Package insert

Single-use **Guyoudao®**

Bone Repairing Material
(Medical Device)
Package Insert

Please read the package insert carefully and use under the guidance of the physician.

Product Name: Generic Name: Bone Repair Material

Model Specification: 0.3mg rhBMP-2/vial, 0.5mg-I rhBMP-2/vial, 0.5mg-II rhBMP-2/vial, 0.8mg rhBMP-2/vial, 1.0mg rhBMP-2/vial, 1.2mg rhBMP-2/vial, 1.5mg rhBMP-2/vial, 2.0mg rhBMP-2/vial, 2.4mg rhBMP-2/vial, 3.0mg rhBMP-2/vial, 1.6mg rhBMP-2/vial, 0.4mg rhBMP-2/vial, 0.4mg-I rhBMP-2/vial, 0.6mg rhBMP-2/vial, 0.6mg-I rhBMP-2/vial, 0.75mg rhBMP-2/vial, 0.8mg-I rhBMP-2/vial, 1.0mg-I rhBMP-2/vial.

Structural Component: The product is using recombinant human bone morphogenetic protein-2 (rhBMP-2) as the active ingredient and using medical gelatin, soy lecithin and hydroxyapatite as the carrier materials. It is of sterile packaging.

Product Property: The product can induce directional differentiation of intracorporal mesenchymal stem cells into osteoblasts, after filled at the defect area of bone tissue, osteogenesis can be induced to stimulate the formation of bone and cartilage, so as to achieve tissue repair. It could be degraded and absorbed by the body.

Indications: The product is indicated for fill repair of bony defects, bone nonunion, bone delayed union, and graft repair of spinal fusion, joint fusion, and orthopedic bone graft.

Instructions for Use: The implantation dose of the product must be determined by orthopaedic surgeons with professional knowledge and the dosage should depend on the specific condition and size of trauma or defected area. The recommended dose for one single part is 4-6mg of rhBMP-2; the maximum dosage for one single use is 6mg of rhBMP-2. The product can be used alone or combined with other conventional therapy. If the defect is large, the product can be used in combination with autogenous/allogenous graft or other degradable grafting materials.

Contraindications:
1. The product is contraindicated for the patients with severe cardiac or renal insufficiency, liver function impairment and hematopoietic dysfunction.
2. The product should not be used in patients with the history of malignant tumors.
3. The product should be used with caution in patients needing systemic application of glucocorticoids.
4. The product should be used with caution in patients with metabolic bone disease.
5. The product should be used with caution in pregnant women, nursing mothers and children.

Precautions:
1. The product has no mechanical intensity; therefore mechanical fixation is required when it is used at force-bearing sites.
2. The product should not be placed in the articular cavity when used in the joints.
3. The maximum dose for single use should not exceed 6mg of rhBMP-2.

4. The product is a porous and spongy solid material and could be compressed moderately or be slightly modified with surgical scissors on the operating table depending on the magnitude and shape requirement required at surgical sites for patients.
5. Before the product is implanted, hemostasis should be performed in the implantation site. After implantation, do not rinse the wound, suture the soft tissue so as not to lose active ingredient, and avoid draining.
6. For the treatment of bone non-union or obsolete bone fracture, the medullar cavity of both the ends should be exposed for the exposure of rhBMP-2 to the target cells.
7. If there are slight inflammation or fluid accumulation after the implantation of the product, only symptomatic treatment and anti-infective treatment are needed. If those reactions last for a long time, and have the tendency of aggravation, the product implanted must be removed and followed by cleaning the wound.
8. If any allergic reactions found after implantation of the product, the patients with mild symptoms should be given symptomatic treatment in time, and for patients with severe symptoms, the product implanted has to be removed.
9. This product is a sterilized product. If the package is opened or damaged, it should not be used to prevent adverse reactions.
10. The product is not permitted to be used with other chemicals, such as acids and bases, to prevent those chemicals from changing the performance of the product.
11. If there are any questions during clinical application, please contact our company immediately so that we can provide timely explanation and help.

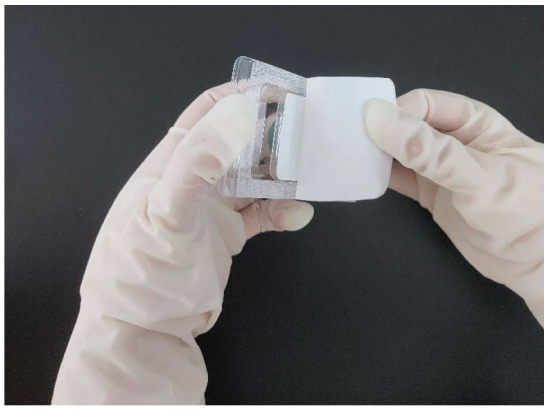
Warnings: A few patients may have low fever, wound exudation & swelling. But the ADRs may spontaneously disappear or disappear after therapy.
Storage: Keep at 2~8ºC and avoid the exposure to harmful radiation.
Shelf Life: Shelf life of the product is 2 years from the date of manufacturing; manufacturing date and expiry date can be seen on the label and outer package. Please use before the expiry date.
Product Registration No.: GuoXieZhuZhun 20173134462
Product Technical Requirement Code: GuoXieZhuZhun 20173134462
Registrant Name: Hangzhou Jiuyuan Gene Engineering Co., Ltd.
Registrant Address: No. 23, No. 8th Street, Hangzhou Economic and Technological Development Zone
Manufacturer: Hangzhou Jiuyuan Gene Engineering Co., Ltd.
License No. of Manufacturer: Zhejiang Provincial Food & Drug Administration Medical Device Manufacturing License No. 20110097
Manufacturing Address:1st Floor, 4th Building, HEDA Medicine Valley center & 1st Floor, 1st Building, HEXIANG Science and Technology center, No. 291, Fucheng Road, Xiasha District, Hangzhou Economic and Technological Development Zone.
After-sales Service:
Telephone No.: +86-571-86910099 ext.
Reporting of Suspected Adverse Reactions: www.china-gene.com; +86-571-87831586
Revision Date: September 2022

Hangzhou Jiuyuan Gene Engineering Co., Ltd.

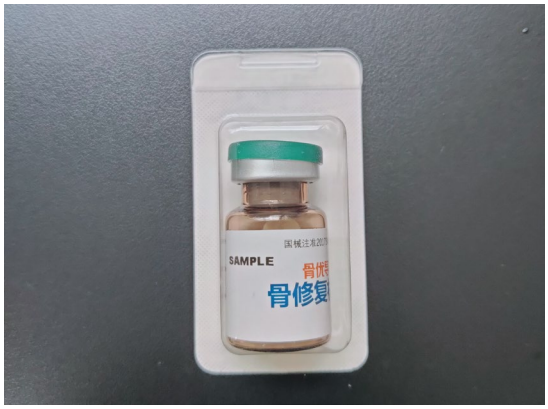
Instruction Manual

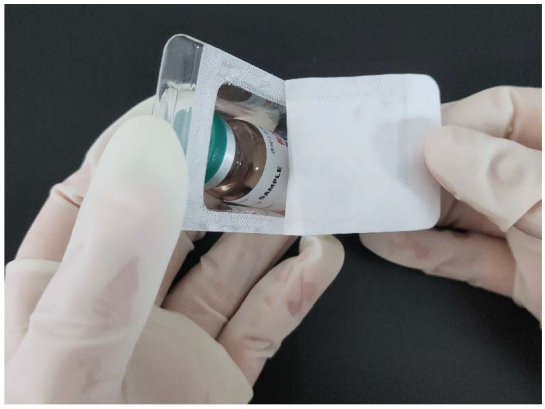
Instruction Manual for Bone Repairing Material

1. In the operating room, the circulating nurse opens the plastic box, takes out the product, and confirms if the sterility indicator label adhered to the blister package are red (if it turns yellow, the product cannot be used), and then opens the outer blister gently along the seal. Because the inside of the outer blister is sterile, open cautiously to keep the inner blister sterile.

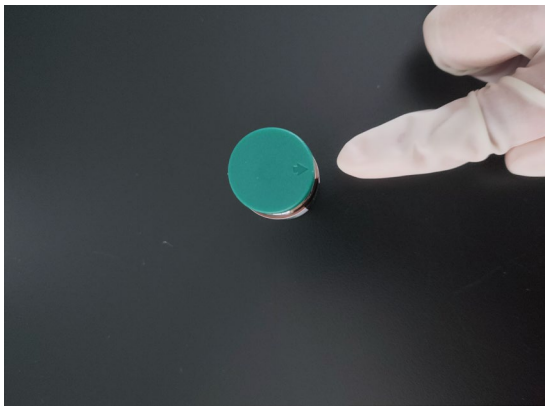
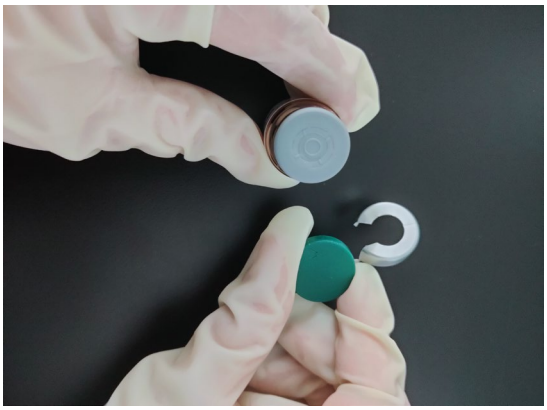



2. The scrub nurse or surgeon takes out the sterile inner blister, and opens it along the seal.



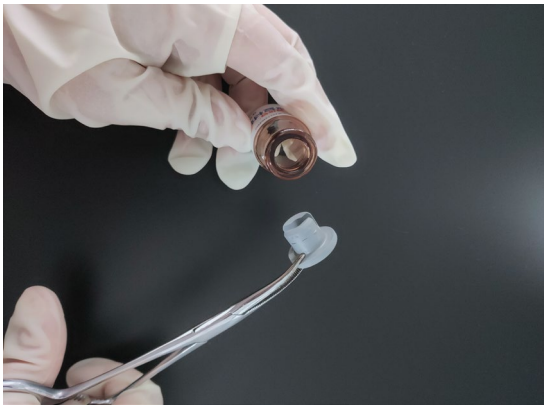


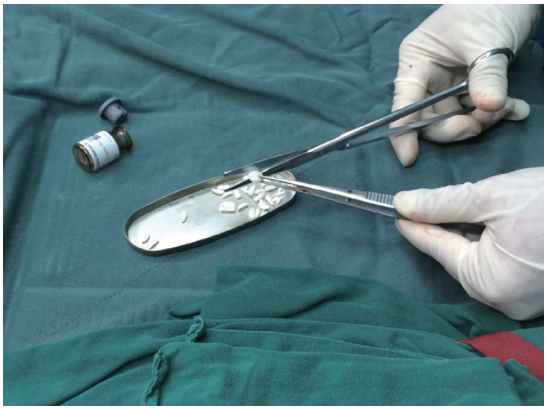
3. On the operating table, the scrub nurse or surgeon takes out the vial, and screws off the aluminum-plastic cap by one-time opening following the arrow on the cap.

4. The scrub nurse or surgeon removes the rubber stopper with haemostatic forceps, and takes the bone repairing material out of the vial, for the surgeon to use it in the surgery on the operating

table. The product can be modified appropriately by the surgeon according to the size of bone defect in clinical application, but it could not be soaked in water.





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