



BioPro Modular Thumb Implant

Indications for use:

A painful, instable thumb, one with limited range of motion, or subluxation of the trapeziometacarpal joint with the following indications:

1. Rheumatoid arthritis
2. Traumatic arthritis
3. Osteoarthritis
4. Post fracture deformation or bone loss

CANADA ONLY: Osteoarthritis

Contra-indications:

The age of the patient must be balanced against the severity of the disability and the need for surgery

1. A debilitating general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure
2. A previously infected thumb that has not been quiescent for at least six months
3. A local or systemic infection (i.e. osteomyelitis)
4. Insufficient bone stock to support the prosthesis
5. Scapho-Trapezium joint arthritis

Warning: The Modular Thumb Implant has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

Sterile:

Sterilized with ethylene oxide gas. **Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged.** This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device has not been validated.

Instructions for use:

Identify the CMC joint. Make an incision to expose the joint. Preserve the capsul for future closure and implant stability.

Resect approximately 5mm off the base of the metacarpal parallel to the varus positioned articular surface in the sagittal plane.

Utilize a 5-7mm rotary burr a medialized concentric concavity is fashioned into the articulating surface of the trapezium. Care is taken to preserve the radial border of the trapezium. Gradually enlarge the recess in the trapezium to approximately 10-12mm in diameter. Trapezial socket depth should be approximately 4-5mm. Gradually enlarge the socket with the provided hemispherical burrs. Progressively increase the size of the socket as large as possible, while taking care to preserve the radial rim of the trapezium.

Assess the stability and freedom of motion and examine the angle of the metacarpal resection using the head sizing guide. If the thumb cannot be brought to the full range of abduction without undue force, the joint has been over spaced and must be corrected by resecting an additional amount of bone from the metacarpal or by deepening the socket. If the joint is too lax, a 2mm or 4mm neck length head is used for trial.

With the one-piece stem broach positioned in anatomical varus in the sagittal plane it is inserted into the medullary canal without removing cancellous bone stock. The size of the stem is increased progressively until the cancellous bone has been fully compressed to provide an optimally tight medullary interference fit.

Once the desired stem broach size is achieved, the one-piece broach is exchanged for the corresponding size trial stem. The trial ball matching the trapezial socket is now applied to the seated trial stem. Range of motion and stability are assessed.

After the desired status of articulation has been assured, the trial component is exchanged for the assembled implantable prosthesis. Use the assembly block to assemble the appropriate head and stem in-vitro. Do not assemble in-vivo. In vitro **assembly allows for maximum assembly strength of the implant.** The longitudinal contiguous capsule is closed tightly.

Postoperative management:

The thumb is immobilized in a position of abduction at the carpometacarpal joint and slight flexion at the metacarpalphalangeal joint for two weeks. A removable thumb spica is worn for four weeks. Hand therapy may be required to regain motion and strength. Unrestricted activity is allowed 8-12 weeks post-op. Contact surgeon if a change in performance or pain level is noticed.



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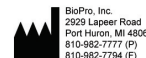
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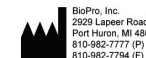
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