

*Sgarlato*  
*Silastic System*



**Fusion**  
ORTHOPEDICS

GAIT Implant  
Surgical Technique

## DESCRIPTION OF THE MEDICAL DEVICE



The GAIT Implant is a double stemmed flexible implant specifically designed to act as a spacer following a Keller arthroplasty of the first metatarsophalangeal joint when correcting the hallux valgus and hallux limitus deformities.

The GAIT Implant is made from medical-grade high performance silicone elastomer. It is available in three sizes that adequately meet most operative requirements. A sizing set is available for the proper size determination during surgery.

The design of the prosthesis incorporates a central area and rectangular steps shaped to fit the intramedullary canals of the first metatarsal shaft and the proximal phalanx stump.

## Sgarlato Silastic System



### INDICATIONS FOR USE

The GAIT Implant is intended for patients presenting with class 3 degeneration of the first metatarsophalangeal joint with narrowing of the joint space, loss of joint cartilage, bony spurring surrounding the joint space, and a painful range of motion of the first metatarsophalangeal joint both with rotation and with walking.

This application is not expected to recreate a normal range of motion of the first metatarsophalangeal joint. The GAIT Implant is a spacer that augments the Keller arthroplasty procedure by stabilizing the hallux to the first metatarsal.

### CONTRAINDICATIONS

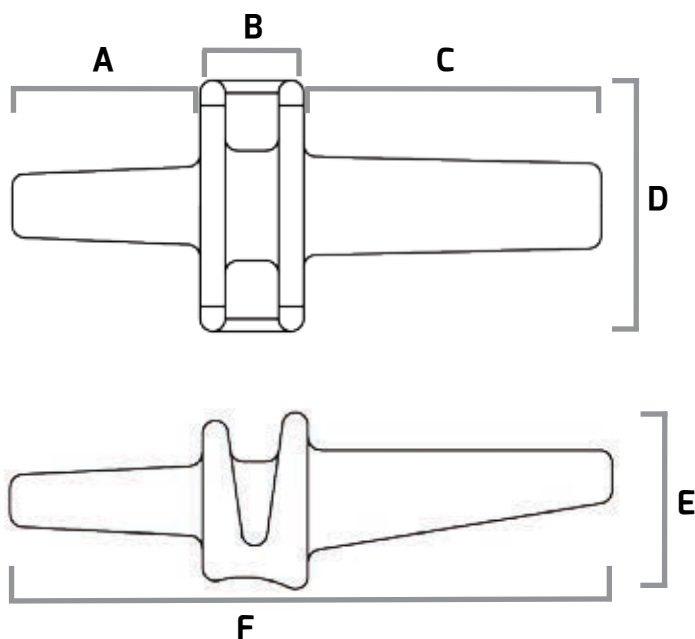
- Circulatory deficiency or inadequate skin coverage
- Scarred or chronically infected skin
- Pre-existing joint infection
- Severe bone demineralization
- Poorly motivated patient
- Inability of patient to return at the proper follow-up intervals




### NOTE:

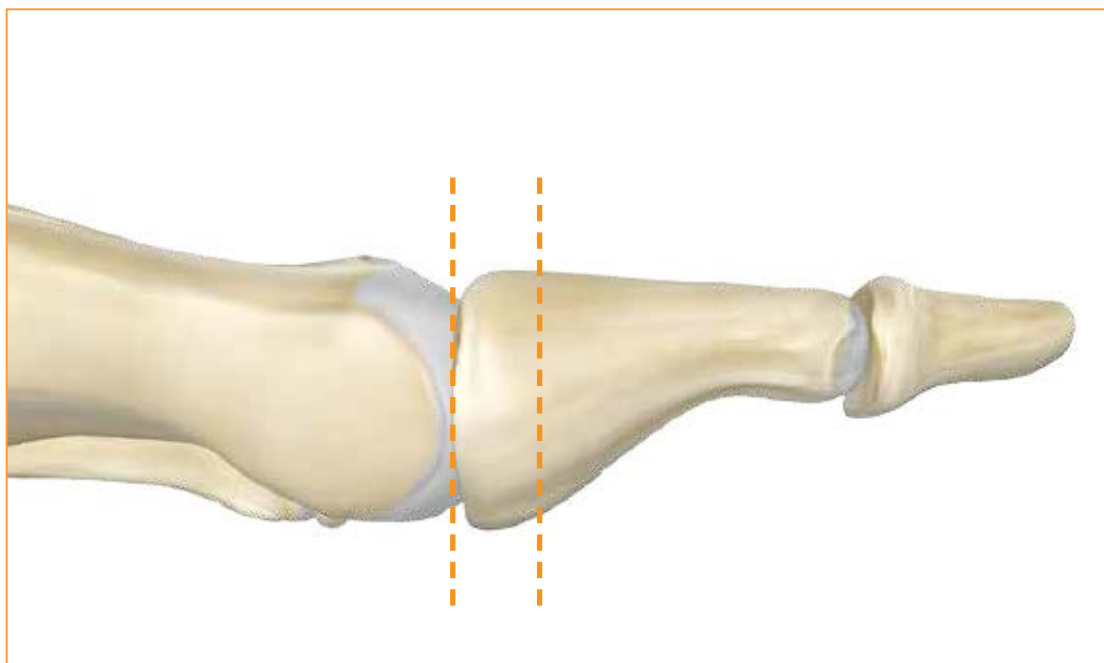
Push-off phase of each walking cycle must be carefully analyzed to assure that this procedure is not applied to patients demonstrating a full and normal push-off rotation of the first metatarsophalangeal joint

**General Rule of 60/60**  
*60 years of age*  
*< 60% normal push off ability*



Implant Sizes	Size	A	B	C	D	E	F
	Small	12.0mm	6.0mm	19.0mm	14.5mm	10.0mm	37.0mm
	Medium	12.0mm	6.6mm	19.0mm	16.0mm	11.0mm	37.6mm
	Large	12.0mm	7.2mm	19.0mm	17.5mm	12.0mm	38.2mm

Resection Without Grommets



On the metatarsal head, the cartilage is not excised with exception of a small flat surface to buttress the implant.

1

Remove the bony exostosis from the first metatarsal head and base of the proximal phalanx. With the foot in weight bearing position, perform osteotomies perpendicular to the weight bearing surface. On the metatarsal head, the cartilage is not excised with exception of a small flat surface to buttress the implant. Excise approximately 10-12mm of the proximal phalanx base.

Proximal

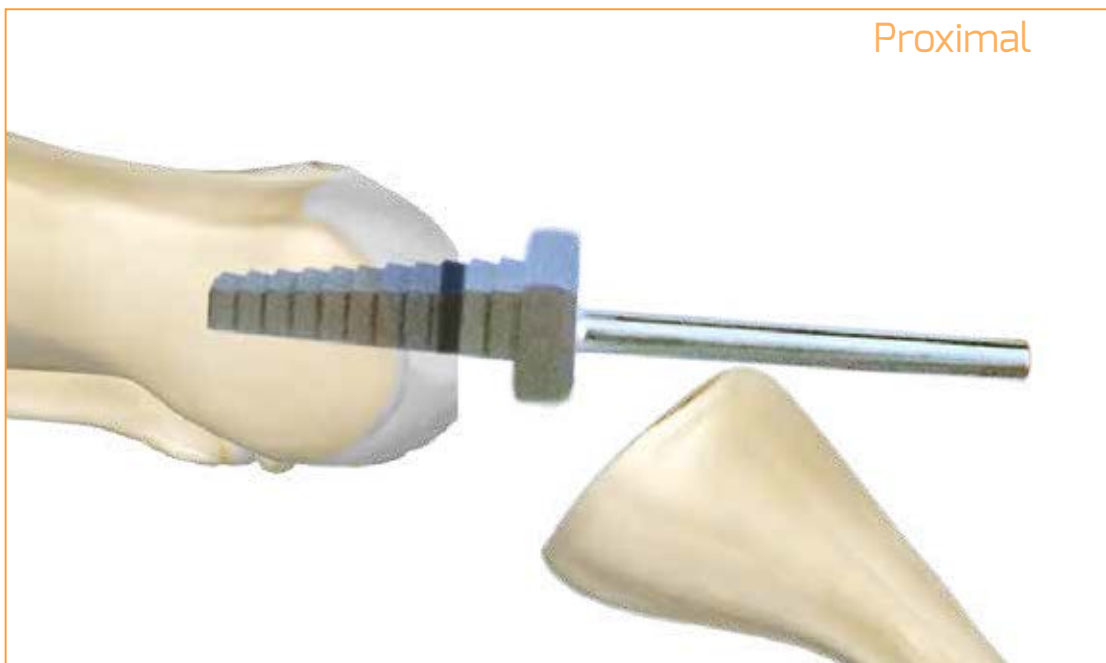


Place the canal slightly dorsal within the central aspect of the metatarsal. This will help to prevent the two bones from colliding with dorsiflexion.

2

Utilizing the burr, drill a pilot hole through the center of the first metatarsal head and shaft to prepare the proximal side of the joint for the broach.

Proximal



Broach to the hard stop when using the GAIT with Grommets. Broach to the laser mark if grommets are NOT utilized.

3

Place the Metatarsal Broach on a reciprocating rasp and broach to the laser mark.

Distal

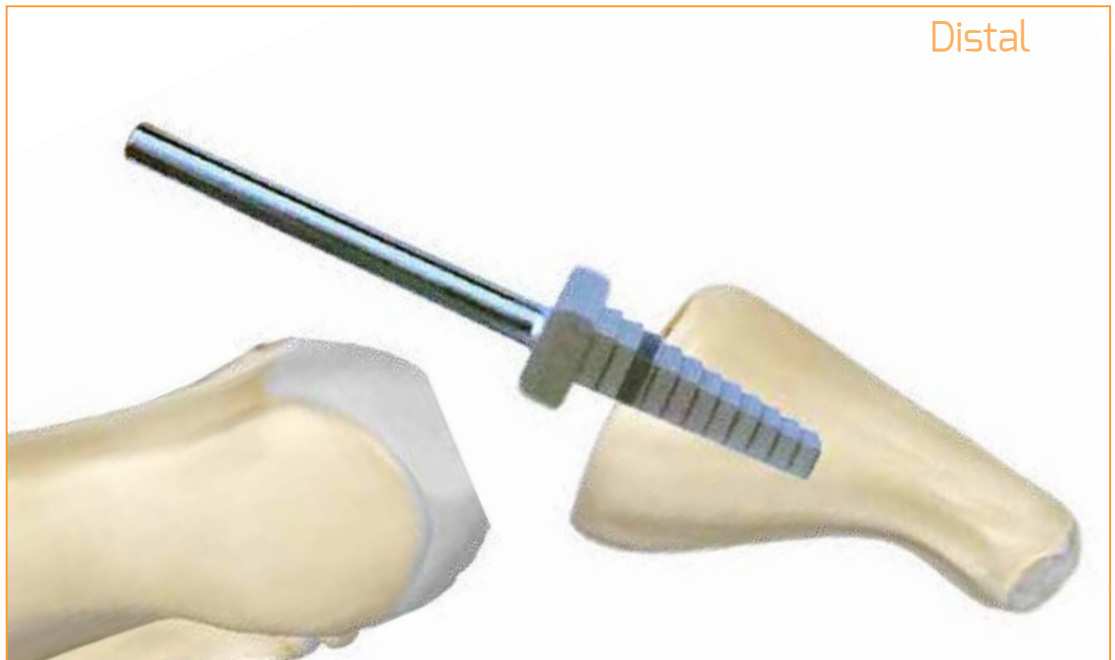


Place the canal slightly dorsal within the central aspect of the phalanx. This will help to prevent the two bones from colliding with dorsiflexion.

4

Utilizing the burr, drill a pilot hole through the center of the base of the Proximal Phalanx and shaft to prepare the Distal side of the joint for the broach.

Distal



Broach to the hard stop when using the GAIT with Grommets. Broach to the laser mark if grommets are NOT utilized.

5

Place the Distal Phalanx Broach on a reciprocating rasp and broach to the laser mark.



6

The joint preparation is checked with the provided trial sizer. The foot is taken through range of motion.

Note: If out of balance, perform appropriate release of the extensor hallucis longus tendon



7

Once the sizing has been finalized, the corresponding GAIT implant is placed and range of motion is confirmed. The joint is closed per surgeon preference to stabilize the Hallux to the first metatarsal.

## Removal Technique



1

The joint is exposed through a longitudinal incision made over the dorso-medial aspect of the first metatarsophalangeal joint.

The Distal shorter stem is pulled out of the intramedullary canal of the phalanx first, allowing for easier extraction of the implant from the joint space.

# Sgarlato Silastic System



Implants	Description	Sterile Packed
	GAIT Flexible 1st MPJ Implant Small	30-100-01-S
	GAIT Flexible 1st MPJ Implant Medium	30-100-02-S
	GAIT Flexible 1st MPJ Implant Large	30-100-03-S

Implants	Description	Sterile Packed
	GAIT Small Grommets	Coming Soon
	GAIT Medium Grommets	Coming Soon
	GAIT Large Grommets	Coming Soon

Instruments	Description	Sterile Packed	Non-Sterile
	GAIT Sizer Small	30-099-01-S	30-099-01
	GAIT Sizer Medium	30-099-02-S	30-099-02
	GAIT Sizer Large	30-099-03-S	30-099-03
	GAIT Sizer Kit	30-099-04-S	

Instruments	Description	Sterile Packed	Non-Sterile
	GAIT Distal Broach (Diamond)	30-301-01-S	30-301-01
	GAIT Proximal Broach (Diamond)	30-301-02-S	30-301-02
	GAIT Distal Broach (Lined)	30-301-51-S	30-301-51
	GAIT Proximal Broach (Lined)	30-301-52-S	30-301-52
	GAIT Football Burr	30-300-01-S	30-300-01
	GAIT Grommet Pick and Press Inserter	30-300-02-S	30-300-02
	GAIT Instrument Kit	30-301-INST-S	

Sgarlato	Description	Sterile Packed	Non-Sterile
	Universal Broach	70-097-01-S	70-097-01
	Burr	70-098-01-S	70-098-01
	Burr with Stop	70-098-02-S	70-098-02
	Shannon Burr	70-098-03-S	70-098-03

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**FDA Cleared**

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