MedPark

S1 NEW BONE NEW LIFE

MedPark S1 is a single use medical device,
safely sterilized by gamma irradiation.

Product Description

1. S1 is a xenograft using bovine cancellous bone and its main ingredient is HA (Hydroxyapatite). 2. Pores in this material are interconnected, which facilitates the formation of new bone tissue into the material when implanted in oral and maxillofacial bone. 3. During the manufacturing process, the organic components were completely removed through chemical treatments and heat treatment. 4. Hydrogel agent makes the bone graft viscous upon hydration. 5. S1 should be used by trained/qualified licensed persons familiar with bone grafting.

Intended Use

MedPark S1 is a xenograft material derived from bovine cancellous 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.

Preoperative Preparation

1. Deliver a double packed product to the operating room while keeping it sterilized. 2. Do not use S1 if the sterile package is damaged or opened. 3. Do not use it if any foreign materials are found inside the vial. 4. Do not use S1 bone graft after the expiration date. The validity period is 5(five) years from the date of manufacture. 5. Read and fully understand 'Directions for Use' before surgery and be sure that surgeon knows exactly how to use S1. 6. The surgical instruments must be sterilized before the operation. 7. S1 is an implantable medical device and it should be used in a clean environment, operating room.

Directions for Use

The general principles of sterile handling and patient medication must be followed when using S1. 1. When using it, peel off blister Tyvek film. Holding S1 vial firmly, remove the cap. Dispense the granules of S1 into a sterile container. 2. After exposure the bony defect with mucoperiosteal flap, completely remove the granulation tissue and inflammatory tissue. 3. When opening the sterile package, never store remained product. 4. Put saline solution in the bone graft material that has been placed in the sterilized container. **5. Make sure that Recommended amount of saline solution by weight to use S1 successfully.** 1) Please keep the following points in mind!- Please comply with the recommended allowance - Do not divide the product for multiple uses - Do not mix with other bone graft- Mix with saline solutions well enough

2) The amount of saline is most important!- Place S1 in the tray and hydrate the materials with saline- Please use the recommended amount of saline only.- Do not soak in saline after shaping for a surgery. 3) It is important to knead S1 evenly!- Knead the dough enough for at least 30 seconds by using hands or tools to form a lumpy shape before using S1. 6. After making the product in a paste form suitable for the defect area, apply it to the surgical site using a dental instrument and press it down. 7. After filling the graft, cover the surgical site with mucoperiosteal flap and should be fixed by sutures. Be sure to completely seal the implantation site to prevent exposure.

※ Fundamentally, the use of powder type is recommended for small defects (up to 2 dental alveoli). The chip type is recommended for large defects (> 2 dental alveoli, sinus lifts), however, preferences can vary from dentist to dentist. Powder and Chip type can be mixed together at the dentist's discretion.

TYPE	PARTICLE SIZE (mm)	WEIGHT (g)	SALINE SOLUTION AMOUNT (cc)
POWDER	0.2 ~ 1.0	0.15	0.2
		0.25	0.35
		0.5	0.7
		1.0	1.4
		2.0	2.8
		3.0	4.2
CHIP	1.0 ~ 2.0	0.15	0.27
		0.25	0.45
		0.5	0.9
		1.0	1.8
		2.0	3.6

Precautions

1. Warnings 1) Discard any unused material after opening. Never reuse! 2) Disposal of this product would be in accordance with the medical waste management regulations of the using hospital. 3) Do not use if package is opened or damaged or if expiration date has been exceeded. 4) This product should only be used by trained dentists or oral surgeons. **2. Patients with the following diseases are prohibited.** 1) Patients with osteomyelitis 2) Patients with severe liver dysfunction 3) Patients with severe cardiac dysfunction **3. 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.

4. 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. (Although S1 meets "ISO 10993-10 Test for irritation and skin sensitization", allergic reaction may occur in someone with S1 sensitivity.)
3) For bone regeneration, the product is only implantable to bone tissue that is directly connected to living bone tissue and host bone. 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. 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. **5. Pregnant and lactating women, infants, children** 1) Do not use S1 for pregnant or lactating women. 2) S1 should not be used in patients who are skeletally immature. (<18 years of age of no radiographic evidence of epiphyseal closure) **6. Application notes** 1) Do not leave any parenchyma or other soft tissue on the defective area to be implanted. 2) This product has a low mechanical strength, so be careful when filling the contents. 3) Do not overfill defective or surgical sites. 4) The defect site and the surgical site must be completely closed.

Storage and Expiration date

This product is supplied in a sterile container. Store as it is at room temperature(1℃ to 30℃) in the shade before use.
If the sterile packaging is damaged or opened, the product must not be used. The contents of the blister package or vial are designed for single use only. Discard any unused material after opening.
Expiration date is 5 years from date of manufacture.
Do not use and re-sterilize products that have expired.

Product List

TYPE	PARTICLE SIZE (mm)	MODEL NAME	WEIGHT (g)
POWDER	**Average particle size** 1. HA(Hydroxyapatite) : 0.2 ~ 1.0mm 2. Additive Agents : less than 0.2mm	S1-XB-P015	0.15
		S1-XB-P025	0.25
		S1-XB-P050	0.5
		S1-XB-P100	1.0
		S1-XB-P200	2.0
		S1-XB-P300	3.0
CHIP	**Average particle size** 1. HA(Hydroxyapatite) : 1.0 ~ 2.0mm 2. Additive Agents : less than 0.2mm	S1-XB-C015	0.15
		S1-XB-C025	0.25
		S1-XB-C050	0.5
		S1-XB-C100	1.0
		S1-XB-C200	2.0

Symbol Description

	Manufacturer	EC REP	Authorised representative in the european community/ European Union		Date of manufacture
	Use-by date	LOT	Batch code	REF	Catalogue number
	Importer		Distributor	STERILE R	Sterilized using irradiation
	Single sterile barrier system with protective packaging inside		Do not resterilize		Do not use if package is damaged and consult instructions for use
	Fragile, handle with care		Keep away from sunlight		Keep dry
	Temperature limit		Humidity Limitation		Do not re-use
	Consult instructions for use		Caution	MD	Medical device
UDI	Unique device identifier		Patient identification		Health care centre or doctor
	Patient information website		Date		Contain biological material of animal origin

CE 1434

Manufacturer

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