Cervical Solutions

ROI-C® Range
Anterior Cervical Cage

Surgical Technique
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Surgical technique

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The ROI-C® family is composed of various profiles of cages whose availability may vary upon markets.

ANATOMIC PROFILE

ROI-C® Anatomic: Designed with a curved superior surface that compliments healthy endplate contours. The anatomic implant has a 6° of built-in lordosis. ROI-C® Anatomic’s design is available in both PEEK-OPTIMA® and PEEK-OPTIMA® Titanium-Coated. PEEK-OPTIMA® version is also available pre-filled with synthetic bone substitute (ROI-C® Bi-Pack®).

CONICAL PROFILE

ROI-C® Lordotic: Features a tapered profile for patients with flattened endplates. The lordotic implant has a 7° of built-in lordosis. ROI-C® Lordotic’s design is available in both PEEK-OPTIMA® and PEEK-OPTIMA® Titanium-Coated.
SURGICAL TECHNIQUE

STEP 1 - DISC LOCATION

- The approach to the intersomatic space is realized after locating the affected level under fluoroscopy. The surgical protocol and the technique used for the exposure of the intersomatic space are the same as for the standard anterior approach for cervical vertebral surgery.

STEP 2 - DISCECTOMY

- Place the retractor fixation pin 8mm from the superior and inferior endplates of the treated level in order not to impede insertion of the implant.

- Place the retractor on the pins.

- Distract the intersomatic space, then start disc resection with a thin, long scalpel and disc forceps.

- Continue the discectomy to the back of the endplates.

**Remark:** It is not necessary to remove all of the annular disc tissue laterally. It is sufficient to remove only the amount corresponding to the cage (between the uncus); maintaining the lateral annular layers optimizes cage stability and arthrodesis. The use of the microscope is recommended to achieve a perfect release.

STEP 3 - ENDPLATE PREPARATION

- Prepare the implant space and the grafting surfaces with a curette and/or a rasp. Thorough preparation of the endplates favors the fusion.
STEP 4 - TRIAL IMPLANT SELECTION

Trial implant selection*

The trial implants vary in: depth x width and height. They are recognizable with color code: each color representing a footprint (depth x width).

**ANATOMIC TRIAL IMPLANT**

12x14mm
14x14mm
12x15.5mm**
14x15.5mm
14x17mm

**LORDOTIC TRIAL IMPLANT**

Remark: The lordotic cage has a flat and conical profile in the sagittal plane. It meets the needs of patients with flattened endplates.

The use of specific trial implant is thus essential during the implantation of this type of cage.

* Product availability may vary upon markets.
** Available in option.
The continuation of the surgical technique is illustrated with the anatomic cage.

Depth selection

- Insert the chosen trial implant into the intervertebral space.
- Under fluoroscopy, check the correct positioning of the trial implant in depth and rotation.

**Important:** The posterior side of the trial implant should be a minimum of 1mm from the posterior edge of the vertebra. If it is not the case, choose a trial implant of inferior depth.

**Remark:** the trial implant hole must be visible, to assure the lack of rotation.

Width selection

- After depth measurement, insert the chosen trial implant into the intervertebral space.
- Choose the trial implant that offers the best coverage of the vertebral endplate.

**Remark:** The trial implant should be as large as possible, while allowing stable seating on the vertebral endplate.
Height selection

• Insert the trial implant of the color corresponding to the previously chosen size (depth x width) into the intervertebral space.

• Release momentarily the distraction in order to make sure the trial implant is stable in the intervertebral space.

• Under fluoroscopy, check:
  • The consistency between the selected trial and the disc heights of the adjacent levels.
  • The congruency between the trial and the superior and inferior endplates.
  • The restoration of the lordotic curve.

• Restore the distraction of the retractor in order to remove the trial implant from the intervertebral space.
STEP 5 - CAGE SELECTION AND POSITIONING

Cage selection

The color code and the trial implant height determine the choice of the final implant.

This information is present on the side of the implant boxes and vary by type of implant.
Cage preparation

The fusion chamber of the cages has to be filled with autograft or bone substitute.

Option A* - Use of a ROI-C Bi-Pack cage
(Available only for anatomic cages)

Cage comes pre-filled with synthetic bone substitute.

Option B* - Pre shaped bone substitute
(Available only for anatomic cages)

The BF+ bone substitute has an anatomic shape and is perfectly adapted to the cage dimensions.

• Insert the superior part (dome-shaped) of the bone substitute through the inferior opening of the cage.
• Place the bevelled sides of the bone substitute (dome on top) in front of the cage slots to free the way for the anchoring plate.

Option C - Filling with other types of graft

• Compact the graft in the fusion chamber of the ROI-C cage with the graft compactor.

Option: Use of the graft support :

• Assemble the graft support (1a).
• Position and lock the cage into the graft support by rotating the knob (1b).
• Compact the graft using the graft compactor (1c).

Note: The cage can be assembled on the implant holder before the graft compaction (see page 9).

Note: The continuation of the surgical technique is illustrated with an anatomic cage pre-filled with bone substitute.
*This is an optional component. Optional components may not be approved in all regions.
Loading the cage onto the implant holder

**Remark:** For ROI-C Bi-Pack the double blister packaging allows for a direct « no touch » loading of the cage onto the implant holder.

- Bring the cage close to the **implant holder** in such a way as to slot the implant holder hook in the notch on the left side of the cage.

- Secure the cage on the implant holder with the **threaded rod** by screwing the **impaction knob**.
STEP 6 - CAGE POSITIONING

- Set the **adjustable stop** to zero by screwing or unscrewing the **knurled wheel**.

**Important**: Always use the adjustable stop.

**Remark**: The choice of the use of the standard or enlarged stop is made according to the preferences of the surgeon.

**Important**: During cage positioning, make sure the cage is perfectly inserted in the alignment to the intersomatic space.

- Insert the cage in the intervertebral space under fluoroscopy in order to check its correct positioning.

**Remark**: From the lateral view, the marker shows the posterior position of the cage. It is positioned at 1 mm from the posterior edge of the cage.

The implant holder’s adjustable stop comes into contact with the anterior wall of the superior vertebra.

Antero-posterior positioning can be adjusted millimeter by millimeter with the knurled wheel.

**Important**: Each scale marked on the adjustable stop enables millimetric advancement of the cage towards the vertebral body’s posterior wall.

- Once the antero-posterior positioning has been adjusted, compress the segment.
Important: If the pins have not been properly placed during the discectomy, they can impede anchoring plate preparation and insertion. In this case, remove the retractor and the retractor fixation pins.

When the cage position is optimal and the segment put into compression, the anchoring plate (composed of two half anchoring plates) can be inserted. Impaction of the half anchoring plates is done one after another (in the inferior vertebra, then in the superior vertebra) following preparation of their pathway with the sterile starter awl for ROI-C anchoring plate.

In normal bone structure, the insertion of the anchoring plate is a simple and effortless step. Nevertheless, in order to prepare the half anchoring plate pathway in vertebrae, the use of the sterile starter awl is recommended for each ROI-C surgery. Its use is left to the surgeon’s own estimation, according to his experience of surgery, of the product, of the patient pre-operative assessment, and per-operative signs on the bone density of the instrumented level(s).

Important: The starter awl is only destined to prepare the trajectory of the anchoring plate. It is single use, non-implantable and delivered individually packed in sterile box.

Pathway preparation of the first half anchoring plate

Choice of the ROI-C sterile starter awl for ROI-C anchoring plate

- Select the sterile starter awl (Short « S » or Long « L ») according to the half anchoring plate length to be inserted.
  - Use a sterile short starter awl (« S ») for the use of a short half anchoring plate.
  - Use a sterile long starter awl (« L ») for the use of a long half anchoring plate.

Note: The starter awls are delivered per unit in sterile box.
Assembly of the sterile starter awl onto the starter awl impactor for ROI-C anchoring plate

Take the sterile starter awl previously selected and assemble it onto the starter awl impactor through the next steps:

- Take the sterile starter awl out of its packaging holding it by the silicone protective cap.

- Insert the sterile starter awl as described below, making sure the correct orientation is used.

  - Adjust the « S » or « L » marking face to the starter awl impactor, and insert the open part of the sterile starter awl onto the starter awl impactor, letting it slide past the blue pawn.

  - Remove and discard the silicone protective cap.

  - Slide the guide forward so that the awl seats fully in the groove as shown.
USE OF THE STERELE STARTER AWL FOR THE PATHWAY CREATION

**Important:** Check the sterile starter awl’s integrity (the cutting edge of the sterile starter awl) before impaction.

During its use, the sterile starter awl comes in contact with the ROI-C instrumentation and the patient’s cortical bone, it is normal to observe superficial marks without its integrity is questioned. Non acceptable damage to the starter awl can be observed for instance in case of contact with an obstacle on its trajectory (pins,…).

![Acceptable vs Not acceptable](image)

**Acceptable**

**Not acceptable**

Discard the damaged starter awl and take a new sterile one.

**Important:** For each instrumented level, it is essential to follow the next steps:

- Pathway preparation in the first vertebra.
- Insertion of the half anchoring plate into the same vertebra.
- Pathway preparation into the second vertebra.
- Insertion of the second half anchoring plate into the second vertebra.

The pathway in the second vertebra must not be prepared at the same time that the one of the first vertebra.
**Important:** The impaction of the sterile starter awl must be done progressively by respecting the complete withdrawal steps, as described below:

- Insert the starter awl impactor rod into the implant holder’s groove (Fig.01).

- To prepare the pathway for the half anchoring plate in the inferior vertebra, position the laser marking « 1 » located on the guide side, so it is the facing away from the implant holder’s body (Fig.02) as shown.

- Insert the sterile starter awl into the superior slot of the implant holder head. No resistance must be felt during the sterile starter awl insertion into the slot. If resistance is felt, remove the sterile starter awl and repeat the step (Fig.03).

- Bring the sterile starter awl in contact to the vertebral endplate bone (light resistance) by applying manual pressure to the starter awl impaction knob (Fig.03).
- Start the insertion with a series of 3 to 4 impactions on the impaction knob with a mallet so that starter awl is only partially inserted into the vertebral body (Fig. 04).

- Back out sterile starter awl completely by reverse impaction under the impaction knob (Fig. 05).

- Repeat these steps until the starter awl impactor body reaches its mechanical stop with the guide (Fig. 06).

- Perform a fluoroscopic control to confirm proper insertion of the sterile starter awl (Fig. 07).

- Remove the sterile starter awl using mallet.

**Important:** In case where a strong resistance is felt, immediately stop the insertion and perform fluoroscopic control to determine the reason of the resistance (contact with retractor fixation pins,...). Remove if necessary the material at the origin of the conflict in order to avoid any interferences.
Insertion of the first half anchoring plate

- The first half anchoring plate is inserted in the superior slot of the implant holder with the ROI-C anchoring plate holder (in the axis of the implant holder with a minimum of obstruction).

**Important:** During half anchoring plate insertion, make sure to push the plate all the way to the bottom of the implant holder head with the anchoring plate holder.

- Engage the thinnest part of the ROI-C impactor (marked 1) in the groove of the implant holder.

- Bring the first half anchoring plate into contact with the bone by pushing manually on the impactor.

- Impact the half anchoring plate using the ROI-C impactor (marked 1) until it reaches its mechanical stop.

**1st stage: ROI-C impactor (marked 1)**
• Complete impaction using the **ROI-C final impactor** (marked 2), inserted into the slot of the implant holder until the mechanical stop on the implant holder.

**Remark:** Make sure the impactions are done in the axis of the intervertebral space.

**Note:** Use fluoroscopy during each step in order to check correct positioning of the half anchoring plate.
Pathway preparation of the second half anchoring plate

**Important:** Before every reuse, slide the guide in order to check:
- The sterile starter awl’s integrity for anchoring plate (chapter « Pathway preparation of the first half anchoring plate »).
- The sterile starter awl’s mobility in the starter awl impactor head.

- In order to prepare the pathway of the half anchoring plate destined to the superior vertebra, position the laser marking «2» located on the guide side, so it is the facing away from the implant holder’s body.
- Insert the sterile starter awl into the inferior slot of the implant holder head.
- For the next steps, consult the chapter « Pathway preparation of the first half anchoring plate ».

- Discard the sterile starter awl at the end of the surgery.
Insertion of the second half anchoring plate

- Once the second pathway created with the sterile starter awl, insert the second half anchoring plate and impact it by following the same technique that the one used for the first half anchoring plate, while ensuring to insert this second half anchoring plate into the slot at the opposite of the one used for the first half anchoring plate.

Reminder: The half anchoring plate inserted in the implant holder’s inferior slot penetrates into the superior vertebral body and inversely.

1\textsuperscript{st} stage: ROI-C impactor (marked 1)

2\textsuperscript{nd} stage: ROI-C final impactor (marked 2)

Note: Use fluoroscopy during each step in order to check correct positioning of the half anchoring plate.
STEP 8 - IMPLANT HOLDER REMOVAL AND FINAL CONTROLS

Implant holder removal

• Unscrew the impaction knob to release the cage from the threaded rod of the implant holder.

• Disengage the implant holder hook from the cage notch by moving the implant holder to the left.

• Carefully remove the implant holder in the axis of the intervertebral space.

• Remove the retractor and the retractor fixation pins.

Final controls

• An image under fluoroscopy, from an anterior-posterior (AP) and lateral view, of anchoring plate position enables to ensure the optimal trajectory.
STEP 9 - REVISION

Plate removal instrument assembly

• Join the tube and the grooved knob.

• Insert the hook inside the grooved knob and tube previously assembled. The laser marks have to be aligned.

• Screw the grooved knob until it is flush with the hook’s handle.

Remark: The laser mark (line) indicates the hook orientation. If the laser mark is up so is the hook.
**PEEK strips removal**

It is recommended to use a burr to remove the PEEK strips situated in front of each half anchoring plate, releasing access to the removal hole (1a and 2a).

If no burr is available, an osteotome may be used. Proceed as follows:

- Place the **osteotome** at one extremity of the PEEK strip and cut. Proceed the same way for the second extremity in order to pre-cut the PEEK strip (1b and 2b).

- If the PEEK strip is still attached to the cage, wedge the osteotome between the strip and the half anchoring plate and impact (3 and 4).

**Important:** The PEEK strip can be ejected during this step. Protect the area and secure the procedure using a surgical compress.

- Repeat the process on the second PEEK strip.
Half anchoring plate removal

Half anchoring plate removal is done using the plate removal instrument.

- Insert the hook inside the removal hole of the half anchoring plate.

- Screw the grooved knob until the tube is in contact with the cage or the vertebra.

- Carry on screwing in order to completely extract the half anchoring plate and lock it inside the instrument.

- Repeat the process for the remaining half anchoring plate.
Cage removal

- To assist removing the cage, use if needed, an osteotome to break bone bridges and a Caspar distractor.

- Assemble the ROI-C implant holder without the adjustable stop.

- Insert the implant holder hook into the notch on the left side of the cage.

- Secure the cage on the implant holder with the threaded rod by screwing the impaction knob. Then extract the cage from the disc space.
## INSTRUMENT SET
### ROI-C AND ROI-C BI-PACK

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### ROI-C AND ROI-C BI-PACK (continuation)

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* Choice between 2 types of Caspar by priority order: Caspar U&I (IG007R (x1) + IG008R (x3) + IG009R (x1) + IG010R (x3)) and Caspar Medlane (X844 (x1) + X846 (x3) + N819 (x1)); N819, X846 and X844 are Medlane CE marked products.
### ROI-C Lordotic *

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* In addition with ROI-C anatomic instrument set.
**Product description**

The ROI-C® implants (cages and anchoring plates) are devices whose primary functions are to add a solid structure to a graft so as to enable the stabilization of intervertebral height, after diskectomy, during the time of graft setting and achieve a maximum surface of fusion compartmentalized. Various sizes and shapes of these implants (cages and anchoring plates) are available, so that adaptations can be made to take into account the pathology and individual patient. In addition, so as to favour bone growth, the ROI-C® anterior cervical cage must be filled with autologous, allogenic bone or bone substitutes from the BF+® range. ROI-C® Bi-Pack® is a cervical cage, pre-filled with synthetic bone substitute.

The cage allows adding a solid structure to a graft so as to enable the stabilization of the segment and the maintaining or the restoration of intervertebral height, after discectomy, during the time of graft setting and achieve a maximum surface of fusion compartmentalized. It has a convex superior surface and is open on the inferior and superior surfaces. The bone substitute of the range BF+® has an optimized porosity and an optimized surface to allow a quick bone growth. Various sizes of this device are available, so that adaptations can be made to take into account the pathology and individual patient.

**Material:**

The material used in the manufacturing of ROI-C® cages is the (radiolucent) PEEK-OPTIMA® LT1, radiological indicators are in tantalum (radio-opaque).

The materials used in the manufacturing of the ROI-C® Coated Implant are (radiolucent) PEEK Optima® LT1, porous plasma spray coating made of un-alloyed non-ferro-magnetic titanium (Ti) and tantalum alloy radiological position markers.

The anchoring plates (associated system of fixation) are in surgical titanium alloy (Ti6Al4V). Specialized associated instrumentation (ROI-C® ancillary) has been designed for implantation of the implants and has been manufactured from biocompatible materials. The bone substitute is a microporous and macroporous biphasic calcium phosphate ceramic consisting of 60% Hydroxyapatite (HA) and 40% Beta-Tricalcium Phosphate (β-TCP).

ROI-C® Bi-Pack® and ROI-C® Coated are compatible with anchoring plates ROI-C® and instruments of the ROI-C® ancillary marketed by LDR Medical Company.

**Indications**

The ROI-C® range implant is indicated in skeletally mature patients to perform a cervical arthrodesis (limited to three levels), in the context of disk(s) treatment:

- Between C2 and T1 vertebra
- With intractable symptomatic cervical disc disease (SCDD), defined as radiculopathy and/or myeloradiculopathy (neck pain, arm pain, and/or a functional neurological deficit in a specific nerve root situated between C2 and T1 vertebra), and refractory to non-operative treatment conducted during at least six weeks.
- With at least one of the following conditions confirmed by imaging (CT, MRI, or X-rays):
  - Herniated nucleus pulposus,
  - Discarthrosis.

The ROI-C® range implant is implanted via an open anterior approach following partial discectomy. Following the implantation of the ROI-C® range implant, and in order to ensure its stability in the intervertebral space, the ROI-C® cage has to be used with its ROI-C® anchoring plate so as to fix the cage on the two proximal vertebral plates.

**Contraindications**

- Marked cervical Instability on the lateral or flexion-extension radiographs demonstrated by:
  - Translation ≥ 3.5 mm, and/or
  - Greater than 11° angular difference to that of either adjacent level
- Recent context of trauma on the disk(s) to operate, dislocation.
- Incompatible patient age and/or physical condition.
- Cardiac problems.
- Abuse of medicine, drugs, tobacco or alcohol (which change the ossification power).
- Material sensitivity, documented or suspected.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care.
- Bony abnormalities or bone stock compromised by disease (such as osteopenia, osteoporosis), infection or prior implantation preventing safe support and/or fixation to the implant and/or the anchoring plates.
- Morbid Obesity can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- Recent infection, fever or hyper-leukocytosis.
- Pregnancy.
• Inflammation.
• Patient under treatment which inhibits bone fusion.
• Other medical (for example: anesthetics risks) or surgical conditions which would preclude the potential benefit of spinal implant surgery such as the presence of bone tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases.

In addition for ROI-C®:
- Open wounds.
- Patients having inadequate tissue coverage over the operative site.

In addition for ROI-C® Bi-Pack®:
- Osteomyelitis.
- Implantation in a necrotic surgical sites.
- Opening meninx.

Precautions
• Being a technically demanding procedure presenting a risk of serious injury to the patient, the implantation of intersomatic systems should be performed only by experienced spine surgeons with specific training in the use of this system and who have knowledge of the present instructions for use and the associated surgical technique.
• The surgeon should consider the level of implantation, the weight of the patient, the patient’s activity level or general conditions and any other factor which may have an impact on the performance of the system based on published fatigue test results of the system.
• Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
• If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., running, lifting of important loads, or muscle strain), resultant forces can cause failure of the device.
• In some cases, progression of degenerative disease may also be so advanced at the time of implantation that they may substantially decrease the expected useful life to the implant. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.
• Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the system. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions and potential risks associated with spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre and post-operative patient management are considerations essential to a successful surgical outcome.
• Patients should be instructed in detail about the limitations of the implants, including but not limited to the impact of excessive loading through patient weight or activity, and should be taught to govern their activities accordingly. ROI-C® implants (cages and anchoring plates) are load sharing devices which hold a vertebra in alignment until healing occurs. If healing is delayed or does not occur, the implant could eventually break due to material fatigue. An active, debilitated or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
• Risks associated with general surgery by anterior approach, orthopaedic surgery and the use of general anaesthesia as well as the per-operative lesions inflicted on the nervous system, possibly leading to temporary or permanent weaknesses, pain or functional lameness, and potential post-operative vascular disorders should be explained to the patient prior to surgery.
• Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life.
• Care must be taken to protect the components from being marred, nicked or notched as a result of a contract with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
• Inspection and trial assembly are recommended prior to surgery to determine if the instruments have been damaged during storage or prior procedures.
• After any surgery, it is necessary to check the proper position of the implants and to follow the evolution of the fusion using appropriate techniques.
• In case of implantation a cage higher than 7 mm, the long ROI-C® anchoring plates must be used.

In addition for ROI-C Bi-Pack:
• It is recommended to moist the synthetic bone substitute with physiologic serum before implantation, in order to reduce osmotic shocks risks.
• After any surgery, it is necessary to check the proper position of the implants and to follow the evolution of the fusion using appropriate techniques. The bone substitute BF+® is radio-opaque until the reduction. Radio-opacity
may mask underlying pathological conditions. Radiopacity may also make difficult the radiographic evaluation of the growth of the recently formed bone.

**Warnings**

- The safety and effectiveness of intersomatic spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring intervertebral fusion (implantation of a cage and a fusion system with associated instrumentation). These conditions are significant mechanical instability or deformity of the cervical spine secondary to degenerative disc disease, kyphosis and failed previous fusion (Pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

- Potential risks associated with the use of this system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular injury.

- All the implants damaged in any way that can infringe on their aspect or functioning must not be implanted.

- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it, or small defects may exist which may lead to fracture.

- Implants removed from a patient or that came in contact with bodily tissues or fluids should never be reused at risk of contamination of the patient.

- Devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until arthrodesis of segment(s) is confirmed, do not subject this device to the stress of heavy loads, or implant failure may result.

- Manufacturers employ different materials, manufacturing specifications and differing design parameters. Components of the ROI-C® System should not be used in conjunction with components from any other manufacturer. Any such use will negate the responsibility of LDR Médical for the performance of the resulting mixed component implant.

- If a non-fusion develops or if the components migrate and/or break, the devices should be revised and/or removed immediately before serious injury occurs.

- Any decision by a surgeon to remove the device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.

- Implant removal should be followed by adequate postoperative management to avoid fracture.

- Before implanting the ROI-C® anterior cervical cage, the vertebral plates must be carefully curetted and cleaned up without make them fragile so as to avoid the risk of subsidence.

- The setting and possible repositioning of the ROI-C® anterior cervical cage must be done with the cage holder attached to the cage. The anchoring plate must not be in the cage holder when the cage is set or repositioned.

- Once the cage is setting and is fixed to the vertebral plates with the anchoring plate, repositioning of the cage is not possible.

- In case of return of products, potential scrapping is managed by LDR Médical. If there is no return, distributor or health care center is responsible for the scrapping of products according to the local regulation.

- Mixing Metal: Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process, or even produce electric shocks. The presence of corrosion may accelerate fatigue fracture of implants and the amount of metal compounds released into the body system may also increase.

In addition for ROI-C Coated:
- Once the ROI-C® coated Implant is setting and is fixed to the vertebral plates with the anchoring plate, the use of instruments type electrocoagulator/electric scalpel is not recommended due to a risk of electric arc generation by interaction with the cage coating.

In addition for ROI-C Bi-Pack:
- The non respect of the single use can conduct to septic issues. Additionally the resorption process of this bone substitute started immediately after its implantation on the osseous defect so it cannot be re-used.

**MRI Safety Information**

**ROI-C®, ROI-C® Coated**

Non-clinical testing has demonstrated that the Interbody Cage Systems are MR-Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field of 3000 G/cm (30 T/m) or less.
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of 3.2-3.5 W/kg for 1.5T systems and 3.2-3.6 W/kg for 3T systems.
- When other methods of supplemental fixation are used, also follow the MR conditional labeling for the additional
components.

Under the scan conditions defined above, the ROI-C Implant System is expected to produce a maximum temperature rise of less than 1°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 0.8 cm from the ROI-C Implant when imaged with a gradient-echo pulse sequence in either a 1.5T or a 3T MRI system.

**ROI-C® Bi-Pack®**

ROI-C® Bi-Pack® is comprised of non-ferromagnetic titanium alloy (Ti6Al4V), polyetheretherketone (PEEK), Hydroxyapatite (HA), Beta-Tricalcium Phosphate (β-TCP) and tantalum.

Non-clinical testing has demonstrated that the Interbody Cage Systems are MR-Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T).
- Maximum spatial gradient field of 11,550 G/cm (115.50 T/m) for 1.5T systems and 5,780 G/cm (57.80 T/m) for 3.0T systems.
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of:
  - 4.0 W/kg for 15 minutes of scanning at 1.5T.
  - 4.0 W/kg pour 15 minutes de scanner à 3.0T.

Caution: 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.

- **1.5 T RF heating or 3 T RF heating**

  Under the scan conditions defined above, ROI-C® Bi-Pack® is expected to produce a maximum temperature rise of less than 1.0°C after 15 minutes of continuous scanning.

  Caution: 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.

- **1.5 T MR Artifacts**

  In non-clinical testing, the image artifact caused by the device extends approximately 0.7 cm from ROI-C® Bi-Pack® when imaged with a gradient-echo pulse sequence in a 1.5 T MRI system.

- **3 T MR Artifacts**

  In non-clinical testing, the image artifact caused by the device extends approximately 0.8 cm from ROI-C® Bi-Pack® when imaged with a gradient-echo pulse sequence in a 3 T MRI system.