

OPERATIVE TECHNIQUE

G-Beam[™]

Fusion Beaming System



G-BeamTM

Fusion Beaming System

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the Instructions for Use for the complete list of indications, warnings, precautions, and other important medical information.

INTRODUCTION

This operative technique explains the recommended procedures for using the G-Beam™ Fusion Beaming System's implants and instruments. Please refer to the corresponding instructions below on specific steps. The IFU (Instruction For Use) leaflet contains the indications for use as well as the contraindications and has been included in the packaging of all implants. It can also be found at <http://ifu.orthofix.it>.

INTENDED USE

The G-Beam is intended to be inserted in the bones of the foot and ankle for alignment, stabilization and fixation of various fractures and osteotomies, fusions and reconstructions.

GENERAL DESCRIPTION

The G-Beam Fusion Beaming System has been designed to address the specific demands of advanced deformity and trauma reconstructions of foot and ankle applications. The system was developed for the treatment of neuropathic deformities, such as Charcot, requiring fusion of the medial and/or lateral columns, with or without corrective osteotomies as well as for joint fusions within the mid- and hindfoot.

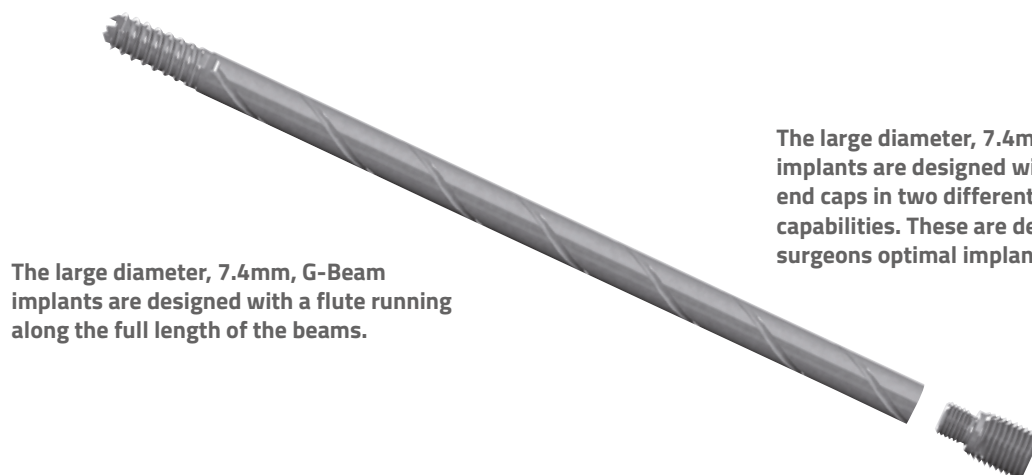
The G-Beam Fusion Beaming System consists of two different diameter implant ranges, designed for optimal implant selection for wide ranging patient anatomies, and an instrumentation including the dedicated G-Beam Sterilization Tray.

The G-Beam Fusion Beaming System is designed with an instrumentation and technique that have been developed to simplify the surgery.

IMPLANTS AND INSTRUMENTS

- The G-Beam Fusion Beam thread has been designed with a short length and a stepped drill to allow for accurate implant placement and reduce the probability of placing the thread within the joint line.
- The G-Beam Fusion Beams are designed with a wide range of lengths for optimal implant selection.

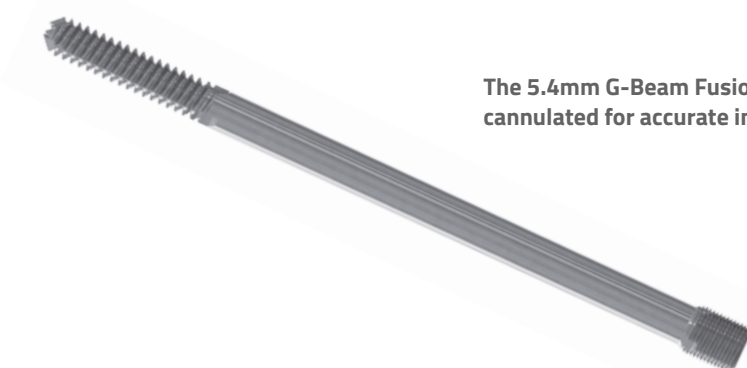
The 7.4mm G-Beam Fusion Beams are fully cannulated for accurate implant placement.



The large diameter, 7.4mm, G-Beam implants are designed with a flute running along the full length of the beams.

The large diameter, 7.4mm, G-Beam implants are designed with modular end caps in two different compression capabilities. These are designed to provide surgeons optimal implant selection.

The small diameter, 5.4mm, G-Beam implants have been designed as a single piece beam with built-in compression capabilities.



The 5.4mm G-Beam Fusion Beams are fully cannulated for accurate implant placement.

TABLE 1

	COLOR CODE	GUIDEWIRE	STEPPED DRILL	HEX SCREWDRIVER	EXTRACTION TOOL
Large Ø 7.4mm G-BEAM	Blue	Large Ø 2.8mm	Large Ø 5.1-7.5mm	Large 5mm	Large Ø 7.4mm
Small Ø 5.4mm G-BEAM	Yellow	Small Ø 1.9mm	Small Ø 4-5.5mm	Small 4mm	Small Ø 5.4mm

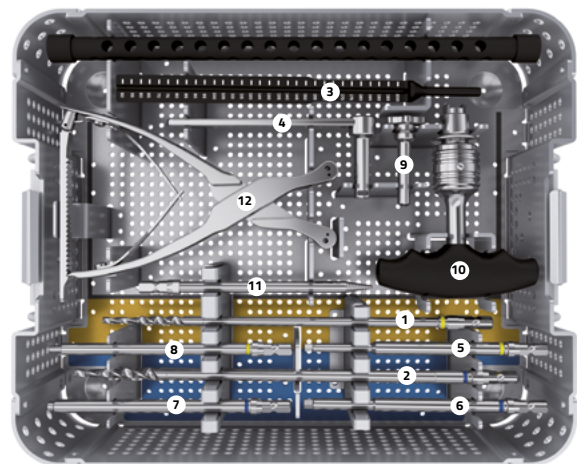
TABLE 2: Available G-Beam lengths and diameters

LARGE Ø 7.4mm G-BEAM	
Code	G-BEAM Lengths
99-877200	200mm
99-877195	195mm
99-877190	190mm
99-877185	185mm
99-877180	180mm
99-877175	175mm
99-877170	170mm
99-877165	165mm
99-877160	160mm
99-877155	155mm
99-877150	150mm
99-877145	145mm
99-877140	140mm
99-877135	135mm
99-877130	130mm
99-877125	125mm
99-877120	120mm
99-877115	115mm
99-877110	110mm
99-877105	105mm
99-877100	100mm
99-877095	95mm
99-877090	90mm
99-877085	85mm
99-877080	80mm
99-877075	75mm
99-877070	70mm
99-877065	65mm
99-877060	60mm
99-877055	55mm
99-877050	50mm

SMALL Ø 5.4mm G-BEAM	
Code	G-BEAM Lengths
99-875170	170mm
99-875165	165mm
99-875160	160mm
99-875155	155mm
99-875150	150mm
99-875145	145mm
99-875140	140mm
99-875135	135mm
99-875130	130mm
99-875125	125mm
99-875120	120mm
99-875115	115mm
99-875110	110mm
99-875105	105mm
99-875100	100mm
99-875095	95mm
99-875090	90mm
99-875085	85mm
99-875080	80mm
99-875075	75mm
99-875070	70mm
99-875065	65mm
99-875060	60mm
99-875055	55mm
99-875050	50mm

TABLE 3: Instrument Set

Code	Description
187284	1 Small Stepped Drill D4/5.5mm
187283	2 Large Stepped Drill D5.1/7.5mm
187274	3 Sizing Gauge
187213	4 Drill Guide
187321	5 Small Hex Screwdriver 4mm
187320	6 Large Hex Screwdriver 5mm
187335	7 Large Extraction Tool D7.4mm
187336	8 Small Extraction Tool D5.4mm
187223	9 Wire Guide
187279	10 Ratcheting T-Handle
187337	11 Conical Threaded Extractor
001-A-40007	12 Joint Compression Forceps
001-A-1502P	Guide wire 1.5mm, 4.0/5.5mm Bite Compression Screw (Kit of 2)
99-187287	Small Guidewire D1.9mm Sterile
99-187288	Large Guidewire D2.8mm Sterile
187990	G-Beam Sterilization Tray
187990C	G-Beam Sterilization Tray Complete
187995	G-Beam Kit
187995C	G-Beam Kit Complete



PREOPERATIVE PLANNING

Accurate preoperative planning is important for determining the appropriate G-Beam diameter, length, placement and surgical approach (retrograde vs antegrade; dorsal vs plantar) for the desired procedure(s) being performed.

The preoperative plan should also consider the use of adjunct fixation (e.g. external fixation, plating system...) to provide additional rotational stability and/or the use of multiple G-Beams.

SURGICAL TECHNIQUE

The operative technique listed below is designed to provide a general recommendation on the instruments and procedure required for the intramedullary fixation of the medial column of the foot with the G-Beam Fusion Beaming System.

Patient positioning

Place the patient in supine position with a roll under the hip of the affected foot. Toes should be straight up in a resting position.

Correction of equinus contracture

Ankle dorsiflexion should be evaluated with the knee extended and flexed. In case of equinus contracture that does not improve with knee flexion, a percutaneous Achilles tendon lengthening should be considered. If ankle dorsiflexion improves with knee flexion, a gastrocnemius recession is indicated.

Surgical exposure

Exposure of midfoot/hindfoot

Make a medial utility incision along the axis of the medial column to allow access and exposure of the talonavicular, navicularcuneiform and tarsometatarsal joints (**Fig. 1**).



NOTE: When dorsal dissection is necessary, carefully elevate the soft tissues and protect the dorsalis pedis artery and deep peroneal nerve.



NOTE: Preserve the insertion of the anterior and posterior tibial tendons. In case of fragmentation involving the navicular and/or medial cuneiform, restore these insertions when stabilizing the medial column when possible.

Exposure of the 1st metatarsal phalangeal joint (only if a dorsal approach is planned)

Expose the 1st metatarsal phalangeal joint by directing the medial approach dorsal and distal or by performing an isolated dorsal straight incision (**Fig. 2**).



NOTE: The extensor hallucis longus tendon is mobilized and retracted laterally exposing the joint capsule.



Fig. 1



Fig. 2

Resection of bone and joint preparation for medial column fusion

Instrumentation	
Code	Description
99-187288	Large Guidewire Ø 2.8mm Sterile
001-A-40007	Joint Compression Forceps
001-A-1502P	Guide wire 1.5mm, 4.0/5.5mm Bite Compression Screw (Kit of 2)

The goal of this procedure is to establish a stable, plantigrade foot. This requires a linear relationship of the long axis of the medial column (Meary's angle = 0°). This may also require insertion of additional G-Beams (see also pag. 10). Consider to resect osteophytes or bridging bone to adequately mobilize the medial column segments. If dorsal angulation of the forefoot is present, resect the plantar apex to achieve a Meary's angle of 0°.

Meticulous preparation of each viable joint is paramount to the success of this procedure. Carefully prepare the surfaces of the talonavicular, navicularcuneiform and tarsometatarsal joints where viable. Remove joint cartilage and any fibrous tissue from within the joint. Using a drill and/or osteotome, create multiple defects in the subchondral bone to stimulate subchondral bleeding.

Use guidewires with or without the use of joint compression forceps to reduce and stabilize multiple segments. Ensure that provisional fixation will not interfere with guidewire or G-Beam placement.

Once each joint/segment interval is stabilized, use fluoroscopy to confirm Meary's angle (0°) in both the AP and ML planes. It is important to ensure each joint or segment interface is adequately compressed. If necessary, use joint compression forceps to compress the bone segments.



PRECAUTION: Screen with an image intensifier during guidewire insertion.

Retrograde approach - Guidewire insertion

Instrumentation

Code	Description
99-187288	Large Guidewire Ø 2.8mm Sterile
187223	Wire Guide
187213	Drill Guide

Guidewire insertion can be performed through either a dorsal approach or percutaneously through the plantar aspect of the foot. With either approaches, inserting and advancing the guidewire should be performed using the image intensifier to ensure precise placement. Ideal guidewire placement is in the center of the medial column from both the sagittal and coronal planes.

For dorsal insertion, carefully release the medial and lateral capsule to allow plantarflexion of the hallux and expose the first metatarsal head (**Fig. 3a**). If plantar insertion is desired, dorsiflex the hallux (**Fig. 3b**) and make a 1cm sagittal incision centered over the metatarsal head.

Using the wire guide and the drill guide, under fluoroscopic control insert the Ø 2.8mm guidewire through the desired entry point and across the tarsometatarsal, the navicularcuneiform and the talonavicular segments into the body of the talus (**Fig. 4**).



Fig. 3a



Fig. 3b

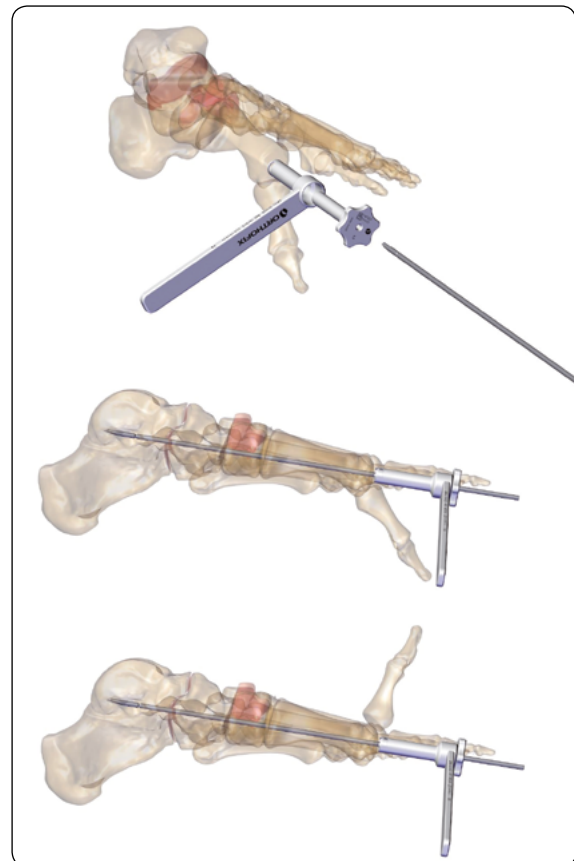


Fig. 4

Frequently confirm position with image intensifier in both the sagittal and coronal planes. It may be necessary to translate an individual segment for desired alignment.

Confirm placement of the guide wire tip to desired G-Beam position in the talus.



PRECAUTION: If preoperatively the patient is able to actively plantarflex the great toe metatarsal phalangeal joint, the plantar approach is not recommended as this may damage the plantar plate, one or both flexor tendons and possibly the sesamoids.



PRECAUTION: Avoid penetrating the posterior cortex/subchondral bone of the talus in order to obtain good bone purchase.



PRECAUTION: Screen with an image intensifier during guidewire insertion.

Measurement of G-Beam length

Instrumentation	
Code	Description
187274	Sizing Gauge

Use the sizing gauge to determine the appropriate G-Beam length.

Place the sizing gauge over the Ø2.8mm guidewire and down to the surface of the metatarsal head (**Fig. 5**).

If the length measured is between two readings, the surgeon must evaluate the most appropriate G-Beam length for the procedure being performed.

Remove the sizing gauge.

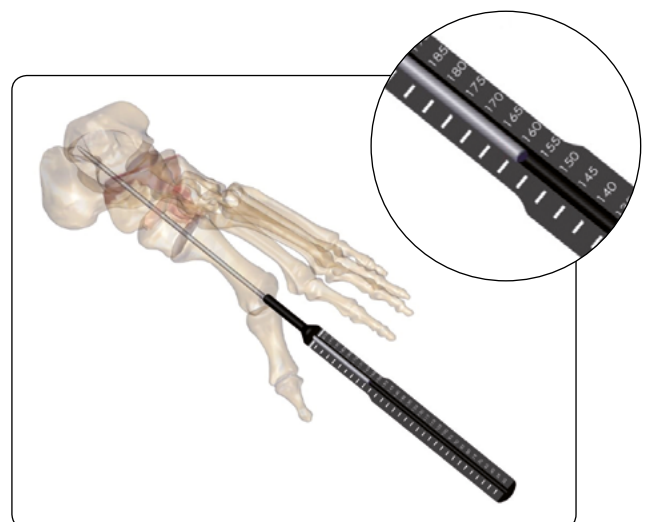


Fig. 5

Drilling

Instruments

Code	Description
187283	Large Stepped Drill Ø 5.1/7.5mm
187213	Drill Guide

Place the stepped drill with the drill guide over the guidewire. Advance the drill under fluoroscopy and verify that the narrow end of the drill does not stop within a joint line. If so, drill further until the narrow end of the drill is not in the joint line (**Fig. 6**).

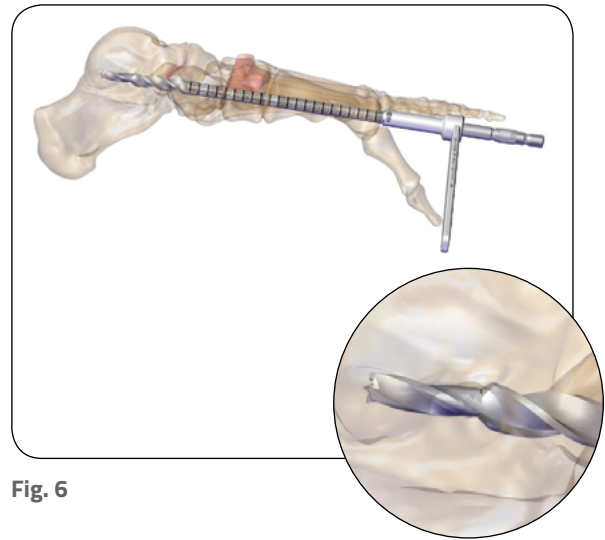


Fig. 6

Confirm the correct G-Beam length by checking through the "window" on the drill guide (**Fig. 7**) or by slightly backing out the drill guide.

Remove the step drill ensuring the guidewire remains in place.



PRECAUTION: Avoid penetrating the posterior cortex/subchondral bone of the talus in order to obtain good bone purchase.



PRECAUTION: The G-Beam threads will be in the same position as the narrow end of the drill when drilling is completed. Make sure the narrow end of the drill does not stop within a joint line so that the G-Beam threads will not be placed within a joint line.



PRECAUTION: Screen with an image intensifier during drilling.

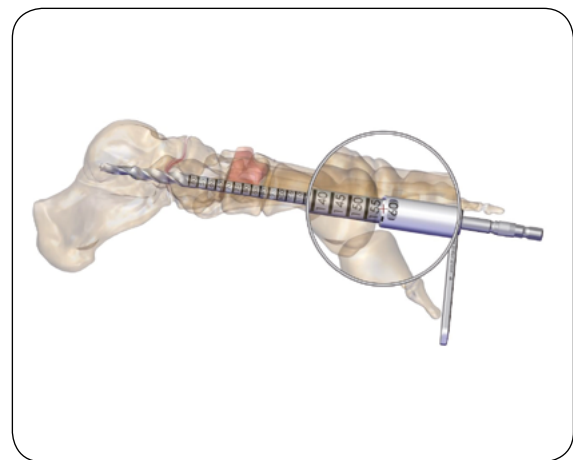


Fig. 7

Selection of the end cap (only for Ø 7.4mm G-Beam)

Implants

Code	Description
99-870010	G-BEAM Stainless Steel End Cap High Compression Sterile
99-870005	G-BEAM Stainless Steel End Cap Low Compression Sterile

Select the appropriate end cap for the desired compression and connect it to the selected Ø 7.4mm G-Beam (**Fig. 8**).



PRECAUTION: Always assemble the 7.4mm diameter G-Beam with the chosen end cap before insertion.

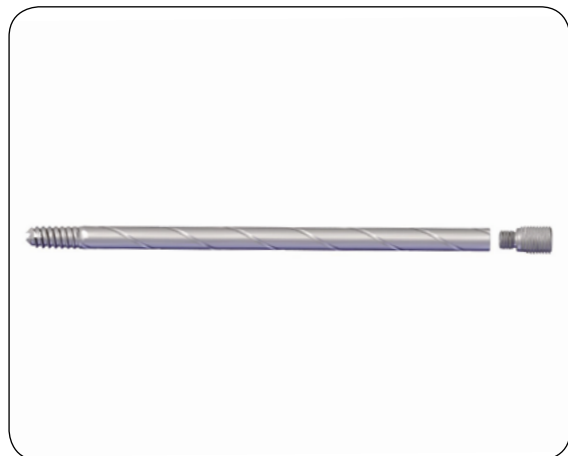


Fig. 8

G-Beam Insertion

Instruments

Code	Description
187279	Ratcheting T-Handle
187320	Large Hex Screwdriver 5mm

Connect the Hex screwdriver to the ratcheting T-Handle. Set the T-handle on "R" for ratcheting clockwise turning (**Fig. 9a**). In central position it is used as a standard handle (**Fig. 9b**).

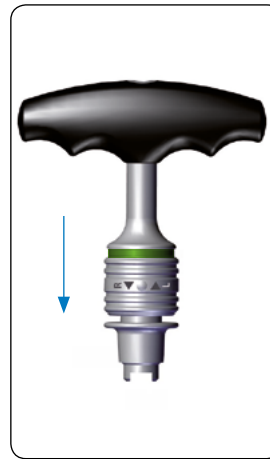


Fig. 9a

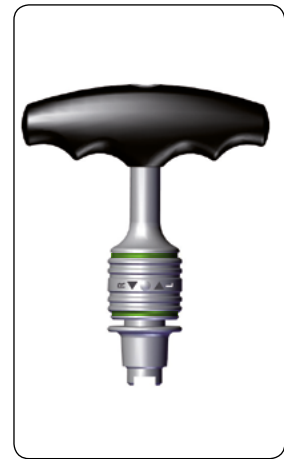


Fig. 9b

Place the selected G-Beam over the guidewire and insert it until the end cap is fully seated in the metatarsal head (**Fig. 10**). Use fluoroscopy to confirm correct implant positioning and joint alignment in the AP and lateral plane.



NOTE: Adjunct fixation - stabilization of one or more segments may require interfragmentary compression screw or plate fixation.



PRECAUTION: Ensure that the leading threads have purchase of the bone of the talar body or neck/body junction and that the trailing threads have purchase of subchondral bone of the metatarsal head.



PRECAUTION: Screen with an image intensifier during G-Beam insertion.

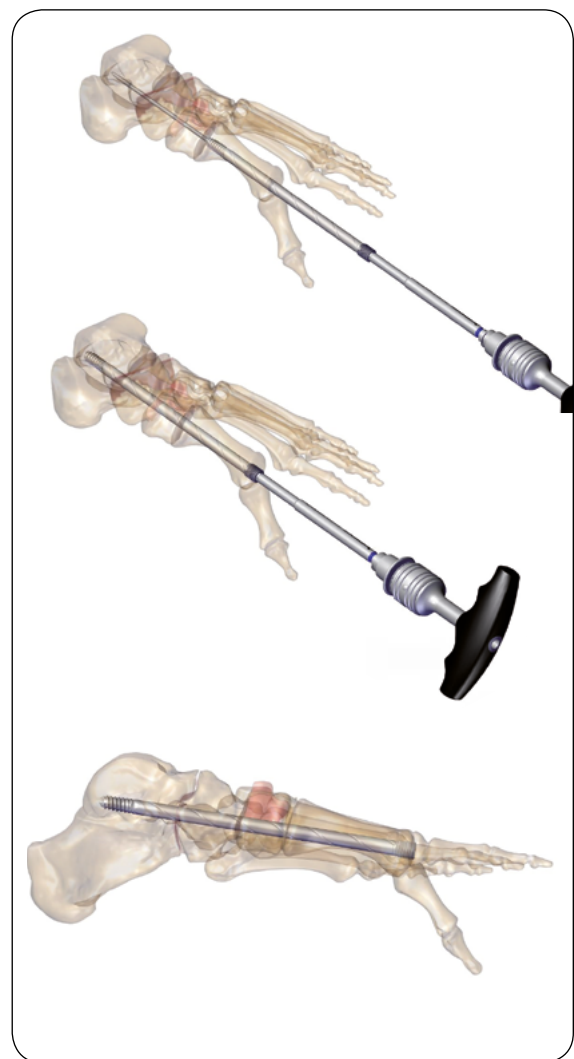


Fig. 10

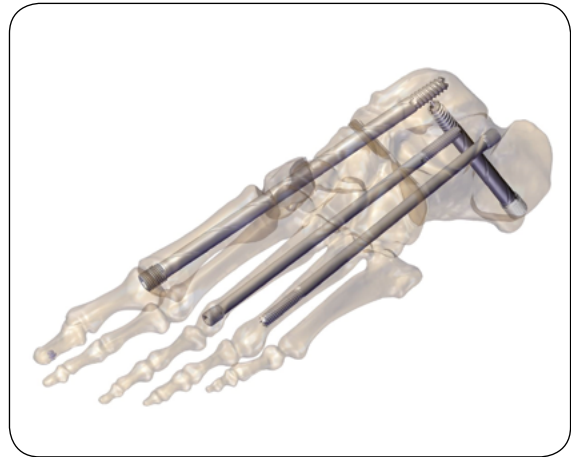
Additional G-Beams insertion

The goal of the surgery is to establish a stable, plantigrade foot. This may also require realignment and stabilization of the lateral column as well as correction of any subtalar deformity that may be influencing weight bearing stress. The latter may be addressed with either a realigning arthrodesis, calcaneal osteotomy or a combination of both. The position of the os calcis/ subtalar joint is paramount and will have a significant influence on forces applied through the forefoot or in the subtalar region of the foot.

Based on weight bearing alignment and structural integrity of the foot, placement of additional G-Beams might be considered.

Select the appropriate instruments for the insertion of additional G-Beams (see Table 1 pag. 2) and follow the surgical steps described above.

Example of possible G-Beams applications



Surgeons must evaluate the quantity, the dimensions and the placement of the G-Beam implants based on patient's anatomy and clinical condition.

G-BEAM REMOVAL

Option A: Removal with the extraction tools or with the hex screwdrivers

Instruments	
Code	Description
187279	Ratcheting T-Handle
187335	Large Extraction Tool Ø 7.4mm
187336	Small Extraction Tool Ø 5.4mm
187320	Large Hex Screwdriver 5mm
187321	Small Hex Screwdriver 4mm
001-A-1502P	Guide wire 1.5mm, 4.0/5.5mm Bite Compression Screw (Kit of 2)

If necessary, remove overgrown bone.
Under fluoroscopic control insert the guidewire in the implanted G-Beam.
Set the T-handle on "L" for ratcheting counterclockwise turning (**Fig. 11a**). In central position it is used as a standard handle (**Fig. 11b**).

Connect the appropriate extraction tool or screwdriver to the ratcheting T-handle and slide it over the guidewire.

If the screwdriver is used, attach it to the G-Beam and turn counterclockwise to remove the implant.

If the extraction tool is used, connect it to the G-Beam by turning counterclockwise. Continue turning counterclockwise to remove the G-Beam (**Fig. 12**).

If during removal the end cap disengages from the Ø 7.4mm G-Beam, connect the conical threaded extractor to the beam by turning counterclockwise and then continue turning counterclockwise to remove the implant.

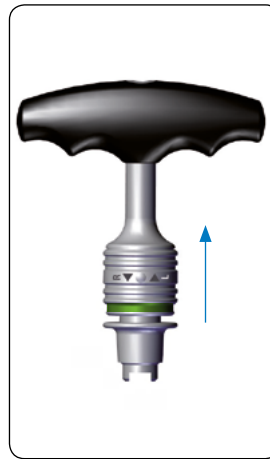


Fig. 11a

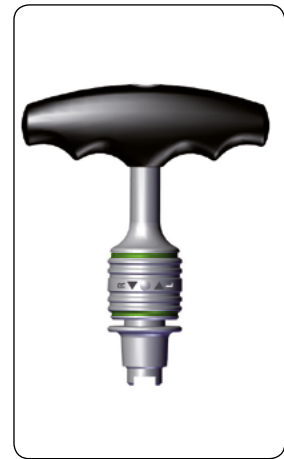


Fig. 11b

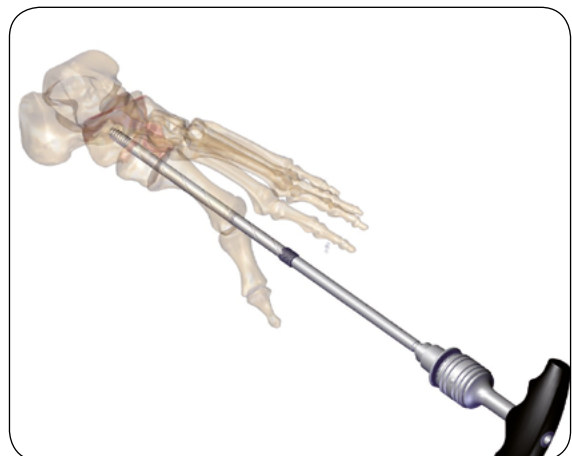


Fig. 12

Option B: Removal with the conical threaded extractor

Implants	
Code	Description
187279	Ratcheting T-Handle
187337	Conical Threaded Extractor

If necessary, remove overgrown bone.
Set the T-handle on "L" for ratcheting counterclockwise turning. In central position it is used as a standard handle (**Fig. 11b**). Connect the conical threaded extractor to the ratcheting T-handle.

Connect the conical threaded extractor to the G-Beam by turning counterclockwise. Continue turning counterclockwise to remove the G-Beam (**Fig. 13**).

If during removal the end cap disengages from the Ø7.4mm G-Beam, re-connect the conical threaded extractor to the G-Beam by turning counterclockwise and then continue turning counterclockwise to remove the implant.

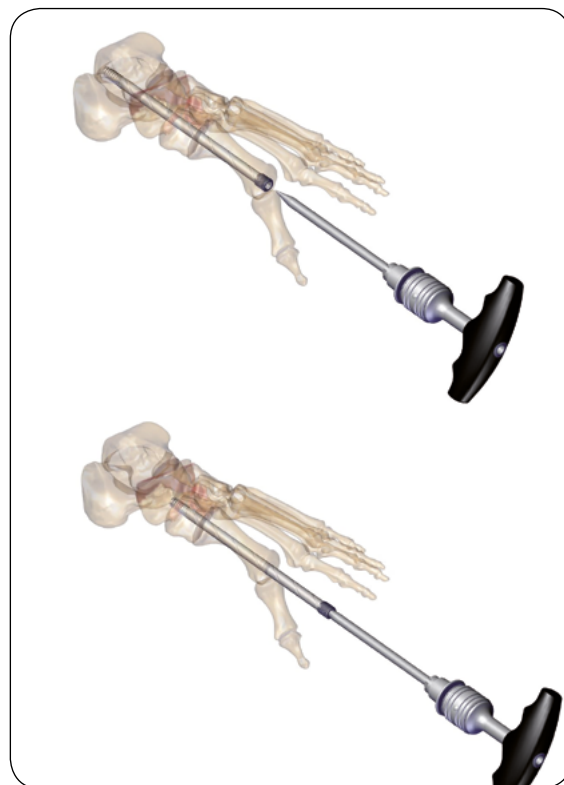


Fig. 13

POSTOPERATIVE CARE

Weight bearing restriction is recommended until soft tissues are stable and adequate bone healing is achieved.

Implants - 7.4mm Beams

Code	Description
99-877050	G-BEAM STAINLESS STEEL FUSION BEAM L50mm D7.4mm STERILE
99-877055	G-BEAM STAINLESS STEEL FUSION BEAM L55mm D7.4mm STERILE
99-877060	G-BEAM STAINLESS STEEL FUSION BEAM L60mm D7.4mm STERILE
99-877065	G-BEAM STAINLESS STEEL FUSION BEAM L65mm D7.4mm STERILE
99-877070	G-BEAM STAINLESS STEEL FUSION BEAM L70mm D7.4mm STERILE
99-877075	G-BEAM STAINLESS STEEL FUSION BEAM L75mm D7.4mm STERILE
99-877080	G-BEAM STAINLESS STEEL FUSION BEAM L80mm D7.4mm STERILE
99-877085	G-BEAM STAINLESS STEEL FUSION BEAM L85mm D7.4mm STERILE
99-877090	G-BEAM STAINLESS STEEL FUSION BEAM L90mm D7.4mm STERILE
99-877095	G-BEAM STAINLESS STEEL FUSION BEAM L95mm D7.4mm STERILE
99-877100	G-BEAM STAINLESS STEEL FUSION BEAM L100mm D7.4mm STERILE
99-877105	G-BEAM STAINLESS STEEL FUSION BEAM L105mm D7.4mm STERILE
99-877110	G-BEAM STAINLESS STEEL FUSION BEAM L110mm D7.4mm STERILE
99-877115	G-BEAM STAINLESS STEEL FUSION BEAM L115mm D7.4mm STERILE
99-877120	G-BEAM STAINLESS STEEL FUSION BEAM L120mm D7.4mm STERILE
99-877125	G-BEAM STAINLESS STEEL FUSION BEAM L125mm D7.4mm STERILE
99-877130	G-BEAM STAINLESS STEEL FUSION BEAM L130mm D7.4mm STERILE
99-877135	G-BEAM STAINLESS STEEL FUSION BEAM L135mm D7.4mm STERILE
99-877140	G-BEAM STAINLESS STEEL FUSION BEAM L140mm D7.4mm STERILE
99-877145	G-BEAM STAINLESS STEEL FUSION BEAM L145mm D7.4mm STERILE
99-877150	G-BEAM STAINLESS STEEL FUSION BEAM L150mm D7.4mm STERILE
99-877155	G-BEAM STAINLESS STEEL FUSION BEAM L155mm D7.4mm STERILE
99-877160	G-BEAM STAINLESS STEEL FUSION BEAM L160mm D7.4mm STERILE
99-877165	G-BEAM STAINLESS STEEL FUSION BEAM L165mm D7.4mm STERILE
99-877170	G-BEAM STAINLESS STEEL FUSION BEAM L170mm D7.4mm STERILE
99-877175	G-BEAM STAINLESS STEEL FUSION BEAM L175mm D7.4mm STERILE
99-877180	G-BEAM STAINLESS STEEL FUSION BEAM L180mm D7.4mm STERILE
99-877185	G-BEAM STAINLESS STEEL FUSION BEAM L185mm D7.4mm STERILE
99-877190	G-BEAM STAINLESS STEEL FUSION BEAM L190mm D7.4mm STERILE
99-877195	G-BEAM STAINLESS STEEL FUSION BEAM L195mm D7.4mm STERILE
99-877200	G-BEAM STAINLESS STEEL FUSION BEAM L200mm D7.4mm STERILE

Implants - End Caps

Code	Description
99-870005	G-BEAM STAINLESS STEEL END CAP LOW COMPRESSION STERILE
99-870010	G-BEAM STAINLESS STEEL END CAP HIGH COMPRESSION STERILE

Sterile Instruments

Code	Description
99-187287	SMALL GUIDEWIRE D1.9mm STERILE
99-187288	LARGE GUIDEWIRE D2.8mm STERILE
001-A-1502P	Guide wire 1.5mm, 4.0/5.5mm Bite Compression Screw (kit of 2)

Implants - 5.4mm Beams

Code	Description
99-875050	G-BEAM STAINLESS STEEL FUSION BEAM L50mm D5.4mm STERILE
99-875055	G-BEAM STAINLESS STEEL FUSION BEAM L55mm D5.4mm STERILE
99-875060	G-BEAM STAINLESS STEEL FUSION BEAM L60mm D5.4mm STERILE
99-875065	G-BEAM STAINLESS STEEL FUSION BEAM L65mm D5.4mm STERILE
99-875070	G-BEAM STAINLESS STEEL FUSION BEAM L70mm D5.4mm STERILE
99-875075	G-BEAM STAINLESS STEEL FUSION BEAM L75mm D5.4mm STERILE
99-875080	G-BEAM STAINLESS STEEL FUSION BEAM L80mm D5.4mm STERILE
99-875085	G-BEAM STAINLESS STEEL FUSION BEAM L85mm D5.4mm STERILE
99-875090	G-BEAM STAINLESS STEEL FUSION BEAM L90mm D5.4mm STERILE
99-875095	G-BEAM STAINLESS STEEL FUSION BEAM L95mm D5.4mm STERILE
99-875100	G-BEAM STAINLESS STEEL FUSION BEAM L100mm D5.4mm STERILE
99-875105	G-BEAM STAINLESS STEEL FUSION BEAM L105mm D5.4mm STERILE
99-875110	G-BEAM STAINLESS STEEL FUSION BEAM L110mm D5.4mm STERILE
99-875115	G-BEAM STAINLESS STEEL FUSION BEAM L115mm D5.4mm STERILE
99-875120	G-BEAM STAINLESS STEEL FUSION BEAM L120mm D5.4mm STERILE
99-875125	G-BEAM STAINLESS STEEL FUSION BEAM L125mm D5.4mm STERILE
99-875130	G-BEAM STAINLESS STEEL FUSION BEAM L130mm D5.4mm STERILE
99-875135	G-BEAM STAINLESS STEEL FUSION BEAM L135mm D5.4mm STERILE
99-875140	G-BEAM STAINLESS STEEL FUSION BEAM L140mm D5.4mm STERILE
99-875145	G-BEAM STAINLESS STEEL FUSION BEAM L145mm D5.4mm STERILE
99-875150	G-BEAM STAINLESS STEEL FUSION BEAM L150mm D5.4mm STERILE
99-875155	G-BEAM STAINLESS STEEL FUSION BEAM L155mm D5.4mm STERILE
99-875160	G-BEAM STAINLESS STEEL FUSION BEAM L160mm D5.4mm STERILE
99-875165	G-BEAM STAINLESS STEEL FUSION BEAM L165mm D5.4mm STERILE
99-875170	G-BEAM STAINLESS STEEL FUSION BEAM L170mm D5.4mm STERILE

Instruments

Code	Description
187990C	G-BEAM STERILIZATION TRAY COMPLETE
187990	G-BEAM STERILIZATION TRAY
187274	SIZING GAUGE
187213	DRILL GUIDE
187223	WIRE GUIDE
001-A-40007	JOINT COMPRESSION FORCEPS
187279	RATCHETING T-HANDLE
187337	CONICAL THREADED EXTRACTOR
187284	SMALL STEPPED DRILL D4-5.5mm
187321	SMALL HEX SCREWDRIVER 4mm
187336	SMALL EXTRACTION TOOL D5.4mm
187283	LARGE STEPPED DRILL D5.1-7.5mm
187320	LARGE HEX SCREWDRIVER 5mm
187335	LARGE EXTRACTION TOOL D7.4mm

Please refer to the “Instructions for Use” supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Electronic Instructions for use available at the website <http://ifu.orthofix.it>

Electronic Instructions for use - Minimum requirements for consultation:

- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days):

tel +39 045 6719301, fax +39 045 6719370,

e-mail: customerservice@orthofix.it

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.



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