EIT Cellular Titanium® Cervical Cage

Consumer Medical Device Information

What is in this leaflet

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

The EIT Cellular Titanium Cervical Cage is an implant made from a titanium alloy for the anterior stabilization of the cervical spinal column using an Anterior Cervical Discectomy and Fusion (ACDF) surgery. EIT Cellular Titanium Cervical Cages are offered in a variety of geometries and sizes to accommodate patient anatomy.

What is EIT Cellular Titanium Cervical Cage used for?

The EIT Cellular Titanium Cervical Cages are 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 cervical 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.

EIT Cellular Titanium Cervical Cages are used to restore the intervertebral height and to facilitate intervertebral body fusion in the cervical spine (C2-T1) and are placed via an anterior approach. In cases of segmental instability, supplemental internal fixation using a cervical plating system should be considered.

How is the EIT Cellular Titanium Cervical Cage used?

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

When should EIT Cellular Titanium Cervical Cage not be used?

Do not use the EIT Cellular Titanium Cervical 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 Cervical Cage should be used in your treatment, talk to your surgeon.

What to do after EIT Cellular Titanium Cervical 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, 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 Cervical 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:
  - 24,330 G/cm (243.30 T/m) for 1.5 T systems
  - 12,160 G/cm (121.60 T/m) for 3 T systems
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 4.0 W/kg for 15 minutes of scanning in First Level Controlled Operating Mode at 1.5 T
  - 4.0 W/kg for 15 minutes of scanning in First Level Controlled Operating Mode at 3 T

1.5 T RF heating

In non-clinical testing with body coil excitation, the EIT Cellular Titanium Cervical Cage produced a temperature rise of less than 0.5 ºC at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 T Siemens Espree (MRC30732) MR scanner with SYNGO MR B19 software.

3 T RF heating

In non-clinical testing, the EIT Cellular Titanium Cervical Cage produced a temperature rise of less than 0.5 ºC at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3 T Siemens Trio (MRC20587) MR scanner with SYNGO MR A35 4VA35A 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 gradient-echo sequencing, the shape of the image artefact follows the approximate contour of the device and extends radially up to 1.7 cm from the device.

Reporting adverse reactions

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