ArcPhix™

EXSOMED™
Innovations in Hand Surgery

Instructions for Use: ExsoMed ArcPhix

Description and Intended Use:

The ExsoMed ArcPhix is an angled stainless steel bone compression screw intended for use in minimally invasive repair or reconstruction of small bone joints, including by percutaneous insertion into the medullary cavity. It is designed for permanent implantation to provide functional flexion of the joint. ArcPhix implantation requires the use of three accessory devices provided in the same kit as the implant: A guide wire; a drill to be used over the guide wire to prepare the bones and joint to receive the implant; and a hexalobe driver to insert the bone screw. The kit including the implant and instruments are both provided STERILE via Gamma Irradiation.

Indications for Use:

ExsoMed ArcPhix is indicated for use in the surgical fixation of small bones, bones fragments, and osteotomies. The device is not indicated for soft tissue fixation.

Contraindications:

- Active or latent infection or sepsis
- Insufficient quantity or quality of bone or soft tissue to support fixation
- Material sensitivity: If material sensitivity is suspected, tests should be performed prior to implantation
- Patients who are unwilling or incapable of following postoperative care instructions
- These devices are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine

MRI Safety Information:

ArcPhix has not been evaluated for safety and compatibility in the MR environment. ArcPhix has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in an MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Warnings:

For safe, effective use of the implant, the surgeon must be thoroughly familiar with the implant, the methods of application, instruments, and the recommended surgical technique for the device

- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity.
- Improper insertion of the device during implantation may increase the probability of hardware failure.
- The patient should be cautioned, about the use, limitations, and possible adverse effects of this implant. These cautions include the possibility of the device or treatment failing because of inadequate fixation and / or hardware loosening, stress, excessive activity, or load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the implant.
- The patient should be warned that failure to follow postoperative care instructions can cause the implant and / or treatment to fail.
- The implants may cause distortion and / or block the view of anatomic structures on radiographic images.
- The ArcPhix and accessories are single-use only. Do not attempt to re-sterilize.

Precautions:

- Avoid overtightening the ArcPhix; this may strip the threads, preventing removal of the implant if later desired.
- When placing the K-wire, it is important to ensure it is not bent or damaged.

Prescription Device:

Caution: Federal law restricts this device to sale by or on the order of a physician. This device requires surgical implantation under sterile conditions.

Directions for Use:

Surgical techniques are available describing the uses of this system. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use. Surgical Techniques can be found on the ExsoMed website (www.exsomed.com).

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