Flat foot implant

Surgical technique

newdeal
New ideas for foot surgery™
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.

<table>
<thead>
<tr>
<th>Trial implant</th>
<th>119859</th>
<th>119860</th>
<th>119861</th>
<th>119862</th>
<th>119863</th>
<th>119864</th>
<th>119865</th>
<th>119867</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kalix® II implant</td>
<td>141009</td>
<td>141010</td>
<td>141011</td>
<td>141012</td>
<td>141013</td>
<td>141014</td>
<td>141015</td>
<td>141017</td>
</tr>
<tr>
<td>Diameter</td>
<td>9 mm</td>
<td>10 mm</td>
<td>11 mm</td>
<td>12 mm</td>
<td>13 mm</td>
<td>14 mm</td>
<td>15 mm</td>
<td>17 mm</td>
</tr>
</tbody>
</table>
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.

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**
Step No.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.
Clinical cases

Adult case

Child case
Bibliography

• 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


• Viladot R, Torner CE & Rochera R:
  Nueva tecnica quirurgica para el tratamiento del pie plano.


Acknowledgment: Anatomical trials and validation have been conducted with the cooperation of Prof. Dr. GOLANO at the department of Pathology and Experimental Therapeutics (Human Anatomy Unit) Universidade 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 be 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 self high density polyethylene according to ISO 8034-1/2 and ASTM 696 Standards.

2. Indications:

The KALIX® - KALIX®II implant is indicated for the 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 sequelae.

• Flat foot deformities in children and adolescents
• Congenital flat foot
• Non successful long term orthopaedic treatment (shoes, insoles, ...)
• Tarsal coalition
• Paralytic flat foot
• سابقة في تدليك العروق في الأнихة
• خيراليدية
• خائراليدية

3. Contraindications:

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

• Still or fixed deformity of the flat foot
• Flat foot with a flat foot deformity
• Chorea or other movement disorders of the foot
• Symptomatic arthritis
• Neurological affection (e.g. paraplegia, ...) etc.
• Suspected or documented metal allergy or intolerance.

4. Warnings:

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

• Lacks good general physical condition
• Has severe osteoporosis
• Demonstrates psychiatric or anaesthetic anomalies;
• Has anaesthetic responses, sensitivity, or hypersensitivity to foreign materials;
• Has severe osteoporosis;
• Demonstrates physiologic or anatomic anomalies

5. Precautions for use:

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

• Obesity and or alcohol and or smoke addiction and/or abuse
• Infection disease
• Malignancy
• Local bone erosion
• Systemic or metabolic disorder or replacement
• Compromised wound healing
• Obesity
• Severe psychiatric or psychological instability
• A lack of understanding, inappropriate motivation, or attitude

6. Use of the implant:

The implant must be used in compliance with the use of the profession and the art standards. Do not attempt a surgical procedure with
the implant if the implant has been damaged or not used in the operating theatre.

7. Reuse of the implant:

Orthopaedic implants already implanted must never be re-used. The company accepts no responsibility for such
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 intense physical effort
• Avoid wearing orthopaedic shoes according to the surgeon’s prescription
• Re-sterilization of the implant is not performed
• Maintain medical attention for any infection that could occur, whether at the implantation level or elsewhere in the body.

10. Storage: 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 here out of this product. Newdeal neither assumes nor authorizes any person to assume to the user any other or additional liability or responsibility in connection with these products. Newdeal insists that this device should be used only by physicians having received proper training in orthopaedic techniques for use of this device.

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

INFORMATION: Should any information regarding the products or their use be required, please contact your representative or distributor directly or 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**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>141 009</td>
<td>External diam. 09 MM</td>
</tr>
<tr>
<td>141 010</td>
<td>External diam. 10 MM</td>
</tr>
<tr>
<td>141 011</td>
<td>External diam. 11 MM</td>
</tr>
<tr>
<td>141 012</td>
<td>External diam. 12 MM</td>
</tr>
<tr>
<td>141 013</td>
<td>External diam. 13 MM</td>
</tr>
<tr>
<td>141 014</td>
<td>External diam. 14 MM</td>
</tr>
<tr>
<td>141 015</td>
<td>External diam. 15 MM</td>
</tr>
<tr>
<td>141 017</td>
<td>External diam. 17 MM</td>
</tr>
</tbody>
</table>

**Instrumentation**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>119 880</td>
<td>Sterilization container</td>
</tr>
<tr>
<td>119 825</td>
<td>Viladot lever</td>
</tr>
<tr>
<td>119 850</td>
<td>Impactor</td>
</tr>
<tr>
<td>119 859</td>
<td>Trial implant 09 MM</td>
</tr>
<tr>
<td>119 860</td>
<td>Trial implant 10 MM</td>
</tr>
<tr>
<td>119 861</td>
<td>Trial implant 11 MM</td>
</tr>
<tr>
<td>119 862</td>
<td>Trial implant 12 MM</td>
</tr>
<tr>
<td>119 863</td>
<td>Trial implant 13 MM</td>
</tr>
<tr>
<td>119 864</td>
<td>Trial implant 14 MM</td>
</tr>
<tr>
<td>119 865</td>
<td>Trial implant 15 MM</td>
</tr>
<tr>
<td>119 867</td>
<td>Trial implant 17 MM</td>
</tr>
</tbody>
</table>

- 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**

- See instructions for use
- Single use
- Sterile

---

Kalix and newdeal are registered trademarks of Integra LifeSciences Corporation. New ideas for foot surgery and the Integra wave logo are trademarks of Integra LifeSciences Corporation. ©2006 Integra LifeSciences Corporation, all rights reserved. ND 00322:02:06