Instructions For Use
LATITUDE-C™ CERVICAL INTERBODY SPACER

DESCRIPTION
The DeGen Medical Latitude-C™ Cervical Interbody Spacer is an interbody fusion device. The Latitude-C™ consists of various sizes of footprint and comes in heights from 5mm to 14mm measured at anteriormost location. Each device can be parallel, lordotic or convex in shape.

Latitude-C™ PEEK Cervical Interbody Spacer is made of PEEK and tantalum pins.
Latitude-C™ Porous Ti Cervical Interbody Spacer is made of PEEK, tantalum pins and commercially pure titanium.
Latitude-C™ HA PEEK Cervical Interbody Spacer is made of PEEK-OPTIMA HA and tantalum pins.
Latitude-C™ CFR Cervical Interbody Spacer is made of CFR PEEK-OPTIMA and tantalum pins.
Latitude-C™ Ti Cervical Interbody Spacer is made of titanium alloy, Ti-6Al-4V ELI.

INDICATIONS:
The Latitude-C™ Interbody Spacer is indicated for spinal fusion procedures at one level in the cervical spine (C2-T1), in skeletally mature patients with degenerative disc disease. Degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.

The Latitude-C™ Interbody Spacer is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation, eg. Hyper-C™ Anterior Cervical Plate System.

Patients must have undergone a regimen of at least six weeks of non-operative treatment prior to being treated with the Latitude-C™ Interbody Spacer in the cervical spine.

CONTRAINDICATIONS
Contraindications include, but are not limited to:
- Active or suspected local or systemic infection
- Obesity: An overweight or obese patient 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
- Fractures and tumors with loss of anterior support
- Pregnancy
- Osteoporosis
- Systemic or metabolic bone conditions
- Foreign body sensitivity
- Patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during healing and may be at higher risk for implant failure
- Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count, or marked left shift in the WBC differential count.

PRECAUTIONS
- The implantation of spinal fixation devices should be performed only by experienced surgeons with specific training in the use of such devices. This is a technically demanding procedure presenting a risk of serious injury to the patient.
- Patient Selection: In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
  1. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant.
  2. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant.
  3. Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
  4. Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures where bone graft is used.
  5. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Size Selection: The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant.
- Implant Failure: Implants can break when subjected to increased loading associated with delayed union or non-union. External fixation appliances are load-sharing device that are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to fatigue. The success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of implants.
- Do not reuse surgical implants: An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

WARNINGS
- Prior to use, read all package insert instructions and precautions. Proper device selection should be made for the individual anatomical needs.
- Magnetic Resonance (MR) Safety: The DeGen Medical Latitude-C™ Cervical Interbody Spacer has not been evaluated for safety and compatibility in the MR environment. The system has not been tested for heating or migration in the MR environment.
- Unless stated otherwise, DeGen Medical devices are not to be combined with the components of another system. Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage. Proper placement must take into consideration of anatomy of the patient in and around the surgical site to avoid potential damage.
- Removing of implant after healing: The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
- Instructions to the Patient: Postoperative care and the patient's willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and follow the postoperative care regimen as instructed by his or her physician.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

POSSIBLE ADVERSE EFFECTS

- Infection, early or late; Pain, discomfort, or abnormal sensations due to the presence of the device; Nonunion, delayed union; Bending or fracture of implant; Loosening of the implant; Metal sensitivity or allergic reaction to a foreign body, including possible tumor formation; Decrease in bone density due to stress shielding; Fracture of bony structures; Injury to the neck, including the esophagus, trachea, carotid artery, larynx, or laryngeal nerves; Cessation of growth of the fused portion of the spine; Loss of proper spinal curvature, correction, height and/or reduction; Nerve damage due to surgical trauma or presence of the device; Neurological difficulties including radicular pain, tethering of nerves in scar tissue, muscle weakness and paresthesia; Early or late hoarseness, dysphagia, or dysphonia; Vascular damage could result in catastrophic or fatal bleeding; Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period; Bursitis; Reflex sympathetic dystrophy; Spinal cord impingement or damage, dural tear or leak; Degenerative changes or instability in segments adjacent to fused vertebral levels; Paralysis; Death.

CLEANING of INSTRUMENTS and IMPLANTS

- Unless just removed from an unopened package, all instruments and implants must be disassembled (if applicable) and cleaned before sterilization
- Cleaning Precautions: Avoid excessively acidic or alkaline solutions. Do not exceed two hours soaking in any solution. Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

A. PRE-CLEANING

- Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. Remove gross contaminants with a steady stream of lukewarm/cool water (below 110° F/43° C). Disassemble the devices where possible to expose all surfaces and clean separately.

B. MANUAL CLEANING

- Immerse the devices in solution of tap water and enzymatic cleaner. Follow manufacturers' directions regarding concentration, temperature, and contact time. Use a syringe to ensure that solution reaches all parts of cannulations and close mating surfaces where necessary. Ensure that air is not trapped within features of the device when immersing in the solution.
- After soaking is completed use nylon brushes to clean the devices thoroughly paying particular attention to features where soil may be shielded from the brushing. Use a firm bristle brush for cleaning bone-cutting features such as drill tips, reamer flutes, teeth of broaches, etc. Use a bottle brush of appropriate diameter for cannulations. Ensure that the brush passes the whole length of each cannulation at least three times.
- If a device may not be disassembled, or has a long cannula, use an ultrasonic bath and process at the frequency, temperature, contact time, and concentration recommended by the enzymatic agent manufacturer. Immerse the device completely in solution of tap water and enzymatic agent and activate the ultrasonic bath.
- Remove the instruments from the cleaning solution and transfer to a purified water bath and soak for 1 minute.
- Thoroughly rinse with purified water for a minimum of 1 minute paying attention to flush lumens, blind holes and difficult to reach areas.
- Carefully inspect each device to ensure that all visible contamination has been removed and thoroughly clean. If contamination is noted repeat the cleaning process.

C. AUTOMATED CLEANING (OPTIONAL)

- Automated cleaning is in addition to manual cleaning (step B.) and automated cleaning does not replace manual cleaning.
- If automated cleaning equipment is used, ensure the washer meets approved efficacy (Validated according to ISO 15883).
- Load the medical devices into the washer. Ensure cannulations and blind holes are not horizontal. Articulating devices should be in the open position. Connect cannulations to the rinsing ports of the washer where possible. Make sure all instruments stay in place and do not touch or overlap each other.
- Operate the washer-disinfector cycle.
- Carefully inspect each device to ensure that all visible contamination has been removed and thoroughly clean. If contamination is noted repeat the cleaning process.

D. DRYING

- Place on drying rack and allow to air dry until no water remains. Drying may be expedited by use of lint free cloth or clean compressed air.

INSPECTION

- Inspect all devices before sterilization or storage to ensure the complete removal of soil from surfaces, lumens, holes and movable parts.
- If damage or biological residue is observed, the implant or instrument must be discarded. Return damaged items to DeGen Medical.
- Do not use if damage or wear is noted that may compromise the proper function of the instrument or instrument case. Contact customer service or your DeGen Medical representative for a replacement.
- If corrosion is noted, do not use and contact customer service or your DeGen Medical representative for a replacement.

STERILIZATION

Unless marked sterile and clearly labeled as such in an unopened sterile package, all implants and instruments used in surgery must be sterilized prior to use. Remove all packaging materials prior to sterilization. All implants and instruments should be cleaned and sterilized prior to surgery. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled within the instrument tray(s). Implants and instruments should be positioned to allow the steam to come into contact with all surfaces. Do not stack trays during sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be wrapped in a FDA cleared sterilization wrap and steam sterilized.

The following is the recommended sterilization cycle:

Method:	Steam
Cycle:	Pre-Vacuum
Temperature:	270° F (132° C)
Exposure Time:	4 minutes
Drying Time:	45 minutes

STERILE IMPLANTS

For implants supplied sterile, the contents are sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Do not use the implants if the condition of the package and/or labeling indicates a chance that the devices may not be sterile. Implants supplied sterilized from the manufacturer must not be re-sterilized.

WARRANTY

The DeGen Medical products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties are hereby disclaimed.

CAUTION

Federal law (USA) restricts this device to sale, distribution and use by or on the order of a physician.

INFORMATION

To view Surgical Technique Guide or for further information, please contact customer service via phone or mail at:

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