

KALIX® II

Flat foot implant



Surgical technique

Introduction

Newdeal, in co-operation with specialists in foot surgery (European Foot Platform Group), has developed an endorthesis for the specific treatment of flatfoot, in pediatric as well as in adult application, thanks to its innovative mechanical characteristics.

The implantation of the endorthesis can be an isolated surgical treatment or it can be associated to other soft tissue or/and bony procedures (for example: Achilles tendon lengthening, tibialis tendons procedures, tarsal coalitions removal or medial arch arthrodesis).



Indications

The KALIX®II implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

- Flat foot treatment in children and adolescents
- congenital flat foot
- non successful long term orthopaedic treatment (shoes, insoles...)
- tarsal coalitions
- painfully flat foot
- supple deformity in posterior tibial tendon dysfunction
- paralytic flat foot
- subtalar instability.

The KALIX®II implant should be removed :

- at the end of the growth when used in pediatric patients,
- after 15 to 18 months when used in adult patients.

The KALIX®II implant must be removed.

Contra-indications

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

- Stiff or fixed deformity of the flat foot.
- Flat foot with a forefoot abductus
- Chronic rupture of the posterior tibialis tendon.
- Symptomatic arthritis
- Neurological affections (paraplegia...)
- Suspected or documented metal allergy or intolerance.

Surgical technique

NEWDEAL® as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Step N° 0 (optional)

Lengthening of the Achilles tendon.

This lengthening is indicated in case of retraction of the Achilles tendon, frequently associated to flat foot. It helps correcting the valgus of the calcaneus, and implanting the endorthesis. Percutaneous lengthening is recommended

Technique :

2 incisions are performed on the lateral border of the tendon, and 1 incision on its medial border.

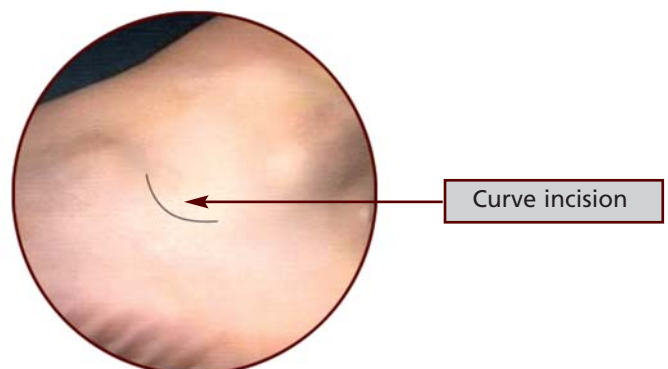
Always validate the length of the Achilles tendon when implanting the KALIX®II endorthesis.

With the knee in extension and the hindfoot in neutral position, the foot is passively dorsiflexed. If 10° of dorsiflexion can not be achieved, Achilles tendon lengthening is recommended.

Step N°1

Incision.

The implantation of the Kalix II requires a minimal (2 cm) slightly curve skin incision just anterior and plantar to the lateral malleolus. Care is taken in order to safeguard the peroneal tendons and the intermediate dorsal cutaneous nerve (branch of the superficial peroneal nerve), which is located close to the malleolus



Step N°2

Surgical approach

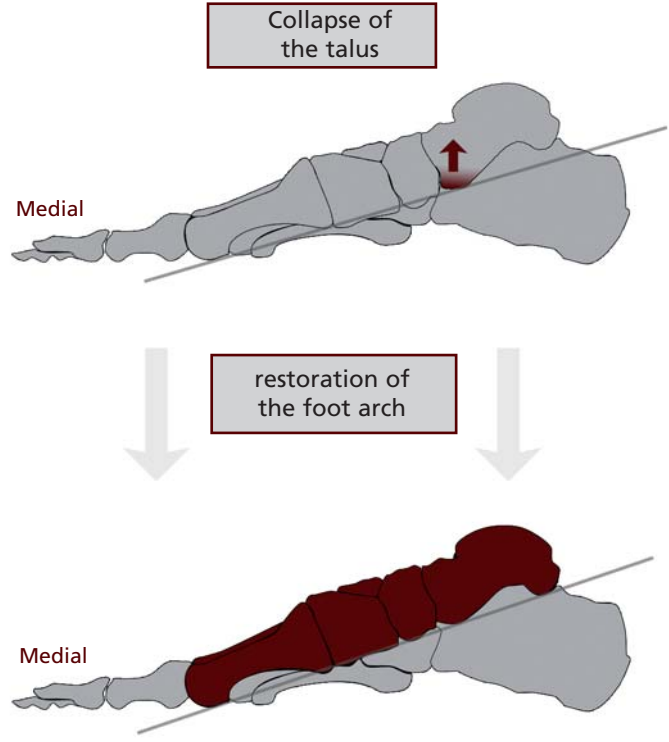
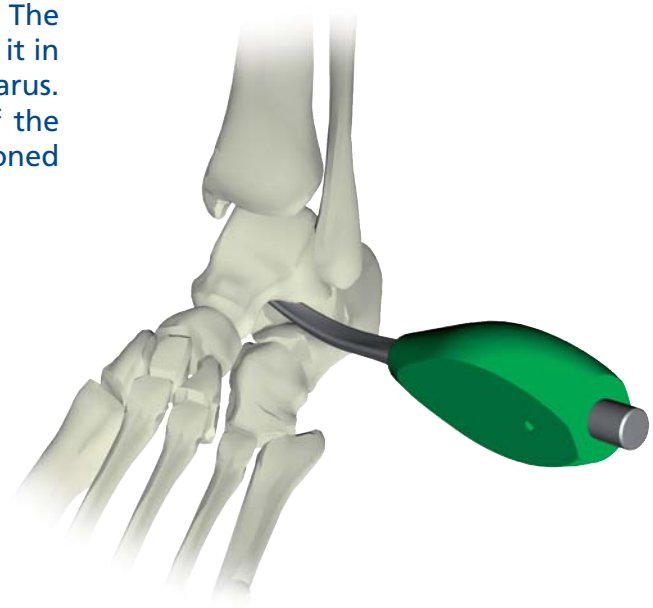
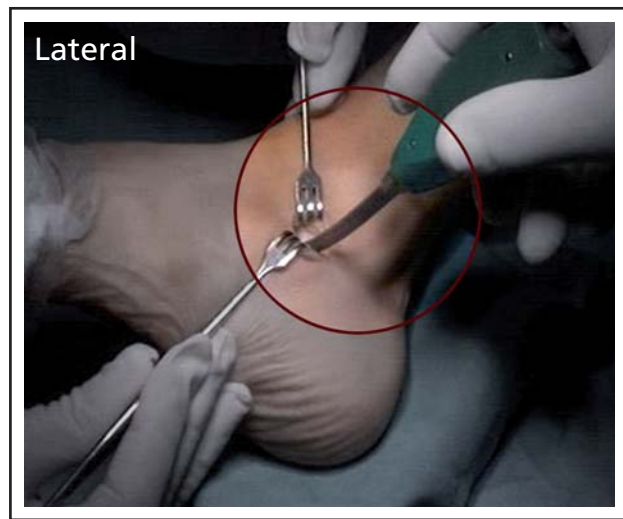
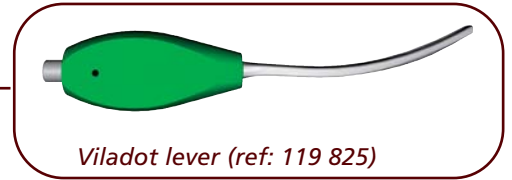
A direct access to the Sinus Tarsi is obtained, followed by a surgical debridement and cleaning in order to introduce the trial and the final endorthesis.

The cervical and interosseous ligaments should be respected.

Step N°3

Restoration of the foot arch.

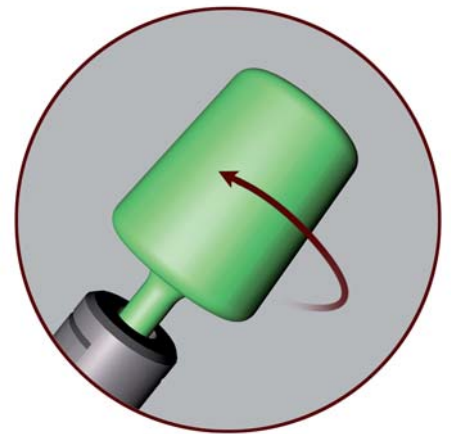
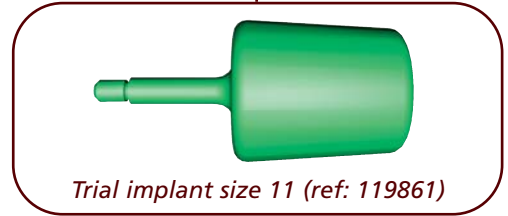
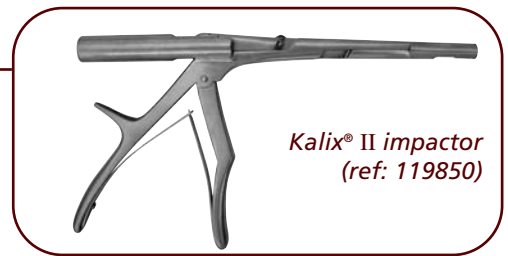
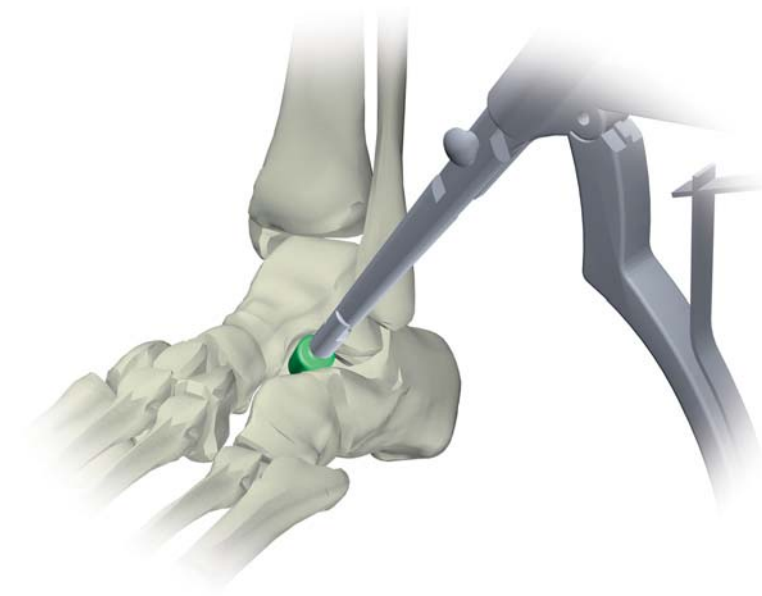
The collapse of the talus is corrected. For this purpose, the Viladot Lever is carefully introduced in the Sinus Tarsi. The reduction is achieved by handling the lever and pushing it in plantar direction, so that the hindfoot is deviated in varus. At the same time, the assistant performs pronation of the forefoot. In this way, the talus is anatomically repositioned and valgus deviation of the calcaneus is corrected.



Step N°4

Choice of the implant size.

The trial implants are to be screwed at the extremity of the impactor. The trial implants are introduced -with increasing diameters- in the Sinus Tarsi as to achieve an optimal filling of the cavity. The trial implant should be inserted at the level of the lateral border of the talus in the sinus tarsi.



The size of the optimum trial implant will be retained as it corresponds to the final size of the endorthesis. The optimum size corresponds to the trial implant that remains stable at the Sinus Tarsi while performing varus-valgus movements of the subtalar joint. The final endorthesis should not be oversized as it would lead to an over-expanded, unstable subtalar joint.

A color code identical between trial and final implants enables confirmation of the appropriate size selection.

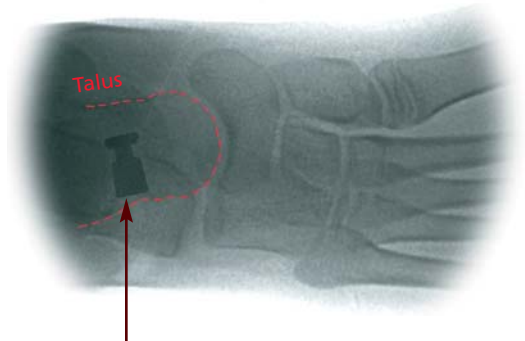
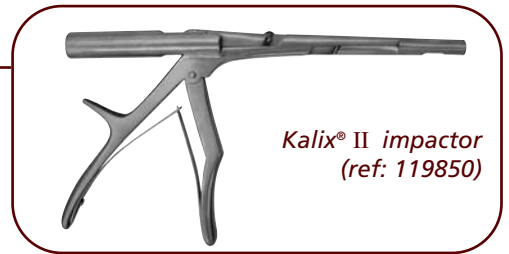
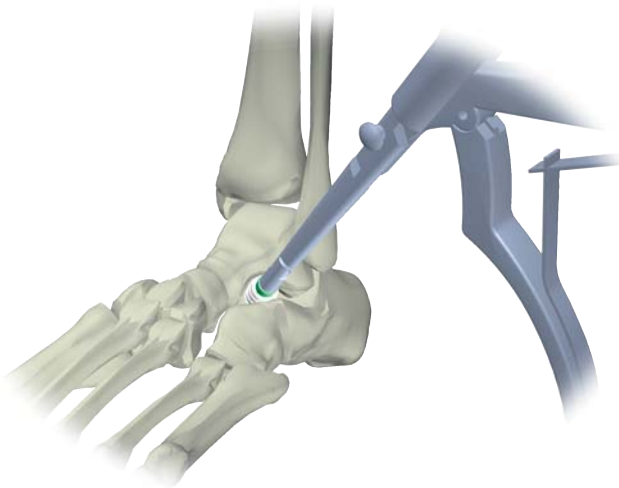
Color code

Trial implant	119859	119860	119861	119862	119863	119864	119865	119867
Kalix® II implant	141009	141010	141011	141012	141013	141014	141015	141017
Diameter	9 mm	10 mm	11 mm	12 mm	13 mm	14 mm	15 mm	17 mm

Step N°5

Positioning of the implant

Once the size of the endorthesis is defined, the implant is fixed to the impactor by a screwing maneuver. Care should be taken to perform this maneuver on the full threaded part of the axis until base of the conical part of the implant is flush to the tip of the impactor. The endorthesis is set in the Sinus Tarsi, at the level of the lateral border of the talus.



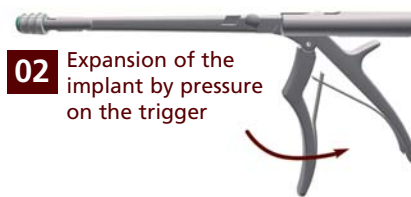
Precise positioning of the implant

A firm pressure on the trigger of the impactor enables the expansion of the implant in the Sinus. The trigger has then to be released.

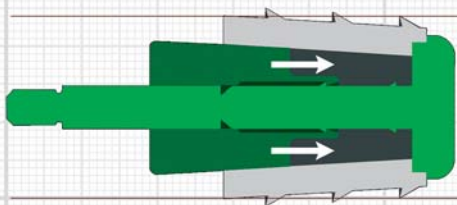
A sharp lateral move enables then to separate the implant from the impactor, by breakage of the snap-off axis.

WARNING

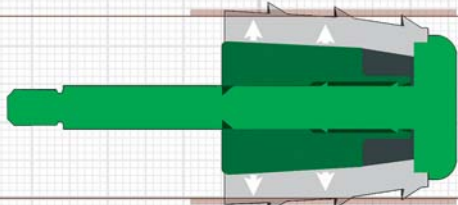
Once expansion is complete, one should release the trigger before breaking the snap-off axis.



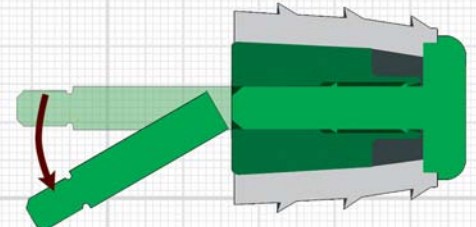
A : Starting position



B : Expansion of the implant

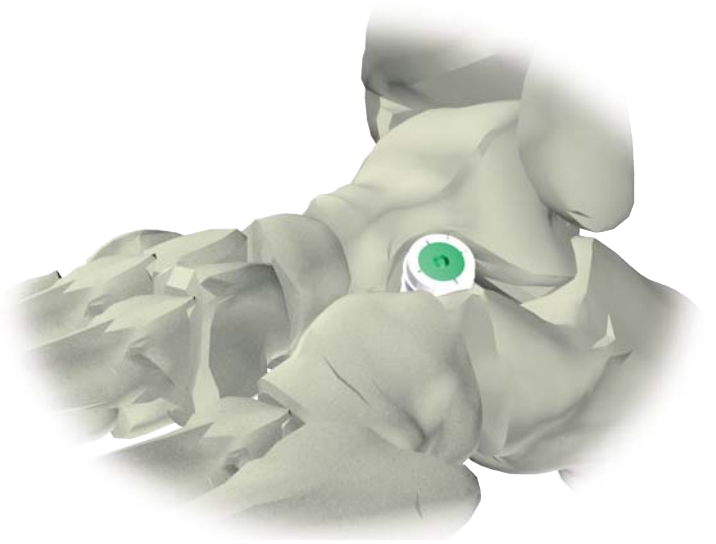
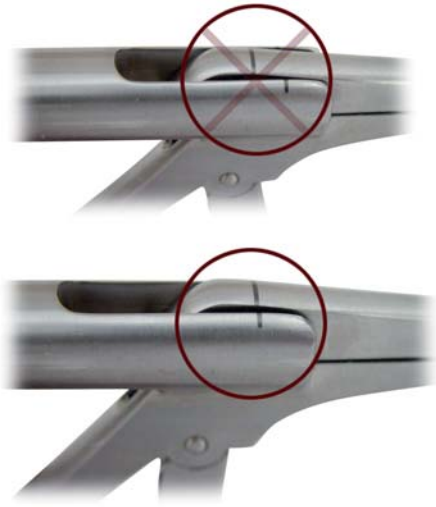


C : Breakage of the snap-off axis



WARNING

In order to have a complete expansion, the pressure should be exerted until stop is reached, which means until mark on the impactor body and mark on the piston are aligned.

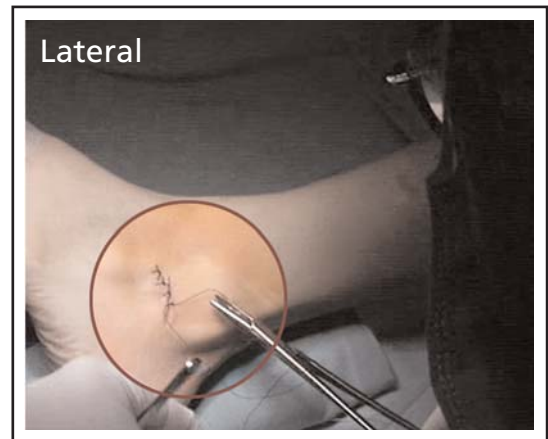


Step N°6

Closure.

The endorthesis is then in place. The metallic part of the endorthesis is completely embedded within the polyethylene mantle so there is no contact with the surrounding bones.

Closure is then performed in the routine fashion.



Post-operative treatment

It is suggested to maintain the operated foot immobilized in a plaster bandage for 3 or 4 weeks. This period can be extended when, beside the implantation of the KALIX®II implant, other surgical techniques (soft tissues or bony procedures) were performed. In every case, weightbearing is allowed 10 days post-operatively, after suture removal. It is advised to use an orthopaedic insole for supporting the reduction for a period of 6 to 12 months post-operatively.

The KALIX®II implant should be removed:

- At the end of the growth when used in pediatric patients.
- After 15 to 18 months when used in adult patients, if they refer pain in the sinus tarsi zone.

The KALIX®II implant must always be removed.

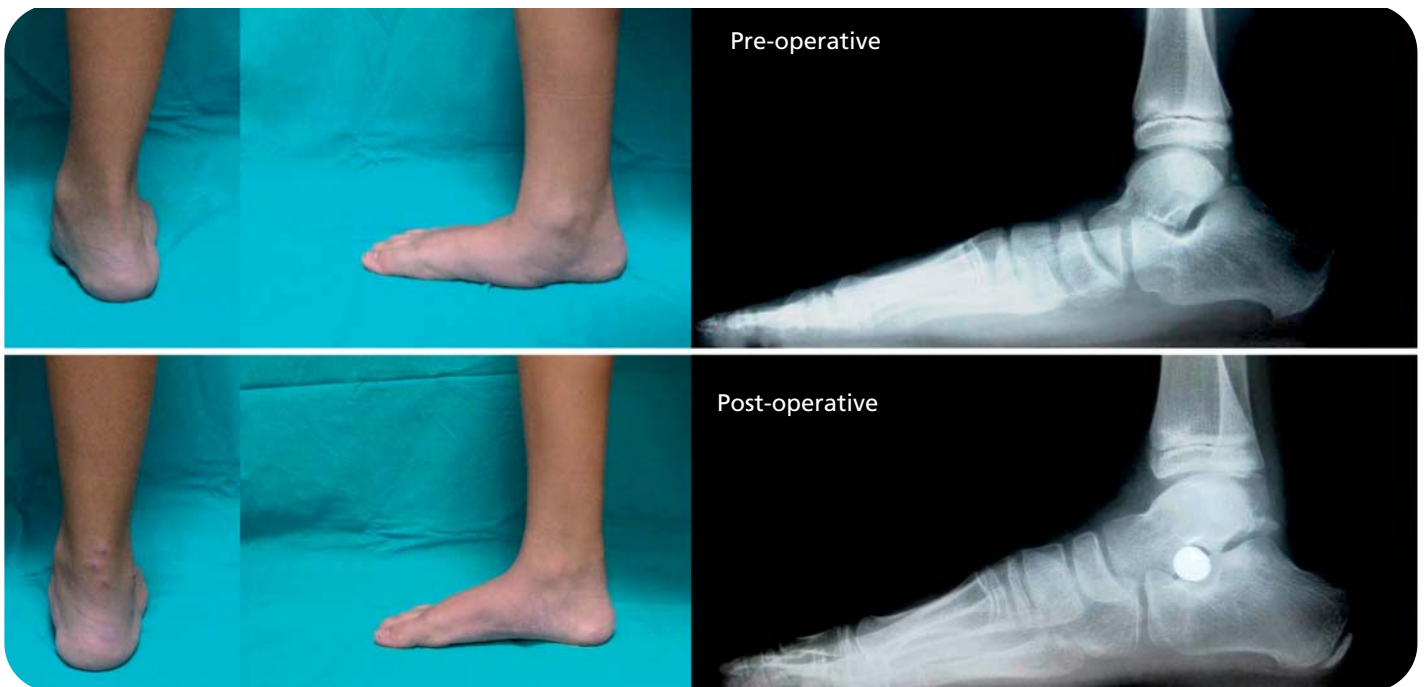
KALIX® III

Clinical cases

Adult case



Child case



Bibliography *(list is not exhaustive)*

- Viladot R., Pons M., Alvarez F., Omana J.: Subtalar Arthroereisis for Posterior Tibial Tendon Dysfunction
Foot & Ankle International • 2003, Vol. 24 - 8
- Viladot A: Surgical treatment of the Child's flat foot
Clin. Orthop. 283: 34-38, 1992
- Viladot-Voegeli A, Lopez I, Angulo T, Crespo F & Viladot R: A long term follow up after Setrite implant for Flat Foot. In Benamou, P.H. and Montagne J (eds).
Medecine et chirurgie du pied. Ed.Masson, pp 118-123, Paris, 1993.
- Viladot R, Torner CE & Rochera R:
Nueva tecnica quirurgica para el tratamiento del pie plano.
Ann, Med, 6: 80-87, 1976.
- Giannini S, Girolami M, Ceccarelli F: il trattamento chirurgico del piede piatto infantile mediante endortesi ad espansione. *G.I.O.T*, 11, 3, 1985.



Acknowledgment: Anatomic trials and validation have been conducted with the cooperation of Prof. Dr. GOLANO at the department of Pathology and Experimental Therapeutics (Human Anatomy Unit) Universidad de Barcelona, Spain.

Instructions for use

STERILE IMPLANTS FOR FOOT SURGERY • SINGLE USE

In accordance with EC directive 93/42 relative to medical devices, this product must be handled and/or implanted by WELL-TRAINED, QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

1- Description of the medical device:

The implants - delivered sterile - are:

Flat foot implant existing in different lengths and diameters, they are made out of titanium alloy according to NF ISO 5832.3 and ASTM F136 Standards in ultra high density polyethylene according to ISO 5834-1/2 and ASTM F 648 Standards.

2 - Indications :

The KALIX® - KALIX®II implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

- Flat foot treatment in children and adolescents
- congenital flat foot
- non successful long term orthopaedic treatment (shoes, insoles...)
- tarsal coalitions
- painfully flat foot
- supple deformity in posterior tibial tendon dysfunction
- paralytic flat foot
- subtalar instability.

The KALIX® - KALIX®II implant should be removed :

- at the end of the growth when used in pediatric patients,
 - after 15 to 18 months when used in adult patients.
- The KALIX® - KALIX®II implant must be removed.

3 - Contra-indications :

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

- Stiff or fixed deformity of the flat foot.
- Flat foot with a forefoot abductus
- Chronic rupture of the posterior tibialis tendon.
- Symptomatic arthritis
- Neurological affections (paraplegia...)
- Suspected or documented metal allergy or intolerance.

4 - Warnings:

Serious post-operative complications may occur from use of the implant in a patient who :

- Lacks good general physical condition;
- Has severe osteoporosis;
- Demonstrates physiologic or anatomic anomalies ;
- Has immunological responses, sensitisation, or hypersensitivity to foreign materials;
- Systemic or metabolic disorders;

5 - Precautions for use:

Physician must determine if implant is appropriate for patients who have any of the following conditions :

- Drug and/or alcohol and/or smoke addiction and/or abuse;
- Infectious disease;
- Malignancy;
- Local bone tumors;
- Systemic or metabolic disorders or replacement;
- Compromised wound healing;
- Obesity;
- Demonstrated psychological instability, displayed a lack of understanding, inappropriate motivation, or attitude;
- Unwillingness to accept the possibility of multiple surgeries for revision or replacement;
- Lacks an understanding that a metallic implant is not as strong as normal healthy bone and will bend, loosen, or fracture if excessive demand is placed on it;
- Lacks an understanding that their preoperative capacity may not be fully recovered even after successful implantation;

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and post-operative patient management are considerations essential to a successful outcome. Criteria for patient selection is the responsibility of the surgeon. Information contained within this document should be taken into consideration during the selection process. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon. Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience. The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.

Each patient must be evaluated by the surgeon to determine the specific risk/benefit relationship in light of the patient's condition and the surgeon's practice, training, experience, and knowledge of the related medical literature. Complications with the use of flat foot implants have been reported in the medical literature. Any patient undergoing a surgical procedure is subject to intra-operative and post-operative complications. Each patient's tolerance to surgery, medication, and implantation of a foreign object may be different.

Possible risks, adverse reactions, and complications associated with surgery and the use of flat foot implants should be discussed with and understood by the patient prior to surgery. The implant is composed of titanium alloy and ultra high density polyethylene materials; therefore, it is subject to possible reactions and complications, including those listed herein. The patient should not be led to unrealistic expectations as to the performance or results that the surgery and implant can provide. The patient should be informed that the life expectancy of the device is unpredictable once implanted, and that successful results cannot be guaranteed.

IT IS THE RESPONSIBILITY OF THE SURGEON TO PROVIDE THE PATIENT WITH INFORMATION PRIOR TO SURGERY.

Complications may include but are not limited to :

- Pain, discomfort, or abnormal sensations due to presence of the implant ;
- Bending, loosening, and/or breakage, which could make removal impracticable or difficult ;
- Risk of additional injury from post-operative trauma ;
- Migration of the implant position or implant material resulting in injury ;
- Bone loss due to stress shielding ;

Side effects may include but are not limited to :

- Infections ; - Hematoma ;
- Allergy ; - Thrombosis ;

Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and/or amputation of the limb. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture.

Interference risks during medical imaging : MRI/SCANNER : ask the patient to systematically mention that he/she has undergone a surgical intervention at the foot level.

6 - Use of the implant :

This product is sold sterile. Check packing and labelling integrity before use. The sterility is guaranteed as long as the packing has not been damaged (film scratched, label missing, questionable packing ...etc) and before the end of the sterility validity. Do not use any implant for which the packing has been opened or damaged outside the operating theatre. Inner packing should be handled under sterile conditions (persons/instruments).

The surgeon must use the instrumentations recommended in accordance with the operative technique available from the manufacturer. The medical device must be used in compliance with the use of the profession and the art standards. Do not attempt a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.

Opening of the instruments set must be done according to aseptic condition.

When handling the implants, avoid any contact with other material or tools which may damage the implant surface. Under no circumstances the implant should be modified .

7 - Re-use of the implant : Orthopaedic implants already implanted must never be re-used. The company accepts no responsibility for such a use.

8 - Re-sterilization of the non implanted products : Re-sterilization is not allowed.

9 - Preventing actions for the patient to avoid post-operative complications :

- Avoid extreme position like flexion-extension
- wear orthopaedic shoes according to the surgeon's prescription
- receive prompt medical attention for any infection that could occur, whether at the operated-member level or elsewhere in the body.

10 - Storage : Store in dry place

11 - Product information disclosure / Liability :

Newdeal, an Integra LifeSciences Company, has exercised reasonable care in the selection of materials and the manufacture of these products. Newdeal excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Newdeal shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Newdeal neither assumes nor authorizes any person to assume for it any other or additional liability or responsibility in connection with these products. Newdeal intends that this device should be used only by physicians having received proper training in orthopedic surgery technique for use of the device.

WARNING : This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

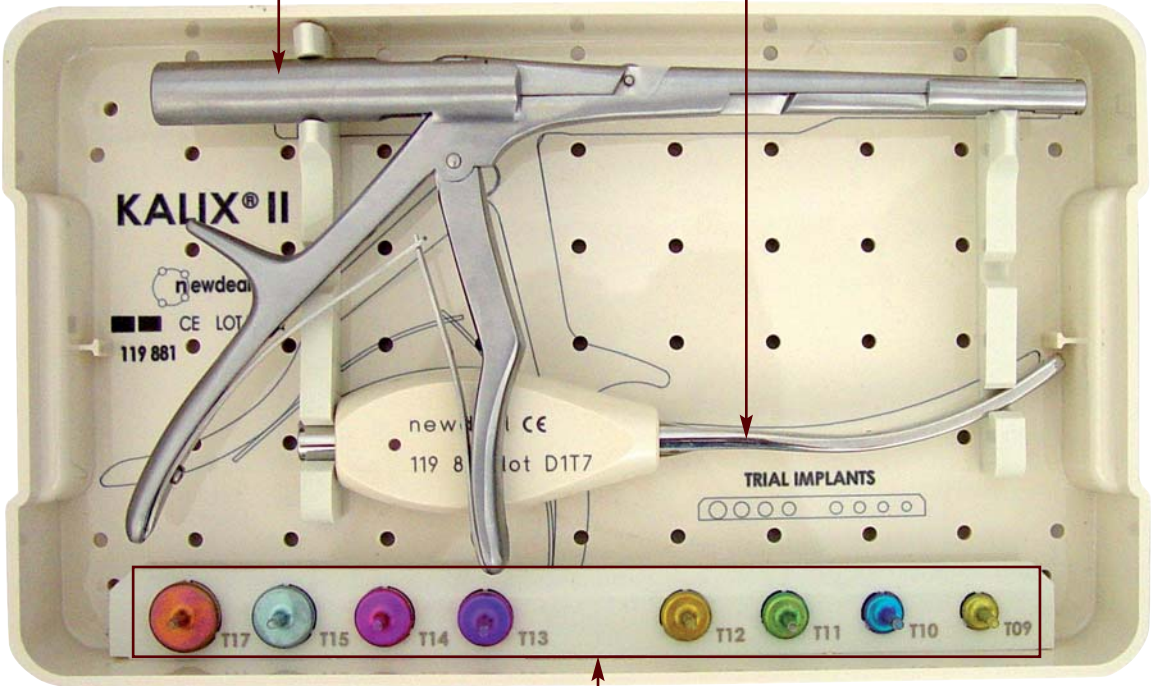
INFORMATION : Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.

Instrumentation set



Kalix® II impactor









Viladot lever











Trial implants (size 09, 10, 11, 12, 13, 14, 15 and 17 mm)

KALIX® II

KALIX® II

REFERENCE		DESCRIPTION
141 009		EXTERNAL DIAM. 09 MM
141 010		EXTERNAL DIAM. 10 MM
141 011		EXTERNAL DIAM. 11 MM
141 012		EXTERNAL DIAM. 12 MM
141 013		EXTERNAL DIAM. 13 MM
141 014		EXTERNAL DIAM. 14 MM
141 015		EXTERNAL DIAM. 15 MM
141 017		EXTERNAL DIAM. 17 MM

INSTRUMENTATION

REFERENCE		DESCRIPTION
119 880		STERILIZATION CONTAINER
119 825		VILADOT LEVER
119 850		IMPACTOR
119 859		TRIAL IMPLANT 09 MM
119 860		TRIAL IMPLANT 10 MM
119 861		TRIAL IMPLANT 11 MM
119 862		TRIAL IMPLANT 12 MM
119 863		TRIAL IMPLANT 13 MM
119 864		TRIAL IMPLANT 14 MM
119 865		TRIAL IMPLANT 15 MM
119 867		TRIAL IMPLANT 17 MM

- The products are manufactured and referenced within the frame of the standards in force.
 - Implantation procedures are described in the surgical technique.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
 - WARNING : Federal law (USA) restricts this device to sale by or on the order of a physician.

Distributed by

CE 0120

- See instructions for use
- Single use
- Sterile



STERILE EO



INTEGRA LIFESCIENCES CORPORATION
 311 Enterprise Drive • Plainsboro NJ 08536
 t 800-654-2873 • 609-275-0500
 f 609-275-5363 • www.integra-ls.com

NEWDEAL SAS
 10, place d'Helvetie • 69006 Lyon • FRANCE
 t +33 (0)4 37 47 51 51 • f +33 (0)4 37 47 51 52
 newdeal@newdeal.info • www.newdeal.info

