# iNSitu TOTAL HIP SYSTEM
# Instructions For Use (IFU)

## iNSitu Total Hip System

### IMPORTANT SURGEON INFORMATION
Please read prior to implanting this device in a clinical setting. The surgeon should be familiar with the information provided and the surgical technique.

ALL IMPLANTS ARE PROVIDED STERILE

DEVICE DESCRIPTION
The iNSitu Total Hip System is an artificial hip replacement system. The system includes femoral stems, femoral heads, acetabular shells, acetabular liners, acetabular bone screws, screw hole covers for the screw holes in the acetabular shell, and apical hole covers for the apical holes in the acetabular shells.

The femoral stems are forged titanium alloy and feature a proximal roughened surface (commercially pure titanium) for interlocking press fit and stability, a polished neck, a tapered multi-wedge geometry, a reduced lateral shoulder, and a reduced distal tip. The stems come in a range of sizes and are offered in both 'Standard' and 'Lateralized' offset options.

The femoral heads are offered in both cobalt chromium alloy and ceramic (BIOLOX®*delta*). The heads come in a range of diameters and offset options. The variety of head and stem sizes and offsets accommodate differences in patient anatomy.

The acetabular cups are manufactured from titanium alloy and feature a porous structured surface. The cup's porous structured surface has fully interconnected porosity. The cups feature a threaded apical hole and are available with or without a screw hole pattern for supplemental screw fixation. The acetabular cups come in a variety of sizes, and the porous structure is designed to provide both initial mechanical fixation as well as long term biologic fixation. Acetabular screw hole covers (3-Holed cup only), and acetabular apical hole covers are available to occlude holes in the acetabular cup prior to insertion of the acetabular liner.

The acetabular liners are manufactured from highly crosslinked vitamin E UHMWPE. The liners are mechanically assembled to acetabular cups via engagement of mating geometry. Liners are available in neutral (standard), hooded, and face-changing versions.

Acetabular bone screws are manufactured from titanium alloy and are available in a variety of lengths to provide supplemental fixation to bone.

INDICATIONS
The iNSitu Total Hip System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The iNSitu Total Hip System femoral stems are intended for cementless fixation. The iNSitu Total Hip System acetabular cup is intended for cementless fixation. The porous structured surfaces provide biological fixation in a cementless application.

CONTRAINDICATIONS
Contraindications may be relative or absolute and must be considered by the physician when making a decision on whether to use the device.

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders and are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, and 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

WARNINGS
Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants.

- All NextStep Arthropedix iNSitu Total Hip Systems implant components are sold sterile. If packages appear damaged or tampered with, they should be returned to the supplier.
- Do not implant any device that has been used, even if it appears undamaged.
- Machined taper surfaces of the femoral stem and head must be clean and dry at the time of assembly to ensure proper seating of the implant.
- Care must be taken to properly impact the femoral head to prevent any discrepancy in neck length, disassociation, or dislocation.
- Do not bend or contour an implant, as this may reduce its fatigue strength and may cause immediate or eventual failure under load.
- Never tamper with implants. Tampering may have a detrimental effect on the performance of the implant.
- The surgeon and O.R. staff must be extremely careful to protect all components from being marred, nicked, or notched as a result of contact with metal or any abrasive objects. This is particularly important for polished bearing areas and machined taper surfaces.
- Only unused BIOLOX®*delta* ball heads taken from the original packaging may be used. Never use a BIOLOX®*delta* ball head again. For example, a BIOLOX®*delta* ball head that has been placed once on a stem and then removed must not be placed on the stem again. Likewise, a BIOLOX®*delta* ball head with any kind of damage may not be used but discarded instead. This also applies to a BIOLOX®*delta* ball head that has fallen to the floor, for example.
- BIOLOX®*delta* ball heads may only be combined with the iNSitu Total Hip Systems femoral stems.
- BIOLOX®*delta* ball heads may only be used with new, never implanted, unused stem tapers.

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## PRECAUTIONS

Before any implant is used, the surgeon should be completely familiar with all aspects of the surgical procedure and the limitations of the device. The BIOLOX®*delta* ball head may only be applied by qualified operating surgeons who possess in-depth knowledge and experience in the field of hip joint replacement.
The patient must be informed that the same demands cannot be made of artificial joints as of real ones. Every form of competitive sport or sport involving jolts or jerky movements is contra-indicated. The patient must be informed of possible post-operative complications, and these must conform to the current state of medical findings. Increased risk exists for patients with unrealistic expectations of the artificial joint or for patients with excessive body weight or with weak bone structure, who are physically very active.

- Excessive physical activity may result in premature failure of the implant system due to loosening, component fracture, and/or wear. Patients should be instructed on the limitations of the prosthesis and how to modify their activities accordingly.
- Obese patients may place severe loading on the affected extremity which can be expected to accelerate joint failure.
- Proper selection of fixation type and placement of the femoral stem and acetabular component are critical factors in the prevention of unusual stress conditions and their potentially harmful effects on the life expectancy of the implant.

It is essential for safe function that care is taken when placing the BIOLOX®*delta* ball head on the stem.

- Do not remove the plastic protective cap, which protects the stem taper from damage, until immediately before the ball head is put on.
- Before placing the BIOLOX®*delta* ball head on the stem:
    - Thoroughly rinse the stem taper.
    - Carefully dry the stem taper.
    - Inspect the stem taper and the inner taper of the BIOLOX®*delta* ball head carefully and remove any foreign bodies such as tissue, bone or cement particles.
    - The BIOLOX®*delta* ball head is placed on the stem taper by twisting lightly and using axial manual pressure until it sits firmly.
    - Now place the plastic head impactor on the pole of the BIOLOX®*delta* ball head, and with a moderate tap of the hammer in an axial direction, firmly and definitively fix it on the stem taper. The surface structure of the metal taper becomes distorted plastically by the tapping of the impactor, causing an optimal distribution of pressure and a torsion-resistant fixation.

**Caution**: Never use a metal hammer on the BIOLOX®*delta* ball head. Use only the plastic head impactor provided by NextStep Arthropedix for this purpose.

## POSSIBLE ADVERSE EFFECTS

All prosthetic replacements have the potential for adverse effects, including but not limited to, infection, loosening, fracture, breakage, bending of the components, component disassembly, or positional changes of the components.

- Sensitivity reactions to component materials could occur and should be ruled out preoperatively.
- Total joint replacement surgery is associated with serious complications including, but not limited to: nerve injury, direct arterial injury, false aneurysm, spontaneous vascular occlusion, deep vein thrombosis, ectopic ossification, non-union, dislocation, disassociation, superficial and deep infection, aseptic loosening, or component failure.
- Acetabular pain due to loosening of the implant, and/or localized pressure associated with incongruencies of the fit, or tissue inflammation of unknown etiology.
- Reoperation may be necessary to correct adverse effects.
- Other complications generally associated with surgery, drugs, blood use, or ancillary devices used.
- In very isolated cases, fracture of ceramic implementation components can occur. The cause of this can be an overload on the prosthesis, for example through incorrect placement of the BIOLOX®*delta* ball head on the stem taper or a wrong or missing fit between the BIOLOX®*delta* ball head and the stem taper. BIOLOX®*delta* ball heads may only be combined with the iNSitu Total Hip System femoral stems that are indicated for use with the BIOLOX®*delta* ball heads. If a ceramic component breaks, a pairing of metal (ball head) with polyethylene (insert) and of metal with metal must not be used for revision.

## MRI SAFETY INFORMATION

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

## STERILIZATION

All implant components have been sterilized through an Ethylene Oxide (EO) sterilization process. Do not use any component if the package has been breached.

A BIOLOX®*delta* ball head must not be re-sterilized.

The iNSitu Total Hip System components are all nonpyrogenic.

**Rx ONLY**

## CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician.

For further information, please contact:

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Sterilized using Ethylene Oxide

Do Not Reuse

Consult Instructions For Use