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NUVASIVE® ATTRAX® PUTTY
INSTRUCTIONS FOR USE

For Symbols Glossary, please refer to www.nuvasive.com/eifu
(doc# 9402624)

DESCRIPTION
Attrax Putty is a synthetic, resorbable, osteoconductive bone void filler for the repair of bony defects. The product consists of granules of > 90% TCP [Tri-Calcium Phosphate] and < 10% Hydroxyapatite, premixed with a synthetic polymeric binder (Alkylene Oxide Copolymer, AOC) that provides cohesion between the granules and allows the device to be molded into specific shapes as desired by the clinician.
The granules of *Attrax Putty* provide for the three dimensional regeneration of bone in the defect site into which it is implanted. When placed next to viable host bone, new bone will be deposited on the surface of the implant. The implant resorbs and is replaced by bone during the natural process of bone remodeling.
Attrax Putty is E-beam sterilized, comes in cylinder, strip, and block forms, and is packaged for single use only. *Attrax Putty* is a ready for use product.

INDICATIONS FOR USE
Attrax Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e. posterolateral spine and pelvis) and may be used in combination with autogenous bone. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. *Attrax Putty* resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS
Use of Attrax Putty is CONTRAINDICATED in the presence of one or more of the following clinical situations:
- To treat conditions in which general bone grafting is not advisable
- In conditions where the surgical site may be subjected to excessive impact or stresses, including those beyond the load strength of fixation hardware (e.g. defect site stabilization is not possible)
- In cases of significant vascular impairment proximal to the graft site
- In cases of severe metabolic or systemic bone disorders that affect bone or wound healing
- In cases of acute and chronic infections in the operated area (soft tissue infections; inflamed, bacterial bone diseases; osteomyelitis)
- When intraoperative soft tissue coverage is not planned or possible
- In direct contact with the articular space
- In cases of treatment with pharmaceuticals interfering with the calcium metabolism

WARNINGS, CAUTIONS AND PRECAUTIONS
Attrax Putty does not possess sufficient mechanical strength to support reduction of the defect site. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all planes. *Attrax Putty* cannot be used to obtain purchase for screws. Screws must gain purchase in the host bone.
The granules structure of *Attrax Putty* must not be damaged or altered (e.g. by excessive compaction or crushing of the implant).
Avoid overfilling of the defect as tension free wound closure is required.
Do not implant the resorbable calcium salt bone filler in a patient with pre-existing calcium metabolism disorder (e.g. hypercalcemia).
Attrax Putty radiopacity is comparable to that of bone and diminishes as it is resorbed. This moderate radiopacity may mask underlying pathological conditions and must be considered when evaluating X-rays.
Attrax Putty is to be stored at ambient temperature (max 50°C). Higher temperatures may affect the consistency and the ability of the device to retain its shape.
Inspect all packaging and components for damage before use. Do not use the device if it is damaged in any way.
Dosage is for SINGLE USE ONLY. DO NOT re-sterilize.
Confirm expiration date before use. Do not use if expiration date has been exceeded.

PRE-OPERATIVE WARNINGS
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the device.
4. Devices should be inspected for damage prior to implantation.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POST-OPERATIVE WARNINGS
Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.

INSTRUCTIONS FOR USE
1. The device can be manually shaped to fit the defect contours.
2. The desired consistency and malleability can be achieved by pressure and warming in the surgeon's hands.
3. The product is ready for use: mixing with aqueous solutions is not recommended.
4. Use *Attrax Putty* alone or, optionally, mix *Attrax Putty* with autograft bone.
5. Defect site should be filled completely and secured to prevent migration of the implant.

Attrax Putty is intended for use by surgeons familiar with bone grafting and rigid fixation techniques. Familiarization with the device and proper knowledge of bone grafting and rigid fixation techniques are extremely important.
Radiographic evaluation of the defect site is essential to accurately assess the extent of a traumatic defect and to aid in the selection and placement of the bone void filler and fixation devices. *Attrax Putty* must only be employed by or under the supervision of medical professionals with experience in the required surgical techniques and the use of biomaterials.
The exact operating procedures depend on the location, type and size of the defect. Close contact with vital bone is important for its function as a bone regeneration material and, therefore, a thorough freshening of the bone surface before applying the device is recommended (i.e. removal of bone fragments and necrotic tissue).
The defect must be completely filled with putty. Strong compacting or destruction of device structure (e.g. by crushing) must be avoided. Overfilling must be avoided to achieve a tension free closure.
Fixation of the implant site must be sufficient to prevent collapse and deformity secondary to functional loading. Anatomical reduction and rigid fixation in all planes must be obtained to ensure that the graft is not supporting load.
Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.

PACKAGING
Packages for each of the components should be intact upon receipt. Damaged packages or products should not be used, and should be returned to NuVasive.

STERILIZATION
Attrax Putty is provided sterile (E-beam irradiation). DO NOT resterilize.

HOW SUPPLIED
Attrax Putty is provided as a sterile, single-use device. Do not use if package is opened or damaged.

INFORMATION
To obtain additional information regarding *Attrax Putty*, please contact your local representative or NuVasive directly at +1-800-475-9131. You may also email: info@nuvasive.com.

This Instructions for Use document is intended for the US market only. For OUS Instructions for Use, please refer to document #9401028.