



Augment Product Range

Instructions for Use 191-332-002 Rev. E

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Caution:

Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions for use.

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

Device Description

Signature Orthopaedics' range of augments are ancillary devices intended for use with Signature Orthopaedics range of joint replacement components. The augments aid in positioning and supporting the prosthesis to improve biomechanics, and act as a wedge or spacer with retaining screws to supplement bony fixation. Signature Orthopaedics' range of augments are manufactured from titanium or titanium alloy, as indicated on the implant package label. The augments are porous to allow fixation with bone cement or to promote bony ingrowth for biological fixation without bone cement. Signature Orthopaedics' augments are available in a range of sizes that may be used interchangeably to accommodate varying patient anatomies.

1 Indications

Signature Orthopaedics' augment range are ancillary devices intended for use only with compatible joint replacement ranges and are subject to the joint replacement system's indications for use.

Signature Orthopaedics' augment range are intended to provide the orthopaedic surgeon with a prosthetic alternative to structural allograft to correct deformity or deficiency in the patient's existing anatomy. Signature Orthopaedics' augment range are indicated for primary or revision use in skeletally mature patients with sufficient existing bone stock to support the implant.

Signature Orthopaedics' augment range may be intended for cemented or cementless use. Please verify whether the particular component is intended for cemented or cementless use by checking the device labelling.

2 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.

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.
- 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.

Possible Adverse Effects

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.

Bone Fracture: 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: 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, component migration, subluxation, anatomical discrepancies, heterotopic bone formation, prosthetic protrusion from the bone, myositis ossificans, vascular injury and/or delayed wound healing, inaccurate joint reconstruction causing biomechanical change or pain in the joints of the affected or contralateral extremity.

WARNINGS AND PRECAUTIONS

3 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.

4 Operative Information

Prosthetic components from different manufacturers must not be combined. All devices should only be used according to the package directions in conjunction with the specified surgical technique and instructions for use. Additional warnings and precautions may be included in component literature.

5 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. 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 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.

The patient should be warned about the potential adverse events associated with exposure to strong magnetic fields after implantation of device components made of titanium. During MR imaging exposure

to pulsed radio frequency fields can generate heat within tissue and metal components significant enough to cause serious burns. Metallic implants may create imaging artefacts or distortions to varying degrees in MR images.

Signature Orthopaedics does not recommend MR imaging for any patients implanted with metallic prosthetic component(s) without prior consultation with an expert radiologist for assessment of potential adverse events such as device movement, localized burns, torsional or shear strain on the implanted device. The safety of the devices in the MR environment is unknown, and scanning of patients who have the device may result in patients' injuries (i.e. the device is MR unsafe).

6 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. It is recommended that components at least one size larger and one size smaller than were preoperatively determined be available at surgery to accommodate intraoperative selection of the appropriate size. The patient's 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.

When performing revision surgery, it is imperative that any fibrous membrane encapsulating the failed prosthesis be removed in its entirety. Residual fibrous membranes may interfere with implant fixation. Improper selection, placement, or positioning of implants may result in unusual stress conditions and a subsequent reduction in the functional life of the implant.

Perforation entirely through the bone should be avoided when drilling for or placing screws for fixation of the augments as damage to neurovascular structures may occur from the drill or screws of excessive length. Screws must be completely seated in the augment to allow proper seating for the mating prosthetic components.

Before assembly of components, surgical debris must be cleaned from the surfaces. Debris, including bone, bone cement, or soft tissue may inhibit the component coupling mechanism. Incorrectly assembled components may migrate or disassociate from the prosthesis.

For implants designed for bone cement fixation, care should be taken to ensure that a complete cement mantle is achieved by the elimination of air inclusions, or areas where the prosthesis is unsupported by bone cement. Insufficient support of the implant, by the bone cement, may lead to increased stress loads on the implant, on the cement, and/or cement-bone interface, resulting in failure of fixation, or fracture of the device.

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 waste regulations of the country where the implant is removed.

The wound site should be thoroughly cleaned of cement, 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.

7 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.

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

The use of post operative physiotherapy is recommended to rehabilitate the muscles affecting joint 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.

8 Packaging and Labeling

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

9 Sterilization and Resterilization

Implants are supplied sterile and have been double sterile packaged. The method of sterilisation is noted on the package label. Dispose of the implant if the packaging is damaged. Resterilisation of the implants is not recommended, as it may alter the mechanical integrity of the device.

Unless specifically labelled sterile, instruments are supplied non-sterile and must be sterilised prior to use.

A complete guide for reprocessing reusable instruments is provided with the instruments. As a guideline, the following sterilisation method is recommended:

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

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

10 Cleaning

Implants are supplied sterile and intended for single use only. Dispose of the implant 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 is provided with the instruments. 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 Sterilisation

Instruments may be cleaned using a 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 that 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.

11 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.

12 Limited Warranty / Liability

Signature Orthopaedics Europe. Ltd. 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 having received appropriate training in orthopaedic surgical techniques.

13 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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14 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 #5-148
	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 #5-148
	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 #5-148
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.	ISO 15223-1 Ref # 5.2.6 FDA Recognition #5-148
	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 #5-148
	Do not use if package damaged	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	ISO 15223-1 Ref # 5.2.8 FDA Recognition #5-148
	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 #5-148
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1 Ref# 5.1.3 FDA Recognition #5-148
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1 Ref # 5.1.1 FDA Recognition #5-148
	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 #5-148
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ISO 15223-1 Ref # 5.4.4 FDA Recognition #5-148
	Keep Dry	Indicates medical device that needs to be protected from moisture.	ISO 15223-1 Ref # 5.3.4 FDA Recognition #5-148
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely expose.	ISO 15223-1 Ref # 5.3.7 FDA Recognition #5-148
	Distributor	Indicates the entity distributing the medical device into the locale.	ISO 15223-1 Ref # 5.1.9 FDA Recognition #5-148