GROUP FH ORTHO

CALCAnail

INSTRUCTIONS FOR USE

be POD

Consult instructions for use

STERILE R

Sterilized by irradiation

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CALCAnail **A → Arthrodesis nail**

Rx Only

Keep away from rain

Keep away from sunlight

Do not use if package is damaged

Do not re-use

Do not resterilize

Imprimée en France
EMNI 2402 004 ind. C
Revision 2017-07

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WARNING AND INDICATIONS
IT IS IMPORTANT TO CAREFULLY READ THIS LEAFLET
If you need further information, do not hesitate to contact the distributor's sales department. This document is not exhaustive. Neither is it an operative technique manual giving implantation details. In all cases, refer to the documents supplied.

CAUTION: Federal law (USA) restricts this device to sale, distribution and use by or on the order of a physician.

I – DESCRIPTION, INDICATIONS, COMPATIBILITY, AND PERFORMANCE

The CalcaNail Orthopedic Arthrodesis Nail is intended for subtalar arthrodesis in the treatment of patients with:

- Comminuted fractures of the calcaneus
- Post-traumatic osteoarthritis and/or poor function resulting from calcaneal fracture sequelae
- Osteoarthritis of the posterior subtalar joint, or
- Valgus flatfoot deformities

II- CONTRAINDICATIONS

1 - Infection or latent infection is a major contraindication: it will be diagnosed in patients with the following symptoms: Fever and/or localized inflammation
2 - Unexplained increase in sedimentation rate
3 - Increased number of white blood cells or changes noticed during patient follow-up.
4 - Mental or neuromuscular disorders that may constitute an unacceptable risk to the patient and be a source of postoperative complications.
5 - Bones weakened by diseases or infection, not providing sufficient support and fixation.
6 - Obesity that could subject the prosthesis to stresses which may adversely affect device fixation or the device itself.
7 - Known allergy to one of the components of the material mentioned on the product label.
8 - Metabolic diseases that may compromise bone regrowth
9 - Drug-dependency

III – PRECAUTIONS

- The lifetimes of the implants depend on many biological, biomechanical and other factors. Therefore, strict compliance with the indications, contraindications, precautions and warnings is essential.
The results of arthroplasty depend on the orthopaedic history of the patient. The psychological preparation of the patient is essential.
The patients must be informed of the limitations of the prosthesis, including the impact of excessive stresses due to weight and intense activity. The patients must be given advice on how to adapt their activity. The patient should consult the surgeon in case of trouble in the region of the device.
- Before clinical use, the surgeon and operating theatre personnel must familiarize with the device and associated ancillary material. They must have an understanding of all the aspects of the surgical operation and the limitations of the device.
- It is important to protect the components and all polished or coated bearing surfaces from abrasion, scratches or any other adverse effect of metal and abrasive objects.
- The bearing surfaces must be clean and free from pieces of bone, etc., before implantation. The surgeon should make sure that the implant is in full contact with the bone.
- Make sure that the presence of other devices will not impair the functional integrity of the device.
- Do not mix implants of various sources nor different systems from FH ORTHOPEDICS. The only possible component combinations are indicated in the procedures for the relevant prostheses.

IV - IMPLANTATION TECHNIQUE

Specific instrumentation, delivered nonsterile, is necessary for the placement of implants designed by FH Industrie and distributed by FH ORTHOPEDICS or their distributors. The operative techniques are available from FH ORTHOPEDICS or their distributors. For some implants, FH ORTHOPEDICS or their distributors can supply X-ray templates for the surgeon to select the implant size.

V - WARNINGS

Patients receiving a joint prosthesis must be informed that the lifetime of the implant may depend on their weight and activity
- Damaged or defective implants must not be used,
- Using an implant of inappropriate size may reduce resistance to strain.
- FH Industrie will accept no responsibility if components from another manufacturer are used or if their components are put to other than their intended use.
- The implants must not be modified or subjected to any treatment.

VI - UNDESIRABLE SIDE EFFECTS

It is the surgeon's responsibility to provide the patient with all the information before the operation, and especially to inform the patient of:
- the risk of rupture of the implant following inappropriate activity, trauma, or other stresses specific to the patient's activity,
- the risk of the implant coming loose following insufficient initial fixation, latent infection, premature or excessive stressing, component malpositionning, or trauma,
- the risk of allergy to one of the components of the material mentioned on the product label,
- side effects that may require further operation, or revision.

The Calcanail has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Calcanail in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

IMPORTANT INFORMATION FOR THE SURGEON:
The most common side effects of an arthroplasty are the following:
- Haematoma, late healing, deep vein thrombosis, pulmonary thrombosis, and blood vessel or nerve injury
- Pulmonary embolism
-Infection
- Cardiovascular problems
- Pseudarthrosis

During MRI/CT scan examinations, ask the patient if he or she wears a metal implant.

VII - IMPLANT MATERIALS

The implant materials are mentioned on each product label.
cobalt-chromium alloy
TA6V4 titanium alloy
Stainless steel. This stainless steel usually contains nickel

VIII – PACKAGING AND STERILIZATION

The product label information gives traceability of manufacture.

Check for perfect sealing of packaging items (peel pouches or shells and seals) and overall integrity before using the implants. Do not use a product with a damaged package or a broken tamper-proof label.
The product must not be resterilized. The stick-on dot on the outer package confirms sterilization. A stick-on dot that is yellow or purple may indicate an unsterile product. In this case, the product must be returned. Desterilized implants are not taken back.

IX - STORAGE AND HANDLING

The product must be stored away from moisture and heat

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STERILE R

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