

# Intas - BIOCOSMETE INTERFERENCE SCREW

## INSTRUCTIONS FOR USE

### Description

INTAS – Biocomposite Interference Screw is indicated for ligament reconstruction. It is designed to fixate the soft tissue grafts (ligament, tendon) to the bone. INTAS is a Class III medical device, not a medication. The material of the INTAS comprises a TCP30PLGA biocomposite material. INTAS features a tubular and threaded geometry. It is administered over guide wires.

The product dimensions are provided in the following table,

Intas	Ø6mm x L25mm
Intas	Ø6mm x L30mm
Intas	Ø7mm x L25mm
Intas	Ø7mm x L30mm
Intas	Ø8mm x L25mm
Intas	Ø8mm x L30mm
Intas	Ø9mm x L25mm
Intas	Ø9mm x L30mm
Intas	Ø10mm x L25mm
Intas	Ø10mm x L30mm
Intas	Ø11mm x L25mm
Intas	Ø11mm x L30mm

### Auxiliary Products

Drivers, guide wires, tappers.

### Indications

INTAS can be used for fixing the grafts to both the femur and the tibia during tendon transfer to the bone and during inner and collateral ligament reconstructions, proximal and distal biceps tendon fixation during anterior cruciate ligament reconstruction.

Intas can be used,

- During anterior cruciate ligament reconstruction at the knee,
- For fixation of grafts to both femur and tibia bone,
- Medial, lateral and collateral ligament reconstructions,
- For fixation of proximal and distal biceps tendon,
- At tendon transfers, and
- For fixation of tendon to the bone.

### 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

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

Intas 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**.

INTAS 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.**

INTAS 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](http://www.bmtbaps.com)

Check the integrity of the guide wire and the screw, Intas and the package thereof before use.

If any resistance is encountered when driving the screw over the guide wire during implantation, the screw driving process should be suspended and the screw should be removed. Then, the wire and the screw should be checked against damages, and if any damage is observed, the wire and the screw should be replaced.

Make sure that the screw tightly fits on the driver. Otherwise, damages that prevent driving of the screw might occur.

Before placing the Screw, 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 placement of the tendon or bone tendon graft, 1.2 mm Nitinol guide wire is inserted within the tunnel. The screw is then driven using adequate screwdriver over this wire. This process allows the graft or the tendon being compressed within the bone tunnel, thus become fixated.

### Storage Conditions

Store in cool and dry places without exposing to direct sunlight. Intas 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 and Disposal

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















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

### Recommendations

INTAS is available in the market with detailed instructions for use. The product is sterilized with Ethylene Oxide. The INTAS is safe for MR procedures. The INTAS 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 Number
-  Reference number
-  Sterilized using ethylene oxide
-  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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