COLLA

INSTRUCTION FOR USE

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

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 opened or damaged. 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 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 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 Bone 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 must be kept at 1 to 30℃. 8) Before use, 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 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 si ngle 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

Classification	Model Name	Width(mm)	Length(mm)
BS Type	BS-1020	10	20
	BS-1520	15	20
	BS-2030	20	30
	BS-3040	30	40
BH Type	BH-1020	10	20
	BH-1520	15	20
	BH-2030	20	30
	BH-3040	30	40

Symbol Description

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

Manufacturer

MedPark

MedPark Co., Ltd.
24, Nakdong-daero 1570 beon-gil, Buk-gu, Busan, Republic of Korea
biz@medpark.net

EC Representative

EC REP

Meridius Medical Europe Ltd.
Unit 3D, North Point House, North Point Business Park, New Mallow Road, Cork,
T23 AT2P, Ireland
AR@meridiusmedical.com

CE 1434