Hive™ Stand-alone Anterior Lumbar Interbody System

PURPOSE

The Hive™ Stand-alone Anterior Lumbar Interbody System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to instrumented fusion of the lumbar and sacral spine.

DESCRIPTION

The Hive™ Stand-alone Anterior Lumbar IBFD System consists of interbody fusion cages made from Ti-6Al-4V implant-grade titanium conforming to ASTM F3001 using additive manufacturing technology and screws & screw cover plates made from Ti-6Al-4V conforming to ASTM F136. The titanium takes the form of a highly porous core which is surrounded at the cephalad and caudal ends by protective solid titanium endplates. The implant is anatomic in shape and has teeth to ensure placement is maintained after implantation. Implants incorporate features for fixating the device to the vertebral body in a stand-alone manner using either interfixated features within the intervertebral space or outer plate fixation on the anterior surface of the vertebral bodies. Inter-fixation and outer-fixation allow adjustable placement of fixation components.

The implants of the Hive™ Stand-alone Anterior Lumbar IBFD System are offered in a variety of lengths, widths and cross-sectional geometries to accommodate patient anatomy and surgical approach. The implants are also offered in various lordotic configurations to ensure proper stability and alignment of the spine for differing patient anatomy. The implants are provided pre-sterile, in validated sterile packaging, and are one-time use only.

Provided with the Hive™ Stand-alone Anterior Lumbar IBFD System are stainless steel and silicone instruments used for implantation of the device. The perforated instrument cases hold the instruments and must be sterilized in an FDA-approved steam autoclave using the sterilization cycle described below. Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA-approved sterilization wrap to maintain sterility.

No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Never use titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct. Medical grade titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy may be used together.

None of the Hive™ Stand-alone Anterior Lumbar IBFD System components should ever be reused under any circumstances.

INDICATIONS

The Hive™ Stand-alone Anterior Lumbar Interbody System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone and allograft bone comprised of cancellous and/or corticocancellous bone. These devices are intended to be used with the screws which accompany the implants. When used with the accompanying screws, these devices may be used as stand-alone interbody devices. If the accompanying screws are not used the device is intended for use with supplemental fixation.

Hyperlordotic implants (20° and greater lordosis) must be used with supplemental fixation (e.g. posterior fixation) that are cleared by the FDA for use in the lumbar spine.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection (immunocompromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
12. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
13. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
14. Any patient unwilling to follow postoperative instructions.
15. Any case not described in the indications.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

1. Severe bone resorption.
2. Osteomalacia.
3. Severe osteoporosis.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Disassembly, bending, and/or breakage of any or all of the components.
2. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
3. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
4. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
5. Infection.
6. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
7. Loss of neurological function, including complete or partial paralysis, dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
8. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
9. Urinary retention or loss of bladder control or other types of urological system compromise.
10. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
11. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
12. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
13. Non-union (or pseudarthrosis). Delayed union. Mal-union.
14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility.
16. Inability to perform the activities of daily living.
17. Bone loss or decrease in bone density, possibly caused by stresses shielding.
18. Graft donor site complications including pain, fracture, or wound healing problems.
19. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
20. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

WARNING

The safety and effectiveness of Interbody spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses. In the absence of fusion, the implants may fracture as a result of exposure to everyday mechanical stresses for a period greater than that tested in the pre-clinical evaluation.

The Hive™ Stand-alone Anterior Lumbar Interbody System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Hive™ Stand-alone Anterior Lumbar Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRECAUTION

The implantation of a stand-alone interbody spacer should be performed only by experienced spinal surgeons with specific training in the use of stand-alone interbody spacer devices because this is a demanding procedure presenting a risk of serious injury to the patient. A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. Use of this product without the provided screws or other supplemental fixation or in cases that develop into a non-union will not be successful. Spinal implants cannot withstand body loads without the support of bone. In this event breakage of the device(s) will eventually occur. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the intervertebral body fusion device. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol-abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

PHYSICIAN NOTE Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

IMPLANT SELECTION

It is always important to select the right height and footprint implant for the patient anatomy. This sizing should be based both on radiographic review of the patient anatomy and in situ evaluation using the provided sizing tools.

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to

minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling of the implant components. The implants should not be scratched or otherwise damaged.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.
6. All instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Sizing tools must be used to ensure that an oversized implant is not used. Always insert the spacer that is the appropriate size for the patient according to the sizing tool.
4. Utilize an imaging system to facilitate surgery.
5. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications that may occur as a result of excessive or early weight-bearing or muscular activity. The risk of breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the Hive™ Stand-alone Anterior Lumbar Interbody System components should never be reused under any circumstances.

PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components, including instruments, should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used and should be returned to NanoHive Medical.

Do not use if package is opened or damaged or if expiration date has passed.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened NanoHive Medical package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to NanoHive Medical. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

The Following Instruments require disassembly for cleaning: **Stand-alone ALIF Inserter (Gen 1), Stand-alone ALIF Inserter (Gen 2) - Inserter Handle,** and **Anterior Spreader.**

Cleaning Instructions:

The recommended manual cleaning instructions are described below:

1. Immediately after the surgical procedure, remove as much debris as possible from each instrument using a water moistened gauze pad, exchanging the gauze pad if it becomes soiled. Instruments should be soaked immediately after use; soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately, wrap them in a moist towel to prevent desiccation.
2. If applicable, dissemble the instruments.
   a. Disassemble Gen 1 Inserter stylet and knob from the shaft.
   b. Disassemble Gen 2 Inserter stylet from the shaft.
   c. Disassemble Anterior Spreader tips from the handle. Fix the spreader handle in a semi-open position.
3. Prepare a neutral pH enzymatic soak per the manufacturer's instructions. Soak the instruments for a minimum of 15 minutes. Actuate any working mechanisms 5X (such as Angled Driver rotation, hex nut on Gen 2 and Gen 3 Stand-alone ALIF Inserter - Implant Holders). Change the soak solution if grossly soiled.
4. While still in the soak solution, use a soft bristled brush or clean cloth to remove all visible soil. Use an appropriate size cleaning brush to thoroughly brush the entire length of any lumens.
5. After the enzymatic soak, rinse instruments thoroughly with clean warm water, taking care to flush all lumens or crevices, for at least one minute each until water runs clear.
6. Rinse the instruments again in Deionized water. Repeat until all visible residues have been removed and the water runs clear. If instruments are not visibly clean, repeat cleaning steps #2-#6.
7. Dry the instruments with a sterile gauze pad and use clean compressed air or 70% isopropyl alcohol to dry the lumens or crevices.
8. Perform a visual inspection on the instruments and verify that they are clean, dry and in good working order prior to sterilization.

The Stand-alone ALIF Inserter (Gen 1), Stand-alone ALIF Inserter (Gen 2) - Inserter Handle, and Anterior Spreader must be cleaned disassembled to achieve sterilization. The Anterior Spreader may be re-assembled for sterilization.

STERILIZATION

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by NanoHive Medical, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are to be steam sterilized by the hospital using the process parameter below:

Method	Sterilization Temperature	Sterilization Duration	Dry Time
Pre-vacuum	270° F (132°C)	4 minutes	20 Minutes

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperatures, times) used for their equipment.

*For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

PRODUCT COMPLAINTS

Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the manufacturer, NanoHive Medical. Further, if any implanted spinal system component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the manufacturer distributor should be notified immediately. If any NanoHive Medical product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FOR FURTHER INFORMATION:

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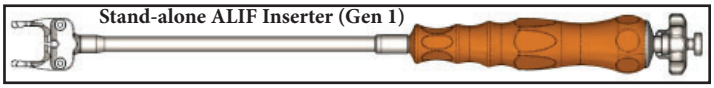
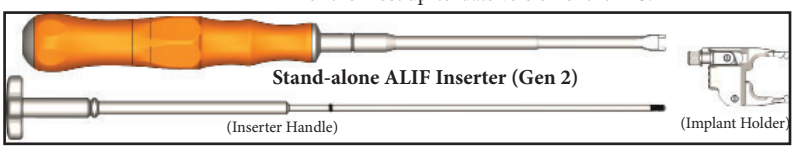
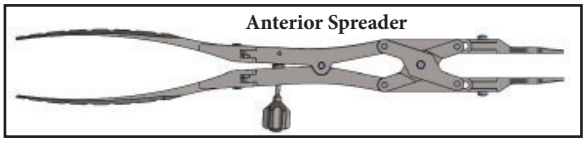
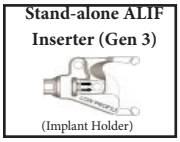
Contact Customer Service or your Sales Representative for the most up-to-date version of the IFU.









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