Two cages can be used to correct degenerative lumbar fusion with disc height preservation and need for direct nerve root decompression.

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
- Hemiated disc
- Isthmic or Grade 1 degenerative spondylolisthesis
- Spondylolisthesis

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 arthritis, or instable discs). Place the cage holder in the epidural veins on both sides.

1.2 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.
- 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. Use gradually larger distractor blades to determine the amount of sagittal correction needed.
- Use bipolar cautery to control any bleeding of the epidural veins on both sides.

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
- 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, flavocyscopy is needed to check the endplate length to be sure the length markers on the curved scissors are not exceeded.
- Under flavocyscopy 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

1.5 Cage length selection
- Select the appropriate implant size for the desired amount of sagittal correction

1.6 Cage length selection
- 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

Cage filling (additional procedure for empty cages)
- Screw the packing funnel into the cage
- Add the graft to the funnel
- Use the stylus to impact the graft
- Posterior fixation
- Apply sufficient compression to achieve the desired stability and/or correction
- Close the wound and insert a drain.

1.10 Postoperative care
- Anticoagulant usage 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 for 3 years, 5 years, 10 years

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.

1. 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:

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 (osteopenia, 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

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 and 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 bioresorbable, 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.

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: