CE Technical Documentation

<According to MEDICAL DEVICE REGULATION (EU) 2017/745>

Summary of Safety and Clinical Performance (SSCP)

Synthetic Absorbable Suture With or Without Needle

（WEGO-PGA）

Revision No. A/1

Audited By/Date	Sun Long/2023.03.08	Approved By/Date	Yv HC/2023.03.09
Issuing Department	Technical Department	Drafted By/Date	王磊 Wang Lei/2023.03.06
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Content

SSCP for Users/healthcare Professionals

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1.0 Device identification and general information

1.1. Device name and trade name

Device Name: Synthetic Absorbable Suture With or Without Needle

Trade name:

WEGO-PGA

1.2. Manufacturer name and address

Manufacturer Name:

Foosin Medical Supplies Inc., Ltd.

Address:

No.20, Xingshan Road, Weihai Torch Hi-tech Science Park, 264210 Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

1.3. Manufacturer single registration number (SRN)

SRN: CN-MF-000006957

1.4. Basic UDI-DI

69418136AB-suturesIIIGM6

1.5. Class of device

Class Ⅲ according to Rule 8, Annex VIII of REGULATION (EU) 2017/745

1.6. Year when the first certificate (CE) was issued covering the device

2008

1.7. Authorised representative's name and the SRN

Name: MedNet EC-REP CIII GmbH

SRN: DE-AR-000000002

1.8. NB's name (the NB that will validate the SSCP) and the NB's single identification number

Name: TÜV SÜD Product Service GmbH.

NB's single identification number: 0123

2.0 Intended use of the device

2.1. Intended purpose

WEGO-PGA suture is an absorbable suture indicated for general soft tissue approximation and/or ligation.

2.2. Indications

WEGO-PGA suture is indicated for general soft tissue approximation and/or ligation, mainly in general surgery, gynecology and obstetrics surgery, urinary surgery, orthopedics surgery, gastrointestinal surgery, thoracic surgery, pediatric surgery, oral surgery, otorhinolaryngologic surgery and ophthalmologic surgeries.

2.2. Intended patient groups

Adults and paediatric patients (0-18 years old)

2.3. Contraindications and/or limitations

This suture, being absorbable should not be used where extended approximation of tissues under stress is required. The safety and effectiveness of WEGO-PGA sutures in cardiovascular tissue and neurological tissue have not been established.

3. Device description

3.1. Description of the device

WEGO-PGA sutures are synthetic, absorbable, sterile surgical sutures composed of Polyglycolic Acid (PGA, content 94-99wt.%). The empirical formula of the polymer is (C2H2O2)n. WEGO-PGA sutures are available undyed and dyed violet with D&C Violet No.2 (Colour Index number 60725, content ≤0.2wt%).

WEGO-PGA sutures are available as braided strands in EP sizes 0.4-6 (USP sizes 8-0 through 3), in a variety of lengths, with and without stainless steel needles of varying types and sizes. Braided sutures are uniformly coated with polycaprolactone and calcium stearate (content 1-5wt.%, depend on suture diameter).

WEGO-PGA sutures are also available as monofilament in EP sizes 0.2-0.3 (USP size 10-0 through 9-0), in a variety of lengths, with and without stainless steel needles of varying types and sizes. Monofilament sutures are uncoated.

WEGO-PGA suture complies with the requirements of the European Pharmacopoeia for “Sutures, Sterile Synthetic Absorbable Braided” and the requirements of United States Pharmacopoeia for “Absorbable Surgical Suture”.

Principles of operation

1). Operation principle: the product is sterilized by ethylene oxide and can be used after opening the outer package. The suture should be selected and used according to the patient's condition, surgeon's experience, operation method and wound size.

2). During the operation, it is necessary to avoid the damage of tweezers or needle holding pliers to the suture, and the suture knot shall be safe and reliable.

3). Attention shall be paid not to damage the suture needle during the suture operation. The needle holding point is between one third (1 / 3) and one half (1 / 2) from the end of the needle. Improper needle holding point will affect the puncture ability of the suture needle and may cause the fracture of the suture needle.

Mode of action

Its major function is general soft tissue approximation and/or ligation.

WEGO-PGA Sutures elicits a minimal initial inflammatory reaction in tissues and are eventually replaced with an in-growth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of sutures occurs by means of hydrolysis, where the polymer degrades to glycolic which are subsequently absorbed and eliminated by the body. Absorption begins as a loss tensile of strength followed by a loss of mass. Absorption of WEGO-PGA sutures is essentially complete between 60 and 90 days

Single use: ☒ Yes ☐ No

Method of sterilization: EO Sterilization

Shelf-life: 5 Years

Loss of stability and the absorption time:

Absorption begins as a loss tensile of strength followed by a loss of mass. Implantation studies in rats show the following profile.

Days Implantation	**Approximate % original Strength Remaining**
14 days	75%
21 days	40%

The complete mass absorption of WEGO-PGA sutures takes place at 60 to 90 days.

3.2. A reference to previous generation(s) or variants if such exist, and a description of the differences

N/A

3.3. Description of any accessories which are intended to be used in combination with the device

N/A

3.4. Description of any other devices and products which are intended to be used in combination with the device

Suture is primarily intended to be used in combination with needle holder or forceps.
Needle holder and forceps are mainly made of stainless steel, used for gripping needle to suture various tissues. It is also sometimes used for suture knotting.

4.0 Risks and warnings

4.1. Residual risks and undesirable effects

Quantitative data on side-effects or residual risks have been obtained from the following sources:

- Systematic review of the scientific literature (expected frequencies)
- Proactively obtained clinical data from PMCF Study pertaining to the subject device
- Proactively obtained clinical data from PMCF Survey pertaining to the subject device

Data from spontaneously reported incidents or serious incidents is not used as one of the sources for estimating quantitative data on side-effects or residual risks, due to its significant under-reporting nature.
The individual rates are all sourced from the clinical evaluation report of the subject device. The data from high-level scientific publications has been prioritized and disclosed as the

risk quantification. When the individual rate from PMCF study and/or PMCF survey is higher than that obtained from publications, the rate from PMCF study and/or PMCF survey is used for risk quantification. All the sources have been detailed disclosed in the table below according to the requirements of MDCG 2019-9 Rev.1 Summary of safety and clinical performance - A guide for manufacturers and notified bodies.

General soft tissue approximation and/or ligation (except for ophthalmic use)							
Residual risk / undesirable side effect	**Risk Quantification per Source of Data**			**Final Risk Quantification**	**Source of Data**	**Relation to time**	**References**
	Systematic review of the scientific literature	**Proactively obtained clinical data - PMCF Study**	**Proactively obtained clinical data - PMCF Survey**				
Wound dehiscence	3.8%	0.73%	0.1%	**3.8%**	Systematic review of the scientific literature	Perioperative period, mostly within 30 days of surgery	1) 2) 3) 4) 5)
Anastomotic leak	5.4%	Both anastomotic leak and bleeding are grouped together to be 2.24%	0%	**5.4%**	Systematic review of the scientific literature	Perioperative period, mostly within 30 days of surgery	2) 6)
Surgical Site Infection	8.7%	0.73%	0.2%	**8.7%**	Systematic review of the	Perioperative period, mostly within	1) 2) 3) 7) 8) 9)

					scientific literature	30 days of surgery	
Sinus or fistula formation	1.7%	0%	0%	**1.7%**	Systematic review of the scientific literature	Relatively long-term complications, no time point specified	1)
Incisional hernia	11.5%	0%	0%	**11.5%**	Systematic review of the scientific literature	At one year or more of follow-up	1)
Wound haematoma	0.3%	0%	0%	**0.3%**	Systematic review of the scientific literature	Perioperative period, no time point specified	10)
Wound seroma	1.4%	0%	0%	**1.4%**	Systematic review of the scientific literature	Perioperative period, no time point specified	10)
Wound exudation	4.0%	0%	0.2%	**4.0%**	Systematic review of the scientific literature	Perioperative period, no time point specified	11)
Abscess	2.2%	0%	0%	**2.2%**	Systematic review of the scientific	Within 56-84 days post-op, no time point	11) 12)

					literature	specified	
Allergic reaction	3.9%	0%	0.1%	**3.9%**	Systematic review of the scientific literature	Perioperative period, no time point specified	12)
Inflammation (Redness, swelling, pain)	4.4%	0%	0.4%	**4.4%**	Systematic review of the scientific literature	Perioperative period, within 30 days of surgery	12)
Anastomotic bleeding	1.55%	NA (not separately listed)	0%	**1.55%**	Systematic review of the scientific literature	Perioperative period, no time point specified	6)
Anastomotic stricture	0.15%	0%	0%	**0.15%**	Systematic review of the scientific literature	Relatively long-term complications, no time point specified	6)
Needle stick injury	3.8%	0%	0%	**3.8%**	Systematic review of the scientific literature	If happens, then immediate when handling the needles	11)
Tissue granulation or fibrosis	NA	NA	0%	**0%** (considered as part of the	Proactively obtained clinical	Perioperative period	NA

				normal wound healing process)	data - PMCF Survey		
Edema	NA	0%	0%	**0%**	Proactively obtained clinical data - PMCF Study and Survey	Perioperative period, within 90 days	NA
Suture extrusion and delayed absorption	NA	NA	0.1%	**0.1%**	Proactively obtained clinical data - PMCF Survey	About 90 days post-op	NA
Ophthalmic use							
Residual risk / undesirable side effect	**Risk Quantification per Source of Data**			**Final Risk Quantification**	**Source of Data**	**Relation to time**	**References**
	Systematic review of the scientific literature	**Proactively obtained clinical data - PMCF Study**	**Proactively obtained clinical data - PMCF Survey**				
Wound dehiscence/ leakage	0%	NA	0.5%	**0.5%**	Proactively obtained clinical data - PMCF	1-day post-op (normally appear during the early	13) 14) 15) 16)

					Survey	postoperative period)	
Wound infection	0%	NA	0%	**0%**	Systematic review of the scientific literature	Perioperative period, mostly within 30 days of surgery	13) 14) 15) 16)
Foreign body sensation	0%	NA	0.9%	**0.9%**	Proactively obtained clinical data - PMCF Survey	1-day post-op (disappeared within a week after applying medication)	13) 14) 15) 16)

Note:

Data from spontaneously reported incidents or serious incidents is **not** used as one of the sources for estimating quantitative data on side-effects or residual risks, due to its significant under-reporting nature.

References:

See **Chapter 10 References**.

4.2. Warnings and precautions

— Users should be professional medical staff that familiar with surgical procedures and techniques and trained in professional surgical suture techniques involving absorbable sutures before employing WEGO-PGA suture for wound closure, as risk of wound dehiscence, may vary with the site of application and the suture material used. Surgeons should consider the in vivo performance (described in ACTION section) when selecting a suture.

— As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. As an absorbable suture, it may act transiently as a foreign body.

— Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

— As this is an absorbable suture material, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distension, or which may require additional support.

— Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.

— Under some circumstances, notably orthopaedic procedures, immobilisation of joints by external support may be employed at the discretion of the surgeon.

— Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.

— Subcuticular sutures should be places as deeply as possible to minimize the erythema and induration normally associated with the absorption process.

— This suture may be inappropriate in elderly, malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing.

— When handling this or any other suture, care should be taken to avoid damage. Avoid crushing or crimping damage due to the application of surgical instruments such as forceps or needle holders.

— Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the attachment end to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the butt or attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Broken needles may result in extended or additional surgeries or residual foreign bodies.

— Adequate knot security requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting any monofilament suture.

— Users should exercise caution when handing surgical needles to avoid inadvertent needle stick injury. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

— Discard used needles in “Sharps” container.

— Dispose of material in accordance with all the state, local, and hospital regulations.

Responsibility for proper waste disposal is with the owner of the waste.

— Do not re-use: Infection hazard for patients and/or users and impairment of products functionality due to re-use. Risk of injury, illness or death due to contamination and/or impaired functionality of the product.

— Do not re-sterilize: Infection hazard for patients and/or users and impairment of products functionality due to use of re-sterilized suture. Risk of injury, illness or death due to contamination and/or impaired functionality of the product.

— Do not use if package is opened or damaged. Discard opened unused sutures.

— Do not use after exp. Date.

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

N/A

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to equivalent device, if applicable

N/A

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

N/A

5.3 Summary of clinical data from other sources, if applicable

- A Systematic literature review has been conducted and there have been no articles retrieved in which the subject device is used.
- Clinically relevant information based on clinical data obtained from the implementation of the manufacturer's PMCF and PMS plans.
  - **Conducted PMCF investigations**

    The summary of the PMCF investigations performed for the subject device is listed in table below:

	Post-market clinical investigation	Post-market clinical

	#1	investigation #2
Identity of the investigation/study	**Title of the study:** Clinical Investigation Report of Absorbable Surgical Sutures (PGA) General report of a multicenter, prospective, randomized, single-blind, parallel controlled clinical trial of the efficacy and safety of absorbable surgical sutures (PGA) for **skin and soft tissue** suturing and/or ligation in surgical procedures	**Title of the study:** Clinical Investigation Report of Absorbable Surgical Sutures (PGA) Report of a multicenter, prospective, randomized, single-blind, parallel controlled clinical trial analyzing the efficacy and safety of absorbable surgical sutures (PGA) for **intraluminal soft-tissue** suturing and/or ligation in surgical procedures
	PMCF investigation performed under the MDD. Study start time: May 22, 2018 Study end time: July 20, 2019 Country where the study is performed: China Participating institutions: 1) 254th Hospital of Chinese People's Liberation Army 2) Beijing Ditan Hospital, 3) Xingtai People's Hospital 4) Handan Central Hospital CIP number: WGFS2017003 Version number and date: 2.0/January	PMCF investigation performed under the MDD. Study start time: June 19, 2018 Study end time: July 15, 2019 Country where the study is performed: China Participating institutions: 1) 254th Hospital of Chinese People's Liberation Army 2) Shanghai Yangpu District Central Hospital 3) 10th Shanghai People's Hospital 4) Xingtai People's Hospital CIP number: WGFS2017004

<table>
<tr><td></td><td>15, 2018

CIR not available in Eudamed.</td><td>Version number and date of plan: 2.0/January 20, 2018

CIR not available in Eudamed.</td></tr>
<tr><td>Identity of the device including any model number/version</td><td>Absorbable surgical sutures (PGA) produced by Foosin Medical Supplies Inc. (WEGO-PGA)
The suture specifications were not detailed in the CIR. The following suture specifications have been provided by the manufacturer for the study:
<table>
<tr><td>Product code</td><td>USP size</td></tr>
<tr><td>G11402-90</td><td>0#</td></tr>
<tr><td>G23243-70</td><td>2-0</td></tr>
<tr><td>G33193-70</td><td>3-0</td></tr>
<tr><td>G33243-70</td><td>3-0</td></tr>
<tr><td>G43243-70</td><td>4-0</td></tr>
<tr><td>G43193-70</td><td>4-0</td></tr>
<tr><td>G53163-45</td><td>5-0</td></tr>
<tr><td>G53133U-45</td><td>5-0</td></tr>
<tr><td>G63133U-45</td><td>6-0</td></tr>
</table></td><td>Absorbable surgical sutures (PGA) produced by Foosin Medical Supplies Inc. (WEGO-PGA)
The suture specifications were not detailed in the CIR. The following suture specifications have been provided by the manufacturer for the study:
<table>
<tr><td>Product code</td><td>USP size</td></tr>
<tr><td>GC1482-90</td><td>2#</td></tr>
<tr><td>GB1402-90</td><td>1#</td></tr>
<tr><td>GB2653-100</td><td>1#</td></tr>
<tr><td>G11262-70</td><td>0#</td></tr>
<tr><td>G21302-70</td><td>2-0</td></tr>
<tr><td>G21372-90</td><td>2-0</td></tr>
<tr><td>G31222-70</td><td>3-0</td></tr>
<tr><td>G31262-70</td><td>3-0</td></tr>
<tr><td>G41222-70</td><td>4-0</td></tr>
<tr><td>G41172-70</td><td>4-0</td></tr>
<tr><td>G51172-70</td><td>5-0</td></tr>
</table></td></tr>
</table>

		G51172D-90 / 5-0
Intended use of the device in the investigation	Soft tissue approximation and/or ligation	Soft tissue approximation and/or ligation
Objectives of the study	The objective of this study is to evaluate the efficacy and safety of absorbable surgical sutures (PGA) used for suturing and/or ligating of skin and soft tissue in surgical procedures. The efficacy evaluation indicators were grade A healing rate of surgical wound, subjective pain evaluation, suture performance evaluation and absorbability. The safety evaluation indicators were blood and urine routine, blood biochemistry and other laboratory tests, vital signs of subjects, adverse events, serious adverse events, and complications.	The objective of this investigation is to evaluate the efficacy and safety of absorbable surgical sutures (PGA) used for suturing and/or ligating of intraluminal soft tissue in surgical procedures. The efficacy evaluation indicators include effective rate of suturing and/or ligation, subjective pain assessment, suture operation performance evaluation, blood loss, and postoperative drainage. The safety evaluation indicators were blood and urine routine, blood biochemistry and other laboratory tests, vital signs of subjects, adverse events, serious adverse events, and complications.
Study design	multicenter, prospective, randomized, single-blind, parallel controlled clinical trial	multicenter, prospective, randomized, single-blind, parallel controlled clinical trial
Duration of the follow-up	90±10 days	90±10 days
Primary and secondary endpoint(s)	Primary endpoint: Grade A wound healing rate at 90±10 days after operation.	Primary endpoint: The effective rate of successful ligation and/or suturing soft tissues from immediate

	Grade A wound healing is defined as good healing, without redness and infection of the incision, linear healing. Secondary endpoint: Subjective pain evaluation Suture operating performance evaluation Suture absorption evaluation	intraoperative to 7±2 days after operation without bleeding or leakage of tissue fluid. Secondary endpoint: Evaluation of pain by visual analogue scoring Operation performance evaluation
Inclusion/exclusion criteria for subject selection	Inclusion criteria: 1) Age >18 years old and ≤75 years old, no gender limitation; 2) Patients undergoing subcutaneous/skin suture in orthopedic surgery; 3) Patients with normal coagulation time; 4) Subjects or their guardians can understand the purpose of the study, have good compliance with the follow-up of the study, and voluntarily sign the informed consent. Exclusion criteria: 1) Severe fracture, vascular and nerve injury, serious complications of heart, brain, liver and kidney or underlying diseases; 2) Patients with existing infection around ligation and/or suture site;	Inclusion criteria: 1) Age >18 years old and ≤75 years old, no gender limitation; 2) Patients undergoing hepatobiliary, gastrointestinal, pancreatic, urinary system surgical anastomosis and/or ligation; 3) Patients with normal coagulation time; 4) Subjects or their guardians can understand the purpose of the study, have good compliance with the follow-up of the study, and voluntarily sign the informed consent. Exclusion criteria: 1) Severe fracture, vascular and nerve injury, serious complications of heart, brain, liver and kidney or

	3) Patients with major organ dysfunction or other serious diseases who cannot tolerate treatment; 4) Pregnant or lactating women; 5) Patients who have participated in clinical trials of any other drug or medical device within 3 months prior to screening; 6) Patients considered unsuitable for the clinical trial by the investigator.	underlying diseases; 2) Patients with existing infection around ligation and/or suture site; 3) Patients with serious diseases who cannot tolerate treatment; 4) Pregnant or lactating women; 5) Patients who have participated in clinical trials of any other drug or medical device within 3 months prior to screening; 6) Patients considered unsuitable for the clinical trial by the investigator.
Number of enrolled subjects	276 subjects were enrolled. 138 subjects in the experimental group (WEGO-PGA) and 138 subjects in the control group (Safil from B.Braun). Among the enrolled subjects, 8 subjects were significantly deviated from the protocol and violated the inclusion criteria, and the remaining 268 subjects were included in PPS set, which resulted in 135 subjects in the experimental group (WEGO-PGA) and 133 subjects in the control group (Safil from B.Braun).	276 subjects were enrolled. 138 subjects in the experimental group (WEGO-PGA) and 138 subjects in the control group (Safil from B.Braun). Among the enrolled subjects, 6 subjects were significantly deviated from the protocol and violated the inclusion criteria, and the remaining 270 subjects were included in PPS set, which resulted in 134 subjects in the experimental group (WEGO-PGA) and 136 subjects in the control group (Safil from B.Braun).

Study population	There were 89 males and 49 females in experimental group. In the control group, there were 95 males and 43 females. The average age of experimental group was 41.20±18.02 years; The average age of the control group was 43.47±17.84 years. The average height of experimental group was 169.40±7.29 cm; The average height of the control group was 170.33±7.79 cm. The average body weight of experimental group was 71.58±11.28 kg; The average body weight of the control group was 72.11±10.57 kg.	There were 85 males and 53 females in experimental group. In the control group, there were 77 males and 61 females. The average age of experimental group was 44.28±13.52 years; The average age of control group was 47.52±14.37 years. The average height of experimental group was 163.58±7.39 cm; The average height of the control group was 165.36±6.70 cm. The average body weight of experimental group was 67.53±10.55 kg; The average body weight of the control group was 66.15±12.53 kg.
Summary of study methods	This study adopts the multicenter, randomized, single blind, parallel controlled clinical study design. Patients requiring soft tissue suturing and/or ligation were divided into two groups (experimental group and control group) in a 1:1 proportion. Experimental group applied WEGO-PGA absorbable surgical sutures, and the control group applied Safil absorbable surgical sutures (manufactured by B.Braun) marketed in European Union for many years. Standard skin and soft tissue suturing and/or ligation procedures were performed at the same time by a	This study adopts a multi-center, randomized, single-blind, parallel-controlled clinical study design. The patients who meet the inclusion criteria have been divided into two groups (experimental group and control group) according to the ratio of 1:1. The experimental group applied the absorbable surgical sutures (PGA) of Foosin Medical Supplies Inc., Ltd. The control group used absorbable surgical sutures (Safil®) produced by B. Braun Surgical SA, which has been marketed for a long time and

	specialist authorized investigator who compared two products used in the operation and clinical efficacy, evaluated the efficacy and safety of WEGO-PGA absorbable surgical sutures for skin and soft tissue suturing and/or ligation.	widely used in clinical practice. The investigators, who were authorized by professional department, performed surgical treatment in accordance with the standard of soft tissue suture and/or ligation in the same period, compared the use and clinical efficacy of the two products in surgery, and evaluated efficacy and safety of the absorbable surgical sutures produced by Foosin Medical Supplies Inc., Ltd. for suturing and/or ligating of intraluminal soft tissues in surgery.
Summary of results	The grade A wound healing rate of the FAS analysis group was 95.65% (n=138) at 90±10 days after operation (WEGO-PGA). In the control group (Safil), grade A healing rate was 94.20% (n=138) at 90±10 days after operation. The results of grade A wound healing rate analysis at 90±10 days after surgery: Fisher's exact test showed no significant difference between the two groups. No significant differences in pain or suture operating performance between the two groups. Experimental group suture absorbability evaluation at 90±10 days after surgery grade I: complete absorption (no foreign body sensation, no indentation) 97.78% (n=135).	The effective rate of successful ligation and/or suturing of vessels and/or internal tissues without bleeding or leakage of tissue fluid was 97.10% (n=138). In the control group, vessels and/or tissue were successfully ligation and/or sutured without bleeding or leakage of tissue fluid, the effective rate was 97.83% (n=138). Results of effective rate analysis at 7±2 days after operation: Fisher's exact test showed no significant difference between the two groups. For the PPS group, that is, the included subjected only, the effective rate of successful ligation and/or suturing of vessels and/or tissues

The safety performance evaluation results are:

Complications related to WEGO-PGA	Post-op 14±3 days	Post-op 90±10 days
Pain	3.62% (5/138)	0.00% (0/135)
Edema	0.00% (0/138)	0.00% (0/135)
Wound exudation	0.00% (0/138)	0.00% (0/135)
Wound infection	0.73% (1/138)	0.00% (0/135)
Abdominal abscess	0.00% (0/138)	0.00% (0/135)
Prolonged healing	1.45% (2/138)	0.00% (0/135)
Bleeding	0.00% (0/138)	0.00% (0/135)
Fever	0.00% (0/138)	0.74% (1/135)
Rejection	0.00% (0/138)	0.00% (0/138)

There are no adverse events related to WEGO-PGA and Safil sutures. 5 serious adverse events occurred in 5 patients in the experimental group (WEGO-PGA, n=138) are: wound without bleeding or leakage of tissue fluid for the subject device group was 97.76% (n=134), which equals to 2.24% anastomotic leak and bleeding rate.

No significant differences in pain, suture operating performance, blood loss or drainage between the two groups.

There are no adverse events related to WEGO-PGA and Safil sutures. 14 serious adverse events were recorded for the experimental group (WEGO-PGA, n=138): incision cracked and oozed (1), left shoulder injury (1), lung infection (1), diarrhea (1), the right-hand fracture (1), sigmoid colon cancer postoperative (2), postoperative chemotherapy for rectal cancer (3), postoperative chemotherapy for colon cancer (2), postoperative chemotherapy for ascending colon cancer (2).

None of these serious adverse events are related to internal soft tissue anastomosis/ligation with the WEGO-PGA sutures.

Percentage completeness of follow-up: 97.1% (134/138)

The study is completed and not ongoing for long-term follow up.

	dehiscence (1), crus fracture (1), skin necrosis (1), urinary tract infection (1), skin infections (1). All the symptoms disappeared during the study period. The 3 serious adverse events that are rated as "May have nothing to do with the test equipment" are: wound dehiscence (0.73%, 1/138), skin necrosis (0.73%, 1/138), skin infections (0.73%, 1/138). Percentage completeness of follow-up: 97.8% (135/138) The study is completed and not ongoing for long-term follow up.	
Limitations	The USP 9-0 and 10-0 sutures were not studied in this clinical investigation. Paediatric population, pregnant women, lactating women were not included in this clinical investigation.	The USP 9-0 and 10-0 sutures were not studied in this clinical investigation. Paediatric population, pregnant women, lactating women were not included in this clinical investigation.
Any device deficiency and any device replacements related to safety and/or performance during the study	None.	None.

- **Conducted PMCF survey**

  Foosin Medical Supplies Inc has conducted proactive PMCF data collection in

the form of PMCF surveys for the device under evaluation according to the PMCF plan as part of the PMS activities, to fulfil the requirements of the EU MDR 2017/745 Annex XIV Part B and MDCG 2020-7. The aim of the PMCF surveys is to confirm the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

PMCF survey results regarding general soft tissue approximation and/or ligation

There have been 27 surveys collected from 8 countries including both EU and non-EU countries: Poland, Hungary, Lithuania, Romania, Morocco, China, US, Indonesia. 22 healthcare facilities participated in the survey so far. Altogether there are **1023** cases regarding the use of the WEGO-PGA sutures for general soft tissue approximation and/or ligation collected (ophthalmic use not included and collected separately) covering the time period 26/05/2021 – 31/12/2022.

The patient characteristics are summarized below:

Gender	Female 597 cases, Male 426 cases
Age Categories	
Less than 1 month	5
1 month - 1 year	10
1 year - 12 years	78
12 years - 18 years	104
18 years - 60 years	678
More than 60 years	148
Special populations	
Diabetic patients	25
Pregnant women	8

Lactating women	150

The surgery types covered are:

Surgery types	**Number of cases**
General surgery	188
Gynecology and obstetrics surgery	222
Urinary surgery	56
Orthopedics surgery	98
Gastrointestinal surgery	244
Thoracic surgery	62
Pediatric surgery	66
Oral surgery	88
Otorhinolaryngologic surgery	5

The tissue types covered are: Skin, Subcutaneous tissue, Muscle, Fascia, Mucosa, Peritoneum, Pleura, Joint capsule, tendon sheath, blood vessels, Uterus, Ovaries, Stomach and intestine, Esophagus, Pancreas, Liver and gall, Thyroid gland, Kidney, Prostate, Bladder, Urethra, Lung.

The usage of the WEGO-PGA sutures in the general soft tissue approximation and/or ligation cases collected (ophthalmic use not included and collected separately) include: EP 6 (USP 3), EP 5 (USP 2), EP 4 (USP 1), EP 3.5 (USP 0), EP 3 (USP 2-0), EP 2 (USP 3-0), EP 1.5 (USP 4-0), EP 1 (USP 5-0), EP 0.7 (USP 6-0), EP 0.5 (USP 7-0).

In all cases, the WEGO-PGA sutures have been used for soft tissue approximation and/or ligation as intended. There are no cases of off-label use or misuse of the device.

Regarding the handling of the suture (usability survey), the overall evaluation of the handling of the WEGO-PGA suture has been summarized below:

Overall evaluation of the handling of the WEGO-PGA suture	**Summary**
1. very good	88.89% (24/27)
2. good	11.11% (3/27)
3. moderate	0.00% (0/27)
4. not good	0.00% (0/27)
5. inadequate	0.00% (0/27)

As shown by the survey result, 100% of the users have rated the handling of the WEGO-PGA suture as good (2) and very good (1). There have been no cases at or below the average rating (3).

The handling/usability of the WEGO-PGA suture is therefore considered as appropriate. No usability issues have been detected during this survey period.

Regarding the device problems encountered, there have been 3 cases reported out of the 1023 cases (which are 2712 packages of the WEGO-PGA sutures). The overall device problem rate is 0.1%. The device problems include blunt needle point (1 case), needle separated from the suture (1 case) and deformed needle (1 case). There have been no patient harms resulted.

The successfulness of wound closure (tissue approximation and/or ligation) has been asked in the PMCF survey. Out of the 1023 cases, there are 1020 cases of successful would closure using the WEGO-PGA sutures, which is a successful rate of **99.7%**.

The device performance and safety problems reported during this survey have been summarized in the table below:

Device performance and safety endpoints	**PMCF survey result**	**Acceptance criteria (SOTA)**	**Result**

Wound dehiscence	0.1% (1/1023)	⩽ 3.8%	Within the acceptance criteria
Wound infection	0.2% (2/1023)	⩽ 8.7%	Within the acceptance criteria

The absorption of the WEGO-PGA sutures shall be completed between 60 or 90 days. There was 1 case of incomplete absorption reported out of the 1023 cases (0.1%).

The wound healing process is a complex process. The patient's overall health status can affect the speed of the healing process and the absorption profile of synthetic sutures. The exact cause of the small residual suture material after 3 months reported during this PMCF survey is unknown. Due to the low occurrence rate (1 case out of 1023 cases), it is very likely to be patient-specific and not likely to be related with the general quality of the WEGO-PGA suture. There have been no similar cases reported in the PMS process. It is therefore considered as acceptable and the claim of complete absorption within 90 days is still supported with sufficient clinical evidence (99.9% complete absorption).

In addition, the following patient harms / post-operative complications (8 cases) have been reported during this PMCF survey: wound exudation (0.2%, 2/1023), inflammation (redness, swelling, pain) (0.4%, 4/1023), allergic reaction (0.1%, 1/1023), and local rejection of the suture (0.1%, 1/1023). The occurrence rate of the clinical risks/post-operative complications are compared with the acceptance criteria identified in the state-of-the-art literature analysis. For wound exudation, inflammation, and allergic reaction, the occurrence rates detected in this PMCF survey are within the acceptance criteria identified from the state-of-the-art. There was no rate of local rejection of the suture identified from the

state-of-the-art. Polyglycolic acid sutures have been marketed since the 1970s which use well-established technologies. Local rejection of sutures happened rarely and was normally not reported in the recent literatures. The device under evaluation has not been associated with rejection issues since the device has been placed on the market in 2008. The 1 case of local rejection of the suture is therefore considered as a sporadic case and patient-specific, which does not affect the device performance and safety.

Regarding special populations, there are 25 diabetic patients, 8 pregnant women and 150 lactating women included in the survey. No failure of wound closure using the WEGO-PGA sutures have been reported. The clinical data pertaining to the special populations will be continuously collected during the PMS including PMCF activities to reach a more reliable sample size.

Regarding paediatric population, there have been altogether 66 cases collected during this PMCF survey period. 5 neonates (less than 1 month), 10 infants (1 month – 1 year), 78 children (1 year - 12 years) and 104 teenagers (12 years - 18 years) have been included in the survey. For paediatric population, no failure of wound closure using the WEGO-PGA sutures have been reported. No specific clinical risks regarding the paediatric population have been reported. The clinical data pertaining to the paediatric populations will be continuously collected during the PMS including PMCF activities to reach a more reliable sample size. Based on the current available dataset, the clinical performance and safety of the WEGO-PGA sutures are considered as acceptable for the paediatric population.

PMCF survey results regarding ophthalmic use of the WEGO-PGA sutures

There have been 8 surveys collected from China focusing on the ophthalmic use of the WEGO-PGA sutures. The eye tissue that can be sutured does not present differences between different races. The data collected on the Asian population

is considered to be representative for all populations.

8 healthcare facilities participated in the survey so far. Altogether there are **215** cases collected regarding the use of the WEGO-PGA sutures for soft tissue approximation and/or ligation in ophthalmological surgical procedures, covering the time period 26/05/2021 – 31/12/2022.

The patient characteristics are summarized below:

Gender	Female 102 cases, Male 113 cases
Age Categories	
Less than 1 month	0
1 month - 1 year	4
1 year - 12 years	20
12 years - 18 years	20
18 years - 60 years	99
More than 60 years	72
Special populations	
Diabetic patients	10
Pregnant women	0
Lactating women	1

The surgery types covered and the sizes of the WEGO-PGA sutures used are presented in the table below:

Surgery type	**Surgery name**	**Tissue name**	**WEGO-PGA Suture Specifications (USP)**	**Number of cases**
Cataract surgery	Extracapsular cataract extraction	corneoscleral limbus	10-0 9-0	14

	Phacoemulsification and intraocular lens implantation	corneoscleral limbus conjunctiva	10-0 9-0 8-0	67
Glaucoma surgery	Trabeculectomy	scleral flap conjunctiva superior rectus muscle traction	8-0 5-0	11
	Drain valve implantation	scleral flap conjunctiva	8-0	21
	Iridectomy	scleral flap	8-0	3
Strabismus surgery	Rectus muscle setback	extraocular muscles conjunctiva	5-0 6-0 8-0	6
	Rectus muscle suspension	extraocular muscles conjunctiva	5-0 6-0 8-0	2
	Rectus muscle shortening	extraocular muscles conjunctiva	5-0 6-0 8-0	2
	Inferior oblique retrograde	extraocular muscles conjunctiva	5-0 6-0 8-0	4
	Inferior oblique myotomy	extraocular muscles conjunctiva	5-0 6-0 8-0	2

	Rectus tendon junction	extraocular muscles conjunctiva	5-0 6-0 8-0	4
	Superior oblique plication	extraocular muscles conjunctiva	5-0 6-0 8-0	4
	Superior oblique tendon advancement	extraocular muscles conjunctiva	5-0 8-0	2
	Superior and inferior rectus transposition	extraocular muscles conjunctiva	5-0 8-0	1
Retinal/Vitreous surgery	Vitrectomy	sclera conjunctiva	5-0 6-0 7-0 8-0	14
	Scleral buckling	sclera conjunctiva	6-0 8-0	28
Lacrimal surgery	Dacryocystorhinostomy	lacrimal sac nasal mucosa	6-0	3
	Lacrimal canaliculus anastomosis	canaliculus skin subcutaneous tissue	5-0 8-0	5
	Pterygium excision	conjunctiva	8-0	17

Others			9-0 10-0	
	Orbicularis muscle shortening	extraocular muscles skin	6-0	5

In all cases, the WEGO-PGA sutures have been used for soft tissue approximation and/or ligation in ophthalmological surgical procedures as intended. There are no cases of off-label use or misuse of the device.

Regarding the handling of the suture (usability survey), the overall evaluation of the handling of the WEGO-PGA suture has been summarized below:

Overall evaluation of the handling of the WEGO-PGA suture	**Summary**
1. very good	87.50% (7/8)
2. good	12.50% (1/8)
3. moderate	0.00% (0/8)
4. not good	0.00% (0/8)
5. inadequate	0.00% (0/8)

As shown by the survey result, 100% of the users have rated the handling of the WEGO-PGA suture as good (2) and very good (1). There have been no cases at or below the average rating (3).

The handling/usability of the WEGO-PGA suture in ophthalmological surgical procedures is therefore considered as appropriate. No usability issues have been detected during this survey period.

Regarding the device problems encountered, there have been 1 case of

deformed needle reported out of the 215 cases. There has been no patient harm caused. The occurrence rate of “deformed needle” is calculated considering the total units of devices used in this survey as 0.06%.

The successfulness of wound closure (tissue approximation and/or ligation) has been asked in the PMCF survey. Out of the 215 cases, there are 214 cases of successful would closure using the WEGO-PGA sutures, which is a success rate of **99.5%**. There was one case of “wound leakage” reported which resulted in an occurrence rate of 0.5%.

The absorption of the WEGO-PGA sutures shall be completed between 60 or 90 days. All the 215 cases collected have reported complete absorption.

In addition, there were 2 cases of post-operative complications reported, both are “foreign body sensation”, that are related to the WEGO-PGA sutures (occurrence rate 0.9%).

Polyglycolic acid sutures have been marketed since the 1970s which use well-established technologies. The ophthalmic application of polyglycolic acid sutures for wound closure has been reported since the market approval of Dexon, for example, corneolimbal incision wound closure in cataract surgeries (Nielsen et al., 1980). However, there have been no high-quality clinical evidence such as systematic reviews or meta-analysis published in the recent years identified in the SOTA review focusing on the use of sutures and suture-specific safety and performance outcomes in ophthalmological surgical procedures, since sutures are considered as general surgical instruments as part of the general surgical supplies. Publications in ophthalmology generally focus on the ophthalmological specific surgical outcomes instead of suture outcomes. The currently identified publications are all relatively low-quality comparative studies with small sample sizes, where 0% of wound dehiscence/leakage or infection has been reported for the benchmark device Dexon and other sutures (medical alternatives).

In the current PMCF survey, 1 case of wound leakage has been reported, which resulted in an occurrence rate of 0.5% (i.e., success rate 99.5%.). This is based on the large number of 215 cases collected, which is much more than the sample sizes in the identified publications. The two cases of foreign body sensation are temporary effects with low severities of harm, and the occurrence rate is low (0.9%). Under these circumstances, the clinical performance and safety of the WEGO-PGA sutures are considered as acceptable for the ophthalmic use.

Regarding special populations, there are 10 diabetic patients and 1 lactating woman included in the survey. No failure of wound closure using the WEGO-PGA sutures have been reported. The clinical data pertaining to the special populations will be continuously collected during the PMS including PMCF activities to reach a more reliable sample size.

Regarding paediatric population, there have been altogether 44 cases collected during this PMCF survey period. 4 infants (1 month – 1 year), 20 children (1 year - 12 years) and 20 teenagers (12 years - 18 years) have been included in the survey. The surgery types in the collected cases include mainly vitrectomy and strabismus surgery. For paediatric population, no failure of wound closure using the WEGO-PGA sutures have been reported. No specific clinical risks regarding the paediatric population have been reported. The clinical data pertaining to the paediatric populations will be continuously collected during the PMS including PMCF activities to reach a more reliable sample size. Based on the current available dataset, the clinical performance and safety of the WEGO-PGA sutures are considered as acceptable for the ophthalmic use for the paediatric population.

- New or changed likelihood of an undesirable side-effect(s), or significant increase in the frequency or severity of incidents, or any identified trends, or any other main findings from the PMCF evaluation report or PSUR

N/A

- Analysis of clinical data from medical device registries.

  N/A

5.4 An overall summary of the clinical performance and safety

The clinical benefits of the WEGO-PGA sutures are enabling soft tissue approximation and/or ligation. Successful approximation or ligation of soft tissue is demonstrated by good wound healing which is expressed by the absence of dehiscence, leakage, infection or other complications after wound closure, as identified in the state-of-the-art literature review. Specific for absorbable sutures such as the WEGO-PGA sutures is that they are absorbed over time and there is no need for suture removal.

The relevant and specified clinical outcome parameters are as summarised in the table below.

<table>
<tr><th colspan="2">General soft tissue approximation and/or ligation (except for ophthalmic use)</th></tr>
<tr><td>Clinical Performance and Safety</td><td>Wound dehiscence: ≤ 3.8% [1) 2) 3) 4) 5)]
Anastomotic leak: ≤ 5.4% [2) 6)]
Surgical Site Infection: ≤ 8.7% [1) 2) 3) 7) 8) 9)]</td></tr>
<tr><td>Clinical Safety</td><td>Post-operative complication rates:
<table>
<tr><td>Sinus or fistula formation</td><td>≤ 1.7% [1)]</td></tr>
<tr><td>Incisional hernia</td><td>≤ 11.5% [1)]</td></tr>
<tr><td>Wound haematoma</td><td>≤ 0.3% [10)]</td></tr>
<tr><td>Wound seroma</td><td>≤ 1.4% [10)]</td></tr>
<tr><td>Wound exudation</td><td>≤ 4.0% [11)]</td></tr>
<tr><td>Abscess</td><td>≤ 2.2% [11) 12)]</td></tr>
<tr><td>Allergic reaction</td><td>≤ 3.9% [12)]</td></tr>
<tr><td>Inflammation</td><td>≤ 4.4% [12)]</td></tr>
</table></td></tr>
</table>

	Anastomotic bleeding	≤ 1.55% [6]
	Anastomotic stricture	≤ 0.15% [6]
	Needle stick injury	≤ 3.8% [11]
Ophthalmic use		
Clinical Performance and Safety	Wound dehiscence/leakage: 0% [13] [14] [15] [16] Wound infection: 0% [13] [14] [15] [16] Note: the above acceptance criteria are based on currently available low-quality evidence with small sample sizes. The number could change when new evidence emerges from the state of the art. 0% shall be interpreted as “as low as possible” to be realistic when the sample size is bigger.	
Absorption profile		
Complete Absorption	100% absorption is expected within 90 days	

The subject device, WEGO-PGA sutures, as conventional absorbable sutures, remains to be the state-of-the-art wound closure techniques. The clinical outcomes achievable with benchmark devices, similar devices and medical alternatives are used to establish the benchmarks for safety and performance for the WEGO-PGA sutures. The safety and performance outcome parameters identified in the state-of-the-art literature review, as in the table above, are used as the indicative list and specifications of parameters to determine the benefit-risk ratio for the indications and intended purpose of the devices under evaluation. The benefit-risk ratio will be considered as acceptable when the acceptance criteria of the identified safety and performance outcome parameters are proved to be fulfilled.

Based on sufficient clinical evidence presented in the Clinical Evaluation Report and also summarized in this chapter, including clinical data collected from the PMCF studies and the PMCF survey, the acceptance criteria of the identified safety and performance outcome parameters have been proved to be fulfilled, with the results summarized

below:

Summary of the benefit-risk ratio					
General soft tissue approximation and/or ligation (except for ophthalmic use)	**Clinical Performance and Safety**	**Benchmarks (Acceptance criteria)**	**Results from PMCF Study**	**Results from PMCF Survey**	**Conclusion (Pass/Acceptable/Fail)**
	Wound dehiscence	≤ 3.8%	0.73%	0.1%	Pass
	Anastomotic leak	≤ 5.4%	Both anastomotic leak and bleeding are grouped together to be 2.24%	0%	Pass
	Surgical Site Infection	≤ 8.7%	0.73%	0.2%	Pass
	Clinical Safety	**Benchmarks (Acceptance criteria)**	**Results from PMCF Study**	**Results from PMCF Survey**	**Conclusion (Pass/Acceptable/Fail)**
	Sinus or fistula formation	≤ 1.7%	0%	0%	Pass
	Incisional hernia	≤ 11.5%	0%	0%	Pass
	Wound haematoma	≤ 0.3%	0%	0%	Pass

	Wound seroma	≤ 1.4%	0%	0%	Pass
	Wound exudation	≤ 4.0%	0%	0.2%	Pass
	Abscess	≤ 2.2%	0%	0%	Pass
	Allergic reaction	≤ 3.9%	0%	0.1%	Pass
	Inflammation	≤ 4.4%	0%	0.4%	Pass
	Anastomotic bleeding	≤ 1.55%	NA (not separately listed)	0%	Pass
	Anastomotic stricture	≤ 0.15%	0%	0%	Pass
	Needle stick injury	≤ 3.8%	0%	0%	Pass
Ophthalmic use	**Clinical Performance and Safety**	**Benchmarks (Acceptance criteria)**	**Results from PMCF Study**	**Results from PMCF Survey**	**Conclusion (Pass/Acceptable/Fai)**
	Wound dehiscence/ leakage	0%	NA	0.5%	Acceptable
	Wound infection	0%	NA	0%	Acceptable
	Note: the above acceptance criteria are based on currently				

	available low-quality evidence with small sample sizes. The number could change when new evidence emerges from the state of the art. 0% shall be interpreted as “as low as possible” to be realistic when the sample size is bigger.				
Absorption profile	**Clinical Performance and Safety**	**Benchmarks (Acceptance criteria)**	**Results from Post-market Clinical Study**	**Results from PMCF Survey**	**Conclusion (Pass/Acceptable/Fail)**
	Complete Absorption	100% absorption is expected within 90 days	The absorption was evaluated at 90±10 days: 97.78%	100% for Ophthalmic use; 99.9% complete absorption within 90 days for general soft tissue approximation and/or ligation	Acceptable

In conclusion, after all the risk control measures have been implemented and verified, the overall residual risk has been evaluated, taking account of all the available data and literature review result for the WEGO-PGA sutures and similar devices on the market,

can be judged as acceptable, in relation to the clinical benefits of the intended use.

The parameters to be used to determine the acceptability of the benefit-risk ratio for the intended purpose are consistent with defined clinical safety and performance outcome parameters identified in line with the state of the art. The device under evaluation, WEGO-PGA sutures, has met the acceptance criteria of the clinical performance and safety outcome parameters. Therefore, the benefit-risk ratio for the WEGO-PGA sutures is considered acceptable.

5.5 Ongoing or planned post-market clinical follow-up

The manufacturer conducts Post-Market Clinical Follow-up as a continuous process that updates the clinical evaluation of the WEGO-PGA sutures. This Post-Market Clinical Follow-up (PMCF) plan is according to the requirements of the EU MDR 2017/745 Annex XIV Part B and follows the recommendations of MDCG 2020-7. The manufacturer will proactively collect and evaluate clinical data from the use of the WEGO-PGA sutures with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence. There is no unanswered questions relating to the use of the device. The WEGO-PGA suture is a legacy device which uses well-established technologies according to the MDR Article 61 6(b). The demonstration of conformity with the relevant GSPRs has been based on sufficient clinical data according to the MDR and MDCG 2020-6. Clinical studies are not deemed necessary in this case.

The PMCF plan includes the screening of scientific literatures as a general method and high-quality PMCF survey as a specific method.

Screening of scientific literatures related to WEGO-PGA sutures and similar devices is conducted using the Literature Search Protocol (Document number: WGFS-CEMDR/FHXG-06-03) every year. The result will be analysed and documented in the PMCF evaluation report, PSUR, and the Clinical evaluation report.

The PMCF survey will be conducted according to the PMCF survey protocol and attached

survey questionnaire (Document number: WGFS-FHX/SP-G-01). This survey is designed as a high-quality cross-sectional User Survey across hospitals and clinics that use the WEGO-PGA sutures as part of the surgeries.

Anonymous safety, performance and usability data related to the use of the WEGO-PGA sutures as part of hospital/clinic's standard of care will be collected to obtain clinically relevant information related to the WEGO-PGA' use in general soft tissue approximation and/or ligation. Ophthalmic use of the device will be separately collected.

All data related to the use of the WEGO-PGA sutures will be provided exclusively by surgeons using the subject devices, providing both qualitative, quantitative, and subjective information on the subject devices. Real-world performance, safety and usability data pertaining to the use of the subject devices will be proactively collected, which serves as PMCF clinical data to confirm the safety and performance of the WEGO-PGA sutures.

The PMCF survey questionnaire will be sent to the surgeons using the subject devices worldwide per email or mail or handed over during customer visits by representatives or distributors of Foosin Medical Supplies Inc. Ltd as applicable. The representatives of Foosin Medical Supplies Inc. Ltd will explain the background and content of the survey questionnaire to the survey participants and emphasize that all the data shall be filled in completely, clearly and correctly according to the patient's medical records (without patient information).

The data will be analysed by Foosin Medical Supplies Inc. Ltd. Descriptive statistics will be used in the data analysis to express quantitative variables including such as mean, standard deviation, median, minimum, maximum, ranges, etc. Statistics will be performed using Microsoft Office Excel. The results will be compared with the acceptance criteria and analysed in the PSUR.

There are no emerging risks/complications or unexpected device failures detected.

6.0 Possible diagnostic or therapeutic alternatives

As detailed in **Chapter 4 State of the art** of the Clinical Evaluation Report, the medical alternatives to the WEGO-PGA sutures include other sutures (non-absorbable sutures, other absorbable sutures, barbed suture, antibiotic-impregnated sutures), which are mostly discussed in **Section 4.1.2.1 Sutures**, and other wound closure techniques, including staples, tissue adhesives, suture tapes, zipper device, negative pressure wound therapy, cellular and tissue-based products / amnionic membranes, as discussed in **Section 4.1.2.1.6 Other wound closure techniques.**

Non-absorbable sutures

A great variety of non-absorbable sutures are available and are used for their superior handling characteristics (Byrne et al., 2019). Some of the most commonly used materials are briefly presented in the following:

Silk: Silk is a natural product that is renowned for its ease to handle and tie. It has the lowest tensile strength of any nonabsorbable suture. It is rarely used for suturing of minor wounds because stronger synthetic materials are now available. However, it is frequently employed to secure percutaneous central lines, chest tubes, and other similar cannulas.

Nylon: Nylon was the first synthetic suture introduced; it is popular due to its high tensile strength, excellent elastic properties, minimal tissue reactivity, and low cost. Its main disadvantage is prominent memory that requires an increased number of knot throws (three to four) to hold a suture in place.

Polypropylene: Polypropylene is a plastic, synthetic suture that has low tissue reactivity and high tensile strength similar to nylon. It is slippery and requires extra throws to secure the knot (four to five). Prolene (Ethicon) for example is especially noted for its plasticity, allowing the suture to stretch to accommodate wound swelling. When wound swelling recedes, the suture will remain loose.

Polyvinylidene fluoride: PVDF sutures have been developed in the 1990s. Good handling

characteristics and favourable long-term stability of PVDF sutures have been demonstrated in several non-clinical experiments.

Polytetrafluoroethylene: Polytetrafluoroethylene (PTFE) is a synthetic fluoropolymer of tetrafluoroethylene that has numerous applications. PTFE is one of the most biologically and chemically inert, biocompatible and autoclavable synthetic materials known. It is composed of solid nodules of PTFE interconnected by minute fibrils, resulting in a highly porous fibrous matrix that allows fibrovascular ingrowth, collagen penetration and its incorporation into host tissue. In addition, it shows resistance to infection, is not weakened by tissue enzymes and is easily sutured to the surrounding tissue. The well-established Gore suture (expanded PTFE, ePTFE) has been firstly cleared by the FDA in 1986 already.

Polyester: Polyethylene terephthalate (PET, Polyester) is produced by the polymerization of ethylene glycol and terephthalic acid. Braided polyester sutures are used as surgical sutures for decades. Numerous publications are available reporting on the clinical use of coated and braided polyester sutures. Favourable stability and local tolerance of polyester sutures in humans could be shown by Postlethwait already in the 1970s. The tissue reaction to this material is very similar to that seen to silk except overall the reaction is considerably less. The suture usually remains compact, the fibrous tissue capsule is lined by histiocytes, and giant cells may be present.

Polybutester: Polybutester suture is composed of a monofilament synthetic copolymer with tensile strength and healing properties similar to nylon and polypropylene. Polybutester also handles well but has greater elasticity than either nylon or polypropylene. Its use may be associated with decreased potential for suture marks because of its ability to expand if wound edema occurs.

Other absorbable sutures

Absorbable sutures are typically made from either mammalian collagen, which is ultimately digested by body enzymes, or synthetic polymers that undergo hydrolysis. Maintaining the balance between rapid absorption and the prolongation of tensile strength has been aided

by treatments and chemical structuring, which lengthen absorption time (Byrne et al., 2019). Following the successful development of the synthetic absorbable polymer PGA (Dexon), a series of polymers and copolymers based on a few cyclic lactones were synthesized, characterized, and produced commercially (Pillai et al., 2010). Some major types include:

Polyglactic acid: Polyglactic acid (polygycolide-L-lactide, PGLA)) is a copolymer of lactide and glycolide and is coated with a synthetic lubricant. It is also degraded through hydrolysis but is absorbed at a faster rate than PGA. Poly(L-Lactide-co-c-Caprolactone) (PGCL), the copoloymer of L-lactide with ε-caprolactone exhibited good strength and flexibility suitable for monofilament sutures. It also showed improved handling characteristics.

Multifilament braided Vicryl® sutures developed by Ethicon contain 90/10 molar ratio of GA to LA and they are coated with 2–10% of a 50:50 mixture of an amorphous polyglactin 370 (a 65/35 mole ratio of PLGA copolymer) and calcium stearate (Pillai et al., 2010).

Poly (ε-caprolactone):

The well-established and most commonly used PGCL copolymer for the manufacturing of sutures is poliglecaprone 25 (copolymer made from 75% glycolide and 25% -caprolactone; brand name e.g., Monocryl®). Poliglecaprone 25 is a monofilament suture that has superior pliability for easier handling and tying of knots. All of its tensile strength is lost by 21 days post-implantation (Pillai et al., 2010).

Polydioxanone: Polydioxanone (PDO) is a synthetic monofilamentous polymer. Polydioxanone sutures take 180 days to be absorbed, longer than both PGLA and PGA. Thus, this suture is a good choice for wounds that require prolonged tensile strength. Additionally, it has low tissue reactivity (Pillai et al., 2010).

Yag-Howard et al. (Yag-Howard, 2014) summarised the advantages and disadvantages of some commonly used suture materials (see following overview table):

Suture	Advantages	Disadvantages
Nylon	High tensile strength	Poor knot security
	Good elasticity	High memory
	inexpensive	Difficult to handle
Polypropylene	Very high tensile strength	Poor knot security

	Low tissue reactivity	Low elasticity
	High infection resistance	expensive
	Low coefficient of friction	
	High plasticity	
	Good for running subcuticular (but must be removed)	
Polybutester	High tensile strength	
	High elasticity	
	Low coefficient of friction	
	Easy to handle	
	High pliability	
	Good for running subcuticular (but must be removed)	
Polyester	High tensile strength	High coefficient of friction
	Low tissue reactivity	expensive
	Good knot security	
	Easy to handle	
Silk	Good knot security	Low tensile strength
	Easy to handle	High coefficient of friction
	High pliability	High tissue reactivity
	Good for mucosal surfaces	High capillarity
Poly(glycolide-L-lactide)	Easy to handle	High coefficient of friction
Polyglycolide	Good knot security	High knot extrusion
Polyglyconate	High tensile strength	
	Low tissue reactivity	
	High knot security	
	Easy to handle	
Polyglytone 6211	Rapid absorption	
	Low tissue reactivity	
	Good knot security	
	Easy to handle	
Polyglecaprone-25 (Poly(gycolide-co-caprolactone)	High tensile strength Low tissue reactivity Low coefficient of friction High elasticity Moderately easy to handle	Moderate knot security
Polydioxanone	High and prolonged tensile strength	Poor knot security
	Low tissue reactivity	Poor handling

According to NICE guideline NG125 (NICE, 2019), very low to moderate quality evidence from up to 5 RCTs, including 2,497 people, could not differentiate length of stay, the number of people who experience surgical site infections or wound dehiscence between the use of absorbable or non-absorbable sutures for wound closure. Very low to low quality evidence from up to 1 RCT, including 550 people, could not differentiate the number of people who experience surgical site infections or wound dehiscence following caesarean section between the use of fast-absorbable or slow-absorbable sutures for wound closure.

Barbed suture / Antibiotic-impregnated sutures

The barbed suture was invented in 1964 and was approved by the United States' Food and Drug Administration in 2004. Barbed sutures are monofilament sutures with barbs that allow them to self-anchor while maintaining tissue approximation without the need for surgical knots. The design of the suture also maintains constant tension on the suture line, which results in better control of bleeding from adjacent small blood vessels. Since its introduction, this material has been used in cosmetic, urological, general, orthopedic, and gynecological surgeries.

Triclosan (polychlorophenoxyphenol) has been used for its antiseptic properties for many years. Triclosan has been used to successfully coat the following sutures and gained US food and drug administration approval in 2002: braided polyglactan 910 (Vicryl Plus), poliglecaprone 25 (Monocryl Plus) and polydioxanone (PDS Plus).

There is currently no high-quality clinical evidence confirming any superiority of barbed sutures or antibiotic-impregnated sutures regarding the clinical performance and safety of wound closure (Chaouch et al., 2020, Velotti et al. 2022, Lin et al., 2019, Sun et al., 2020, Almed et al., 2019, Henriksen et al., 2017, Elsolh et al., 2017, Konstantelias et al., 2017).

Other wound closure techniques

Staples

Evidence from several thousand observations in the identified panoramic meta-analysis

(Hemming *et al.*, 2013), systematic reviews and meta-analysis (Cochetti *et al.*, 2020, Elbardesy *et al.*, 2021, Krishnan *et al.*, 2019, Liu *et al.*, 2021) have demonstrated that clinical performance and safety of both staples and sutures as wound closure methods are acceptable and considered to be similar. According to NICE guideline NG125, the high-quality evidence from up to 3 RCTs (1,908 patients) showed that the use of staples for wound closure increases the number of people who experience wound dehiscence in comparison to the use of sutures. Very low to moderate quality evidence from up to 6 RCTs (3,792 people) could not differentiate length of stay, the number of people who experience surgical site infections or the number of people readmitted to hospital or who require antimicrobial treatment between the use of staples or sutures for wound closure (NICE, 2019). At the time of 30 days after surgery, the use of staples for wound closure in caesarian section increases the number of women experience wound dehiscence in comparison to the use of sutures (2 RCTs, 828 patients) (NICE, 2019). The same outcomes could be seen 1 year after surgery. High quality evidence from up to 2 RCTs, (1,144 people) showed that the use of staples for wound closure in caesarean section increases the number of women who experience wound dehiscence in comparison to the use of sutures (NICE, 2019). In a recent network meta-analysis conducted by Huang *et al.*, evidence from 26 RCTs showed that the risk of skin separation with absorbable suture after cesarean delivery was reduced compared with staple, and does not increase the risk of wound complications, but the wound closure time would slightly prolonged (Huang *et al.*, 2022).

Tissue adhesives

Skin adhesives are popular for closure of low-tension wounds and pediatric traumatic lacerations and serve as a suitable wound dressing in many elective breast and abdominal wall procedures (Byrne et al., 2019). Tissue adhesives offer the advantages of an absence of risk of needlestick injury and no requirement to remove sutures later. Dumville et al. looked in their review (33 studies) at the use of tissue adhesives in the operating room/theatre where surgeons are using them increasingly for the closure of surgical skin

and found that there was low quality evidence that sutures were significantly better than tissue adhesives for reducing the risk of wound breakdown (dehiscence; RR 3.35; 95% CI 1.53 to 7.33; 10 trials, 736 participants that contributed data to the meta-analysis). One trial compared tissue adhesives with a variety of methods of wound closure and found both patients and clinicians were significantly more satisfied with the alternative closure methods than the adhesives. There appeared to be little difference in outcome for different types of tissue adhesives. Eventually, the authors concluded that Sutures are significantly better than tissue adhesives for minimizing dehiscence (Dumville et al., 2014).

Pterygium is a fibrovascular wing-shaped mass of bulbar conjunctiva extending onto the corneal surface. Surgical removal of pterygium with conjunctival autografting has been considered the best and standard treatment. In an autologous limbal conjunctival autograft technique, the bulbar conjunctiva, including limbal tissue, is attached to the exposed scleral bed either by sutures or fibrin glue after the pterygium is excised (Zloto *et al.*, 2016). The study conducted by Alamdari *et al* demonstrated the superiority of fibrin glue to nylon suture in saving operating time and elimination of recurrence without any complications in pterygium surgery. Additional studies are necessary to determine the long-term effects (Alamdari et al., 2018).

Suture tapes

Suture tapes have become popular as they are perceived to be easier to use with less soft tissue irritation. Boksh *et al.* performed a systematic review and meta-analysis on the biomechanical properties, incidence of retears, and reported outcomes between suture tapes and conventional sutures (Boksh *et al.*, 2021). The analysis suggested that suture tapes distribute force better across degenerated tissue (higher contact pressure), increase the construct strength (higher load to failure and stiffness), and reduce pullout (lessen gap formation). However, this did not translate to a lower incidence of retears or significantly improve clinical outcomes.

Zipper device

Recently, a novel atraumatic, non-invasive zipper surgical wound closure device has become popular in orthopaedic and cardiothoracic surgical procedures. It is sterile, adjustable, hydrocolloid adhesive-based, and designed to replace staples and sutures for closure of the superficial skin layer, which can be applied directly to intact skin on either side of the incision and provides uniform force along the wound edge. Xie *et al.* conducted a systematic review and meta-analysis to compare the efficacy of the zipper device and sutures for wound closure after surgery (Xie *et al.,* 2020). The zipper device achieved a lower SSI rate, a shorter wound closure time and a better scar score than sutures. No significant difference was shown in the incidence of wound dehiscence and total wound complications. However, the results of this meta-analysis should be interpreted in light of its limitations, and more well-designed studies are needed.

Negative pressure wound therapy

In the early 1990s Argenta and Morykwas developed a system that uses suction to help draw wound edges together; it was commercialized in 1995 and is called negative pressure wound therapy (NPWT) (Orgill et al., 2013). Negative pressure wound therapy (NPWT) may assist wound healing by increasing local blood flow and the production of granulation tissue and may encourage other changes to the microenvironment of the wound by reducing bacterial contamination, oedema, and exudate. A Cochrane review performed by Webster et al. assess the effects of negative pressure wound therapy for preventing surgical site infection in wounds healing through primary closure. Despite the addition of 25 trials (2957 participants), it is not clear whether NPWT compared with a standard dressing reduces or increases the incidence of important outcomes such as mortality, dehiscence, seroma, or if it increases costs (Webster *et al.*, 2019).

Cellular and tissue-based products (CTPs) / Amnionic membranes

As for cellular and tissue-based products such as amniotic membranes, ideally designed to be used as either definitive wound coverage or as part of a staged wound closure process. The amniotic membranes are avascular structures that contain growth factors. They may

increase the healing of the wounds, because of growth factors contained in the products. However, these products can be costly, and thus, they must only be applied in the appropriate setting. Most of the products that are available go through a preservation or cryopreservation process to preserve the components of the placental membrane. They are typically applied weekly in the clinic setting (Garwood et al., 2016).

In conclusion, based on the systematic literature analysis which has been detailed in the Clinical Evaluation Report, the device under evaluation, WEGO-PGA sutures, as conventional absorbable sutures, remains to be the state-of-the-art wound closure techniques.

7.0 Suggested profile and training for users

User should be professional medical staff that familiar with surgical procedures and techniques and trained in professional surgical suture techniques involving absorbable suture before employing.

8.0 Reference to any harmonised standards and CS applied

Regulation (EU) 2017/745, EN ISO 11135:2014, EN ISO 15223-1:2021, EN ISO 13485:2016, EN ISO 11737-3:2020, EN ISO 14971:2019, European Pharmacopoeia (Ph. Eur.) 10th Edition 0667 Sterile, absorbable, synthetically, braided suture, MEDDEV 2.7.1 rev4, MEDDEV 2.12/2 rev2, MDCG 2020-5, MDCG 2020-6, MDCG 2019-9.

9.0 Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
A/0	2022.08.27	Initial Release	☐ Yes Validation Language:

			☒ No (only applicable for class IIa or some class IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
A/1	2023.03.09	Update according to NB deficiency report.	☐ Yes Validation language: ☐ No

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