

restor3d

Velora™ Acetabular System Instructions for Use FOR CEMENTLESS USE ONLY

CAUTION: USA FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

THE restor3d™ Velora™ Acetabular System IS INTENDED FOR USE ONLY BY MEDICALLY TRAINED PHYSICIANS.

IF THERE ARE ANY QUESTIONS, CONTACT restor3d, INC. AT +1.781.345.9001 OR YOUR LOCAL SALES REPRESENTATIVE OR DISTRIBUTOR.



Important Information: Please read before use.



Refer to <https://www.restor3d.com/resources/instructions-for-use/> for an electronic version of this IFU. For a printed copy or to have an electronic copy e-mailed to you, call +1.781.345.9001



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Device Description

The Velora™ Acetabular System is an uncemented, total hip replacement composed of 3D-printed titanium alloy acetabular components and fixed bearing polyethylene liners that can be used in conjunction with femoral components from the Actera™ or Cordera™ Hip Systems. All implants and single-use instruments are provided sterile.

The acetabular component consists of a standard size shell with standard screw hole placement, a mating polyethylene liner, and cancellous screws. The acetabular component is designed for uncemented use; initial implant fixation is achieved through press-fit design. The 6.5mm diameter cancellous screws with low profile head fit into the acetabular shell screw holes and are driven using a 3.5mm hex driver. The acetabular component has matching circumferential scallops on the shell and liner that rotationally secure the liner in the shell and allow for dialing the liner in a desired orientation. The liner locks into the acetabular component creating a fixed bearing construct. Single-use trial liners may be used with the Velora cup. The trial liners are manufactured from biocompatible nylon material.

Indications for Use

Total hip replacement using the Velora™ Acetabular System is indicated for use in skeletally mature individuals undergoing total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia.
- Treatment of non-displaced non-unions of the hip, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
- Revision procedures for failed previous hip surgery (excluding situations where hardware is present).

The Velora™ Acetabular System implants are intended for cementless fixation using an anterior or posterior surgical technique.

Contraindications

The following conditions are contraindications for total hip replacement:

- Active or recent local or systemic infection.
- Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustified.
- Poor bone quality, such as osteoporosis, where, in the surgeon's opinion, there could be considerable migration of the prosthesis or a significant chance of fracture of the femoral shaft and/or the lack of adequate bone to support the implant(s).
- Charcot's or Paget's disease.
- Any disease, ligamentous or severe muscle laxity or inadequate soft tissue coverage which may compromise the normal healing process or function of the implant.
- Pathological conditions, neuromuscular disorders or mental conditions whereby the risks associated with these conditions outweigh the benefits to be derived.
- Metal sensitivity

Warnings and Precautions

Implants and/or trials from different manufacturers or implant systems should never be used together. Hip prosthesis components should never be reused. Even though the implant

appears undamaged, the implant may have developed microscopic imperfections which could lead to failure.

- Acetabular screws are to be fully seated in the cup to assure stable fixation and to avoid interference with the acetabular liner component.
- Caution is to be used when determining and selecting the length of screws to be used, as perforation through the pelvic bone with screws that are too long can cause damage to body structures (blood vessels, etc.) located on the interior side of the pelvis.
- Prior to seating the liner into the shell component, all surgical debris (tissue fragments, etc.) must be removed from the interior of the shell component, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell component.
- Always use trial prosthesis for trial purposes. Trials must have the same configuration size, etc., as the corresponding components to be permanently implanted. The guides and trials are for use to fit the components and must never be left implanted.
- Do not alter or modify implants in any way.
- Avoid notching, scratching, or striking the device during preparation and insertion.
- Do not use bone cement for fixation of a hydroxyapatite coated prosthesis.
- Using bio-contamination controls can minimize the potential for deep sepsis.

CAUTION: The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure of the total hip replacement:

- Obesity or excessive patient weight.
- Heavy labor.
- Active sports participation.
- High levels of patient activity.
- Likelihood of falls.
- Alcohol or drug addiction.
- Other disabilities, as applicable.
- Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as infection or slow wound healing, the surgeon should carefully consider the advisability of hip replacement in the diabetic patient.

In addition to the above risks, the following conditions, alone or in combination, tend to adversely affect the fixation of hip replacement implants:

- Marked osteoporosis or poor bone stock.
- Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g., including but not limited to diabetes mellitus, steroid therapies, immunosuppressive therapies).
- History of general or local infections.
- Severe deformities leading to impaired fixation or improper positioning of the implant.
- Tumors of the supporting bone structures.
- Allergic reactions to implant materials (e.g., metal, polyethylene).
- Congenital dysplasia of the hip which may reduce the bone stock available to support the acetabular cup prosthesis in total hip replacement.
- Tissue reactions to implant corrosion or implant wear debris.
- Disabilities of other joints (i.e., knees and ankles). The incidence of implant failure may be higher in paraplegics, and patients with cerebral palsy or Parkinson's Disease.

WHEN THE SURGEON DETERMINES THAT TOTAL HIP REPLACEMENT IS THE BEST MEDICAL OPTION AVAILABLE AND DECIDES TO USE THIS PROSTHESIS IN A PATIENT WHO HAS ANY OF THE ABOVE CONDITIONS, IT IS IMPERATIVE THAT THE PATIENT BE INSTRUCTED ABOUT THE STRENGTH LIMITATIONS OF THE MATERIALS USED IN THE DEVICE AND FOR IMPLANT FIXATION, AND THE RESULTANT NEED TO SUBSTANTIALLY REDUCE OR ELIMINATE ANY OF THE ABOVE CONDITIONS.

The surgical and postoperative management of the patient must be carried out with due consideration for all existing conditions. Mental attitudes or disorders resulting in a patient's failure to adhere to the surgeon's orders may delay postoperative recovery and/or increase the risk of adverse effects including implant or implant fixation failure.

Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

Excessive physical activity or trauma to the replaced joint may contribute to premature failure of the hip replacement by causing a change in position, fracture, and/or increased wear of the implants. The functional life expectancy of prosthetic total hip implants is, at present, not clearly established. The patient should be informed that factors such as weight and activity levels may significantly affect the functional life expectancy of the device.

General Information for Use

Preoperative

THE SURGEON SHOULD DISCUSS ALL PHYSICAL AND MENTAL LIMITATIONS PARTICULAR TO THE PATIENT AND ALL ASPECTS OF THE SURGERY AND THE PROSTHESES WITH THE PATIENT BEFORE SURGERY. The discussion should include the limitations and possible consequences of joint replacement, and the necessity to follow the surgeon's instructions postoperatively, particularly in regard to patient activity and weight. The surgical techniques for implantation of the Velora™ Acetabular System evolved from the surgical experience gained during the development of many hip prostheses. Surgeons should not begin the clinical use of any hip prosthesis before they have thoroughly familiarized themselves with its specific implantation technique. Certain methods may change with time as further clinical experience is gained. Critical appraisals of such changes are presented at regularly scheduled surgical instruction courses for which periodic attendance is advised. Surgical technique brochures are available from restor3d™.

Correct handling of an implant is important. The Velora™ Acetabular System implants should be used without nicks, scratches, or other alterations. These can produce defects and stresses which may cause eventual failure of the implant.

Intraoperative

It is recommended that femoral head 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.

Protective covers should be left on until the components are ready to be implanted. **Do not use components if they have been dropped or have impacted a hard surface. Damage to the component may not be visible, but could cause early failure of the prosthesis.**

Bent or damaged instruments should be replaced as they may lead to improper implant position and result in device failure.

Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, etc. Foreign particles at the metal/plastic or ceramic/plastic interface may cause excessive wear. Range of motion should be thoroughly checked for improper mating, instability, or impingement and corrected as appropriate.

Postoperative

Strict adherence by the patient to the surgeon's instructions and warnings is extremely important. Accepted practices should be followed in postoperative care.

The patient should be released from the hospital with complete written instructions and warnings regarding exercises and therapies and any limitations on their activities.

Continuing periodic patient follow-up is recommended. Because of the unknown functional lifetime of the implant, particularly with respect to the maintenance of implant fixation and bearing surfaces, A-P radiographs of the pelvis should be taken at intervals and compared with previous radiographs and correlated with the clinical assessment of the patient. If any radiographic changes are observed, such as the occurrence of radiolucencies, bone resorption, or any changes in the position of an implant, these changes should be closely monitored to determine whether they are static or progressive and the patient treated appropriately.

Adverse Events and Complications

The following are generally the most frequently encountered adverse events and complications in total hip arthroplasty:

- Early or late postoperative infection.
- Tissue reactions, osteolysis, and/or implant loosening caused by metallic corrosion, allergic reactions, or the accumulation of wear debris.
- 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.
- Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
- Periarticular calcification or ossification which may lead to a decrease in joint mobility and range of motion.
- Subluxation or dislocation of the hip joint due to implant size or configuration selection, positioning of components and/or muscle and fibrous tissue laxity.
- Undesirable lengthening or shortening of limb.
- Fatigue fracture of component can occur as a result of loss of fixation, malalignment, trauma, non-union, or excessive weight/activity, particularly in the presence of poor bone stock caused by severe osteoporosis, bone defects from previous surgery, intraoperative reaming procedures, or bone resorption.
- Fretting and crevice corrosion can occur at interfaces between components.
- Wear and/or deformation of articulating surfaces.
- Trochanteric avulsion from excessive muscular tension, weight-bearing, or inadvertent intraoperative weakening of the trochanter.

- Aggravation of problems in the ipsilateral or contralateral knee and ankle joints due to leg length discrepancy, femoral medialization and/or muscular deficiencies.
- Postoperative bone fracture and pain.
- Cardiovascular disorders including venous thrombosis, pulmonary embolism and myocardial infarction.
- Temporary or permanent nerve and/or blood vessel damage.

How it is Supplied

Components of the Velora™ Acetabular System are packaged and supplied STERILE. Check implant packaging labels prior to opening the components. Remove from the package using accepted aseptic technique only after the correct size has been determined. **DO NOT USE IF THE STERILE BARRIER APPEARS TO BE COMPROMISED OR THE PACKAGE IS DAMAGED.**

CAUTION: Do not re-sterilize or reprocess components. These components are for single use only. The risk of reuse could compromise performance or sterility.

Reference the “restor3d™ Hip Instruments” IFU (LS-04315) for sterilization instructions for the hip reusable instruments.










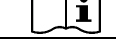
Magnetic Resonance (MR) Environment

The Velora™ Acetabular System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Velora™ Acetabular System in the MR environment is unknown. Scanning a patient who has a device may result in patient injury.

Additional Information

If further information is desired, please contact restor3d, Inc. at +1.781.345.9001.

Labeling Symbol Definitions

	Catalog Number
	Lot Number
	Do not use if package is open or damaged
	Single Use Only. Do Not Reuse
	Expiration Date. (Use by)
	Sterilized Using Ethylene Oxide
	Manufacturer
	Caution. Consult Accompanying Documents
	Prescription Use Only
	Consult Electronic Instructions for Use

For symbols not shown here, refer to the IFU symbol glossary (<https://www.restor3d.com/resources/instructions-for-use/>)

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