BI-MENTUM PE Liner

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Consumer Medical Device Information

What is in this leaflet

This leaflet answers some common questions about BI-MENTUM PE 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 BI-MENTUM PE Liner against the benefits that are expected. This leaflet does not contain all the available information about Bi-MENTUM PE 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 BI-MENTUM PE 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. BI-MENTUM PE 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 BI-MENTUM PE Liner used for?

BI-MENTUM PE Liner is used for patients with conditions such as osteoarthritis of the hip, fractures of the femoral neck, recurring dislocations, osteonecrosis, periacetabular metastatic disease, patients with a risk of instability, initial post traumatic surgery, osteoporotic bone, or for rehabilitation after severe Paprosky type IIIA and IIIB acetabular destruction. Replacement of the damaged hip joint aims to increase mobility and reduce pain or stiffness to allow patients to resume many daily activities that may have been limited due to pain or stiffness.

BI-MENTUM PE Liner can only be implanted surgically by a qualified surgeon. You 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.

When should BI-MENTUM PE Liner not be used?

BI-MENTUM PE Liner should not be used in patients with:

- An infection
- Heart disease
- Uncompensated diabetes
- Severe osteoporosis
- Regular haemodialysis
- Alteration of the immune system
- Severe muscular, neurological or vascular deficiencies affecting the extremity concerned
- Serious deformation of the joint that needs replacing
- Systemic or metabolic issues
- Obesity or excess weight
- Intense activity or intensive sports training

If you are unsure whether BI-MENTUM PE Liner should be used in your treatment, talk to your surgeon.

What to do after BI-MENTUM PE Liner has been implanted?

Having a hip joint replaced is a major operation. While most people have a good result and an active recovery, there are potential surgical and medical risks and recovery takes time. Ask your surgeon for more details and talk to them if you have any unusual symptoms such as:

- Pain, redness and swelling in the lower limb
- Suddenly becoming short of breath, chest pain and a cough
- Allergic reaction
- Infection of the surgical site
- Increasing pain in the operated hip joint

The performance of BI-MENTUM PE Liner is dependent on factors such as age, physical condition, weight and activity level. Factors such as weight, excessive physical activity or trauma to the area may affect the function and lifespan of the hip joint replacement. It is designed for activities of daily living, not high impact sports. Walking, swimming and cycling are recommended. High impact sports such as jogging or running, playing tennis or repeated heavy lifting can affect the function and lifespan of your new joint. However, ongoing physiotherapy and exercise are important for recovery so speak to your surgeon or physiotherapist about rehabilitation exercises and your lifestyle and specific activity goals.

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

Speak to your surgeon about whether you can have MRI scans. You should inform the technicians performing the scan that you have the BI-MENTUM hip replacement system implanted.

Reporting adverse effects

If you notice any serious adverse effects that you believe are a result of BI-MENTUM PE Liner, please talk with your surgeon and report the information to Johnson & Johnson Medical Product Safety Department on productsafetyjjmanz@its.jnj.com and to the Therapeutic Goods Administration via the website:

https://www.tga.gov.au

Sponsor

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