SUMMARY of SAFETY and CLINICAL PERFORMANCE
SSCP

TLS® BIO-C

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Dated: DEC 2023

SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for HEALTH CARE PROFESSIONNALS
TLS® Bio-C screw

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): **TLS® BIO-C**

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: **376017704B15D5**

1.5. Medical device nomenclature description / EMDN nomenclature: **P09120605 - interference screws**

1.6. Class of device: **Class III** according to (EU) MDR 2017/745, rule 8, Annex VIII

1.7. Year when the first certificate (CE) was issued covering the device: **2009**

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

2.1. Intended purpose

TLS BIO-C® screws are intended to be used for attaching short semitendinosus ligament grafts to bone via synthetic tapes in ligamentoplasty surgeries following the TLS® technique.

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

Indications

TLS® BIO-C screws are indicated in knee anterior cruciate ligament reconstruction procedures only with the TLS® tapes.

Target populations

Adult patients in need of knee ligament reconstruction.

2.3. Contraindications or restriction for use

- Procedures other than those stated in the INDICATIONS section

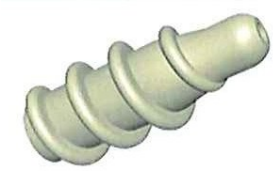
- Insufficient bone quantity or quality which can compromise sound attachment of the screw
- Patients susceptible to allergic reactions to the components of the device and its products of metabolism.
- Due to non-sufficient available clinical evidence, the device is contraindicated in paediatric patients, and breast-feeding or pregnant women.

3. Device description

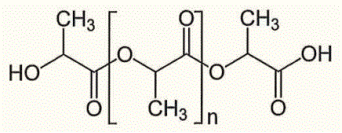
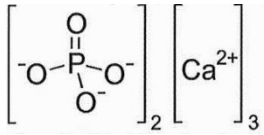
3.1. Description of the device

TLS® BIO-C devices are cannulated bio-absorbable interference screws used exclusively for anterior cruciate ligament (ACL) reconstruction according to the method called the Tape Locking Screw System (TLS® System).
This method, developed by FH Orthopedics, is an all-inside ligamentoplasty technique which uses a 4-strand semi-tendinous graft with polyethylene terephthalate (PET) tapes, fixed to the bone by interference screws.

The screw comprises one large thread that has a relatively smooth profile, in order to prevent synthetic tape friction as well as a distal tip with a rounded form. The screw head presents a tapered hexagonal keyhole for receiving the distal end of a driver instrument, as represented below:



TLS® BIO-C is composed of:

Poly (70/30 ; L/DL) lactide (PLA)	67-73 %	
Tricalcium phosphate $Ca_3(PO_4)_2$ (TCP)	27-33 %	
+ Potential trace of heavy metal (Pb, Hg, Bi, As, Sb, Sn, Cd, Ag, Cu, Mo) at a total concentration < 10 mg/kg.		

The presence of TCP into the PLA matrix keeps a neutral pH of the material by buffer effect during the degradation time and reduces the risk of inflammation. TCP is also an osteoconductive material which promotes bone ingrowth.

TLS® BIO-C screws are available in 2 references, including 1 diameter and 2 lengths:

DESIGNATION - Ø mm	REFERENCE
Ø 10 mm LG 20 mm	264648
Ø 10 mm LG 25 mm	264649

TLS® BIO-C is a single use product.

Lifetime:
The screw is an implantable device, intended to be totally absorbed after an average of 4 years. This period may vary depending on the physiological condition of the patient. 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

TLS® BIO-C interference screw isn't issued from a previous generation and has no variants.

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

TLS® BIO-C interference screws are designed to be used with a dedicated screwdriver provided by FH ORTHO Company.

Designation	Reference
Screwdriver TLS	T067230-TLS

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

TLS® BIO-C interference screws are designed to be used with TLS® tapes provided by FH ORTHO Company.

Designation	Reference
TLS® TENDON ANCHORING TAPE (x2)	265 746
TLS® TENDON ANCHORING TAPE (x1) - OPTION	256 193

4. Risks and warnings

4.1. Residual risks and undesirable effects

- Complications usually encountered with bioabsorbable implants: inflammatory reaction, osteolysis or cyst formation (0.45% in a clinical study, 1.6% in a published series[1]).
- Complications usually encountered with interference screws: failure of the fixation or graft rupture (4.9% in a clinical study, 3.3% in a published series[2]), migration or loosening of the screw (up to 3% in the TPLC database[3]), screw breakage (0.9% in a clinical study, 4.8% in the literature[4]).
- Other reported side effects include: swelling (5% in a published series[1]), arthro-fibrosis, transient post-operative pain or stiffness (0.45% in a clinical study, 5.2% in a published series[1]).

4.2. Warnings and Precautions for use

Read instructions for use carefully prior to use and follow preparation and handling instructions of TLS BIO-C®.
Ignoring the instructions for use may lead to potential undesirable effects.
For an optimum use of the device, 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 resterilisation 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 resterilisation 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.

[1] Ramsingh V, Prasad N, Lewis M. *Pre-tibial reaction to biointerference screw in anterior cruciate ligament reconstruction*. Knee. 2014 Jan;21(1):91-4.

[2] Bourke et al. *Randomized Controlled Trial of Osteoconductive Fixation Screws for Anterior Cruciate Ligament Reconstruction: A Comparison of the Calaxo and Milagro Screws*. Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol 29, No 1 (January), 2013: pp 74-82

[3] TPLC database

[4] Barber FA, Hrnack SA. *Poly L-lactide co-glycolide/β-tricalcium phosphate interference screw fixation for bone-patellar tendon bone anterior cruciate ligament reconstruction*. J Knee Surg. 2013 Dec;26(6):423-8

- 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 printed on the package.

Use
- Examine the product visually to identify any defects such as crack or deformation. Do not implant products with defects.
- When removing the product from its packaging, be sure to follow asepsis rules.
- If packaging is unintentionally opened before use or damaged, do not use the product.
- Use the device accessories during the procedure. All other screwdrivers are not recommended.
- Firmly mount the screw onto the screwdriver and ensure that it is fully engaged. It is essential to insert the TLS BIO-C® screwdriver fully into the screw in order to prevent the screwdriver from slipping and damaging the internal cavity of the screw or breaking the screw during its insertion or removal.
-Oversizing the screw diameter versus the femoral tunnel diameter can: damage the graft, make impossible the insertion of the screw or even break the screw. Recommendation is to have a screw diameter smaller or equal (≤) to the tunnel diameter.
- Ensure axial alignment when inserting the screw.

4.3. Other relevant aspect of safety, including a summary of any field safety corrective action (FSCA) if applicable
NA. No FSCA have been issued for this device.

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
Not applicable. No equivalence with other interference screws is claimed under the (EU) MDR 2017/745.

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable
No clinical investigations have been conducted before the CE-marking.
At the time of its first CE-marking in 2009, TLS® BIO-C were assessed and endorsed by the Notified Body on the basis of their equivalence with other marketed interference screws. Sufficient clinical data were available for the equivalent devices so that no pre-CE clinical investigations were required.

5.3. Summary of clinical data from other sources, if applicable
NA. No other sources than those described in the PMCF Plan were used to collect clinical data.

5.4. Overall summary of the clinical performance and safety
Claims for performance and safety of TLS® BIO-C have been verified and confirmed through 2 successive Post-Market Clinical Follow-up (PMCF) studies and through a continuous Post-Market Surveillance (PMS).

a) Summary of clinical data analysis from a first retrospective PMCF study is presented below.
Population: 76 patients (70% males and 30% females), mean age 32 years old (range 18-56).
Surgery: Ligamentoplasty of the anterior cruciate ligament (ACL) with the Tape Locking Screw (TLS®) system.
No complication, no hematoma, no joint stiffness, no infection, no phlebitis and no other adverse effect were reported during the surgery.
Postoperative outcomes: Pain was assessed using the Lysholm-Tegner pain score. At 2-year, 65% patients reported no pain versus 18% at baseline and 19% reported 'light and intermittent pain in case of heavy effort' versus 19% at baseline. 98.2% of patients were satisfied at 1y FU and 90.8% at 2y FU. The slight decrease at 2y FU could be explained by the return to sports with sometimes unreached expected level of return to previous performances.
At 2y FU, the TLS Bio-C screws survival rate, taking any revision as endpoint, whatever the reason, is 85.9%.
Complications and adverse events: The global complications rate, whatever the reason, is 26.3% (n=20) at 2y FU. When considering only complications related to TLS Bio-C screw, the complications rate is 5.2% (n=4). The complications are: 3 cases of pain at the tibial screw level and 1 ligament rupture.

Conclusion: Surgical treatment for partial or total ACL reconstruction using TLS® anchorage system with TLS® BIO-C screws provide efficacity and a low screw-related revision rate of 2.6%. Implant safety is demonstrated by a high satisfaction rate at 2y FU of 91% and a TLS® BIO-C screw-related complications rate of 5.2%.

b) Summary of clinical data analysis from a second prospective PMCF study is presented below.

Population: 222 (77 females and 145 males), young (29.2 ± 9.2-year-old [16 - 51,6]) patients were included. 14 (6.3%) patients were sports professionals, 83 (37,4%) declared a sport practice at a competition level, and 92 (41.4%) a regular practice. 26 (11.7%) patients declared only an occasional practice and 7 (3.2%) none.

Surgery: 209 (94.1%) of ACL ruptures were total and 13 (5.6%) were partial. 17 (7.7%) adverse events occurred perioperatively, all of them due to the fixation mode (13 split screws left in place, 1 (0.45%) split screw, 1 (0.45%) poor fixation of tibial screw with addition of a staple to the graft, 1 (0.45%) broken screw replaced by a Titanium screw, 1 (0.45%) graft broken in the clamp but complete traction in the tunnel.

Postoperative outcomes: The Lysholm score was 90.2% at 2y FU versus 72% at baseline. The subjective IKDC score (/100) was 85.4 at FU versus 59.8 at baseline. 123 (68.3%) patients returned to running after a mean 9.9 ±8.3 months and 99 (55%) patients returned to usual sports practice after a mean 12.6 ±8 months. The recovered level of sports (compared to the level before the surgery) was 'superior' for 14 (7.8%) patients, 'identical' for 68 (37.8%), and 'inferior' for 58 (32.2%). 17 (9.4%) patients changed of sport and 23 (12.8%) patients practiced 'no more sports'.

11 (4.9%) patients endured a new homolateral re-tear in a mean follow-up of 14.1 ±4.8 months. All re-tear occurred following a new sport accident: 7 with a pivotal and contact sport, 2 with a pivotal sport, and 2 with a non-pivotal sport.

Safety: 28 (12.6%) patients reported an adverse event during the first 2y follow-up, of which only 1 (0.45%) was related to the screw: an intra-osseous cyst treated by curettage/cyst filling.

Conclusions: In this series of 122 patients 11 (4.9%) patients reported a new homolateral rupture occurring at a mean follow-up of 14.1 ±4.8 months, all of them during a new sports accident. 10 (4.5%) patients reported a contralateral ACL rupture during this period. The annual homolateral ACL iterative rupture rate at 2y FU was 2.5%. All functional scores were significatively and drastically improved at 2y FU as compared to baseline. 68.3% of athletic patients returned to running and 55% returned to their preoperative usual sports practice. 91.6% of patients were very satisfied or satisfied with the surgical procedure at 2y FU. 17 (7.7%) adverse events occurred during the surgery, all concerning the fixation mode and necessitating, in 1 case, the replacement of the resorbable screw by a Titanium screw. 16 (7.2%) patients developed an adverse event during the first postoperative week. 28 (12.6%) patients presented an adverse event other than a homolateral or contralateral re-tear during the first 2 years post-surgery, of which 1 patient with an intra-osseous cyst on a resorbable screw. To conclude, this study confirmed that TLS® BIO-C screws represent a performing and secure option for the reconstruction of knee ACL surgical reconstruction.

c) Safety findings from continuous post-market surveillance (PMS)

During the past 5 years period (from OCT 2017 to SEP 2022), from the more than 5600 sold units, no serious adverse events other than those reported from the PMCF studies were recorded in France:

No trend for device malfunction leading to patient harm was detected for the reviewed period in any relevant European Member State (France). The rate of complaints in proportion to the sales for the same period is significantly low and confirms the expected performance of the device.

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

The PMCF study described in section 5.3.b) above is on-going.

6. Possible diagnostic or therapeutic alternatives

There are a large number of interference screws designs available on the market. They mainly differ by their materials (metallic or bioabsorbable), but also by their sizes (diameter and length), tapering, thread geometry, and thread pitch. The 2 most commonly used metals are stainless steel and Titanium. Metallic interference screws have represented the traditional fixation for ligamentoplasty for many years. This fixation technique has been shown to provide high initial

fixation strength while promoting early osseous integration. Yet, despite favourable reports on metal interference screws, concerns exist regarding damage of bone - tendon junction during screw placement, violation of the posterior cortex, presence of intra-articular hardware, distortion on postoperative magnetic resonance imaging (MRI) evaluation, and requirement for hardware removal. Therefore, biodegradable screws have been proposed.
Biodegradable interference screws can be divided into fast and slow- degradable screws. Fast-degradable screws might have a higher incidence of soft tissue reactions. Composite materials have been introduced more recently. These materials are composed of a combination of biodegradable polymers and osteoconductive materials, such as beta-tricalcium phosphate (β-TCP) or hydroxyapatite (HA). Particularly, β-TCP as part of a composite implant seems to offer good ultrastructural properties for cell adhesion. Composite implants are designed to degrade over time. Unlike biodegradable implants, however, Composite implants degrade more quickly, while their osteoconductive properties promote faster graft incorporation and faster new bone formation.
More recently, plastic implants made of poly-ether-ether-ketone (PEEK) and polyethylene terephthalate (PET) are becoming popular. They do not resorb, but are inert, and do not interfere with imaging examinations. Moreover, they can be over drilled in cases of ACL revision.
To conclude, no significant differences in the benefit-risk balance for the above-described types of interference screws have been clearly demonstrated in the scientific literature. Their respective benefits and risks are still controversial. Consequently, the type of screw used will usually be decided upon by the surgeon, based on the patient age, lifestyle, and the surgeon's past experience.

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 ligamentoplasty procedures. 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 ISO 14155	2020	Clinical investigation of medical devices for human subjects — Good clinical practice	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
> Product			
ISO 2859-1	1999 / 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
ISO 13781	2017	Implants for surgery - Homopolymers, copolymers and mixtures on poly (lactide) -- In vitro degradation testing	Fully whenever applicable

EN ISO 14602	2011	Non-active surgical implants — Implants for osteosynthesis — Particular requirements	Fully whenever applicable
ASTM F2502	2017	Standard Specification and Test Methods for Bioabsorbable Plates and Screws for Internal Fixation Implants	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
ASTM F1088	2023	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation	Fully whenever applicable
ASTM F1925	2022	Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants	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 10993-2	20226	Biological evaluation of medical devices — Part 2: Animal welfare requirements	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 10993-9	2021	Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products	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 10993-13	2010	Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices	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 materials	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 F 2096	2011	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	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	JAN 2023	Creation	☐ Yes, language: English ☑ No
1.1	AUG 2023	Modifications following Clinical review under MDR (BSI): - §8.: Update of list of standards	☐Yes, language: English ☑ No
1.2	OCT 2023	Modifications following Clinical review under MDR (BSI): - rectification of the date of first CE marking (2009)	☐Yes, language: English ☑ No
1.3	DEC 2023	Modifications following Technical review under MDR (BSI): - update of Intended purpose and composition	☑ Yes, language: English ☐ No

SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for PATIENTS

TLS® BIO-C

Document revision: 2.0
Date issued: OCT 2023

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 information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an implant card or the Instructions For Use to provide information on the safe use of the device.

1. Device Identification and general information

1.1. Device Trade Name: **TLS® BIO-C**

1.2. Manufacturer name and address(es):

TEKNIMED SAS		
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. Basic UDI-DI: **376017704B15D5**

1.4. Year when the device was first CE-marked: **2009**

2. Intended use of the device

2.1. Intended purpose

TLS BIO-C® are used to repair strong tissue connecting to bone (ligaments in ligamentoplasty procedures) with synthetic tapes following the TLS® technique.

2.2. Indication(s) and intended patient groups

Indication:
TLS BIO-C + are used in knee repair (knee anterior cruciate ligament reconstructions in ligamentoplasty procedures, only with the TLS® tapes).

Target Population:
Adult patients in need of knee repair (ligament).

2.3. Contraindications

- Do not use in procedures other than those stated in the INDICATIONS section.
- Do not use with bone poor quality resulting in poor attachment of the screw.
- Do not use in case of intolerance to constituents of the product.
- Not enough data are available on some categories of patients. TLS BIO-C® cannot be used in children. TLS BIO-C ® cannot be used in breast-feeding or pregnant women.

3. Device description

TLS® BIO-C are screws used only for knee ligament repair by the TLS® technique (Tape Locking Screw System).
This method is used to attach the new ligament to the bone with tapes.

TLS® BIO-C screw

TLS® BIO-C is composed of resorbable materials (70% poly(L/DL) lactic acid (PLDLLA) and 30% β-tricalcium phosphate (TCP). Some minimal traces of heavy metals can also be present (inferior to 10mg/kg). The presence of TCP keeps a neutral acidity during the degradation of the screw. This effect reduces the risk of inflammation. TCP is also a material which promotes bone ingrowth.

TLS® BIO-C screws are available in 2 references, including 1 diameter and 2 lengths:

DESIGNATION - Ø mm	REFERENCE
Ø 10 mm LG 20 mm	264648
Ø 10 mm LG 25 mm	264649

TLS® BIO-C is a single use product.

Lifetime:
The screw is an implantable device. It is intended to be totally absorbed after an average of 4 years. This period may vary depending on the physiological condition of the patient. The device is not intended to be removed. It doesn't need any maintenance, unless a medical complication would require a surgery.

4. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1. Remaining risks and undesirable effects

- Absorbable implants can lead to some issues: inflammatory reaction, bone destruction (osteolysis) or cyst formation (0.45% in a clinical study, 1.6% in a scientific article[5]).
- Interference screws can lead to some issues: failure of the fixation or graft rupture (4.9% in a clinical study, 3.3% in a scientific article series[6]), migration or loosening of the screw (up to 3% in a materio-vigilance database[7]), screw breakage (0.9% in a clinical study, 4.8% in a scientific article[8]).
- Other side effects have been reported: swelling (5% in a scientific article[1]), arthro-fibrosis, transient post-operative pain or stiffness (0.45% in a clinical study, 5.2% in a scientific article[1]).

[5] Ramsingh V, Prasad N, Lewis M. *Pre-tibial reaction to biointerference screw in anterior cruciate ligament reconstruction*. Knee. 2014 Jan;21(1):91-4.

[6] Bourke et al. *Randomized Controlled Trial of Osteoconductive Fixation Screws for Anterior Cruciate Ligament Reconstruction: A Comparison of the Calaxo and Milagro Screws*. Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol 29, No 1 (January), 2013: pp 74-82

[7] TPLC database

[8] Barber FA, Hrnack SA. *Poly L-lactide co-glycolide/ß-tricalcium phosphate interference screw fixation for bone-patellar tendon bone anterior cruciate ligament reconstruction*. J Knee Surg. 2013 Dec;26(6):423-8

4.2. Warnings and Precautions

No warning and precautions for patients. This device is only used by healthcare professionals.

4.3. Summary of any field safety corrective action (FSCA) if applicable

None. No FSCA have been issued since the release of TLS® BIO-C on the market.

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

5.1. Clinical background

TLS® BIO-C comes from a safe technology. It has been used in surgery for many years. It repairs knee. Patients have pain alleviation. Patients have improved quality of life. Performance and safety have been shown by clinical studies.

5.2. Clinical evidence for CE marking

2 clinical studies were performed with TLS® BIO-C screws. One study analysed data from 76 patients. The other analysed data from 222 patients. All patients were rather young and practices one sport.
In both studies, patients were relieved from their pain. More than half of them were able to return to sports after some months. More than 90% of patients were satisfied of their surgery.
Few complications related to the screw were reported: 3 cases of pain at the tibial screw level, 1 ligament rupture, 1 intra-osseous cyst.

5.3 Safety

Clinical studies and surveys are continuously conducted. They document and evaluate the benefits and risks of the product. No complaints have been received from the surgeons for the TLS® BIO-C screws.

6. Possible diagnostic or therapeutic alternatives

Patients who don’t want to be treated with TLS® BIO-C screws have alternatives. Different other types of screws exist. They can be absorbable or non-absorbable. Clinical studies didn’t show significant differences. Your surgeon will choose the best type of screw for you, based on your age and lifestyle, and also her/his past experiences.

7. Suggested profile and training for users

Product should only be used in clinics or hospitals. It should be used by qualified health care professionals (surgeons). They need to be expert in surgery using screws for ligament repair.