



Signature Resurfacing Head Product Range

- *Signature Resurfacing Femoral Head*

Instructions for Use 111-142-022 Rev. A

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Caution:

Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. Additional warnings and precautions may be included in the surgical technique or on the label. This product must only be used by trained, qualified persons, aware of the directions for use. Surgical techniques are distributed to the surgical representatives or alternatively can be requested through info@signatureortho.com.au

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

1 Device Description

Signature Resurfacing Femoral Head Prostheses are designed to replace the outer surface of the femoral head while preserving as much natural bone as possible. The device retains the diameter the natural femoral head and articulates against the natural acetabulum (hemi-hip).

2 Indications

Cemented Femoral Head Resurfacing:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis

The device is a single use implant intended for use with bone cement.

Press-Fit Head Resurfacing Device:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis

The device is a single use implant intended for press-fit application.

Patient selection factors to be considered include:

1. need to obtain pain relief and improve function,
2. ability and willingness of the patient to follow instructions, including control of weight and activity level,
3. a good nutritional state of the patient, and
4. the patient must have reached full skeletal maturity.

3 Contraindications

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include:

1. uncooperative patient or patient with neurologic disorders who 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,
7. vascular insufficiency, muscular atrophy, or neuromuscular disease.

4 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 may lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) may lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris, or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) may lead to crevice corrosion, fretting, fatigue fracture, and/or excessive wear. Do not modify implants.

The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris and other surgical debris at the implant

site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.

Signature Orthopaedics' joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from fell load bearing until adequate fixation and healing have occurred Excessive activity, trauma and weight have been implicated with premature failure of the implant by loosening, fracture and/or wear. Loosening of the implants may result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

5 Precautions

Specialized instruments are designed for Signature Orthopaedics' joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear, and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Signature Orthopaedics' recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

6 Possible Adverse Effects

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant. Further, there has been a report regarding an association between articulating surfaces of: 1) CoCrMo alloy on CoCrMo alloy, 2) CoCrMo alloy on polyethylene, and 3) Titanium alloy on polyethylene in hip replacements and increased genotoxicity. This report, however, did not assess either the clinical relevance of the data or make any definite conclusions as to which metal ions or interactions between metal ions or particulate metals might be responsible for the observed data. The report further cautioned that an association does not necessarily mean a causal relationship, and that any potentially increased risk associated with metal ions needs to be balanced against the benefits resulting from hip replacement.
2. Early or late postoperative, infection, and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening or migration of the implants may occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components
7. Undesirable shortening of limb
8. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity may also contribute to these conditions.
9. Fatigue fracture of component may occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10. Fretting and crevice corrosion may occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment
13. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14. Intraoperative or postoperative bone fracture and/or postoperative pain.

7 Patient Consent

As with all surgical procedures, the patient should be made aware of the risks and possible adverse effects. In particular the patient should be warned of limitations of the prosthetic device components being implanted, including the limited expected service life of the device and the possible requirement for revision surgery to replace worn or damaged prostheses.

8 Preoperative

Care should be taken when handling the prosthetic components to avoid damage to the surface of the device. Denting, notching or scratching can greatly reduce the tensile strength, fatigue resistance or wear properties of the component potentially leading to fracture or failure of the device.

The porous or coated surfaces of the device should be protected from contact with gauze, cloth or other fibre-releasing materials.

Surgical technique information is available for each device component. The surgeon should familiarise themselves thoroughly with the technique prior to consideration of the use of the device for any specific patient.

Implants are only to be used with approved Signature Orthopaedics instrumentation and/or devices or third party devices that have been evaluated and considered to be compatible. Implants have been designed and tested for use with one another, and use with third party devices is untested and strictly prohibited unless they have been tested and found to be compatible. The surgical instrumentation prescribed within the technique for the implantation of the prosthesis should not be used for any other device or in a manner contrary to its intended use. Failure or breaking of instruments can occur. Instruments have a limited service life and should be examined for wear or damage and replaced prior to surgery if required.

Instrumentation and implants should be sterilised according to the manufacturer's protocols. Do not resterilise component parts which have been assembled, or implants connected to surgical instruments. Do not cool hot components in cold water.

9 MRI Safety Information

The Signature Orthopaedic hip replacement product range 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 the Signature Orthopaedics hip replacement product range 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.

10 Intraoperative

Correct implant selection is extremely important. The use of preoperative imaging, templating and the intraoperative use of trial components is recommended to facilitate the choice of an optimum size and type of component for the specific patient. The patients overall anatomical and medical condition should also be considered in conjunction with age, expected activity level, life expectancy and potential for future revision surgeries. The incorrect selection of implant type or size may result in failure of the component and/or bone.

The correct selection and positioning of the acetabular component and the choice of the appropriate neck length and / or offset of the stem is important to prevent complications. Malposition of the components can result in loosening, or joint dislocation.

Implants should be inspected before use. Do not use any implants that have visible damage such as scratching, chipping or bending. Do not use any implants that have been dropped on the floor.

Penetration of the inner cortex of the pelvis should be avoided when drilling for or placing screws for fixation of the acetabular component as damage to neurovascular structures may occur from the drill or screws of excessive length. Similarly, drilling and/or placing screws in the acetabular prosthesis when oriented in an anterior or medial direction, is associated with a high risk of serious vascular injury. Screws must be completely seated in the shell to allow proper seating for the acetabular liner.

The stem taper and femoral head bore must be clean and dry prior to assembly or postoperative separation of the head from the stem may occur. Assemble the stem and head by gently placing the head on the stem while maintaining alignment, then sharply hitting the ball with the soft plastic hammer instrument to firmly connect the components.

Before assembly of components, surgical debris must be cleaned from the surfaces. Debris may inhibit the component coupling mechanism. When inserting acetabular liners, ensure soft tissue does not impinge between the shell and liner. Modular components such as femoral heads must be assembled securely to prevent disassociation. Incorrectly seated acetabular liners may loosen and disassociate from the shell.

If assembled modular components must be disassembled then those components must be disposed of and new components used. Disassembly can damage the components and cause a reduction in assembly strength. If a liner is disassembled from a cup then the liner must be disposed of. If a femoral head is disassembled from a stem, both the stem and head must be disposed of.

Where removal of the prosthetic femoral head is required in revision surgery, a ceramic head should not be placed on a previously used taper connection. Irregularities in the femoral taper may induce stress concentrations in the ceramic head which could result in fracture of the ceramic head.

Implants removed from the patient at revision surgery should never be reimplanted as the fatigue state of the implant cannot be determined by visual examination. Removed implants must be treated as biological hazards and are required to be treated or disposed of according to the country's waste regulations where the implant is removed.

The wound site should be thoroughly cleaned of bone and other debris before closure. Range of motion should also be assessed before closure. Osteophytes, ectopic bone or old scar tissue causing impingement should be removed to reduce the possibility of reduced range of motion or dislocation.

In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metal shell for uncemented, press-fit fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the bone or bone cement interface through the use of orthopaedic bone fixation devices such as bone screws, spikes, screw threads, fins, or other bone fixation devices.

Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or extended liners).

11 Precautions for Specific Conditions

A higher incidence of sciatic nerve palsy is associated with arthroplasty in the treatment of congenitally dislocated hips. Also, in such patients, a pseudoacetabulum should not be utilized as a placement site for the acetabular cup.

12 Postoperative Care

It is extremely important that patients are provided with clear directions regarding the extent, type and progression of post operative physical activity. The level of weight bearing should be determined for the individual patient depending on the type of procedure and components used. In the event of bone grafting or extensive revision surgery a non-weight bearing period should be considered.

Patients should be warned against unassisted activity, particularly the use of bathing and toilet facilities and other activities requiring significant non-gait motion of the hip.

When manual patient handling is required, care should be taken to support the operative leg and pelvis to minimise the risk of dislocation.

The use of post operative physiotherapy is recommended to rehabilitate the muscles affecting hip function as physical activity is increased.

Staged follow up with x-ray comparison to the immediate postoperative imaging is recommended to detect evidence of detrimental change in the implant. Any indication of structural failure of the implant, radiolucencies, or osteolysis should be monitored carefully for the potential need of early revision surgery. The patient should be advised that prophylactic antibiotics therapy may be required for subsequent treatments, procedures, or situations which may result in bacteremia.

13 Packaging and Labeling

Components should only be used if the factory packaging and labelling are intact. If the sterile barrier has been broken, return the component to Signature Orthopaedics.

14 Sterilization and Resterilization

Implants are supplied sterile and have been double sterile packaged. The entirety of the implants listed hereby, included in the Signature Orthopaedics Hip Replacement Product Range IFU, are EO (ethylene oxide) for all products. The method of sterilization, sterilize EO is noted on the package label. Return the implant to Signature Orthopaedics if the packaging is damaged. Resterilization of the implants is not recommended, as it may alter the mechanical integrity of the device. Do not sterilise implants using moist heat.



Unless specifically labelled sterile, instruments are supplied non-sterile and must be sterilized prior to use. A complete guide for reprocessing reusable instruments may be provided upon request. As a guideline, the following sterilization method is recommended:

Method: Steam Autoclave
Cycle: Pre-vacuum
Temperature: 132° (270°F)
Exposure time: 4 minutes
Drying time: 30 minutes

Note: Drying time is subject to variation depending on machine load.

15 Cleaning

Implants are supplied sterile and intended for single use only. The implant should be returned to Signature Orthopaedics if the packaging is damaged. Cleaning of the implants is not recommended.



Re-usable instruments are delivered non-sterile. A complete guide for reprocessing reusable instruments may be provided upon request. As a guideline, the following cleaning method is recommended.

Manual Cleaning

Instruments are to be cleaned immediately after use with warm water and a mild detergent. Instruments consisting of multiple components must be disassembled prior to cleaning. After cleaning, the parts should be rinsed thoroughly with de-ionized water and dried.

Cleaning before Sterilization

Instruments may be cleaned using broad spectrum bactericide and fungicide agent in accordance with the instructions of the manufacturer of the agent.

Caution:

Do not clean instruments with products containing Sodium Hypochlorite (NaOCl) and Sodium Hydroxide (NaOH).

Corrosive products or abrasive instruments should not be used.

Instruments should be thoroughly inspected to ensure they are in good condition and operating order. Instruments should be returned to Signature Orthopaedics at the address provided below at least once every 2 years for review/repair/replacement. Instruments may be returned to Signature Orthopaedics for review/repair/replacement earlier if the user deems necessary.

16 Storage and Handling

Implants and instruments are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilisation tray respectively.

17 Limited Warranty / Liability

Signature Orthopaedics products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Signature Orthopaedics Europe Ltd. shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Signature Orthopaedics Europe Ltd. neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Signature Orthopaedics Europe Ltd. intends that these instruments should be used only by physicians with appropriate training in orthopaedic surgical techniques.

18 Contact Information

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate Signature Orthopaedics location for current information. For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Signature Orthopaedics location as listed below:



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19 Glossary of Symbols

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD REFERENCE
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1 Ref # 5.1.6 FDA Recognition #5-117
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Ref # 5.1.5 FDA Recognition #5-117
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Ref # 5.4.3 FDA Recognition #5-117
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.	ISO 15223-1 Ref # 5.2.6 FDA Recognition #5-117
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Ref # 5.4.2 FDA Recognition #5-117
	Do not use if package damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 Ref # 5.2.8 FDA Recognition #5-117
	Symbol for Prescription Device	Caution: Federal law restricts this device to sale by or on the order of a physician.	Guidance for Industry and FDA on Alternative to certain Prescription Device Labelling Requirements
	Sterilized by Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 Ref # 5.2.3 FDA Recognition #5-117
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1 Ref# 5.1.3 FDA Recognition #5-117
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 89/79/EC	ISO 15223-1 Ref # 5.1.1 FDA Recognition #5-117
	Use-by-date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Ref # 5.1.4 FDA Recognition #5-117

	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 Ref # 5.4.4 FDA Recognition #5-117
	Keep Dry	Indicates medical device that needs to be protected from moisture.	ISO 15223-1 Ref # 5.3.4 FDA Recognition #5-117
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely expose.	ISO 15223-1 Ref # 5.3.7 FDA Recognition #5-117
	Distributor	Indicates the entity distributing the medical device into the locale.	ISO 15223-1 Ref # 5.1.9 FDA Recognition #5-117