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France

CE 0459

PLIFBOX LUMBAR CAGE

1 – DESCRIPTION

This instruction leaflet applies to the following Innov'Spine products:

PLIFBOX		
PLB-09-20-08-00-S	PLB-09-25-08-00-S	PLB-09-28-08-00-S
PLB-09-20-09-00-S	PLB-09-25-09-00-S	PLB-09-28-09-00-S
PLB-11-20-10-00-S	PLB-11-25-10-00-S	PLB-11-28-10-00-S
PLB-11-20-11-00-S	PLB-11-25-11-00-S	PLB-11-28-11-00-S
PLB-11-20-12-00-S	PLB-11-25-12-00-S	PLB-11-28-12-00-S
PLB-11-20-13-00-S	PLB-11-25-13-00-S	PLB-11-28-13-00-S
PLB-11-20-14-00-S	PLB-11-25-14-00-S	PLB-11-28-14-00-S
PLB-11-20-10-06-S	PLB-11-25-10-06-S	PLB-11-28-10-06-S
PLB-11-20-11-06-S	PLB-11-25-11-06-S	PLB-11-28-11-06-S
PLB-11-20-12-06-S	PLB-11-25-12-06-S	PLB-11-28-12-06-S
PLB-11-20-13-06-S	PLB-11-25-13-06-S	PLB-11-28-13-06-S
PLB-11-20-14-06-S	PLB-11-25-14-06-S	PLB-11-28-14-06-S
PLB-09-20-08-10-S	PLB-09-25-08-10-S	PLB-09-28-08-10-S
PLB-09-20-09-10-S	PLB-09-25-09-10-S	PLB-09-28-09-10-S
PLB-11-20-10-10-S	PLB-11-25-10-10-S	PLB-11-28-10-10-S
PLB-11-20-11-10-S	PLB-11-25-11-10-S	PLB-11-28-11-10-S
PLB-11-20-12-10-S	PLB-11-25-12-10-S	PLB-11-28-12-10-S
PLB-11-20-13-10-S	PLB-11-25-13-10-S	PLB-11-28-13-10-S
PLB-11-20-14-10-S	PLB-11-25-14-10-S	PLB-11-28-14-10-S
PLB-11-32-08-00-S	PLB-11-32-10-00-S	PLB-11-32-12-00-S
PLB-11-32-09-00-S	PLB-11-32-11-00-S	PLB-11-32-13-00-S
		PLB-11-32-14-00-S
PLIFBOX pre-filled		
PLB-09-20-08-00-PF	PLB-09-25-08-00-PF	PLB-09-28-08-00-PF
PLB-09-20-09-00-PF	PLB-09-25-09-00-PF	PLB-09-28-09-00-PF
PLB-11-20-10-00-PF	PLB-11-25-10-00-PF	PLB-11-28-10-00-PF
PLB-11-20-11-00-PF	PLB-11-25-11-00-PF	PLB-11-28-11-00-PF
PLB-11-20-12-00-PF	PLB-11-25-12-00-PF	PLB-11-28-12-00-PF
PLB-11-20-13-00-PF	PLB-11-25-13-00-PF	PLB-11-28-13-00-PF
PLB-11-20-14-00-PF	PLB-11-25-14-00-PF	PLB-11-28-14-00-PF
PLB-11-20-10-06-PF	PLB-11-25-10-06-PF	PLB-11-28-10-06-PF
PLB-11-20-11-06-PF	PLB-11-25-11-06-PF	PLB-11-28-11-06-PF
PLB-11-20-12-06-PF	PLB-11-25-12-06-PF	PLB-11-28-12-06-PF
PLB-11-20-13-06-PF	PLB-11-25-13-06-PF	PLB-11-28-13-06-PF
PLB-11-20-14-06-PF	PLB-11-25-14-06-PF	PLB-11-28-14-06-PF
PLB-09-20-08-10-PF	PLB-09-25-08-10-PF	
PLB-09-20-09-10-PF	PLB-09-25-09-10-PF	
PLB-11-20-10-10-PF	PLB-11-25-10-10-PF	
PLB-11-20-11-10-PF	PLB-11-25-11-10-PF	
PLB-11-20-12-10-PF	PLB-11-25-12-10-PF	
PLB-11-20-13-10-PF	PLB-11-25-13-10-PF	
PLB-11-20-14-10-PF	PLB-11-25-14-10-PF	

These products are for **single use** and are sold **sterile**.

2 - PRODUCT USE

These devices must only be implanted by a person who is well-trained in spine surgery. Device implantation must be performed using appropriate instrumentation provided by the manufacturer.
Before using the device, inspect the packaging (plastic-wrapped box sealed with a red "STERILE" sticker) to ensure that cage sterility has not been compromised. Remove the implant from its packaging using aseptic technique. Make sure the cage does not contact objects that could alter its surface finish.

Warning:

-Never reuse a cage that has previously been implanted.Reuse and/or resterilization of the device is prohibited because of the chemical, biological (allergy, toxicity, contamination, infection) and mechanical (deterioration, implant wear, etc.) risks.

-If removing the cage, appropriate extraction instrumentation must be used to avoid damaging bone, dura mater and/or nerve roots that could be hidden under fibrous tissue.

3 INDICATIONS

The PLIFBOX cage was designed to be used for posterior lumbar interbody fusion (PLIF). It is indicated in cases where the anterior spine must be stabilized during spinal canal decompression and posterior fixation procedures:

* Fusion with disc height preservation and need for direct nerve root decompression
* Instability where the nerve root requires direct decompression and the disc/vertebral height and proper lordotic curve need to be restored (an anterior approach must be used to correct pelvic retroversion and lordosis)
* Post-surgical iatrogenic destabilization of the lumbar spine
* Disc diseases
* Herniated disc
* Stenosis
* Isthmic or Grade 1 degenerative spondylolisthesis
* Degenerative lumbar scoliosis

The 10° PLIFBOX cage is preferably implanted at L5-S1.It can be used at adjacent levels if the patient's normal lordotic curvature is maintained.

4 CONTRAINDICATIONS

The following is a non-exhaustive list of contraindications:

* Acute or chronic, local or systemic infection (necrosis)
* Severe muscular, neurological, or vascular deficiency in the involved limb
* Bone damage (osteoporosis) or poor bone quality
* Bone tumor at the implantation site
* Any concurrent disease that could affect implant function
* Known or suspected metal allergy or intolerance
* Pregnancy
* Morbid obesity
* Mental illness, alcoholism or drug dependency
* Inadequate activity
* Use of a drug product in combination with this cage during implantation is the sole responsibility of the surgeon.
* Any case not included in the indications.

The contraindications for these devices are similar to those for other spine devices. This medical device is designed, intended and sold only for the uses indicated.

5 SIDE EFFECTS

The side effects are the same as those encountered during any surgical procedure: infection, pain, hematoma, nerve damage or injury, intolerance to materials, adjacent segment disease, and decompensation above or below fusion site.
Non-union at the bone fusion site or cage instability is possible. If this occurs, an additional surgical procedure may be needed.

Warning: Patients receiving a PLIFBOX Lumbar Cage should be advised that implant longevity may be affected by their weight, age and activity level, and that premature or inappropriate physical activity could also reduce its longevity.

6 - MATERIALS

PLIFBOX cages are made of PEEK-OPTIMA® LT, a material with proven biocompatibility.
The biocompatible, resorbable, calcium phosphate bone substitute is made of:
- 60% hydroxyapatite
- 40% tricalcium phosphate

Use of these components with devices other than those recommended by INNOV'SPINE is prohibited. The instrumentation is made of non-implantable stainless steel, titanium or RADEL®.
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7 – PACKAGING AND STERILITY

All implantable products are individually packaged in sterile protective tubes or boxes (gamma sterilized at min. 25 kGy).The expiry date is shown on a label on the outer packaging.

8 – RESTERILIZATION

Do not re-sterilize the implants. The manufacturer is not responsible for implants re-sterilized by the customer.

9 – HANDLING AND STORAGE

Implants should be stored away from humidity or external conditions that could lead to deterioration of the packaging and/or medical device. When handling the product, protect packaging and medical device from damage.

10 - SURGICAL TECHNIQUE

The PLIFBOX cage was designed to be used during posterior lumbar interbody fusion (PLIF).It is indicated in cases where the anterior spine must be stabilized during spinal canal decompression and posterior fixation procedures:
Fusion with disc height preservation and need for direct nerve root decompression
Instability where the nerve root requires direct decompression and the disc/vertebral height and proper lordotic curve need to be restored (an anterior approach must be used to correct pelvic retroversion and lordosis)
Isthmic or Grade 1 degenerative spondylolisthesis
Degenerative lumbar scoliosis
The preferred implantation site for the 10° PLIFBOX cage is L5-S1.It can be used at adjacent levels if the patient's normal lordotic curvature is maintained.
Posterior fixation must be performed in all cases.Aposterolateral(gutter) fusion procedure is not needed due to the high quality bone-bone interface provided by the PLIFBOX cage and its implantation technique.This spares the blood vessels and nerves in the posterior muscle compartments.

1.1. Perform a mid-line posterior approach to expose the three levels of laminae and spinous processes needed a single-level fusion.
1.2. To access the spinal canal, perform a laminectomy of the lower part of the laminae below the fusion level and the upper half of the laminae above the fusion level, and partial or complete arthrectomy (for cases ofretrolisthesis, degenerative spondylolisthesis and rotational dislocation).
1.3. After decompressing the nerve root, insert the pedicle screws under fluoroscopy guidance.
1.4. Use bipolar cautery to controlany bleeding of theepidural veins on both sides.
1.5. Disc space preparation
- Insert the nerve root retractor as far as the midline
- Have visual control over the nerve root in the intervertebral foramen above the fusion site at all times
- Incise the intervertebral disc using a scalpel with a thin-blade
- Use disc forceps to perform the discectomy
- Use the intradiscal probe to make sure the anterior longitudinal ligament is still intact
- If needed, apply a slight distraction to the pedicle screws to expose the disc; this distraction will be gradually increasedduring the next surgical steps
- CAUTION: in osteoporotic bone, both sides can be exposed to allow placement of a trial cage in one side while the other side is being prepared

1.6. Endplate preparation
- Use gradually largerdistractorblades to determine the appropriate cage size
- Insert the disc space probe again to check the strength of the anterior longitudinal ligament
- Although anterior longitudinal ligament rupture is not a contraindication to the use of this cage, fluoroscopy is needed to check the endplate length to be sure the length markers on the cylindrical reamer are not exceeded
- Under fluoroscopy guidance, use the cylindrical reamer corresponding to the chosen cage size to freshen the bone

1.7. Cage angle selection
- Select the appropriate cage angle based on the angle of the endplates at the instrumented level.The following two cage angle options are available:0° and 6°.If using an empty cage, fill the cage before inserting it into the intervertebral disc space.

1.8. Cage placement
- To insert the cage, screw the holder into the threaded hole on the back of the cage
- Insert the cage with itsteeth facing the vertebral endplates and then impact the cage
- Remove the cage holder and then the nerve root retractor
- Check the nerve root tension

1.9. Posterior fixation
- Apply sufficient compression to achieve the desired stability and/or correction

1.10. Close the wound and install a drain.

11 – PRODUCT-RELATED COMPLAINTS

Any health professional who is not satisfied with or who has a complaint regarding the quality, identification, reliability, safety, effectiveness or performance of PLIFBOX cages must notify INNOV'SPINE. If a serious adverse event occurs or if such an event could have caused or led to the death or to serious deterioration in the health of a patient or user, INNOV'SPINE must be notified immediately by telephone, fax or mail.

Year CE mark was received for the empty cage: 2012

Year CE mark was received for the pre-filled cage: 2015

	Manufacturer	REF	Catalog number	LOT	Batch code		Use by	STERILE R	Sterilized using irradiation		Keep away from sunlight
	Do not resterilize		Do not reuse		Caution, consult accompanying documents		Consult instructions for use		Do not use if package is damaged		Keep dry

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