POLARSTEM®
Femoral Stems with Ti/HA (Standard, Lateral, Valgus and Collar)

Smith & Nephew Orthopaedics AG
Oberneuhofstrasse 10d
CH-6340 Baar
Phone + 41 41 766 22 22
swiss.implants@smith-nephew.com

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NON-STERILE	non-sterile
	cemented
	non-cemented
	manufacturer

Additional symbols according to EN 980.

Important Notice to Users in the United States:
This package insert is for product distributed in US only.

℞ ONLY U.S. Federal law restricts this device to sale by or on the order of a physician.

General Safety Instructions

Products of Smith & Nephew Orthopaedics AG should only be used by surgeons that are familiar with joint replacement surgery. Moreover, Smith & Nephew Orthopaedics AG recommends taking part in product-specific training sessions, and/or demo surgeries performed by Smith & Nephew Orthopaedics AG primary reference surgeons. Before using the enclosed product, the operating surgeon must carefully read this package insert, the implant labels and the corresponding product and surgical technique information. Documentation as to the use of these products can be obtained by contacting the appropriate Smith & Nephew sales representative.

The manufacturer is not liable for complications that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice or handling of material and/or surgical instruments, asepsis and others.

Duty to inform the patient

Before starting the operation, the physician has the duty to inform the patient about the details of the surgical procedure, contraindications, risk factors, and possible side effects (refer to the Product-specific Information section). This package insert has been designed to provide this information. The patient must also be made aware of how his/her own behavior can affect the safety and life span of the implant. The operating surgeon should document all information given to the patient in writing.

Implant passport

The operating surgeon should issue an implant passport to her/his patients. This passport should be retained and used to inform health providers in case of dental infection, of any systemic infection, of accident justifying an emergency operation or before examination with diagnostic active medical devices (e.g. MRI). This document is also useful when the patient passes through airport metal detectors. In case of loss, the patient should contact immediately her/his physician to get a new passport.

Combination restrictions of Smith & Nephew products with third-party products

Smith & Nephew implants and implant components must not be combined with other manufacturer implants and should always be implanted using Smith & Nephew surgical instruments, unless these are commonly used in the operating room and/or described in the surgical technique. All liability is excluded for the unauthorized use of third-party products.

Patient sensitivity to implant materials

Patient sensitivities or allergies to the materials of the implants, particularly to metal ions are possible. The type of materials for each implant is provided on the box label. The operating surgeon should include possible risk factors concerning sensitivities to implant materials as part of the preoperative planning. The POLARSTEM® femoral stems have not been evaluated for safety and compatibility in the MR environment. The POLARSTEM femoral stems have not been tested for heating or migration in the MR environment.

Reuse or modifications

Implants are intended for single use only and must only be used in their original condition. Modifications of any kind shall not be done, unless the surgical technique expressly describes it. Any re-use of single use labeled products can cause serious harm to the patient which can lead to serious injury or death.

Cleaning, disinfection and sterilization/ resterilization

The recommendations given below are provided for information only.

- In general, implants have been sterilized by a minimum of 25 KGy of gamma irradiation or by the use of ethylene oxide. Implants provided as sterile must not be resterilized by the purchaser.
- Implants and instruments supplied as non-sterile must be cleaned, disinfected and sterilized before use, and can be resterilized as required.
- Implants and instruments must not come into contact with agents containing the following components: aromatic or halogenated hydrocarbon, oxalic acid, oily substances, powerful acid and alkalis, peroxide/extreme oxidizing substances, organic solvents, ammoniac alkaline solutions and mercurial compounds.
- For sterilization, instruments and non-sterile implants are to be placed in a suitable container.

Note to US customers: Only FDA cleared sterilizers and wraps are to be used in the sterilization processes.

Do not sterilize instruments in the protective bags in which they are supplied.

Only the dynamic air removal steam sterilization methods listed below may be used for sterilization:

- The weight of the fully loaded trays must not exceed 10kg (this must be observed if additional instruments are sterilized loosely in the tray)
- Steam sterilizer according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA:FDA clearance)
- Validated according to DIN EN ISO 17665 (valid IQ/OQ (Commissioning) and product-specific qualification (PQ))
- Maximum sterilization temperature 138°C (280°F plus tolerance in accordance with DIN EN ISO 17665)
- Sterilization time (exposure time at the sterilization temperature) at least 4 min at 132°C (270°F) / 134°C (273°F)

When the instruments have been used in a surgery with a risk of contamination by TSE agents, the instruments should be properly disposed. User should only use the steam sterilizations cycles validated by the manufacturer as recommended in the Package Insert.

Storage

Implants must always be stored sealed in their original packaging protected from direct sunlight. The implants shall not be used in any surgical procedure after the expiration date printed on each device label. Careful planning is recommended to assure that all products provided for a surgery are within their expiration date. Implants, implant parts and instruments that can no longer be used may be returned to the manufacturer for proper disposal.

General Surgical Steps

Implantation must be carried out as defined in the surgical technique. This documentation is available from Smith & Nephew. To ensure the success of the operation, it is essential that the surgeon is familiar with the surgical technique recommended for this system and applies this technique with great care.

Preoperative planning

Preoperative planning allows the surgeon to assess the choice of suitable components and possible combinations. Surgery should be planned in great detail based on analytical findings (i.e. X-ray, MRI). Additional implants should be available, in case other sizes are required or if the planned implant cannot be used. Failure to carry out a proper planning could lead into choosing the wrong implant type and/or size or incorrect implant positioning.

For information about preoperative planning and the use of X-ray templates, please read the corresponding surgical technique and/or contact a Smith & Nephew representative.

Preoperative preparation

Instruments

Only Smith & Nephew instruments should be used to prepare the bone bed and to fit and insert the implant. Instruments may only be used in their original condition.

The instruments are supplied as non-sterile and must be cleaned, disinfected and sterilized before use, applying the sterilization standards and operational procedures in force of the relevant institution. Please refer to the operating instructions for the autoclave to determine the correct settings for the sterilization temperature and time.

Before use, the functionality of surgical instruments should be checked. The use of damaged instruments may lead to early failure of the implants.

Implants

When removing the implant from its packaging, check that the description on the package (REF number and size) is correct and ensure that surgical personnel follow the rules of asepsis. For traceability purposes, the LOT number of the inserted implant must be documented in the appropriate patient files. Additional labels are included in the product box to facilitate this purpose.

Avoid implant contact with materials that might damage its surface. It is important to check the implant before it is inserted to ensure it is not damaged. Protective packaging shall only be removed immediately prior to use.

The following may not be implanted under any circumstances:

- Implant components that have been damaged or scratched
- Implants that have been handled inappropriately or processed in a way that is not part of the surgical technique
- Implants that have already been used
- Implants where the packaging and/or labelling is damaged or not intact

Please return the affected devices to the appropriate Smith & Nephew representative or sales office.

Intraoperative

For implants intended for cemented fixation, the surgeon must follow the cement manufacturer instructions concerning the preparation, cementing technique and other information, and recommendations for use.

Fixation is an essential factor for a firm and long-term implant seating. The following problems may cause the implant to loosen or can lead to complications:

- Excessive weakness of the bone structure caused by preparation of the bone bed
- Unsuitable choice of implant size
- Inadequate cleaning of the bone bed before implantation
- Application of excessive pressure when placing or fixing the implant can provoke fractures or bone damage

Prior to closure, the surgical site has to be thoroughly cleaned from foreign particles, bone cement, bone chips or other debris.

Postoperative follow-up

Every patient with a Smith & Nephew joint replacement requires consistent postoperative care by the surgeon or a suitably qualified expert. Postoperative care and treatment should incorporate recognized procedures and should take into account information from the surgical technique. Postoperative treatment should be documented according to hospital internal guidelines.

The patient has to be instructed regarding allowed activity levels and possible motion. The patient should be encouraged to promptly report any unusual changes with regard to the operated site to their physician.

Product-specific Information

Smith & Nephew total hip prosthesis is intended to replace a hip joint. This device is intended for primary or revision patients.

Device Description

The POLARSTEM® femoral stems for non-cemented use are made of titanium alloy with a fully porous titanium plasma/hydroxyapatite-coating (Ti/HA) and have a highly polished neck area. Proximal grooves perpendicular to internal curve and perpendicular to average load direction ensure that there is no groove discontinuity and distal grooves (reverse to the rotation direction) increase rotational stability.
The stems have a 12/14 taper.

POLARSTEM femoral stems are available in different offset versions, as standard offset with a neck-shaft angle (CCD) of 135°, as lateral (high offset) with a neck-shaft angle of 126° and as valgus option (reduced offset) with a neck-shaft angle of 145°. Standard and lateral versions are also available with a collar to provide an additional safety stop against implant subsidence. POLARSTEM material and surface characteristics are the same for all different options.

The POLARSTEM is suitable for partial or total replacement of the hip joint to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in skeletally mature individuals.

Indications

The POLARSTEM femoral stems with Ti/HA are indicated for:

- Advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis.
- Fracture or avascular necrosis of the femoral head.
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

The POLARSTEM with Ti/HA is intended for single use only and is to be implanted without bone cement.

Contraindications

- Acute or chronic infections, local or systemic
- Local infections of the area operated
- Severe muscle, nerve or vascular diseases that endanger the extremity in question
- Lacking bone substance or inadequate bone quality that endangers a stable seating of the prosthesis
- All concomitant diseases that may endanger the function of the implant, such as:
  - Any allergies to implant materials
  - Renal insufficiency
  - Cardiac insufficiency (e.g. as a result of increased metal/ions concentration in the blood)
- Pregnancy

Risk factors

These factors can influence the success of the operation:

- Osteoporosis
- Osteomalacia
- Severe deformations, congenital hip luxation
- Generally weakened patient resistance (HIV, tumours, infections)
- Systemic diseases and metabolism disorders
- History of infections
- History of falls
- Drug, nicotine, alcohol or medication abuse
- Overweight patient, obesity (body mass index >30)
- Excessive shock and strain
- Active sports and heavy labour
- Thrombosis or pulmonary embolism during the operation caused by preparing the implant bed or inserting the implant
- Postoperative morphological changes in the patient with weakening of the load bearing structures (e.g. tumours, hypertrophy, etc.) and/or changes in the materials used (e.g. attrition or fracture of the cement bed and/or tissue reactions to the implant) can lead to the following implant failures:
  - Loosening, bending, crack formation or fracture of the components, the bone or the cement (if applicable)
  - Wear and loosening of the implant can make it necessary to re-operate on the artificial joint

Possible side effects

The complications listed below are among the most common adverse events resulting from hip arthroplasty:

- Dislocation, subluxation, insufficient range of movement, undesirable shortening or lengthening of the limb
- Infection
- Pain
- Venous thrombosis and pulmonary embolism
- Cardiovascular, pulmonary (e.g. fat embolism) and neuronal dysfunction
- Haematoma, wound haematoma and delayed wound healing
- Bone fractures resulting from unilateral strain or weakened bone substance
- Abnormal bending, loosening and repositioning of the implant
- Abrasion of implant surfaces and development of osteolysis as a reaction to foreign bodies
- Fracture of the implant, bone or cement

Special information for use

Important Information on combination of Smith & Nephew products

Implants and instruments manufactured or distributed by Smith & Nephew Orthopaedics AG and the former manufacturers Plus Orthopedics AG, Intraplant AG and PLUS Endoprothetik AG may be combined with each other. The surgeon must always ensure that the individual components are compatible and should take into account the following general restrictions on material combinations:

Restrictions on head/insert combinations

- BIOLOX® forte / delta ceramic inserts must only be combined with BIOLOX® forte / delta ceramic ball heads

Restrictions on head/taper combinations

Material

- Do not combine femoral heads made of stainless steel (FeCrNiMoNbN) with any hip stem made of titanium (Ti6Al4V, Ti6Al7Nb) or cobalt-chromium (CoCr,CoCrMo) alloys.
- Do not combine hip stems made of stainless steel (FeCrNiMoNbN) with femoral heads or modular neck sleeves made of cobalt-chromium alloys (CoCr,CoCrMo).

Sizes

Ball heads should only be combined with Smith & Nephew hip stems of identical taper dimensions and from Smith & Nephew Orthopaedics AG (or formerly Plus Orthopedics, Intraplant or PLUS Endoprothetik).

Reliable fit of femoral ball heads on stem tapers

The taper connection can only be reliably and firmly seated if the surface of the ball head cone and the surface and structure of the hip stem taper are completely intact. To ensure that the ball head performs as required, it is essential to take great care when attaching it to the stem taper. The disposable plastic cap protecting the stem taper from damage shall not be removed until the trial ball is attached.

Important information

The ball head cannot simply be pressed in place by hand. Gently impact the ball head using a plastic impactor.

For the revision of a femoral ball head, apply the following:

- The corresponding insert also has to be removed.
- Replacement only by a metal ball head or a ceramic revision femoral ball head coupled with a metallic taper adaptor.
- Never reuse a femoral ball head that has been impacted onto a stem cone and then removed.
- The use of ceramic ball heads is limited to new hip stems.
- In case of breakage of one component (femoral ball head or insert) used in a CE/CE tribological pairing, the other component has to be revised as well. All ceramic particles must be removed.
- It is recommended that neither metal nor OXINIUM° ball heads be used in the case of revision due to ceramic fracture as remaining fragments increase the risk of accelerated wear and reduced implant life of the replacement ball heads and polyethylene inserts. This may necessitate the removal and replacement of the femoral component to provide a suitable femoral taper to attach the new ceramic ball head. A ceramic on ceramic or ceramic on polyethylene articulating surface is recommended for any revision due to ceramic fracture. In the US, the revision option would be ceramic on polyethylene. If broken ceramic material is encountered, remove all loose identifiable fragments and thoroughly irrigate and lavage the operative site.

Important: Also refer to the surgical techniques and/or contact the appropriate Smith & Nephew sales representative for further information on the use of our products.

BIOLOX® forte / delta are registered trademarks of CeramTec GmbH, Germany.

International Patent Protection:
Hip Acetabular Component

US 6,537,321	EP 0 944 368	
US 6,325,829	EP 0 998 245	
US 5,443,520	EP 0 601 224	
US 6,059,833	EP 0 732 903	EP 0 137 040

Hip Femoral Component

US 6,652,589	EP 0 985 387	EP 1 157 678
US 6,540,788	EP 1 044 665	
US 6,436,147	EP 1 062 923	
US 6,808,539	EP 1 044 665	
US 6,383,228	EP 0 943 297	
US 6,344,060	EP 1 985 387	
US 6,613,094	EP 1 044 664	
US 6,540,788	EP 1 044 665	
US 5,456,717	EP 0 601 223	
US 5,593,446	EP 0 715 835	

For U.S. package insert information visit:
www.smith-nephew.com/ortholabeling
or call 1 800 238 7538.