Colla-D

Colla-DM Resorbable Collagen Membrane

Instruction For Use

MedPark Colla-DM is a single use medical device, safely sterilized by gamma irradiation

Product Description

Colla-DM is made of bovine-derived collagen, is a resorbable membrane, which is to used to cover the surgical site to block foreign material invasion, while promoting be guided bone regeneration. As it is a resorbable substance, no further treatment or surgery is needed.

Intended Use

The main function of this product is to block the graft implanted in the surgical site and the outside to prevent the invasion of foreign objects. This barrier prevents graft loss and, in addition, promotes bone conduction and production. This barrier prevents graft loss, and promotes bone conduction and production during the degradation process, as well. Therefore, it can be applied in the following cases.

- Periodontal/infra bony defects
- Ridge augmentation
- Sinus lifts
- Extraction sites (implant preparation/placement)
- Guided bone regeneration (GBR) procedures

Preoperative Preparation

1. Deliver a double packed product to the operating room while keeping it sterilized. 2. Never use if the outer package or sterilized inner package is found either openedor compromised. 3. Never use if any foreign materials are found inside the sterile packaging. 4. The clinician must read Directions for USE before the surgery, and completely understand its characteristics and usage methods.

Directions for Use

1. Incise the gingiva in the surgical area to expose the periosteum. 2. Completely remove the granulation tissue, inflammatory tissue and other soft tissue in the binding site. 3. Check the type and size of the product as shown on packaging/labels to prepare the proper product. ※ Colla-DM is identical on both front and back sides. It can be used without any distinction. 4. Depending on the size of the surgical site, the selected product may need to be cut to a suitable size with sterile surgical scissors. ※ It is recommended to cut at least 2mm larger than the surgical area to cover the entire area. ※ If necessary, this membrane can be moistened for flexibility. 5. After implanting the bone graft, cover it with Colla-DM and gently press it. ※ The defect should not be overfilled. 6. The membrane should overlap the walls of the defect by at least 2mm to allow complete bone contact and to prevent gingival connective tissue invasion below the material. 7. The mucoperiosteal flap is sutured over the collagen membrane with non-absorbable surgical suture. ※ At your discretion, additional suture work may be needed.

Precautions

1. Handling Precautions 1) This product shall not be reused or re-sterilized as a sterilized disposable medical device. 2) This product shall be used in sterile environments with sterile surgical instruments. 3) Do not use the product for any purpose other than GBR(Guided Bnoe Regeneration) case, or modify the product for other uses. 4) The surgical instruments must be cleaned and sterilized before being used. 5) Immoderate GBR(Guided Bone Regeneration) results in the exposure of the alveolar bone, thus, leading to failure of bone augmentation due to external infection. Therefore, both clinician and patient should be careful to avoid maximum exposure and the exposed area should be regularly screened and treated by clinicians. 6) If the product is bent or trimmed excessively, it may be damaged. 7) Colla-DM must be kept at 1 to 30℃. 8) Before use, check the Instructions for use to check the product's precautions and instructions. 9) This product should only be used by trained dentists or a oral surgeons. **2. Contraindications** Surgery should be avoided in patients with contraindications, including: 1) Patients with known allergy to collagen of bovine origin. 2) Patients with advanced lesions with a significant reduction in residual alveolar bone volume. 3) Patients with lesions difficult to secure space, such as horizontal bone defect. 4) Patients with progressive lesions across multiple teeth that require multiple, continuous use of the product. 5) Uncontrollable diabetic patients, excessive smoking or alcoholism. **3. Side effects** 1) As this product is based on bovine-derived type Ⅰ collagen, an allergic reaction may occur. 2) This product is for one of the periodontal surgeries. Periodontal surgeries can cause gum distortion, deadlock and absorption of the root, inflammation, gingival changes, and complications due to anesthetics. 3) Depending on the severity and type of complications, the clinician may choose to remove the barrier and perform additional treatments. **4. Others** 1) One patient can be implanted with a maximum of one 30x40(mm) size Colla-DM during one procedure and their lifespan. 2) It is recommended to use the size corresponding to the defect within the maximum allowable dosage. The size of the product can be determined at the discretion of the dentist.

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 Tyvek® pouch are designed for single use only. Discard any unused material after opening. Expiration date is 3(three) years from date of manufacture. Do not use and re-sterilize products that have expired.

Product List

Product name	Classification	Model Name	Width(mm)	length(mm)
Colla-DM	BS Type	BS-1010	10	10
		BS-1020	10	20
		BS-1030	10	30
		BS-1520	15	20
		BS-2030	20	30
		BS-2530	25	30
		BS-3040	30	40
	BH Type	BH-1010	10	10
		BH-1020	10	20
		BH-1030	10	30
		BH-1520	15	20
		BH-2030	20	30
		BH-2530	25	30
		BH-3040	30	40
	DM Type	DM-1010	10	10
		DM-1020	10	20
		DM-1030	10	30
		DM-1520	15	20
		DM-2030	20	30
		DM-2530	25	30
		DM-3040	30	40

Symbol Description

LOT	Batch code	REF	Catalogue number
	Caution		Consult instructions for use
STERILIZE	Do not resterilize		Do not re-use
	Manufacturer		Date of manufacture
30℃ 1℃	Temperature limit		Use by
	Keep away from sunlight		Keep dry
STERILE R	Sterilized using irradiation		Do not use if package is damaged

Manufacturer

MedPark

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