H1 IMPLANT INSTRUCTIONS FOR USE

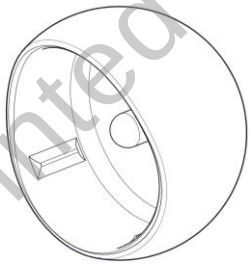
DESCRIPTION OF DEVICE

The H1 Implant consists of a stemmed femoral head resurfacing component, and a hemispherical acetabular cup, both with a contoured rim, both made from zirconia toughened alumina (ZTA). Both implants are designed for cementless, press-fit fixation and have vacuum plasma sprayed titanium and hydroxyapatite (HA) coating.

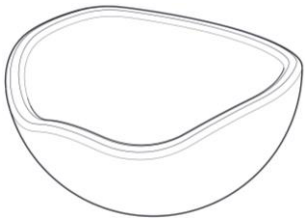
The H1 Implant is a single-use sterile medical device. This device is intended only for use by a trained professional orthopaedic surgeon.

The H1 Implant is supplied in 10 sizes, each head is compatible with a single cup:

Femoral head			Acetabular cup		
Size	**REF**	**UDI-DI**	**Size**	**REF**	**UDI-DI**
40	19540	05060768010227	47	19847	05060768010326
42	19542	05060768010234	49	19849	05060768010333
44	19544	05060768010241	51	19851	05060768010340
46	19546	05060768010258	53	19853	05060768010357
48	19548	05060768010265	55	19855	05060768010364
50	19550	05060768010272	57	19857	05060768010371
52	19552	05060768010289	59	19859	05060768010388
54	19554	05060768010296	61	19861	05060768010395
56	19556	05060768010302	63	19863	05060768010401
58	19558	05060768010319	65	19865	05060768010418



H1 HEAD



H1 CUP

The H1 Implant has 3 constituent materials:

Material	Standard	% in H1 Femoral Heads	% in H1 Acetabular Cups	Composition	
				Name	**Proportion (%)**
BIOLOX®*delta*	ISO 6474-2	96.1%	90.6%	Aluminium oxide (Al_2O_3)	72.0-76.0%
				Zirconia + Hafnia (ZrO_2 + HfO_2)	24.0-25.5%
				Chromia, Yttria, Strontia (Cr_2O_3, Y_2O_3, SrO)	1.51-1.87%
Titanium	ISO 13179-1	3.1%	8.2%	Carbon (C)	≤ 0,10 %
				Hydrogen (H)	≤ 0,20 %
				Iron (Fe)	≤ 0,60 %
				Nitrogen (N)	≤ 5,00 %
				Oxygen (O)	≤ 10,00 %
				Titanium (Ti)	Balance
Hydroxyapatite	ISO 13779-2	0.8%	1.2%	Arsenic (As)	≤ 0.0003%
				Cadmium (Cd)	≤ 0.0005%
				Mercury (Hg)	≤ 0.0005%
				Lead (Pb)	≤ 0.0030%
				Hydroxyapatite ($Ca_5(PO_4)_3(OH)$)	Balance

INTENDED PURPOSE

The intended purpose of the H1 Implant is to provide an artificial substitute for a disease-damaged hip joint to replace the articulating surfaces of the hip while preserving the underlying femoral head and natural femoral neck. This is standard for a resurfacing hip prosthesis.

INDICATIONS

The H1 Implant is intended for use in skeletally mature patients requiring primary hip resurfacing arthroplasty due to:

- Primary osteoarthritis
- Osteoarthritis secondary to e.g. trauma, avascular necrosis, developmental hip dysplasia or other self-limiting conditions

CONTRAINDICATIONS

The H1 Implant is not intended for patients with any of the following:

- BMI greater than 40 kg/m^2
- Active infection or sepsis (treated or untreated)
- Insufficient bone stock at the hip (>1/3 necrosis of the femoral head or large and multiple cysts) or in general as in severe osteopenia or osteoporosis (Tscore < -2.5 as measured with BMD)

USER INFORMATION

The H1 femoral head and acetabular cups are supplied sterile and double pouched to maintain sterility. Inspect the shelf box and pouches for punctures or other damage prior to surgery. Do not re-sterilise. Do not use any implant from a damaged or previously opened package.

The H1 is supplied with the H1 Instruments, which must be used to implant the H1 Implant. The H1 Implant is not supplied with the power tools required to drive the shafts of the cutters, or the mallet needed for implant impaction. A general orthopaedic surgery kit (osteotome, retractors, scalpel, bone nibblers, etc.) will also be required.

All the routine practices and precautions used in routine arthroplasty should be employed when using the H1 Implant. These should include the use of sterile technique, in a specialised clean air theatre suitable for arthroplasty, combined with antibiotic prophylaxis.

The skills learnt in basic arthroplasty training should be used to minimise the risk of:

- Poor positioning of either component which can lead to e.g. impingement, limited ROM, dislocation, edge-loading.
- Fracture of the femoral head and neck and acetabulum during bone preparation.
- Damage to the bone surfaces required for adequate implant fixation and therefore implant loosening; bone surfaces require careful use of bone preparation tools (reamers and cutters).
- Instability and dislocation of the H1 Implant due to the biomechanics of the hip not being respected.
- Under- or over-impaction of the H1 Implant.

Should the acetabular component of the H1 Implant need to be revised, there is a risk of pelvic fracture. Use of the correctly-sized explantation osteotome is recommended. There is no total hip replacement femoral head option available for the H1 Implant; if the femoral head component of the H1 Implant needs to be revised to a total hip, the acetabular cup component of the H1 Implant should also be removed, even if it is well fixed. Using implants with untested compatibility to the H1 Implant is considered to be off-label use and can lead to excessive wear or premature failure of the H1 Implant.

TRAINING REQUIREMENTS

The H1 system is designed for use by trained hip arthroplasty surgeons. Prior to use, the surgeon should receive training in the indications for the H1, and in the H1 Surgical Technique. The H1 Surgical Technique describes the surgical steps that must be followed for correct use of the H1 Implant. Familiarity with the H1 Surgical Technique is essential for optimal results. The surgical technique can be downloaded from: www.embody-ortho.com/downloads.

REPORTING OF SERIOUS INCIDENTS

If a serious incident occurs with the device, report it to Embody immediately on +442075943600 and info@embody-ortho.com. A serious incident means any incident that directly or indirectly led, might have led or might lead to any of the following:

a. The death of a patient, user or other person;
b. The temporary or permanent serious deterioration of a patient's, user's or other person's state of health;
c. A serious public health threat.

SAFE DISPOSAL OF THE DEVICE

If the device is opened in error and cannot be used, dispose of the device and its packaging immediately and as close to the point of use as possible into the correct segregated colour coded UN 3291 approved waste bag (either orange/yellow) or container (sharps box) as necessary.

WARNINGS

Possible adverse events relating to orthopaedic surgery include:

- Haematoma or damage to blood vessels
- Intra-operative peri-prosthetic fracture
- Delayed wound healing
- Deep vein thrombosis
- Transient nerve palsy
- Thromboembolic disease
- Infection
- Heterotopic ossification
- Intra-operative blood-loss
- Post-anaesthetic complications such as post-dural headaches
- Sciatica
- Death

Possible adverse device effects include:

- Pain/stiffness
- Reduced range of motion
- Femoral neck fracture
- Femoral head collapse
- Femoral head crush
- Implant fracture
- Implant loosening
- Avascular necrosis
- Dislocation
- Impingement
- Squeaking/grinding/clicking

Surgeons should warn patients of all the possible relevant adverse events and adverse device effects. All of these adverse events and adverse device effects may require medical or surgical intervention. Very rarely these events and effects lead to death.

No known surgical implant material has ever been found to be completely free of adverse reactions in the human body. However, long-term clinical experience of use of alumina, zirconia, titanium and hydroxyapatite (the main components of the H1 Implant) as biomaterials has shown that an acceptable level of biological response can be expected when these materials are used in appropriate applications.

CLINICAL INFORMATION

The H1 Implant has the expected clinical benefit of improved pain and function scores (Harris Hip Score and Oxford Hip Score) 6 months post-operatively.

A summary of safety and clinical performance for the H1 Implant may be downloaded from EUDAMED.

PRECAUTIONS

1. The H1 must not be used in any of the contra-indicated situations listed above.
2. Training on the use of the H1 Implants must be undertaken prior to use. If the H1 surgical technique has not been used for over 1 year, training should be repeated prior to surgery.
3. Patients with a known allergy to titanium should consider alternatives to the H1 system.
4. Incorrect sizing may result in a device related failure. Sizing should be carried out pre-operatively, and confirmed by direct measurement of the femoral head and neck during the procedure. Please contact info@embody-ortho.com or +442075943600 for further information regarding our 2D and 3D templating and planning options.
5. Do not use the H1 Implant if it appears to be damaged or is known to have been dropped.
6. Poor femoral head placement and/or notching of the femoral neck may lead to femoral neck fracture, bone-implant movement, femoral head crush, or other implant-related problems; care must be taken to place the femoral head correctly, in enough but not too much valgus, without any exposed cancellous bone around the implant rim.
7. Both components of the H1 need to be orientated anatomically to avoid bony or soft tissue impingement. The contours of the femoral head and acetabular cup must be considered when trialling and implanting the device.
8. Inadequate seating of the H1 Implant can occur through under-impaction; check seating has occurred before stopping the impaction process.
9. Destabilisation of the H1 Implant can occur through over-impaction; once seating has been detected, stop impacting.
10. Cups left substantially uncovered are at risk of component fracture.
11. The stability of the acetabular cup must be checked after impaction.
12. Bearing surfaces must be cleaned with sterile wash and must be free of debris before joint reduction. Care must be taken so that the polished bearing surfaces of the H1 Implant do not come into contact with any hard or abrasive objects.
13. The H1 Implants are supplied sterile and must be used within the stated shelf life – do not used expired product.
14. The H1 Implants are supplied sterile and must not be re-used – do not use product that has been previously opened, do not re-sterilise; this can lead to infection or other serious biological response.

INFORMATION FOR PATIENTS

The patient is to be made aware and warned of the general surgical risks and possible adverse events and adverse device effects as listed in this IFU in advance of the operation. Patients receiving joint replacements should be advised that the longevity of the implant may depend on their weight and level of activity. They should also be informed of the following:

- Post-operative care, including rehabilitation and follow-up visits, should be undertaken as instructed. Failure to do so may adversely affect the results of the procedure.
- All of the adverse events and adverse device effects listed may require further operation or revision of the involved hip.
- Full load bearing of the hip must be avoided until healing and implant fixation are sufficient to support the H1 Implant. This may have a short-term impact on the patient's lifestyle.
- High loading (e.g. through running, weight-lifting, etc.) should be avoided for at least the first 12 months.
- Premature failure of this type of device due to wear, fracture, loosening, subluxation or dislocation, may be caused by trauma, excessive weight and/or activity, or unusual movements.
- There is no guaranteed period before the H1 Implant may require to be replaced. No replacement joint, including the H1 Implant, can be equivalent to healthy human bone and tissue.
- The H1 Implant is a ceramic-on-ceramic hip replacement and, as such, presents a risk of the joint "squeaking" or other noise generation.

After their operation, patients should be given the H1 Patient Implant Card, complete with surgery details and patient implant card stickers taken from the implant boxes used in the procedure.

IN THE EVENT OF THE PACKAGE BEING DAMAGED OR OPEN UPON RECEIPT

If the packing is damaged or open DO NOT use the device. Contact Embody Orthopaedic Limited immediately: +442075943600.

MAGNETIC RESONANCE (MR) SAFETY AND COMPATIBILITY

The risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration, and image artefacts at or near the implant site. Non-clinical assessment has demonstrated that the H1 Implant is MR Conditional and can carry the MR Conditional symbol on the labelling. A patient with this device can be safely scanned in a MR system meeting the following conditions:

MR Information

Safety information for the use of MRI procedures (i.e. imaging, angiography, functional imaging, spectroscopy, etc.) pertains to shielded MRI systems under the following specifications:

- Static magnetic field of 1.5-Tesla (1.5T) and 3.0-Tesla (3.0T)
- Maximum spatial gradient field of 2500 Gauss/cm
- Maximum MR System reported, whole-body-averaged specific absorption rate (SAR) of:
    - 2 W/kg for 15 minutes of scanning for patient landmarks above the umbilicus and
    - 1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus.
- Quadrature Transmit Mode only
- Padding for protection against Radio Frequency (RF) burns should be placed between the wall of the bore and extremities
- Insulating padding between the knees to prevent legs from touching
- Arms and hands of the patient should not touch each other or other bare skin

The effects of MRI procedures using MR systems and conditions above these levels have not been determined. The health state of the patient or the presence of other implants may require a lowering of MR limits.

MR Heating

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than 3°C after 15 minutes of continuous scanning.

Image Artefacts

The artefact caused by the device is expected to extend approximately 80mm from the device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system

Other

Due the materials in the device, it is not expected that any magnetically induced displacement force or torque will occur that would result in migration of the device in the spatial gradient and static fields identified above.

THE CE MARK IS VALID ONLY IF IT IS ALSO PRINTED ON THE PRODUCT LABEL

EMBODY

CE 0123

Embody Orthopaedic Limited
Sir Michael Uren Hub
86 Wood Lane
London W12 0BZ
United Kingdom

EC REP

Advena Ltd.
Tower Business Centre, 2nd Floor
Tower Street
Swatar, BKR 4013, Malta

Single-use, do not re-use

Do not use if the package is damaged

MR

MR Conditional

STERILE R

Gamma sterilised

Consult Instructions for Use for more information

MD

The H1 Implant is a medical device