Radial Head Replacement System

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Consumer Medical Device Information

What is in this leaflet

This leaflet answers some common questions about the Radial Head Replacement System. 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 the Radial Head Replacement System against the benefits that are expected. This leaflet does not contain all the available information about the Radial Head Replacement System. 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 the Radial Head Replacement System?

The Radial Head Replacement System is used for partial replacement of the elbow joint to restore elbow stability and forearm rotation, preserve elbow motion and maintain the length of the radius. It is used for patients requiring:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting with pain, crepitation and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with joint destruction and/or subluxation visible on x-ray and/or resistance to conservative treatment
- Primary replacement after fracture of the radial head
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty

The Radial Head Replacement System is made from cobalt chromium molybdenum alloy. It can only be implanted surgically by a qualified surgeon, who will choose the appropriate replacement for you. As with any medical treatment, individual results may vary.

When should the Radial Head Replacement System not be used?

The Radial Head Replacement System should not be used in:

- Growing children with open epiphyses
- Patients with dislocations of radius on ulna that would not allow articulation
- Rheumatoid arthritis

If you are unsure whether the Radial Head Replacement System should be used in your treatment, talk to your surgeon.

What to do after the Radial Head Replacement System has been implanted?

Having a radial head replaced is a significant operation. As the same as other surgical procedures, there are potential surgical and medical risks and recovery takes time. Some risks are listed below. Ask your surgeon for more details and talk to them if you have any unusual symptoms and follow your surgeon's guidance if further diagnosis and medical treatment are deemed necessary.

- Allergic reaction
- Infection of the surgical site
- Dislocation
- Poor joint movement
- Pain or discomfort
- Damage to other tissue

After surgery, it is important to follow the instructions of your surgeon to aid in healing, reduce recovery time, and increase mobility and strength. This may include restricting movement during the initial healing phase followed by specific rehabilitation exercises.

Magnetic Resonance Imaging (MRI) Safety Information

Speak to your surgeon about whether you can have MRI scans. You should inform the technicians performing the scan that you have the Radial Head Replacement System implanted.

Non-clinical testing has demonstrated the Radial Head Replacement System is MR Conditional and can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3.0 T or less
- Maximum spatial field gradient of 4,180 G/cm (41.8 T/m)
- Maximum MR system-reported, whole-body averaged specific absorption rate (SAR) of 2 W/kg (First Level Control Mode)

Reporting adverse effects

If you wish to report any adverse effects you believe are a result of the Radial Head Replacement System, please talk with your surgeon or report the information to Johnson & Johnson Medical Product Safety Department on:

Email:

productsafetyjjmanz@its.jnj.com

Reports may also be made directly to the Therapeutic Goods Administration via the website:

https://www.tga.gov.au

Sponsor

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