**BaPin – BIOCOMPOSITE PIN**
**INSTRUCTIONS FOR USE**

## Description

BaPin is used for fixation of bone grafts used for bones, bone cartilages, cartilage partial fractures, arthrodesis or post osteotomy.

The material of the BaPin comprises a TCP30PLGA biocomposite material.

BaPin is a Class III medical device, not a medication. The product dimensions are provided in the following table.

| | |
|---|---|
| BaPin | Ø2mm x L25mm |
| BaPin | Ø2mm x L40mm |
| BaPin | Ø3mm x L25mm |
| BaPin | Ø3mm x L40mm |
| BaPin Mini | Ø1.3mm x L12mm |
| BaPin Basic | Ø1.7mm & 2.3mm x L20mm |

## Auxiliary Products

Drivers, tappers

## Indications

BaPin is indicated for fixation of cartilage matrix or scaffolds used for osteochondral lesions at the knee, waist, hip, wrist and elbow articulations, and for fixation for minor fracture fragments in the articulation.

## 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

BaPin is **SINGLE USE DEVICE** and is sterilized with Ethylene Oxide.

BaPin **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.

BaPin 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 BİYO MALZEME SAN. ve TİC. 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**.

BaPin 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.**

BaPin 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 BaPin for damages before use.
BaPin should be checked against damages, and if any damage is observed, should be replaced with a brand new BaPin.

Before placing BaPin, the application site should be opened using the tappers with suitable dimension.
If any resistance is encountered when driving BaPin, then BaPin implantation process should be suspended and the product should be removed or the application site should be re-opened using the tappers.

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 adequate placement of the bone or the cartilage fragments, first of all a site is prepared in the bone or the cartilage for BaPin using adequate size tapper. Then BaPin is placed in this opened site and driven to the implant by driving with its driver, thus ensuring fixation of the bone cartilage or the cartilage scaffolds.

## Storage Conditions

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

## Shelf Life

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

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

## Recommendations

BaPin is available in the market with detailed instructions for use. The product is sterilized with Ethylene Oxide. The BaPin is safe for MR procedures. The BaPin is packed in Aluminum packaging in transport and storage box. The tags to be used on the patient documents are also be included in the package in addition to the present instructions 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 BİYO MALZEME SAN. ve TİC. A.Ş.**

## Label Symbols and Their Meanings

- Manufacturer
- Date of manufacture
- Use-by date
- LOT Number
- REF Reference number
- STERILE EO Sterilized using ethylene oxide
- Do not resterilize
- 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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CE 1984

BAP.IFU.01.EN
Date of Issue: 01.11.2018
Rev01/Rev. Date: 12.03.2019

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