

ChondRoD OSTEOCHONDRAL IMPLANT INSTRUCTIONS FOR USE

Description

ChondRoD osteochondral implant is indicated for restoration of articular cartilage and/or osteochondral defects. It is interchangeable with cartilage and subchondral bone ChondRoD in case of local cartilage defects. Bone and cartilage integrity is achieved, the palliative pain problems of the patient are resolved and the root cells in the bone marrow transform into cartilage and bone due to the skeletal structure of the implant.

The material of the ChondRoD comprises a TCP30PLGA biocomposite material.

ChondRoD is a Class III medical device, not a medication.

The product dimensions are provided in the following table,

ChondRoD	Ø6mm x L5mm
ChondRoD	Ø6mm x L10mm
ChondRoD	Ø8mm x L5mm
ChondRoD	Ø8mm x L10mm
ChondRoD	Ø10mm x L5mm
ChondRoD	Ø10mm x L10mm
ChondRoD	Ø15mm x L7mm

Auxiliary Products

Drivers, tappers.

Indications

ChondRoD is used at the knee, waist, hip, wrist and elbow articulations for treatment of osteochondral lesions.

Contraindications

- In case of infection at the intended site of use,
- In case of insufficient bone stock at the intended site of use,
- In case of insufficient blood flow that would promote nutrition at the intended site of use,
- At patients with underdeveloped skeletal maturity,
- In cases of implant sensitivity, foreign body sensitivity,
- In case of any psychiatric or substance use that would prevent the patient to pursue treatment process and restrictions

Warnings For The Implant

ChondRoD is **SINGLE USE DEVICE** and is sterilized with Gama method.

ChondRoD **SHOULD NOT BE RE-STERILIZED**, if re-sterilized, the chemical and biomechanical potency

of the product might suffer losses. Moreover, reuse might also lead to disease transmission. ChondRoD is packed sterile, and should not be re-sterilized. This product is supplied to the end-user in sterile form only.

If the sterile packing is damaged, you should inform **BMT BAPS BIYO MALZEME SAN. ve TIC. A.Ş.** The product should be discarded and returned to **BMT BAPS**.

Check the expiry date before use, and **DO NOT USE ANY EXPIRED PRODUCTS**.

ChondRoD is available on the market with dual packing system with blister as primary packing and Aluminum as secondary packing. The inner blister package should be opened in the sterile environment immediately before implantation. **USE ONLY THE PRODUCTS WITH INTACT PACKING.**

ChondRoD should be used by authorized healthcare personnel, and the patients should be informed by the authorized healthcare personnel on the contraindications and the precautions to be taken.

Precautions

The surgical method should be reviewed before using the products. Detailed technical information and instructions for use and videos are available at the internet site. www.bmtbaps.com

Check the integrity of the ChondRod and the package thereof before use.

If the ChondRoD encounters any resistance during implantation, the implant application should be suspended and the implant should be removed. Then, the ChondRoD checked against damages, and if any damage is observed, the ChondRoD should be replaced. The new implant is then applied after the application site re-opened using the tappers.

Before placing the ChondRoD, the application site should be opened using the tappers with suitable dimension.

Post-op recovery is important. The patient should be informed by the physician on the restrictions that the implant will impose. The patient should be informed on lifting weight and body stress by the physician in order to ensure safe bone recovery.

The lower extremity and the upper extremity should not be used for lifting loads after implantation and the recommendations of the physician should be observed during rehabilitation period.

Adverse Effects

- Foreign substance reactions and mild inflammatory reactions,
- Implant breakage after implantation due to extreme load lifting, incomplete or insufficient recovery,
- Implant breakage during implantation due to exerting extreme force,
- Nerve damage due to surgical trauma,

- Bone necrosis or bone resorption ,
- Embolism,
- Pain,
- Loosening or dislocation of implant, which requires revision surgery.

Instructions for Use

After determining the osteochondral zone in the articulation, the defect is removed using adequate size tapper following arthroscopically, or by open surgery, and a nitinol guide is installed. Using such nitinol guide, a suitable site is prepared for ChondRoD using tappers. Then the Nitinol guide is used again to drive the ChondRoD further until secured in place.

Storage Conditions

Store in cool and dry places without exposing to direct sunlight. ChondRoD should be stored in controlled environment where heat and humidity monitored at minimum 25 °C, minimum 2 °C. Examine the product packing before use against any deterioration or contamination with water.

Shelf Life and Disposal

The shelf life of ChondRoD is estimated to be 2 years. The expiry date is printed on the label.

ChondRoD is an environmentally friendly product. It requires no special disposal procedure. The packaging material is made of recyclable material.

Recommendations

ChondRoD is available in the market with detailed instructions for use. The product is sterilized with Gamma Radiation. The ChondRoD is safe for MR procedures. The ChondRoD is packed in Aluminum packaging in transport and storage box. The tags to be used on the patient documents are also included in the package in addition to this instruction for use. It is recommended to thoroughly review the instructions for use and surgical techniques before use.

For detailed information on the product and the uses thereof, contact **BMT BAPS BIYO MALZEME SAN. ve TIC. A.Ş.**

Label Symbols and Their Meanings



Manufacturer



Date of manufacture



Use-by date



LOT LOT Number



Reference number



Sterilized using irradiation



Do not re-sterilize



Do not use if package is damaged



Do not re-use



Temperature limit



Consult instructions for use



Keep dry



Keep away from sunlight



CE symbol and Notified Body identification Number

Please read before use.



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