REINFORCED SUTURE BIOCOMPOSITE ANCHOR INSTRUCTIONS FOR USE

Description

Reinforced Suture Biocomposite Anchors are used for soft tissue (ligaments, tendons), and ligament tendon restoration at the joints and/or for torn muscles, ensures integration of the muscle or soft tissue bone. The material of the Reinforced Suture Biocomposite Anchor comprises a TCP30PLGA biocomposite material. The Reinforced Suture Biocomposite Anchor is a Class III medical device, not a medication. The instrument has Reinforced (UHMWPE) sutures (yarns) for the products listed hereunder in the product table, which twists up around the connection point within the bodies thereof. The anchor named Bankas anchor can be screwed or impaled down; in addition Bankas, which is also suitable for knotless use, provides the fixation to the bone by loading the sutures of other anchors used during the operation. The anchors, Pentas and Basat, are screwable anchors. The product dimensions are provided in the following table,

Product Name	Suture Data
Bankas Ø2.34mm x L10mm	0.40 mm White
Bankas Ø2.95mm x L12mm	0.40 mm White + 0.40 mm Black Stripe
Pentas Ø5.5 mm x L16mm	0.55 mm White + 0.55 mm Blue Stripe
Pentas Ø6.5 mm x L16mm	0.55 mm White + 0.55 mm Blue Stripe
Basat Ø5.5 mm x L16mm	0.55 mm White + 0.55 mm Blue Stripe
Basat Ø6.5 mm x L16mm	0.55 mm White + 0.55 mm Blue Stripe

The materials used for this implant and the auxiliary products are specified hereunder,

- TCP30PLGA Biocomposite implant
- Stainless steel and ABS polymer handle
- UHMWPE surgical suture

Auxiliary Products

Tappers

Indications

Can be used for fixing the soft tissue to the bone in treatment of the lesions associated with soft tissue (tendon, muscle, fascia, ligament) ruptures at the shoulder, knee, ankle, hip, wrist and elbow joints.

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

The Reinforced Suture Biocomposite Anchor is **SINGLE USE DEVICE** and is sterilized with Ethylene Oxide.

The Reinforced Suture Biocomposite Anchor **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.

The Reinforced Suture Biocomposite Anchor 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.**

The Reinforced Suture Biocomposite Anchor is available on the market in Aluminum packaging. The packing should be opened in the sterile environment immediately before implantation. **USE ONLY THE PRODUCTS WITH INTACT PACKING.**

The Reinforced Suture Biocomposite Anchor 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 Reinforced Suture Biocomposite Anchor and the sutures attached to the implant before use. Before placing the Reinforced Suture Biocomposite Anchor, the application site should be opened using the tappers with suitable dimension. If the Reinforced Suture Biocomposite Anchor encounters any resistance during implantation, the implant application should be suspended and the implant should be removed. Then, the Reinforced Suture Biocomposite Anchor checked against damages, and if any damage is observed, the implant should be replaced. The new implant is then applied after the application site 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.

User Instructions

After completing preparations on the soft tissue intended to be repaired, first an adequate site is prepared for the implant in the bone using bız and tap placed adequately either arthroscopically or during open surgery. After such preparations, the implant is screwed and secured to the bone. Thereafter, the soft tissue is fixed to the bone by tying the yarns using 2 Reinforced 5.5 mm sutures protruding from the body.

Storage Conditions

Store in cool and dry places without exposing to direct sunlight. 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 the Reinforced Suture Biocomposite Anchor is estimated to be 1 year. The expiry date is printed on the label.

The Reinforced Suture Biocomposite Anchor should be disposed in compliance with the Waste Control Regulation published by the Ministry of Environment and Urban Planning. The packaging material is made of recyclable material.

Recommendations

The Reinforced Suture Biocomposite Anchor is available in the market with detailed instructions for use. The product is sterilized with Ethylene Oxide. The Reinforced Suture Biocomposite Anchor is safe for MR procedures. The Reinforced Suture Biocomposite Anchor 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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