
Alternatives

You should thoroughly discuss the options for treating your finger joint with your doctor before selecting surgery as an alternative. Arthritis of the proximal interphalangeal joint can be treated non-surgically with splints, joint injections and medications (including the aspirin-type drugs).

Current surgical treatments include fusion of the bones together, surgery on the joint with tendon or joint replacement with silicone implants. Fusion has the benefit of relieving pain, and restoring pinch strength, however it has the limitation of no motion in that joint. Fusion may be a preferable treatment of the index finger when compared to silicone implants when good pinch strength is needed. It is possible that a fusion procedure may need to be revised due to undesirable motion between the two bones.

Joint replacement, with silicone implants has been available for a number of years and has the advantages of relieving pain and allowing motion at the joint. Some of the risks of silicone implants include the possibility for breakage, deformation, and side to side instability. If you are very active and use your hand heavily, you may not be a good candidate for silicone implants. You should be aware, all implants will wear over time with use. Therefore, some degree of wear particle formation is inevitable with all implants, including those made with silicone. The patient's biological response to these particles is variable.

There are also reports in the medical literature suggesting possible link between silicone implants and immunological abnormalities and autoimmune rheumatic disorders.

Warnings

- It is unlikely that your finger joint will be restored to the condition it was before your injury, arthritis or previous surgery. You should discuss your expectations of having surgery with your doctor before having surgery, as this procedure may not meet your expectations.
- You should be aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.



SMALL BONE INNOVATIONS, INC.

1380 So. Pennsylvania Ave.

Morrisville, PA 19067

Customer Service: 800-778-8837

www.totalsmallbone.com

MKT 10820 Rev. B 11/09

Copyright © Small Bone Innovations, Inc. 2009. All rights reserved.

Caution: United States federal law restricts these devices to sale

by or on the order of a physician.

SR™ PIP is a Humanitarian Use Only Device.



Finger Prosthesis Patient Brochure

Introduction

Small Bone Innovations, Inc. has developed an implant for the Proximal Interphalangeal (PIP) finger joint. The PIP joint is the joint which is the second one from the end of your finger. This implant is available for sale in the United States as a humanitarian use device. A humanitarian use device is one which is used for conditions or diseases which typically affect fewer than 4,000 people in the United States per year, and when there is no comparable device marketed to treat/diagnose those conditions or diseases. Your physician has determined that you may benefit from implantation of this finger joint implant. You should be aware that the effectiveness of this device for this use has not been demonstrated.



SBI
SMALL BONE INNOVATIONS, INC.

Humanitarian Device

The SBI Proximal Interphalangeal (PIP) Finger Prosthesis is authorized by Federal law for use in arthroplasty (surgery) of the PIP joint when either the:

- patient is in need of a revision of failed PIP prosthesis(es); or
- patient expects to place his/her hands under loading situations, which preclude the use of an alternative implant in the painful osteoarthritic and post traumatic arthritic PIP joint.

The effectiveness of this device for this use has not been demonstrated.

Contraindications

- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Skeletal immaturity.

Description of Surgical Procedure

This surgery involves the use of a finger joint replacement device for treatment of patients with certain kinds of arthritis (osteo - arthritis or post traumatic arthritis) and who expect to place their hands in heavy loading situations, or patients needing revision of a failed implant placed in the PIP joint. A joint replacement surgery is

an operation where the arthritic joint is removed and a metal and plastic joint is inserted to replace the natural joint. The surgery is expected to last about 2 hours. The procedure is done in the operating room and requires general anesthesia or an axillary block. (General anesthesia affects the entire body and is accompanied by a loss of consciousness. An axillary block results in anesthesia of the hand and forearm only. A tourniquet is applied to the arm to prevent bleeding during the surgery.)

In joint replacement surgery, your hand is opened at the finger joint, and the bones are trimmed. The metal and plastic joint replacement parts are fixed to the bones using bone cement, or used in a cementless application. Antibiotics are usually given during and after the operation to prevent infection, as is normal with current surgical treatment of these cases. After the operation, your hand will be in a bandage. This will be removed 2-5 days following the operation. You may need to wear a splint for up to 3 weeks. When the bandage or splint is removed, you will start a physical therapy regimen.



Foreseeable Risks

General Surgery-Related Risks:

- Bleeding
- Infection
- Loss of the use of your hand
- Permanent disability
- Death

Joint Replacement Related Risks:

- Pain
- Injury to your surrounding nerves, blood vessels, tendons or soft tissue (e.g., numbness)
- Stiffness
- Night and weather related pain
- Loss of motion
- Implant fracture
- Rotation of implant
- Accelerated wear of the device components
- Loosening of the implant from your bones
- Dislocation of your joint
- Cement protrusion injury
- Infection
- Lengthening or shortening of your finger
- Amputation
- Bone weakening around the implant
- Decrease in range of motion
- Allergic or other reactions to the metal or plastic materials
- Additional surgery may be required for revision or fusion of the joint
- Surgery may be started but a joint replacement cannot be done resulting in fusion of your joint
- Notification in accordance with the Californian Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity

Potential Benefits:

- Improved range of motion
- Relief of pain
- Improved grip and pinch strength