

INSTRUCTION FOR USE

IMPORTANT MEDICAL INFORMATION
TIGERTRACK® and EXRAY® system

Reference: SUP_7.049 version 1
Product manufactured by:



ADSM

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CAUTION: USA Federal law restricts this device to sale by or on the order of physician.

INTENDED USE

The TIGERTRACK® and EXRAY® screws system is intended for small bone extremity and large/long bone reconstruction fixation/arthrodesis procedures for general use in skeletally mature individuals. The TIGERTRACK® screws system is intended to be permanently implanted without any other additional device and are delivered sterile.

PURPOSE

The TIGERTRACK® and EXRAY® screws are designed to relieve pain and disability of the forefoot by attaching and stabilising bone segments in elective osteotomies on metatarsal bones and phalanges of the foot, in order to optimise the correct bone fusion of the segments concerned. These devices are only intended for use in the forefoot of a mature skeleton.

DESCRIPTION

The TIGERTRACK® screw system is intended for single use and is composed of TIGERTRACK® self-compressive headless screws (TIGER22, TIGER29 and TIGER45), TIGERTRACK® snap-off screws (TIGER18 and TIGER25) and Weil's snap-off screws TIGER1W.

TIGERTRACK® self-compressive headless screws (TIGER22, TIGER29 and TIGER45) comprise a single part implant. These self-compressive headless screws are available in several different diameters and lengths. Snap-off TIGERTRACK® screws (TIGER18 and TIGER25) comprise a single part implant fitted with a threaded portion and a snap-off connector portion with a wider diameter. These are self-compressive, headless screws.

Weil's snap-off TIGERTRACK® screws (TIGER1W) comprise a single part implant fitted with a threaded portion and a snap-off connector portion with a wider diameter. These are self-compressive screws with a head.

TIGERTRACK® screws are manufactured in Ti-6Al-4V ELI titanium according to Standard ISO 5832-3 / ASTM F 136. With the exception of the TIGER18 which is manufactured in a chrome-cobalt alloy according to ISO 5832-7.

The EXRAY® screw system is intended for single use and is comprised EXRAY® 30 and EXRAY® 35 screws.

EXRAY® 30 screws comprise a single part implant. These 3mm self-compressive headless screws are available in several different lengths.

EXRAY® 35 screws comprise a single part implant. These 3.5mm self-compressive headless screws are available in several different lengths.

EXRAY® screws are manufactured in PEEK according to Standard ASTM F2026.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE SIDE EFFECTS

Indications:

The TIGERTRACK® and EXRAY® screws system is intended for small bone extremity and large/long bone reconstruction fixation/arthrodesis procedures for general use in skeletally mature individuals. The TIGERTRACK® and EXRAY® screws system is intended to be permanently implanted without any other additional device and are delivered sterile.

The TIGERTRACK® and EXRAY® screws system, diameters 3.5mm or smaller (1.8mm, 2.2mm, 2.5mm, 2.9mm, 3.0mm), is indicated for use in fixation small bone fractures or for small bone reconstruction including: mono or bicondylar osteotomies in the foot or hand; distal or proximal metatarsal or metacarpal osteotomies; well osteotomy; fusion of the first metatarsal phalangeal joint and interphalangeal joint; fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.); Akin type osteotomy; distal radius fractures (articular fragments), ulnar styloid fractures, radial head fractures, capitellum fractures, humeral head fractures, glenoid fractures, intercarpal distal and proximal fusions, malleolar fractures, patellar fractures, osteochondral fractures, talonavicular fusions, tibiotalar fusions, and cuboid fusions.

The TIGERTRACK® screws system, with diameters 4.5mm, is indicated for use for fractures, corrective osteotomies, pseudoarthrosis, degenerative transformations of long bones in the hindfoot and large bone intra-articular fractures of the humerus, femur, and tibia. The size of the chosen screw should be adapted to the specific indication.

The TIGERTRACK® and EXRAY® screws system is not for spinal use.

The devices described in this manual must be accompanied with a form of immobilisation suited to the pathology being treated.

CAUTION: to be used by or on the order of a surgeon. The surgeon must take note of the documents accompanying the device. No specific training is required for the understanding and use of the device. The surgeon's qualifications and the reading of the accompanying documents are enough.

Contraindications:

A non-exhaustive list of contraindications is as follows:

Therapeutic:
Generalised or localised infection including immune deficiency, local inflammation; pregnancy; obesity; fever; abnormal increase or decrease of leucocytes; mental illness affecting the patient's ability to follow postoperative procedure; allergy or intolerance to the materials contained in the device; malignant tumours; serious hereditary abnormalities or diseases; abnormally high or unexplained sedimentation rates due to some other identified disease; an increase or decrease in the number of white cells; any other surgical or medical contraindication likely to compromise the desired result, such as abuse of drugs, medicines or alcohol; progressive joint diseases such as rheumatoid polyarthritis or other; osteoporosis that is either serious, or at a level likely to be detrimental to the stability of the device, or any other condition not permitting grafting or bone fusion.

Physical:
Malformations preventing sufficient bone anchoring of the device; skin impairment or impairment of the tissues in the area to be operated on; unsuitable choice of implant in terms of the length, size and shape of the phalanges; possible interference with nearby anatomical structures restricting or preventing usage in terms of the desired result; unsuitability

of the patient's age in terms of ensuring a functional and therapeutic result or bone immaturity; excess weight; intense professional or sporting physical activity subjecting the implant to excessive or repetitive strain.

Psychological:

The patient's lack of observance of postoperative instructions and procedures.

Mechanical:

Combination with other types of osteosynthetic devices; non use of the specific instruments designed for implantation of the device; articular conflict.

General:

Any case not listed in the indications. Contraindications of the material are the same as those pertaining to any other instrumentation relating to arthrodesis or osteosynthesis material.

Possible side effects:

All pre-, per- and postoperative complications relating to both instrumented and non-instrumented arthrodesis. Non exhaustive list of side effects, in random order:
Early or late disassembly of one or all elements of the structure; rupture or deformation of one or all of the elements of the structure due to confines that are too severe; local or generalised infection; allergic reaction to the components of the implant; corrosion of the implant which may lead to metallosis, skin lesion if tissue cover over the structure is inadequate, with all the complications associated with this type of lesion (irritation, fibrosis etc.); lesions on "soft" tissue and/or on nervous and muscle tissue due to implantation of the implant; poor positioning of the implant also associated with the use of the basic and specific implant instrumentation; postoperative change in morphology; dual lesions; pseudomeningocele; leakage of cerebrospinal fluid; neurological complications such as full or partial paralysis; radiological; the onset or persistence of pain; neuropathy; sensory loss; visual impairment; numbness; spasms; paraplegia; reflex impairment; loss of muscle mass; impairment of the urinary and vesical system; graft rejection; fracture or microfracture caused by the dislodging of a bone element; pseudoarthrosis; retarded consolidation; misaligned bone fusion (malunion); mobility and functioning of the modified segment; growth of the fixed osteosynthesised segment; loss of bone density with or without lysis relating to the confines of the implanted device; complications or pain in the harvested graft area; complications in the intestinal and gastrointestinal system; haematological and cardiac complications; hypertension; embolism; cerebral haemorrhage; phlebitis; necrosis of the wound and/or cicatrization problems; malfunctioning of the reproductive organs leading to sterility; respiratory-related complications; pulmonary embolism; pneumonia; bronchitis; the patient's mental regression; limitations in or inability to resume certain daily activities; death.

NOTE: Some additional surgical procedure may be required to remedy some of these possible undesirable events.

INSERTION OF THE DEVICE

The TIGERTRACK® and EXRAY® screw system must be used with instruments specially designed for the device according to the surgical technique concerned. It must not be used with any other instruments, unless this has specifically been recommended in some other ADSM documentation, as using the system with other instruments poses the risk of incompatibility, and cannot be guaranteed. ADSM shall not be held responsible in the case of using instruments that are not associated with the implanted system.

NEVER REUSE AN IMPLANT.

Reuse of an implant presents the risk of contamination and loss of mechanical integrity.

PACKAGING

The packaging of the device must be intact on receipt. Any device that has been damaged or any device whose packaging is damaged must not be used, and must rather be returned to ADSM.

STORAGE AND HANDLING CONDITIONS

The implants must be stored in their original packaging, out of direct sunlight, humidity and extreme temperatures.

MAGNETIC RESONANCE

Magnetic Resonance Imaging (MRI) is a medical imaging technique that provides non-invasive views of the body interior using a strong magnetic field. Consequently, any ferromagnetic metallic foreign body is to be proscribed which can cause burns or injuries by displacement of the body under the effect of attraction of the magnetic field. Titanium Ti6Al4V ELI used for TIGER22, TIGER25, TIGER29, TIGER45 and TIGERW screws as well as Phynox used for TIGER18 screws are non-ferromagnetic metallic materials which pose no known risk for possible migration due to exposure to the magnetic resonance environment. It is the same for the heating which has been observed only on conductive loops which is not the case of the TIGERTRACK® system. A delay of 6-8 weeks is recommended after implantation before performing this type of examination. Some artifacts can be observed.

The PEEK used to manufacture the EXRAY® screw system is therefore a non-ferromagnetic and non-conductive polymer (plastic). Consequently, it poses no known risk of possible heating or migration due to exposure to the magnetic resonance environment.

VERIFICATION

The devices must always be checked before use. Those that present signs of damage or scratches on the surface must not be used. TIGERTRACK® and EXRAY® implants are delivered sterile and have been sterilised through gamma radiation.

You need to carefully check that the round disc (sterilisation mark) on the packaging is red. Do not use an implant whose disc isn't red.

You also need to check that the expiry date on the packaging has not passed. ADSM disengages itself from any liability in the case of the use of implants past their expiry date. Any implant with damaged or torn packaging must not be sterilised and must rather be returned to ADSM.

TAKE NOTE: Do not resterilise an implant that has already been sterilised.

WARNINGS AND PRECAUTIONS

This device can and may only be used by surgeons experienced in surgery of upper or lower limbs.

The practitioner must follow the operating procedure; and implantation of the device must be done (except for an approach and other surgical procedures peripheral to the segment being operated on) using the specific ancillary instruments, under the conditions described in the operating procedure.

It is imperative to perform abrasion on the articular surfaces prior to them being fused as a result of fixation using the devices described in this manual, to ensure the stabilisation of the arthrodesis, as mechanical constraints on the device that are too severe will cause possible rupturing,

slippage or disassembly of one or all of the elements of the structure, thereby compromising the desired result. It is to be noted that not all surgically treated cases end in success, as certain factors may compromise the result.

The success of an operation to implant the devices described in this manual depends on selection of a suitable patient, the proper use of the device, the suitable choice and proper positioning of the implant, the good quality and rigidity of the obtained reduction, as well as the quality of bone fusion.

Certain types of patients could have fusion problems: smokers, alcohol abusers, drug addicts, patients who are obese or have dietary deficiencies, those in poor physical or mental condition, those with poor muscle and/or bone quality. These types of patients must be warned and informed about possible consequences.

The patient must follow postoperative care, procedures and recommendations in order to avoid excessive strain on the device which could cause a stress-induced rupture of the device, requiring a new operation and premature removal of the device.

Note: The surgeon must inform the patient about the indications, contraindications and warnings contained in this document (patient's informed consent).

OTHER PREOPERATIVE, PEROPERATIVE AND POSTOPERATIVE WARNINGS

Implant selection

Selecting the suitable size of the implant for each patient is a crucial factor in the success of the operation, and it is important to refer to the surgical technique in this regard. Once implanted, the implant is subjected to repeated strain, and its strength is limited by adaptation of its geometrical structure to the size and shape of human bone. In order to minimise this strain and to avoid compromising the desired bone fusion, it is important to pay careful attention to the patient's selection criteria, the correct placement of the implant, and postoperative care.

Preoperative:

Patients likely to be operated on for implantation of the devices described in this manual are listed in the indications. The abovementioned contraindications must be observed. Before the operation, it is necessary to check on the availability of sterile implants in sufficient quantity to ensure surgery can proceed. A greater number of sterile implants than that required by the surgery must be available to the practitioner, to be able to respond to any unforeseen circumstance, should an unexpected event arise. The ancillary instruments must have been pre-checked on a functional and quantitative level. The ancillary instruments must have been cleaned, decontaminated and sterilised according to the standards followed in the establishment (in accordance with methodology followed by the establishment). All instruments, implants and ancillary equipment must be handled with great care. The implants should not show any signs of impairment. An implant that comes from a previous surgery - even one that has been decontaminated and sterilised - may not be used. The practitioner, as well as the surgical team, must be trained in the use of the instruments. The surgical team must follow rules relating to asepsis, dress-code and implementation procedures observed in sterile environments.

Peroperative:

As with any surgical procedure, caution and particular care must be practised in the wound environment. The operating procedure must be available to the surgical unit, with its instructions and recommendations followed by the surgical team. As the devices described in this manual form mechanical structures, misuse of the material can cause the patient, as well as the attending staff, harm.

Implantation of the devices described in this manual must be done under the same precautionary and radiological control conditions as for any classic arthrodesis or osteosynthesis system. The suitable size will have been determined in a precise manner, before insertion. The usage instructions must be followed. Before closing the wound, the surgeon must ensure a proper mechanical fit.

Postoperative:

The same recommendations as for any other arthrodesis or osteosynthesis system must be put forward and explained to the patient so that they are fully aware of the implanted device's limitations. The patient must be warned about the possible abovementioned complications should the rehabilitation procedure not be followed and/or in the case of excessive strain on the joints. The practitioner must advise the patient to avoid any jolts, vibrations, bumps or harmful mechanical constraints that could cause the disassembly or rupture of an element of the implemented structure. Neuroalgodystrophy (possible treatment with positive change), superficial infection (antibiotherapy), skin necrosis (graft), damage to the collateral nerve with hypoesthesia in the finger or the toe.

Certain movements must be restricted and limited, upon the surgeon's advice. The practitioner must inform the patient about any behaviour that could be harmful to the stabilisation and fusion of the implemented arthrodesis such as tobacco use, the consumption of alcoholic beverages, drug abuse, excessive weight strain, the taking of certain medication which may be harmful to bone consolidation (steroids, anti-inflammatories etc.). Explanations must be given to the patient so that they learn how to compensate for the loss of mobility in the segment operated on, without necessarily putting constraints on the treated area. Partial exterior support of the area operated on may be necessary to optimise consolidation. The patient must be monitored closely on a clinical and radiological level to monitor the progress of bone fusion. In the case of an ongoing lack of consolidation, excessive mechanical constraints on the device could cause disassembly or rupture of one or several elements of the structure. The affected area must be immobilised and followed closely on a radiological level. In the case of disassembly or rupture of the device, observed clinically and/or radiologically, a corrective surgical operation will be necessary to remove the defective device and so prevent serious harm. Suitable antibiotic therapy is advised for at-risk patients before they undergo any new surgical or dental surgery.

The devices described in this manual provide temporary fixation to encourage bone fusion. Where fusion is noted, removal of the device may be indicated at the surgeon's advice, depending on the patient's condition. Removal is recommended where possible, as the implant has not been mechanically designed to withstand strain placed on it in the long term during normal activities engaged in, following fusion. Complications may arise, such as movement of the implant, disassembly or rupture of one of the elements of the structure, which could lead to lesions and bone lysis caused by the transfer of the device's constraints on the bone, physical irritation and pain relating to the presence of the device as well as any other unknown or unexpected complication in the long term.

Following removal of the device, the surgeon will prescribe a postoperative procedure and schedule for the patient, to avoid new fractures or other complications. Implants collected following removal may not, under any circumstances, be reused in another surgical operation or for any other use.

ADDITIONAL INFORMATION

For any additional information about the device or to enquire about specific surgical techniques, kindly contact ADSM's client services or the distributor.

PRODUCT COMPLAINTS

Any customer or user of this system who has a complaint or any reason for dissatisfaction concerning the quality of a product, its identity, durability, reliability, safety, effectiveness and/or its performance must notify the distributor or ADSM. In addition, should any of the implanted components not function well, or if poor functioning is suspected, the distributor or ADSM must be notified about this. If one of ADSM's products is ever suspected of having caused or contributed towards a patient's death or serious injury, ADSM or the distributor and the competent authority of the Member State in which the user and/or patient is established should be informed of this immediately by telephone, fax or written correspondence. For any complaint, please indicate the name, reference number and batch number of the component(s) concerned, your name and address, the nature of your complaint, and specify whether a written report is requested from the distributor or ADSM.

INFORMATION TO BE PROVIDED TO THE PATIENT

The TIGERTRACK® and EXRAY® screw system is designed for attachment and stabilisation of bone segments during elective osteotomies of metatarsal bones and phalanges of the foot. The device has only been designed for use in the forefoot. Specific instructions for the implant are described in the paragraph: "INDICATIONS, CONTRAINDICATIONS AND POSSIBLE UNDESIRABLE EFFECTS".

This device does not restore the functionality that can be expected of healthy bone and the patient should not expect unrealistic functional results. In addition, the anatomy of the human body limits the size of any artificial consolidation device used in surgery. This geometrical limitation increases the possibility of the onset of mechanical complications such as dismantling, deformation or rupturing of the device. Any complication may lead to an additional surgical procedure to remove the device or potentially insert another device. Consequently, it is very important that you carefully follow your doctor's postoperative instructions. It is recommended that the activities you do be limited to those on your surgeon's advice. Immobilisation and other devices that partially or fully support your weight must be used on your medical practitioner's advice. By following these instructions, you will increase your chances of achieving the desired result, and you will be reducing the risk of injury and/or additional surgical procedures.

REMOVAL AND DISPOSAL OF MEDICAL DEVICES

The removal and handling of surgical instruments is to be done in accordance with the recommendations standard ISO 12891-1 "Removal and Analysis of Surgical Implants. Part 1: Removal and Handling". The surgical technique details the surgical steps related to removal of the implant. Waste must be disposed of in compliance with the applicable legislation in the country of use. In France, waste is to be handled in accordance with Decree no. 97-1048 of 6 November 1997 relating to the disposal of infectious and related health care waste and anatomical parts.

No specific provision is required for the disposal of unused medical devices.

WARNINGS

The manufacturer's responsibility is limited to the instructions and applications included in this instruction manual.

SYMBOL	MEANING
	SINGLE USE
	DO NOT RESTERILISE
	VALID UNTIL
	BATCH CODE
	STERILISATION BY RADIATION
	CAUTION: SEE INSTRUCTION MANUAL
	MANUFACTURER
	DO NOT USE IF PACKAGING DAMAGED
	STORE OUT OF DIRECT LIGHT
	KEEP DRY
	READ THE INSTRUCTIONS
	REFERENCE
	MATERIAL
	DIAMETER
	NUMBER OF UNITS IN THE PACKAGING
	CAUTION : FEDERAL (USA) LAW RESTRICTS THE SALE AND/OR THE USE OF THIS DEVICE TO OR ON THE ORDER OF A PHYSICIAN
	COMPATIBLE WITH MRI UNDER CERTAIN CONDITIONS
	MEDICAL DEVICE UNIQUE DEVICE IDENTIFIER