INSTRUCTION FOR USE

IMPORTANT MEDICAL INFORMATION
TOEGRIP®CLASSIC and TOEGRIP®EVO

Reference: SUP_7.048 version 1
Date of last update: 01/2021
Product manufactured by:

CE 0197

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

INTENTED USE – FDA Specific

The TOEGRIP®CLASSIC and TOEGRIP®EVO are intended for toes for general use in skeletally mature individuals undergoing surgery limited to interdigital fusion. The TOEGRIP®CLASSIC and TOEGRIP®EVO devices are intended to be permanently implanted without any other additional device as an intramedullary bone fastener device for forefoot.

PURPOSE

The TOEGRIP®CLASSIC and TOEGRIP®EVO interphalangeal implants are designed to relieve pain and disability of the forefoot by restoring and/or maintaining the alignment of two adjacent digital bone segments to optimize the achievement of a correct bone fusion for the concerned segments. These devices are only intended to be used for the forefoot of a mature skeleton.

DESCRIPTION:

The TOEGRIP®CLASSIC implant consists of a single part implant with three flexible intramedullary rods inserted into each part of the phalanx. The rods are attached by a T-shaped structure. The attachment concept is based on a press-fit contact due to its tapered shape and the macrostructures solidly anchored once impacted, thus avoiding any displacement of the implant.
The TOEGRIP®CLASSIC implant is intended for single use only and is available in a range of 5 sizes with 3 possible degrees: 0°, 10° or 20°.

The TOEGRIP®EVO implant consists of a single part implant with three flexible intramedullary rods inserted into each part of the phalanx. The rods are connected by a cylindrical structure with a sagittal height offset between the proximal and distal portion. The attachment concept is based on a press-fit contact due to its tapered shape and the macrostructures solidly anchored once impacted, thus avoiding any displacement of the implant.
The TOEGRIP®EVO implant is intended for single use only and is available in a range of 5 sizes with 3 possible degrees: 0°, 10° or 20°.

TOEGRIP®CLASSIC and TOEGRIP®EVO are made from PEEK according to Standard ASTM F2026.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE SIDE EFFECTS

Indications:
The TOEGRIP®CLASSIC and TOEGRIP®EVO are intended for toes for general use in skeletally mature individuals undergoing surgery limited to interdigital fusion. The TOEGRIP®CLASSIC and TOEGRIP®EVO devices are intended to be permanently implanted without any other additional device as an intramedullary bone fastener device for toes or fingers.
The TOEGRIP®CLASSIC and TOEGRIP®EVO devices are indicated for small bone reconstruction limited to interdigital fusion of toes in the following cases, listed in random order:

- Rigid PIP joints deformities
- Rigid hammertoes deformities
- Claw toes deformities (PIP and DIP joints)
- Revision hammertoes surgeries
- Shortening osteotomies of the proximal phalanx

ATTENTION: to be used by or on the order of a licensed physician.
The licensed physician must take note of the documents accompanying the device. (IFU and surgical technique). No specific training is required for the understanding and implantation of the device. The medical doctor's qualifications and the reading of the accompanying documents are sufficient

Contraindications (Non-exhaustive list)**:**
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; articulatory 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 arthodesis or osteosynthesis material.

Possible side effects:
All pre-, per- and postoperative complications relating to both instrumented and noninstrumented 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; dural lesions; pseudomeningocele; leakage of cerebrospinal fluid; neurological complications such as full or partial paralysis; radiculopathy; 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; pseudarthrosis; 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 cicatrisation 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.

INSERTION OF THE DEVICE

The TOEGRIP®CLASSIC and TOEGRIP®EVO implants 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 related to 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. The PEEK used to manufacture the TOEGRIP®CLASSIC and TOEGRIP®EVO systems 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. The TOEGRIP®CLASSIC and TOEGRIP®EVO 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 resterilised but 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 articulatory 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.
In fact, conversely, these constraints can lead to excessive strain placed on the material, resulting in deformation, rupture or loosening of the device likely to cause damage or the need to remove the implant prematurely. Any use in body areas not recommended by ADSM cannot be guaranteed.
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 practiced 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 device. 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. Neuro-algodystrophy (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 in order to optimise consolidation. The patient must be monitored closely on a clinical and radiological level in order 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 in order 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 in order 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, in order 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 TOEGRIP®CLASSIC and TOEGRIP®EVO interphalangeal implant is designed to restore and/or maintain two adjacent digital bone segments in anatomically correct alignment so as to optimise the obtaining of correct bone fusion for the segments concerned. This device is only intended 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 the likelihood 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 of 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
LOT	BATCH CODE
STERILE R	STERILISATION BY RADIATION
	CAUTION : SEE INSTRUCTION MANUAL
	MANUFACTURER
	DO NOT USE IF PACKAGING DAMAGED
	STORE OUT OF DIRECT LIGHT
	KEEP DRY
	READ THE INSTRUCTIONS
REF	REFERENCE
MAT.	MATERIAL
°	ANGLE AS A °
QTY	NUMBER OF UNITS IN THE PACKAGING
Rx only	CAUTION : FEDERAL (USA) LAW RESTRICTS THE SALE AND/OR THE USE OF THIS DEVICE TO OR ON THE ORDER OF A PHYSICIAN
MR	COMPATIBLE WITH MRI
MD	MEDICAL DEVICE
UDI	UNIQUE DEVICE IDENTIFIER