Hip Replacement Product Range

Femoral Heads and Stems

- *Everglade Hip Stem*

Acetabular Cups

Instructions for Use 111-142-006 Rev. A Issue Date: 22-SEP-2025

CE 2797

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

This device is restricted to sale by or on the order of a physician.

1 Device Descriptions

All devices described herein are supplied individually sterile packed and are intend for single patient use only. Additionally, all devices described herein are available in a range of sizes to allow correct selection to match the patient's anatomy.

Everglade Hip Stem

Intended purpose: The intended clinical use of the Everglade Stem is replacement of a diseased hip joint thereby reducing pain and improving hip joint mobility, range of motion and the patient's daily living function.

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F136 with titanium and HA plasma spray coating per ASTM F1580 and ISO 13779-2 respectively.

The Everglade Hip Stem is straight and tapered with a rectangular cross-section intended for use without bone cement. The stem has a polished distal tip to reduce fixation leading to proximal stress shielding. The stem is sequentially coated with titanium then HA and is intended for uncemented, press-fit fixation.

1 Indications and Performance Characteristics

Components of the Signature Orthopaedics hip replacement range are intended to replace a hip joint where bone stock is sufficient to support the implant. When a surgeon has selected prosthetic replacement as the preferred treatment, the devices are indicated for:

- Non-inflammatory degenerative joint disease including osteoarthritis or avascular necrosis
- Inflammatory joint disease including rheumatoid arthritis
- Correction of functional deformity including congenital hip dysplasia
- Traumatic injury involving the hip joint including traumatic arthritis or femoral head or neck fracture
- Failed previous hip surgery including internal fixation or joint fusion, reconstruction, hemiarthroplasty, surface replacement, or total replacement

Signature Orthopaedics' Everglade Hip femoral stems are intended for cementless fixation only.

The Signature Orthopaedics Everglade Stem is to be implanted using its own instrumentation, for which it was specifically designed. The selection of appropriate implants can be made using the recommendations of the surgical technique and trial implants and templates supplied with the instrumentation.

The Everglade Stem is compatible with a range of Signature Orthopaedics Acetabular components including the Evolve UniPolar, BiPolar heads, Logical and World shells, cups and liners.

Signature Orthopaedics' Evolve UniPolar Head and BiPolar Head are intended for hemi-hip arthroplasty only, where the natural acetabulum does not require replacement. The Evolve UniPolar Head and BiPolar Head are indicated for bone fractures or pathologies involving only the femoral head/neck and/or proximal femur, such as:

- Acute femoral head or neck fracture
- Fracture dislocation of the hip
- Avascular necrosis of the femoral head
- Non-union of femoral neck fractures
- Certain high subcapital and femoral neck fractures in the elderly
- Degenerative arthritis involving only the femoral head

Signature Orthopaedics' SignaSure Logical/World Metal Insert is indicated for use with a cementless Signature Orthopaedics' Logical/World Acetabular Cup to provide dual mobility articulation.

Signature Orthopaedics' constrained liner components are indicated particularly for patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

2 Clinical Benefits

The use of Signature Orthopaedics hip replacement systems is intended to elicit the following clinical benefits to the indicated patients:

- Significant reduction in pain
- Improved hip mobility

These claims are supported by a review of the clinical data for Signature Orthopaedics hip replacement systems obtained from one or more of the following sources: national joint replacement registries, clinical studies, and/or a review of the clinical literature. These data, in conjunction with bench-top test data and engineering analyses, substantiate that the device performs as intended and remain state of the art for use in hip arthroplasty procedures.

3 Summary of Safety and Clinical Performance (SSCP)

The SSCP is available in the European database on medical devices (EUDAMED) and is linked to the device identifiers (basic UDI-DI). To locate the SSCP for the subject devices, refer to the Basic Unique Identifier (BUDI) table below:

Device	Basic-UDI-DI
Everglade Hip Stem	93482151111-45Q4

4 Contraindications

In general, prosthetic components require adequate bone support for correct fit and function. The use of prosthetic components is therefore contraindicated where any pathological condition may reduce the quantity and or strength of the bone which is supporting the prosthesis. Some contraindications are relative to the extent and severity of conditions and the benefits of prosthetic arthroplasty should be considered based on the patient's overall evaluation and the possibility of alternative treatment. Examples of such conditions include; osteoporosis, osteomalacia, osteogenesis imperfecta, or hypophosphatemia. Other contraindications include:

- Conditions limiting blood supply to the bone or joint.
- Systemic or local infection.
- Previous high dose radiotherapy.
- Psychological or neurological conditions which would restrict the patient's ability or compliance in restricting physical activity.
- Skeletal immaturity
- Conditions or activity which may place excessive load on the components such as; obesity, muscle, tendon & ligament deficiencies, multiple joint disabilities, and Charcot joints.
- Allergies to implanted materials, particularly metals (e.g. cobalt chromium as well as polyethylene and bone cement)

The Signature Ceramic Femoral Head (containing Zirconia) is contraindicated for use with any other than an UHMWPE cup or a metal backed UHMWPE cup. This head must only be used with the Logical™ Cup with a UHMWPE or Vit-E HXLPE Logical™ Liner.

The Signature Orthopaedics' constrained liners are contraindicated particularly for active patients.

Signature Orthopaedics' constrained liners are also contraindicated for use with the Signature Orthopaedics Origin-NS stem and Cemented TSI stem due to decreased range of motion.

Signature Orthopaedics' Cemented TSI is contraindicated for use with CoCr femoral heads due to a potential risk of increased fretting corrosion.

5 Patient Selection Precautions

The following factors may be relevant to the success of the procedure:

- The patient's body mass. An obese patient may place increased loads on the prosthesis which can lead to failure of the device or loosening in the bone. The risk increases with smaller size implants and increasing patient weight.
- The patient's regular type and level of activity or employment may affect the durability of the components. If the patient's occupation or activity includes significant impact loads, the increased forces can cause failure of the implant or failure of the fixation of the device to bone. High levels of physical activity over time can accelerate the normal wear process that occurs with the bearing surface of prosthetic joints.
- Mental illness, or substance dependence which may tend to reduce the patient's compliance with prescribed precautions and limitations on physical activities, which may cause implant failure or other complications.
- Material sensitivity. Patients should be screened for potential sensitivity to the constituent materials composing the device. If sensitivity is suspected, Preoperative tests should be conducted.

6 Materials

The constituent material of the Everglade Stem is included on packaging labels.

Component	Material	Composition	
Everglade Hip Stem	Wrought Titanium Alloy - Ti6AL4V	**Element**	**ASTM F136 (%mass/mass)**
		Aluminium	5.5-6.5
		Vanadium	3.5-4.5
		Iron	0.25 max.
		Oxygen	0.13 max.
		Carbon	0.08 max.
		Nitrogen	0.05 max.
		Hydrogen	0.012 max.
		Titanium	Balance
Everglade Hip Stem	Titanium and Hydroxyapatite BiCoat	**Element**	**ASTM F1580 (Weight %)**
		Nitrogen	0.05
		Carbon	0.08
		Iron	0.50
		Hydrogen	0.05
		Oxygen	0.40
		Titanium	Balance

7 Possible Adverse Effects

Wear: The bearing surfaces of components may wear with use over time. The presence of third body particles of metal, bone or other materials which can develop as a result of the surgical procedure may cause abrasion of the articulating surfaces and lead to accelerated wear. Higher rates of wear may reduce the functional life of the hip replacement and result in the need for early revision surgery to replace the worn components.

Osteolysis: Progressive bone resorption or osteolysis may occur around the prosthetic components as a consequence of the body's immune reaction to particulate wear debris. Particles are generated by interaction between the prosthetic components, as well as between the components and bone interface. Particles may also be generated by third-body debris between the articulating surfaces. Osteolysis can lead to failure of the fixation between the implant and bone requiring the removal or replacement of the prosthetic components.

Structural Failure: Deformation or fracture of implant components may result from failure to observe the Warnings and Precautions contained herein. Fracture of the implant can also occur as a result of traumatic injury, acute excessive loading, or improper anatomical alignment.

Fracture: Pelvic or femoral: May occur intraoperatively, due to reaming, broaching or implant insertion. May occur postoperatively, due to prosthesis stress transfer caused by inappropriate early weight bearing or trauma.

Nerve Injury: Femoral, sciatic, peroneal nerve, and lateral femoral cutaneous nerve injury resulting in temporary or permanent nerve damage, with consequential pain or numbness of the affected limb.

Infection: Local or systemic, acute post-operative wound infection and late onset prosthetic infection.

Hematoma: Deep and superficial wound hematoma. Thromboembolic incidents including venous thrombosis, pulmonary embolus, cerebrovascular events or myocardial infarction.

Material Sensitivity: Metal sensitivity reactions and/or allergic reactions to foreign materials may occur.

Other possible adverse events include; decreased range of motion, dislocation, subluxation, leg length discrepancies, heterotopic bone formation, penetration of the femoral prosthesis through the femoral cortex, acetabular fracture, intrapelvic protrusion of the acetabular component or prosthetic femoral head, myositis ossificans or femoral impingement, vascular injury and/or delayed wound healing, excess femoral medialisation, or lateralisation, causing gait change or pain in the joints of the affected or contralateral extremity.

8 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.

9 Preoperative

Note: reuse of a prosthetic component or use of an explanted prosthetic component is strictly prohibited. The mechanical, chemical and biological properties of a used component cannot be verified for adequate safety and performance.

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. Further information on the use or implantation of the device can be found in the surgical technique provided. Additionally, the verification of correct device usage and implantation can be conducted by referring to and following the instructions provided in the surgical technique. The surgical technique also provides a list of necessary instrumentation required for successful implantation and their

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.

Implants have been sterilized by ethylene oxide (ETO). Refer to package label for sterilisation method. Sterile implants are NOT to be re-sterilized.

Single use devices cannot be explanted and subsequently reimplanted as the physical forces required for explantation may compromise the physical integrity, dimensions and/or surface finishes of the devices. Sterility cannot be assured for explanted devices and cleaning and re-sterilization procedures for such cases is unverified.

10 MRI and Other Diagnostic or Therapeutic Procedure 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.

Additionally, the Signature Orthopaedic hip replacement product range has not been evaluated for safety in other diagnostic or therapeutic environments and use in these environments may result in interference with such procedures or adverse effects such as implant heating or signal distortion.

11 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).

12 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.

13 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.

14 Information to be Conveyed to the Patient

The following information should be provided to the patient:

- Undesirable adverse effects and complications listed in the present documentation
- Precautions to take in daily use to guarantee maximum implant survival
- The effect that body mass and level of activity can have on the durability of the device
- Information about MRI exposure
- The patient must inform the surgeon of any change in performance (mobility, pain etc.) or possibly malfunction of the device
- The patient must report any serious incident that occurs in relation to the device to the competent authority of their region and to the manufacturer
- The overall qualitative and quantitative information on the materials and substances to which the patient can be exposed and the possible adverse effects that may be experienced as a result (possible sensitisation, allergic reaction etc.)
- The implant card with the appropriate information
- The patient is able to access updates on this information at the website indicated on their implant card

15 Packaging and Labeling

Components should only be used if the factory packaging and labelling are intact. If the sterile barrier has been broken, do not use component and return the component to Signature Orthopaedics.

16 Cleaning and Sterilization

Unless otherwise explicitly labelled, implants are provided ethylene oxide (ETO) sterilised and are not intended for end-user cleaning, sterilisation or reuse. All implants are single-use only.

Unless otherwise explicitly labelled sterile, instrumentation is provided non-sterile and is intended for end-user cleaning and sterilisation. A complete guide for reprocessing reusable instruments is stated in 199-051-100. A copy of these instructions is provided with each instrument tray and can also be provided upon request.

17 Storage and Handling

As per implant labelling, Implants and instruments are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilisation tray respectively. Where a component is to be explanted from a patient, the component is to be disposed of as per the institution's protocols for disposal of contaminated medical waste.

18 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.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
REF	**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
LOT	**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 resterilize**	Indicates a medical device that is not to be resterilized.	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
STERILE EO	**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
STERILE R	**Sterilized by irradiation**	Indicates a medical device that has been sterilized using irradiation	ISO 15223-1 Ref # 5.2.4 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 moister.	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
MD	**Medical Device**	Indicates the item is a 'medical device'	ISO 15223-1 Ref # 5.7.7
	**Double Sterile Barrier System**	Indicates two sterile barrier systems. The symbol shall be placed adjacent to or in combination with "Sterile EO" or "Sterile R" symbols	ISO 15223-1 Ref # 5.2.12
CE 2797	**CE Mark + NB Number**	The CE mark is only included on products cleared for the EU market. The number affixed to the CE mark symbol should match the notified body who performed the confomirty assessment of the device.	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 Article 20