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INTEGRATE®-C FUSION SYSTEM
INSTRUCTIONS FOR USE

DESCRIPTION

The HAPPE® INTEGRATE®-C Fusion Device is for Anterior Cervical Discectomy and Fusion (ACDF). The INTEGRATE®-C Fusion Device is made from Hydroxyapatite Porous PolyEtheretherketone (HAPPE®).[1] The INTEGRATE®-C Fusion Device is monolithic with porous regions derived directly from the implant body, not a sintered or otherwise additive coating, and extended through the device. Hydroxyapatite is fully integrated throughout porous and dense regions of the device. Porous regions are designed to mimic anatomic cancellous bone with interconnected spherical pores and hydroxyapatite exposed on pore surfaces. Unlike nonporous PEEK, the porosity and surfaces of the HAPPE material are designed to promote cell signaling, ongrowth, ingrowth and fusion.[2] The INTEGRATE®-C Fusion Device may provide increased opportunity for bone ingrowth and achieving early integration. *In vitro performance or animal studies may not be representative of clinical performance*. The device is available in a variety of footprints, lordosis and heights to accommodate variations in the individual pathology and anatomy of the patient. The superior and inferior surfaces of the device contain a pattern of teeth to aid initial stability. The device is radiolucent allowing post-operative assessment of fusion, while radiopaque markers are placed in the device to aid in determining the location of the implant intra- and post-operatively.

INDICATIONS FOR USE

The INTEGRATE®-C Fusion System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The INTEGRATE®-C Fusion System is intended for use in anterior cervical interbody fusion for patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy,

[1] HAPPE® by HAPPE Spine, LLC, Grand Rapids, MI.

[2] R.K. Roeder, J.F. Nagle and D. Snell, "Translating Porous and Bioactive PEEK to Interbody Spinal Fusion Implants," *Society for Biomaterials Annual Meeting*, 2021. University of New South Wales – Surgical & Orthopaedic Research Laboratories – Evaluation of osteointegration in a large animal model. Note: the porous structure of the HAPPE® material in the INTEGRATE®-C Fusion Device has been modified from that used for this ovine study with the intent to further increase pore interconnectivity for bone in-growth

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myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The INTEGRATE®-C Fusion System is intended to be used with supplemental fixation. The INTEGRATE®-C Fusion System is designed for use with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate as an adjunct to fusion. Nonoperative treatment prior to treatment with INTEGRATE®-C Fusion System is six (6) weeks. INTEGRATE®-C Fusion Devices are to be implemented via an open anterior approach.

CONTRAINDICATIONS

- Active local infection in or near the operative region.
- Active systemic infection and/or disease.
- Severe osteoporosis or insufficient bone density, which in the medical opinion of the physician precludes surgery or contraindicates instrumentation.
- Prior surgical procedure using the desired operative approach.
- Spinal conditions other than cervical degenerative disc disease.
- Current metastatic tumors of the vertebrae adjacent to the implant.
- Known or suspected sensitivity to the implant materials.
- Endocrine or metabolic disorders known to affect osteogenesis (e.g., Paget's disease, renal osteodystrophy, hypothyroidism).
- Systemic disease that requires the chronic administration of nonsteroidal anti-inflammatory or steroidal drugs.
- Significant mental disorder or condition that could compromise the patient's ability to remember and comply with preoperative and postoperative instructions (e.g., current treatment for a psychiatric/psychosocial disorder, senile dementia, Alzheimer's disease, traumatic head injury).
- Neuromuscular disorder that would engender unacceptable risk of instability, implant fixation failure or complications in postoperative care. Neuromuscular disorders include spina bifida, cerebral palsy and multiple sclerosis.
- Pregnancy.
- Patients unwilling to follow postoperative instructions, especially those in athletic and occupational activities.
- Morbid obesity.
- Symptomatic cardiac disease.
- Skeletal immaturity.
- Grossly distorted anatomy.
- Conditions other than those indicated.

POTENTIAL ADVERSE EVENTS & COMPLICATIONS

As with any major surgical procedure, there are risks involved in spinal/orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional

surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; pleural effusions, hemothorax, chylothorax, pneumothorax, subcutaneous emphysema, need for chest tube insertion, intercostal neuralgia, rib fracture, diaphragm injury; atelectasis; impotence; permanent pain and/or deformity. Rarely, some complications may be fatal. The treatment of multilevel degenerative scoliosis may be associated with a lower interbody fusion rate compared to one- and two-level interbody fusions. Potential risks identified with the use of this system, which may require additional surgery, include:

- Bone loss or decrease in bone density possibly caused by stress shielding.
- Bending, fracture or loosening of implant component(s).
- Loss of fixation, and implant migration.
- Loss of spinal mobility or function.
- Nonunion or delayed union.
- Subsidence of the device into vertebral body(ies).
- Fracture of the vertebra.
- Neurological, vascular or visceral injury.
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise.
- Graft donor site complications including pain, fracture, infection, or wound healing problems.
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Ileus, gastritis, bowel obstruction or other types of gastrointestinal complications.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and/or meningitis.
- Metal sensitivity or allergic reaction to a foreign body.
- Infection.
- Pain, discomfort or abnormal sensations due to the presence of the device.
- Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.
- Change in mental status.
- Inability to perform the activities of daily living.
- Nerve damage due to surgical trauma.
- Bursitis.
- Dural leak.
- Paralysis.
- Death.

Note: additional surgery may be necessary to correct some of these anticipated adverse events.

WARNINGS

- Surgery is not always successful. Preoperative symptoms may not be relieved or may worsen. Surgical knowledge of the procedure and the device are important, as is patient selection. Patient compliance is also important. Tobacco and alcohol abuse may lead to unsuccessful results.
- Appropriate device selection is crucial to obtain proper fit and to decrease the stress placed on the implant.
- Delayed healing can lead to fracture or breakage of the implant due to increased stress and material fatigue. Patients must be fully informed of all the risks associated with the implant and the importance of following postoperative instructions regarding weight bearing and activity levels to facilitate proper bone growth and healing.
- The implant must be handled carefully following manufacturer's instructions to prevent damage to the implant.
- Implants must not be modified or otherwise processed in any way.
- Once a device has been implanted, it must never be reused. If the package is damaged, opened, or if the expiration date has passed, but the device is not used, the device must be returned to HAPPE Spine. The device must not be re-sterilized by the end user.
- Supplemental fixation is required. The surgeon must be familiar with fixation techniques and appropriate supplemental hardware.

MRI COMPATIBILITY

The INTEGRATE®-C Fusion Device has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of INTEGRATE®-C Fusion Device in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction

SURGEON PRECAUTIONS

The implantation of an intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
The surgeon must have a thorough knowledge of the mechanical and material limitations of semicrystalline polymeric surgical implants and be thoroughly familiar with the surgical technique for implanting the INTEGRATE®-C Fusion Device for the given Indications for Use.
The surgeon should be familiar with the various devices and instruments and verify that all are available before beginning the surgery. Additionally, the packaging and implant should be inspected for damage prior to implantation.
In the event that removal of the implant is considered (e.g., due to loosening, fracture, migration of the implant; infection; increased pain, etc.), the risks versus benefits must be carefully weighed. Such events can occur even after healing, especially in more active patients.

Appropriate postoperative care must be given following implant removal to avoid further complication.
The surgeon must be thoroughly familiar with the options for supplemental internal fixation systems and the associated surgical techniques.
Implants must be fully seated within the inserter prior to use. Care must be taken not to over-tighten the implant inserter assembly. Additionally, care must be taken not to manipulate the inserter implant interface in a way not recommended by the surgical technique.
The surgeon must ensure the implant is properly seated prior to closing of the soft tissue.
Extreme caution must be used around the spinal cord, nerve roots and blood vessels.

PATIENT EDUCATION

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

SINGLE USE/DO NOT REUSE

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.

METHOD OF USE

Please refer to the Surgical Technique for this device.

PACKAGING

Packages for each of the components should be intact upon receipt. Devices should be carefully examined for completeness and for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to HAPPE Spine. Instruments are provided non-sterile and should be reprocessed using instructions provided in this Instructions for Use.

HANDLING OF THE STERILE IMPLANT

Before removing the implants from the package, make sure that the protective packaging is unopened and undamaged. If the packaging is damaged, the implants have to be considered as NON-STERILE and may not be used.
Upon removal from the package, compare the descriptions on the label with the package contents (product number and size).
Note the STERILE expiry date. Implants with elapsed STERILE expiry dates have to be considered as non-sterile and may not be used.
Take particular care that aseptic integrity is assured during removal of the implant from the inner packaging.

Open the packages carefully. Take suitable measures to ensure that the implant does not come into contact with objects that could damage its surfaces. Use only the recommended instruments for implantation of the implants. Damaged implants must not be used.

CLEANING OF INSTRUMENTATION

Instrumentation should be reprocessed as soon as possible after use. If device is able to be disassembled, disassemble prior to cleaning. Devices with lumens/cannula should be manually processed prior to cleaning. Clear lumen/cannula of any debris by brushing thoroughly using an appropriately sized, tight fitting, soft-bristle brush with a twisting action. Using a brush that is too large or small for the diameter of the lumen/cannula may result in an inadequately cleaned surface. After brushing, blow clean, compressed air through lumen/cannula to clear debris. Use a firm bristle brush for cleaning bone-cutting features such as drill tips and reamer flutes and teeth. Soak soiled devices using a neutral pH enzymatic soak or detergent prior to cleaning to loosen debris. Follow the enzymatic cleaner or detergent manufacturers' instructions for correct exposure time, water quality, and concentration. Rinse with cold tap water for two minutes. Manual cleaning is recommended for the cleaning of the instrument set. Automated washing systems are not recommended as the only cleaning method for the instruments.

1. Disassemble all instrumentation prior to cleaning.
2. Rinse soiled devices under cold running tap water for a minimum of two minutes. Use a soft bristled brush to assist in the removal of gross debris.
3. Soak the device for a minimum of fifteen minutes in a neutral pH enzymatic cleaner or detergent solution. Follow the enzymatic cleaner or detergent manufacturer's instructions for correct exposure time, water quality, and concentration.
4. Rinse the devices under cold running water for a minimum of two minutes using syringe, pipette, or water jet to clear lumens/cannulas and other hard to clean areas.
5. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Scrub interfaces several times using a twisting action. If the device can be retracted or moved, retract or open the part in order to access and clean these areas. Scrub the inside of lumens/cannulas of any debris by brushing thoroughly using an appropriately sized, tight fitting soft-bristle brush with a twisting action. Using a brush that is too large or small for the diameter of the lumen/cannula may result in an inadequately cleaned surface. Use a firm bristle brush for cleaning bone-cutting features such as rasp teeth.
6. Rinse device thoroughly with deionized (DI) or purified water for a minimum of two minutes. Make sure to irrigate the hard to access areas of the device. If the device can be retracted or moved, it is necessary to retract or open the part for thorough rinsing at these areas. Blind holes should be repeatedly filled and emptied.
7. Visually inspect the device under normal lighting for cleanliness. For hard to access areas of the device, apply a 3% hydrogen peroxide solution. Bubbling indicates the presence of blood and debris. If contamination is present, repeat steps 1 through 7 and reinspect.

8. Prepare an ultrasonic bath with a fresh cleaning solution using a neutral pH enzymatic cleaner or detergent solution at the concentration and temperature recommended by the detergent manufacturer.
9. Immerse device completely in the bath and ultrasonically clean for a minimum of fifteen minutes using a minimum frequency of 40 kHz.
10. Perform a final rinse using DI or purified water for a minimum of two minutes. If device can be retracted or moved, retract or open the part in order to rinse thoroughly under running water.
11. Visually inspect the device under normal lighting for cleanliness. For hard to access areas of the device, apply a 3% hydrogen peroxide solution. Bubbling indicates the presence of blood and debris. If contamination is present, repeat steps 1 through 10 and reinspect.
12. Perform a final rinse using DI or purified water for a minimum of two minutes.
13. Dry the device using a clean, lint-free cloth or clean compressed air.

INSPECTION

1. Inspect prior to use. Use normal lighting and no magnification to visually inspect for soiling, corrosion, cracks and or for any other damage to the instruments and their components.
2. Check for functionality, up to and including rotating components and actuations.
3. Do not use or discontinue use if the instrument is damaged, malfunctioning or performance is in question.
4. Instruments that are damaged should be reprocessed prior to return to the manufacturer for repair.

STORAGE & HANDLING OF INSTRUMENTATION

Instrumentation must be stored and handled with care. Storage must be in a dry, clean location protected from pests and extremes of temperature and humidity. The instruments must not be stored in contact with or near products which may have a corrosive effect.

STERILIZATION OF INSTRUMENTATION

All non-sterile instruments are sterilizable by steam autoclave using standard hospital practices, in addition to HAPPE Spine's parameters. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed below:

Type of Sterilization: Pre-Vacuum Steam
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Dry Time: 30 minutes vacuum

The sterilization parameters identified in this section require the use of an FDA cleared wrap and are to be wrapped using an FDA cleared wrap prior to performing steam sterilization; the instrument set may alternatively be placed into a reusable rigid container system (e.g., Aesculap Sterilcontainer JK444 with corresponding lid, or equivalent system). Instruments are to be sterilized with steam sterilization at a temperature not to exceed 140°C. Consult your sterilization equipment manufacturer's instructions and your internal sterilization procedures for

the specific sterilizer and load configuration to be used. The aforementioned sterilization parameters are recommended for the instrumentation including the case. Do not stack trays during sterilization.

INFORMATION

To obtain a Surgical Technique Manual or any information regarding the products or their uses, please contact your local representative or HAPPE Spine directly at +1-616-984-0204.

This Instructions for Use document is intended for the US market only.

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



Manufacturer



Catalog Number



Batch Code



Use-By Date



Quantity per Package



Consult Instructions for Use



Do not use if package is damaged



Caution



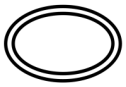
Do Not Resterilize



Do Not Reuse



Sterilized using Irradiation



Double Sterile Barrier System



Federal (USA) law restricts sale by or on the order of a physician



Keep Dry



Medical Device



Non-Sterile

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