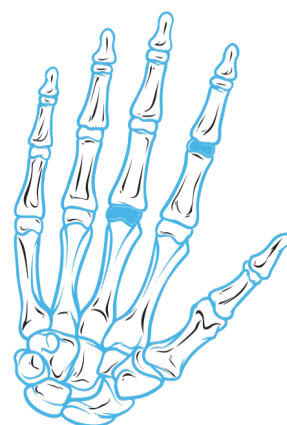
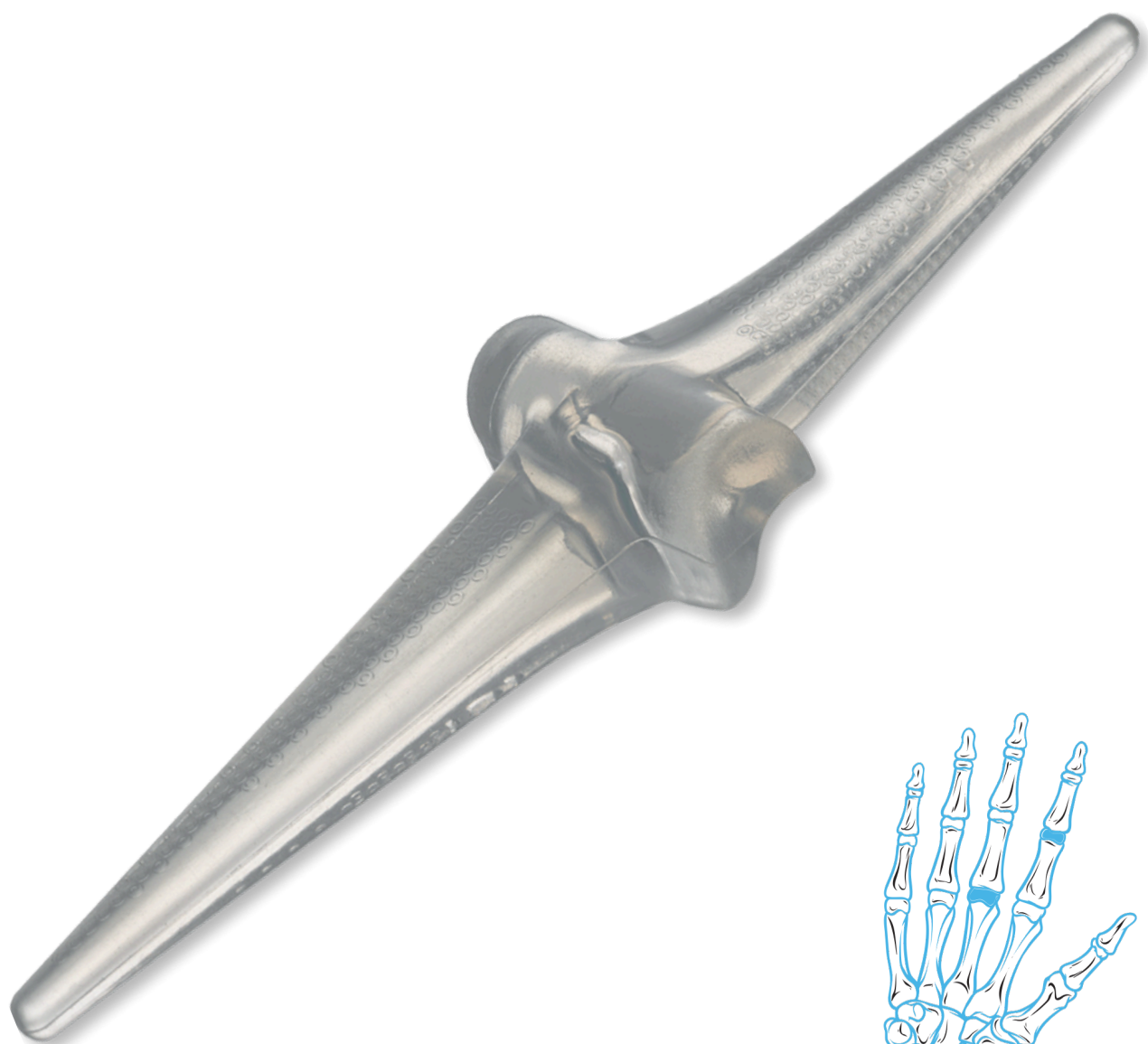


Osteotec™

SILICONE FINGER IMPLANT

SURGICAL TECHNIQUE



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For both MCP and PIP
joint replacement

THIS SURGICAL TECHNIQUE MUST BE READ CAREFULLY PRIOR TO IMPLANTATION PROCESS

Identify the correct size of Osteotec Silicone Finger Implant prior to surgery using a recent X-ray. If the X-ray suggests an intermediate size to those available, selection of the smaller size is recommended.

Indications

The Osteotec Silicone Finger Implant is designed for use in arthroplasty for the following indications involving either the metacarpophalangeal (MCP) or proximal interphalangeal (PIP) joint:

- Osteoarthritis
- Rheumatoid arthritis
- Destroyed articular surface(s)
- X-ray evidence of joint destruction or subluxation
- In the case of MCP joints, ulnar drift, not correctable by more conservative treatment

Contraindications

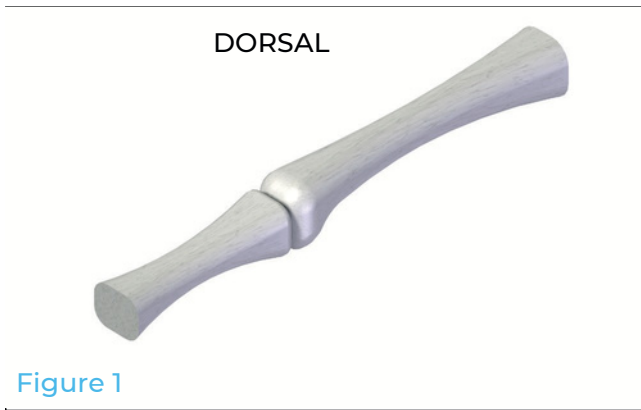
The Osteotec Silicone Finger Implant is contraindicated for the conditions listed below:

- Inadequate condition of bone, skin or neurovascular system
- Dysfunctional musculoskeletal system
- Patients below the age of 18 years
- Use for any joint replacement other than MCP and PIP joints

Claims

Clinical benefits resulting from implantation of the Osteotec Silicone Finger Implant are:

1. Restoration of function of MCP and PIP joints as evidenced by:
 - improvement of range of motion post-implantation; and
 - reduction of QuickDASH score post-implantation.
2. Reduction in pain in PIP joints (as evidenced by reduction of Pain VAS score post-implantation)



1 Preparation

For MCP

Expose the joint by making a single transverse incision over the necks of the metacarpal bones, or a longitudinal incision over the dorsum of the MCP joint.

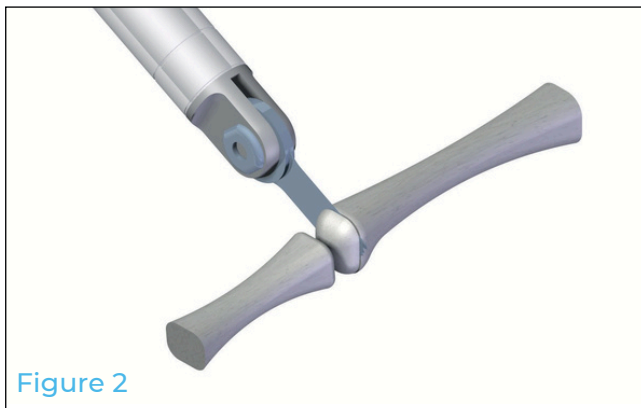
Expose the joint so that the MCP joint and origins of the collateral ligaments are visible.

For PIP

Expose the PIP joint using either a lateral or C-shaped dorsal incision.

The central tendon is then cut longitudinally from the base of the middle phalanx up to, and including, the triangular ligament to allow the central tendon to be reflected during the procedure.

In all cases, preserve the joint capsule as far as possible for later repair. Care should also be taken to avoid damage to the dorsal veins and digital nerves.



2 Removing the damaged bone

For MCP

Use an oscillating saw to remove the metacarpal head whilst retaining some of the metaphyseal flare.

If necessary, remove the head of the proximal phalanx, removing only the minimum amount of bone (Figure 2). Otherwise, simply remove osteophytes and sharp edges to form a good surface for the distal side of the implant to sit against.

For PIP

Use an oscillating saw to remove the head of the proximal phalanx distal to the metaphyseal flare. If possible, leave the collateral ligaments intact. If this is not possible they can be reattached using a non-resorbable suture. If necessary, remove the base of the middle phalanx, but only remove the minimum amount of bone (Figure 2). Otherwise, simply remove osteophytes and sharp edges to form a good surface for the implant to fit flush against.

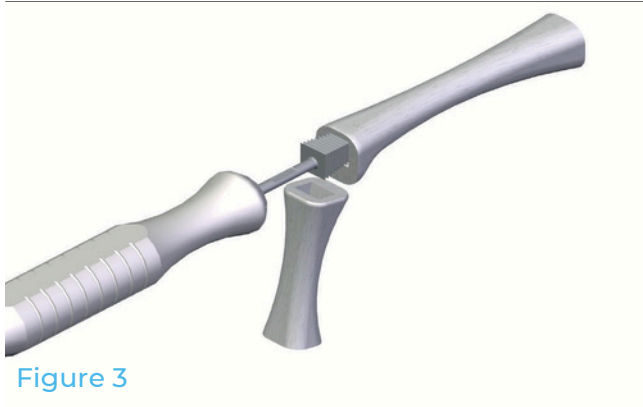


Figure 3

For MCP

Using the Osteotec SFI Instruments, use the starter awl to puncture the proximal end of the phalanx along its axis and then the distal end of the metacarpal (Figure 3).

Open up the canals using the appropriate size of distal rasps for the distal metacarpal and proximal rasps for the proximal phalanx.

For all rasps used, ensure that the dorsal side is facing upwards.

Initially the smaller rasps should be used and then increased to the intended implant size.

Do NOT rotate the rasps or hit them with a mallet.

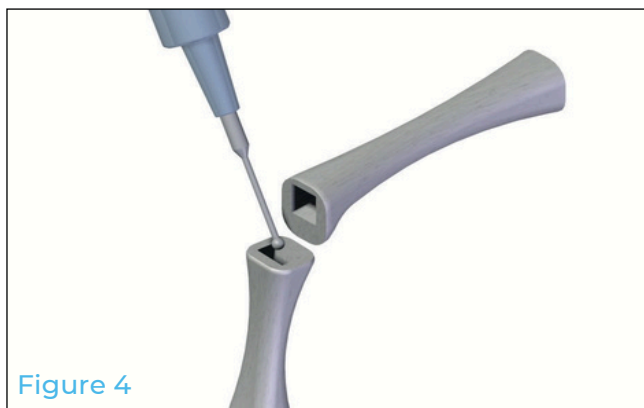


Figure 4

Use a fine burr to remove osteophytes and sharp edges that could damage the implant (Figure 4).

Irrigate the bone canals with saline solution to remove any bone debris.

3

Opening up the canals

For PIP

Using the Osteotec SFI Instruments, use the starter awl to puncture the proximal end of the middle phalanx along its axis and then the distal end of the proximal phalanx.

Open up the canals using the appropriate size of distal rasps for the proximal phalanx and proximal rasps for the middle phalanx.

4

Preparation for implantation

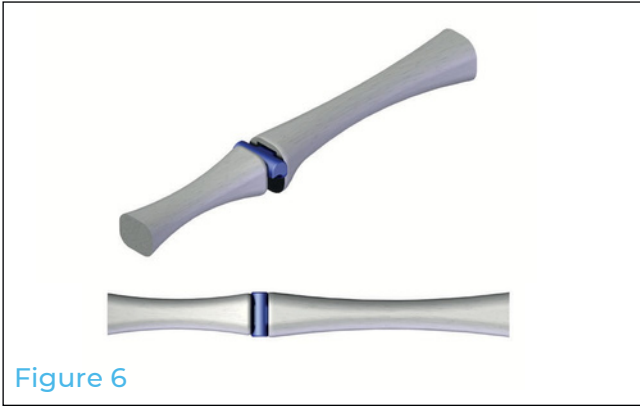


Figure 6

For MCP

Ensure that the proximal stem of the sizer is inserted into the distal end of the metacarpal bone.

In both MCP and PIP indications, it is easiest to flex both the finger and the sizer and insert the longer proximal stem first.

Ensure that the finger has full movement and that the flat sides of the hinge area fit flush against the bone on both sides (Figure 6).

Ensure that the joint is not too tightly packed. Conservatively remove additional bone as described in Step 2.

5

Trial fit

Insert a Osteotec SFI Sizer. Ensure that the sizer is inserted with the dorsal side facing upwards as shown below (Figure 5):

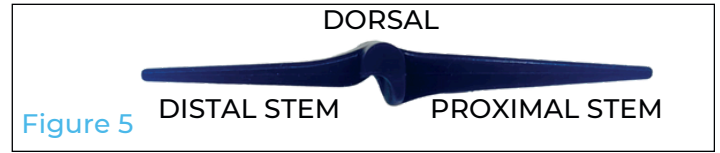


Figure 5

For PIP

Ensure that the proximal end of the sizer is inserted into the distal end of the proximal phalanx.

6

Implanting and closing

Remove the sizer and insert the Osteotec Silicone Finger Implant in the same orientation as the sizer with the dorsal side facing upwards (Figure 7). Again, ensure a good fit and that the finger has a full range of motion.

Atraumatic forceps should be used to avoid damaging the implant.



Figure 7

Once the size of Osteotec Silicone Finger Implant has been selected following Step 5, open the box containing the implant. Remove the outer blister from the box. Hold the outer blister and peel back the lid to present the inner blister without touching it. Leaving the inner blister closed, gently tip the inner blister onto the sterile field. Immediately before implantation, hold the inner blister and peel back the lid to present the implant ready for implantation.

Perform any necessary soft tissue reconstruction and close the wound in the usual manner.

The implant becomes stabilized by the encapsulation process and no permanent fixation is required. Joint stability is achieved from reconstruction of the ligamentous and musculotendinous systems.

7

Removal of the Osteotec Silicone Finger Implant

If removal of the implant is required due to revision or failure of the device, follow the instructions of Step 1. Remove the implant using atraumatic forceps to avoid damaging the implant.

According to clinical judgement, follow the surgical technique to either replace the implant or consider alternative treatment options.

Perform any necessary soft tissue reconstruction and close the wound in the usual manner.

Please contact Osteotec using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device for investigation.

Implant and Instrumentation Guide

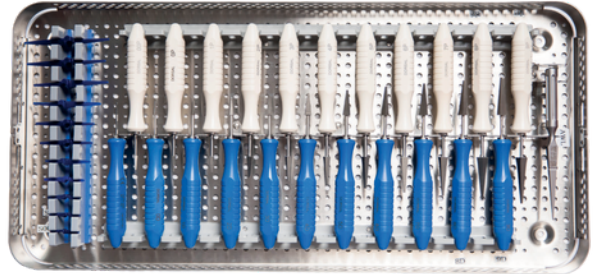
Osteotec Silicone Finger Implant



Osteotec SFI Sizer

Osteotec SFI Tray containing:

1. Osteotec SFI Sizer; and
2. Osteotec SFI Instruments



Implants

Catalogue No.	Size
OSTF-00	00
OSTF-0	0 1 2
OSTF-1	3 4
OSTF-2	5 6
OSTF-3	7 8
OSTF-4	9
OSTF-5	
OSTF-6	
OSTF-7	
OSTF-8	
OSTF-9	

Sizers

Catalogue No.	Size
OSTF-S00	00
OSTF-S0	0 1 2
OSTF-S1	3 4
OSTF-S2	5 6
OSTF-S3	7 8
OSTF-S4	9
OSTF-S5	
OSTF-S6	
OSTF-S7	
OSTF-S8	
OSTF-S9	

Catalogue No.	Size
OSTF-INS9	Set of proximal and distal bone rasps and starter awl
OSTF-INS8	Instrument tray, empty

Individual rasps are also available on request

Caution: US Federal law restricts this device to sale by or on the order of a physician



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