

KALIX[®]

SURGICAL TECHNIQUE



Flat foot implant

MID & HINDFOOT SOLUTIONS[™]



Newdeal, in cooperation 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 either an isolated surgical treatment that may include also soft tissue techniques and/or surgical intervention on bones (for example: Achilles tendon, Tibialis muscles in the child or an arthrodesis of the internal arch in the adult).

STEP 1

OPTIONAL: Percutaneous 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 (1).

Technique: 2-3 incisions are performed on the lateral border of the tendon, and 1-2 incision(s) on its medial border.

Always validate the length of the Achilles tendon when implanting the KALIX® endorthesis (2).

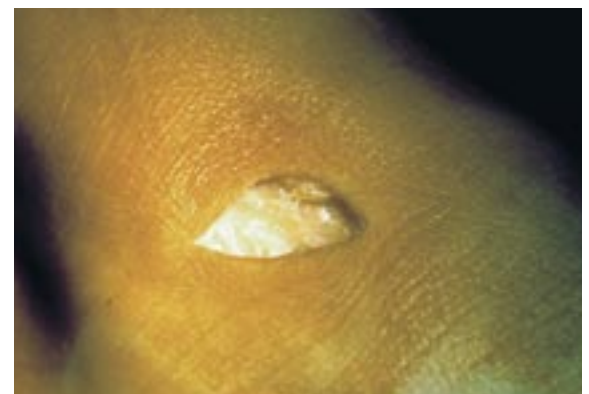
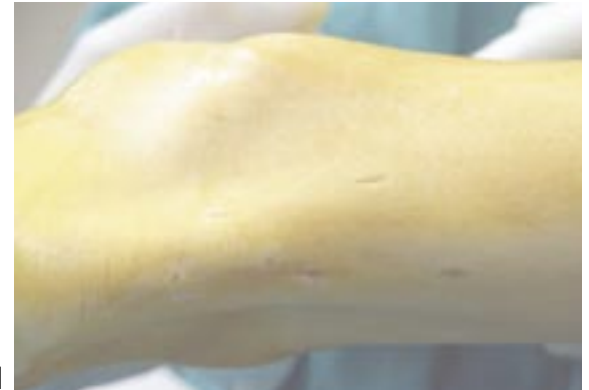
STEP 2

- The implantation of the KALIX® requires a minimal incision just anterior (+/- 1.5 cm) and plantar to the external malleolus. An «S» shape incision allows excellent access to the Sinus Tarsi (3). Care is taken in order to safeguard the peroneal tendon. As well as the Nervus Safena and its ramification which is located close to the malleolus (4).

Note: The anatomical specimen are realized by Prof. Dr. Golano - Barcelona / Spain.

STEP 3

- A direct access to the Sinus Tarsi is obtained, followed by a surgical debridement and cleaning in order to be able to introduce the trial - endorthesis as well as the final endorthesis. There should be no destruction of the cervical and interosseous ligaments.





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STEP 4

- The collapse of the Tallus has to be anatomically reduced. For this, the Viladot Lever, is carefully introduced in the Sinus Tarsi (5). Finally, by handling the Viladot Lever, the Tallus is repositioned anatomically over the calcaneum. The reduction will be maintained by positioning the forefoot in pronation and the hind-foot in supination (held by the assistant in surgery) (6).

STEP 5

- The trial implants are introduced, with increasing diameters, in the Sinus Tarsi to achieve an optimal filling of the cavity (7). The trial implant should be inserted at the level of the lateral border of the tallus 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 final endorthesis should not be oversized as it would lead to an overexpanded, unstable subtalar joint (8).



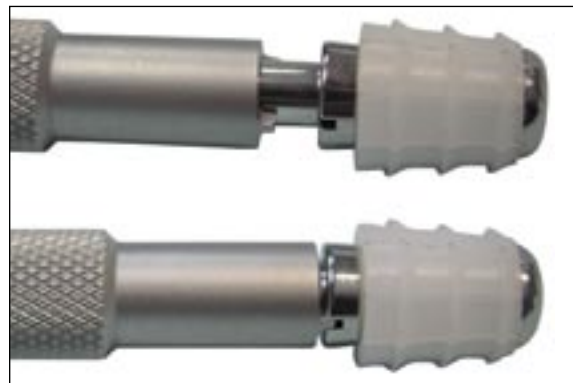
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STEP 6

- Once the size of the endorthesis is defined, the implant is fixed to the specific Kalix®-holder by turning the holder clockwise. The peaks of the unscrewdriver will be introduced in the imprints of the metallic insert for the unscrewing maneuver (9). The endorthesis is set in the Sinus Tarsi, at the level of the lateral border of the talus (10). The holder is retrieved from the implant by unscrewing (counter-clockwise) of the holder while the unscrewdriver remains in steady position (with the two peaks in the metallic cone).



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The double screwdriver is used for the final implantation of the endorthesis (holding it in the sinus tarsi along with a press-fit positioning). The external part of the screwdriver has two peaks which fit into the imprints in the metallic conical insert, whereas the central part of the screwdriver will fit into the central axis of the endorthesis (11). This way, the final setting of the implant is achieved by clockwise manipulation of the internal part of the screwdriver. The screwing maneuver will be finalized by the locking of the system (12).

Warning: The function of this screwdriver is to position and stop the metallic part of the implant. It is recommended not to apply force when screwing, as no mechanical load tends to unscrew the assembly.



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STEP 7

- When the screwing maneuver is completed, the screwdriver is removed and the endorthesis is in place. The metallic part of the endorthesis is completely embedded within the polyethylene mantle so there is no contact with the surrounding bones (13 & 14).



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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® implant, other surgical techniques (soft tissues or osteotomies) were performed. In every case, weightbearing is allowed 10 days post-operative, after suture removal. It is advised to use an orthopedic insole for supporting the reduction for a period of 6 to 12 months post-operatively.

The Kalix 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® implant must always be removed.



Preoperative



Postoperative



INSTRUMENT SET



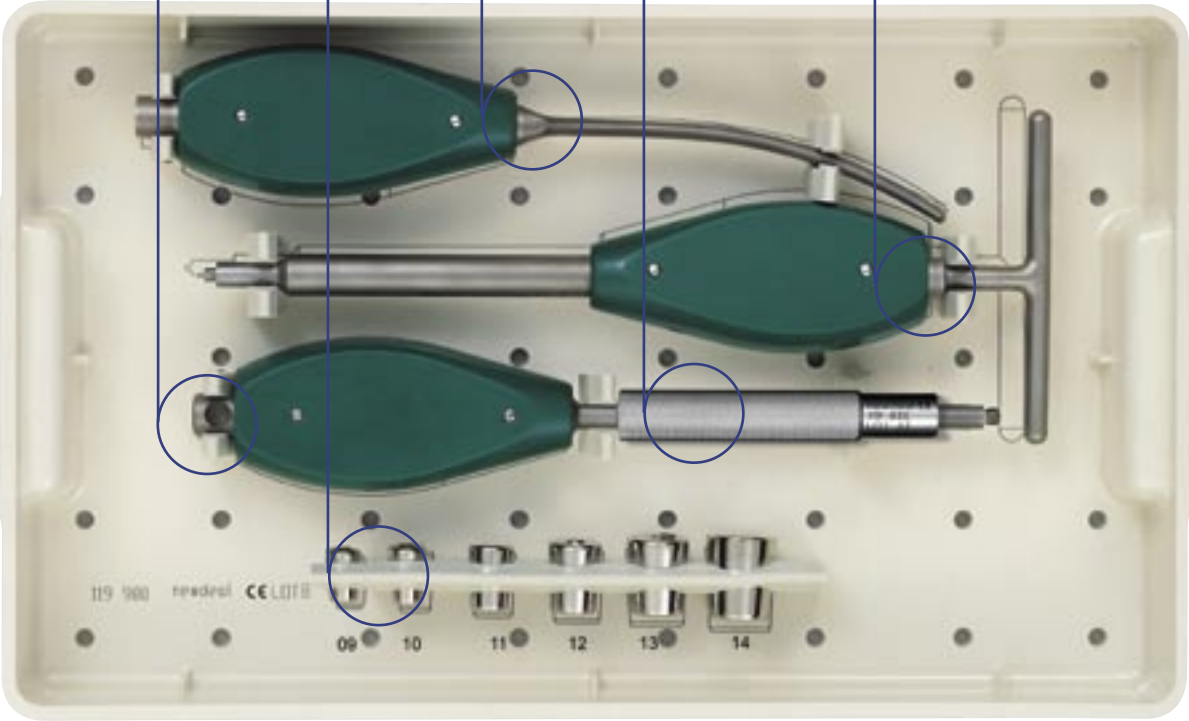
Holder

Trial implant

Viladot lever

Unscrewer

External and internal screwdriver



BIBLIOGRAPHY

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- 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.
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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 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 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 orthopedic treatment (shoes, insoles)
- tarsal coalitions
- painfully flat foot
- supple deformity in posterior tibial tendon dysfunction
- paralytic flat foot
- subtalar instability.

3 - Contraindications:

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.

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).

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:

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: Orthopedic 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 orthopedic 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 - Liability:

Newdeal shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Newdeal neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Newdeal intends that this device should be used only by physicians having received appropriate training in orthopaedic surgery techniques.

WARNING: Federal law (USA) restricts this device to sale by or on the order of a physician.

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.



CATALOG NUMBER	KALIX®	DESCRIPTION
140 009ND		EXTERNAL DIAMETER 09 MM
140 010ND		EXTERNAL DIAMETER 10 MM
140 011ND		EXTERNAL DIAMETER 11 MM
140 012ND		EXTERNAL DIAMETER 12 MM
140 013ND		EXTERNAL DIAMETER 13 MM
140 014ND		EXTERNAL DIAMETER 14 MM

OTHER SIZES AVAILABLE ON REQUEST

INSTRUMENT SETS

CATALOG NUMBER	DESCRIPTION
119 980ND	STERILIZATION CONTAINER
119 820ND	EXTERNAL SCREWDRIVER
119 825ND	VILADOT LEVER
119 830ND	HOLDER
119 835ND	UNSCREWER
119 840ND	INTERNAL SCREWDRIVER
119 809ND	TRIAL IMPLANT 09 MM
119 810ND	TRIAL IMPLANT 10 MM
119 811ND	TRIAL IMPLANT 11 MM
119 812ND	TRIAL IMPLANT 12 MM
119 813ND	TRIAL IMPLANT 13 MM
119 814ND	TRIAL IMPLANT 14 MM

OTHER SIZES AVAILABLE ON REQUEST



- 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.

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