BIOABSORBABLE INTERFERENCE SCREW INSTRUCTION FOR USE

Description

POWERBONE Bioabsorbable Interference Screws are used to restore the bone continuity after fractures and osteotomies (osteosynthesis) as well as for treatment of pseudarthroses. Besides, Bioabsorbable Interference Screws intended to achieve anatomical retention of bone sections that have been joined together by surgical splinting following prior reduction until the bone has healed. The product is designed for single use only.

Material and Classification

Bonegraft Bioabsorbable Interference Screw is a biomarterial which is made up of Poly(L-lactide-co-D,L-lactide) (PLDLA, l-lactide:dl-lactide 70/30) or Composite material which is %30 Beta Tricalcium Phosphate (β-TCP)+Poly(L-lactide-co-D,L-lactide) (PLDLA, l-lactide:dl-lactide 70/30). Bonegraft Bioabsorbable Interference Screws is a Class III, implantable, MRI compatible medical device and it is not a medicine.

Indications

The POWERBONE Bioabsorbable Interference Screw is designed for the interference fixation of bone-patellar tendon bone grafts in anterior cruciate ligament construction. The screws are cannulated or non-cannulated and available in different sizes. They have a specific head, which allows for a more even distribution of the torsional stresses. To achieve the optimal result, the Bonegraft Bioabsorbable Interference Screw should be implanted using a dedicated screwdriver.

Contraindications:

- Active infection.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Patient conditions including: blood supply limitations, insufficient quantity or quality of bone for attachment or latent infections.
- Pathologic soft tissue conditions, which may prevent secure fixations.

Surgical Precautions

Before the products are used, the surgical technique should be checked Before use, it is necessary to check that the POWERBONE Bioabsorbable Inteference Screws are not damaged. If there is any damage at the product, the product should not be used and replaced with a new Bonegraft Bioabsorbable Inteference Screw. POWERBONE Bioabsorbable Inteference Screw must be used with surgical instruments compatible with the products' contact surface and points. Surgical instruments should only be used for their intended purpose. Intraoperative fracture of instruments has been reported. All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant. Before the POWERBONE Bioabsorbable Inteference Screw is implanted, its location must be opened using spacers of the appropriate size. If resistance is encountered during the implantation of the POWERBONE Bioabsorbable Inteference Screw, the implantation process of the POWERBONE Bioabsorbable Inteference Screw should be stopped and the product should be removed or re-opened with a spacer. Post-operative care is important. The patient should be informed about the limitations of the implant by the physician. For safe bone healing, attention should be paid to the patient's weight-bearing and body stress in line with the physician's information. After implantation, attention should be paid not to load the lower extremity, to not carry any weight for the upper extremity, and the rehabilitation period, in line with the physician's recommendations.

Possible Adverse Effects:

- Infection can lead to failure of the procedure.
- Neurovascular injuries can occur due to surgical trauma.
- Bending, fracture, loosening, rubbing, and migration of the implant may occur as a result of excessive activity, trauma, or load bearing.
- Implantation of foreign materials can result in an inflammatory response or allergic reaction.
- Inadequate healing which may lead to breakage of the implant or failure of the graft material.
- Pain, discomfort, or abnormal sensation due to the presence of the device.
- Necrosis of the bone or tissue.

Recommendation For Use

The POWERBONE Bioabsorbable Interference Screw is FOR SINGLE USE and has been sterilized by Ethylene Oxide method. POWERBONE Bioabsorbable Interference Screw should not be re-sterilized, if it is resterilized, the chemical and biomechanical strengths of the product may be lost. However, if they are reused, they can cause disease transmission. POWERBONE Bioabsorbable Interference Screw is packaged sterile. This product is provided sterile only to the end user. If the sterile packaging is damaged, BONEGRAFT BIOMATERIALS should be informed and the product should not be used. The expiry date should be checked before use, and products with expired expiration should not be used. Bonegraft Bioabsorbable Interference Screw is offered in a double package. The inner pack must be opened in a sterile environment just before implantation. Products without package integrity should not be used. POWERBONE Bioabsorbable Interference Screw should be used by authorized medical personnel, patients should be informed by authorized health personnel about contraindications and measures to be taken.

Application

The POWERBONE Bioabsorbable Interference Screw must be used only for ligament reconstruction. Until graft healing is complete, fixation by means of this device should be considered to be temporary, and the construct must not be subjected to excessive loading or stress. Early stress on the screw or premature resumption of activity may lead to backing-out, bending, breakage or displacement of the screw. Bioabsorbable intereference screws are resorbed at a rate of 90.98% 22 months after implantation. For this reason, appropriate immobilization, followed by supervised mobilization, will be required for a period of 22 months after surgery for completely degradation, or until there is a clinical evidence of graft healing. The POWERBONE Bioabsorbable Interference Screw must be completely buried below the joint surface. The POWERBONE Bioabsorbable Interference Screw must not be cut or altered under any circumstances. Screwdriver must not be subjected to bending stress. A hole suitable for the screw diameter should be drilled in the application area.

SCREWS DIAMETER	HOLE DIAMETER
Ø7 mm	Ø7 mm
Ø8 mm	Ø8 mm
Ø9 mm	Ø9 mm
Ø10 mm	Ø10 mm
Ø11 mm	Ø11 mm
Ø12 mm	Ø12 mm

Storage

The POWERBONE Bioabsorbable Interference Screws are to be stored at between 17-27°C temperature and normal relative humidity (30-60%). Avoid exposure to direct sunlight. Storage conditions must be such as not to compromise the integrity of the packaging. Examine the product packaging for deterioration or contamination with water before use.

Shelf Life

POWERBONE Bioabsorbable Interference Screws shelf life estimated to be 3 year. POWERBONE Bioabsorbable Interference Screws is an environmentally friendly product. It requires no special disposal procedure.

Packaging

The POWERBONE Bioabsorbable Interference Screws are supplied in in double sterile peel-open packs. Prior to the use of the product, the integrity of the packaging must be checked. Products with damaged packaging should not be used. It must be delivered BONEGRAFT BIOMATERIALS.

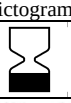
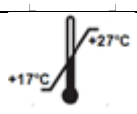
Sterilization

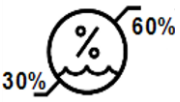
The POWERBONE Bioabsorbable Interference Screw is sterilized by Ethylene Oxide method. Do not re-sterilized. Sterility of The POWERBONE Bioabsorbable Interference Screw is guaranteed unless opening of package and damaged.

More Information

For detailed information about the product and its uses please contact with BONEGRAFT BIOMATERIALS. The address is printed on this information page.

Pictogram for Product

Pictogram	Description
	Expiration Date
	Conformity Mark
	Do not use if the package is damaged
	Sterilized by Ethylene-Oxide.
	See instructions for use.
	Temperature Limitation

	Humidity Limitation
	MR Safe
	Manufacturer
	Lot Number
	Do not reuse
	Do not resterilize
	Catalog Number
	Production Date and Place
	Warnings
	Keep away from sunlight
	Store in a dry place
	Double sterile barrier system
	Medical Device
	Unique device identifier
	QR

PLEASE READ BEFORE USING

BONEGRAFT BIOMATERIALS. A.Ş.
Keçiliköyosb Mahallesi İsmail Kahraman Cad. No:1/1/A YUNUSEMRE /MANİSA

Tel: +90232 373 33 38

Hazırlayan	Onaylayan
KALİTE YÖNETİM TEMSİLCİSİ Burak TÜLÜ	GENEL MÜDÜR Zafer ÇAVUŞ

Fax: +90232 373 33 39
E-mail: info@bonegraft.com.tr
Web: www.bonegraft.com.tr

Hazırlayan	Onaylayan
KALİTE YÖNETİM TEMSİLCİSİ Burak TÜLÜ	GENEL MÜDÜR Zafer ÇAVUŞ