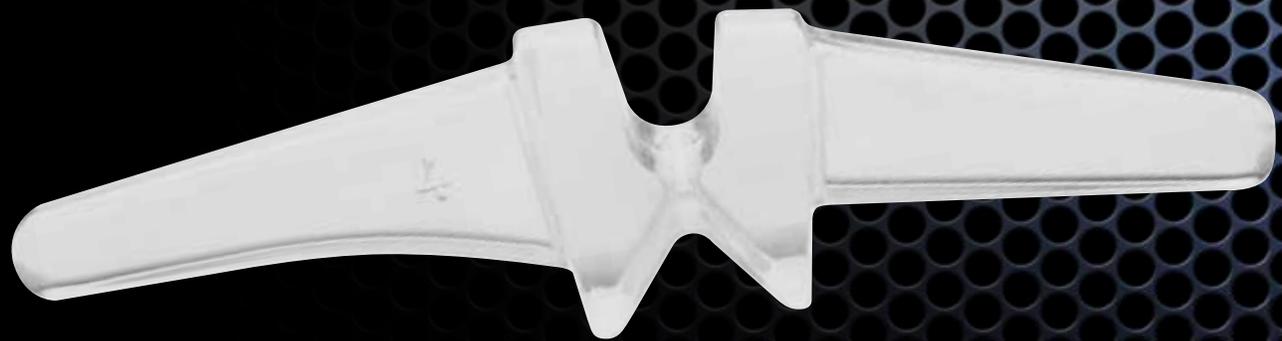


Integra®

Silicone PIP Implant

SURGICAL TECHNIQUE



INTEGRA®
LIMIT UNCERTAINTY



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Indications

The indications for use of the Silicone PIP are for cementless replacement of the proximal interphalangeal joint in patients with advanced osteoarthritis, post-traumatic arthritis, and rheumatoid arthritis.

Contraindications

- Active local or systemic infection;
- Destruction of the metacarpal, phalanx, or phalanges or poor bone quality which prevents adequate fixation of the implant;
- Loss of musculature, neuromuscular compromise, or vascular deficiency in the affected finger;
- Growing patients with open epiphyses;
- Patients with high activity levels; and
- Patients unwilling or unable to comply with physician's instructions.

See package insert for full prescribing information.

Warnings

- The following conditions, singularly or concurrently, tend to place excessive loads on the finger joint prosthesis and, thereby, place the patient at higher risk for failure of the prosthesis. If excessive loading of the affected finger joint cannot be prevented, this finger joint prosthesis should not be used.
 - Excessive activity of the affected joint;
 - Uncorrected or recurrent deformity;
 - Incorrect sizing of the implant;
 - Inadequate soft tissue or bony support;
 - Implant malposition.

The benefits of finger joint replacement may not meet the patient's expectations or may deteriorate over time. Pain, swelling, instability, and/or deformity may persist or return after finger joint replacement.

Precautions

- Do not reuse this device. Any implant that has been damaged, mishandled, or removed from the sterile field should be discarded.

Surgical Technique

This technique has been developed in conjunction with Brian Adams, MD.



As the manufacturer of this device, Integra LifeSciences Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

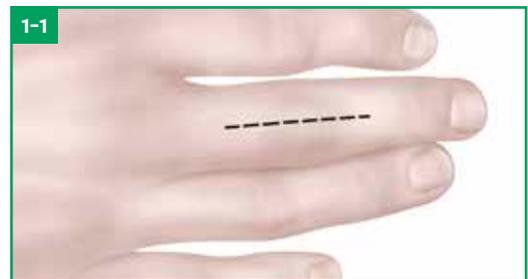
Caution: Federal law restricts this device to sale by or on the order of a physician or practitioner.

Preoperative Assessment

Prior to the procedure, template using the Silicone PIP X-ray template to assist in determining implant size. When using the template, reference inside the black line and choose the component size that best fills the medullary canal of the proximal and middle phalanges.

Step 1 • Initial Incision & Joint Exposure

- 1-1** Incise the central slip tendon longitudinally from the middle of the proximal phalanx and distally past its insertion point into the middle phalanx. Using sharp dissection, elevate the extensor mechanism radially and ulnarly, separating it from the underlying periosteum over the proximal phalanx. Elevate the extensor insertion at the base of the proximal phalanx radially and ulnarly, and flex the middle phalanx. This will create radial and ulnar tendinous bands with each, including 1/2 of the central tendon and a lateral band. At the end of the procedure, the “split tendon” halves are sutured to each other with or without drill hole fixation to the middle phalangeal insertion.



Step 2 • Medullary Canal Opening & Alignment

- 2-1** Flex the joint to 90°. Using the Starter Awl, pierce the cortical bone to create an opening for the Alignment Awl into the medullary canal. The entry point is made in the head of the proximal phalanx and centered across the width of the head. The opening should be aligned with the long axis of the phalanx's medullary canal.
- 2-2** Attach the Alignment Guide to the Alignment Awl and insert it into the medullary canal. The position of the Alignment Guide should be parallel to the dorsal surface and in line with the long axis of the bone. Confirm with X-ray.



Step 3 • Proximal Osteotomy – Vertical Cut

- 3-1** Maintain Alignment Awl position and replace the Alignment Guide with the Vertical Cut Guide. The osteotomy is placed 0.5-1.0 mm distal to the proximal attachments of the collateral ligaments. Using a sagittal saw, remove the articular surface of the proximal phalanx using the Vertical Cut Guide to start the cut. Remove the awl and complete the vertical cut established with the Vertical Cut Guide.



Step 4 • Proximal Component Broaching

4-1 Attach the Alignment Guide to the Size 0 SPIP Proximal Broach. Insert the broach into the medullary canal. The broach must be inserted fully into medullary canal. Broach sequentially with larger sizes until cortical contact is obtained. In some cases, proximal phalanx bone stock may be hard and sclerotic. If broach cannot be fully inserted, additional bone stock must be removed. A side-cutting burr or twist drill may be required.



Step 5 • Middle Phalanx Exposure & Distal Surface Preparation

After completion of the proximal side, hyper-flex the joint to expose the articular surface of the middle phalanx. Use a rongeur to remove spurs from the base of the middle phalanx. The articular surface is then contoured (side cutting burr/oscillating saw/osteotome) to provide a surface against which the implant will be flush. Using the Starter Awl, pierce the cortical bone to create an opening for the Alignment Awl into the medullary canal. The entry point is made in the dorsal 1/3 of the base of the middle phalanx and centered across the width of the base.

Step 6 • Distal Component Broaching

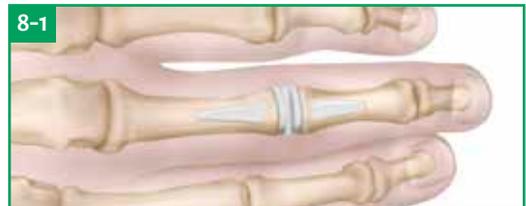
Attach the Alignment Guide to the Size 0 SPIP Distal Broach. Insert the broach into the medullary canal. The broach must be inserted fully into the medullary canal. Broach sequentially with larger sizes until cortical contact is obtained. In some cases, middle phalanx bone stock may be hard and sclerotic. If the broach cannot be fully inserted, additional bone stock must be removed. A side-cutting burr or twist drill may be required.

Step 7 • Trial insertion – Reduction – Removal

Flex the joint and insert the appropriate size SPIP Trial. Using smooth forceps, insert the proximal stem first, followed by the distal stem with the finger in flexion to aid final seating. Extend the joint and check for proper sizing, the trial should fit flush against the middle and proximal phalanges. The finger should extend and flex passively with ease but with minimal lateral play or laxity with traction.

Step 8 • Implant Placement

8-1 After successful sizing, trial insertion and reduction, open the appropriate Silicone PIP sterile component. Using smooth forceps insert the proximal stem first, followed by the distal stem with the finger in flexion to aid final seating. Extend the joint and confirm proper sizing, motion, and stability previously obtained with the trials.



Step 9 • Closure

Repair the extensor apparatus using a row of 4.0 non-absorbable sutures. Close the skin with non-absorbable sutures. With the finger in resting posture of **10-20° PIP flexion and 30° MP flexion**, apply a padded dressing with a plaster splint.

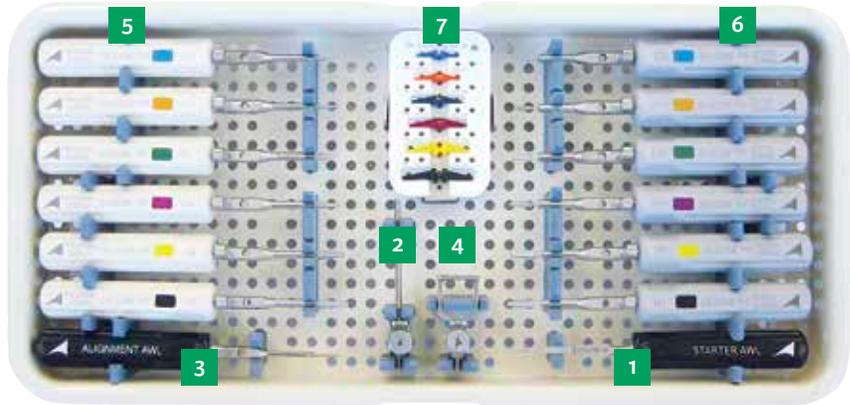
Postoperative Care

Guarded active flexion and extension exercises can commence several days after the procedure, ensuring that any repaired collateral ligaments are protected from deviating forces for 4-6 weeks. Alternatively, the finger can be splinted in a resting position for up to 4 weeks, after which range of motion exercises can begin.



Instrumentation

1. Starter Awl
2. Alignment Guide
3. Alignment Awl
4. Vertical Cut Guide
5. Proximal Broaches
6. Distal Broaches
7. Trials

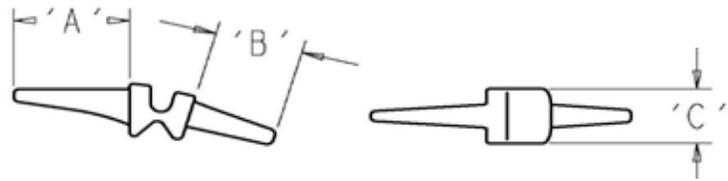


Implants

Catalog Number	Description
SPIP-520-0	Silicone PIP Implant, Size 0
SPIP-520-1	Silicone PIP Implant, Size 1
SPIP-520-2	Silicone PIP Implant, Size 2
SPIP-520-3	Silicone PIP Implant, Size 3
SPIP-520-4	Silicone PIP Implant, Size 4
SPIP-520-5	Silicone PIP Implant, Size 5

Instruments

Catalog Number	Description
ALG-100-00	Alignment Guide
AWL-100-01	Starter Awl
AWL-200-00	Alignment Awl
BRH-525-0P	Proximal Broach, Size 0
BRH-525-1P	Proximal Broach, Size 1
BRH-525-2P	Proximal Broach, Size 2
BRH-525-3P	Proximal Broach, Size 3
BRH-525-4P	Proximal Broach, Size 4
BRH-525-5P	Proximal Broach, Size 5
BRH-525-0D	Distal Broach, Size 0
BRH-525-1D	Distal Broach, Size 1
BRH-525-2D	Distal Broach, Size 2
BRH-525-3D	Distal Broach, Size 3
BRH-525-4D	Distal Broach, Size 4
BRH-525-5D	Distal Broach, Size 5
OSG-442-00	Vertical Cut Guide
TRL-520-0	SPIP Trial, Size 0
TRL-520-1	SPIP Trial, Size 1
TRL-520-2	SPIP Trial, Size 2
TRL-520-3	SPIP Trial, Size 3
TRL-520-4	SPIP Trial, Size 4
TRL-520-5	SPIP Trial, Size 5



Implant Dimensions (mm)

Catalog Number	Size	(A) Proximal Stem Length	(B) Distal Stem Length	(C) Hinge Width
SPIP-520-0	0	11.5	8.5	6.4
SPIP-520-1	1	12.7	9.7	7.2
SPIP-520-2	2	13.7	11.8	8.2
SPIP-520-3	3	15.2	13.1	9.3
SPIP-520-4	4	16.8	14.7	10.2
SPIP-520-5	5	19.0	16.6	11.2

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