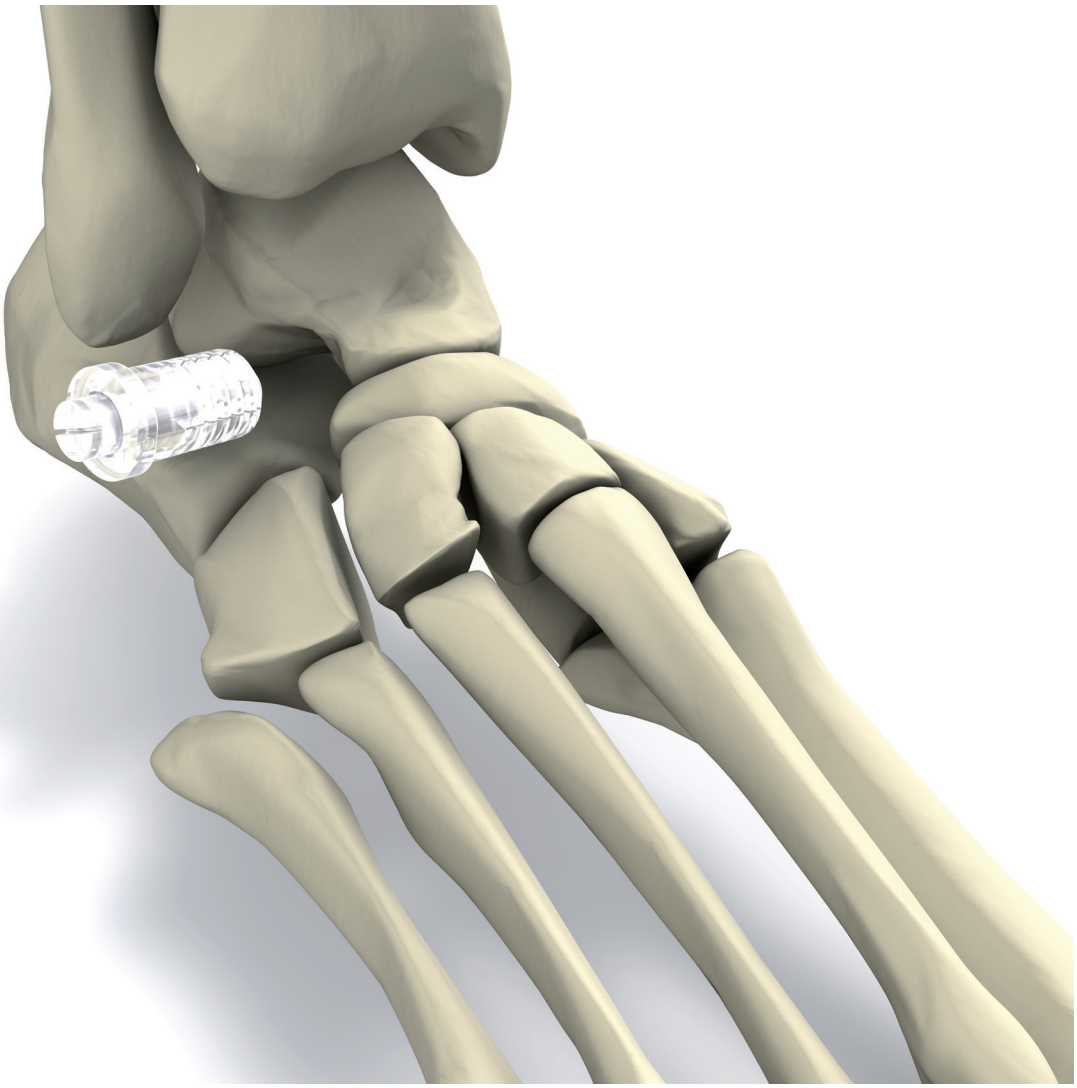
BIORESORBABLE FLAT FOOT IMPLANT

Surgical Technique
Pediatric
Treatment



NOVAGENIT®

INDICATIONS & CONTRAINDICATIONS

FLEXIBLE FLAT FOOT SURGICAL TREATMENT IN CHILDREN

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Patents:
Giannini US5360450
Giannini EP0560249B1

Indications

Main indications:

- When the functional issue ceatly assessed whith clinical examinaton, or in uncertain cases, when it is confirmed by gait analysis.
- Flat foot with tarsal fusion. In this case after the fusion removal the implant allows correction of the deformity associated.
- Congential vertical talus. In this case after soft tissue release, the device fills the gap between talus and calcaneous avoiding recuissence deformity.
- Adult flat foot. In this case the added procedures (Achilles tendon lengthening and posterior tibial tendon retention) are necessary.
- Posterior tibial tendon dysfunction type 1° and 2°, associated with suture repair of tendon transfer and Achilles tendon lengthening when necessary.

CONTRAINDICATIONS

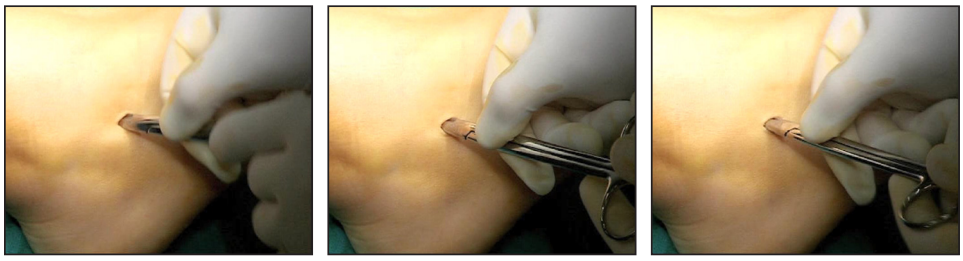
- Neurological flat foot
- Flat foot due to severe ligaments laxity
- Adult flat foot with arthritis of the hindfoot joints

ANAESTHESIA

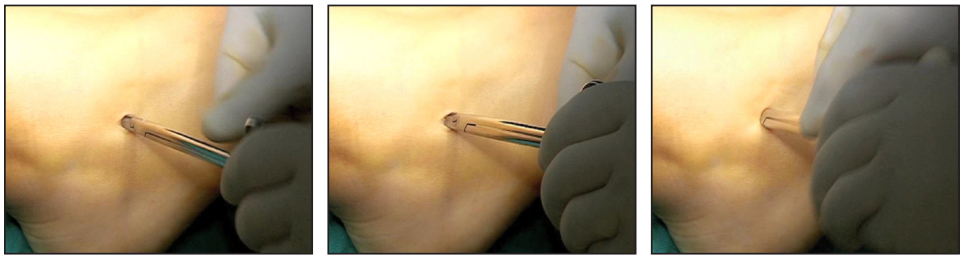
Anaesthesia can be general, peridural or peripheral, depending upon the individual case. General anaesthesia is usually preferred for children.
Tourniquet:
The use of a tourniquet is optional.

OPERATIVE TECHNIQUE

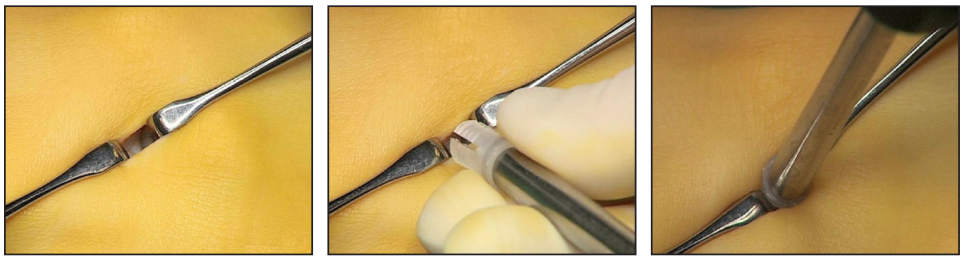
The patient is placed in the supine position with the foot internally rotated.
A 1cm incision over the sinus tarsi is performed.



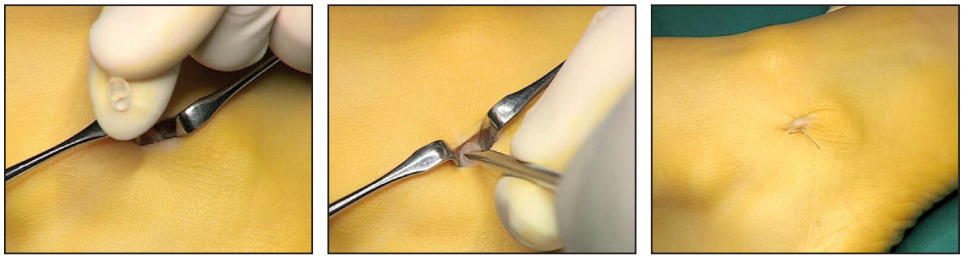
The extensor retinaculum is opened to the cuboid bone using curved scissors. By turning the tip of the scissors upwards and pushing in a medial direction towards the internal malleolus, the tip of the scissors can be felt going into the deepest region of the sinus tarsi.



A 6mm rod is introduced in the same direction followed by 8 and 10mm rods until the correction is obtained.
The skin and the fibres of the retinaculum are opened with 2 small retractors to allow for the placement of the outer cylinder of the implant with a universal introducer.



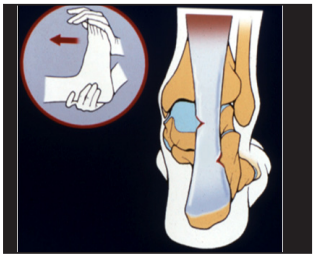
The inner screw is inserted to open and stabilize the implant. The screw is tightened until the characteristic “squeaking” is heard from the material.
The retinaculum is sutured with N. 3-0 reasorbable thread and the skin is sutured with another stitch.

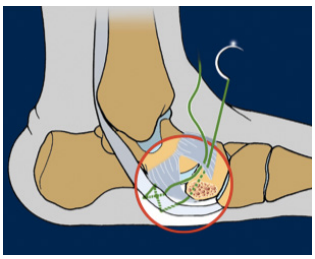


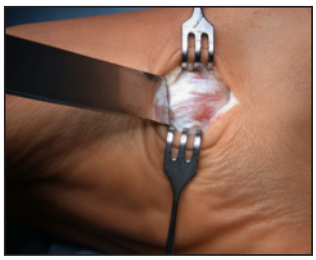
Usually this is the only procedure necessary if the patient is still on the growth age.

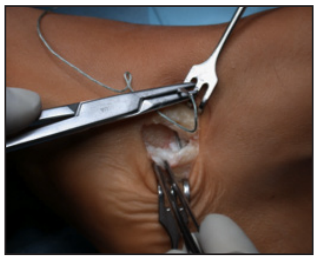
ADDED SURGICAL PROCEDURES

After correcting the deformty by inserting the implant, the dorsiflexion of the foot is checked with the knee in extension. If the Achille feits toserch 90°, the Achilles tendon is lengthened subcutaneously by two or three alternate hemisections, starting distally-laterally, then 3 cm above the previous one. The foot is forced in dorsal flexion to stretch the tendon until 10° dorsiflexion is achieved.





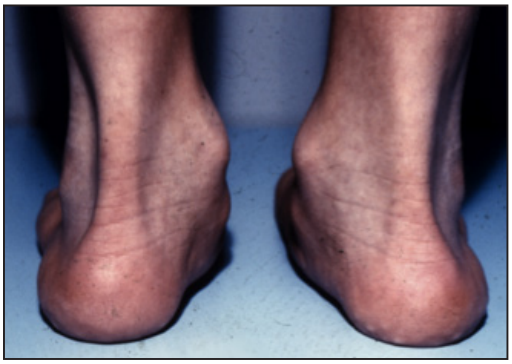


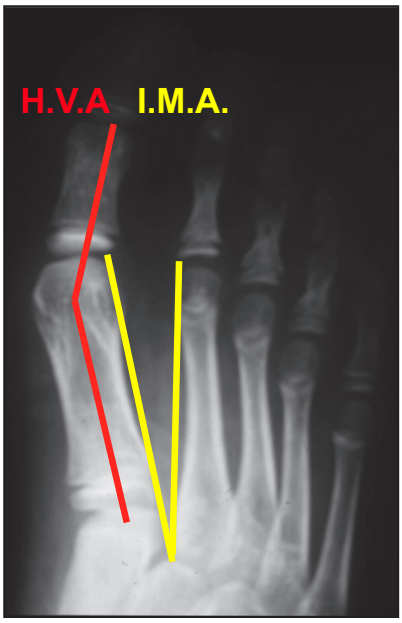
POSTOPERATIVE TREATMENT

When only the implant is inserted, it is preferable to use a walking boot for 2 weeks in order to reduce potential pain during walking and allow earlier return to normal activity.
If other surgical procedures are associated, the recommended period of immobility with a boot is 5 weeks without weight bearing and 2 weeks with weight bearing.
In both cases, when the boot is removed, normal footwear is worn and cycling and swimming are recommended.

In case of navicular accessory or prominent painful navicular bone, or the interruption of the Meary`s line at the naviculocuneiform with an angle greater than 10°, a medial procedure is performed with retention of the posterior tibialis.
With a 3cm incision over the navicular prominence, the navicular bone is revealed along with the posterior tibialis.
The periosteum is detached from the navicular bone and the posterior tibial tendon, maintaining the metatarsal expansion and
fibres directed towards the navicular bone.
After tangential resection of the navicular prominence, remove any navicular accessory.
The posterior tibialis is put under tension using a No. 2 reabsorbable stitch which passes through the dorsal periosteal flap.
Take the tendon of the posterior tibialis with a stitch, according Bunnell, and pass from plantar to dorsal through the spongy part of the navicular bone.
Added Surgical Procedures
By pulling the two ends of the thread, the tendon is advanced distally and fixed under the navicular bone. The suture is reinforced with another cross stitch.
The sheath of the posterior tibialis is sutured with No. 3-0 thread.

CLINICAL CASES

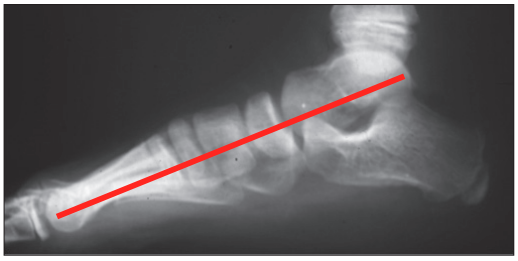


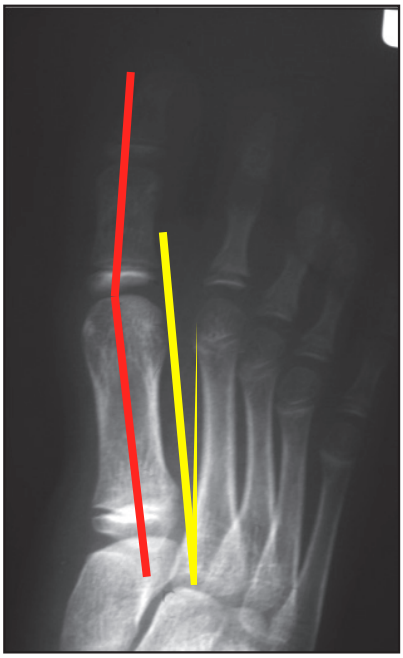


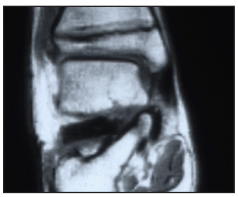
Clinical aspect of an eleven-year-old boy before and after surgery and Rx before and after operation.

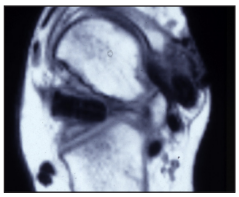
BEFORE

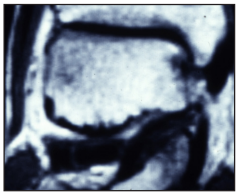
AFTER

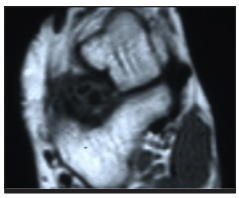


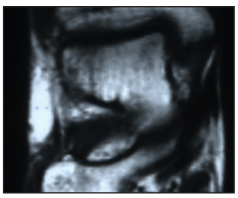












MRI after 6 months shows the maintenance of the shape of the device, the device is breaking after 1.5 years, is partially reabsorbed after 3 years, and completely reabsorbed after 5years.

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NOTE

IMPLANTS AND INSTRUMENTS

CODE IMPLANTS	DESCRIPTION
2100008	BFFI 8mm in sterile package
2100010	BFFI 10mm in sterile package

The flat foot implant is a Class III medical device

INSTRUMENTS (Not sterile Class I medical device)

FA00000	BFFI complete instrument set
FA00100	Cylindric spacer 6mm
FA00200	Cylindric spacer 8mm
FA00300	Cylindric spacer 10mm
FA00400	Implant introducer 8mm
FA00700	Implant introducer 10mm
FA00500	BFFI Screwdriver

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