper literatures

(3) Secondly, abstracts were examined to select proper literatures

(4) Lastly, the full contents of literatures selected from the second step were examined in terms of their number of samples, test protocols and results in order to select suitable literatures.

7) Methodology of literature selection

For the literatures, the weighing is assigned by grading and the category is as followings.

a. 9~12 points : Sufficient for scientific literature databases

b. 13~16 points : Not enough for scientific literature databases, but available for clinical databases

c. 17~22 points : Inappropriate for clinical evaluation

Suitability Criteria	Description	Grading	Weight (point)
Appropriate device	Were the data generated from the device in question?	D1	1
		D2	2
		D3	3
Appropriate device application	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	A1	1
		A2	2
		A3	3
Appropriate patient group	Where the data generated from a patient group that is representative of the intended treatment population (e.g.,age,sex,etc.) and clinical condition(i.e.,disease, including state and severity)?	P1	1
		P2	2
		P3	3
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	1
		R2	2
		R3	3

[D1. Appraisal criteria for suitability]

Contribution Criteria	Description	Grading	Weight (point)
Data source type	Was the design of the study appropriate?	T1	1
		T2	2
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1	1
		O2	2
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	1
		F2	2
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1	1
		S2	2
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1	1
		C2	2

[D2. Appraisal criteria for data contribution]

14.4 Criteria for review

1) Sample Appraisal Criteria for Suitability

Suitability Criteria	Description	Grading system	
Appropriate device	Were the data generated from the device in question ?	D1	Actual device
		D2	Equivalent device
		D3	Other device
Appropriate device application	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	A1	Same use
		A2	Minor deviation
		A3	Major deviation

Appropriate patient group	Where the data generated from a patient group that is representative of the intended treatment Population(e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)?	P1	Applicable
		P2	Limited
		P3	Different population
Acceptable report/data collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	High quality
		R2	Minor deficiencies
		R3	Major deficiencies

2) Sample Appraisal Criteria for Data Contribution

Suitability Criteria	Description	Grading system	
Data source type	Was the design of the study appropriate?	T1	Yes
		T2	No
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1	Yes
		O2	No
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
		F2	No
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1	Yes
		S2	No
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1	Yes
		C2	No

☞) The more level 1 grades, the greater the weight of evidence provided by that particular data set in comparison to other datasets

14.5 Possible methodology for documenting the screening and selection of literature within a literature search report

(1) Potentially relevant literature identified through the search (copy of all citations)

① JAMA & Archives (JAMA Facial Plastic Surgery) (http://archfaci.jamanetwork.com/journal.aspx)

Potentially relevant literature : 3 items (by 'polydioxanone suture' key word)

A. Effects of Different Suture Materials on Cartilage Reshaping
B. Reconstruction of the Nasal Septum Using Polydioxanone Plate
C. Versatile Applications of the Polydioxanone Plate in Rhinoplasty and Septal Surgery

② 'ScicenceDirect' online tools on ELSEVIER (www.elsevier.com),
(journal hompage: www.elsevier.com/locate/biomaterials)

Potentially relevant literature : 7 items (by ‘polydioxanone suture’ key word)

A. Benign anastomotic stricture of the rectum complicated by metal stent insertion: Salvage by placement of a biodegradable polydioxanone stent
B. Chest wall reconstruction in a canine model using polydioxanone mesh, demineralized bone matrix and bone marrow stromal cells
C. Electrospinning polydioxanone for biomedical applications
D. In vitro and in vivo degradation behaviors of synthetic absorbable bicomponent monofilament suture prepared with poly(p-dioxanone) and its copolymer
E. A 5-fluorouracil-loaded polydioxanone weft-knitted stent for the treatment of colorectal cancer
F. Tissue-engineered bone formation using periosteal-derived cells and polydioxanone/pluronic F127 scaffold with pre-seeded adipose tissue-derived CD146 positive endothelial-like cells
G. A polydioxanone electrospun valved patch to replace the right ventricular outflow tract in a growing lamb model

③ US National Library of Medicine National Institutes of Health

- Potentially relevant literature : 5 items (by ‘Aptos methods’ key word)

A. Treatment of postblepharoplasty lower eyelid malposition by Aptos thread.
B. Successful treatment of thread-lifting complication from APTOS sutures using a simple MACS lift and fat grafting.
C. A novel option of uninterrupted closure of surgical wounds.
D. APTOS suture lifting methods: 10 years of experience.
E. Barbed sutures: a review of the literature.

- Potentially relevant literature : 2 items (by ‘Facial lifting suture thread ’ key word)

A. Facial Rejuvenation With Fine-Barbed Threads: The Simple Miz Lift.
B. Reduction of face and neck laxity with anchored, barbed polypropylene sutures (Contour Threads).

- Potentially relevant literature : 3 items (by ‘Barbed threads facial rejuvenation ’ key word)

A. Barbed sutures for aesthetic facial plastic surgery: indications and techniques.
B. Use of barbed threads in facial rejuvenation.
C. Barbed sutures in facial rejuvenation.

- Potentially relevant literature : 8 items (by ‘Polydioxanone suture biocompatibility ’ key word)

A. Biocompatibility and adhesion formation of different endoloop ligatures in securing the base of the appendix.
B. An electrospun polydioxanone patch for the localisation of biological therapies during tendon repair.
C. Ideal suture methods for skin, subcutaneous tissues and sternum
D. Autologous endothelial progenitor cell-seeding technology and biocompatibility testing for cardiovascular devices in large animal model.

E. Novel biodegradable polydioxanone stents in a rabbit airway model.
F. Randomized clinical study of polydioxanone and nylon sutures for laparotomy clousure in high-risk patients
G. Biological response to a new composite polymer augmentation device used for cruciate ligament reconstruction.
H. Comparative study on biocompatibility and absorption times of three absorbable monofilament suture materials (Polydioxanone, Poliglecaprone 25, Glycomer 631).

(2) Literature excluded, with reasons

Literature less than those associated with our product were excluded.

(3) Literature retrieved for more detailed assessment

① JAMA & Archives (JAMA Facial Plastic Surgery) (http://archfaci.jamanetwork.com/journal.aspx)

More specifically relevant literature : 2 items

A. Effects of Different Suture Materials on Cartilage Reshaping

B. Reconstruction of the Nasal Septum Using Polydioxanone Plate

② 'ScicenceDirect' online tools on ELSEVIER (www.elsevier.com),
(journal hompage: www.elsevier.com/locate/biomaterials)

-More specifically relevant literature : 4 items

A. Chest wall reconstruction in a canine model using polydioxanone mesh, demineralized bone matrix and bone marrow stromal cells
B. In vitro and in vivo degradation behaviors of synthetic absorbable bicomponent monofilament suture prepared with poly(p-dioxanone) and its copolymer
C. Tissue-engineered bone formation using periosteal-derived cells and polydioxanone/pluronic F127 scaffold with pre-seeded adipose tissue-derived CD146 positive endothelial-like cells
D. A polydioxanone electrospun valved patch to replace the right ventricular outflow tract in a growing lamb model

③ US National Library of Medicine National Institutes of Health

- More specifically relevant literature : 3 items

A. Successful treatment of thread-lifting complication from APTOS sutures using a simple MACS lift and fat grafting.
B. A novel option of uninterrupted closure of surgical wounds.
C. Barbed sutures: a review of the literature.

- More specifically relevant literature : 2 items
   A. Facial Rejuvenation With Fine-Barbed Threads: The Simple Miz Lift.

- More specifically relevant literature : 2 items
   A. Barbed sutures for aesthetic facial plastic surgery: indications and techniques.
   B. **Use of barbed threads in facial rejuvenation.**

- More specifically relevant literature : 3 items
   A. Ideal suture methods for skin, subcutaneous tissues and sternum
   B. Randomized clinical study of polydioxanone and nylon sutures for laparotomy clousure in high-risk patients
   C. Comparative study on biocompatibility and absorption times of three absorbable monofilament suture materials (Polydioxanone, Poliglecaprone 25, Glycomer 631).

(4) Literature excluded from clinical evaluation, with reasons

The literature that is less directly related to performance and safety of our products the content is excluded.

(5) Final selection and exclusion

No.	Title	Selected or excluded	Excluded reason
1	Effects of Different Suture Materials on Cartilage Reshaping	Selected	Suitable
2	Reconstruction of the Nasal Septum Using Polydioxanone Plate	Excluded	Our product is different from Pdo plate
3	Chest wall reconstruction in a canine model using polydioxanone mesh, demineralized bone matrix and bone marrow stromal cells	Excluded	Not equivalent device
4	In vitro and in vivo degradation behaviors of synthetic absorbable bicomponent monofilament suture prepared with poly(p-dioxanone) and its copolymer	Selected	Suitable
5	Tissue-engineered bone formation using periosteal-derived cells and polydioxanone/pluronic F127 scaffold with pre-seeded adipose tissue-derived CD146 positive endothelial-like cells	Excluded	Our devoce is not intended for bone defect formation.
6	A polydioxanone electrospun valved patch to replace the right ventricular outflow tract in a growing lamb	Excluded	Improper

	model		
7	Successful treatment of thread-lifting complication from APTOS sutures using a simple MACS lift and fat grafting.	Selected	Performance has been demonstrated
8	A novel option of uninterrupted closure of surgical wounds.	Selected	Performance has been demonstrated
9	Barbed sutures: a review of the literature.	Excluded	Performance is not proven.
10	Facial Rejuvenation With Fine-Barbed Threads: The Simple Miz Lift.	Selected	Performance has been demonstrated
11	Barbed sutures for aesthetic facial plastic surgery: indications and techniques.	Selected	Performance has been demonstrated
12	Use of barbed threads in facial rejuvenation.	Selected	Performance has been demonstrated
13	Ideal suture methods for skin, subcutaneous tissues and sternum	Excluded	Japanese article
14	Randomized clinical study of polydioxanone and nylon sutures for laparotomy clousure in high-risk patients	Excluded	Can't be found the full text
15	Comparative study on biocompatibility and absorption times of three absorbable monofilament suture materials (Polydioxanone, Poliglecaprone 25, Glycomer 631).	Selected	Safety has been demonstrated

14.6 Data analysis

☞ Data analysis for the literature search was performed in accordance with literature search protocol.

14.6.1 Selected literature list

No.	Title	Performance	Safety	Objective of Use
1	Effects of Different Suture Materials on Cartilage Reshaping	O		
2	In vitro and in vivo degradation behaviors of synthetic absorbable bicomponent monofilament suture prepared with poly(p-dioxanone) and its copolymer	O	O	

3	Successful treatment of thread-lifting complication from APTOS sutures using a simple MACS lift and fat grafting.	O	O	
4	A novel option of uninterrupted closure of surgical wounds.	O		
5	Facial Rejuvenation With Fine-Barbed Threads: The Simple Miz Lift.	O	O	
6	Barbed sutures for aesthetic facial plastic surgery: indications and techniques.	O	O	
7	Use of barbed threads in facial rejuvenation.	O		
8	Comparative study on biocompatibility and absorption times of three absorbable monofilament suture materials (Polydioxanone, Poliglecaprone 25, Glycomer 631).		O	

1) Literature(1st)

(1) Literature analysis

Literature title	Description	Grading system	
Effects of Different Suture Materials on Cartilage Reshaping	Were the data generated from the device in question?	D1	Actual device
		D2	**Equivalent device**
		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	**A1**	**Same use**
		A2	Minor deviation
		A3	Major deviation
	Where the data generated from a patient group that is Representative of the intended treatment population ? (e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	**P1**	**Applicable**
		P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	**R1**	**High quality**
Can Alper Cagici, MD; Ozcan Cakmak, MD; Nebil Bal, MD; Haluk Yavuz, MD; Ilhan Tuncer, MD		R2	Minor deficiencies
		R3	Major deficiencies
	Was the design of the study appropriate?	**T1**	**Yes**
Issued date		T2	No
Arch Facial Plast Surg. 2008;10(2):124-129	Do the outcome measures reported reflect the intended performance of the device?	**O1**	**Yes**
		O2	No
	Is the duration of follow-up long enough to	F1	Yes

Application/Non-application	assess whether duration of treatment effects and identify complications?	**F2**	**No**
Application	Has a statistical analysis of the data been provided and is it appropriate?	**S1**	**Yes**
		S2	No
Literature search report No.	Was the magnitude of the treatment effect observed clinically significant?	**C1**	**Yes**
YRM-LSR-01		C2	No

(2)Literature summary report (YRM -LSR-01)

NO	Item	Contents
	Source	JAMA Facial Plastic Surgery.*-Formerly Archives of Facial Plastic Surgery* *http://archfaci.jamanetwork.com/journal.aspx*
	Title	**Effects of Different Suture Materials on Cartilage Reshaping**
	Summary	**Objective:** To examine the effects of different suture materials and suturation techniques on cartilage reshaping in a rabbit model. **Methods:** Twenty-two rabbits were used. Posterior skin flaps were elevated, and 4 cartilage struts were prepared on each auricula. Each strut was bent at its midpoint, and the skin under the bent area was elevated only in 1 side. The strut was sutured either with catgut, polyglactin 910, polydioxanone, or polypropylene sutures. Anteriorly, the suture was passed subcutaneously on 1 side, while transcutaneously on the other. Animals were killed at the first and fourth months. The shape of the struts was macroscopically evaluated. Inflammation and foreign body reaction around the suture were examined under light microscopy. **Results:** Maintenance of shape with all suture materials was significantly lower in the transcutaneously sutured group than in the subcutaneously sutured group. Because of high rates of suture loss in the transcutaneously sutured group, further evaluations on cartilage tissue were made only in subcutaneously sutured group. Success rate in maintenance of shape was similarly high in the polydioxanone, polyglactin 910, and polypropylene suture groups; however, it was significantly lower in the catgut suture group.
	Conclusion	**Conclusion:** Long-lasting absorbable suture materials are as effective as nonabsorbable ones, and the subcutaneous technique is more effective than the transcutaneous technique.

2) Literature (2nd)
(1) Literature analysis

Literature title	Description	Grading system	
In vitro and in vivo degradation behaviors of synthetic absorbable	Were the data generated from the device in question?	D1	Actual device
		D2	**Equivalent device**

bicomponent monofilament suture prepared with poly(p-dioxanone) and its copolymer		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	**A1**	**Same use**
		A2	Minor deviation
		A3	Major deviation
	Where the data generated from a patient group that is Representative of the intended treatment population ? (e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	**P1**	**Applicable**
		P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	**R1**	**High quality**
• Jung Nam Im[a], • Jeong Kyung Kim[a], • Hyun-Kyoon Kim[a], • Chang Hoon In[a], • Kuen Yong Lee[b], • Won Ho Park[c]		R2	Minor deficiencies
		R3	Major deficiencies
	Was the design of the study appropriate?	**T1**	**Yes**
Issued date		T2	No
11 January 2007	Do the outcome measures reported reflect the intended performance of the device?	**O1**	**Yes**
		O2	No
	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Application/Non-application		**F2**	**No**
Application	Has a statistical analysis of the data been provided and is it appropriate?	**S1**	**Yes**
		S2	No
Literature search report No.	Was the magnitude of the treatment effect observed clinically significant?	**C1**	**Yes**
YRM -LSR-02		C2	No

(2)Literature summary report(YRM -LSR-02)

NO	Item	Contents
	Source	Polymer Degradation and Stability Volume 92, Issue 4, April 2007, Pages 667–674 http://www.sciencedirect.com/science/article
	Title	In vitro and in vivo degradation behaviors of synthetic absorbable bicomponent monofilament suture prepared with poly(p-dioxanone) and its copolymer
	Summary	Abstract A synthetic absorbable bicomponent monofilament suture (MonoFlex), composed of poly(*p*-dioxanone) and its copolymer, was prepared by a conjugate spinning

		method, and its degradation behavior was investigated *in vitro* and *in vivo*. MonoFlex degraded by hydrolysis, and retained approximately 55% of its original strength after four weeks of incubation in PBS at 37 °C. About 70% of the original strength was maintained after four weeks of implantation in rats, and the suture material was completely absorbed after 180–210 days post-implantation in rats. No remarkable tissue reactions were observed during degradation, and foreign body reactions were similar to those of commercially available suture materials composed of poly(*p*-dioxanone). This study to monitor the degradation behavior of monofilament sutures *in vitro* as well as *in vivo* may be useful in the development of novel suture materials for extended wound support. Keywords : Monofilament suture; Bicomponent; Degradation; Absorption; Tissue reaction
	Conclusion	The degradation behavior of MonoFlex, a synthetic absorbable bicomponent monofilament suture material with a sea/island type structure, was investigated in vitro and in vivo. MonoFlex maintained approximately 55% of its original breaking strength after four weeks of incubation in vitro, which was quite comparable to that of commercially available suture materials. In vitro studies demonstrated that MonoFlex degraded by chemical hydrolysis via two stages of bulk erosion mechanisms. MonoFlex retained about 83% of its original strength following two weeks of implantation in rats, and maintained about 50% of original strength even after six weeks of implantation in vivo. The tissue responses were evaluated and found to be minimal, and the foreign body reations were similar to those of commercially available PDO sutures. MonoFlex was completely absorbed after 180-210 days of implantation, which was slightly faster than some commercially available PDO sutures. This was attributed to the sea/island type bicomponent structure of MonoFlex. From the results, it was concluded that MonoFlex can be used as a suture material for a wound support for extended time periods.

2) Literature (3rd)

(1) Literature analysis

Literature title	Description	Grading system	
Successful treatment of thread-lifting complication from APTOS sutures using a simple MACS lift and fat grafting	Were the data generated from the device in question?	D1	Actual device
		D2	**Equivalent device**
		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	**A1**	**Same use**
		A2	Minor deviation
		A3	Major deviation
	Where the data generated from a patient group that is representative of the intended treatment population ? e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	**P1**	**Applicable**
		P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain	**R1**	**High quality**

Sapountzis S, Kim JH, Li TS, Rashid A, Cruz PC, Hwang YS.	sufficient information to be able to undertake a rational and objective assessment?	R2	Minor deficiencies
		R3	Major deficiencies
	Was the design of the study appropriate?	**T1**	**Yes**
Issued date		T2	No
2012 Dec;36(6):1307-10. doi: 10.1007/s00266-012-9975-1. Epub 2012 Oct 6.	Do the outcome measures reported reflect the intended performance of the device?	**O1**	**Yes**
		O2	No
	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	**F1**	**Yes**
Application/Non-application		F2	No
Application	Has a statistical analysis of the data been provided and is it appropriate?	**S1**	**Yes**
		S2	No
Literature search report No.	Was the magnitude of the treatment effect observed clinically significant?	**C1**	**Yes**
YRM -LSR-03		C2	No

(2)Literature summary report(YRM -LSR-03)

NO	Item	Contents
	Source	US National Library of Medicine National Institutes of Health
	Title	Successful treatment of thread-lifting complication from APTOS sutures using a simple MACS lift and fat grafting.
	Summary	**Abstract** Facial soft tissue lifting with subdermal sutures has a significant attraction for physician and patient alike. The case report describes a 48 year old woman who presented with pain and discomfort over the left cheek after a thread-lift procedure with anti-ptosis (APTOS) sutures performed 13 months previously. The clinical examination showed extrusion of the APTOS thread (Aptos, Moscow, Russia) accompanied by slight soft tissue tightness and tenderness along its course to the temporal area, indicating complete removal of the thread. A simple minimal access cranial suspension lift was performed with the patient under local anesthesia to remove the subdermal sutures together with autologous fat grafting to enhance the aesthetic result. At the 1 year follow-up visit, no complications were reported, and the patient was entirely satisfied with the final result
	Conclusion	

4) Literature(4th)
(1) Literature analysis

Literature title	Description	Grading system	
A novel option of uninterrupted closure of surgical wounds.	Were the data generated from the device in question?	D1	Actual device
		D2	**Equivalent device**
		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	**A1**	**Same use**
		A2	Minor deviation
		A3	Major deviation
	Where the data generated from a patient group that is Representative of the intended treatment population ? (e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	**P1**	**Applicable**
		P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	**R1**	**High quality**
Sulamanidze MA, Sulamanidze GM		R2	Minor deficiencies
		R3	Major deficiencies
	Was the design of the study appropriate?	**T1**	**Yes**
Issued date		T2	No
2009 Jul;2(2):81-7. doi: 10.4103/0974-2077.58520.	Do the outcome measures reported reflect the intended performance of the device?	**O1**	**Yes**
		O2	No
	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Application/Non-application		**F2**	**No**
Application	Has a statistical analysis of the data been provided and is it appropriate?	**S1**	**Yes**
		S2	No
Literature search report No.	Was the magnitude of the treatment effect observed clinically significant?	**C1**	**Yes**
YRM -LSR-04		C2	No

(2)Literature summary report (YRM -LSR-04)

NO	Item	Contents
	Source	US National Library of Medicine National Institutes of Health
	Title	**A novel option of uninterrupted closure of surgical wounds.**
	Summary	**Abstract** **BACKGROUND:** A cosmetically pleasing postoperative scar is an important aim of all aesthetic surgeries. Use of proper suture materials for delicate and gentle suturing of the operative injury is an important requirement for achieving satisfactory scars.

		However, closure of the edges of wounds by means of conventional suture materials does not always meet the requirements to achieve this objective. **AIM:** To simplify and facilitate the process of surgical wound closure, to improve the quality of scar, and to achieve a good cosmetic effect through the introduction of a new type of suture material. **MATERIALS AND METHODS:** We have introduced a new surgical suturing material-a nontraumatic, barbed thread connected with the suture needle-APTOS SUTURE (European patent 1075843 as of 1999). Presented herein is a new modification of the technique of uninterrupted subcutaneous and intracutaneous suturing of wound edges, and the details of our experience with this material. **RESULTS:** Our experience shows that, with use of APTOS, wound closure is carried out easily and quickly. The wound remains stable, the time of healing is shortened, and the process of suture removal is simplified, resulting in an aesthetically pleasing scar.
	Conclusion	The technique of surgical wound suturing proposed herein is a simple, facilitated, and efficient option of wound-edge closure, which can successfully be used, both in general and in aesthetic surgery for wound closure, such as plasty of scars, face lift, mammoplasty, and abdominal plasty.

5) Literature(5th)
(1) Literature analysis

Literature title	Description	Grading system	
Facial Rejuvenation With Fine-Barbed Threads: The Simple Miz Lift.	Were the data generated from the device in question?	D1	Actual device
		D2	**Equivalent device**
		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	**A1**	**Same use**
		A2	Minor deviation
		A3	Major deviation
	Where the data generated from a patient group that is Representative of the intended treatment population ? (e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	**P1**	**Applicable**
		P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	**R1**	**High quality**
Park TH, Seo SW, Whang KW.		R2	Minor deficiencies
		R3	Major deficiencies
	Was the design of the study appropriate?	**T1**	**Yes**
Issued date		T2	No
2013 Jun 29. [Epub ahead of print]	Do the outcome measures reported reflect the intended performance of the device?	**O1**	**Yes**
		O2	No

	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Application/Non-application		**F2**	**No**
Application	Has a statistical analysis of the data been provided and is it appropriate?	**S1**	**Yes**
		S2	No
Literature search report No.	Was the magnitude of the treatment effect observed clinically significant?	**C1**	**Yes**
YRM -LSR-05		C2	No

(2)Literature summary report(YRM -LSR-05)

NO	Item	Contents
	Source	US National Library of Medicine National Institutes of Health
	Title	**Facial Rejuvenation With Fine-Barbed Threads: The Simple Miz Lift.**
	Summary	**Abstract** **BACKGROUND:** Since the invention of the first barbed (short) suture by Sulamanidze in the late 1990s, different techniques have been described including Woffles (long) thread lifting, Waptos suture lifting, Isse unidirectional barbed-threads lifting, and silhouette lifting. The authors have implemented a newly developed type of thread integrating more small cogs and a soft and fragile feeling of the material (medical grade polypropylene: 16.5 cm long, 15 cm of length covered with cogs, and 0.40 mm in diameter). This study aimed to describe the authors' thread and the surgical techniques they have adopted to counteract the descent and laxity of facial soft tissues. **METHODS:** A retrospective chart review was performed during a period of 2 years, from March 2010 to February 2012. The procedure was performed with the patient under local anesthesia and intravenous sedation. The face was marked preoperatively to determine the appropriate vector of the thread and its five end fixation points. The superior border of the incision was approximately at the level of the lateral brow, and the lower border was about 2 cm above the superior margin of the helical root. After the temporal incision was made, the dissection was carried all the way down to the deep temporal fascia to create a plane between the superficial and deep temporal fascias. Using blunt cannulas, the dissection was continued in an inferomedial direction from the temporal incision to the lower face through the sub-submucosal aponeurotic system (sub-SMAS) plane, which was marked preoperatively. This sub-SMAS dissection could easily proceed to the premasseteric space (PMS). The face-lift sutures (Gusan Inc., Seoul, Republic of Korea) then were inserted through the cannula from the lower face to the temporal incision line. The sutures were trimmed, and the proximal ends were secured on the deep temporal fascia reinforced with Vicryl interrupted sutures. The results were assessed objectively using serial photography and subjectively according to patient assessment. Complications also were recorded. **RESULTS:** All but two patients (100/102, 98.1 %) were satisfied with the outcomes after surgery. Consensus ratings by two independent plastic surgeons found that objective outcomes were divided among "excellent," "good," and "fair." The postoperative course was uneventful except for one patient (1/102, 1 %) who

		presented with minor skin dimpling and another patient (1/102, 1 %) who had a temporary facial weakness. These two complicated cases were resolved spontaneously without any surgical interventions.
	Conclusion	The reported technique has several advantages over current approaches. First, the use of nonabsorbable sutures with sufficient maintenance potential can produce long-lasting, satisfying results. Second, use of the authors' fine thread can avoid complications such as extruded or visible thread, which often have been complaints with thread lifting. Third, use of a loose areolar plane, including sub-SMAS and PMS free of vital structures, which is deeper than the traditional lift procedure, can avoid any traction line during rest or animation without any significant complications.

6) Literature (6th)
(1) Literature analysis

Literature title	Description	Grading system	
Barbed sutures for aesthetic facial plastic surgery: indications and techniques.	Were the data generated from the device in question?	D1	Actual device
		D2	**Equivalent device**
		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	**A1**	**Same use**
		A2	Minor deviation
		A3	Major deviation
	Where the data generated from a patient group that is Representative of the intended treatment population ? (e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	**P1**	**Applicable**
		P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	**R1**	**High quality**
Paul MD.		R2	Minor deficiencies
		R3	Major deficiencies
	Was the design of the study appropriate?	**T1**	**Yes**
Issued date		T2	No
2008 Jul;35(3):451-61. doi: 10.1016/j.cps.2008.03.005.	Do the outcome measures reported reflect the intended performance of the device?	**O1**	**Yes**
		O2	No
	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Application/Non-application		**F2**	**No**
Application	Has a statistical analysis of the data been provided and is it appropriate?	**S1**	**Yes**
		S2	No
Literature search report No.	Was the magnitude of the treatment effect	**C1**	**Yes**

YRM -LSR-06	observed clinically significant?	C2	No

(2)Literature summary report(YRM -LSR-06)

NO	Item	Contents
	Source	US National Library of Medicine National Institutes of Health
	Title	**Barbed sutures for aesthetic facial plastic surgery: indications and techniques.**
	Summary	**Abstract** This article describes the indications and techniques related to the use of barbed sutures in facial aesthetic plastic surgery. The principle applications for barbed sutures in facial aesthetic plastic surgery are those involving lifts of the brow, midface, and the lower face and neck. Usually all three areas require surgical maneuvers to create a harmonious rejuvenation. Regardless of where in the face bidirectional barbed sutures are planned, five essential steps are needed: (1) making the incision or incisions, (2) dissecting soft tissue, (3) proximal anchoring, (4) deploying threads, and (5) molding soft tissue.
	Conclusion	

7) Literature (7th)
(1) Literature analysis

Literature title	Description	Grading system	
Use of barbed threads in facial rejuvenation.	Were the data generated from the device in question?	D1	Actual device
		D2	**Equivalent device**
		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	**A1**	**Same use**
		A2	Minor deviation
		A3	Major deviation
	Where the data generated from a patient group that is Representative of the intended treatment population ? (e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	**P1**	**Applicable**
		P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	**R1**	**High quality**
Kalra R.		R2	Minor deficiencies
		R3	Major deficiencies
	Was the design of the study appropriate?	**T1**	**Yes**
Issued date		T2	No

2008 Oct;41(Suppl):S93-S100.	Do the outcome measures reported reflect the intended performance of the device?	**O1**	**Yes**
		O2	No
Application/Non-application	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
		F2	**No**
Application	Has a statistical analysis of the data been provided and is it appropriate?	**S1**	**Yes**
		S2	No
Literature search report No.	Was the magnitude of the treatment effect observed clinically significant?	**C1**	**Yes**
YRM -LSR-07		C2	No

(2)Literature summary report(YRM -LSR-07)

NO	Item	Contents
	Source	US National Library of Medicine National Institutes of Health
	Title	**Use of barbed threads in facial rejuvenation.**
	Summary	**Abstract** Use of barbed threads, available with uni- and bi-directional cogs or barbs, is a semi-invasive method of lifting sagging skin of the face. Areas treated with this method include the eyebrows, the cheeks, the jowls and the neck. Ease of use and a shorter down-time have made their use popular. Specific indications, operative procedures, risks and complications are described and some clinical results of the author shown. **KEYWORDS:** APTOS, CONTOUR, SILHOUETTE, barbed threads, barbs, cogs, facial rejuvenation, thread lift
	Conclusion	

8) Literature(8th)
(1) Literature analysis

Literature title	Description	Grading system	
Comparative study on biocompatibility and absorption times of three absorbable monofilament suture materials (Polydioxanone, Poliglecaprone 25, Glycomer 631).	Were the data generated from the device in question ?	D1	Actual device
		D2	**Equivalent device**
		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	**A1**	**Same use**
		A2	Minor deviation
		A3	Major deviation
	Where the data generated from a patient group	**P1**	**Applicable**

	that is Representative of the intended treatment population ? (e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	**R1**	**High quality**
Molea G, Schonauer F, Bifulco G, D'Angelo D.		R2	Minor deficiencies
		R3	Major deficiencies
	Was the design of the study appropriate?	**T1**	**Yes**
Issued date		T2	No
2000 Mar;53(2):137-41.	Do the outcome measures reported reflect the intended performance of the device?	**O1**	**Yes**
		O2	No
	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Application/Non-application		**F2**	**No**
Application	Has a statistical analysis of the data been provided and is it appropriate?	**S1**	**Yes**
		S2	No
Literature search report No.	Was the magnitude of the treatment effect observed clinically significant?	**C1**	**Yes**
YRM -LSR-8		C2	No

(2)Literature summary report(YRM -LSR-8)

NO	Item	Contents
	Source	US National Library of Medicine National Institutes of Health
	Title	**Comparative study on biocompatibility and absorption times of three absorbable monofilament suture materials (Polydioxanone, Poliglecaprone 25, Glycomer 631).**
	Summary	**Abstract** Monofilament synthetic absorbable suture materials offer excellent glide characteristics and cause minimal tissue trauma as a result of their smooth monofilament structure and gradual bio-absorption. An investigation was conducted on 72 rats to compare three types of monofilament absorbable suture material (Polydioxanone, Poliglecaprone 25, Glycomer 631), with respect to their clinical characteristics, tissue inflammatory reaction and suture absorption times. The results identified different qualities for each suture: Poliglecaprone 25 and Glycomer 631 suture materials were found to be less reactive than Polydioxanone in rat skin. However, because of their extremely low tissue reaction values, all three materials were deemed particularly suitable for use as intracuticular sutures. Absorption times in rat skin were less than 3 months for Poliglecaprone 25, between 3 and 6 months for Glycomer 631 and 6 months for Polydioxanone. The differences in suture characteristics which were detected in our study can help in the surgical selection of the most appropriate suture material.

	Conclusion	

14.7 Evaluation for literature searching

As above data analysis, the data of literature has been acceptable to performance and safety of a medical device. So, the literature searching has been verified

15. CLINICAL DATA ANALYSIS

15.1 Evaluation for literature

(1) In the literature, “Effects of Different Suture Materials on Cartilage Reshaping”, It proved the performance of product as the result that Long-lasting absorbable suture materials are as effective as nonabsorbable ones.

(2) In the literature, “In vitro and in vivo degradation behaviors of synthetic absorbable bicomponent monofilament suture prepared with poly(p-dioxanone) and its copolymer”, the result is “A synthetic absorbable bicomponent monofilament suture(MonoFlex) degraded by hydrolysis, and retained approximately 55% of its original strength after four weeks of incubation in PBS at 37 °C. About 70% of the original strength was maintained after four weeks of implantation in rats, and the suture material was completely absorbed after 180–210 days post-implantation in rats. No remarkable tissue reactions were observed during degradation, and foreign body reactions were similar to those of commercially available suture materials composed of poly(p-dioxanone). This study to monitor the degradation behavior of monofilament sutures in vitro as well as in vivo may be useful in the development of novel suture materials for extended wound support.MONOFLEX” It proved the performance and safety of this product.

(3)) In the literature, “Successful treatment of thread-lifting complication from APTOS sutures using a simple MACS lift and fat grafting”, the result, “At the 1 year follow-up visit, no complications were reported, and the patient was entirely satisfied with the final result” proved the performance and safety of this product.

(4) In the literature, “A novel option of uninterrupted closure of surgical wounds”, the result, “The wound remains stable, the time of healing is shortened, and the process of suture removal is simplified, resulting in an aesthetically pleasing scar” proved the performance of this product.

(5) In the literature, “Facial Rejuvenation With Fine-Barbed Threads”, the result, “All but two patients (100/102, 98.1 %) were satisfied with the outcomes after surgery. Consensus ratings by two independent plastic surgeons found that objective outcomes were divided among "excellent," "good," and "fair." The postoperative course was uneventful except for one patient (1/102, 1 %) who presented with minor skin dimpling and another patient (1/102, 1 %) who had a temporary facial weakness. These two complicated cases were resolved spontaneously without any surgical interventions” proved the performance and safety of this product.

(6) In the literature,” Barbed sutures for aesthetic facial plastic surgery” proved the performance of this product.

(7) In the literature, “Use of barbed threads in facial rejuvenation”, the result, “Use of barbed threads, available with uni- and bi-directional cogs or barbs, is a semi-invasive method of lifting sagging skin of the face. Ease of use and a shorter down-time have made their use popular” proved the performance and safety of this product.

(8) In the literature, “Comparative study on biocompatibility and absorption times of three absorbable monofilament suture materials”, the result, “Monofilament synthetic absorbable suture materials offer excellent glide characteristics and cause minimal tissue trauma as a result of their smooth monofilament structure and gradual bio-absorption”, “Absorption times in rat skin were less than 3 months for Poliglecaprone 25, between 3 and 6 months for Glycomer 631 and 6 months for Polydioxanone. The differences in suture characteristics which were detected in our study can help in the surgical selection of the most appropriate suture material” proved the safety of this product.

As above data analysis, the data of literature has been acceptable to performance and safety of a medical device. So, the literature searching has been verified

15.2 Protection measure for residual risk in risk management.

(1) In Biological part (Bacteria, Viruses, Re-or cross-infection) of identification of possible hazards, by the measure of label warning, the frequency of residual risk could be reduced from 2 level to 1 level

(2) In Chemical part (Residues, Degradation products) of identification of possible hazards, by the measure of chemical test, the frequency of residual risk could be reduced from 2 level to 1 level

(3) In Bio compatibility part (Toxicity of chemical constituents, e.g., Allergenicity / irritancy, Pyrogenicity) of identification of possible hazards, by the measure of Sterilization&Packing Validation / Biological evaluation report/QC inspection /Label warning, the frequency of residual risk could be reduced from 2 level to 1 level

(4) In Function part (Loss or deterioration of function) of identification of possible hazards, by the measure of “Write function of device clearly in manual and label”, the frequency of residual risk could be reduced from 2 level to 1 level

(5) In Use error part (Attention failure) of identification of possible hazards, by the measure of “Write attention of device clearly in manual and label”, the frequency of residual risk could be reduced from 2 level to 1 level

In Use error part (Rule-based failure) of identification of possible hazards, by the measure of “Write rule of device clearly in manual and label”, the frequency of residual risk could be reduced from 3 level to 2 level

(6) In Labeling part (Incomplete instructions for use / Inadequate description of performance characteristics / Inadequate specification of intended use / Inadequate disclosure of limitations) of identification of possible hazards, by the measure of “Write instructions for use / performance characteristics / intended use / limitation of device clearly in manual and label”, the frequency of residual risk could be reduced from 3 level to 2 level

(7) In Operating Instructions part (Inadequate specification of pre-use checks) of identification of possible hazards, by the measure of “Write specification of accessories of device clearly in manual and label”, the frequency of residual risk could be reduced from 3 level to 2 level

(8) In Warnings part (Of side effects / Of hazards likely with re-use of single-use medical devices) of identification of possible hazards, by the measure of "Write side effects / single use of device clearly in manual and label", the frequency of residual risk could be reduced from 3 level to 2 level

15.3 MDD Essential Requirements(ER)

Performance related items for MDD ER are as shown in the below. Attached are the verification documents for each item. The table shows that the requirements for MDD ER have been met and verified.

No.	Verification	Verification documents & Verification contents
1	MDD ER 1 (Benefit VS Risk)	The ER 1 requirement that the benefit to the patient is more than the risk it may cause is satisfied. The result can be verified through the risk management report and the clinical evaluation report.
2	MDD ER 3 (Clinical performance)	The ER 3 requirement about the clinical performance has been satisfied. The performance data can be confirmed through the literature section on other similar products and the field test result in the clinical evaluation report
3	MDD ER 4 (Side effect & Risk)	The ER 4 requirement is satisfied. The product evaluation reports of users in the risk management report show that there is no serious side-effect and the risk surrounding the product is within the allowable level through our control procedure.
4	MDD ER 6 (Side effect, Performance)	The ER 6 requirement is satisfied. The risk management report shows that there is no serious side-effect and the clinical evaluation report verifies the performance data.

16. ADDITIONAL LITERATURE SEARCHING

Key words : body dysmorphic disorder, body dysmorphic disorder treatment, dysmorphic disorder and polydioxanone suture, polydioxanone suture and dysmorphic disorder, dysmorphic disorder medical treatment, administration of medicine of dysmorphic, invasive suture, dysmorphic disorder polydioxanone, dysmorphic disorder suture, monofilament and dysmorphic

16.1 Potentially relevant literature identified through the search (copy of all citations)

- Prevalence of body dysmorphic disorder on a psychiatric inpatient ward and the value of a screening question
- Body dysmorphic disorder in a facial plastic and reconstructive surgery clinic: measuring prevalence, assessing comorbidities, and validating a feasible screening instrument.
- Clinical features, cognitive biases, and treatment of body dysmorphic disorder.
- Preoperative Symptoms of Body Dysmorphic Disorder Determine Postoperative Satisfaction and Quality of Life in Aesthetic Rhinoplasty
- Prevalence of depression and body dysmorphic disorder in patients before functional rhinosurgery
- A novel dysmorphic syndrome with open calvarial sutures and sutural cataracts maps to chromosome 14q13-q21.
- Surgical and Nonpsychiatric Medical Treatment of Patients With Body Dysmorphic Disorder

- Nonpsychiatric Medical Treatment of Body Dysmorphic Disorder
- Body Dysmorphic Disorder and Cosmetic Surgery
- Vertical Enlargement of the Palpebral Aperture by Static Shortening of the Anterior and Posterior Lamellae of the Lower Eyelid: A Cosmetic Option for Asian Eyelids
- Combined Rhinoplasty and GenioplastyLong-term Follow-up
- The Efficacy of Oral Celecoxib for Acute Postoperative Pain in Face-lift Surgery
- Body Image Dissatisfaction and Body Dysmorphic Disorder in 100 Cosmetic Surgery Patients.
- Negative Predictors for Satisfaction in Patients Seeking Facial Cosmetic Surgery: A Systematic Review
- Evaluating the Effectiveness of the Lateral Intercrural Suture to Decrease the Interdomal Distance to Improve the Definition of the Nasal Tip in Primary Rhinoplasty
- Should Plastic Surgeons Operate on Patients Diagnosed with Body Dysmorphic Disorder?
- Reply: Eumorphic Plastic Surgery for the Treatment of Dysmorphopathies
- Surgical and Nonpsychiatric Medical Treatment of Patients With Body Dysmorphic Disorder
- Two-Year Follow-Up of Behavioral Treatment and Maintenance for Body Dysmorphic Disorder
- Outcomes of polydioxanone knotless thread lifting for facial rejuvenation
- Body dysmorphic disorder in cosmetic surgery patients.
- Surgical and nonpsychiatric medical treatment of patients with body dysmorphic disorder
- Non-psychiatric medical treatment of body dysmorphic disorder
- Body dysmorphic disorder in a sample of cosmetic surgery applicants
- Soft Tissue Trauma and Scar Revision
- Surgical and Minimally Invasive Cosmetic Procedures among Persons with Body Dysmorphic Disorder
- Body image disorders and other psychiatric symptoms in aesthetic plastic surgery
- The “Ogee” of the Midface: Aesthetic and Technical Considerations
- Vertical Enlargement of the Palpebral Aperture by Static Shortening of the Anterior and Posterior Lamellae of the Lower Eyelid: A Cosmetic Option for Asian Eyelids
- Body dysmorphic disorder and aesthetic surgery: A systematic review
- Soft tissue trauma and scar revision
- Body image and cosmetic medical treatments
- The psychology of cosmetic surgery : A review and reconceptualization
- The effects of cosmetic surgery on body image, self-esteem, and psychological problems
- Body Dysmorphic Disorder and Aesthetic Surgery: Case Report
- Body dysmorphic disorder and appearance enhancing medical treatments

16.2 Literature excluded, with reasons

Literature less than those associated with our product were excluded.

16.3 Literature retrieved for more detailed assessment

- Body dysmorphic disorder in a facial plastic and reconstructive surgery clinic: measuring prevalence, assessing comorbidities, and validating a feasible screening instrument.
- Preoperative Symptoms of Body Dysmorphic Disorder Determine Postoperative Satisfaction and Quality of Life in Aesthetic Rhinoplasty
- Outcomes of polydioxanone knotless thread lifting for facial rejuvenation

- Evaluating the Effectiveness of the Lateral Intercrural Suture to Decrease the Interdomal Distance to Improve the Definition of the Nasal Tip in Primary Rhinoplasty
- Body Dysmorphic Disorder and Cosmetic Surgery
- Surgical and Nonpsychiatric Medical Treatment of Patients With Body Dysmorphic Disorder
- Soft Tissue Trauma and Scar Revision
- Surgical and Minimally Invasive Cosmetic Procedures among Persons with Body Dysmorphic Disorder
- The psychology of cosmetic surgery : A review and reconceptualization
- The effects of cosmetic surgery on body image, self-esteem, and psychological problems
- Vertical Enlargement of the Palpebral Aperture by Static Shortening of the Anterior and Posterior Lamellae of the Lower Eyelid: A Cosmetic Option for Asian Eyelids
- Body dysmorphic disorder and appearance enhancing medical treatments
- The “Ogee” of the Midface: Aesthetic and Technical Considerations

16.4 Literature excluded from clinical evaluation, with reasons

The literature that is less directly related to performance and safety of our products the content is excluded.

16.5 Final selection and exclusion

No.	Title	Selected or excluded	Excluded reason
1	Body dysmorphic disorder in a facial plastic and reconstructive surgery clinic: measuring prevalence, assessing comorbidities, and validating a feasible screening instrument.	excluded	No clear mention of pdo suture
2	Outcomes of polydioxanone knotless thread lifting for facial rejuvenation	Selected	Clear mention of pdo suture and treatment effect available
3	Evaluating the Effectiveness of the Lateral Intercrural Suture to Decrease the Interdomal Distance to Improve the Definition of the Nasal Tip in Primary Rhinoplasty	Selected	Clear mention of pdo suture and treatment effect available
4	Body Dysmorphic Disorder and Cosmetic Surgery	excluded	No clear mention of pdo suture
5	Surgical and Nonpsychiatric Medical Treatment of Patients With Body Dysmorphic Disorder	excluded	No clear mention of pdo suture
6	Soft Tissue Trauma and Scar Revision	Selected	Clear mention of pdo suture and treatment effect available
7	Surgical and Minimally Invasive Cosmetic Procedures among Persons with Body Dysmorphic Disorder	excluded	No clear mention of pdo suture
8	Vertical Enlargement of the Palpebral Aperture by Static Shortening of the Anterior and Posterior Lamellae of the Lower Eyelid: A Cosmetic Option for Asian Eyelids	Selected	Clear mention of pdo suture and treatment effect available

9	The effects of cosmetic surgery on body image, self-esteem, and psychological problems	excluded	No clear mention of pdo suture
10	Body dysmorphic disorder and appearance enhancing medical treatments	excluded	No clear mention of pdo suture

16.6 Data analysis

Selected literature list

No.	Title
1	Soft Tissue Trauma and Scar Revision
2	Evaluating the Effectiveness of the Lateral Intercrural Suture to Decrease the Interdomal Distance to Improve the Definition of the Nasal Tip in Primary Rhinoplasty
3	Vertical Enlargement of the Palpebral Aperture by Static Shortening of the Anterior and Posterior Lamellae of the Lower Eyelid: A Cosmetic Option for Asian Eyelids
4	Outcomes of polydioxanone knotless thread lifting for facial rejuvenation

1) Literature(1st)

(1) Literature analysis

Literature title	Description	Grading system	
Soft Tissue Trauma and Scar Revision	Were the data generated from the device in question?	D1	Actual device
		D2	Equivalent device
		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	A1	Same use
		A2	Minor deviation
		A3	Major deviation
	Where the data generated from a patient group that is Representative of the intended treatment population ? (e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	P1	Applicable
		P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	High quality
Steven R. Mobley, MD*, Phayvanh P. Sjogren, MD		R2	Minor deficiencies
		R3	Major deficiencies
	Was the design of the study appropriate?	T1	Yes
Issued date		T2	No
2014 Nov;22(4):639-51	Do the outcome measures reported reflect the intended performance of the device?	O1	Yes
		O2	No

	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Application/Non-application		F2	No
Application	Has a statistical analysis of the data been provided and is it appropriate?	S1	Yes
		S2	No
Literature search report No.	Was the magnitude of the treatment effect observed clinically significant?	C1	Yes
YR-LSR-09		C2	No

(2)Literature summary report (YR-LSR-09)

NO	Item	Contents
	Source	US National Library of Medicine National Institutes of Health
	Title	Soft tissue trauma and scar revision
	Summary	Abstract Numerous techniques and treatments have been described for scar revision, with most studies focusing on the adult population. A comprehensive review of the literature reveals a paucity of references related specifically to scar revision in children. This review describes the available modalities in pediatric facial scar revision. The authors have integrated current practices in soft tissue trauma and scar revision, including closure techniques and materials, topical therapy, steroid injection, cutaneous laser therapy, and tissue expanders.

2) Literature(2nd)

(1) Literature analysis

Literature title	Description	Grading system	
Evaluating the effectiveness of the lateral intercrural suture to decrease the interdomal distance to improve the definition of the nasal tip in primary rhinoplasty	Were the data generated from the device in question?	D1	Actual device
		D2	Equivalent device
		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	A1	Same use
		A2	Minor deviation
		A3	Major deviation
	Where the data generated from a patient group that is Representative of the intended treatment population ? (e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	P1	Applicable
		P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain sufficient	R1	High quality

Soares CM[1], Mocelin M[2], Pasinato R[2], Berger CA[1], Grocoske FL[3], Issa MJ[2].	information to be able to undertake a rational and objective assessment?	R2	Minor deficiencies
		R3	Major deficiencies
Issued date	Was the design of the study appropriate?	T1	Yes
		T2	No
2014 Apr;18(2):92-107	Do the outcome measures reported reflect the intended performance of the device?	O1	Yes
		O2	No
	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Application/Non-application		F2	No
Application	Has a statistical analysis of the data been provided and is it appropriate?	S1	Yes
		S2	No
Literature search report No.	Was the magnitude of the treatment effect observed clinically significant?	C1	Yes
YR-LSR-10		C2	No

(2)Literature summary report (YR-LSR-10)

NO	Item	Contents
	Source	US National Library of Medicine National Institutes of Health
	Title	Evaluating the effectiveness of the lateral intercrural suture to decrease the interdomal distance to improve the definition of the nasal tip in primary rhinoplasty
	Summary	Abstract Introduction Several surgical techniques emphasizing sutures on the lower lateral cartilage have been studied by surgeons as instruments to improve nasal tip remodeling. It is already known that the domal divergence angle and its definition angle can be modified by lateral intercrural suture (LIS). Techniques for measuring these structures are not yet standardized. Objectives Assess the efficacy of LIS using polydioxanone 4-0 absorbable thread by interdomal distance and systematize the LIS technique to improve nasal tip definition. Materials and Methods This prospective study measured and analyzed interdomal distances measured preoperatively and perioperatively compared with 3- and 6-month postoperative measurements. Results LIS was efficient on reducing interdomal distances. Conclusion LIS is statistically safe and efficient and has low morbidity when utilized in patients with mild to moderate deformities, because it reduces the domal divergence angle, effectively sustaining the nasal tip.

3) Literature(3rd)

(1) Literature analysis

Literature title	Description	Grading system

Vertical enlargement of the palpebral aperture by static shortening of the anterior and posterior lamellae of the lower eyelid: a cosmetic option for Asian eyelids.	Were the data generated from the device in question?	D1	Actual device
		D2	Equivalent device
		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	A1	Same use
		A2	Minor deviation
		A3	Major deviation
	Where the data generated from a patient group that is Representative of the intended treatment population ? (e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	P1	Applicable
		P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	High quality
Hirohi T[1], Yoshimura K.		R2	Minor deficiencies
		R3	Major deficiencies
	Was the design of the study appropriate?	T1	Yes
Issued date		T2	No
2011 Jan;127(1):396-406	Do the outcome measures reported reflect the intended performance of the device?	O1	Yes
		O2	No
	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Application/Non-application		F2	No
Application	Has a statistical analysis of the data been provided and is it appropriate?	S1	Yes
		S2	No
Literature search report No.	Was the magnitude of the treatment effect observed clinically significant?	C1	Yes
YR-LSR-11		C2	No

(2)Literature summary report (YR-LSR-11)

NO	Item	Contents
	Source	US National Library of Medicine National Institutes of Health
	Title	Vertical enlargement of the palpebral aperture by static shortening of the anterior and posterior lamellae of the lower eyelid: a cosmetic option for Asian eyelids

	Summary	Abstract BACKGROUND: Although double eyelid plasty, levator aponeurotic surgery, and epicanthoplasty are well-accepted cosmetic treatments for Asian eyes, some patients are incompletely satisfied with the outcomes and request further surgery. Although lower eyelid descent is generally recognized as a symptom of aging or a complication after blepharoplasty, the authors propose a perceptional change: a lowering the lower eyelid procedure to vertically enlarge the palpebral aperture in selected Asian patients. METHODS: A total of 125 Japanese patients underwent the lowering the lower eyelid procedure between 2005 and 2009. The main indications were patients with vertically narrow palpebral aperture or an up-slanting appearance. The lowering the lower eyelid procedure is performed by a combination of the removal of approximately 4 to 6 mm of the subciliary skin (usually the lateral one-third to two-thirds of the lower eyelids) and static shortening of the lower eyelid retractors (posterior lamella) through a transconjunctival approach. The middle lamella was not touched during the procedure. RESULTS: The up-slanting lower eyelid margin was lowered and the lateral part of the palpebral aperture was enlarged by the procedure in all cases. Cosmetic outcomes were encouraging and satisfying to most patients. Three complications occurred (2.4 percent): lagophthalmos in one patient (0.8 percent) and entropion in two patients (1.6 percent). These minor complications resolved within 1 month. Eight revision operations were required for undercorrection. CONCLUSIONS: The lowering the lower eyelid procedure offers Asian patients desiring large oval eyes a novel surgical option. The procedure proved to be a reliable and consistent technique that provided satisfactory results in carefully selected patients.

4) Literature(4th)

(1) Literature analysis

Literature title	Description	Grading system	
Outcomes of polydioxanone knotless thread lifting for facial rejuvenation	Were the data generated from the device in question?	D1	Actual device
		D2	Equivalent device
		D3	Other device
	Was the device used for the same intended use (e.g.,methods of deployment, application. etc.)?	A1	Same use
		A2	Minor deviation
		A3	Major deviation

	Where the data generated from a patient group that is Representative of the intended treatment population ? (e.g.,age,sex,etc.) and clinical condition (i.e.,disease, including state and severity)	P1	Applicable
		P2	Limited
		P3	Different population
Author	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	R1	High quality
Suh DH[1], Jang HW, Lee SJ, Lee WS, Ryu HJ.		R2	Minor deficiencies
		R3	Major deficiencies
	Was the design of the study appropriate?	T1	Yes
Issued date		T2	No
2015 Jun;41(6):720-5	Do the outcome measures reported reflect the intended performance of the device?	O1	Yes
		O2	No
	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1	Yes
Application/Non-application		F2	No
Application	Has a statistical analysis of the data been provided and is it appropriate?	S1	Yes
		S2	No
Literature search report No.	Was the magnitude of the treatment effect observed clinically significant?	C1	Yes
YR-LSR-12		C2	No

(2)Literature summary report (YR-LSR-12)

NO	Item	Contents
	Source	US National Library of Medicine National Institutes of Health
	Title	Outcomes of polydioxanone knotless thread lifting for facial rejuvenation
	Summary	Abstract BACKGROUND: Thread lifting is a minimally invasive technique for facial rejuvenation. Various devices for thread lifting using polydioxanone (PDO) are popular in aesthetic clinics in Korea, but there have been a few studies regarding its use. OBJECTIVE: To describe PDO thread and techniques adopted to counteract the descent and laxity of the face. METHODS: A retrospective chart review was conducted over a 24-month period. A total of 31 thread lifting procedures were performed. On each side, 5 bidirectional cog threads were used in the procedure for the flabby skin of the nasolabial folds. And, the procedure was performed on the marionette line using 2 twin threads.

		RESULTS: In most patients (87%), the results obtained were considered satisfactory. Consensus ratings by 2 physicians found that objective outcomes were divided among "excellent," "good," "fair," and "poor." Texture wise, the outcome ratings were 13 as excellent and 9 as good. Lifting wise, ratings were 11 as excellent and 6 as good. The incidence of complications was low and not serious. CONCLUSION: Facial rejuvenation using PDO thread is a safe and effective procedure associated with only minor complications when performed on patients with modest face sagging, fine wrinkles, and marked facial pores.

16.7 Evaluation for literature searching

As above data analysis, the data of literature has been acceptable to performance and safety of a medical device. So, the literature searching has been verified

17. CONCLUSTION

Clinical evidence is demonstrated by way of

- Comparison chart of predicate device
- Experience from previous use
- Testing reports, analysis
- New material is not applied
- Market surveillace
- Recall and side effect case in website.
- Evaluation risk management
- Evaluation for literature searching

From the above clinical evidence, we can conclude that

1) The ‘Sterile Polydioxanone Suture with Needle’ is substantially equivalent to the marketed predicate device, and do not raise any new issues of safety or effectiveness

2) Our device is similar to product of the investigated thesis and our device is not new development medical device and using it on the field is safe.

3) All details regarding the essential requirements mentioned corresponds clinical evidence has been verified in performance and safety as it originally intended. Therefore, it is confirmed that there is no problem using this device.

4) These ‘Sterile polydioxanone suture with needle’ have not been changed in all following essential characteristics with the device

5) About 300,000 pcs of ‘Sterile polydioxanone suture with needle’ had been sold in domestic and oversea market during 2015 year.

6) There were no any incidents

7) There were no any complaints for harm of patient

8) We could find some recall cases of similar products for suture tensile strength in website. We enhanced the drying process in order to prevent weakening of the suture tensile strength. And we reflected this expected risk in risk management, clinical assessment report.

9) For literature searching, the safety of our product was also demonstrated.

10) From the all above information, we can declare that this ‘Sterile polydioxanone suture with needle’ has no clinical and technical problems