

Smith+Nephew

SILICONE TOE MTP Arthroplasty System

Surgical Technique

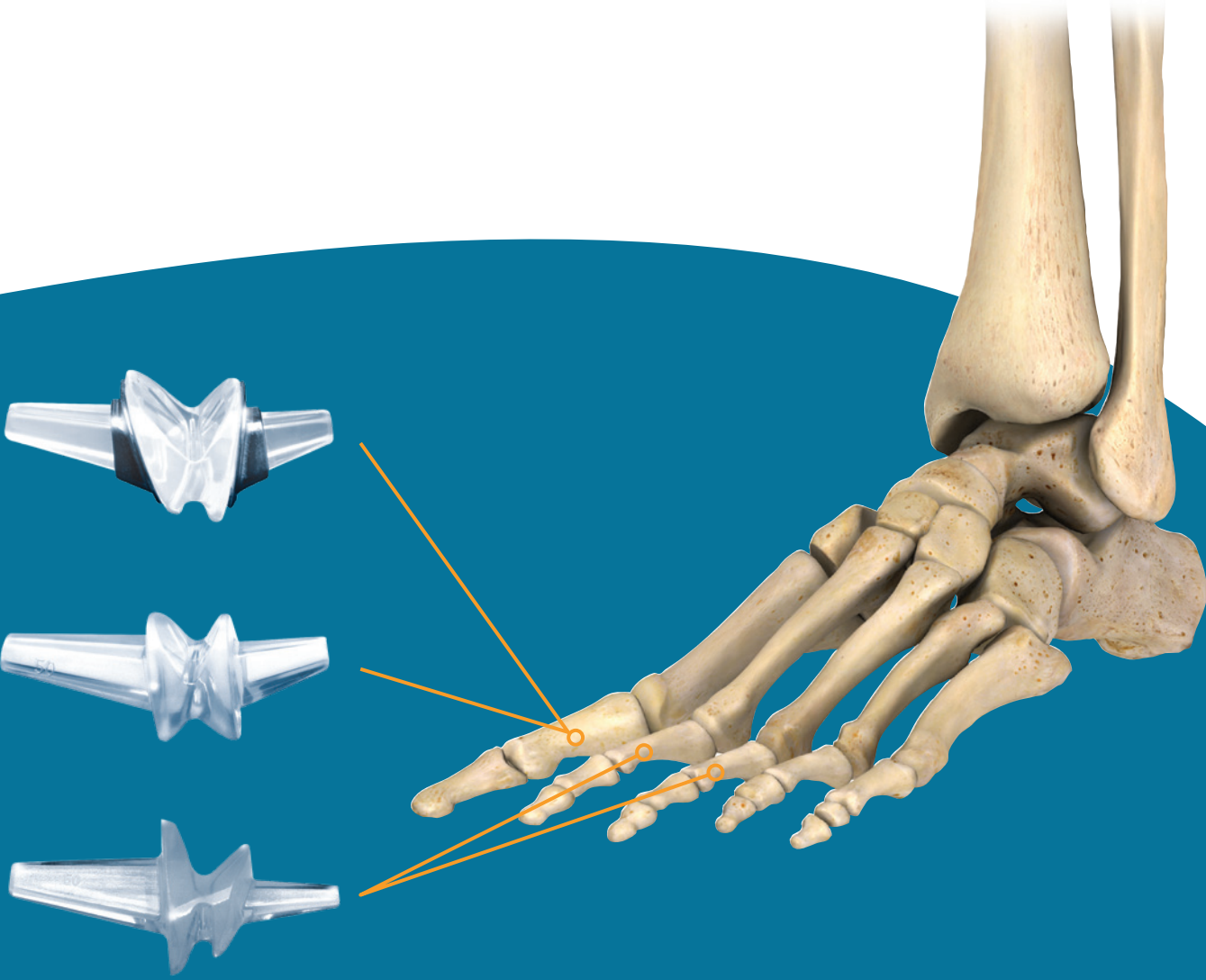


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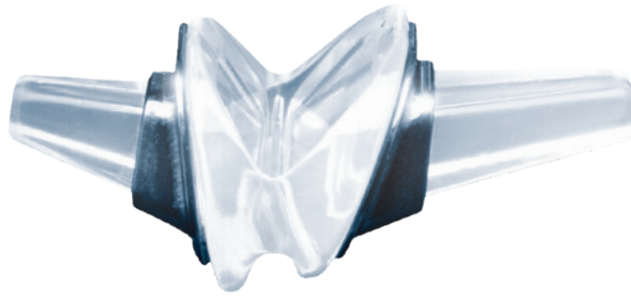
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Description - Flexible Great Toe (FGT)

The Flexible Great Toe (FGT) is a third generation flexible implant for first metatarsophalangeal joint arthroplasty. It is constructed of UltraSIL™ silicone elastomer and its anatomically designed hinge allows for free and natural movement of the 1st MP joint. The design incorporates angled osteotomies, allowing for the preservation of the flexor hallucis brevis tendon to function in its natural state.

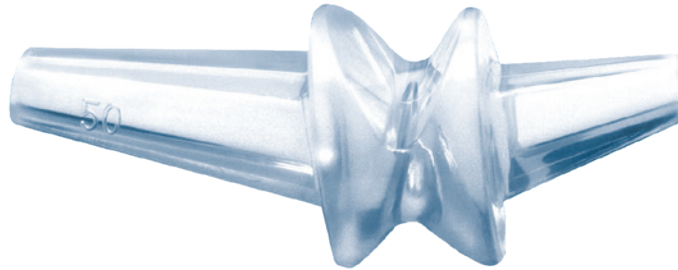


The Flexible Great Toe Advantage

Design Feature	Advantage
Anatomical Hinge	Patented axial offset hinge designed to reduce stress on the prosthesis and improve biomechanical function
Angled Osteotomies	Flexor hallucis brevis tendon preserving
Optional Titanium Grommets	Allows for intraoperative flexibility to determine the best approach for each patient
Prosthesis Stems Match Canal Shapes	Phalangeal stem is trapazoidal and metatarsal stem is rectangular
Hinge Buttresses	A highly engineered hinge offers 95 degree range of motion and prevents the grommets from contacting each other
Rib on Inferior Aspect of Hinge	Patented strength rib designed to increase overall construct strength and provide rigidity

Description - Classic Flexible Great Toe (CGT)

The Classic Flexible Great Toe (CGT) is a third generation implant for first metatarsophalangeal joint arthroplasty. It is constructed of UltraSIL™ silicone elastomer and its anatomically designed hinge allows for free and natural movement of the 1st MP joint. The implant requires vertical osteotomies, eliminating the need to use a cutting guide.

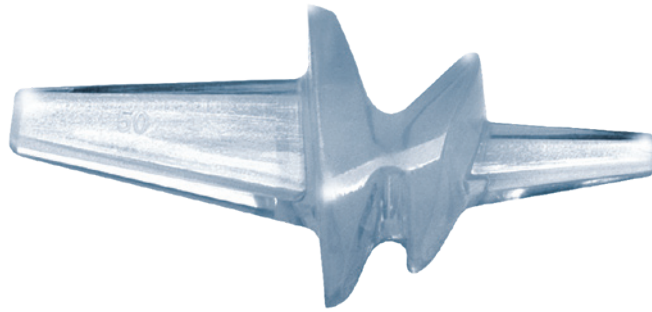


The Classic Flexible Great Toe Advantage

Design Feature	Advantage
Anatomical Hinge	Patented axial offset hinge designed to reduce stress on the prosthesis and improve biomechanical function
Requires Vertical Osteotomies	Simple cuts require no cutting guide
Anatomically Matched Stems	The stem geometry is optimized for the unique anatomy of the intramedullary canals of the phalanx and metatarsal bones
Rib on Inferior Aspect of Hinge	Patented strength rib designed to increase overall construct strength and provide rigidity
Hinge Buttresses	A highly engineered hinge offers 95 degree range of motion and prevents the grommets from contacting each other

Description - Lesser Metatarsal Phalangeal Implant (LMP)

The Lesser Metatarsal Phalangeal Implant (LMP) is the first prosthesis designed specifically to supplement lesser metatarsal phalangeal joint arthroplasty. It is constructed of UltraSIL™ silicone elastomer and its anatomically designed hinge allows for free and natural movement of the lesser MP joints.



The Lesser Metatarsal Phalangeal Implant (LMP)

Design Feature	Advantage
Anatomical Hinge	Hinge designed to allow for range of motion while minimizing stress on the prosthesis
Minimal Bone Resection	A vertical osteotomy in the metatarsal head is all the cutting that is required
Anatomically Matched Stems	Rectangular stems match the anatomy of each medullary canal
Hinge Buttresses	A highly engineered hinge offers range of motion and prevents wgrommets from contacting each other
Variable Sizes	The LMP is offered in four sizes and is supported by an instrumentation set

Warnings- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.

Implants are mechanical devices that can be worn away, fatigued or broken. An implant site may become infected, painful, swollen, or inflamed. The status of the adjacent bone and soft tissue may be inadequate to support the implant, or may deteriorate in time resulting in instability, deformity, or both. The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

Precautions- This product is provided sterile in an undamaged package and is for **one time use only**. If either the implant or the package appears damaged, expiration date has been exceeded or if the sterility is questioned for any reason, the implant should not be used. **Do not** clean, re-sterilize or reuse as this may damage or compromise performance of the devices and may expose patient to risk of transmitting infectious diseases. Implants should only be handled with blunt instruments to avoid scratching, cutting or nicking the device. Meticulous preparation of the implant site and selection of the proper size implant increase the potential for successful outcome. A complete range of trial sizers is available to aid in bone preparation. It is suggested that the proper size implant be removed from its sterile package only after the implant site has been prepared and properly sized.

Adverse Events- Potential adverse events reported with toe joint prostheses include pain, loosening, fracture, dislocation, or infection. There have been some reports of patients with silicone sensitivity reactions following joint replacement. Implantation of materials such as silicone may result in foreign body reaction adjacent to the implant site. Injury to the surrounding nerves, blood vessels, tendons, or soft tissues can occur as a consequence of implanting this device.

In some patients, wear particles from silicone elastomer implants used in bone and joint reconstruction may participate in, or exacerbate, synovitis or bone cyst complications in contiguous bone. Contributing factors have been reported to include the use of implants in physically overactive patients, associated preoperative pathology such as cysts and degenerative changes, intraoperative temporary stabilization with Kwires, subluxated implants, implant over or undersizing, and uncorrected or recurrent deformity.

Nota Bena:

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the product, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use packaged with the product.

Flexible Great Toe Surgical Technique

A longitudinal incision is made on the dorsal aspect of the first metatarsophalangeal joint. The incision is deepened by sharp and blunt dissection to the level of the joint, and the vital structures are retracted. A longitudinal capsulotomy is performed, and the joint is dissected free. The base of the proximal phalanx and the head of the metatarsal are completely exposed. All hypertrophic bone is resected from both the metatarsal and phalanx. Any soft tissue contractures must be released as dictated by the deformity.

Step 1 • Sizing and Positioning Guide

1-1 The cutting guide instrument is then utilized to resect the base of the proximal phalanx and distal portion of the metatarsal head. The tab on the inferior side of the guide is placed within the joint space, and the saw blade is placed in each of the slots of the cutting guide to start the bone cuts.

Step 2 • Bone Resection

2-1 After the appropriate angles have been established, the cutting guide is removed and the bone cuts are completed.

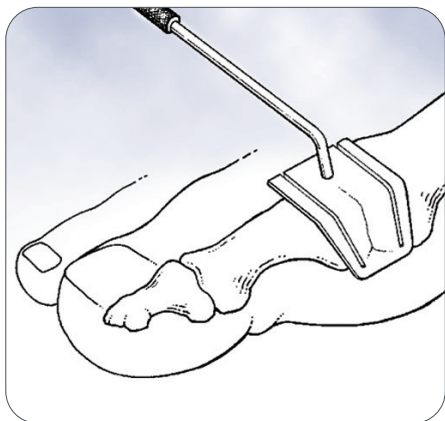


Figure 1-1

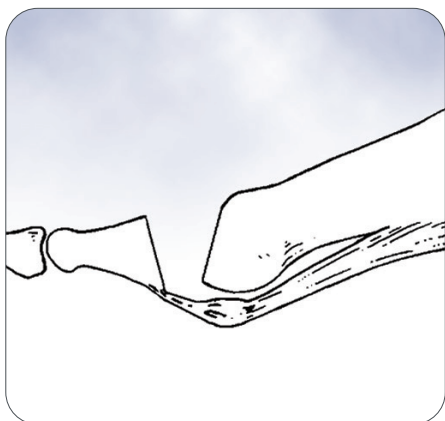


Figure 2-1

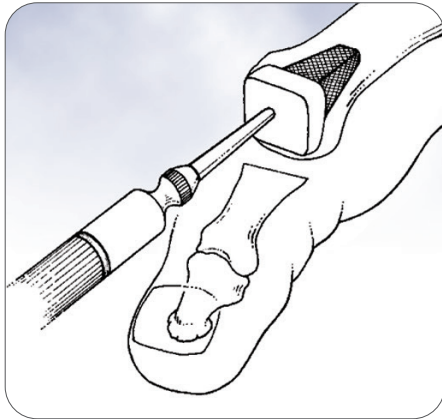


Figure 3-1

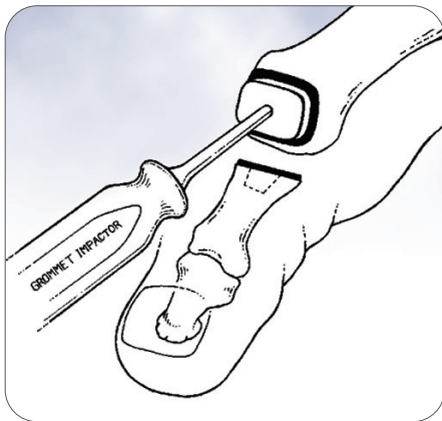


Figure 4-1

Step 3 • Joint Preparation

3-1 A pilot hole is then made in the medullary canal of the metatarsal. The trial sizers are used to choose the correct size implant. The rectangular broach instrument corresponding to the selected trial sizer is utilized to complete the preparation of the medullary canal. A similar procedure is now used to broach the medullary canal of the proximal phalanx, using the appropriate size trapezoidal broach.

3-2 Range of Motion Test

The sizer is now used to check for fit and range of motion. An “Accordion Test” is recommended to be certain there is no jamming of the implant. This test is performed by loading the foot while holding the hallux in its corrected position and checking the medial side of the joint to see if there is any compression of the sizer in a similar manner as an accordion would be compressed.

Note: If there is compression of the sizer, then inadequate bone has been resected and additional bone is removed from the base of the proximal phalanx.

Step 4 • Implant Placement

4-1 When all soft tissue contractures have been released and full range of motion is achieved, the trial sizer is removed and the surgical site is thoroughly irrigated.

4-2 If the surgeon elects to use grommets, the grommets are press-fit in place using the grommet impactor instrument. The grommets must seat against the resected bone ends without protruding into the soft tissues.

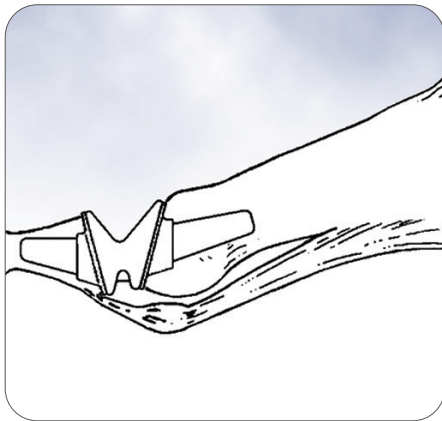
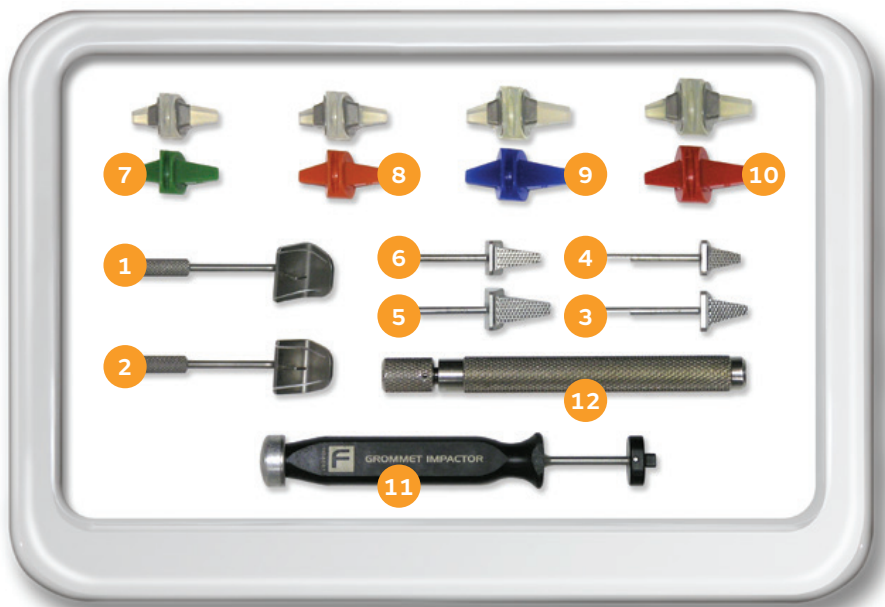


Figure 5-1

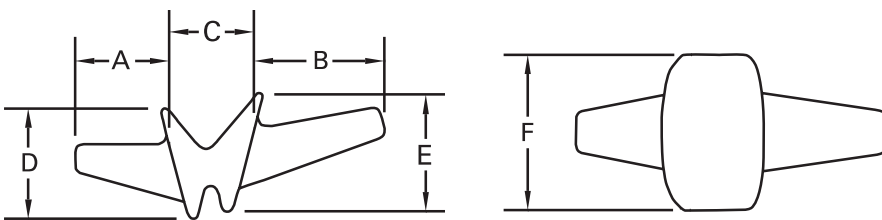
Step 5 • Closure

5-1 The appropriate size implant is then inserted. The joint capsule is sutured being certain to completely cover the prosthesis. Wound closure is performed with suture of the surgeon's choice. Bandaging and post-operative management corresponds to other arthroplasty procedures of this joint.

20 = Green
 30 = Yellow/Orange
 40 = Blue
 50 = Red



Picture above is representative of instruments only not actual surgical tray.



Size (mm)	A	B	C	D	E	F
FGT-20T	9.9	13.7	8.9	11.6	12.3	16.3
FGT-30T	9.9	13.7	9.9	12.7	13.5	18.0
FGT-40T	11.9	16.7	10.9	14.0	14.9	19.8
FGT-50T	11.9	16.7	12.0	15.3	16.3	21.6

Product #	Description
1 FGT-CG2LT	FGT Cutting Guide - Gen II, Large, Assembly
2 FGT-CG2ST	FGT Cutting Guide - Gen II, Small, Assembly
3 FGT-DLT	FGT System Distal Broach Large
4 FGT-DST	FGT System Distal Broach Small
5 FGT-PLT	FGT System Proximal Broach Large
6 FGT-PST	FGT System Proximal Broach Small
7 FGT-205T	FGT System Implant Trial Sizer 20
8 FGT-305T	FGT System Implant Trial Sizer 30
9 FGT-405T	FGT System Implant Trial Sizer 40
10 FGT-505T	FGT System Implant Trial Sizer 50
11 FGT-IMPT	FGT Impactor
12 MHT-LGTHT	Universal Handle
FGT-LIDT	Lid for FGT Case
17-5075T	Base for FGT Case
17-5077T	Tray Mat 6.7x1.6

Classic Great Toe Surgical Technique

A longitudinal incision is made on the dorsal aspect of the first metatarsal phalangeal joint. The incision is deepened by sharp and blunt dissection to the level of the joint, and the vital structures are retracted. A longitudinal capsulotomy is performed, and the joint is dissected free. The base of the proximal phalanx and head of the metatarsal are completely exposed. All hypertrophic bone is resected from both the metatarsal and phalanx.

Step 1 • Incision and Joint Preparation

1-1 An appropriate portion of the distal aspect of the metatarsal head and base of the proximal phalanx are then resected. A pilot hole is made in the medullary canal of the metatarsal. The rectangular broach instrument is used to prepare the medullary canal of the metatarsal. A similar procedure is used to broach the medullary canal of the proximal phalanx, using the trapezoidal broach. The trial sizers are utilized to determine the correct implant size. When all soft tissue contractures have been released and full range of motion is achieved, then the trial sizer is removed.

Step 2 • Resection of Phalangeal Base and Soft Tissue

2-1 The resection of the phalanx base may detach the flexor hallucis brevis tendon. If this occurs, the surgeon should consider performing a flexor tenodesis procedure to maintain functional stability of the joint. A hole is drilled at the inferior aspect of the stump of the proximal phalanx. The flexor hallucis longus tendon is sutured through this hole to the stump of the proximal phalanx.



Figure 1-1

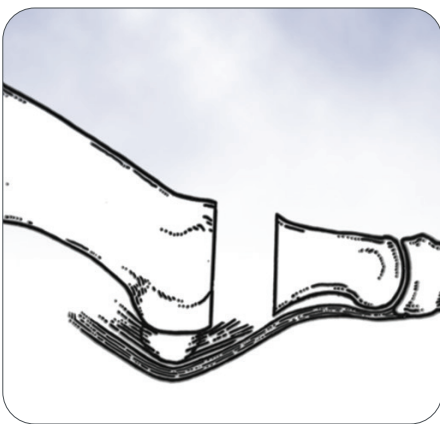


Figure 2-1



Figure 3-1

Step 3 • Soft Tissue and Sesmoid Positioning

3-1 The flexor hallucis brevis tendon is then sutured to the tendon of the flexor hallucis longus, with the sesmoids in a natural position.

Step 4 • Implantation

4-1 The appropriate size implant is then inserted in the joint. The capsule is sutured being certain to completely cover the prosthesis.

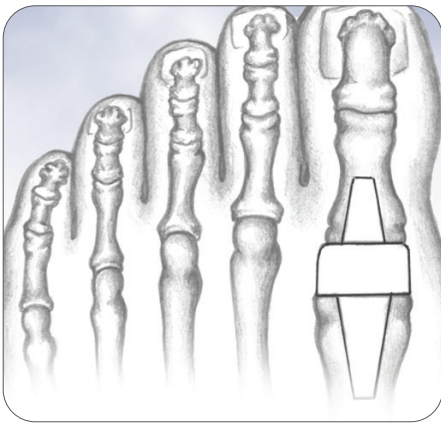


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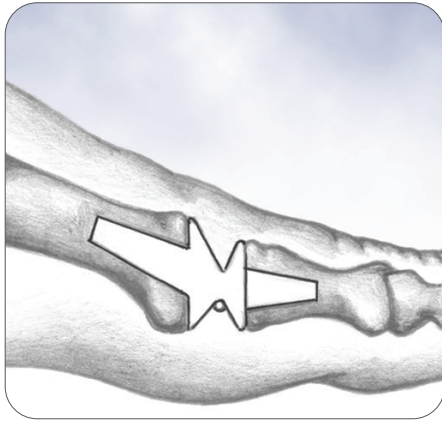
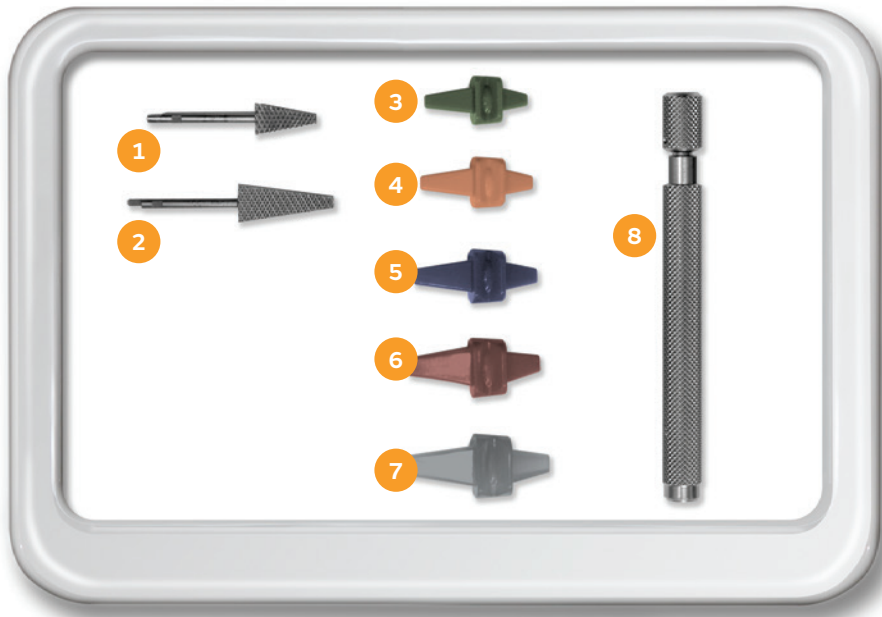


Figure 5-1

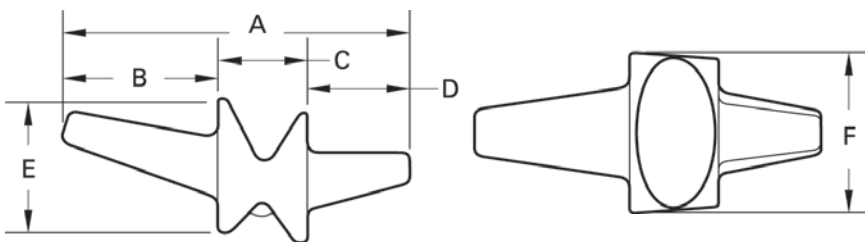
Step 5 • Closure

5-1 Surgical site closure is performed with suture of the surgeon's choice. Bandaging and post-operative management corresponds to other arthroplasty procedures of this joint.

20 = Green
 30 = Yellow/Orange
 40 = Blue
 50 = Red
 60 = Gray/White



Picture above is representative of instruments only not actual surgical tray.



Size (mm)	A	B	C	D	E	F
CGT-20T	33.3	15.0	8.8	9.5	12.5	16.0
CGT-30T	36.1	16.2	9.4	10.5	13.5	16.9
CGT-40T	39.6	17.8	10.0	11.8	15.0	17.9
CGT-50T	43.1	20.0	10.7	12.4	15.6	19.0
CGT-60T	47.3	21.5	11.4	13.7	17.1	21.0

	Product #	Description
1	CGT-DST	CGT Broach Distal 1-Size
2	CGT-PST	CGT Broach Proximal 1-size
3	CGT-205T	CGT Sizer Size 20
4	CGT-305T	CGT Sizer Size 30
5	CGT-405T	CGT Sizer Size 40
6	CGT-505T	CGT Sizer Size 50
7	CGT-605T	CGT Sizer Size 60
8	MHT-LGHT	Universal Handle
	17-5185T	Base for CGT Case
	CGT-LIDT	Lid, CGT Case

Lesser Metatarsal Phalangeal Surgical Technique

Step 1 • Incision

1-1 An incision is made on the dorsal aspect of the appropriate lesser metatarsal phalangeal joint. The incision is deepened by sharp and blunt dissection to the level of the joint. A longitudinal capsulotomy is performed and the joint is dissected free.

The base of the proximal phalanx and the head of the metatarsal are completely exposed. All soft tissue contractures must be released as dictated by the deformity.

Note: In most cases, the base of the proximal phalanx is preserved.

A pilot hole is made through the joint cartilage of the phalanx base. The medullary canal is reamed to accept the distal stem of the implant, using the smaller broach to create a transverse rectangle.

Step 2 • Joint Preparation

2-1 The distal portion of the metatarsal head is resected at the appropriate level for the existing disease or deformity. A pilot hole is made in the medullary canal and the larger broach is utilized to ream the canal, creating a vertical rectangle to accept the proximal stem of the implant.

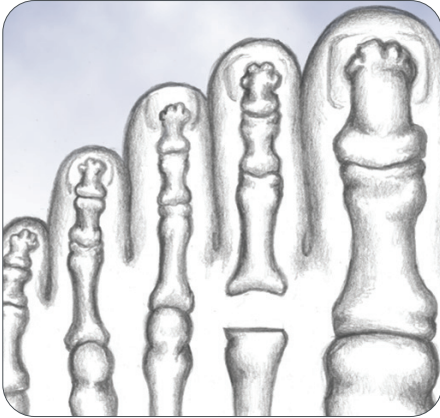


Figure 1-1



Figure 2-1

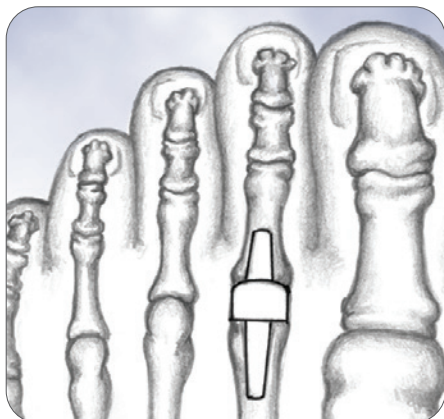


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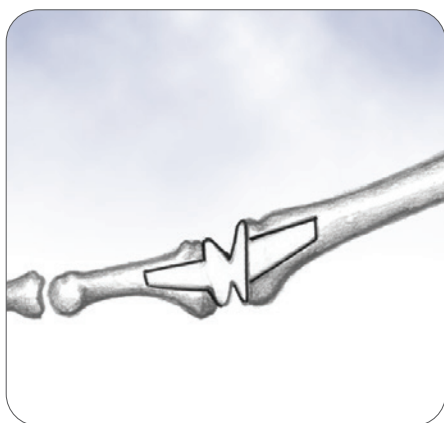


Figure 4-1

Step 3 • Implant Sizing

3-1 The trial sizers are used to select the correct size implant, and to be certain that all soft contractures have been released. It is important to load the foot with the trial sizer in place to be certain there is no jamming of the implant.

Step 4 • Implant Placement

4-1 The sizer is then removed and the wound thoroughly irrigated. The appropriate size implant is then inserted.

Step 5 • Closure

5-1 The joint capsule is sutured being certain to completely cover the prosthesis. Wound closure is performed with suture of the surgeon's choice. Bandaging and post-operative management corresponds to other arthroplasty procedures of this joint.

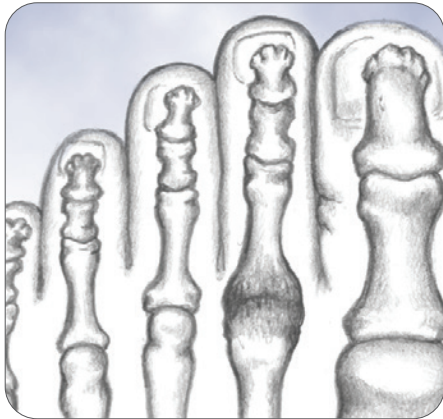
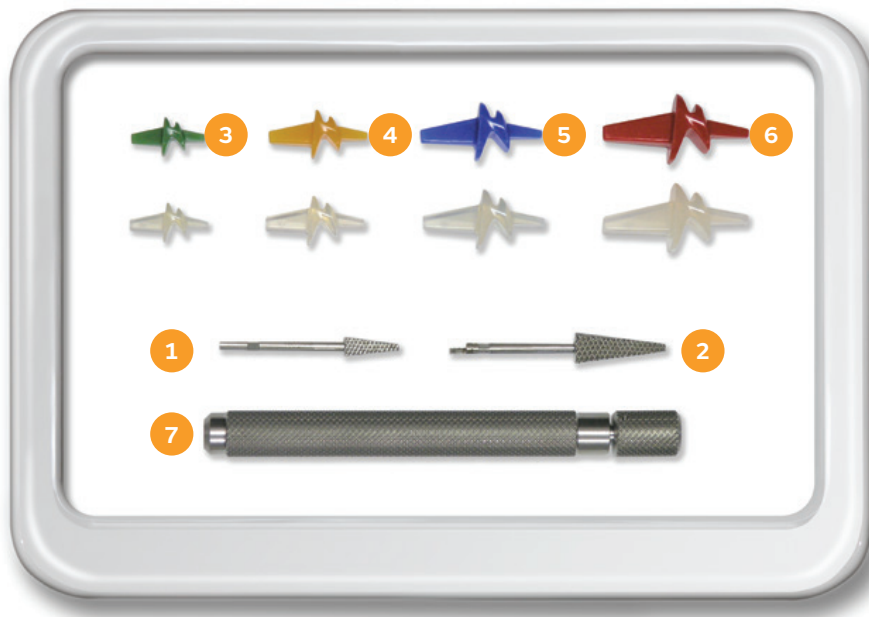


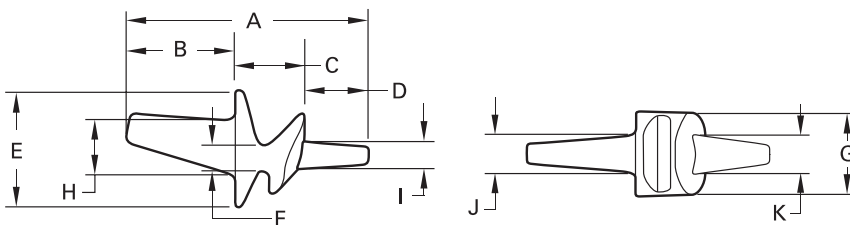
Figure 5-1

20 = Green
 30 = Orange
 40 = Blue
 50 = Red



	Product #	Description
1	LMP-DST	LMP System Distal Broach, One Size
2	LMP-PST	LMP System Broach, One Size
3	LMP- 205T	LMP System Implant Trial Sizer 20
4	LMP-305T	LMP System Implant Trial Sizer 30
5	LMP-405T	LMP System Implant Trial Sizer 40
6	LMP-505T	LMP System Implant Trial Sizer 50
7	MHT-LGHT	Universal Handle
	LMP-LIDT	Lid for LMP Case
	17-5189T	Base for LMP Case

Picture above is representative of instruments only not actual surgical tray.



Size (mm)	A	B	C	D	E	F	G	H	I	J	K
LMP-20T	21.1	9.2	6.3	5.6	11.2	2.5	8.0	5.1	2.9	3.6	3.7
LMP-30T	28.3	12.7	8.0	7.6	14.0	3.1	10.0	6.4	3.4	4.4	4.4
LMP-40T	35.1	16.3	9.6	9.2	16.8	3.7	12.0	7.7	3.6	5.2	5.0
LMP-50T	42.0	19.8	11.1	11.1	19.6	4.3	14.0	9.0	4.3	6.1	5.9

Flexible Great Toe Instruments

Reference	Description
FGT-CG2LT	FGT Cutting Guide - Gen II, Large, Assembly
FGT-CG2ST	FGT Cutting Guide - Gen II, Small, Assembly
FGT-DLT	FGT System Distal Broach Large
FGT-DST	FGT System Distal Broach Small
FGT-PLT	FGT System Proximal Broach Large
FGT-PST	FGT System Proximal Broach Small
FGT-205T	FGT System Implant Trial Sizer 20
FGT-305T	FGT System Implant Trial Sizer 30
FGT-405T	FGT System Implant Trial Sizer 40
FGT-505T	FGT System Implant Trial Sizer 50
FGT-IMPT	FGT Impactor
MHT-LGTHT	Universal Handle
FGT-LIDT	Lid for FGT Case
17-5075T	Base for FGT Case
17-5077T	Tray Mat 6.7x1.6

Flexible Great Toe Implants

Reference	Description
FGTTOTE	Flexible Great Toe Tote
FGT-20T	FGT Implant Size 20
FGT-30T	FGT Implant Size 30
FGT-40T	FGT Implant Size 40
FGT-50T	FGT Implant Size 50

Classic Flexible Great Toe Instruments

Reference	Description
CGT-DST	CGT Broach Distal 1-Size
CGT-PST	CGT Broach Proximal 1-size
CGT-205T	CGT Sizer Size 20
CGT-305T	CGT Sizer Size 30
CGT-405T	CGT Sizer Size 40
CGT-505T	CGT Sizer Size 50
CGT-605T	CGT Sizer Size 60
MHT-LGTHT	Universal Handle
17-5185T	Base for CGT Case
CGT-LIDT	Lid, CGT Case

Classic Flexible Great Toe Implants

Reference	Description
CGTTOTE	Classic Great Toe Tote
CGT-20T	CGT Implant Size 20
CGT-30T	CGT Implant Size 30
CGT-40T	CGT Implant Size 40
CGT-50T	CGT Implant Size 50
CGT-60T	CGT Implant Size 60

Lesser Metatarsal Phalangeal Implant Instruments

Reference	Description
LMP-DST	LMP System Distal Broach, One Size
LMP-PST	LMP System Proximal Broach, One Size
LMP-205T	LMP System Implant Trial Sizer 20
LMP-305T	LMP System Implant Trial Sizer 30
LMP-405T	LMP System Implant Trial Sizer 40
LMP-505T	LMP System Implant Trial Sizer 50
MHT-LGTHT	Universal Handle
LMP-LIDT	Lid for LMP Case
17-5189T	Base for LMP Case

Lesser Metatarsal Phalangeal Implants

Reference	Description
LMPTOTE	Lesser Metatarsal Phalangeal Tote
LMP-20T	LMP Implant Size 20
LMP-30T	LMP Implant Size 30
LMP-40T	LMP Implant Size 40
LMP-50T	LMP Implant Size 50

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