Healix Advance Knotless BR Anchor

Product Codes: *222885, 222886, 222887*

Consumer Medical Device Information

What is in this leaflet

This leaflet answers some common questions about Healix Advance Knotless BR Anchor. 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 Healix Advance Knotless BR Anchor against the benefits that are expected. This leaflet does not contain all the available information about Healix Advance Knotless BR Anchor. 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 Healix Advance Knotless BR Anchor?

Healix Advance Knotless BR Anchor is used for soft tissue injuries of the shoulder and foot/ankle (including rotator cuff repair, biceps tenodesis, deltoid repair, and achilles tendon repair) to reattach soft tissue to bone. Reattachment of soft tissue to bone aims to alleviate pain and improve limb function to allow patients to resume many daily activities that may have been limited due to pain, weakness or restricted range of motion.

Healix Advance Knotless BR Anchor consists of an anchor component that is implanted into bone and pre-loaded sutures that are used to hold the soft tissue to the bone after surgery. The anchor is made of an absorbable polyglycolic copolymer called BIOCRYL RAPIDE (BR). The suture is a composite of dyed absorbable polydioxanone and undyed non-absorbable polyethylene. It is coated with a copolymer of caprolactone and glycolide.

Healix Advance Knotless BR Anchor can only be implanted surgically by a qualified surgeon, who will choose the appropriate implant for you. As with any medical treatment, individual results may vary.

When should Healix Advance Knotless BR Anchor not be used?

Healix Advance Knotless BR Anchor should not be used in patients with:

- Pathologic conditions of bone such as cystic changes or severe osteopenia
- Pathologic changes to the affected soft tissue that would prevent secure fixation
- Fragmented or fractured bone
- Physical conditions that would affect implant support and healing, such as blood supply limitation or previous infection
- Conditions that would limit the ability to restrict activities during the healing period

If you are unsure whether Healix Advance Knotless BR Anchor should be used in your treatment, talk to your surgeon.

What to do after Healix Advance Knotless BR Anchor has been implanted?

Having a soft tissue repair is a significant 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:

- Inflammation
- Foreign body reactions
- Infection
- Worsening of original symptoms

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

Having Healix Advance Knotless BR Anchor implanted does not prevent you from having MRI scans.

Reporting adverse effects

If you wish to report any adverse effects you believe are a result of Healix Advance Knotless BR Anchor, please talk with your surgeon or report the information to Johnson & Johnson Medical Product Safety Department at 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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