SUMMARY of SAFETY and CLINICAL PERFORMANCE
SSCP

SUTUR'LINK®

Document: SSCP_SUTURLINK_V1.2
Dated: JUL2024

Prepared by	**Date**	**Signature**
Name: S. Van de Moortele Function: **Clinical Research Manager** *PRRC for PMS*		

Approved by	**Date**	**Signature**
Name: F. Marcq Function: **R&D Manager**		
Name: S. Salles Function: **Regulatory Affairs Manager** *PRRC for Technical file and EU DoC*		
Name: F. Druilhet Function: **Quality Manager** *PRRC for QMS and Materiovigilance*		

SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for HEALTH CARE PROFESSIONNALS
SUTUR'LINK®

Foreword

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of 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 intended to provide diagnostic or therapeutic suggestions to intended users or patients

The following information is mainly intended to users (health care professionals such as surgeons). A summary intended for patients can be found at the end.

1. Device Identification and general information

1.1. Device Trade Name(s): **SUTUR'LINK®**

The medical device has also the following private labels:

Name of the company	Name of the private label
AMPLITUDE	SUTORTHO
FH	CORTTAPE LINK
FH	ARROWLINK

1.2. Manufacturer name and address(es):

TEKNIMED S.A.S.		
Headquarters 8, rue du Corps Franc-Pommiès 65500 Vic en Bigorre France	*Production and facilities* 11-12, rue d'Apollo - ZI de Montredon 31240 L'Union France	*Distribution site (labelling)* ZI de la Herray 65500 Vic en Bigorre France

1.3. Manufacturer's SRN (Single Registration Number): **FR-MF-000001224**

1.4. Basic UDI-DI: **376017704B19DD**

1.5. Medical device nomenclature description / EMDN nomenclature: **H0102010299 - Synthetic nonabsorbable multifilament sutures - other**

1.6. Class of device: **IIb**

1.7. Year when the first certificate (CE) was issued covering the device: **2013**

The medical device has been introduced for the first time in the following countries:

Country	Year of introduction
Europe	2013
UKRAINE	2016
MACEDONIA	2017
LEBANON	2019
SERBIA	2019
MALAYSIA	2020

ECUADOR	2020
BRAZIL	2021
SOUTH AFRICA	2021
COLOMBIA	2021

1.8. Authorised representative if applicable; name and SRN: **NA** as the manufacturer is located in the EU.

1.9. NB's name (the NB that will validate the SSCP) and single identification number: **BSI Netherlands (CE 2797)**

2. Intended use of the device

1.1. Intended purpose

SUTUR'LINK® is intended for repairing or reinforcing ligaments, closure and/or ligation of soft tissues, and tuberosity reinsertions during orthopaedic surgery.

2.2. Indication(s) and target population(s)

SUTUR'LINK® is indicated for orthopaedic surgeries such as rotator cuff repair or closure of capsule after arthroplasty surgery.
The target population is: Adult patient in need of arthroplasty surgery, ligation of soft tissues, closure of capsule or rotator cuff repair.

2.3. Contraindications or restriction for use

- Procedures other than those stated in the INDICATIONS section.
- Muscular, neurological, metabolic or vascular deficiencies or any concomitant affliction likely to affect the fixation of the suture.
- Allergy or hypersensitivity to one of the product's components.
- Due to non-sufficient available clinical evidence, the device is contraindicated in paediatric patients, pregnant or breast-feeding women.

3. Device description

3.1. Description of the device

SUTUR'LINK® is a suture thread with two crimped needles.
It is made of white ultra-high-density polyethylene (UHMWPE) thread, braided with a blue UHMWPE/polypropylene (PP) wire, and crimped at each extremity by a stainless-steel needle:
- One round needle, 3/8 x 25 mm, intended for suturing tendons and ligaments
- One triangular needle, 1/2 x 40 mm, intended for trans-bone reinsertions and tuberosity fixations.

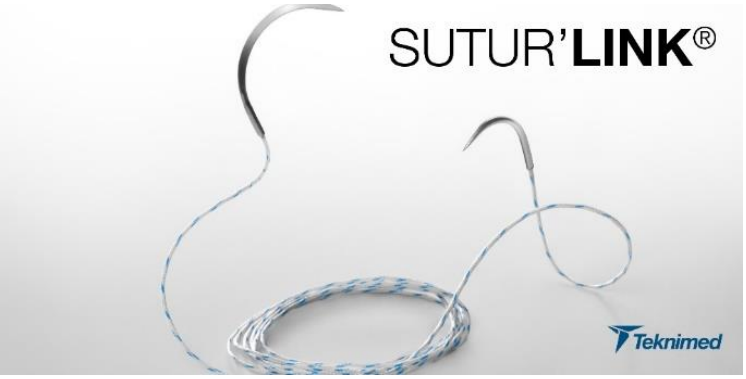

Figure 1: Picture of SUTUR'LINK®

SUTUR'LINK® is available under the following references:

Reference	Device name	Blue thread	White thread	Needles	Status
T362034	SUTUR'LINK®	PP (12.5%)	UHMWPE USP¾ (87.5%)	Stainless steel	CE marked under MDD
T362041	SUTUR'LINK®	UHMWPE (100%) USP¾		Stainless steel	new
T362040	SUTUR'LINK®	UHMWPE (100%) USP2		Stainless steel	new

Table 1: Composition of SUTUR'LINK®

The device is delivered sterile and ready to be used.

Principles of operation of the device and mode of action
SUTUR'LINK® suture threads are indicated for repair or reinforcement of ligaments or tendons, closure and/or ligation of soft tissues, and tuberosities reinsertions. The large needle allows suturing tendon to tendon or tendon to bone, while the small needle is used only for suturing tendon to tendon or ligament.

SUTUR'LINK® is a unique usage device.
SUTUR'LINK® is not absorbable and does not undergo in situ degradation. It is specifically built for strong repair and for long term suture stability.
The device is not intended to be removed and does not need any maintenance, unless a medical complication would require a surgery.

3.2. Reference to previous generation(s) or variants if such exist, and a description of the differences
SUTUR'LINK® is not issued from any previous generation.

3.3. Description of any accessories which are intended to be used in combination with the device
NA. No accessories are intended to be used in combination with the device.

3.4. Description of any other device or products which are intended to be used in combination with the device
No other devices or products are intended to be used in combination with the device.

4. Risks and warnings

4.1. Residual risks and undesirable effects
Even if the following undesirable side effect haven't been reported in any clinical studies on SUTUR'LINK® (0%, n=0), they remain nonetheless risks inherent to any surgery:
- Infection
- Tissue inflammatory reaction

Any serious incident occurring in relation to the device must be reported without delay to TEKNIMED and the competent local authority where the user and/or the patient is established.

4.2. Warnings and Precautions
Read instructions for use carefully prior to use and follow handling instructions.
Ignoring the instructions for use may lead to potential undesirable effects.
For an optimum use, it is essential to perform a thorough pre-operative review of the patient before the intervention in order to confirm the indication and plan the surgical technique.

Conservation
- It is strictly forbidden to re-sterilise the product. This product is supplied sterile unless package has been opened or damaged.

- This device is packaged and sterilised for single use only. Do not reuse, reprocess or resterilise. Reuse, reprocessing, or re-sterilisation may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury or illness. Also, reprocessing or re-sterilisation of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- Before use, check the packaging carefully to ensure that it has not been opened nor damaged in a way that could affect its sterility.
- Do not use this product after the expiration date mentioned on the package.

Before use
- Examine the product visually to identify any defects such as crack or deformation. Do not implant products with defects.
- When handling this device, as for any device including suture threads, be careful not to damage them.
- Avoid pinching or crushing the suture threads when using surgical instruments such as pliers or needle holders.
- When removing the product from its packaging, be sure to follow aseptic rules.

Use
- Using the large needle for a ligament or tendinous suture can cause tissue injury
- Using the small needle for a trans osseous suture can cause needle breakage, in which case the surgeon must verify that no needle piece remains in the bone.
- As for any device including suture threads, making secure knots requires the use of a recognised surgical technique for flat knots, double knots and additional knots, depending on operative circumstances and the surgeon's experience.
- To avoid damaging the point of the needles or the crimped areas, the needle should be gripped between one-third (1/3) and half (1/2) way along the needle from the crimped area towards the point. Changing the shape of the needles can damage them and leave them weaker.
- Do not apply excessive or abrupt traction to the suture, as this may cause the needle uncrimping.
- Accidental punctures by contaminated surgical needles can lead to transmission of pathogenic agents carried in blood.
- Discard used needles in a container for sharp objects.

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

No FSCA have been issued for SUTUR'LINK® or any private label.

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

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

Conformity of the new SUTUR'LINK® references (T362041, T362040) was assessed and endorsed by the NB on the basis of equivalence with the previously CE marked legacy SUTUR'LINK® reference (T362034).

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

Non applicable. No clinical investigations have been conducted before the CE-marking.

5.3. Summary of clinical data from other sources, if applicable

Performance and safety of SUTUR'LINK® were first evaluated by a Post-Market Clinical Follow-up (PMCF) study, performed in 2014 when the product was first marketed.

Title: Post-Market Follow-up – SUTUR'LINK®

Population: 29 patients (19 women, 10 men, mean age 72.8 year) were included in the study.

Indications: Total shoulder prosthesis (n=11), total knee prosthesis (n=7), total hip prothesis(n=6), revision of total hip prosthesis (n=3), revision of total knee prosthesis (n=2).

Surgery procedures: A total of 78 sutures were used and evaluated during the 29 performed surgeries. 100% of implantation were easily performed; 100% of knots were stable; 100% of fixation were stable; No breakages of needles were reported.

Postoperative outcomes: At a mean follow-up of 3.2 [0.7;7.1] months, no patients reported pain; No revision has been performed since initial surgery; No ruptures of suture have been observed.

Safety: No complications related to the suture were reported. Other complications related to the joint replacement procedure were reported: 1 case of limb stiffness and 1 case of popliteal sciatic nerve paresis.

Conclusion: No perioperative failures such as unstable knots, rupture of suture, uncrimping of the needle, were reported. No side effects, no complications related to the suture were reported. No dissociation phenomenon, rejection, or consolidation problems were reported.

The clinical outcomes of this study confirm that SUTUR'LINK® is a reliable and safe suture to be used in orthopaedic surgery such as total joint arthroplasty.

5.4. Overall summary of the clinical performance and safety

Demonstration of the very long usage, for more than decades, of sutures in tendon or soft tissues repair confirms that the sutures can be considered as an efficient and safe well-established technology.

PMCF studies on SUTUR'LINK® reported outcomes from a total of 71 patients implanted with more than 190 sutures. No complications related to the sutures were reported, except 5 ruptures of sutures during the surgery which has a low impact for the patients as the surgeon just needed to use another suture.

PMS activities showed that no new and/or unexpected risks were identified from the almost 35 000 units sold during the last 5 years, in any relevant European Member State.

Benefits/risks analysis demonstrated that all claims are supported by benefices quantified PMCF studies. The balance benefits/risks of using SUTUR'LINK® tendon or soft tissues repair procedures can be considered positive for the patients.

5.5. On-going or planned post-market clinical follow-up

Teknimed is currently conducting a post-market clinical follow-up which will confirm performance, safety and usability for all the Teknimed range of Sports products, including SUTUR'LINK®.

Title: Safety and performance assessment of sport surgery products - A Post-Market Clinical Follow-Up

Justification/Context: TEKNIMED has developed several devices currently used in orthopaedic surgery. With the increasing use of these procedures, there is a need for real-life long-term safety and efficacy data on these products.

Objective: The objective is to collect immediate, medium and long-term data after surgery, on the related clinical functional and complications outcomes of market-approved TEKNIMED Sports products to confirm their performance and safety in a real-world setting.

Study design: global, single arm, non-controlled, multi-centric, ambispective observational study. Patients will be followed as per local standard medical practices of the investigational sites. Data will be collected pre-operatively, at surgery and at standard of care follow-up (FU) visits.

Performance endpoints: Suture strength, knots stability

Safety endpoints: Adverse events will be documented during the study and categorized as whether they are serious and whether they are related to the TEKNIMED device.

Statistical Analysis: Statistical analyses will primarily be descriptive as no hypotheses are enunciated to be demonstrated. Each outcome will be reported for each product separately, however, some products may be grouped and summarized if the products are related and if needed. There are no intentions to compare or test data across products unless requested for a publication or other clinical evidence need. Should this later case occur, analytical analyses would be performed. According to the multiplicity of the explored parameters, the results of the statistical tests will have to be considered only as an exploratory basis. When needed, Kaplan-Meier survivorship analyses will be performed for several endpoints such as implant revision or aseptic loosening.

An interim analysis has been performed in November 2022, providing the following results:

Population: 42 patients (mean age 71.1-year, min 50 – max 88) were retrospectively enrolled in this study. Most patients

(n=28, 67%) complained from pain and/or stiffness (n=16, 38%). 13 patients (31%) presented no symptoms.

Indications: Closure/ligation of soft tissues (n=33), Shoulder tuberosity fixation (n=5) or rotator cuff repair (n=3). Half of aetiologies were of traumatic origin (52%, n=22) and half (n=20, 48%) were chronic.

Surgery procedures: A total of 113 units of SUTUR'LINK'S® were used during the 42 surgeries analysed in this report. The quality of the suture and the quality of the knots were qualified as 'stable' (n=41, 98%). The suture broke during use in 2 (5%) patients during suturing and in 3 (7%) patients during making knots. In most cases (n=39, 93%), investigators were satisfied with the device. Only in 3 surgeries, where a rupture of the suture occurred (2 during suturing and 1 during making knots), the investigator was not satisfied.

Postoperative outcomes: Knots were qualified as 'stable' at follow-up (up to 20-month postoperative). The stability of knot was qualified as 'unstable' for only 1 patient at short-term FU (2.61-month). No postoperative rupture of suture or failure of tendon healing due to knot loosening were reported postoperatively.

Safety: 4 postoperative complications were reported. 2 serious adverse events: 1 humeral stem loosening on chronic sepsis and periprosthetic fracture for which no action was taken due to the refusal of family (patient at risk); and 1 glenoid loosening after the patient falling down, for which a reoperation surgery was performed. 2 non-serious adverse events: 1 axillary nerve palsy and 1 axillary nerve traction, both treated by other medication onset. All adverse events were qualified as "not related" to SUTUR'LINK®. The relatedness to the procedure was qualified as "definite" in 1 case and as "not related" in 3 cases.

Conclusions: During and after the surgery, no adverse events or complications related to the suture were observed. The 5 reported perioperative ruptures of suture induced no complications and were resolved with no further issues. Investigator's opinion on the device remained favourable, confirming the satisfying usability of the device. The 4 postoperative adverse events (humeral stem loosening, glenoid loosening, axillary nerve palsy or traction) were all unrelated to the device. No ruptures of suture and no inflammatory reactions were observed, confirming the safety and performance of the SUTUR'LINK®. To conclude, this interim analysis confirmed that SUTUR'LINK® is an effective and safe device relevant to be used in tuberosity reinsertion, and ligament or tendon repair.

6. Possible diagnostic or therapeutic alternatives

The material used to fix and repair soft tissues and tendons includes the use of suture anchors, suture tapes, hook plates, screws, pins, wires and patches, thus, the choice of the material depends on the surgeon's experience and preference, and the injury type. When the suture choice is selected, different suture materials are available such as Polydioxanone or polyethylene. Moreover, new knotless sutures are recently used, with no need for knot tying when compared to conventional sutures with knots.

7. Suggested profile and training for users

Implantation of TEKNIMED products should only be performed in an adapted environment and by qualified operators (orthopaedic surgeons) having a sound knowledge and full mastery in preparation techniques specific to TEKNIMED products. Preparation techniques may be acquired from the distributors qualified by TEKNIMED. The operator is responsible for any complications or harmful consequences which might result from an erroneous indication or operative technique, an improper use of the equipment and/or a failure to comply with the safety rules provided in the instructions for use. Neither TEKNIMED as manufacturer nor the authorized TEKNIMED representative can be held responsible for these complications.

8. Reference to any harmonized standards and CS applied

Standard reference	Standard revision	Standard title	Applicability

> General standards

EN ISO 13485	2016/ A11: 2021	Medical devices - Quality management systems - Requirements for regulatory purposes	Fully whenever applicable
EN ISO 14630	2012	Non-active surgical implants - General requirements	Fully whenever applicable
EN ISO 14971	2019 / A11: 2021	Medical devices - Application of risk management to medical devices	Fully whenever applicable
EN 62366	2015 / A1:2020	Medical devices – Application of usability engineering to medical devices	Fully whenever applicable
XP S99-223	2020	Medical Device – Benefit / Risk management	Fully whenever applicable
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects — Good clinical practice	Fully whenever applicable

> Product standards

ISO 2859-1	2011/A1:2011	Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	Fully whenever applicable
ASTM F2503	2020	Standard Practice for Marking Medical Devices and other items for safety in the Magnetic Resonnance Environment	Fully whenever applicable
European Pharmacopea	10th Edition	9.5 "Sutures, sterile non-absorbable sutures"	Fully whenever applicable

> Biocompatibility standards

EN ISO 10993-1	2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Fully whenever applicable
EN ISO 109923-2	2006	Biological evaluation of medical devices — Part 2: Animal welfare requirements	Fully whenever applicable
EN ISO 10993-3	2014	Biological evaluation of medical devices — Part 3 Tests for genotoxicity, carcinogenicity and reproductive toxicity	Fully whenever applicable
EN ISO 10993-5	2009	Biological evaluation of medical devices —— Part 5: Tests for in vitro cytotoxicity	Fully whenever applicable
EN ISO 10993-6	2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation	Fully whenever applicable
EN ISO 10993-10	2021	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Fully whenever applicable
EN ISO 10993-11	2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Fully whenever applicable
EN ISO 10993-12	2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	Fully whenever applicable
EN ISO 10993-17	2009	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances	Fully whenever applicable
EN ISO 10993-18	2020/ A1:2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	Fully whenever applicable
EN ISO 10993-23	2021	Biological evaluation of medical devices — Part 23: Tests for irritation	Fully whenever applicable

> Labelling and packaging standards

EN ISO 14698-1	2003	Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods	Fully whenever applicable
EN 556-1	2001 / AC:2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Part 1 : requirements for terminally sterilized medical devices	Fully whenever applicable

EN 868-5	2018	Packaging for terminally sterilized medical devices — Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods	Fully whenever applicable
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems — Amendment 1	Fully whenever applicable
EN ISO 11607-2	2020	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes — Amendment 1	Fully whenever applicable
EN ISO 15223-1	2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements	Fully whenever applicable
EN ISO 20417	2021/COR: 2021-12	Medical devices — Information to be provided by the manufacturer	Fully whenever applicable
ASTM D 4169	2022	Standard Practice for Performance Testing of Shipping Containers and Systems	Fully whenever applicable
ASTM D 4332	2022	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Fully whenever applicable
ASTM D 4728	2017	Standard Test Method for Random Vibration Testing of Shipping Containers	Fully whenever applicable
ASTM D 5276	2019	Standard Test Method for Drop Test of Loaded Containers by Free Fall	Fully whenever applicable
ASTM D 999	2008	Standard Test Methods for Vibration Testing of Shipping Containers	Fully whenever applicable
ASTM F 1929	2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Fully whenever applicable
ASTM D 6653 / D 6653 M	2021	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads 1	Fully whenever applicable
ASTM D6344	2004	Standard Test Method for Concentrated Impacts to Transport Packages	Fully whenever applicable
ASTM D642	2020	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads 1	Fully whenever applicable
ASTM F88 / F88 M	2021	Standard test method for seal strength of flexible barrier materials	Fully whenever applicable
ASTM F1980	2021	Standard Guide for accelerated aging of sterile medical packages	Fully whenever applicable
ASTM F1886 / F1886 M	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection 1	Fully whenever applicable

> Microbiology standards

EN ISO 11737-1	2018/ A1:2021	Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products	Fully whenever applicable
EN ISO 11737-2	2020	Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	Fully whenever applicable

> Sterilisation standards

EN ISO 11135-1	2014 / A1: 2019	Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Fully whenever applicable
EN ISO 10993-7	2008 / AC1: 2009	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	Fully whenever applicable

9. Revision history

Revision number	Date issued	Change description	Revision validated by the Notified Body
1.0	DEC 2022	Creation	☐ Yes, language: English ☑ No
1.1	APR 2023	Deletion of the SSCP for patients (not required for WET devices) following TD review by BSI	☑ Yes, language: English ☐ No
1.2	JUL 2024	Correction of Private Label name (Sutortho)	☐ Yes, language: English ☑ No