Osteotec Silicone Finger Implant and Sizers IFU

Indications for Use
The Osteotec Silicone Finger Implant is a single piece flexible joint replacement implant for the metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints in the hand; commonly due to rheumatoid or osteoarthritis.

Description
The two intramedullary stems of the implant are joined by an integral flexible hinge which acts as a joint spacer. The implant is not fixed into the bones and becomes stabilized by the encapsulation process. The implant is available in eleven sizes to meet various operative requirements and is supplied sterile. A set of eleven implant sizers is available to determine the appropriate size of implant. They are re-usable, non-sterile products intended to be sterilized prior to use and are not suitable for implantation.

General Indications
As with any joint reconstruction procedure, the following general indications should be considered before deciding whether to use this implant.

- Good patient condition
- Adequate bone stock to support the implant
- Adequate skin coverage
- Patient cooperation
- Good neurovascular status
- Potentially functional musculotendinous system
- Available postoperative care

Clinical Indications
This implant is intended primarily for use in resection arthroplasty of the MCP joints and, in some cases, the PIP joint, in the following cases - In rheumatoid or post-traumatic disabilities of the MCP joint, with:

- Fixed or stiff MCP joints
- X-ray evidence of joint destruction or subluxation
- Ulnar drift, not correctable by more conservative treatment
- Contracted intrinsic and extrinsic musculature and ligament system
- Associated stiff interphalangeal joints

In rheumatoid, degenerative or post-traumatic disabilities of the PIP joint with:

- Destroyed or subluxed joint
- Stiffened joints which could not be corrected by a joint tissue release

Contraindications

- Infection
- Un-cooperative patient
- Inadequate condition of bone, skin or neurovascular system
- Permanently damaged tendon system
- Potentially successful conservative treatment
- Young patients with open epiphyses

Warnings and Precautions

- This implant should not be used in highly active or high-load-bearing patients.
- Osteotec does not recommend a particular surgical technique for use with this implant. It remains the responsibility of the medical professional to evaluate and use the appropriate surgical technique based on their personal clinical training and experience.
- Only handle the implant using blunt instruments in order to avoid contamination or damage to the surface of the implant.
- Do not try to reshape the implant as this can adversely affect its structural integrity.
- Inspect the packaging before use. If the inner packaging is not intact, do not use the implant.
- Rinse the implant in sterile saline solution prior to implantation.
- The implant is for single use only – do not attempt to re-sterilize the implant as this can affect its material properties and can reduce the life of the implant.

Potential Complications and Adverse Side Effects
As with any joint replacement procedure, a number of complications or adverse side effects can potentially occur, these generally include but are not limited to:

- Implant loosening or fracture may necessitate revision surgery
- Excessive patient activity may cause implant wear or failure
- Infection, pain, swelling and inflammation may occur at the implant site
- Patient may have an allergic, immunological reaction, autoimmune disorder or histological response to the implant material requiring removal of the implant
- Implant movement and wear may generate wear particles that may cause or exacerbate synovitis or the formation of bone cysts in the tissues surrounding the implant.

Concerning Magnetic Resonance Environments
The Silicone Finger Implant has not been evaluated for safety and compatibility in the MR environment. The Silicone Finger Implant has not been tested for heating or migration in the MR environment.

Cleaning of the Sizers and Instruments
The sizers and instruments are reusable and should be thoroughly cleaned according to the following parameters:

- Remove excess soil with a disposable cloth/paper wipe. On completion of the surgical procedure the instruments should be soaked or kept moist by wrapping them in a moist towel, to prevent soil from drying.
- Soak the instruments in a neutral pH enzymatic solution for a minimum of 10 minutes.
- Scrub thoroughly using a soft bristled brush to remove any surface contamination.
- Rinse thoroughly with distilled/deionized water for at least two minutes.
- Dry the instrument with a clean towel or filtered air.
- Perform a visual inspection on the instruments and verify that they are clean and dry. If necessary re-clean until it is visibly clean.

Warning: Silicone parts **SHOULD NOT** be cleaned in an ultrasonic bath.

Sizers: These instruments need to be checked for any visible signs of damage; the hinge needs to be checked for surface wear or visible tears in the material. Damaged items must be discarded or replaced.

Sterilization of the Sizers and Instruments
The sizers and instruments are reusable and are supplied non-sterile. The sizers and instruments must be sterilized before use. The following steps are recommended –
• Double wrap the component in an FDA-cleared sterilization wrap.
• Sterilize using moist steam sterilization in a high-vacuum autoclave at 132°C for 4 minutes with 20 minutes of drying time.

These recommendations are consistent with **AAMI ST79:2010** guidelines. Other sterilization methods and cycles may also be suitable. However, individuals and hospitals are advised to validate whichever method they deem appropriate at their institution.

Do not use ethylene oxide to sterilize the sizers as gas residue in the sizers can cause an adverse tissue reaction.

Reprocessing of single use devices
The Silicone Finger implants are labelled as single use only and may not be re-used. A device should never be re-sterilized after contact with body tissues or fluids; once used the implant should be discarded. Use of these devices cause irreversible changes to the micro and macro structure; consequently, performance characteristics of the device will be sub-optimal if re-used. Re-use of a single use device may lead to:

- An increased risk of infection
- Failure of the device to perform as intended
- Material degradation
- Endotoxinic reactions

Storage
All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

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

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