STABILIZORTHO

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SIMPLIFIX HIP SYSTEM

INSTRUCTIONS FOR USE

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

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

INDICATIONS: The SimpliFix Hip System is intended for fracture fixation of large bones and large bone fragments such as femoral neck fractures, slipped capital femoral epiphyses and an adjunct to a dynamic hip screw (DHS) in basilar neck fractures.

MATERIALS: All implants are made from Titanium 6Al-4V ELI.

INFORMATION FOR USE: Physiological dimensions limit the sizes of implant appliances. The surgeon must select the type and size that best meets the patient's requirements for close adaptation and firm seating with adequate support.

CONTRAINDICATIONS: Contraindications for the system are active or latent infection; sepsis; insufficient quantity or quality of bone/soft tissue; and material sensitivity. If sensitivity is suspected, tests must be performed prior to implantation to determine metal sensitivity. Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for these devices. These devices are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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 full weight bearing or excessive activity. Damages to the implants or scratches on the instruments/implants can substantially impair the strength of the product and lead to premature breakage. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing.

Improper insertion of the device during implantation can increase the possibility of loosening or migration.

The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant. These cautions include the possibility of the device or treatment failing as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing 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 must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail.

The SimpliFix Hip System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of SimpliFix Hip System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

PRECAUTIONS: An implant shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure. Instruments should be inspected for wear or damage prior to usage.

Protect implants against scratching and nicking, as such stress concentrations can lead to failure.

ADVERSE EFFECTS: Possible adverse effects are pain, discomfort, or abnormal sensations and nerve or soft tissue damage due to the presence of an implant or due to surgical trauma. Fracture of the implant may occur due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening may occur. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material may occur.

Nerve or soft tissue damage, necrosis of bone or bone resorption, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.

STERILITY: SimpliFix Hip System implants and certain instruments are provided sterile. All other SimpliFix components are provided non-sterile.

STORAGE INSTRUCTIONS: Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering or water contamination. For components provided sterile, use oldest lots first.

The below recommended process parameters have been validated by the manufacturer for sterilization of this device only in its complete medical device case/tray. Instruments should be sterilized in the mounting configuration provided in the tray.

If other products are added to the sterilizer, the recommended parameters are not valid and the processor must establish new parameters.

Pre-Vacuum	**Minimum Exposure Time**	**4 minutes**
	Minimum Temperature	**270˚ F (132˚ C)**
	Minimum Drying Time[1]	**30 minutes**

[1]Drying times may vary. The processor must validate the appropriate drying time for the sterilizer used.

Only legally marketed, FDA-cleared sterilization barriers (e.g. wraps, pouches, or containers) should be used for packaging these sterilized devices.

The processor must be responsible to:
- Follow ANSI/AAMI ST77, ANSI/AAMI ST79, ANSI/AAMI ST81
- Follow the manufacturer's operating instructions and maximum load instructions.
- Ensure that sterilizer is properly installed, maintained, and calibrated.
- Perform ongoing testing to confirm inactivation of all forms of viable microorganisms.
- Verify that the sterilizer can achieve the validated process parameters.

Any deviation by the processor from the recommendations provided must be properly evaluated for effectiveness and potential adverse consequences.