KAINOS®+ – Bone Graft Substitute

Product description:
KAINOS®+ is a bone graft substitute. KAINOS®+ is a microporous and macroporous biphasic calcium phosphate ceramic consisting of 60% Hydroxyapatite (HA) and 40% beta-Tricalcium Phosphate (ß-TCP). KAINOS®+ is available in various shapes and sizes.

KAINOS®+ may be used with physiological saline, patient's own serum, whole blood, or bone marrow aspirate (BMA).

KAINOS®+ is provided sterile for single patient use.

Indications:
KAINOS®+ is intended for use as a bone void filler for bony voids or gaps of the skeletal system (e.g. extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. KAINOS®+ can be used with autograft as a bone graft extender. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

KAINOS®+ is a bone filler without initial mechanical properties. Therefore rigid fixation techniques may often be recommended.

When packed into a bony site, KAINOS®+ gradually resorbs and is replaced with bone during the healing process.

Contraindications:
KAINOS®+ has limited initial mechanical properties. Therefore, this product is contraindicated where the device is intended as structural support in the skeletal system.

Conditions representing contraindications include also:
- Osteomyelitis
- Implantation in necrotic surgical sites
- Degenerative bone disease
- Intra-articular implantations

Adverse effects:
Possible adverse effects include but are not limited to:
- Wound complications including hematoma, infection, and other complications that are possible with any surgery
- Incomplete, or lack of, osseous ingrowth into bone void, as is possible with any bone void filler

Warnings:
KAINOS®+ is intended for single use only and cannot be reused.
The implant cannot be resterilized.
Reprocessing and/or reuse may result in infection and/or loss of function, which ultimately may result in the death of the patient.

KAINOS®+ should only be used by surgeons experienced with orthopedic fixation devices and bone grafting.

Precautions:
Rigid fixation techniques may be required to assure rigid stabilization of the defect in all planes. Maximum contact between the product and the recipient bone must be established.
The implantation in a revision surgical site containing non-resorbable fragments of material (e.g. polyethylene ligament waste, carbon fibers) is not recommended.
As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes (but is not limited to) individuals with long-term steroidal therapy or treatment acting on the calcium or phosphorus metabolism.
KAINOS®+ is radiopaque until resorbed. Radiopacity may mask underlying pathological conditions. Radiopacity may also make it difficult to radiographically assess the ingrowth of new bone.

Labelling:
Explanation of the symbols

CE 0499	CE mark		Manufacturer and date of manufacture
	Do not reuse	STERILE R	Sterilised by irradiation
REF	Article number	LOT	Batch number
	Use by		Caution: See Instructions for Use
	Do not resterilize		Do not use if unit packaging is damaged

Preparation:
1. Use care to avoid destruction of porous structure.
2. KAINOS®+ may be soaked in patient's serum, whole blood, or bone marrow aspirate (BMA) until graft is completely impregnated.
3. Prior to this, KAINOS®+ must be hydrated without excess with physiological saline to prevent osmotic damage.
4. Based on experiments, the ideal proportion of fluid should be 1 volume fluid to 2 volumes of KAINOS®+.
5. Prepared KAINOS®+ should be used immediately to preserve cell viability.

Handling and use:
KAINOS®+ is provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. This product must not be resterilized. The sterilization process of this product using radiations was validated during its conception. We do not guarantee the sterility of the product if a new sterilisation is performed on it.

Precautions must be applied in order to preserve the porous structure. This device is for single patient use only and should never be reused. The non-respect of the single use can conduct to septic issues. Additionally, the resorption process of this bone substitute started immediately after its implantation on the osseous defect so it can not be re-used.

KAINOS®+ should be stored at ambient temperature.

USA: Federal law restricts this device to sale by or on the order of a physician.

Product Guarantee:
SIGNUS Medizintechnik GmbH guarantees that every spinal implant is manufactured with the greatest possible care and from selected materials. All processes, including manufacture, packaging and testing, are subject to continuous quality control. SIGNUS Medizintechnik GmbH has no influence on the conditions under which the implant is selected and used, the diagnosis of the patient, the surgical technique or handling of the implant once it has been dispatched from the company and therefore SIGNUS Medizintechnik GmbH cannot guarantee the outcome or the absence of complications.

Please inform SIGNUS immediately of any report of (possible) malfunction, quoting the article number(s) and the batch number(s).

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