INNOV'spine
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France

CE 0459

TLIFBOX LUMBAR CAGE

1 - This instruction leaflet applies to the following products

TLIFBOX		
TLB-20-09-07-04-S	TLB-25-09-07-04-S	TLB-30-09-07-04-S
TLB-20-09-08-04-S	TLB-25-09-08-04-S	TLB-30-09-08-04-S
TLB-20-11-09-04-S	TLB-25-11-09-04-S	TLB-30-11-09-04-S
TLB-20-11-10-04-S	TLB-25-11-10-04-S	TLB-30-11-10-04-S
TLB-20-11-11-04-S	TLB-25-11-11-04-S	TLB-30-11-11-04-S
	TLB-25-11-12-04-S	TLB-30-11-12-04-S
	TLB-25-11-13-04-S	TLB-30-11-13-04-S
TLB-35-09-07-04-S	TLB-35-11-10-04-S	TLB-35-11-12-04-S
TLB-35-09-08-04-S	TLB-35-11-11-04-S	TLB-35-11-13-04-S
TLB-35-11-09-04-S		
TLIFBOX pre-filled		
TLB-20-09-08-04-PF	TLB-25-09-08-04-PF	TLB-30-09-08-04-PF
TLB-20-11-09-04-PF	TLB-25-11-09-04-PF	TLB-30-11-09-04-PF
TLB-20-11-10-04-PF	TLB-25-11-10-04-PF	TLB-30-11-10-04-PF
TLB-20-11-11-04-PF	TLB-25-11-11-04-PF	TLB-30-11-11-04-PF
	TLB-25-11-12-04-PF	TLB-30-11-12-04-PF
	TLB-25-11-13-04-PF	TLB-30-11-13-04-PF
TLB-35-09-08-04-PF	TLB-35-11-10-04-PF	TLB-35-11-12-04-PF
TLB-35-11-09-04-PF	TLB-35-11-11-04-PF	TLB-35-11-13-04-PF

TLIFBOX lumbar cages are for **single use** and 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 TLIFBOX cage was designed to be used during transforaminal lumbar interbody fusion (TLIF). 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
* Herniated disc
* Isthmic or Grade 1 degenerative spondylolisthesis
* Stenosis

4 – CONTRAINDICATIONS

The following is a non-exhaustive list of contraindications:
* Acute or chronic, local or systemic infection
* Severe muscular, neurological, or vascular deficiency in the involved limb
* Bone damage or poor bone quality (osteoporosis, necrosis, etc.)
* 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

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, bleeding, nerve damage, etc.
Non-union at the bone fusion site or cage instability is possible. If this occurs, an additional surgical procedure may be needed.

6 - MATERIALS

TLIFBOX 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®.

7 – PACKAGING AND STERILITY

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

8 – RESTERILIZATION

Do not resterilize 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 TLIFBOX cage was designed to be used during transforaminal lumbar interbody fusion (TLIF). 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
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* Stenosis

Posterior fixation must be performed in all cases. An additional poster lateral (gutter) fusion procedure is not needed due to the high quality bone-bone interface provided by the TLIFBOX cage and its implantation technique. This spares the blood vessels and nerves in the posterior muscle compartments.

1. Perform a mid-line posterior approach to expose the three levels of laminae and spinous processes needed for a single-level fusion.

1.1 To access the spinal canal, perform a laminectomy of lower part of the laminae below the fusion site and the upper half of the laminae above the fusion level, and partial or complete arthrectomy (for cases of retrolisthesis, degenerative spondylolisthesis and rotational dislocation).

1.2 After decompressing the nerve root, insert the pedicle screws under fluoroscopy guidance.

1.3 Use bipolar cautery to control any bleeding of the epidural veins on both sides.

1.4 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 increased during 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

1.5 Endplate preparation
- Use gradually larger distractor blades 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 curved scissors are not exceeded
- Under fluoroscopy guidance, use the curved scissors corresponding to the chosen cage size to freshen the bone
- Use a reversed angle curette to perform additional freshening of the vertebral endplates

1.6 Cage length selection
- Select the appropriate implant size for the desired amount of sagittal correction
- Two cages can be used to correct degenerative lumbar scoliosis and obtain better stability (all the listed cage sizes are fully compatible and can be combined with each other)

Cage placement
- To insert the cage, screw the holder into the threaded hole on the back of the cage
- Insert the cage with its flat side facing the vertebral endplates – insertion should be easy
- Verify the A/P position of the cage and then use the holder to rotate it into place
- The half-moon shaped impactor can also be used to rotate the cage
- Remove the cage holder and then the nerve root retractor
- Check the nerve root tension

1.7 Cage filling (additional procedure for empty cages)
- Screw the packing funnel into the cage
- Add the graft to the funnel
- Use the stylet to impact the graft

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

1.9 Close the wound and install a drain.

1.10 Postoperative care
- Anticoagulant use depending on risk factors
- Patient can get up once drain is removed
- If the patient has fragile bones, sitting is allowed at Day 45 after surgery
- Patients with fragile bones should wear a Lombostat back brace
- Rehabilitation can start during the third week post-surgery
- Postoperative follow-ups: 45 days, 3 months, 6 months, 1 year, 3 years, 5 years, 10 years

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

Last revision: 03/2015