SUMMARY of SAFETY and CLINICAL PERFORMANCE
SSCP

EUROSCREW® NG

Document: SSCP_EUROSCREW_NG_V1.3
Dated: FEB 2024

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
EUROSCREW® NG

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): **EUROSCREW® NG / EUROSCREW® NG TCP**

The medical device has also the following private labels: ARTHROTWIST NG / ARTHROTWIST TCP NG; ROCK SCREW / ROCK SCREW TCP; CORTTAPE SCREW; NOVSCREW / NOVSCREW TCP; HC SCREW NG / HC SCREW NG TCP; B-Screw / B-Screw TCP; ECLIPSE NG / ECLIPSE NG TCP.

1.2. Manufacturer name and address(es): **TEKNIMED** - 8, rue du Corps Franc-Pommiès – FR 65500 Vic en Bigorre

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

1.4. Basic UDI-DI: **376017704B13CZ**

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: **2014**

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

Country	Year of introduction
Europe	2014
MACEDONIA	2017
UKRAINE	2017
VIETNAM	2018
SAUDI ARABIA	2018
IRAN	2019
LEBANON	2019
INDIA	2019
MOROCCO	2019
SERBIA	2019

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

EUROSCREW® NG and EUROSCREW® TCP NG are intended for attaching ligaments or tendons to bone in orthopaedic surgical procedures.

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

Indications

EUROSCREW NG screws are indicated in knee cruciate ligaments or ankle lateral ligament reconstruction in ligamentoplasty procedures.

EUROSCREW TCP NG screws are indicated in knee cruciate ligaments reconstruction in ligamentoplasty procedures.

Target populations

Adult patients in need of knee or ankle 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

EUROSCREW® NG are bioabsorbable cannulated screws specially designed to reduce the risk of breakage, with a better distribution of torque.

Their main characteristics are:

- A triangular inner cone which ensures perfect contact between the screwdriver and the screw. This contact allows transmission of torque in a compression mode and not in shearing mode. This increases the torque failure resistance of EUROSCREW® NG.
- A conical tip and specific threads avoid the need to tap. Internal design of the tip avoids any contact between the screw driver and soft tissues.
- A double thread allows a reduced number of turns needed to introduce the screw into the pre-drilled tunnel. As a result, improved insertion preserves graft's integrity.
- A flat head prevents tissue' s friction at the bone surface after implantation. The screw can be inserted as far as needed; this is particularly suitable for tibial tunnel.

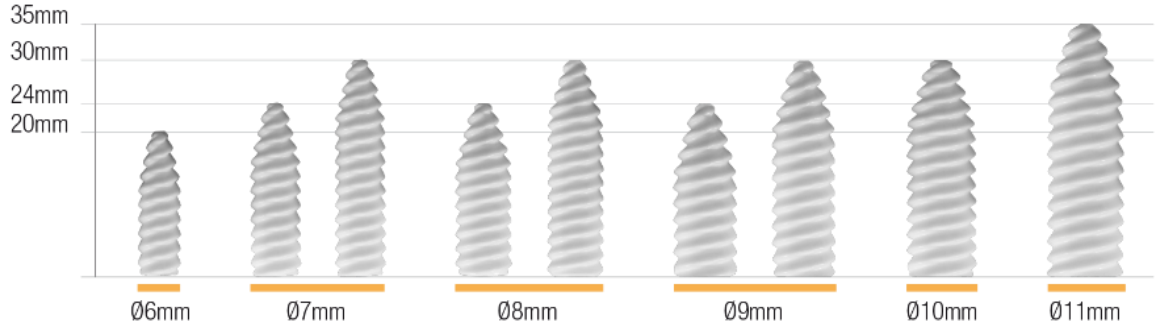
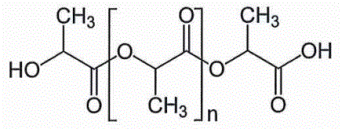
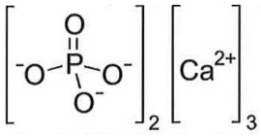


Figure 1: EUROSCREW® NG

EUROSCREW® NG are available in 2 compositions, PLA only or PLA with TCP, as described below:

EUROSCREW® NG	EUROSCREW® NG TCP
100% poly(L/DL) lactic acid (PLDLLA)  *Polylactic acid (PLA)* PLA is a well-known synthetic polymer, which breaks down through hydrolytic deterioration. EUROSCREW® NG is radiotransparent.	70 % poly(L/DL) lactic acid (PLDLLA) 30 % β-tricalcium phosphate (TCP  *Tri-calcium 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. B-TCP is also an osteoconductive material which promotes bone ingrowth. EUROSCREW® TCP NG is radiopaque.

EUROSCREW® NG are available in 9 references, including 6 diameters and 4 lengths suitable for current ligamentoplasty techniques.

EUROSCREW® NG		EUROSCREW® NG TCP	
DESIGNATION - Ø mm	**REFERENCE**	**DESIGNATION - Ø mm**	**REFERENCE**
Ø 6 mm L 20 mm	T720620NG	Ø 6 mm L 20 mm	T730620NG
Ø 7 mm L 24 mm	T720724NG	Ø 7 mm L 24 mm	T730724NG
Ø 7 mm L 30 mm	T720730NG	Ø 7 mm L 30 mm	T730730NG
Ø 8 mm L 24 mm	T720824NG	Ø 8 mm L 24 mm	T730824NG
Ø 8 mm L 30 mm	T720830NG	Ø 8 mm L 30 mm	T730830NG
Ø 9 mm L 24 mm	T720924NG	Ø 9 mm L 24 mm	T730924NG
Ø 9 mm L 30 mm	T720930NG	Ø 9 mm L 30 mm	T730930NG
Ø 10 mm L 30 mm	T721030NG	Ø 10 mm L30 mm	T731030NG
Ø11 mm L35 mm	T721135NG	Ø 11 mm L35 mm	T731135NG

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.

EUROSCREW® NG 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

EUROSCREW® NG screws are the new generation of the Teknimed EUROSCREW® interference screws. They share the same composition and the same sizes. The main difference is the double thread which reduces the number of turns to insert the screw inside the tunnel drilled into the bone and avoid the taping phase.
They exist as 2 variants: EUROSCREW® NG (PLA alone) and EUROSCREW® TCP NG (PLA + TCP).

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

EUROSCREW® NG are designed to be used with the Teknimed 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 EUROSCREW® NG.

4. Risks and warnings

4.1. Residual risks and undesirable effects

- Complications usually encountered with bioabsorbable implants: inflammatory reaction (up to 2.8% in a clinical study conducted by Teknimed; Cf. section 5.3. below), osteolysis or cyst formation (1.6% in a published series[1]).
- Complications usually encountered with interference screws: failure of the fixation or graft rupture (3.3% in a published series[2]), migration and loosening of the screw (up to 3%[3] in the TPLC database), screw breakage (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 (5.2% in a published series[1]), superficial infection (1.4% in a clinical study by Teknimed; 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 Euroscrew NG® and EUROSCREW TCP NG®.

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.
- Before use, check the protective wrapping 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 wrapping, 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 EUROSCREW® NG 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.

---

[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/ß-tricalcium phosphate interference screw fixation for bone-patellar tendon bone anterior cruciate ligament reconstruction*. J Knee Surg. 2013 Dec;26(6):423-8

-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 2014, EUROSCREW® NG were assessed and endorsed by the Notified Body on the basis of their equivalence with the previous generation of screws and 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

EUROSCREW® NG are issued from a well-known technology which has been used in orthopaedic surgeries for many years. They allow successful ligament or tendons reattachment 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 EUROSCREW® NG have been verified and confirmed through 2 successive Post-Market Clinical Follow-up (PMCF) studies and through a continuous Post-Market Surveillance (PMS).

a) A first PMCF study was conducted by Teknimed in 2016. Summary of the clinical data analysis is presented below.
Population: 18 patients (15 males and 3 females), mean age of 26.3 ± 6.4 years old (range 18-40).
Surgery: Ligamentoplasty of the anterior cruciate ligament (ACL) by the 'Kenneth Jones' technique, with tibial and femoral fixations with EUROSCREW® NG.
No complication, no hematoma, no joint stiffness, no infection, no phlebitis and no other adverse effect were reported during the surgery.
Investigators defined the screwdriver as 'Easy to use'. The screws allowed an "Easy implantation and fixations were defined as 'Stable'. Investigator also defined the global procedure with EUROSCREW® NG as 'Easy to use'.
Postoperative outcomes: Knee function was measured using the International Knee Documentation Committee (IKDC) score. At 12-month FU, the IKDC was 95/100, corresponding to an 'excellent' result.
Quality of life was evaluated by a questionnaire covering 4 domains: Mobility, Usual activities, Pain/discomfort and Anxiety/depression. All domains were improved at FU with most of patients reporting a 'normal' level versus a 'mild' or 'sever' disability level at baseline.
Pain was assessed with a Visual Analogue Scale (0 corresponding to no pain and 10 to the worst imaginable pain). Median pain at baseline was 7 (5 - 7). At 1-month follow-up (FU), median pain was 3.5 (2 - 7) and at 12-month FU at 2 0 - 4).
At 1-month FU, available x-ray images of 14 patients showed 8 good integrations, 2 bone regenerations, 2 bone condensations and 2 unchanged bone sites. All patients presented an implant condensation without osteolysis.
Complications and adverse events: From the surgery to the 12 months FU visit, no serious adverse events were reported. Some minor complications were noted during follow-up visits: 2 (11%) cases of knee stiffness treated by arthrolysis; 1 (5.5%) case of discomfort subsequent to a fall; 1 (5.5%) case of knee torsion during football activity, without ACL injury.
Conclusion: Follow-up of patients demonstrated that pain level decreased by half at 3-month FU (7 *vs* 3.5 at baseline), and was clearly improving all along the study. Quality of Life of patients was also improving continuously during the FU of the patients. X-rays analysis demonstrated good integration of the screw, without inflammation response or osteolysis

in the screw insertion site, confirming the short-term stability of the EUROSCREW® NG. No absorption of the screw is observed in this short-term follow-up, but it is admitted that during the first months, when a stable fixation is required for a secure integration of the graft into the bone, the screw shows almost no absorption. All these clinical and radiological outcomes confirm the short-term performance and safety of EUROSCREW® NG in ACL reconstruction surgery.

b) A second PMCF study was initiated in 2019 and is still currently conducted by Teknimed.

A second interim analysis has been performed in April 2023, of which a summary of results is presented below.

Population: 165 (62 females and 103 males), young (median age 30-year-old) patients were included.

Surgery: 70 patients were concerned by an ankle lateral ligamentoplasty (ALL), 90 were concerned by a knee anterior cruciate (ACL) ligamentoplasty, 2 by a knee posterior cruciate (PCL) ligamentoplasty and 3 were concerned by a long head of biceps tenodesis. No perioperative complications or adverse events were reported, whatever the surgical procedure.

Postoperative outcomes:

ANKLE cohort. Before surgery, all patients had a limited function or suffered from activity limitations or required support for walking. Among them, 41.4% (n=29) defined their function as 'limited daily and recreational activities' and 15.7% (n=11) as 'Severe limitation of daily and recreational activities'. At the short-term visit (1.18 ±0.70 months post-surgery), 10.3% (n=7) subjects reported 'No limitations, no support' and less patients (n= 4, 5.9%) reported 'Severe limitation of daily and recreational activities' compared to baseline. At the mid-term visit (3.60 ±1.01 months FU), no more subjects reported 'severe limitation' and half of subjects (n=32, 55.2%) reported no limitation with no need for support at all. Most patients considered that their health status had improved (92.1%, n=35) and most of them (92.1%, n=35) would accept this intervention again.

KNEE cohort. At baseline, the mean Lysholm Knee Score was 68.1 ±11.9% in the cohort with EUROSCREW® NG and 56.3 ±15.9% in the cohort with EUROSCREW® NG TCP. At mid-term FU (mean 1.14 ±0.36 month for EUROSCREW® NG and 1.91 ±1.53 month for EUROSCREW® NG TCP), the score had almost reached 95% with both screws (94.9% and 94.8% respectively), and had almost reached 100% at long-term FU in the cohort with EUROSCREW® NG (99.2% at a mean 8.17 ± 1.11 month FU), confirming that the surgery improves the mobility and the stability of the knee.

At mid- and long- term FU, all (100%) patients were satisfied, considered that their health status had improved, and would accept this intervention again.

Safety:

ANKLE cohort. No serious adverse event, no allergy, no screw's rejection or migration were observed. 2 non serious adverse events related to the screws were reported: 2 (2.8%) cases of inflammation at 5-month FU: 1 was treated with an infiltration and the other requiring no treatment.

KNEE cohort. No serious adverse events, no allergy, no screw's rejection or migration were observed with EUROSCREW® NG. With EUROSCREW® NG TCP, 1 serious adverse event was reported, non-related to the device but related to the procedure: 1 (1.39%) case of hematoma on a lateral tenodesis 1 month after the index surgery. The hematoma was surgically evacuated (re-hospitalisation). 2 non serious adverse events related to the screw were also reported: 1 (1.38%) case of swelling reported at 1-month FU, treated with physiotherapy and resolved without sequelae; 1 (1.39%) case of inflammation reported at 7-month FU which didn't require any action or treatment.

Conclusions: In this PMCF study, a group of 165 patients was followed during the first-year post-surgery, to verify joint function recovery, stability of the screw, healing of the graft and potential body reactions to the screw. During the surgery procedures, no adverse events or complications related to the screws were observed. In all cohorts, patient's follow-up demonstrated that joint function and mobility were clearly improved postoperatively. During the postoperative follow-up, no serious adverse events or serious side effects were observed. 2 complications related to the screws were reported in the ankle cohort and 2 complications related to the screws in the knee cohort. All these adverse events were already known and expected in these surgical procedures. All the reported post-operative complications were treated and resolved without sequalae. Results of this analysis also showed a survival rate of the screws of 100% and no device failure were reported, confirming both the clinical performance and the safety of the use of EUROSCREW® NG and EUROSCREW® TCP NG.

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

During the past 5 years period (from OCT 2017 to SEP 2022), 3 complaints with a patient impact and involving a EUROSCREW® NG was recorded in Europe. They all concerned a screw explanted one year after implantation due to painful bone conflict. The surgeons complained that the removed screw wasn't resorbed. Yet, the claimed lifetime for the screws is of maximum 4-year. Screws will start to resorb only months after their installation, after the attachment of the ligament of the bone is achieved. Furthermore, as stated in the IFU, a bioresorbable screw implantation may cause an inflammatory response during the osseointegration period.

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

The PMCF study described in section 5.3.b) above is on-going and continues to be currently conducted by Teknimed.

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

> 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	JUN 2023	Initial clinical review under the MDR:	☑ Yes, language: English

		- modification of indications to include knee PCL - precision on the manufacturer address	☐ No

SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for PATIENTS

EUROSCREW® NG

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: **EUROSCREW® NG / EUROSCREW® NG TCP ®**

The medical device has also the following private labels: ARTHROTWIST NG / ARTHROTWIST TCP NG; ROCK SCREW / ROCK SCREW TCP; CORTTAPE SCREW; NOVSCREW / NOVSCREW TCP; HC SCREW NG / HC SCREW NG TCP; B-Screw / B-Screw TCP; ECLIPSE NG / ECLIPSE NG TCP.

1.2. Manufacturer name and address(es): **TEKNIMED** - 8, rue du Corps Franc-Pommiès – FR 65500 Vic en Bigorre

1.3. Basic UDI-DI: **376017704B13CZ**

1.4. Year when the device was first CE-marked: **2014**

2. Intended use of the device

2.1. Intended purpose

EUROSCREW® NG and EUROSCREW® TCP NG are used to repair strong tissue connecting bone (ligaments). They are also used to repair strong tissue connecting bone to muscle (tendon).

2.2. Indication(s) and intended patient groups

Indication:

EUROSCREW NG are used in knee or ankle repair (knee cruciate ligaments or ankle lateral ligament reconstruction in ligamentoplasty procedures).

EUROSCREW TCP NG are used in knee repair (knee cruciate ligaments reconstructions in ligamentoplasty procedures).

Target Population:

Adult patients in need of knee or ankle repair (ligament or tendon).

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. EUROSCREW NG® cannot be used in children. EUROSCREW NG® cannot be used in breast-feeding or pregnant women.

3. Device description

EUROSCREW® NG are bioabsorbable cannulated screws specially designed to reduce the risk of breakage, with a better distribution of torque.

Their main characteristics are:

- A triangular inner cone which ensures perfect contact between the screwdriver and the screw. This contact allows

transmission of torque in a compression mode and not in shearing mode. This increases the torque failure resistance of EUROSCREW® NG.

- A conical tip and specific threads avoid the need to tap. Internal design of the tip avoids any contact between the screw driver and soft tissues.
- A double thread allows a reduced number of turns needed to introduce the screw into the pre-drilled tunnel. As a result, improved insertion preserves graft's integrity.
- A flat head prevents tissue' s friction at the bone surface after implantation. The screw can be inserted as far as needed; this is particularly suitable for tibial tunnel.

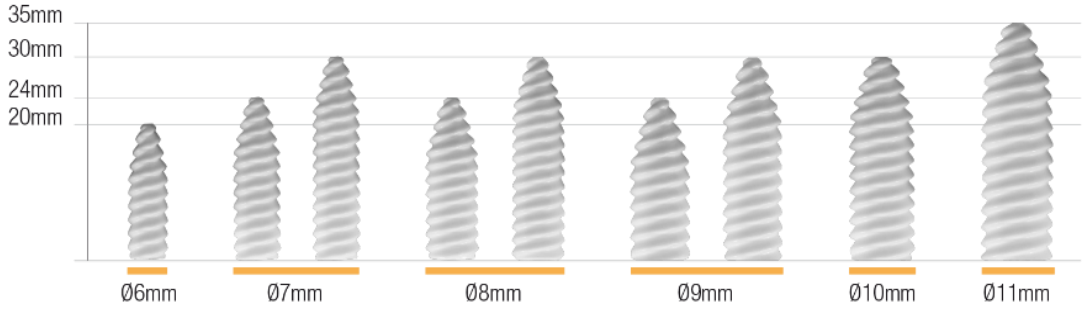
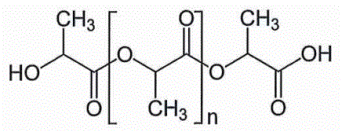
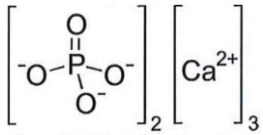


Figure 2: EUROSCREW® NG

EUROSCREW® NG are available in 2 compositions, PLA only or PLA with TCP, as described below:

EUROSCREW® NG	EUROSCREW® NG TCP
100% poly(L/DL) lactic acid (PLDLLA)  *Polylactic acid (PLA)* PLA is a well-known synthetic polymer, which breaks down through hydrolytic deterioration. EUROSCREW® NG is radiotransparent.	70 % poly(L/DL) lactic acid (PLDLLA) 30 % β-tricalcium phosphate (TCP  *Tri-calcium 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. B-TCP is also an osteoconductive material which promotes bone ingrowth. EUROSCREW® TCP NG is radiopaque.

EUROSCREW® NG are available in 9 references, including 6 diameters and 4 lengths suitable for current ligamentoplasty techniques.

EUROSCREW® NG		EUROSCREW® NG TCP	
DESIGNATION - Ø mm	**REFERENCE**	**DESIGNATION - Ø mm**	**REFERENCE**
Ø 6 mm L 20 mm	T720620NG	Ø 6 mm L 20 mm	T730620NG
Ø 7 mm L 24 mm	T720724NG	Ø 7 mm L 24 mm	T730724NG
Ø 7 mm L 30 mm	T720730NG	Ø 7 mm L 30 mm	T730730NG
Ø 8 mm L 24 mm	T720824NG	Ø 8 mm L 24 mm	T730824NG
Ø 8 mm L 30 mm	T720830NG	Ø 8 mm L 30 mm	T730830NG
Ø 9 mm L 24 mm	T720924NG	Ø 9 mm L 24 mm	T730924NG
Ø 9 mm L 30 mm	T720930NG	Ø 9 mm L 30 mm	T730930NG
Ø 10 mm L 30 mm	T721030NG	Ø 10 mm L30 mm	T731030NG
Ø11 mm L35 mm	T721135NG	Ø 11 mm L35 mm	T731135NG

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.

EUROSCREW® NG 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 (up to 2.8% in a clinical study conducted by Teknimed), resorption of bone (osteolysis) or closed sac (cyst) formation (1.6% in a published series[5]).
- Interference screws can lead to some issues: failure of the fixation or graft rupture (3.3% in a published series[6]), migration and loosening of the screw (up to 3%[7] in the TPLC database), screw breakage (4.8% in the literature[8]).
- Other side effects have been reported: swelling (5% in a published series[1]), scar tissue formation (arthro-fibrosis), transient post-operative pain or stiffness (5.2% in a published series[1]), superficial infection (1.4% in a clinical study by Teknimed).

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 EUROSCREW NG® on the market.

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

5.1. Clinical background

EUROSCREW NG® comes from a safe technology. It has been used in surgery for many years. It repairs knee or ankle. 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 (with 18 patients in 2016). No issues (complication, hematoma, joint stiffness, infection, phlebitis and other adverse effect) were reported. Minor issues were reported (knee stiffness, discomfort, knee torsion during football).
Pain level decreased by half. Quality of life improved.
A clinical study is currently on-going. All patients (70 patients for the ankle, 92 for the knee) were treated with EUROSCREW NG®. No issues were reported. Expected minor issues were reported (swelling, inflammation).
No device failure was observed. It shows the clinical performance and safety of the product.

---

[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

5.3 Safety

Teknimed is always doing clinical studies and surveys. They document and evaluate the benefits and risks of the product. Complaints have been filed. They all concerned a screw explanted one year after implantation. It was due to painful bone conflict. The surgeons complained that the removed screw wasn't resorbed. Yet, the claimed lifetime for the screws is of maximum 4-year. Screws will start to resorb only months after their installation, after the attachment of the ligament of the bone is achieved. Furthermore, as stated in the IFU, a bioresorbable screw implantation may cause an inflammatory response during the osseointegration period.

6. Possible diagnostic or therapeutic alternatives

Patients who don't want to be treated with EUROSCREW NG® 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 (based on the patient age, lifestyle, and the surgeon's past experience).

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 bone cements.