

## Polymotion® Hip Resurfacing System

**CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use.**

### INSTRUCTIONS FOR USE

**Carefully read all instructions and be familiar with the surgical technique before use.**

#### Description and Intended Use

The Polymotion® Hip Resurfacing (PHR®) Implants are prosthetic hip joint resurfacing devices that are available in ten (10) sizes for the Femoral Head, and each Femoral Head has two (2) compatible Acetabular Cups: a 3 mm-walled-thickness cup (thin wall) and a 4 mm-walled-thickness cup (thick wall).

The PHR® Implants consist of:

- a metal femoral head, intended for cemented fixation only, using a low viscosity polymethyl methacrylate (PMMA) bone cement; and,
- a titanium-coated, Vit E-XPE acetabular cup, intended for cementless fixation only.

Both components are designed to be permanently implanted together to achieve total reconstructive and functional replacement of the hip joint. The implants may only be used together in the following combinations:

Compatibility identifier	Product Code	Full Description	Compatible	Product Code	Full Description
<b>A</b>	800040	Polymotion Hip Resurfacing Femoral Head IDE 40mm		840346	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thin wall) 46mm
				840448	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thick wall) 48mm
<b>B</b>	800042	Polymotion Hip Resurfacing Femoral Head IDE 42mm		842348	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thin wall) 48mm
				842450	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thick wall) 50mm
<b>C</b>	800044	Polymotion Hip Resurfacing Femoral Head IDE 44mm		844350	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thin wall) 50mm
				844452	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thick wall) 52mm
<b>D</b>	800046	Polymotion Hip Resurfacing Femoral Head IDE 46mm		846352	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thin wall) 52mm
				846454	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thick wall) 54mm
<b>E</b>	800048	Polymotion Hip Resurfacing Femoral Head IDE 48mm		848354	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thin wall) 54mm
				848456	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thick wall) 56mm
<b>F</b>	800050	Polymotion Hip Resurfacing Femoral Head IDE 50mm		850356	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thin wall) 56mm
				850458	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thick wall) 58mm
<b>G</b>	800052	Polymotion Hip Resurfacing Femoral Head IDE 52mm		852358	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thin wall) 58mm
				852460	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thick wall) 60mm
<b>H</b>	800054	Polymotion Hip Resurfacing Femoral Head IDE 54mm		854360	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thin wall) 60mm
				854462	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thick wall) 62mm
<b>I</b>	800056	Polymotion Hip Resurfacing Femoral Head IDE 56mm		856362	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thin wall) 62mm
				856464	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thick wall) 64mm
<b>J</b>	800058	Polymotion Hip Resurfacing Femoral Head IDE 58mm		858364	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thin wall) 64mm
				858466	Polymotion Hip Resurfacing Spiked Acetabular Cup IDE (thick wall) 66mm

The PHR® implants may only be implanted with the PHR® specific instrument sets.

#### Materials

The femoral head is manufactured from wrought cobalt chrome molybdenum (CoCrMo) alloy that complies with ISO 5832-12.

The acetabular cup is manufactured from radiation-crosslinked, compression-molded ultra-high molecular weight polyethylene with vitamin E (Vit E-XPE) that is coated on its exterior surface with a titanium coating (unalloyed titanium to ASTM F1580).

#### Indications for Use

The PHR® System is intended for use in patients requiring primary hip resurfacing arthroplasty due to:

- Non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic arthritis, or mild dysplasia/developmental dislocation of the hip (DDH) up to Crowe Grade 1.

The PHR® System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision.

The PHR® System is a single-use device intended for hybrid fixation: a cemented femoral head component and cementless acetabular component.

#### Contraindications

- Inflammatory (rheumatoid) arthritis.
- Existing infection (including distant foci of infection which may affect hematogenous spread to the implant site).
- Sepsis.
- Severe osteopenia, a medical history or increased risk of severe osteoporosis or severe osteopenia, and other conditions that lead to increased bone resorption.
- Metabolic disorders which may impair bone formation (e.g., osteomalacia).
- Vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability.
- Neuropathic arthropathy (Charcot joint).
- Incompetent or deficient soft tissue surrounding the joint.
- Uncooperative patients or patients with neurological disorders, which could impair their willingness or ability to comply with instructions regarding protecting the implants from excessive stress.
- Patients who are pregnant or planning pregnancy.
- skeletally immature Patients.
- Patients with bone stock inadequate to support the device, including:

- Patients with severe osteopenia or osteoporosis should not receive a PHR<sup>®</sup> procedure.
- Patients with osteonecrosis or avascular necrosis (AVN) should not receive a PHR<sup>®</sup>.
- Patients with multiple cysts of the femoral head (>1cm) or cysts crossing the head-neck junction should not receive a PHR<sup>®</sup>.
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids.
- Patients who are severely overweight (BMI >40).
- Patients with severe acetabular dysplasia/developmental dislocation of the hip, defined as Crowe Grade ≥2, are unsuitable for secure primary fixation of a cross-linked polyethylene cup.
- Patients with severe femoral head deformities, unsuitable for primary fixation of the femoral component without causing femoral neck notching.
- Patients who have undergone previous hip surgery, such as osteotomy, core decompression, hemi resurfacing, or internal fixation.
- Patients with a known or suspected metal sensitivity (e.g., jewelry) or allergy to any implant materials.

## Warnings

- PHR<sup>®</sup> Implants are for single use only and must not be reused. Reuse presents a risk of infection and a risk that implant performance may be adversely affected.
- The implant should not be used if the sterile packaging is open or damaged, or if the indicated expiry date is exceeded.
- Polished bearing surfaces must be clean and free of cement or other debris and must not come into contact with hard or abrasive surfaces.
- Do not use the implant if damage to the implant is found or caused during setup or insertion.
- Do not implant the femoral head **without** bone cement.
- Do not implant the acetabular cup **with** bone cement.
- Do not use the PHR<sup>®</sup> Implants for purposes other than the indications shown above.
- Avoid improper positioning or alignment of the PHR<sup>®</sup> Implants.
- Care should be taken to ensure appropriate size matching of PHR<sup>®</sup> Implant components. Use of mismatched components may result in increased implant wear, implant instability, reduced implant life, increased pain, and loss of joint function.
- Only surgeons who have been certified as trained in the PHR<sup>®</sup> system by JointMedica or an authorized distributor should use this device.
- JointMedica does not offer a commercially available modular metal femoral head for use with a PHR<sup>®</sup> cup. If the PHR<sup>®</sup> femoral head must be revised to a total hip arthroplasty, the acetabular cup should also be revised, even if well fixed.

## Precautions

- Patients should be advised that the usable life of the PHR<sup>®</sup> Implants is not indefinite and can be affected by various biological and physiological factors.
- Patients should be instructed in the limitations of the implants, including possible adverse effects on the implants caused by excessive loading, because of excessive activity, failure to control body weight, or trauma affecting the implants. While prosthetic

hip joint replacement devices are largely successful, they cannot be expected to withstand the activity levels and loads of normal, healthy bone. Patients should be cautioned to protect the implant from unreasonable stresses and to follow the instructions of the treating healthcare professional.

## Possible Adverse Effects

- Loosening and/or disassembly of implants.
- Soft tissue impingement or damage.
- Dislocation or subluxation leading to postoperative joint instability (which may be caused by mispositioning of the implants, or muscle or fibrous tissue laxity).
- Femoral neck fracture.
- Nerve damage.
- Infection.
- Soft tissue swelling or inflammation.
- Leg length discrepancies.
- Hip joint stiffness and/or limited range of motion.
- Delayed wound healing.
- Temporary or permanent neuropathy.
- Cardiovascular disorders, including venous thrombosis, pulmonary embolism, or myocardial infarction.
- Metal sensitivity.
- Corrosion of the metal component.
- Osteolysis, caused by wear debris from polyethylene components.
- Femoral head collapse.
- Avascular Necrosis.
- Sudden, pronounced, intraoperative blood pressure decreases due to the use of bone cement.
- Hematoma or damage to blood vessels resulting in large blood loss and potential transfusion.
- Component loosening or migration due to trauma, loss of fixation, malalignment, or bone resorption.
- Increased hip pain and/or reduced hip function.
- Fatigue fracture of the implants as a result of excessive loading, malalignment, or trauma.
- Unintended bone perforation or fracture occurring either intraoperatively or postoperatively as a result of trauma, excessive loading, osteolysis, or osteoporosis.
- Periarticular calcification or ossification.
- Wear or deformation of the articular surface as a result of excessive loading or implant malalignment.
- Traumatic arthrosis from perioperative positioning of the extremity and/or aggravation of other joint or back conditions due to positioning during surgery.
- Possible detachment of the coating(s) on the components, potentially leading to increased debris particles.
- Adverse events associated with the use of bone cement.
- Device-related noises, such as clicking, popping, snapping, grinding, or squeaking.

## Preoperative

- Do NOT use any component of the PHR<sup>®</sup> system with another manufacturer's implant components, as the designs and tolerances may be incompatible.
- Examine instruments for wear or damage before use. While rare, intraoperative instrument breakage can occur. Instruments that have experienced excessive use or force may be susceptible to breakage.

## Intraoperative

- Implants should be accepted only if received by the hospital or surgeon with the factory packaging and labelling intact. If the sterile barrier has been broken, do not use.
- Avoid notching the femoral neck, as this may lead to a femoral neck fracture.
- Avoid placing the femoral component in Varus. Varus placement of the femoral component has been associated with femoral neck fractures.
- Do NOT re-use an implant. All implants are intended for single-use only.
- Use the recommended instruments and the recommended Surgical Technique.
- Malalignment of the components and/or soft tissue imbalance may cause excessive wear and early implant failure.
- Associated trials and templates should be used for verification of component size. If an appropriate component size cannot be found during preoperative planning, do not use this type of implant.
- Complete pre-closure cleaning of the implant site (complete removal of bone chips, cement fragments, foreign debris, etc.) is critical to prevent wear of the articular surfaces.
- Using instruments other than the associated PHR® instruments may result in inaccurate placement.
- Follow the cement manufacturer's instructions at all times.
- An incomplete cement mantle may lead to early failure of the implant.

## Postoperative

- Excessive physical activity levels, excessive patient weight, and trauma to the joint replacement may cause early failure of the implant.
- Loosening of components may increase the production of wear particles and accelerate damage to the bone, making successful revision surgery more difficult.
- The patient must be instructed to report immediately to the surgeon or their specialist any changes associated with the operated joint.
- Patients with artificial joint replacements require continuous postoperative monitoring by the surgeon or another competent professional colleague. If an unforeseeable premature loosening of the implant, weakening of the materials, breakage of the implant, signs of a threatened complication, etc., occur, this allows prompt corrective action to be taken. The successful prognosis for any revision surgery required is substantially improved by early detection, particularly if the condition of the bone bordering the implant has not yet fundamentally deteriorated.

## Implant Disposal


In cases where the PHR® system or its components are revised, the explants shall be considered as infection or biological hazards and should be decontaminated for further analysis in accordance with the IDE retrieval protocol.

## Patient Education

- Warn the patient of the surgical risks, possible adverse effects, and possible operative complications that can occur with joint arthroplasty.
- Warn the patient of the limitations of artificial joint replacement devices.

- Warn the patient that artificial joint replacement devices can wear out over time and may require replacement.
- Patients should be advised to avoid the use of vibrating plate or power plate exercise and rehabilitation machines.
- Preoperatively, surgeons must educate patients on dislocation precautions for 6-12 weeks (just like a total hip). Please refer to JointMedica's Post-operative Program, document ref. 906904.
- Preoperatively, surgeons must educate patients on the use of an assistive device for 6-12 weeks, such as a cane, walker, etc. Please refer to JointMedica's Post-operative Program, document ref. 906904.
- Preoperatively, surgeons must inform patients of high-impact activity restrictions for 6 months.
- Preoperatively, surgeons must educate patients that the resurfacing procedure does not imply that patients can go back to unrestricted activities and range of motion prematurely.

## Magnetic Resonance Imaging

<b>MRI Safety Information</b>	
 <b>MR Conditional</b>	The PHR® Implants are MR Conditional. A patient with a PHR® Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
<i>Parameter</i>	<i>Condition of Use/Information</i>
Nominal Values of Static Magnetic Field (T)	1.5-Tesla or 3.0-Tesla
Maximum Spatial Field Gradient (T/m and gauss/cm)	1.9-T/m (1,900-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., Quadrature-Transmission)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: Body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of the MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest
















## Sterility and Shelf Life

The PHR<sup>®</sup> Implants are supplied in a sterile condition to a Sterility Assurance Level (SAL) of 10<sup>-6</sup>. Implants are sterilized to a minimum of 25 kiloGrays of gamma irradiation and have a shelf-life of five (5) years when stored unopened in their original packaging, under ambient conditions of temperature and humidity. All components are supplied in protective packaging. The PHR<sup>®</sup> femoral head and PHR<sup>®</sup> acetabular cup are packaged in double peel pouches to maintain sterility. Implant packages should be inspected before use. Do not use an implant if the sterile packaging is open or damaged, or if the indicated expiry date has been exceeded. PHR<sup>®</sup> Implants must not be re-sterilized by the user.

## PHR<sup>®</sup> Instruments

Instruments used to implant the device system are supplied non-sterile and must be sterilized prior to use using one of the validated methods given in the Instrument Reprocessing Instructions (Cat No. 906002).

## Glossary of Symbols Used in PHR<sup>®</sup> Device Labelling

	Manufacturer
	Batch code
	Use-by date
	Catalogue number
	Sterilized using irradiation
	Do not re-sterilize
	Do not use if the package is damaged
	Keep away from sunlight
	Keep dry
	Do not re-use
	Consult instructions for use
	MR Conditional
	Non-sterile
	Medical device
	Unique device identifier

 Manufactured by:  
 JointMedica Ltd  
 Unit 3 Ball Mill Top  
 Hallow  
 Worcestershire  
 WR2 6LS  
 United Kingdom

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