SUMMARY of SAFETY and CLINICAL PERFORMANCE
SSCP

ISOFIX+®

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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 ISOFIX+®

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: **ISOFIX+®**

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: **376017704B14D3**

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: **2015**

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

ISOFIX+® are intended for attaching graft ligaments to bone in ligamentoplasty procedures.

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

Indications

Rupture of the knee anterior cruciate ligament.

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

ISOFIX+® is a bioabsorbable interference screw used in ligament surgery. The screw, specially designed for this purpose, is as suitable for fixing bone-tendon-bone type grafts as soft tissue grafts, such as in the case of anterior cruciate ligament reconstruction.

Its main characteristics are:

- Atraumatic thread and head to protect graft integrity
- No need of pre-tapping (time-saving)
- Special helix drive reducing stress, making screw insertion easier and preventing the risk of implant rupture

Two types of screw are available:

- Femoral screw: with hemispherical head, which minimizes the risks of shearing of the graft
- Tibial screw: flat-head screw for deep, firm screwing inside the tibial tunnel



Figure 1: ISOFIX+®

ISOFIX+® is composed of 70% poly(L/DL) lactic acid (PLDLLA) and 30% β-tricalcium phosphate (TCP).
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.

Composition:	**Concentration**
Poly (70/30 ; L/DL) lactide (PLA) (CAS : 52305-30-3)	70 %
Tricalcium phosphate ($Ca_3(PO_4)_2$; CAS : 7758-87-4)	30 %
Potential trace of heavy metal (Pb, Hg, Bi, As, Sb, Sn, Cd, Ag, Cu, Mo)	total concentration < 10 mg/kg.

ISOFIX+® screws are available in 8 sizes, combining 4 lengths (from 23 to 35 mm) and 6 diameters (from 7 to 10 mm).

Designation	Type	Diameter (mm)	Length (mm)	Reference
ISOFIX+ Ø 7 L 23 mm	Femoral	Ø7mm	L23	IFC0723
ISOFIX+ Ø 8 L 23 mm	Femoral	Ø8mm	L23	IFC0823
ISOFIX+ Ø 9 L 23 mm	Femoral	Ø9mm	L23	IFC0923
ISOFIX+ Ø 8 L 28 mm	Tibial	Ø8mm	L28	ITC0828
ISOFIX+ Ø 9 L 28 mm	Tibial	Ø9mm	L28	ITC0928
ISOFIX+ Ø 9 L 35 mm	Tibial	Ø9mm	L35	ITC0935
ISOFIX+ Ø 10 L 28 mm	Tibial	Ø10mm	L28	ITC1028
ISOFIX+ Ø 10 L 35 mm	Tibial	Ø10mm	L35	ITC1035

Lifetime:
The screw is an implantable device. Once implanted in the body, it remains stable for at least 12 weeks during the critical bone healing phase. Then, the screw is slowly degraded in lactic acid which is metabolised and eliminated from the body as carbon dioxide and water. Finally, the screw will 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.

ISOFIX+® are single use products.
Each product is packaged in sealed double bags and sterilized using ethylene oxide.

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

NA. ISOFIX+® isn't issued from previous generations and has no variant.

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

ISOFIX+® is designed to be used with its dedicated screwdriver, specifically designed to correspond to the inner shape of the screw (provided separately).

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

NA. No other devices or products are intended to be used in combination with ISOFIX+®.

4. Risks and warnings

4.1. Residual risks and undesirable effects

- Complications usually encountered with bioabsorbable implants: inflammatory reaction (even if no cases of inflammation have been reported in the literature, this complication remains at risk), osteolysis or cyst formation (1.6% at 9-month follow-up in a published series[1]).
- Complications usually encountered with interference screws: failure of the fixation or graft rupture (3.3% at 2-month follow-up in a published series[2]), migration and loosening of the screw (up to 3%[3] in the TPLC database), perioperative screw breakage (4.8% in the literature[4], 1.1% in a clinical study, Cf. section 5.3. below).
- Other immediate postoperative reported side effects include: swelling (5% in a published series[1]), arthro-fibrosis, transient post-operative pain or stiffness (5.2% in a published series[1]), infection (1.1% in a clinical study, Cf. section 5.3. below).

4.2. Warnings and Precautions for use

Read instructions for use carefully prior to use and follow preparation and handling instructions of ISOFIX+®.
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: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm

[4] 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

- Before use, check the protective 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 ISOFIX+® 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, ISOFIX+® was assessed and endorsed by the Notified Body on the basis of its equivalence with other marketed bioresorbable 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
ISOFIX+® screws are issued from a well-known technology which has been used in orthopaedic surgeries for many years. They allow successful reattachment of a graft ligament to the living bone, leading subsequently to clinical benefits for the patients such as restoration of function and improvement in quality of life. Claims for performance and safety of ISOFIX+® have been verified and confirmed by a Post-Market Clinical Follow-up (PMCF) study and through a continuous Post-Market Surveillance (PMS).

A) Summary of the clinical PMCF study outcomes

Population: 89 patients (59 males and 30 females, mean age 33 ± 10.7 years old, min 18 - max 62) were included in this study. At baseline (pre-surgery visit), only 1 patient presented a metabolic disease: arterial hypertension.
Indications: All patients presented a ruptured knee anterior cruciate ligament.
Surgery procedures: All patients beneficiated from a ligamentoplasty of the anterior cruciate ligament (ACL), of which 56 patients by the DIDT technique and 32 patients by the 'Kenneth Jones' technique, all performed under general anaesthesia. All tibial fixations of grafts were performed via a tibial tunnel of Ø 8 mm (median) (Min 7,5; Max 10) and a Tibial screw ISOFIX+ (median diameter: 9mm (Min 8; Max 10)). Femoral fixations of grafts were performed via a loop button for 55 patients and via a femoral screw ISOFIX+ (Median diameter: 7mm) for 33 patients, with a femoral tunnel of Ø 9 mm. During the surgeries, only 1 screw failure (breakage of the screw) (1.1%) was reported (patient operated by Kenneth Jones technique). No other complication, no hematoma, no joint stiffness, no infection and no other

adverse effect were reported. Investigators' opinions on the device and associated instrumentation's usability were favourable.

Clinical outcomes: Median time to follow-up was 8 months (Min 1; Max 35 months).

Pain: A clear improvement in pain/discomfort is observed at the follow-up visit, with 88.9% (n=96) patients reporting a 'Normal' level at FU, versus 34.6% (n=37) at baseline. 16 (15%) patients reported their pain/discomfort level as 'severe' at baseline, and none at follow-up.

Restoration of function: An improvement in mobility and in ability to perform usual activities is observed at the follow-up visit. 97.2% of patients reported a 'Normal' level of mobility at FU versus 83.2% at baseline. 91.7% patients reported a 'Normal' ability to perform Usual Activities at FU versus 26.2% at baseline. 15 (14%) patients reported their inability for usual activities as 'severe' at baseline, and only 1 patient (0.9%) at follow-up.

Radiological outcomes: At 1-year FU, available x-ray images of the 89 analysed patients showed good bone integrations including 43 bone condensation stage and 4 cases of bone regeneration. All patients presented an implant condensation without osteolysis and without migration. Among the cohort, implant resorption was observed in 12 patients: 2 were defined as inferior to 25%, 5 between 25-50% and 5 others between 50-75%. All these patients had a follow-up time superior to 9 months.

Safety: From the immediate post-surgery visit to the follow-up visit at 1 year, no complications or adverse events related to the device were reported and no revision surgeries were performed. 3 patients presented a post-operative complication: 1 (1.1%) phlebitis, 1 (1.1%) infection and 1 (1.1%) joint stiffness. Based on these patients' outcomes, the survival rate of the ISOFIX+ screw is of 100% at a mean 1-year FU.

Conclusion: This study aims to evaluate short-term safety, healing, integration and efficacy of a bioresorbable screw: ISOFIX+ in ACL reconstructed patients. During the surgery procedure, no adverse events occurred. One screw failure was reported by the investigator on a patient whose graft quality was qualified as 'mild'. During the postoperative follow-up, no adverse event or complications related to the device were reported. Some post-operative complications (infection, joint stiffness) occurred but none was related to the device. Knee function and patients' pain level was improved during the first postoperative year. The good integration of the screw was determined by X-Ray analysis, without inflammatory response or osteolysis at the screw insertion site, short-term stability of the ISOFIX+® is confirmed. X-Ray analysis also showed that some screws were in resorption process, a normal observation considering that these screws are absorbable. To conclude, this short-term outcome study suggests that ISOFIX+ is an effective and safe device relevant to be used in ACL reconstruction.

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

During the past 5 years period (from OCT 2017 to SEP 2022), 1 complaint involving an ISOFIX+® screw was recorded in France, without any consequence on the patient. No trend for device malfunction leading to patient harm was detected for the reviewed period in. 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 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 (TCP) or hydroxyapatite (HA). Particularly, TCP as part of a composite implant seems to offer good ultrastructural properties for cell adhesion. Composite implants degrade more quickly than biodegradable implants, 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 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
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

> 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	DEC 2023	MDR initial submission (Round 2 Clinical): - Rephrasing of “Indication” - Addition of delays for residuals risks occurrence	☐ Yes, language: English ☑ No
1.2	JAN 2024	MDR initial submission (Round 2 Technical): - Mention of potential presence of heavy metals - Addition of details in lifetime description - Addition of 2 standards	☐ Yes, language: English ☑ No
1.3	JAN 2024	MDR initial submission (Round 2 Clinical): - Update of warnings and precautions in the SSCP for patients	☑ Yes, language: English ☐ No

SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for PATIENTS

ISOFIX+®

Document revision: 1.3
Date issued: JAN 2024

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: **ISOFIX+®**

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: **376017704B14D3**

1.4. Year when the device was first CE-marked: **2015**

2. Intended use of the device

2.1. Intended purpose

ISOFIX+® are used to repair strong tissue connecting bone (ligaments in ligamentoplasty procedures).

2.2. Indication(s) and intended patient groups

Indication:

ISOFIX+ are used in knee repair (rupture of the knee anterior cruciate ligament).

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 if 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. ISOFIX+® cannot be used in children. ISOFIX® cannot be used in breast-feeding or pregnant women.

3. Device description

ISOFIX+® is a bioabsorbable interference screw used in ligament surgery. The screw is specially designed for this purpose. It is as suitable to repair strong tissue connecting bone (knee anterior cruciate ligament reconstructions in ligamentoplasty procedures).
It has an atraumatic thread and head to protect graft integrity. There is no need of pre-tapping (time-saving). There is a special helix drive reducing stress. It makes screw insertion easier. It prevents the risk of implant rupture.
Two types of screw are available (Femoral screw: with hemispherical head, which minimizes the risks of shearing of the graft; Tibial screw: flat-head screw for deep, firm screwing inside the tibial tunnel).



Figure 2: ISOFIX+®

ISOFIX+® is composed of polylactic acid and β-tricalcium phosphate (TCP) (70% poly(L/DL) lactic acid (PLDLLA) and 30% β-tricalcium phosphate (TCP).
The presence of TCP into the PLA matrix keeps a neutral pH. It reduces the risk of inflammation. TCP is also an osteoconductive material which promotes bone ingrowth.

ISOFIX+® screws are available in different sizes.

Designation	Type	Diameter (mm)	Length (mm)	Reference
ISOFIX+ Ø 7 L 23 mm	Femoral	Ø7mm	L23	IFC0723
ISOFIX+ Ø 8 L 23 mm	Femoral	Ø8mm	L23	IFC0823
ISOFIX+ Ø 9 L 23 mm	Femoral	Ø9mm	L23	IFC0923
ISOFIX+ Ø 8 L 28 mm	Tibial	Ø8mm	L28	ITC0828
ISOFIX+ Ø 9 L 28 mm	Tibial	Ø9mm	L28	ITC0928
ISOFIX+ Ø 9 L 35 mm	Tibial	Ø9mm	L35	ITC0935
ISOFIX+ Ø 10 L 28 mm	Tibial	Ø10mm	L28	ITC1028
ISOFIX+ Ø 10 L 35 mm	Tibial	Ø10mm	L35	ITC1035

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 does not need any maintenance, unless a medical complication would require a surgery.

ISOFIX+® are single use products.
Each product is packaged in sealed double bags and sterilized using ethylene oxide.

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 (even if no cases of inflammation have been reported in the literature, this complication remains at risk), osteolysis or cyst formation (1.6% 9 months after the surgery in a published series).
- Interference screws can lead to some issues: failure of the fixation or graft rupture (3.3% 2 months after the surgery in a published series), migration and loosening of the screw (up to 3% in the TPLC database), screw breakage during the surgery (4.8% in the literature, 1.1% in a clinical study).
- Other side effects have been reported immediately after the surgery: swelling (5% in a published series), arthro-fibrosis, transient post-operative pain or stiffness (5.2% in a published series), infection (1.1% in a clinical study,).

4.2. Warnings and Precautions

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

Conservation

- This device is packaged and sterilised for single use only. Do not reuse, reprocess or resterilise. Reuse, reprocessing, or resterilisation may damage the device and/or lead to device failure. This may result in patient injury or illness. Also, reprocessing or resterilisation of single use devices may create a risk of contamination. This may cause patient infection or transmission of infectious disease(s) from one patient to another.
- Before use, check the protective 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 ISOFIX+® screwdriver fully into the screw. This will prevent the screwdriver from slipping and damaging the screw. It will also prevent the breaking the screw during its insertion or removal.
-Choosing a too big size of the screw compared to femoral tunnel diameter can damage the graft, or 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 the screw is well aligned on the axis of the tunnel before insertion.

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

None. No FSCA have been issued since the release of ISOFIX+® on the market.

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

5.1. Clinical background

ISOFIX+® 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

Teknimed performed a clinical study (89 patients). All patient had knee injury (ruptured knee anterior cruciate ligament). One screw breakage occurred (1.1%). No other issue occurred (no hematoma, no joint stiffness, no infection and no other adverse effect). Pain decreased for all patients. Mobility increased for almost all patients. Bone integration of the implant was good for all patients. Three patients reported issues after surgery (1 (1.1%) phlebitis, 1 (1.1%) infection and 1 (1.1%) joint stiffness).
To conclude, ISOFIX+® is effective and safe.

5.3 Safety

Teknimed is always doing clinical studies and surveys. They document and evaluate the benefits and risks of the product. During the past five years, one complaint was recorded. It had no consequences on the patient. No trend of device issue was detected. It confirms the performance of the device.

6. Possible diagnostic or therapeutic alternatives

Patients who don't want to be treated with ISOFIX+® have alternatives. Different other types of screws exist. They can be absorbable or non-absorbable.
Studies didn't show significant differences. The type of screw used will usually be chosen by the surgeon.

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 interference screws.