SUMMARY of SAFETY and CLINICAL PERFORMANCE
SSCP

BIORESORBABLE PINS

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

BIORESORBABLE PINS

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: **BIORESORBABLE PINS**

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: **376017704B17D9**

1.5. Medical device nomenclature description / CND nomenclature: **P09120606 - Osteosynthesis devices, biodegradable screws and bars**

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: **2004**

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

Country	Year of introduction
Europe	2004
Soudan	2015
Ukraine	2016
Macedonia	2017
Uruguay	2019
Lebanon	2020
Morocco	2020
Jordan	2021
Colombia	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

The BIORESORBABLE PIN is intended for the stabilization of metatarsal and phalangeal realignment in osteotomy procedures.

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

Indications

The BIORESORBABLE PINS are indicated for the treatment of hallux valgus.

Target populations

Adult patients suffering from hallux valgus.

2.3. Contraindications or restriction for use

- Procedures other than those stated in the INDICATIONS section.
- Insufficient bone quantity or quality which can compromise correct anchoring of the pin.
- 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

BIORESORBABLE PINS are simple rods, made of a bioresorbable material (PLA), which can be inserted into pre-drilled bone tunnels. They are used in osteotomy procedures for patients with hallux valgus deformities which were not responsive to conservative treatments.

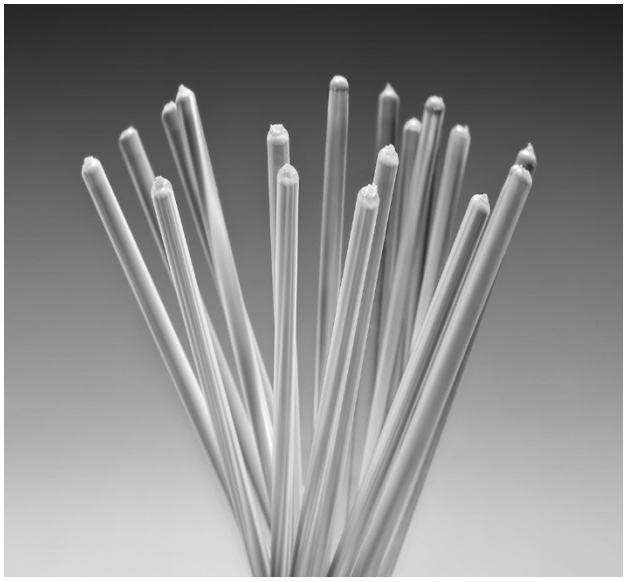

Figure 1: BIORESORBABLE PINS

BIORESORBABLE PINS are made of 100% Poly(70/30; L/DL)lactide (PLA).

BIORESORBABLE PINS are available in 2 references (length = 60 mm):

Designation	Diameter	Length	Reference
BIORESORBABLE Pin	2.0 mm	60 mm	T7100220
BIORESORBABLE Pin	2.4 mm	60 mm	T7100224

Lifetime:
The pin 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.

BIORESORBABLE PINS 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. BIORESORBABLE PINS aren't issued from previous generations and have no variant.

3.3. Description of any accessories which are intended to be used in combination with the device
It is recommended to use the BIORESORBABLE PINS with the dedicated stainless still pins (sold separately).

Designation	Diameter	Length	Reference
Stainless Steel Pin	2.0 mm	150 mm	T067120
Stainless Steel Pin	2.4 mm	150 mm	T067124

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 the BIORESORBABLE PINS.

4. Risks and warnings

4.1. Residual risks and undesirable effects
- Complications usually encountered with bioabsorbable implants: inflammatory reaction (0.8% giant cell granuloma in a published series[1]).
- Complications usually encountered with pin: failure of the fixation, migration and protruding of the pin (up to 8.3% in the TPLC database, up to 5.3% of cases in a Teknimed clinical study (Cf section 5 below), pin breakage (up to 8.3% in the TPLC database).
- Other reported side effects include: pain and swelling (2.6% in the Teknimed clinical study, Cf. section 5 below), wound healing issues (1.3% in the Teknimed clinical study, Cf. section 5 below; up to 3.5% of dehiscence and 8.6% of superficial cellulitis in a published series[2]).
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 for use
Read instructions for use carefully prior to use and follow preparation and handling instructions of BIORESORBABLE Pin. 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

[1] Morandi, Alberto, Emanuele Ungaro, Andrea Fraccia, et Valerio Sansone. 2013. Chevron Osteotomy of the First Metatarsal Stabilized with an Absorbable Pin: Our 5-Year Experience. *Foot & Ankle International* 34 (3): 380-85. Doi: 10.1177/1071100712464956.

[2] Rocchio, Thomas M. 2018. Resorbable Polymer Pin Inserted with Ultrasound Activated Bone Welding Technique Compared with a Screw for Osteotomy Fixation in the Reverse L Bunion Correction. *Clinics in Podiatric Medicine and Surgery* 35 (4): 373-85. doi: 10.1016/j.cpm.2018.05.001.

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 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.

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 bioresorbable pins 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 their first CE-marking, the BIORESORBABLE PINS were assessed and endorsed by the Notified Body on the basis of their equivalence with other marketed bioresorbable pins. 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

BIORESORBABLE PINS are issued from a well-known technology which has been used in orthopaedic surgeries for many years. They allow successful realignment of the metatarso-phalangeal joint of the big toe of patients suffering from hallux valgus, leading subsequently to clinical benefits such as restoration of function and improvement in quality of life. Claims for performance and safety of BIORESORBABLE PINS 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: 56 patients (49 females and 7 males, mean age 31-year, min 28 – max 79) of whom 19 bilateral patients operated on both feet, for a total of 75 operated toes. All patients suffered from a difficult shoe fitting, an important discomfort and pain, associated to critical bone alignment.

Surgery procedures: The device was reported to be 'easy to use' and the surgeon was 'very satisfied' but for 1 exception: a procedural complication due to the small size of the toe bone for which implantation was reported to be difficult and led to pin breakage. All Pins fixations were reported to be stable per-surgery. The surgeon was always satisfied with the usability of the device and its instrumentation. No complications or adverse events were reported during the surgery.

Clinical outcomes: Patients had a first follow-up visit (ST-FU) at 0.97 ±0.16 months post-surgery, a mid-term (MT-FU) follow up visit at 4.42±1.77 months post-surgery and a long-term follow-up (LT-FU) at 8.79 ±0.89 months post-surgery.
Pain and Antalgic Consumption: Pain clearly improved shortly after surgery, decreasing from an average level of 7.7/10 at baseline to 1.26/10 at ST-FU. Pain level kept improving to almost 0 (i.e.: no pain at all) at MT-FU and remained at this level at LT-FU. Before surgery, all toes (100%) were painful. At ST FU, 96% of toes were reported with 'No pain', and no more patients reported a 'high' toe pain. This improvement was maintained at MT-FU with a majority of toes (88%, n=44) with 'No pain'. An increase of stage 1 antalgic consumption at ST-FU was observed, that could be related to usual post-surgery pain management. Antalgic consumption drastically decreased at MT-FU where only 7% (n=5) of patients used painkillers.

Correction of toe alignment: Before surgery, 63 (88.7 %) toes presented a 'poor' alignment. At ST-FU, 96.6% of treated toes presented a correction of deformity and a 'good' toe alignment. This correction was maintained at the MT-FU with 95.6% of toes presenting a 'good' alignment.
Patients' well-being and satisfaction: Patients' general health status was stable at ST-FU, compared to baseline. Patients' well-being tends to slightly decrease during the recovery period (first weeks/month post-surgery) and then improve at longer-term FU.

Radiological outcomes: A stable fixation of the device is observed over time, with no resorption during the follow-up period. At MT-FU, bone regeneration was observed in 83.3% (n=60) of toes and no osteolysis was reported.

Safety: Only 1 complication, not related to the device, occurred before ST-FU: an infectious flow on a stitch due to a non-compliance with the post-operative procedure by the nurse (the bandage was changed too early). This infection was treated locally by surgery and cleaning, and systemically by antibiotics, and was resolved without sequelae. At MT-FU, 7 cases of pain were reported, associated or not with stiffness or oedema, at the level of the operated toe, the concerned foot or the related ankle. 2 of these events were treated surgically (removing or shaving the pin) or with medical devices (i.e.: contention socks or orthopaedic insoles). 5 events were resolved without sequelae, 2 events (stiffness + painful toe) are still ongoing. At LT-FU, 4 cases of pain (due to protrusion of the pins) at the operated toe, were reported. They occurred at an average 9,75 ±0,96 months post-surgery. They were all treated surgically and resolved without sequelae.
Conclusion: To conclude, this long-term outcome analysis demonstrates that BIORESORBABLE PINS used in association with the Stainless-Steel pin instrumentation are effective and safe devices relevant to be used for bone alignment correction in Hallux Valgus.

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

During the past 5 years period (from OCT 2017 to SEP 2022), no complaint involving a BIORESORBABLE PIN screw was reported. No trend for device malfunction leading to patient harm was detected for the reviewed period. 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 (section 5.4.A) is still on-going. New patients will be included and followed-up all along the placement of the device on the market to continuously verify its claimed performances and safety and to detect any trends for new or unexpected risks.

6. Possible diagnostic or therapeutic alternatives

The initial treatment is often self-directed in patients when symptoms affect their lifestyle, consisting of wider, lower-heeled shoes, bunion pads, ice, and over-the-counter analgesics. If unresponsive to the initial treatment, anti-inflammatory non-steroidal drugs may be prescribed in case of symptomatic arthralgias or bursitis. Shoe modifications can be performed, as well as the use of insoles or toe spacers. Meta-analysis showed that orthosis with a toe separator had the best effect on HVA correction, and was critical for the patients' pain relief by acting as a means of biomechanical support to reduce the pressure on the first metatarsal joint and then preventing further degeneration of mobility. A combination of exercise and toe separator, night splints, and dry needling might be a good choice for reducing hallux valgus angles.
Surgical treatment should be considered if there is only a little or no improvement with non-surgical care. It is important to consider that relief of the patient's symptoms should be more important than the simple correction of the appearance (aesthetic goals), considering the occupation, the general condition and the daily activities of the patient. There are more than a hundred different surgical methods to correct hallux valgus, and no consensus about the optimal surgical strategy, which depends on the severity of the deformation. The corrective action for hallux valgus is not only to restore alignment but also to reconstruct the function of the first ray. To achieve these, both distal soft tissue procedures and osseous surgeries can be performed. Osseous surgeries are aimed to correct structural deformities, while soft tissue procedures help to restore the balance of the first metatarsal phalange.

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
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects — Good clinical practice	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
EN ISO 178	2019	Plastics — Determination of flexural properties	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	FEB 2023	Creation	☐ Yes, language: English ☑ No
1.1	JUN 2023	Update following initial MDR clinical review (BSI): - Section 4.1.: addition of wound healing issues - Section 5.5.: precision on the continuous inclusion of patients in the PMCF study	☐ Yes, language: English ☑ No
1.1.1	JUN 2023	Update of §9. Revision History	☑ Yes, language: English ☐ No

SUMMARY of SAFETY and CLINICAL PERFORMANCE (SSCP) for PATIENTS

BIORESORBABLE PINS

Document revision: 1.0
Date issued: FEB 2023

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

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

1. Device Identification and general information

1.1. Device Trade Name: **BIORESORBABLE PINS**

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: **376017704B17D9**

1.4. Year when the device was first CE-marked: **2004**

2. Intended use of the device

2.1. Intended purpose

The device is used to keep aligned cut bones (stabilization of metatarsal and phalangeal realignment in osteotomy procedures).

2.2. Indication(s) and intended patient groups

Indication:
The device is used to treat big toe deformity (hallux valgus).

Target Population:
Adult patients suffering from big toe deformity (hallux valgus).

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 pin.
- Do not use in case of intolerance to constituents of the product.
- Not enough data are available on some categories of patients. The device cannot be used in children. The device cannot be used in breast-feeding or pregnant women.

3. Device description

They are simple rods. They are made of a bioresorbable material (PLA). They can be inserted into pre-drilled bone tunnels. They are used in osteotomy procedures for patients with hallux valgus deformities which were not responsive to conservative treatments.

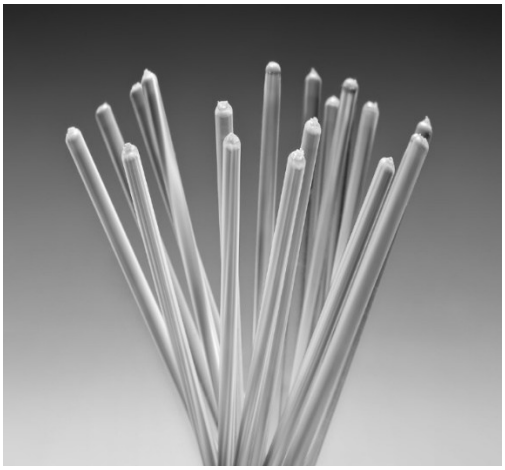

Figure 2: BIORESORBABLE PINS

They are made of 100% Poly(70/30; L/DL)lactide (PLA).
They are available in 2 references (length = 60 mm):

Designation	Diameter	Length	Reference
BIORESORBABLE Pin	2.0 mm	60 mm	T7100220
BIORESORBABLE Pin	2.4 mm	60 mm	T7100224

Lifetime:
The pin 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.
They 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 (0.8% giant cell aggregation of white blood cells (granuloma) in a published series), active resorption of bone matrix (osteolysis).
- Interference pins can lead to some issues: failure of the fixation, migration and protruding of the pin (up to 8.3% in the TPLC database, up to 5.3% of cases in a Teknimed clinical study, pin breakage (up to 8.3% in the TPLC database).
- Other side effects have been reported: pain and swelling (2.6% in the Teknimed clinical study), wound healing issues (1.3% in the Teknimed clinical study and up to 8.6% in a published series).

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

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 BIORESORBABLE PIN on the market.

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

5.1. Clinical background

The device comes from a safe technology. It has been used in surgery for many years. It repairs big toe deformity. 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 (56 patients). No issues (complications or adverse effects) were reported. Surgeon was “very satisfied” with the device. One exception: one issue due to the small size of the bone.
Pain clearly improved shortly after surgery (from 7.7/10 to 1.26/10). This level of pain remained constant.
The correction of the toe alignment was considered “good” in 96.6% of the cases.
A stable fixation of the device is observed over time. No resorption is observed during the follow-up period.
Only 1 issue was recorded. It was not due to the device (infectious flow on a stitch). 7 cases of pain were reported.
This long-term clinical study shows the clinical performances and safety of the product.

5.3 Safety

Clinical studies and surveys are always conducted. They document and evaluate the benefits and risks of the device. No complaints have been received during the past five years.

6. Possible diagnostic or therapeutic alternatives

First patient may use easy solution (wider, lower-heeled shoes, bunion pads, ice, and over-the-counter analgesics). If pain is still present, drug may be prescribed (anti-inflammatory non-steroidal drugs in case of symptomatic arthralgias or bursitis). Shoe modification can also be done.
If non-surgical care is not working, surgery should be considered. Relief of the pain should be more important than the simple correction of the appearance. More than a hundred different surgical methods exist to correct hallux valgus. No consensus exists about the best surgical strategy. It depends on the severity of the deformation.

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 absorbable pins.