

Product Description

NT-Ceram is a sintered composite of hydroxyapatite (Si-HA) and Tricalciumphosphate(β -TCP) and used in processing or crashing disks.

Area of application

NT-Ceram can be used in surgical applications aimed in treating bone defects.

Guidelines for use before surgery

- 1) Special care should be undertaken to maintain sterile conditions when handling and using NT-Ceram.
- 2) The medical staff who will be using the product should carefully read the instruction manual before surgery. They need to be very familiar with the characteristics of NT-Ceram as well as the appropriate ways of using it.

Guidelines for use in surgical applications

- 1) Firstly, know the medical history and assess the physical condition of the patient. Conduct a thorough physical check up of the patient, including conducting visual inspection, palpation and X-ray diagnosis. Conduct other types of medical examinations if needed. Based on the results of the examination of the patient's physical condition, make a decision whether to use NT-Ceram or not.
- 2) To apply NT-Ceram, make an incision on the skin to expose the bony surface when the patient is under general or local anesthesia.
- 3) Remove the lesion and then cut the local bone tissue using bars or disks. Inject the saline solution.
- 4) Mould the bone defect to be filled using various bars injected with saline solution. This is to ensure sufficient early fixation of the NT-Ceram.
- 5) Using various bars or disks, trim or sculpt the NT-Ceram immersed in saline solution containing antibiotics to make sure that it is a precise fit to the bone defect.
- 6) Rinse the sculpted NT-Ceram with sterile water to remove the powder generated during the cutting process, if necessary.
- 7) Embed NT-Ceram into the bone defect to be filled with extra care. If necessary, use wires for fixing.
- 8) If necessary, administer antibiotic as well as anti-inflammatory, analgesic and hemostatic agents after suturing the incision made.

Storage and management after use

The remaining NT-Ceram should be discarded after use. Do not re-use any remaining product.

Precautions for use of NT-Ceram

- 1) Take extra precaution when using the product on patients suffering from:
 - Hypertension and hypotension
 - Asthma
 - Diabetes
 - Rheumatism
 - Hyperthyroidism
- 2) General precautions for using NT-Ceram
 - ① Carefully maintain sterile conditions when using NT-Ceram, which has sterilized packaging.

- ② When cutting or sculpting NT-Ceram, proceed with caution and make sure that a saline solution has been injected when carrying out these processes. NT-Ceram is brittle as it is made from ceramic.
 - ③ Extra caution should be undertaken when using diamond and carbide bars and disks in high speed rotation with NT-Ceram to eliminate or reduce the risk of breakage.
 - ④ NT-Ceram should only be embedded to the bone defect when the lesion is completely removed and the local inflammation is adequately healed.
 - ⑤ When using NT-Ceram for areas with large load, use internal cleats, such as metal plates, or protective devices, such as intervertebral fixation devices, to help reduce the load.
 - ⑥ After NT-Ceram is embedded, fix the lesion firmly until NT-Ceram and the bone around it are strongly bonded.
 - ⑦ Patients who have undergone transplantation using bone restorative materials are likely to show hypotensive reactions, which can last from 30 seconds to more than 5 minutes. Changes in the patient's blood pressure should be carefully monitored when bone restorative materials are used since hypotensive reactions can likely lead to heart attack.
- 3) Precautions for use in spinal fractures
 - ① Adequate evaluation is needed to check if application of NT-Ceram can be tolerated particularly when there is a defect at the front and the side of the vertebral body. This is to eliminate the risk of leakage of the product from the lesion.
 - ② Take sufficient care to avoid damaging the endplate bone when trimming down the vertebral body before the NT-Ceram is embedded.
 - ③ Take extra care to prevent damaging the wall of the vertebral body when creating the insertion port for the NT-Ceram to be used. The insertion port should be at the center of the vertebral body to prevent damaging the front and the side of the vertebrae after filling the body with NT-Ceram.
 - ④ Take extra care to avoid penetrating the front and the side of the vertebral body when filling it with the NT-Ceram. Fill the center of the vertebral body with NT-Ceram and slowly embed it towards the front. Carefully monitor this action with the use of imaging.
 - ⑤ Always fill in the vertebral body with NT-Ceram through the front of the pedicle of the vertebral arch to avoid leakage into the spinal canal. Leakage to the spinal canal can be caused by damage to the internal wall of the pedicle of the vertebral arch.
 - ⑥ Pedicle screw can be used with hooks if necessary. Weak support at the front is likely when using only the hooks.
 - 4) Complications and Adverse Effects
 - ① Falling can occur due to bad fixation after insertion or to biomechanical conditions.
 - ② Damage to NT-Ceram can occur due to the following conditions:
 - a. Excessive load
 - b. Load upon impact
 - c. Inadequate fixation at the location of the filling.
 - ③ Dysraphism in the bones can happen when soft tissues form between the NT-Ceram and the bones due to weak fixation after embedding.
 - ④ Administer proper treatment of symptoms related to the use of NT-Ceram, such as infection, swelling, fistulization or exposure.

Contraindications for Use

- 1) The product should not be reused.
- 2) The product should not be used for patients suffering from the following illnesses and conditions:
 - Blood disorders, such as leukemia, hemophilia and sepsis, among others.
 - Severe liver dysfunction
 - Severe mental illness
 - Infectious diseases with a risk of relapse
 - Long-term use of steroids and anti-coagulant agents in patients
 - Cases declared unsuitable by physicians, i.e. bone diseases, such as osteomalacia

Side effects

Possible complications which may occur with any surgery include infection, swelling, fistulization, and exposure.

Storage Guideline

- Always store NT-Ceram at room temperature(1°C~30°C / 33°F~86°F).

Expiration Date

- The expiration date for NT-Ceram is five years from the date of manufacturing.

SYMBOLS

- Use By
- LOT Batch Code
- EC REP Authorized representative in the EC
- STERILE IR Sterilization using irradiation
- Consult operating instructions
- Caution
- Do not reuse
- Do not re-sterilize
- Manufacturer
- Date of manufacture
- REF Catalogue number
- CE 2195 CE-mark and identification number of notified body
Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC
- Do not use if package is damaged
- Temperature limitation
- Keep away from sunlight

Made in Korea

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