MedPark

S1

NEW BONE
NEW LIFE

DENTAL

NATURAL BONE SUBSTITUTE

Information

- S1 is composed of bovine bone and additive
- S1 has an interconnected micro- and macro-porous structure,
  which facilitates the formation of new bone tissue into the material when implanted in oral and maxillofacial bone.
- The organic components were removed through chemical and heat treatment, followed by thorough cleaning.
  We confirm that the final product contains no manufacturing residues remain that could pose a risk to patients.
- Hydrogel agent makes the bone graft viscous upon hydration.
- The expected lifetime of S1 is estimated 6 months.
- The main ingredient of S1 is HA (Hydroxyapatite).
  Since HA is the principal constituent of bone and has excellent biocompatibility,
  it is considered that there is no risk of interaction with other device.
- This product is a xenograft using bovine cancellous bone and therefore it is not an electronic device
  and it does not require operation, monitoring and maintenance.

Model List

Product	Type	Model	Particle size
S1	Powder	S1-XB-P015	■ Average particle size - HA(hydroxyapatite) :0.2 to less than 1.0mm
		S1-XB-P025	
		S1-XB-P050	
		S1-XB-P100	
		S1-XB-P200	
		S1-XB-P300	
	Chip	S1-XB-C015	■ Average particle size - HA(hydroxyapatite) : 1.0mm ~ 2.0mm
		S1-XB-C025	
		S1-XB-C050	
		S1-XB-C100	
		S1-XB-C200	

Intended Performance of Device

- S1 is performed as scaffold and fundamental structure in the area of the bone defect or bony voids which receive the bone graft materials.

Intended Purpose & Patients

- MedPark S1 is a xenograft material derived from bone for the purpose of securing a space where a new bone tissue is formed by filling defects or bony voids of the oral and maxillofacial region due to a surgical injury or a non-surgical injury.
- This device is intended for adults

Side Effect

- Incompatibility reactions with MedPark S1 cannot be totally excluded.
- Possible complications which may occur with any surgery include swelling at the surgical site, flap sloughing, bleeding, local inflammation, bone loss, infection, or pain.
- Depending on the severity and type of complications, the clinician may choose to remove the bone-graft and perform additional treatments.

Contraindications

Surgery should be avoided in patients with contraindications, including

1) Patients with osteomyelitis.

2) Patients with severe liver dysfunction.

3) Patients with severe cardiac dysfunction.

4) Lactating women.

5) Infants and children who are skeletally immature.
(< 18 years of age of no radiographic evidence of epiphyseal closure)

General precautions

1) In general, the conditions considered as standard contraindications for bone graft are metabolic diseases, osteoporosis, steroid therapy, autoimmune diseases, nicotinism.

2) As S1 derived from bovine cancellous bone, S1 must not be given to patients allergic to bovine bone..

3) Experience has shown that movement due to increased physical loads (compression loads) or implantation of implants (2-step procedures) should be avoided until several weeks after insertion of the product.

4) Experiments have shown that the physical loading (compression load) of this product augmented areas is possible after 6 months at the earliest. Implant placement time is determined by the amount of remaining local bone.

Notice

- Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration
- Manufacturer

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- Therapeutic Goods Administration Website
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