EIT Cellular Titanium® LLIF Cage

Consumer Medical Device Information

What is in this leaflet

This leaflet answers some common questions about the EIT Cellular Titanium LLIF Cage. 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 EIT Cellular Titanium LLIF Cage against the benefits that are expected. This leaflet does not contain all the available information about EIT Cellular Titanium LLIF Cage. 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 EIT Cellular Titanium LLIF cage?

The EIT Cellular Titanium LLIF cage is an implant made from a titanium alloy for the posterior stabilization of the lumbar spinal column using a Lateral Lumbar Interbody Decompression and Fusion (LLIDF) surgery. EIT Cellular Titanium LLIF Cages are offered in a variety of geometries and sizes to accommodate patient anatomy.

What is EIT Cellular Titanium LLIF cage used for?

The EIT Cellular Titanium LLIF Cage is indicated for use in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) and instabilities at one or more levels of the lumbar spine with accompanying radicular symptoms, ruptured or herniated discs, and pseudarthrosis or failed spondylodesis. Patients should have at least six (6) weeks of non-operative treatment prior to surgery.
The EIT Cellular Titanium® LLIF Cages are used to restore the intervertebral height and to facilitate intervertebral body fusion in the lumbar spine (L2-S1) and are placed via a lateral approach. In cases of segmental instability, lateral and/or posterior supplemental internal fixation (e.g., using pedicle screws) should be performed.

How is the EIT Cellular Titanium LLIF Cage used?

The EIT Cellular Titanium LLIF Cage can only be implanted surgically, by a qualified surgeon.

When should EIT Cellular Titanium LLIF Cage not be used?

Do not use the EIT Cellular Titanium LLIF Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopaedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity or degenerative diseases
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

If you are unsure whether EIT Cellular Titanium LLIF should be used in your treatment, talk to your surgeon.

What to do after EIT Cellular Titanium LLIF Cage has been implanted?

Things you must do

Talk to your surgeon if you have unusual symptoms.

Adverse Reactions

Adverse reactions may include:

- Clinical failure (i.e., pain or injury) due to bending, loosening, wear and tear, fracture, loss of fixation, dislocation and/or migration
- Pain, discomfort and/or abnormal sensations due to the presence of the implant
- Primary and/or secondary infections
- Allergic reactions to a foreign body, or implant material sensitivity
- Neurological injury due to surgical trauma or presence of the device. Neurological difficulties include bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness and paraesthesia
- Fracture of vertebrae or other bony structures
- Decrease in bone density due to stress shielding
- Degenerative changes or instability of segments adjacent to fused vertebral levels
- Dural tears experienced as a result of surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis

- Injury to vessels, nerves and organs; malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late post-operative period
- If a pseudarthrosis occurs coupled with the implant, mechanical grinding may occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints. Wear debris can also cause other possible local or systemic adverse reactions.
- Reflex sympathetic dystrophy
- Hematoma and/or impaired wound healing; hemorrhage
- Venous thrombosis, lung embolism, and cardiac arrest
- Nonunion or delayed union
- Spinal cord impingement or damage
- Paralysis
- Bursitis
- Death

Note: This list may not include all complications caused by the surgical procedure itself.

Other adverse reactions not listed here may occur in some patients. Tell your surgeon if you notice anything that is causing you pain or making you feel unwell.

Magnetic Resonance Imaging (MR) Safety information

[MR Status]

Non-Clinical testing demonstrated that the EIT Cellular Titanium LLIF Cage is MR Conditional and can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T)
- Spatial gradient field of up to 4.0 G/cm (40 T/m)
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Controlled Operating Mode)

1.5 T RF heating

In non-clinical testing with body coil excitation, the EIT Cellular Titanium LLIF Cage produced a temperature rise of less than 3.3 ºC at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 T Philips Intera MR scanner with Software Release 12.6.1.4, 2012-05-22.

3 T RF heating

In non-clinical testing, the EIT Cellular Titanium LLIF Cage produced a temperature rise of less than 2ºC at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3 T Siemens Trio Magnetom Trio MR scanner with Numaris/4, Syngo MR B17 software.

WARNING

The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact

In testing with spin-echo sequencing, the shape of the image artefact follows the approximate contour of the device and extends radially up to 29.5 mm from the device.

Reporting adverse reactions

If you wish to report any adverse reactions you believe are a result of the EIT Cellular Titanium LLIF Cage, 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

http://www.tga.gov.au/reporting-problems

Sponsor

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