IMPORTANT INFORMATION
about

ASPEN CERVICAL CAGE

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CE 0459

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PEEK-OPTIMA®

1 – DESCRIPTION

This instruction leaflet applies to the following ATF products:
- Cervical cage made of PEEK-OPTIMA® LT (8 sizes)
Part Numbers:ASPEN45, ASPEN55, ASPEN65, ASPEN75, ASPEN85, ASPENP45, ASPENP55, ASPENP65
- Pre-filled Cervical cage made of PEEK-OPTIMA® LT (8 sizes)
Part Numbers:ASPENR45, ASPENR55, ASPENR65, ASPENR75, ASPENR85, ASPENRP45, ASPENRP55, ASPENRP65.
- Locking Cervical cage made of PEEK-OPTIMA® LT (8 sizes)
Part Numbers:ASPENV45, ASPENV55, ASPENV65, ASPENV75, ASPENV85, ASPENPV45, ASPENPV55, ASPENPV65.
- Pre-filled, locking Cervical cage made of PEEK-OPTIMA® LT (8 sizes)

Part Numbers:ASPENRV45, ASPENRV55, ASPENRV65, ASPENRV75, ASPENRV85, ASPENRPV45, ASPENRPV55, ASPENRPV65.
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 orthopedic 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

This medical device can be used only to treat cervical disc diseases such as refractory radiculopathy (radiating pain) and/or myelopathy (weakness) with a herniated disc and/or osteophyte formation and/or spinal cord compression.The ASPEN Cervical Cage is ananatomically designed cage for the anterior cervical spine.It helps to restore disc height and the normal lordotic curvature.The device's large cavities are pre-filled with a bone substitute to ensure good bone fusion.

4 – CONTRAINDICATIONS

The following is a non-exhaustive list of contraindications:
* Acute or chronic, local or systemic infection
* Bone damage or poor bone quality, osteoporosis, necrosis
* Severe muscular, neurological, or vascular deficiency in the involved limb
* Bone tumor at the implantation site
* Any concurrent disease that could affect implant function
* Pregnancy
* Morbid obesity
* Known or suspected metal allergy or intolerance
* Mental illness, alcoholism or drug dependency
* Inadequate activity
* Metabolic acidosis and insulin-dependent diabetes
* Any known allergies to this type of implant

Use a drug product in combination with this cageduring implantation is the sole responsibility of the surgeon.
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, thrombosis and in very rare cases, reaction to the anesthesia, pulmonary embolism, infarction.Because an anterior cervical surgical approach is used, the following effects can occur:hoarseness or difficulty swallowing, non-union, adjacent segment disease, nerve damage.
As the bone substitute in the pre-filled cages degrades, calcium phosphate particles are released and degraded in the lysosomes of phagocytic cells.
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 pre-filled ASPEN Cervical 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

The cages are made of PEEK-OPTIMA® LT (ASTM F2026), a material with proven biocompatibility.
Pre-filled cages:synthetic bone substitute (ASTM F1185)
These cages have cavities that are pre-filled with a biocompatible, resorbable, synthetic, calcium phosphate bone substitute (MBCP™) made of 60% hydroxyapatite and 40% tricalcium phosphate.
Because of its chemical composition, calcium phosphate cement is replaced by newly formed bone when placed in direct contact with a bone surface.This bone integration is the result of simultaneous bone apposition and cement resorption.
Locking cages:blades and fixation screws are made of TA6V titanium alloy (ISO 5832-3)
Use of these components with devices other than those recommended by ATF is prohibited.The instrumentation is made of non-implantable stainless steel or RADEL®.
Advantages of the pre-filled cage:
Radiopaque, no risk of immunological reaction or infection, biocompatible, no need to harvest an autologous bone graft (painful and high-morbidity procedure), shorter surgery time
Advantages of the locking cage:
No additional fixation is needed to ensure cage does not migrate.

7 – PACKAGING AND STERILITY

All implantable products are individually packaged in sterile protective boxes (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 resterilized 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.

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10 - IMPLANTATION TECHNIQUE

Implant selection:
For the procedure to be successful, selecting the proper implant type, shape and size for each patient is crucial. After implantation, the implants are subjected to repeated loading; their strength is limited by how well their geometry fits to the size and shape of human bones.To minimize implant loads, carefully select patients based on the above indications, make sure the implant is placed correctly, and communicate appropriate postoperative care.
Preoperative management:
Patients must meet the criteria described in the indications.
Implants must be handled and stored very carefully.They must not be scratched or damaged.
Further information on the use of this system is available upon request.

Intraoperative management:
Step 1
Anterior cervical approach,discectomy and decompression
Step 2
Prepare the vertebral endplates.Implant a trial ASPENCervical Cage to verify the flatness of the endplates, ensure maximum contact area and confirm the exact size of the final implant.
Step 3
Thread the selected ASPEN Cervical Cage onto the impactor handle. The cage orientation is marked by a small triangle (tip pointing up Δ) on the front of the cage.If using a cage that is not pre-filled, use the compactor to compact cancellous bone into the graft compartment of the implant.
Warning: Do not damage the threads when screwing the cage onto the handle; any damage could lead to particles being released when the instrumentation is removed.
Step 4
Apply a slight distraction and then carefully impact the ASPEN Cervical Cage into the intervertebral space.
Warning: If using the locking cage, any accessory vertebral distraction devices (Caspar pins) must be removed before turning the blades. Once these are removed and the cage well seated, use the screwdriver to turn and screw the blades into the vertebral endplates.
If using the non-locking ASPEN cage, release the distraction.
Step 5
Close the incision.
Postoperative management:
It is extremely important for the patient to follow the postoperative instructions and warnings provided by the surgeon.
Detailed instructions on the use and limitations of the device must be provided to the patient.The patient should be advised to limit and restrict his/her physical activities, avoid smoking and excessive alcohol consumption during the healing of the bone graft.
Poor bone healing will, over time, result in excessive, repeated loads on the implant.In this case, the fusion level should be immobilized and the healing verified with X-rays.If fusion does not occur, the device must be immediately revised and/or removed before a serious injury occurs.

11 - PRODUCT-RELATED COMPLAINTS

Any health professional who is not satisfied with or who has a complaint regarding product quality, identification, reliability, safety, effectiveness or performance must notify the distributor and/or ATF.In addition, if a part did not work properly and/or could have caused and/or contributed to a patient's death or serious injury, the distributor or ATF must be notified immediately.