

Healix Advance BR Anchor with Dynacord Suture

Product Codes: 222000, 222001, 222002, 222004, 222005, 222006, 222011, 222013, 222015

Consumer Medical Device Information

What is in this leaflet

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

Healix Advance BR Anchor with Dynacord Suture is used for soft tissue injuries of the shoulder, foot/ankle, knee, elbow or hip 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 BR Anchor with Dynacord Suture consists of an anchor 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 made of medical-grade polyethylene, polyester, silicone/sodium chloride composite, and colorant.

Healix Advance BR Anchor with Dynacord Suture 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 BR Anchor with Dynacord Suture not be used?

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

- Pathologic conditions of bone such as cystic changes or severe osteopenia
- Pathologic changes to the affected soft tissues 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 BR Anchor with Dynacord Suture should be used in your treatment, talk to your surgeon.

What to do after Healix Advance BR Anchor with Dynacord Suture 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/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 BR Anchor with Dynacord Suture implanted does not prevent you from having MRI scans. Please consult with your physician.

Reporting adverse effects

If you wish to report any adverse effects you believe are a result of Healix Advance BR Anchor with Dynacord Suture, 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

Johnson & Johnson Medical Pty Ltd t/a DePuy Synthes
1 -5 Khartoum Road
NORTH RYDE, NSW 2113
Tel: 1300 562 711

Revision: 01