

BONEGRAFT — BIOMATERIALS —	BIOABSORBABLE ORTHOPEDIC BONE SCREW & PIN & PLATE INSTRUCTION FOR USE	Dok.No / Doc. No	CE.TL.15.07.02
		Yay.Trh / Pub. D.	22.06.2020
		Rev.No / Rev. No	07
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BIOABSORBABLE ORTHOPEDIC BONE SCREW & PIN & PLATE INSTRUCTION FOR USE

Description

POWERBONE Bioabsorbable Orthopedic Bone Screws, Pins, Plate are used in osteotomy or arthrodesis to fix bone fractures or grafts or when additional mobility is present. This implants perform affixed to properly align the bone and aid in the healing process. Implants intend to help stabilize the fused area and prevent dislodgement of the bone or bone graft. This Implants designed for single use only.

Material and Classification

POWERBONE Bioabsorbable Orthopedic Bone Implants (Screws, Pins, Plate) are biomaterials which are made up of Poly(L-lactide-co-D,L-lactide) (PLDLA, l-lactide:dl-lactide 70/30). Bonegraft Bioabsorbable Orthopedic Bone Implants are Class III, implantable, MRI compatible medical device and it is not a medicine.

Indications

POWERBONE Bioabsorbable Orthopedic Bone Implants are indicated for minor bone fractures, osteotomies and arthrodesis, spongy fragments, and osteochondral fragments in the upper and lower extremities. They can be used in all patients who meet these indications. Biodegradable pins are produced in various sizes and in serrated and straight models. Although the indication for serrated and straight pins is the same, it is less likely to come back from the bone after the serrated pin is fixed to the bone due to the serrations on it. The places of use in the patient's body are determined according to the physician's preference or the patient's body and bone structure. It can be used in all patients who meet these indications.

Contraindications:

POWERBONE Bioabsorbable Orthopedic Bone Implants are contraindicated in the presence of active or latent infection, sepsis, osteoporosis, and insufficient quantity and / or quality of bone. POWERBONE Bioabsorbable Orthopedic Bone Implants are not designed for use in any indication not mentioned above.

Surgical Precautions

Incorrect selection of the Bonegraft Bioabsorbable Orthopedic Bone Implants, their placement, position, and fixation can cause subsequent undesirable consequences. The physician must know the devices, application method and surgical procedure before performing the surgery. Protection the sterile area during the surgery is an important case to success of operation. Before use, it is necessary to check that the POWERBONE Bioabsorbable Orthopedic Bone Implants are not damaged. If there are any damage to the products package integrity, the products should not be used, it should be replaced with new products. POWERBONE Bioabsorbable Orthopedic Bone Implants 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 Orthopedic Bone Implants are implanted, their location must be opened using spacers of the appropriate size. If resistance is encountered during the implantation of the POWERBONE Bioabsorbable Orthopedic Bone Implants, the implantation process of the implants 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 implants 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 Orthopedic Bone Implants are FOR SINGLE USE and have been sterilized by Ethylene Oxide method. POWERBONE Bioabsorbable Orthopedic Bone Implants should not be re-sterilized, if they are re-sterilized, the chemical and biomechanical strengths of the products may be lost. However, if they are reused, they can cause disease transmission. POWERBONE Bioabsorbable Orthopedic Bone Implants are packaged sterile. These products are provided sterile only to the end user. If the sterile packaging is damaged, BONEGRAFT BIOMATERIALS should be informed and the products should not be used. The expiry date should be checked before use, and products with expired expiration should not be used. POWERBONE Bioabsorbable Orthopedic Bone Implants are 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 Orthopedic Bone Implants 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 Orthopedic Bone Implants must be used for bone fracture fixation, osteotomy, arthrodesis operations. Until bone 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 screws/pins/plates or premature resumption of activity may lead to backing-out, bending, breakage or displacement of the implants. Bioabsorbable orthopedic screws, pin and plates are resorbed 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 clinical evidence of healing. The POWERBONE Bioabsorbable Orthopedic Bone Implants must be completely buried below the joint surface. The POWERBONE Bioabsorbable Orthopedic Bone Implants must not be cut or altered under any circumstances.

Storage

The POWERBONE Bioabsorbable Orthopedic Bone Implants 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

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not to compromise the integrity of the packaging. Examine the product packaging for deterioration or contamination with water before use.

Shelf Life

POWERBONE Bioabsorbable Orthopedic Bone Implants shelf life estimated to be 3 year. POWERBONE Bioabsorbable Orthopedic Bone Implants is an environmentally friendly product. They require no special disposal procedure.

Packaging

The POWERBONE Bioabsorbable Orthopedic Bone Implants are supplied in in double sterile peel-open packs. Prior to the use of the products, the integrity of the packaging must be checked. Products with damaged packaging should not be used. They must be delivered BONEGRAFT BIOMATERIALS.






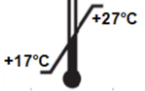

Sterilization














The POWERBONE Bioabsorbable Orthopedic Bone Implants are sterilized by Ethylene Oxide method. Do not re-sterilized. Sterility of The POWERBONE Bioabsorbable Orthopedic Bone Implants are 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
	Do not reuse
	Do not resterilize
	Catalog Number
	Manufacturer
	Warnings
	Keep away from sunlight
	Store in a dry place
	Double Sterile Barrier System
	Medical Device
	Unique Identifier Information
	QR
	Date of Manufacture Manufacturer Country

PLEASE READ BEFORE USING



BONEGRAFT BIOMATERIALS. A.Ş.

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