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CE Technical Documentation

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

Summary of Safety and Clinical Performance (SSCP)

Non-Absorbable Surgical Suture With or Without Needle（WEGO-SILK）

Revision No. B/0

Audited By/Date	Zhou Caijie /2025.02.26	Approved By/Date	Xue Ruipeng /2025.02.26
Issuing Department	Technical Department	Drafted By/Date	Liu Tao /2025.02.26
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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. Device identification and general information

1.1 Device name and trade name

Device Name: Non-Absorbable Surgical Suture With or Without Needle

Trade name: WEGO-SILK

1.2 Manufacturer name and address

Manufacturer Name: Foosin Medical Supplies Inc., Ltd.

Address: No.8-1, Weigao West Road, Chucun Town, Torch Hi-Tech Science Park,264200 Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

1.3 Manufacturer single registration number (SRN)

SRN: CN-MF-000006957

1.4 Basic UDI-DI

69418136NA-suturesIIbS83

1.5 Medical device nomenclature description / text

WEGO-SILK suture is a non-absorbable sterile surgical suture composed of an organic protein called fibroin. Silk for braided material is processed to remove the natural waxes and gums.

EMDN Code	EMDN Name
H0102020203	SUTURE,NON-ABSORBABLE NON-SYNTHETIC MULTIFILAMENT SUTURES,SILK

1.6 Class of device

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

“All implantable devices and long-term surgically invasive devices are classified as class Ⅱb”

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

WEGO-SILK: 2015

1.8 Authorised representative’s name and the SRN

Name: MedNet EC-REP C III GmbH

SRN: DE-AR-000011196

1.9 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. Intended use of the device

2.1 Intended purpose

WEGO-SILK suture is indicated for use in general soft tissue approximation and/or ligation.

2.2 Indications

WEGO-SILK suture is indicated for general soft tissue approximation and/or ligation, mainly in hepatobiliary surgery, urinary surgery, orthopedics surgery, general surgery, anorectal surgery, gynecology and obstetrics surgery, oral surgery and ophthalmologic surgeries.

2.3 Intended patient groups

WEGO-SILK suture applies to all patients meeting the intended use purpose, including pregnancy and infant. Sutures have no restriction regarding the patient age.

2.4 Intended user groups

Users should be professional medical staff that familiar with surgical procedures and techniques and trained in professional surgical suture techniques involving non-absorbable sutures .

2.5 Contraindications and/or limitations

The use of this suture is contraindicated in patients with known sensitivities or allergies to Silk. Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, Silk suture should not be used where permanent retention of tensile strength is required. It’s not indicated for the central circulatory system and central nervous system.

3. Device description

3.1 Description of the device

WEGO-SILK suture is a non-absorbable sterile surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori(B.mori) of the family Bombycidae. Silk for braided material is processed to remove the natural waxes and gums. Braided silk is coated with silicone and is available undyed(Natural Ivory) and dyed in black with Sulphol Black or Logwood Black. Black CI 53185 Sulphol Black 1 (EP Vol III), Logwood Black CI 75290. Natural Tinctorial Wood Extract obtained from Haematoxylon Campechianum. Conforms to US Code of Federal Regulations 21 CFR 73.1410.For virgin silk the sericin gum is not removed and holds the twisted filaments together.

WEGO-SILK suture is available in EP sizes 0.2-7 (USP sizes 10-0 through 5) and a variety of lengths, with and without stainless steel needles of varying types and sizes.Full details are contained in the catalogue.

WEGO-SILK suture complies with the requirements of the European Pharmacopoeia for Sterile Non-absorbable Silk Suture and the United States Pharmacopoeia monograph for Non-absorbable Sutures.

Mode of Action

WEGO-SILK suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures.

Principles of Operation

There is no uniform specification of suture operation technique, and surgeons have many options. Differences in suture operation technique reflect differences in training, experience, and interest of the surgeon, as well as differences among patients, such as the patient's age, weight, physical condition, suture site, and other factors affecting prognosis, such as infection, management of emergencies, and advances in new surgical device or methods.

The common suture operation methods include continuous suture, interrupted suture, mattress suture, purse-string suture, relaxation suture, figure-of-eight suture, and intradermal suture. The target users of sutures are professional medical staff that familiar with surgical procedures and techniques and trained in professional surgical suture techniques. They have professional knowledge and experience in surgical suture operation, so the above suture operation methods will not be specially introduced in this chapter. But the following points mentioned should be especially concerned.

- The suture is sterilized by ethylene oxide gas or radiation and can be used after opening the outer package. Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.
- When handling this or any other suture, care should be taken to avoid damage. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

- Users should exercise caution when handing surgical needles to avoid inadvertent needle stick injury.
- Discard used needles in “Sharps” container.

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.

Needle holder is mainly made of stainless steel, used for gripping needle to suture various tissues. It is also sometimes used for suture knotting.

4. Risks and warnings

4.1 Residual risks and undesirable effects

In order to evaluate qualitative and quantitative aspects of clinical safety of the subject device, the following inputs will be used:

- Usability-related safety issues observed in usability studies conducted by Foosin Medical Supplies Inc.Ltd.
- Safety issues reported in scientific literature pertaining to the device(s) under evaluation or to similar devices.
- 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.

The occurrence probability are shown in following table：

Residual risk / undesirable side effect	Risk Quantification per Source of Data		Final Risk Quantification	Source of Data	Relation to time
	Systematic review of the scientific literature	Proactively obtained clinical data – Clinical Study			
Surgical sit e infection	7.9%	0%（0/30）	7.9%	Systematic review of the scientific literature	Perioperative period, mostly within 30 days of surgery
Wound dehiscence	2%	0%（0/30）	2%	Systematic review of the scientific literature	Perioperative period, mostly within 30 days of surgery
Suture sinus	2.3%	0%（0/30）	2.3%	Systematic review of the scientific literature	Relatively long-term complications, no time point specified

Perioperative complications (include pain, wound errhysis and allergic reaction)	11.9%	0%（0/30）	11.9%	Systematic review of the scientific literature	Perioperative period, mostly within 30 days of surgery
Incisional hernia	11%	$\leq 10^{-6}$ (clinical data come from PMS Report)	11%	Systematic review of the scientific literature	At one year or more of follow-up

Note:Because the quantification data for incisional hernia come from spontaneously reported incidents,the statistical data was much lower than the literature review results due to the possibility of under-reporting.In addition,incisional hernia usually occurs more than one year after surgery,and the follow-up period is too long. Therefore,we will continue to implement PMCF survey to monitor the above residual risks,especially collect and analyse clinical data of incisional hernia.After obtaining new clinical data,we will timely update the information in this table.

4.2 Warnings and precautions

- Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing silksuture for wound closure, as risk of wound dehiscence, may vary with the site of application and the suture material used.

- Larger size of silk suture should be considered to use when silk sutue is broken because the tensile strength is not high enough Silk suture should be used dry,silk suture can be dipped momentarily if want to use wet strands, but do not soak silk suture.

- As with any foreign body, prolonged contact of any suture with sal solutions, such as those fond in the urinary or biliary tracts,may result in calculus formation.

- Adequate knot securty requires the accepted surgical echnique of flat and square ties,with additional throws as indicated by surgical circumstances and he experience of the surgeon.

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

- Care should be taken to avoid damage when handling surgical needles.Avoid crushing or crimping damage due to the application of surgical instruments such as forceps or needle holders.

- 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 but or attachment end could cause bending or breakage.Reshaping needles may cause tem to loose strength and be less resistant to bending and breaking.

- Users should exercise cauton when handling surgical needles to avoid inadvertent needles stick injury.

- 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-sterilise: Infection hazard for patients and/or users and impairment of products functionality due to use of re-sterilised suture. Risk of injury, illness, or death due to contamination and/or impaired functionality of the product.

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 CE-marking

N/A

5.3 Summary of clinical data from other sources, if applicable

5.3.1 Post-Marketing Surveillance

WEGO-SILK suture was marketed in 2008, no severe adverse events have been reported. Complaint data from 2019 to 2023 provided by the manufacturer show that the complaint rate is very low (< 0.001 %). Most complaints address technical issues.The feedback of the past 5 years has been collected and the cause analysis and classification statistics have been carried out.

Market feedback classification statistics for 5years

Time（y）	Product	Problem 1	Problem 2	Problem 3	Problem 4	Problem 5	Problem 6	Else	Total
2019	WEGO-SILK	/	3	/	/	/	1	/	4
2020	WEGO-SILK	/	/	/	1	1	/	/	2
2021	WEGO-SILK	1	1	/	/	/	/	/	2
2022	WEGO-SILK	1	/	/	/	/	2	/	3
2023	WEGO-SILK	/	5	/	/	/	/	/	5

Note：

Problem 1 :Detachment-Needle and wire separation at the joint

Problem 2: Function invalidation-suture-Suture break, etc.

Problem 3: Function invalidation-needle-Needle break, needle blunt, etc.

Problem 4: Suggestions for improvement-Customer's comments or suggestions

Problem 5: Problems of Package-Product packaging problem, such as the appearance of the box, printing information, etc.

Problem 6: Problems of materials-Raw material problem

Else: Other issues besides the above questions: side effects including wound dehiscence and infection; minimal acute inflammatory tissue reaction; localized irritation; bleeding; sinus and so on.

The largest proportion of complaint investigation is “Function invalidation-needle-Needle break, needle blunt, etc”, while the proportion of “Problems of materials-Raw material problem” is second.

The manufacturer analyzed the samples sent back by the customer believed that the bad product is the result of improper operation by the customer or injury of the instrument. Problems with raw materials considered as patient allergy to silk proteins.

In addition, the manufacturer also investigated complaints about several products which are similar to the non-absorbable and absorbable sutures manufactured by Foosin (mainly on the FDA website). According to statistics, there were about 7,000 complaints about sutures on the FDA website in 2018, about 9,000 cases in 2019, more than 8,000 cases in 2020 and more than 10,000 cases in 2021. The total proportion of broken wires, separation and broken needles reached 75%-85%.

Therefore, problems such as broken wires, separations and broken needles are problems that are likely to occur in suture products.

All feedbacks have been investigated, and corresponding control measures have been taken based on the cause analysis. After the survey results are returned to the client/hospital, there is no new feedback.

5.3.2 PMCF investigation

This survey is designed as a high-quality cross-sectional User Survey across hospitals and clinics that use the WEGO-SILK sutures as part of the surgeries. Real-world performance and safety data of the WEGO-SILK suture have be proactively collected.

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

All data related to the use of the WEGO-SILK sutures have 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 have be proactively collected, which serves as PMCF clinical data to confirm the safety and performance of the subject devices.

There have been 8 surveys collected participated in the survey so far. Altogether there are 863 cases regarding the use of the WEGO-SILK sutures for general soft tissue approximation and/or ligation collected (ophthalmic use not included and collected separately) covering the time period 01/01/2023 – 31/12/2023.

The patient characteristics are summarized below:

Gender	Female 395 cases, Male 468 cases
Age Categories	
Less than 1 month	0
1 month - 1 year	4
1 year - 12 years	56
12 years - 18 years	95
18 years - 60 years	528
More than 60 years	180
Special populations	
Diabetic patients	22
Pregnant women	1
Lactating women	4

The surgery types covered are:

Surgery types	**Number of cases**
General surgery	83
Ophthalmic surgery	18
Oral surgery	47
Hepatobiliary surgery	96
Urinary surgery	104
Orthopedic surgery	283
Gynecology and obstetrics surgery	72
Anorectal surgery	160

The tissue types covered are: Skin, mucosa, peritoneum, Sclera and conjunctiva, muscle/tendon, subcutaneous tissue, fascia, joint capsule.

In all cases, the WEGO-SILK 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.

WEGO-SILK sutures used for:	**Number of cases**
Soft tissue approximation and/or ligation	863 (100%)
Others	0 (0%)

The overall evaluation of the handling of the WEGO-SILK suture has been summarized below:

Overall evaluation of the handling of the WEGO-SILK suture	**Summary**
1. very good	100% (8/8)
2. good	0.00% (0/8)
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-SILK 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-SILK suture is therefore considered as appropriate. No usability issues have been detected during this survey period.

Regarding the device problems encountered, there have been 1 cases reported out of the 863 cases. The overall device problem rate is 0.12%. The detailed event description for each device problem encountered is as following:

#	**Device problem**	**Event description**	**Device problem occurrence rate**	**Patient harm**

1	sutures are broken (1 case)	Place: Rongcheng Second People's Hospital Date: 15/07/2023 Device: WEGO-SILK EP 2 Event description: Patient underwent external and internal ligation of mixed haemorrhoids for mixed haemorrhoids. The SILK1 suture was used for suturing. During the operation, the suture was broken, and the suture was replaced immediately. The surgery time was slightly prolonged without real patient harm.	0.12%	No patient harm.

The success of wound closure (tissue approximation and/or ligation) has been asked in the PMCF survey. Out of the 863 cases, there are 861 cases of successful would closure using the WEGO-SILK sutures, which is a successful rate of 99.77%. There were 2 cases about wound infection as follows:

#	**Device clinical performance and safety**	**Event description**
1	Wound infection	Place: Jiangyin People's Hospital Date: 24/02/2023 Device: WEGO-SILK Event description: The patient was sutured after surgery. In the afternoon of next day, the patient complained of erythema at the suture site and subcutaneous suppuration on the second day after surgery.
2	Wound infection	Place: Jiangyin People's Hospital Date: 26/05/2023 Device: WEGO-SILK Event description: SILK suture was used to close the wound in skin, and the patient was asked to change dressing once every three days. Today, the patient changed dressing for the third time, but the wound was still red, swollen, tender, non-healing,

		and purulent secretion exudation. The suture was removed, the patient was asked to change dressing every other day, and the patient was observed continuously.

This resulted in the following occurrence rate for the device performance and safety endpoints. The acceptance criteria identified from the state of the art have all been met. The clinical performance and safety endpoints for the WEGO-SILK sutures have been successfully reached.

Device performance and safety endpoints	**PMCF survey result**	**Acceptance criteria (SOTA)**	**Result**
Wound dehiscence	0.00% (0/863)	≤ 2%	Within the acceptance criteria
Wound infection	0.23% (2/863)	≤ 7.9%	Within the acceptance criteria

There have been 8 surveys collected in the PMCF survey so far. Altogether there are 863 cases regarding the use of the WEGO-SILK sutures for general soft tissue approximation and/or ligation collected covering the time period 01/01/2023 – 31/12/2023. All patient population has been covered. There have been 2 cases of wound infection (0.23%) reported regarding the device performance. This is within the acceptance criteria of the benchmarks identified from the state of the art.

Braided SILK sutures have been marketed since the 1960s which use well-established technologies. Its safety has been fully affirmed in clinical practice. In conclusion, it can be stated that the clinical data demonstrated the performance of WEGO-SILK suture to be acceptable. There is no need for preventive and/or corrective measures.

In conclusion, current PMCF data can effectively demonstrate the side-effects of device under evaluation were acceptable. We will continue conducting PMCF activities according to PMCF plan after device under evaluation CE MDR certified.

5.4 An overall summary of the clinical performance and safety

The clinical benefits of the WEGO-SILK 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.

WEGO-SILK sutures as conventional absorbable sutures, remains to be the state-of-the-art wound closure techniques. The clinical outcomes achievable with benchmark devices and similar devices are used to establish the benchmarks for safety and performance for the WEGO-SILK sutures. The safety and performance outcome parameters identified in the state-of-the-art literature review, as in the table below, are used as the indicative list and specifications of parameters to determine the benefit-risk ratio for the indications and intended purpose of the subject device. 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.

Device performance and safety endpoints	PMCF survey result	PMS data	Acceptance criteria (SOTA)	Result
Wound dehiscence	0.00% (0/863)	< 0.001 %	≤ 2%	Within the acceptance criteria
Wound infection	0.23% (2/863)	< 0.001 %	≤ 7.9%	Within the acceptance criteria

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

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-SILK 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 subject device, WEGO-SILK sutures, has met the acceptance criteria of the clinical performance and safety outcome parameters. Therefore, the benefit-risk ratio for the WEGO-SILK sutures is considered acceptable.

5.5 On-going 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-SILK 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-SILK 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-SILK 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-SILK sutures and similar devices is conducted using the Literature Search Protocol 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 survey questionnaire (Cases Retrospective Survey Form). This survey is designed as a high-quality cross-sectional User Survey across hospitals and clinics that use the WEGO-SILK sutures as part of the surgeries.

Anonymous safety, performance and usability data related to the use of the WEGO-SILK sutures as part of hospital/clinic’s standard of care will be collected to obtain clinically relevant information related to the WEGO-SILK suture’ use in general soft tissue approximation.

All data related to the use of the WEGO-SILK 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-SILK 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. Possible diagnostic or therapeutic alternatives

Depending on clinical indication, knowledge or preference of the surgeon, other technical means like sutures of other materials, staplers, tissue adhesives, negative pressure wound therapy or cellular and tissue based products can also be applied as therapeutic alternatives.

When deciding which suture to use, it is important to consider wound site, wound cleanliness, tension present across the wound edges and the duration needed for the suture to hold the wound edge. The time of maintenance of tensile strength, or to absorption of absorbable sutures, must be greater than the healing time. Furthermore, the possible suture removal and issues of practicality must be addressed. Absorbable sutures may be preferable in extremes of age (e.g. for young children unlikely to tolerate a second procedure to remove sutures, or poorly mobile or cognitively impaired elderly patients in whom scarring is often less of a concern and who would find attendance for wound management more difficult). In general, absorbable sutures cause greater local reactions in healing tissue than nonabsorbable sutures (removed 1-2 weeks postoperatively), and consequently result in increased scarring. In contrast, absorbable sutures may be appropriately used to achieve tissue apposition of the dermis before skin closure, to reduce tension across the wound edge.Contaminated wounds, or those at high risk of developing infection, should be closed with monofilament nonabsorbable sutures. Braided sutures may allow bacteria to seep through, and buried absorbable sutures can become foci of infections.

When a wound reaches maximal strength, sutures are no longer needed. Therefore, it would be better to close slow-healing tissues such as skin, fascia, or tendons with nonabsorbable sutures or long-lasting absorbable sutures and close fast-healing tissues (e.g. stomach, colon, bladder) with absorbable sutures. Where cosmetic results are important, close and prolonged apposition of tissues and avoidance of irritants will produce the best results. In such situations, the smallest inert monofilament suture materials, e.g. nylon or polypropylene, should be used, and subcuticular closure should be preferred. For selecting suture size, use the finest suture commensurate with the natural strength of the tissue to be sutured and use retention sutures to reinforce appropriately sized primary sutures if the patient is at risk of producing sudden strains on the suture line post-operatively.

In short, sutures should provide the most secure wound approximation for an adequate time with minimal adverse effects on the normal wound healing process. When used as ligature, sutures should provide reliable lumen occlusion with a minimal risk for leakage or slip off. Obviously, there is no single suture material which can fulfil all these criteria. The surgeon should choose the right suture for the type of surgery that is performed based on the differing tissue requirements on suture support.

Foreign bodies in the presence of fluids containing high concentrations of crystalloids may act as nidus for precipitation and stone formation. Therefore, in the urinary and biliary tract, rapidly absorbed sutures should be used. For ligatures of subcutaneous blood vessels, absorbable sutures are recommended. In contrast to other parts of the gastrointestinal system, the rectum heals very slowly which has to be taken into consideration when a suture material is chosen. Furthermore, monofilament sutures should be used, since they reduce the risk of bacterial proliferation in the rectum.

Monofilament sutures are smooth and slide well in the tissues but require careful knotting. Moreover, the injudicious use of forceps or needle holders can result in the formation of microfractures within the monofilament predisposing to early fracture of the suture. Multifilament sutures have a much greater surface area than monofilament sutures, hence they are easier to handle and have good knotting qualities. However, they tend to drag as they are drawn through the tissues. Therefore, some sutures are coated with lubricants such as beeswax, silicone, or others. Multifilament sutures have a higher potential to exert capillary action than monofilaments leading to a greater potential for the interstices of the suture to become colonised by bacteria.

Skin staples are useful as a time-saving device for long incisions or to position a skin closure or flap temporarily before suturing.staples have a low tissue reactivity.Staples are ideal for hair-bearing scalp,especially for scalp wounds under significant tension.Staples are particularly useful in the trauma setting when caring for patients with unknown medical histories because risk of needle stick injury is minimized.It is important that staples be removed promptly to prevent skin marks. Disadvantages of percutaneous staples include the potential for staple track formation, bacterial migration into the wound bed and discomfort during staple removal.In GI surgery,staples cause less complications.Nonetheless,it may lead to higher rate of anastomotic bleeding which mandates careful and precise hemostasis of the stapled line.And the use of staples in caesarean section increases the number of women who experience wound dehiscence in comparison to the use of sutures.

Tissue adhesives have been used in variety of different specialties to close skin wounds.The tissue adhesive sets quickly,often in less than 1 min.Furthermore,tissue adhesives offer the advantages of an absence of risk of needlestick injury and no requirement to remove sutures later.And it may reduce postoperative chronic pain and not simultaneously increase the recurrence rate,compared with sutures.However,sutures may minimize dehiscence when compared to tissue adhesives.

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.NPWT after groin incisions for arterial surgery can reduce the incidence of SSI compared with standard wound dressings. Complications are infrequent but can be life-threatening.These include bleeding, infection, pain, rupture of heart, death, life quality, anxiety, and malnutrition.

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.They may increase the healing of the wounds,because of growth factors contained in the products.But,these products can be costly,and thus,they must only be applied in the appropriate setting.

Generally,the selection of SILK suture or other therapeutic alternatives depend on the specific characteristics of the treated wound and the individual need of the patient.before the responsible

physician makes the decision to use non-absorbable sutures,he/she should thoroughly outweigh the expected benefits against the known potential complications.Risks associated with the usage of non-absorbable sutures in general do also apply for the WEGO-SILK suture.

7. Suggested profile and training for users

Users should be professional medical staff that are familiar with surgical procedures and techniques and trained in professional surgical suture techniques involving absorbable sutures.

8. Reference to any harmonised standards and CS applied

No.	Standard No.	No.	Standard No.	No.	Standard No.
1	ISO 20417:2021	19	ISO 11607-1:2019	37	USP<Nonabsorbable Surgical Suture>
2	EN 62366-1:2015	20	ISO 11607-2:2019	38	USP<861>SUTURES—DIAMETER
3	EN ISO 11135:2014	21	ISO 11737-1:2018	39	USP<871>SUTURES—NEEDLE ATTACHMENT
4	EN ISO 13485:2016	22	ISO 11737-2:2019	40	USP<881>TENSILE STRENGTH
5	EN ISO 14155:2020	23	ISO 14644-1:2015	41	YY 0167:2020
6	EN ISO 14630: 2012	24	ISO 14644-2:2015	42	YY 0043:2016
7	ISO 15223-1:2021	25	ISO 14644-3:2019	43	MDCG 2019-9
8	EN ISO 10993-1:2020	26	ISO 14644-4:2022	44	MDCG 2020-5
9	ISO 10993-10:2021	27	ISO 14644-5:2004	45	MDCG 2020-6
10	ISO 10993-11:2017	28	ISO 14698-1:2003	46	MDCG 2020-7
11	ISO 10993-3:2014	29	ISO 14698-2:2003	47	MDCG 2020-8
12	ISO 10993-4:2017	30	EN ISO 14971:2019	48	MDCG 2020-13
13	ISO 10993-5:2009	31	ISO/IEC 15418:2016	49	MDCG 2021-12
14	ISO 10993-6:2016	32	ASTM D4169-22	50	MDCG 2022-21
15	ISO 10993-7:2008	33	ASTM F1980-21		
16	ISO 10993-13:2010	34	MEDDEV 2.12-2 rev 2		
17	ISO 10993-17:2023	35	MEDDEV 2.7-1 rev.4		
18	ISO 10993-18:2020	36	EP 11- 0324		

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
A/0	2021.01.27	Initial release	☐ Yes Validation language:English ☒ 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/2	2023.03.10	Update according to Clinical Evaluation Report	☐ Yes Validation language:English ☒ No
B/0	2025.02.26	Update according to Clinical Evaluation Report, modification of equivalent device description to add PMCF report	☐ Yes Validation language:English ☐ No