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-STAINLESS STEEL）

Revision No. A/3

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Issuing Department	Technical Department	Drafted By/Date	王磊 Wang Lei/2023.10.25
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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. SSCP information is obtained from IFU, labelling and CER and aligned with the information in these documents.

The following information is intended for users/healthcare professionals. There is no SSCP information intended for patients according to relevant requirements of MDCG 2019-9.

1.0 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-STAINLESS STEEL

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

WEGO-STAINLESS STEEL: 69418136NA-suturesIIbGSDZ

1.5. Class of device

Class Ⅱ**b** 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

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

WEGO-STAINLESS STEEL: 2019

1.7. Authorised representative's name and the SRN

Name: MedNet EC-REP C III GmbH

SRN: DE-AR-000011196

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

Name: TÜV SÜD Product Service GmbH.

NB's identification number: 0123

2.0 Intended use of the device

2.1. Intended purpose

WEGO-STAINLESS STEEL suture is used for general soft tissue approximation, bone tissue approximation and/or fixation.

2.2. Indication

WEGO-STAINLESS STEEL suture is indicated for soft tissue approximation, bone tissue approximation and/or fixation in abdominal wound closure, orthopaedic surgery (cerclage and tendon repair), hernia repair and sternal closure. It is designed to remain in the patient.

2.3. Intended patient groups

WEGO-STAINLESS STEEL suture apply to all patients meeting the in-tended use purpose, including pregnancy and infant. Sutures have no restriction regarding the patient age.

2.4. Target user group

Professional medical staff that familiar with surgical procedures and techniques and trained in professional surgical suture techniques

2.5 Contraindications and/or limitations

The use of this suture is contraindicated in patients with known sensitivities or allergies to 316L stainless steel, or constituent metals such as manganese, nickel, chromium or molybdenum.

2.6. Adverse reactions

Adverse effects associated with the use of this device include wound dehiscence, bleeding, allergic response in patients with known sensitivities to 316L stainless steel, or constituent metals such as chromium and nickel, infection, minimal acute inflammatory tissue reaction, pain, edema and local irritation at the wound site. In rare cases, complications may occur, such as mediastinitis, osteomyelitis, bone fracture and nonunion. Broken needles may result in extended or additional surgeries or residual foreign bodies, inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

3. Device description

3.1. Description of the device

WEGO-STAINLESS STEEL suture is a nonabsorbable, sterile surgical suture composed of 316L stainless steel. WEGO-STAINLESS STEEL suture is available as a monofilament suture.

WEGO-STAINLESS STEEL sutures are available in EP sizes 9 through 0.5 (USP sizes 7 through 7-0) in a variety of lengths with or without stainless steel needles of varying types and sizes.

WEGO-STAINLESS STEEL suture complies with the requirements of the European Pharmacopoeia for ’Sutures, sterile non-absorbable’ and the requirements of the United States Pharmacopoeia (U.S.P) for nonabsorbable surgical sutures. Surgical stainless steel suture is also labeled with the B&S gauge classifications.

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.

4.0 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 Medi-cal Supplies Inc. Ltd.
- Safety issues reported in scientific literature pertaining to the device(s) under evaluation or to equivalent devices
- Incident and (severe) adverse event reports published in adverse event databases (e.g. MAUDE, national authorities' websites) pertaining to the device(s) under evaluation, equivalent or similar devices
- Complaints reported to Foosin Medical Supplies Inc. Ltd.
- Non-clinical product testing
- Risk management file

About qualitative aspects of clinical safety, the risk management file, IFUs, literatures collected in SOTA and incident and (severe) adverse event reports were first analysed to

identify device-related clinical risks and patient injuries. Through the above data, the clinical risks identified mainly include:

- Wound dehiscence/ dislocation
- Wound infection(DSWI/SSI),including mediastinitis and sternumosteitis
- Suture sinus
- Incisional hernias
- Bleeding
- Superficial sternal wound infection

Quantitative aspects of clinical safety involve collecting the occurrence probability of the above clinical risks from the clinical data of the device to be evaluated and its equivalents. 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 of equivalent device			
Wound dehiscence/ dislocation	0.3-8%	4.9%（14/284）	＜8%	Systematic review of the scientific literature	Perioperative period, mostly within 90 days of surgery
Wound infection(DSWI/ SSI)	0.5-8%	2.8%（8/284）	＜8%	Systematic review of the scientific literature	Perioperative period, mostly within 30 days of surgery
Suture sinus	2.5%(3/120)	2.5%(3/120)	＜2.5%	Systematic review of the	Relatively long-term

				scientific literature	complications, no time point specified
Incisional hernias	3.4%(10/357, Abdominal wound closure) 5.9%(Repair of hernia)	2%(2/98)	＜5.9%	Systematic review of the scientific literature	At one year or more of follow-up
bleeding	2-7%	4.2% （13/309）	＜7%	Systematic review of the scientific literature	Perioperative period, mostly within 30 days of surgery
Superficial sternal wound infection	6.4% （194/3008）	6.7% （19/284）	＜6.4%	Systematic review of the scientific literature	Perioperative period, mostly within 30 days of surgery

Studies have shown that the overall health of patients will affect the progress of the wound healing, such as old age, osteoporosis, cough and other factors can affect the healing of wounds. These patients have a significantly higher risk of DSWI and sternum dehiscence than the general population.

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 nonabsorbable, stainless steel sutures before employing for wound closure. Suture should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.as the risk of wound dehiscence may vary with the site of application and the suture material used.
- Stainless steel suture should be used with caution when prosthesis of another alloy is

implanted since an unfavorable electrolytic reaction may occur

- patients with extraordinary osteoporosis should use stainless steel suture with caution because suture can tear through the fragile bone.
- Acceptable surgical practice should be followed for the management of contaminated or infected wounds.
- In handling this or any other suture material, care should be taken to avoid damage from handling, such as kinking or excessive twisting.
- 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.
- 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

Stainless Steel Suture by Ethicon, is indicated for abdominal wall and skin closure; retention; tendon repair; orthopaedic & neurosurgery. Sternum closure in cardiovascular surgery.

A latest thorough literature search on clinical data obtained with the Ethicon steel suture has been conducted. The safe and efficient use of Ethicon steel suture, is documented in several clinical studies of CER. twelve clinical studies conducted with equivalent device Ethicon steel suture used in the medical field of abdominal wall and skin closure; retention; tendon repair; orthopaedic & neurosurgery. sternum closure, were identified and discussed. The clinical evaluation report analyzed hundreds cases of application of Ethicon steel suture. These studies result show that Ethicon steel suture can realize the closure of tissue well.

A current search in adverse events databases, FDA’s adverse events database MAUDE and BfArM database of Field Corrective Actions. No new or unexpected risks or adverse events for the product class, including the device of interest. No new knowledge about further or unknown risks or potential hazards was detected by performing an incidents database search.

Since no severe and certifiable adverse events have been reported in the observational period and the remaining risks associated with the use of non-absorbable sutures have to be considered as of minor clinical significance, the benefit/risk ratio of the use of

Ethicon steel suture is regarded as positive.

Through literature screening, search of adverse events databases, suitability of data for demonstration of performance and safety of Ethicon steel suture was evaluated in accordance to Regulation (EU) 2017/745 and MEDDEV 2.7/1 Rev. 4 (2016).

The benefit/risk ratio of Ethicon steel suture used under its normal condition of use is compatible with a high level of protection of health and safety and is regarded as positive and in compliance with the Regulation (EU) GSPR 8.

From the data collected above, it is confirmed that the equivalent device, Ethicon steel suture, meet the requirements for long-term safety and performance.

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

Sutures are exempt from clinical investigations according to Regulation (EU) 2017/745.

5.3 Summary of clinical data from other sources, if applicable

Post-Marketing Surveillance

WEGO- Stainless Steel suture was marketed in 2019, no severe adverse events have been reported. Complaint data from 2020 to 2022 provided by the manufacturer show in following table

Market feedback classification statistics								
No.	1	2	3	4	5	6	7	Total
Time	detachment of needle and wire	function invalidation (suture)	function invalidation (needle)	suggestions for improvement	problems of Package	problems of materials	Other	
2020	0	0	0	0	0	0	0	0
2021	0	0	0	0	0	0	0	0

2022	1	0	0	0	0	0	0	1

During 2020-2022, only one adverse event feedback was received regarding detachment of needle and wire. On October 23, 2022, when the steel suture (USP 6#) was applied to close the sternum, the needle and the wire were separated when the needle passed through the sternum for the next puncture, so the new steel suture was used to continue the operation, affecting the operation and delaying the operation time. This data could not be statistically analyzed because of the low volume of product sales and only one adverse event

Feedback has 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.

5.4 An overall summary of the clinical performance and safety

Numerous prospective, randomized controlled trials and clinical studies have evaluated the use of non-absorbable surgical sutures in patients in the need of abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair. Results from these trials have demonstrated the safe use and performance of the Surgical Stainless Steel Sutures.

Surgical stainless steel suture is a nonabsorbable, sterile surgical suture composed of 316l stainless steel. Surgical stainless steel suture is available as a monofilament suture. Surgical stainless steel suture meets all requirements stablished by the United States Phar-macopoeia (U.S.P) for nonabsorbable surgical suture. Surgical stainless steel suture is also labelled with the B&S gauge classification [1].

Several clinical studies conducted with the equivalent device Stainless Steel Suture by Ethicon used in the medical field of non-absorbable surgical sutures were identified and dis-cussed. Further, the clinical data showed with very good evidence

that the safe use and performance of the equivalent device and therefor for the device under evaluation.

Available data on the state of the art and equivalent devices in literature and adverse events databases have been thoroughly evaluated. Information derived from the state of the art section outline that those of non-absorbable surgical sutures are standardly used and have a very good safety profile.

Inherent risks associated with the use of non-absorbable surgical sutures (i.e. procedure-related risks) have been detailed in CER. These also apply for the device under evaluation and the equivalent devices Stainless Steel Suture by Ethicon. A comprehensive risk analysis for the product under evaluation has been performed by Foosin Medical Supplies Inc. Ltd.. Thereby potential risks have been addressed and discussed. Risk-diminishing measures have been taken and the residual risks for clinical use of the product under evaluation are tolerable after implementation of the risk-minimizing measures. It is concluded that the device under evaluation is considered to be in compliance with the Regulation (EU) 2017/745 GSPR 2, 3, 4 and 5. All clinically relevant safety information including precautions and training requirements is provided to the user in the Instructions for Use.

Clinical data regarding the device under evaluation and its equivalent device emphasize the safety of the Surgical Stainless Steel Sutures indicate an acceptable level of safety. Several clinical studies and case series confirm that use of the device under evaluation is associated with only few well-known side effects of minor severity.

Clinical data on the equivalent devices clearly indicate an acceptable level of safety. With regard to the device under evaluation, there are no special design features that

pose special safety concerns. Material is described as biocompatible in the risk analysis and Biological safety evaluation.

In conjunction with the successful clinical use of the Surgical Stainless Steel Sutures in the last years (as confirmed in manufacturer's post-market surveillance) it can be conclude-ed that the benefit/risk ratio is positive and in compliance with Regulation (EU) GSPR 8. The post-market surveillance indicates that the use of the Surgical Stainless Steel Sutures (Foosin Medical Supplies Inc. Ltd.) is a safe treatment option that comprises benefits such as Surgical stainless steel suture is used to hold body tissues together after an injury or surgery.

5.4 On-going or planned Post-market clinical follow-up

The PMCF measures described in the present PMCF plan aim to:

- Confirm the devices' safety and performance,
- Monitor identified side-effects and contraindications,
- Identify previously unknown side-effects and emerging risks,
- Ensure the continued acceptability of the benefit-risk ratio,
- Identify possible systematic misuse or off-label use and verify the validity of the intended use as defined in the respective clinical evaluations.

Data will be used to update the pertaining clinical evaluations, risk analyses and instruction for use documents throughout the entire devices' life-cycle and to ensure its/their long-term safety and performance.

The clinical performance and safety of WEGO-STAINLESS STEEL have been proved. And the suture is well established device comply with the performance parameters specified in the Ph.Eur, so user feedback and screening of scientific literature are enough. PMCF survey will be used to track clinical risk.

The PMCF will be conducted mainly through a) user feedback and b) screening of scientific literature

a) User feedback

Clinical data concerning performance, safety and usability of the WEGO-STAINLESS STEEL including customer satisfaction of representative customers will be obtained through user survey. Primarily customers worldwide, including 10 hospitals in whole world will be surveyed each year for each WEGO suture type [4].

This will ensure that any unexpected problems with the WEGO-STAINLESS STEEL will be rapidly identified and that appropriate action can be taken. Information on potential off-label use shall be collected as well. All data included in these forms will be collected and recorded. Any occurrence of device malfunction, inadequacy in the information supplied to Foosin Medical Supplies Inc. Ltd. or any undesirable side-effect will be categorized and managed as an incident according to internal processes.

The user survey will be performed by sending questionnaires to the users/customers.

Clinically relevant feedback from users will be obtained through:

-Phone calls, emails, mails, from health-care professionals, patients, or third persons
-Manufactures´s representatives, sales representatives, or other employees
-Service or repair requests
-Competent authorities
-Notified bodies
-Authorised representatives

b) Screening of scientific literature

A general method to gain information on performance and safety of a medical device is screening of scientific literature and other sources of clinical data.

Available clinical data relevant to the devices and their intended purpose, as well as any gaps in clinical evidence shall be identified through a systematic literature review. Scientific literature will be screened to identify and analyse clinical trials and suitable registries related to the WEGO-STAINLESS STEEL suture.

Aim of the scientific literature search and screening of other sources of clinical data is:

- Identify novel information on performance and safety regarding the WEGO-STAINLESS STEEL suture
- Identify previous unknown side effects of the WEGO-STAINLESS STEEL suture
- Identify possible systematic misuse or off-label use of the WEGO-STAINLESS STEEL suture
- Evaluating any change in the state of the art and/or alteration of the benefit-risk profile

The screening of scientific literature will be conducted according to the search strategy regarding performance and safety including systematic and non-systematic searches as described in the current literature search protocol relating to the WEGO-STAINLESS STEEL suture. Available bibliographic data shall be collected by online literature search in established databases. During the CER update existing search terms shall be modified or new search terms shall be created if considered necessary by the responsible evaluator. Usually, only publications published since the last literature search (that was performed for the previous CER) shall be collected.

Relevant literature and data sources will be identified (if available) using the following databases or search strategies:

- Medline (via Pubmed; using text word search and MeSH terms)
- Cochrane (Review library and available information on clinical trials)
- ClinicalTrials.gov
- Non-systematic searches addressing performance and safety of the WEGO-STAINLESS STEEL suture including free web searching (e.g.

manufacturers' websites, guideline databases, MEDLINE via PubMed, Adverse events databases (MAUDE, BfArM, MHRA and Swiss agency for therapeutic products), Google, Google Scholar) as well as manual literature search basing on literature referenced in investigated publication

Data regarding the WEGO-STAINLESS STEEL suture shall be collected but also data regarding the equivalent device. These includes the equivalent device in listed in section. Details, on the literature search, search terms, selection and appraisal criteria applied, will be provided in the literature search protocols as Annex to the upcoming clinical evaluation reports.

Appraisal of the identified literature sources and sources of other clinical data will be conducted according to the respective Literature Search Protocol related to the clinical evaluation reports of the WEGO-STAINLESS STEEL suture and MEDDEV 2.7/1 rev. 4.

5.5 Summary of clinical evaluation

For decades, sutures made of different materials and therefore defined by certain properties have been used for the suturing and ligation of bone structures and soft tissues. Depending on clinical indication, knowledge or preference of the surgeon, other technical means like staplers, tissue adhesives, negative wound pressure or cellular and tissue based products can also be applied.

The Surgical Stainless Steel Sutures are non-absorbable sutures device composed of 316l stainless steel that are indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair. Surgical stainless steel suture meets all requirements stablished by the United States Pharmacopoeia (USP) for nonabsorbable surgical suture. Surgical stainless steel suture is also labelled with the B&S gauge classification.

The Surgical Stainless Steel Sutures is an medical device and classified as a class IIb product according to Annex VIII in the Regulation (EU) 2017/745. To demonstrate safety

and performance of the Surgical Stainless Steel Sutures, biological safety and usability aspects have been evaluated. Product technical testing (verification and validation tests) was con-ducted to demonstrate that the Surgical Stainless Steel Sutures is adequate to fulfil performance and safety requirements. A comprehensive risk analysis was performed and all risks associated with the Surgical Stainless Steel Sutures have been considered. Risk control measures have been implemented and risks related to use have been considered. The device is considered to be in compliance with the Regulation (EU) 2017/745 GSPR 1, GSPR 2, GSPR3, GSPR 4 and GSPR 5, GSPR 6, GSPR 8.

A literature search was conducted to identify published clinical data that assist to demonstrate the state of the art in the medical field of non-absorbable surgical sutures. The ap-plied search strategy included two independent searches: a separate systematic search in Medline and a non-systematic search in web search engines such as Google Scholar.

With regard to design characteristics, the product under evaluation fully complies with the current state of the art. Moreover, there is an equivalent medical device on the market (Surgical Stainless Steel Wire by Ethicon) with demonstrated performance and safety.

The present clinical evaluation takes into account literature data derived from the clinical studies regarding the Surgical Stainless Steel Sutures and Surgical Stainless Steel Wire by Ethicon which are assessed as equivalent according to MEDDEV 2.7/1 rev. 4:2016 and Regulation (EU) 2017/745. Moreover, post-market surveillance data of the Surgical Stain-less Steel Sutures, which is on the market since 2019, serve to demonstrate safety of the medical device.

Sufficient clinical evidence was available to support and demonstrate every intended performance claim. The performance of the device under evaluation was demonstrated and is in compliance with the Regulation (EU) 2017/745 GSPR 1 and GSPR 8. The safety profile of the use of non-absorbable surgical suture is well-known, regarded as acceptable, and no additional product-specific safety concerns exist for the Surgical Stainless Steel Sutures. Sufficient evidence was available to support and demonstrate every safety claim. The

safety of the Surgical Stainless Steel Sutures was demonstrated and in compliance with the Regulation (EU) 2017/745 GSPR 1.

Based on the positive results of the non-clinical testing and the available clinical data, the identified side-effects are acceptable in comparison to the product benefits. The benefit/risk profile of the Surgical Stainless Steel Sutures used under its normal condition is expected to be compatible with a high level of protection of health and safety and is regarded as positive in compliance with the Regulation (EU) 2017/745 GSPR 1, GSPR 2, GSPR 4 and GSPR 8. Nevertheless, Foosin Medical Supplies Inc. Ltd. commits to perform a PMCF study to confirm performance and safety of the Surgical Stainless Steel Sutures.

This clinical evaluation was prepared according to the Regulation (EU) 2017/745 and MEDDEV 2.7/1 rev. 4 to collect, appraise and analyse clinical data pertaining the Surgical Stainless Steel Sutures. As the device under evaluation is not expected to carry significant risks in addition to the well-known device-related or procedural risks, and its intended purpose and mode of action are well-studied, updating the clinical evaluation every year after release of the present report is regarded as adequate as long as no safety-relevant information are received through active or passive post-market surveillance.

6.0 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.

Suture can approximate the tissues that have been cut or broken due to surgery or trauma, eliminate dead space, prevent bleeding and tissue fluid leakage from the wound, promote healing of wound, reduce wound infection. It can also restore tissue function by reconstructing tissue channels Extreme knot security properties and exceptionally high tensile strength qualifies of surgical stainless steel sutures can provide a strong support

force for the wound, so that the wound is not easy to dehiscence.

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 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.

7.0 Suggested profile and training for users

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

8.0 Reference to any harmonised standards and CS applied

No.	Standard No.	No.	Standard No.	No.	Standard No.
1	Regulation (EU) 2017/745	12	MDCG 2020-13	23	EN ISO 11737-1
2	EN ISO 15223-1	13	EN ISO 10993-1	24	EN ISO 11737-2
3	EN 62366-1	14	EN ISO10993-3	25	EN ISO 13485
4	MEDDEV 2.7-1 rev.4	15	EN ISO 10993-4	26	EN ISO 14155
5	MEDDEV 2.12-1 rev.8	16	EN ISO 10993-10	27	EN ISO 14971
6	MEDDEV 2.12-2 rev.2	17	EN ISO 10993-11	28	ISO 14630
7	MDCG 2019-9	18	EN ISO 10993-13	29	ASTM F 1874
8	MDCG 2020-5	19	EN ISO 11607-1	30	ASTM F3014
9	MDCG 2020-6	20	EN ISO 11607-2	31	ISO 16142-1
10	MDCG 2020-7	21	EN ISO 11138-2	32	EP 10.0- 0324
11	MDCG 2020-8	22	EN ISO 11135	33	USP 43

9.0 Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
A/0	2021.01.27	***/***	☐ Yes Validation language: ☒ No
A/1	2022.01.27	Adaptation to deficiency report	☐ Yes Validation language: ☒ No
A/2	2023.03.10	Adaptation to deficiency report	☐ Yes Validation language: ☒ No
A/3	2023.10.25	Address Change	☐ Yes Validation language: ☐ No