SUMMARY of SAFETY and CLINICAL PERFORMANCE
SSCP

TRIHA+®

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SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for HEALTH CARE PROFESSIONALS

TRIHA+®

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): **TRIHA+®**

The medical device has also the following private labels: Optibone, Royal Granules, Z-Bone Granules and Bone Fuse.

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: **376017704B10CT**

1.5. Medical device nomenclature description / EMDN nomenclature: **P900401** – Bone and tendon replacement devices

1.6. Class of device: **III**

1.7. Year when the first certificate (CE) was issued covering the device: **2002**

Year of introduction for the first time in the following countries:

Country	Year of introduction
Europe	2002
USA	2003
Lebanon	2020
Brazil	2022

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

TRIHA® is an osteo-conductive synthetic ceramic for bone ingrowth, intended to be used for filling gaps or bone defects in orthopaedic or spine surgery.

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

Indication: TRIHA+® is indicated for the filling of bone defects in spine surgery (posterolateral fusion) due to degenerative disc disease or to traumatology surgery (open knee fracture).

Target population: Adult patients with a bone defect due to bone injury or surgical procedure.

2.3. Contraindications or restriction for use

- Procedures other than those stated in the INDICATIONS section
- Treatment of large bone defects which could impact the stability of bone structure without implementing a mechanical stabilisation system (such as plate(s), screw(s), nail(s), cage(s))
- Patients susceptible to allergic reactions to the component 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

General description of the device: TRIHA+® is an osteo-conductive synthetic ceramic for bone void filling and bone ingrowth. It consists of a macroporous osteoconductive implant made of synthetic tricalcium phosphate. It has a multidirectional interconnected porosity structure, similar to that of the human cancellous bone.

Operating principles and mode(s) of action: Following its placement in the bone void or gap, TRIHA+® implant is resorbed and progressively replaced by new bone during the natural bone healing and remodelling process.

Composition:
Medical-Grade Beta-Tricalcium Phosphate (β-TCP).
May contain up to 5% of hydroxyapatite (HAP) according to ASTM F1088.

Name	Chemical formula	CAS number
β-TCP (tricalcium phosphate)	$Ca_3(PO_4)_2$	7758-87-4
Hydroxyapatite	$Ca_5(PO_4)_3OH$	1306-06-5

Design characteristics: TRIHA+® is available in various sizes (granules, chips and sticks) to adapt to the volume and specificities of each defect. They share the same composition and their porosity varies according to their size (granules and chips: porosity 60% - 85% ; sticks: porosity 35% - 85%).



Pictures of granules of TRIHA+

Lifetime: TRIHA+® is a unique usage implantable device. Once implanted into bone, it is expected to be totally absorbed after a minimum of 2 years. The lifetime period may vary depending on the size of the defect, the indication and the physiological condition of the patient. TRIAH+® is not intended to be removed and does not need any maintenance, unless a medical complication would require a surgery.

Sterilisation: TRIHA+® is delivered sterile.
Single use product.

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

TRIHA+® is not issued from any previous generation or variant.

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

No accessories are intended to be used in combination with TRIHA+®.

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

No specific other devices are intended to be used in combination with TRIHA+®.
Yet, TRIHA+® has no mechanical properties. So, as mentioned in the Contraindications section (Cf. § 2.3 above), treatment of large bone defects which could impact the stability of bone structure necessitates the implementation of mechanical stabilisation systems, such as plates, screws, nails, cages or any other osteosynthesis material.

4. Risks and warnings

4.1. Residual risks and undesirable effects

No cases of graft displacement or failure (non-union) related to monophasic calcium phosphate have been reported in the literature or during PMCF studies, nonetheless these complications represent an inherent risk to any surgical procedure with bone substitutes.
Likewise, no cases of pain, infection, or inflammation related to the device have been reported in the literature or during PMCF studies, nonetheless these complications represent inherent risks to any surgical procedure.
Any serious incident occurring in relation to the device must be reported without delay to the manufacturer and the competent local authority where the user and/or the patient is established.

4.2. Warnings and Precautions

Read instructions for use carefully prior to use and follow preparation and handling instructions of medical device.
Ignoring the instructions for use may lead to potential undesirable effects.
For an optimum use of TRIHA+®, 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.

Before 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.

Precautions for Use

- Implantation should preferably be done in a spongy bone site
- The ceramics cannot be resized nor support the screwing of osteosynthesis material

- The filling must be complete with a slight impaction (no overfilling)
- The covering must be complete and hermetic by suture of the deep plane.

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

No FSCA have been issued for this product.

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

NA. No devices are claimed to be equivalent to TRIHA+®.

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

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

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

No other sources of data concerning TRIHA+® performance and safety have been identified.

5.4. Overall summary of the clinical performance and safety

TRIHA+® is a product issued from the well-known technology of tricalcium phosphate ceramics which have been used in orthopaedic surgery for decades. It allows successful bone void filling, leading subsequently to clinical benefits for the patients such as pain alleviation and improvement in quality of life. Clinical performance and safety of TRIHA+® have been verified in a Post-Market Clinical Follow-up (PMCF) study. 69 patients, were enrolled in 2 cohorts according to the indication: spine or orthopaedic. Outcomes are summarised below.

Spine cohort: all patients (50 patients, mean age 68.9) suffered from Degenerative Disk Disease and were treated by posterolateral fusion procedure. At a mean 17.4 ± 6.68 months after the surgery, all patients reported a clear alleviation of their pain, from a mean level of 9.3 (on a scale of 10, 10 being the worst pain) at baseline, to a mean level of 4.9. All patients (100%) were satisfied with their surgery and reported an improvement or a stability in their health status at follow-up. All patients would redo the surgery again. At a mean 8.9 ±5.55 months follow-up, bone formation was observed in all patients (100%). The bone/defect ratio increased to 50% in a majority of patients (n=26, 74.3%). Stable osteointegration and bone regeneration were observed in all patients (100%). No cases of osteolysis were observed.

No adverse events or complications were reported at any follow-up visits.

Orthopaedic cohort: all patients (19 patients, mean age 58.0) were treated for a surgical reduction of an open traumatic knee fracture. At a mean 12.2 ±7.08 months after the surgery, all patients reported a clear alleviation of their pain, from a mean level of 8.4 (on a scale of 10, 10 being the worst pain) at baseline, to a mean level of 5.7. All patients were satisfied with their surgery and reported an improvement of their health status. Finally, all patients would accept to redo the surgery again. At a mean 4.6 ±3.54 months follow-up, bone formation was observed in a majority of patients (n=13, 72%). The new bone formation/bone defect ratio increased to 50% in more than half of patients (57.1%). Stable osteointegration and bone regeneration was observed in all patients (100%). No cases of osteolysis were observed.

No adverse events or complications were reported at any follow-up visits.

Conclusion: this analysis allowed to demonstrate that TRIHA+® is an effective and safe device relevant to be used in procedures requiring filling with a bone substitute. Furthermore, in both cohorts, the investigator qualified the filling phase as ‘easy’, and the device handling / usability as ‘good’ in all procedures (100%).

Teknimed is also performing a continuous surveillance of all safety events related to its devices. During the last 5 years, no serious incidents, no complaints with a patient impact, involving TRIHA+®, were registered in Europe and worldwide. No materiovigilance reports or batch recalls were registered for competing products for the last current year. And no trend for device malfunction leading to patient harm or new risk were identified.

The outcomes presented above can be compared to outcomes reported in published series and previously summarized as follows:

Spine indication	Benchmarked acceptable outcomes (reported in published series)	Outcomes from Teknimed PMCF study
Radiological criteria	Fusion rate > 80% at 12-month FU	100% of patients presenting TCP integration and bone regeneration (85.7% of patients with more than 50% of the defect occupied by new bone formation)
Clinical criteria	Improvement of VAS by 4.5 (/10) points at FU vs baseline Improvement of Quality of Life at FU vs baseline	Improvement of VAS by 4.4 (/10) points at FU vs baseline Quality of life improved by 5 (/10) points at FU vs baseline 100% of satisfied patients at FU
Safety criteria	No complication	No complication

Orthopaedic indication	Benchmarked acceptable outcomes (reported in published series)	Outcomes from Teknimed PMCF study
Radiological criteria	> 60% of TRIHA+ integration or bone remodeling at FU	100% of patients presenting TCP integration and bone regeneration (64.2% of patients with more than 50% of the defect occupied by new bone formation)
Clinical criteria	- Pain alleviation - Functional score (Lysholm) > 85/100	Improvement of VAS by 6 points Quality of life improved by 5 points (/10) at FU vs baseline 100% of satisfied patients
Safety criteria	No complication	No complication

All outcomes from the PMCF study are compliant with the benchmarked outcomes identified from the literature on similar devices, confirming the performance and safety of use of TRIHA+®.

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

Teknimed is still currently conducting the post-market clinical follow-up of which interim outcomes are presented above to continuously assess clinical, safety and usability for its Bone Substitutes family of products, including TRIHA+®.

Title: Safety and Clinical Performance Assessment of Bone Substitutes used for Bone Voids Filling - A Post-Market Clinical Follow-Up

Justification/Context: TEKNIMED has developed several bone substitutes currently used in various types of surgery. Due to their increasing use, there is a need of real-life safety and efficacy data on these products.

Objective: The objective is to collect immediate, medium and long-term data (up to 5-year), on the related clinical functional outcomes and complications of market-approved TEKNIMED bone substitutes to assess performance and safety of these products in their current clinical use.

Study design: Global, non-controlled, multi-centric, ambispective observational study. Patients will be followed as per local standard medical practices of the investigational sites. Data will be collected pre-operatively, at surgery and at standard of care follow-up visits. A total of 575 patients will be included for TRIHA+®.

Primary endpoint: Successful bone repair, evaluated through the rate of revision surgery due to failure of the substitute.

Performance endpoints: Bone remodelling, well-being and satisfaction of patients, usability and satisfaction of surgeons

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

6. Possible therapeutic alternatives

Bone grafting is required when the size of the void to be rebuilt is important or when the rebuilding is at risk of being slow (delayed union, disease, old patient…). Several categories of bone grafts exist, which encompass a variety of materials, material sources, and origins, such as:

- Autografts (58% of the bone grafts) which are harvested from the patient's own bone tissue, typically the iliac crest,
- Allografts (34% of bone grafts) which are obtained from banked freeze-dried bones of human cadavers,
- Xenografts which are harvested from one individual and transplanted into another individual of a different species. The common available xenografts are derived from coral, porcine, or bovine source.

All these grafts give good clinical results but, for the patient, they remain at risk of immune reaction leading to acute inflammation, and of infection at the site of collection of the graft. Synthetic bone substitutes, fully biocompatible, have been designed to avoid these types of adverse events.

Therapeutic alternatives	**Advantages** (as reported in the literature)	**Disadvantages** (as reported in the literature)
Natural bone grafts		
Autograft	Complete histocompatibility and good osteoinduction properties[1]	High rate of complications: up to 25% persistent donor site pain, paraesthesia, haematoma and infection[2] , and even 60% of long-term, persistent donor site pain[3]
Allografts	Comparable results to the use of autograft[4]	Limited bone synthesis[4]
Xenograft	No risk of complications at harvesting site[5]	Residual pain and bone non-union[5]
Synthetic bone substitute		
Monophasic tricalcium phosphate	Absence of allergenicity, bioresorbability, and excellent osteoconductivity[6]	No osteoinduction properties and no mechanical properties[6]
Hydroxyapatite	Optimal biocompatibility and osteotrophicity, no toxicity, no antigenicity[3]	Poor outcomes: 46.2% non-union rate in one-level fusion and up to a 75% non-union rate in three-level fusion[3]
Biphasic calcium phosphate	Shortened hospital stays, reduced donor site complications, decreased operative time and blood loss related to ICBG harvesting[3]	Longer fusion time[3]
Calcium sulphate	Osteoconductive properties and good patient toleration[6]	-

No consensus has been clearly established in the literature, relative to which graft is more indicated in which bone defect. The choice belongs to the surgeons, considering the patient's condition (allergies, risk of inflammatory response…), the shape (surgical osteotomy, bone cyst curettage…) and the size (wide or small defect) of the bone defect, or the usage (bone void filling, cage filling) of the graft.

[1] Epstein NE. (2006) A preliminary study of the efficacy of Beta Tricalcium Phosphate as a bone expander for instrumented posterolateral lumbar fusions. J Spinal Disord Tech. 19:424–429

[2] Salamanna F, Tschon M, Borsar, V, Pagani S, Martini L, and Fini M. (2020). Spinal fusion procedures in the adult and young population: a systematic review on allogenic bone and synthetic grafts when compared to autologous bone. J Mater Sci: Mater Med *31*, 51

[3] Cho, D.-Y., Lee, W.-Y., Sheu, P.-C., and Chen, C.-C. (2005). Cage containing a biphasic calcium phosphate ceramic (Triosite) for the treatment of cervical spondylosis. Surgical Neurology *63*, 497–503

[4] Guerado E, Fuerstenberg CH. (2011). What bone graft substitutes should we use in post-traumatic spinal fusion? Injury *42*, S64–S71.

[5] Xie, Y., Chopin, D., Morin C., Hardouin, P., Zhu Z., Tang J. and Lu, J. (2006a). Evaluation of the osteogenesis and biodegradation of porous biphasic ceramic in the human spine. Biomaterials 27 (2006) 2761–2767.

[6] Panchbhavi, V.K. (2010). Synthetic Bone Grafting in Foot and Ankle Surgery. Foot and Ankle Clinics *15*, 559–576.

7. Suggested profile and training for users

Medical devices should only be used in an adapted environment (operating room) and by qualified clinicians (orthopaedic surgeons or neurosurgeons). This product is a ready-to-use device. Its preparation technique is detailed in the accompanying Instruction For Use. Qualified distributors can also provide advises on its use. The clinician 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 manufacturer nor qualified distributor 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 13175-3	2012	Implants chirurgicaux Phosphates de calcium Partie 3 : Substituts osseux à base d'hydroxyapatite et de phosphate tricalcique bêta	Fully whenever applicable
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
ASTM F 1088	2018	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation	Fully whenever applicable
ASTM F2503	2020	Standard Practice for Marking Medical Devices and other items for safety in the Magnetic Resonance 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	2022	Biological evaluation of medical devices — Part 2: Animal welfare requirements	Fully whenever applicable
EN ISO 10993-3	2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Fully whenever applicable
EN ISO 10993-5	2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Fully whenever applicable
EN ISO 10993-6	2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation	Fully whenever applicable
EN ISO 10993-9	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 10993-17	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 F 88	2021	Standard test method for seal strength of flexible barrier materials	Fully whenever applicable
ASTM F1980	2021	Standard Guide for accelerated aging of sterile medical packages	Fully whenever applicable
ASTM D 6344	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

> 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
EN ISO 11138-1	2017	Sterilization of health care products — Biological indicators - Part 1: General requirements	Fully whenever applicable

> Sterilisation standards

EN ISO 11137-1	2015 A2:2019	Sterilization of health care products — Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Fully whenever applicable
EN ISO 11137-2	2015	Sterilization of health care products — Radiation - Part 2: Establishing the sterilization dose	Fully whenever applicable
EN ISO 11137-3	2017	Sterilization of health care products — Radiation - Part 3: Guidance on dosimetry aspects	Fully whenever applicable

9. Revision history

Revision number	Date issued	Change description	Revision validated by the Notified Body
1.0	15 MAR 2023	Creation	☐ Yes, language: English ☑ No
1.1	NA	misnumbering of version	NA
1.2	JUN 2023	Update following on-site initial MDR clinical review: - modification of information on composition in 3.1. - correction of section 3.2. - addition of radiological outcomes, PMS data, and summary of PMCF outcomes versus benchmarked criteria in section 5.4. - rephrasing in the table of advantages / disadvantages of therapeutic alternatives and addition of literature references in section 6. - rephrasing of intended users in section 7. - update of the Revision History table in section 9.	☐Yes, language: English ☑ No
1.3 1.3.1	29 SEP 2023	1.3.: Update following Round2 MDR Clinical review: - addition of CAS number for chemical components - addition of graft displacement and non-union side effects - addition of “specific” - complement in “Warnings and Precautions” of the SSCP for patients 1.3.1.: correction of % of porosity	☑ Yes, language: English ☐ No

A summary of the safety and clinical performance of the device, intended for patients, is provided on next page.

SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for PATIENTS - English Version

TRIHA+®

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: **TRIHA+®**

The medical device has also the following private labels: Optibone, Royal Granules, Z-Bone Granules and Bone Fuse.

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. Basic UDI-DI: **376017704B10CT**

1.4. Year when the device was first CE-marked: **2002**

2. Intended use of the device

2.1. Intended purpose

TRIHA+® is a ceramic having a composition close to human bone. It is used by surgeons to fill gaps or defects in bones. This ceramic supports ingrowth of newly formed bone.

2.2. Indication(s) and intended patient groups

Indication: TRIHA+® is used to fill bone defects in spine or surgery after an accident.
Target population: Adult patients with a bone defect due to bone injury or surgical procedure.

2.3. Contraindications

- Procedures other than those stated in the INDICATIONS section
- Treatment of large bone defects. Without reinforcement by plate, screw, nail, cage… the bone could be damaged
- Use in patients susceptible to allergic reactions to the products components
- Not enough data are available on some categories of patients. TRIHA+® cannot be used in children. TRIHA+® cannot be used in breast-feeding or pregnant women.

3. Device description

General description of the device: TRIHA+® is a ceramic made of synthetic bone. It is used by surgeons to fill gaps or defects in bones. This ceramic supports ingrowth of newly formed bone.

Operating principles and mode(s) of action: After implantation, TRIHA+® is resorbed. It is replaced by new bone during the healing process.

Design characteristics: TRIHA+® is made of calcium phosphate (Tricalcium phosphate or TCP).

Chemical Composition	
Tricalcium phosphate: $Ca_3(PO_4)_2$	100%

Different sizes are available (granules, chips, sticks). The surgeon can adapt the volume of product to the defect.



Pictures of granules of TRIHA+

Lifetime: TRIHA+® can be used only once. After implantation, it is expected to be totally absorbed after a minimum of 2 years. It can depend on the size of the defect. It can depend on the indication. It can depend on the state of the patient. TRIHA+® should not be removed. It doesn't need any maintenance unless a medical complication would require surgery.

Sterilisation: TRIHA+® is delivered sterile. The product is single use.

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

No issue (pain, infection or inflammation) related to the device have been reported (in literature or in clinical studies on the product). They are however risk linked to any surgical procedure.

Any serious incident occurring in relation to the device must be reported without delay to the physician, the manufacturer and the competent local authority where the patient is established.

4.2. Warnings and Precautions

No warning and precautions for use are applicable for patients. This device is only used by healthcare professionals.
No specific precautions are to be taken by the patients during healing period. To avoid situations that could compromise their healing, patients must follow the postoperative protocol and the schedule of follow-up visits assigned by their physician and adapted to their specific surgery.

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

No FSCA have been issued since the release of TRIHA+® on the market.

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

5.1. Clinical background

Synthetic bone substitutes have been developed more than 50-year ago. They offer an alternative to the bone grafts of human or animal origins.
TRIHA+® is a well-known device which has been sold for more than 21 years. A long history of surveillance of its safety since its release on the market has proved that it carries no significant risks.

5.2. Clinical evidence for CE marking

Clinical studies have been done. They confirm the performance and safety.

Clinical study 1
The product was implanted in patients with spine issue (degenerative Disk Disease treated by posterolateral fusion procedure). All patients were satisfied. They reported a better or a stable health status. All patients would redo the surgery again. No adverse events or complications were reported.
The product was implanted in patients with fractures (surgical reduction of an open traumatic fracture). All patients were satisfied. They reported a better or a stable health status. All patients would redo the surgery again. No adverse events or complications were reported.

Clinical study 2 (on-going)
Teknimed is conducting a new clinical study (post-market clinical follow-up). Its goal is to confirm performance and safety. The objective is to collect immediate, medium and long-term data (up to 5-year). Performance and safety of the product will be assessed.

5.3 Safety

Teknimed is always doing clinical studies (Post-Market Surveillance and Clinical Follow-up). They document and evaluate the benefits and risks of TRIHA+®.
Benefits for the patients are a pain alleviation and a better health status.
No residual risks were identified.
When looking at risk versus benefits, the product is considered safe.
Teknimed is currently conducting a new clinical study on TRIHA+®. Its goal is to check safety and performances.

6. Possible therapeutic alternatives

Bone grafting is required when the size of the zone to be rebuilt is important or when the rebuilding is at risk of being slow (delayed union, disease, old patient…). Several categories of bone grafts exist, such as:

- Autografts (58% of the bone grafts) which are harvested from the patient's own bone tissue, typically the iliac crest;
- Allografts (34% of bone grafts) which are obtained from banked freeze-dried bones of human cadavers;
- Xenografts which are harvested from one individual and transplanted into another individual of a different species. The common available xenografts are derived from coral, porcine, or bovine source.

Finally, the choice of the type of graft to use belongs to the surgeons. Multiple factors must be considered: patients' health status (allergies, risk of inflammatory response…), the shape and the size of the bone defect, or the kind of indication (bone void filling, cage filling) of the graft.

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. They need to be expert in orthopaedic or spine surgery.