Triway®

TIBIOTALOCALCANEAL (TTC)
ARTHODESIS SYSTEM

Legal manufacturer

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Single Registration Number is: FR-MF-000005246

Device trade name

TRIWAY®
Tibiotalocalcaneal (TTC)
Arthrodesis System

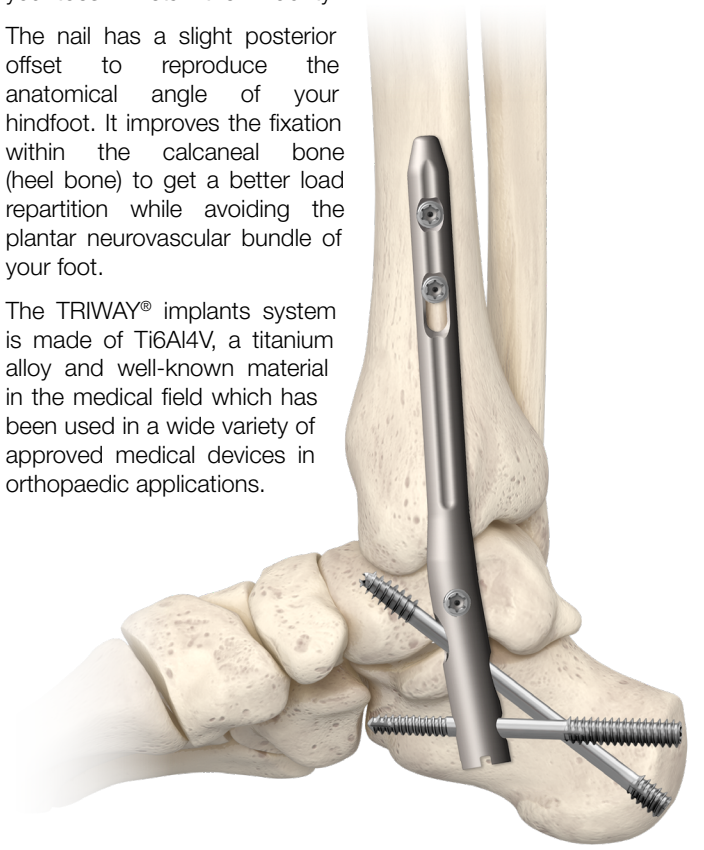
Description of the device

The TRIWAY® Tibiotalocalcaneal (TTC) Arthrodesis System is a nail system for ankle arthrodesis. The ankle arthrodesis is an ankle fusion surgery where the hindfoot and the ankle are stabilized in order to treat your condition or trauma (see further details in paragraph “Indications and intended patient population”). The arthrodesis is achieved by fusing the tibia, talus (ankle bone) and calcaneus (heel bone) thanks to the TRIWAY® system.

The TRIWAY® system is composed of an angulated nail available in several sizes and different screws for bony fixation. The nail is inserted into the marrow cavities of the bones and five screws are inserted through the nail to secure the system with a robust multi-directionally fixation and consolidate the ankle. Your forefoot and your toes will retain their mobility.

The nail has a slight posterior offset to reproduce the anatomical angle of your hindfoot. It improves the fixation within the calcaneal bone (heel bone) to get a better load repartition while avoiding the plantar neurovascular bundle of your foot.

The TRIWAY® implants system is made of Ti6Al4V, a titanium alloy and well-known material in the medical field which has been used in a wide variety of approved medical devices in orthopaedic applications.



Materials / Substances

The TRIWAY® implants are made of a titanium alloy Ti6Al4V according to ISO 5832-3 and ASTM F136 standards.

The TRIWAY® implants are implants in permanent contact (i.e. greater than 30 days) with bone. Appropriate biological safety evaluation was performed in compliance with relevant standards in force, ensuring biocompatibility of these implants. However, sensitivity / allergic reactions cannot be anticipated and are patient specific. The implant should not be used if you currently have or have an history of sensitivity / allergies to the implant materials listed above.

The devices do not contain any CMR (carcinogenic, mutagenic or toxic for reproduction) or endocrine-disrupting substances referred to in Section 10.4.1 of Regulation (UE) 2017/745 Annex I.

Indications and intended patient population

The TRIWAY® system is intended to be used for adult patients for a tibiotalocalcaneal arthrodesis to treat trauma to the hindfoot and distal tibia.

Examples include:

- Post-traumatic and degenerative arthritis involving both ankle and subtalar joints
- Rheumatoid arthritis with severe deformity
- Revision of failed ankle arthrodesis with subtalar involvement or with insufficient talar body
- Revision of failed total ankle arthroplasty with subtalar intrusion
- Talar deficiency conditions, including avascular necrosis (requiring a tibiocalcaneal arthrodesis)
- Neuroarthropathy or neuromuscular deformity or other neuromuscular disease with severe deformity or instability of the ankle, including Charcot foot
- Severe pilon fractures with trauma to the subtalar joint
- Malunited tibial pilon fractures

More simply said, this is an implant system that your surgeon may want to use to treat your condition by fusing bones of your hindfoot and stabilize your ankle joints.

Contraindications and/or limitations

The TRIWAY® system should not be used in a patient who currently has, or who has history of:

- Acute or chronic inflammations,
- Active infections,
- Sensitivity/allergies to the implant materials,
- Bone pathologies that may compromise the rigidity of the implant fixation (examples include: osteoporosis, acute cystic development, acute osteopenia, bone tumor, etc…).

Warnings and precautions

Before implantation, your physician shall determine if the device is appropriate for you if you have any of the following conditions:

- Lack of good general physical condition,
- Use of steroid derivatives, chemotherapy
- Drug and/or alcohol and/or smoke addiction and/or abuse,
- Obesity,
- Compromised wound healing,
- Vascular disorder,
- If you are unwilling or unable to comply with postoperative instructions.

Detailed instructions on the use and limitations of the device should be given to you by your surgeon.

Some X-rays should be periodically done to check the postoperative progress and prevent any complication.

If partial weight-bearing is recommended or required, you must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident. You are encouraged to report to your surgeon any unusual changes of the operated extremity. If evidence suggests loosening of the implant (particular pain and progressive changes in the radiographs), your surgeon may advise an intensified schedule of check-ups and give you new warning and instructions regarding further activity restrictions.

You are encouraged to receive prompt medical attention for any infection that could occur, whether at your operated-member level or elsewhere in the body.

MRI safety information

Before any medical examination, you shall systematically mention that you are implanted with a surgical orthopaedic implant.

Non-clinical testing and electromagnetic simulations were performed to evaluate the orthopedic implants from In2Bones® under MRI conditions. The tests demonstrated that the TRIWAY® implants system is “MR Conditional”: it means that you can be scanned safely in an MR system under specific conditions. Before an MRI scan involving your foot in which a TRIWAY® implant is in place, you shall communicate to your healthcare provider that the following conditions should be used:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Removal of the implant

The implant is intended to be permanent once in place. However, you should be advised that a second more minor procedure for the removal of the implants may be necessary. Particularly in young active patients, the implants may loosen, fracture, migrate, increase the risk of infection, cause pain, or cause reduction in bone density due to a phenomenon called stress shielding even after normal healing. Thus, your surgeon can decide to remove the implant if it is deemed necessary. The removal involves careful postoperative management to avoid re-fractures. If you are elderly with low activity level, your surgeon may elect not to remove the implant to eliminate the risk of another surgery.

Remaining risks and undesirable effects

Contact your surgeon 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 surgeon if needed.

The possible side-effects that can be encountered with the device after the surgery are the followings:

- Pain, discomfort or abnormal sensations due to presence of the implant,
- Implant bending, loosening and/or breakage,
- Migration of the implant position,
- Loss of fixation in bone,
- Limb shortening,
- Bone loss due to stress shielding,
- Deformation recurrence, loss of correction,
- Delayed union or pseudarthrosis,
- Stress fracture,
- Irritational injury of soft tissue, including impingement syndrome,
- Infections, hematoma, allergy, thrombosis.
- Tissue irritation (tendon, nerve, soft tissue),
- Adjacent joint osteoarthritis,
- Foreign body reactions of the tissues adjacent to implants.

Adverse effects may necessitate re-operation, revision or removal surgery and/or amputation of the limb.

The full list of remaining risks and undesirable side effects can be found in the Summary of Safety and Clinical Performance at: https://ec.europa.eu/tools/eudamed

Every serious incident that you may experience in relation to the device should be reported without any delay to the manufacturer and, depending on your location, to the:

- European Union: Competent authority of your country https://ec.europa.eu/
- Australia: Therapeutic Goods Administration https://www.tga.gov.au