CI E Liner

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Consumer Medical Device Information

What is in this leaflet?

This leaflet answers some common questions about CI E Liner. It does not contain all the available information. It does not take the place of talking to your surgeon.
All medical devices and implants have risks and benefits. Your surgeon has weighed the risks of using CI E Liner against the benefits that are expected. This leaflet does not contain all the available information about CI E Liner. Your surgeon has been provided additional information and can answer any questions you may have. Follow your surgeon's advice even if it differs from what is in this leaflet.
Please read this leaflet carefully and keep it in a safe place so you may refer to it in future if needed

What is CI E Liner?

The hip joint can be thought of as a ball and socket joint. Hip joint replacement surgery involves replacing the head of the femur [ball] and/or the acetabulum [socket] with artificial parts.
CI E Liner provides the articulating surface in between the part that replaces the hip socket and the part that replaces the head of the femur. It is made from polyethylene, a medical-grade plastic.

What is CI E Liner used for?

CI E Liner is used for patients in association with NOVAE® cups, the intended used varies with the cup associated, see the specific NOVAE® cups patient leaflet to have their specific intended used. Replacement of the damaged hip joint aims to restore mobility and reduce pain to allow patients to resume many daily activities that may have been limited due to pain.
CI E Liner can only be implanted surgically by a qualified surgeon. Your surgeon will choose the hip joint replacement for you based on durability, level of performance, wear resistance, their experience or preference and your personal needs. As with any medical treatment, individual results may vary.

What are the possible undesirable effects and complications?

Before your surgery, your surgeon informed you of the contraindications, complications and possible side effects related to hip surgery. In the instruction for use, the undesirable effects and complications relative to using Novae® dual mobility cups and liners are:

- allergy to the different materials used to make our implants (inflammation),
- loosening of the prosthesis,
- deformation, cracking or breaking of a component (e.g: wear of the liner / erosion / deformation),
- bone fracture,
- dislocation including intraprosthetic dislocation,
- insufficient range of movement,
- infection,
- deterioration of the femoral and acetabular implant through stem / cup contact during very wide movements,
- residual hip pain,
- deterioration of the patient's state of health,
- bad functional results,
- blockage of the hip joint,
- pseudotumor,
- osteolysis,
- mechanical conflict with the iliopsoas tendon, migration,
- heterotopic ossification,

- the patient falling,
- discomfort.

What to do after CI E Liner has been implanted?

Your prosthesis has a lifespan of approximately 15 years in the case of primary surgery and approximately 10 years in the case of revision. However, this lifespan will depend on how you will use it and in particular your physical activity and your weight load.

Certain precautions must be followed daily for the period determined by your surgeon:

- Sleeping preferably on his back or on his side with a cushion between his legs,
- Taking a shower instead of a bath,
- Using a bar or a stable support to get out of the bath,
- Raising the height of the toilets and installing a support bar,
- Avoiding excessively deep armchairs,
- Getting dressed and putting on shoes in a seated position and using a shoehorn,
- Placing the knee of the operated leg on the floor or putting the operated leg behind in order to bend down,
- Getting into or out of the car by sitting with his back to the seat and pivoting with legs together in a flexed position.

It is important to inform your surgeon of any discomfort and / or any event concerning your operated hip (ex: fall, persistent pain, etc.).
You should also follow the advice of your surgeon and, upon request, submit to periodic checks to detect the appearance of possible complications.

Magnetic Resonance Imaging (MRI) Safety Information with a hip joint replacement

If you undergo an examination involving magnetic and electro-magnetic fields, you must warn the operator that you have an artificial joint and show him your implant card.
Standardized non-clinical testing have shown that a patient with SERF hip implant can be scanned safely immediately after implantation, under the following conditions:

- Static magnetic field of 1.5 or 3-Tesla,
- Maximum spatial gradient magnetic field of 7.4T/m at 1.5T and 12T/m at 3T,
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning,
- Maximal gradient slew rate of 120 T/m/s at 1.5T and 200 T/m/s at 3T.

The quality of the MRI image may be degraded if the region of interest is in the same area as the implant or is close to it.

Reporting adverse effects

If you notice any serious adverse effects that you believe are a result of CI E Liner, please talk with your surgeon and report the information on SERF Complaint email: complaint@serf.fr and to the Therapeutic Goods Administration via the website: https://www.tga.gov.au

Sponsor

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