Spinamer®

CE 1014

General Information on Use of Implants

To the attention of the physician that will be performing the surgery!

Ortovia Bone Fixation Implants:
SPİNAMER produces medical devices (implants) that are applied in surgery with the therapeutic purpose of providing internal stabilization of bones. Devices that are used with this purpose include the following:

- Bone plate,
- Bone screws
- Intramedullary nails
- Kirschner wires
- Mono- and multi-filament wires
- Specialized bone fixation devices

Materials:

- Stainless Steel: ISO 5832-1
- Titanium Alloy: ISO 5832-3

The implants are produced from stainless steel in composition of ISO 5832-1 and titanium alloy at the standard of ISO 5832-3. These materials are not magnetic. They can be used together with implants from different manufacturers, however, these implants should be produced of materials with the above mentioned standards.

Indications:

1. Fixation of fractured bones
2. Fixation of non-union bones
3. Fixation of deformed bones post-correction
4. Augmentation in the case of mechanical inadequacy of bone tissue

Contraindications:

1. Infection
2. Advanced obesity
3. Advanced osteoporosis
4. Patients that will not or can not follow instructions of care post-surgery
5. Metal allergy; for patients where there is such a concern, related tests must be carried out prior to device implantation.

Warnings:
Bone stabilizing devices are used as medical devices supporting the provision and maintenance of anatomical integrity of bone tissue until fusion is completed following bone fractures and corrections. Though successful results are generally achieved in the application of these devices, it cannot be expected that they resist loads as well as healthy bone tissue, especially in cases of non-fusion, delayed fusion and inadequate healing. The dimensions and geometry of bone and soft tissue are determining factors in the dimensions and durability of the implants. In the case that fusion is delayed or fusion does not occur and bone is still bearing load it is likely that the implant will fail. Therefore, using the aid of external supports would be helpful until complete bone fusion is achieved, which should be confirmed with clinical and radiographic investigations. Implants will be epxosed to

frequent loading and may fatigue and fracture as a result. The patient's weight, mobility and level of compliance regarding load-lifting instructions will affect the implant's service life. The surgeon should be knowledgeable on the subjects of the implant's mechanical and metallurgic effects, as well as its medical and surgical respects.

1. Proper implant selection is critical. Healing of fracture is dependent on this factor. While proper selection affects reduction of risk, the bones' dimension and shape yield the effect of limiting the implant's dimension and shape. When unsupported, bone stabilization devices will not resist considerable movement or excessive loads.
2. In the case that bone fusion is delayed or does not occur at all, relevant devices may fracture under excessive loads. Bone stabilization devices are devices used in the alignment of bone until fracture is healed. In the case that fusion is delayed or does not occur it can fracture, bend or yield an unsuccessful result. Load bearing, mobility and carried loads determine the the device's durability.
3. When implanted, metals and their alloys enter an environment containing salts, acids and alkalis and this can lead to corrosion. Implants composed of differing metals being brought together quickens the corrosion process and can cause implants to fracture. When two different implants are being brought together to serve the same purpose (screws, plates), care should be taken that compatible materials and alloys are used.
4. It is very important that implants are used correctly. Implants should not be modified. Implants should not be nicked or bent. If excessive force (torque) is applied when placing bone screws, fracture can occur. Nicks or scratches that occur on the implant during surgical intervention promote implant fracture.
5. Implant should be removed after fracture is healed. Implants can loosen, fracture, rust (abrade), shift or can cause pain. If the implant is not removed post-recovery the implant causes stress shielding, which can cause refracture on an active patient. When deciding on whether the implant will be removed or not the surgeon should take the risks and benefits into consideration. After the implant is removed, appropriate post-surgery care training should be put into use in order to avoid refracture of implant.
6. Patient should be sufficiently informed. Post-surgery care is important. The patient's ability and willingness to follow instructions is of utmost importance. The risk of implant failure is greater in elderly, mentally disabled, alcoholic or narcotic-addicted patients. These patient groups are more likely to disregard instructions or movement limitations. Utilization of external supports and walking aids should assuredly be recommended to patients. It should be explained to the patient in detail that the implant can on no account take the place of healthy bone tissue and that the implant can fracture or suffer damage as a result of stress, excessive activity and considerable loading; the patient should be warned on the matter. The patient should additionally be informed regarding general surgical risks and potential side effects and should be warned about absolutely following the physician's instructions. The patient should be advised to not neglect followup investigations so long as the device is still intracorporeally situated.
7. The matter of which device is to be used in which bone and which size and dimension is to be used should be decided by the surgeon. Pathology and patient's physical condition should certainly be taken into consideration.
8. As these devices are being applied, surgical techniques recommended by the field of science should be fully applied. User recommendations specific to the device should absolutely be followed.
9. These implants are produced of non-magnetic materials and are expected to be magnetic resonance imaging (MRI) compatible. Though clinically no adverse incident has been reported, MRI compatibility has not been tested; the necessary care should be shown on the matter.
10. Bone drills are single use and should not be reused.

Potential Side Effects

1. Nonfusion or delayed fusion can cause implant fracture
2. Implant bending or fracturing
3. Implant loosening or shifting
4. Metal sensitivity or allergic reaction to foreign substances
5. Shortening of foot due to fracture compression or bone resection

6. Reduction of bone density due to stress shileding
7. Pain, discomfort or unusual agitation due to pressure of device
8. Nerve damage due to surgical trauma
9. Necrosis of bone
10. Bone fracture and pain following surgery
11. Inadequate fusion
12. Tissue damage due to contact during or after application
13. Metal reaction
14. Spreading of metal ions in patient's body

MRI Compatability:
Ortovia are produced by non-magnetic raw materials but Ortovia are not be confirmed for MRI compatability.

Non-Sterile:
Ortovia components are provided NON-STERILE. Ortovia recommends that all NON-STERILE components be properly cleaned and sterilized following the recommended cleaning and sterilization procedures.
Product integrity and performance are assured only if packaging is undamaged.

Cleaning & Maintenance:
Prior to use, NON-STERILE product must be cleaned using a mixture of 70% medical grade alcohol and 30% distilled water. After cleaning, the device and/or system components should be thoroughly rinsed in sterile distilled water and dried using clean non-woven fabric. Lubricate all parts, except for cam, bush and ball-joint coupling with lubrication oil for medical applications whenever required (see detailed Operative Technique Manuals or contact with Spinamer or local dealer).
To prevent corrosion, the components must be kept dry, and detergents with fluoride, chloride, bromide, iodide or hydroxyl ions must be avoided when cleaning, as they will damage the anodised coating on any Ortovia products, and this may initiate the process of stress corrosion.
Before sterilization, all components should be inspected, since damage to the surface of metal components can reduce strength and fatigue resistance, and may lead to corrosion. If components are damaged in any way, they should be exchanged immediately for new ones. Assembly of the fixator should then be carried out to ensure that all components are present.
Note: All parts and unit of Ortovia are for SINGLE USE ONLY.

ORTOVIA IS ONLY RESPONSIBLE FOR SAFETY AND EFFECTIVENESS FOR THE FIRST PATIENT USE OF SINGLE USE DEVICES.
The institution or practitioner bears full responsibility for any subsequent use of these devices.

Sterilization:
The recommended, validated sterilization cycle is:

Method	Cycle	Temperature	Exposure Time (Minute)	Drying Time (Minute)
Steam method.1	Gravity	132 °C (270 °F)	15min	30min
Steam method.2	Pre-vacum (min 4puls)	132 °C (270 °F)	4min	30dk

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The sterilization tray must be used for sterilization. Sterility cannot be assured if the sterilization tray is overloaded. Do not overload the sterilization tray or include additional implants or instruments from any source. If the fixator is not implanted, ıt can be re-sterilized.

CAUTION:
Care should be taken that LEGAL RESTRICTION in some countries may be present for this device to be sold by or on the order of a physician.

Storage and Trasport:
Ortovia must be stored and transported in special metal container or packages. Any biological, physical or chemical contaminants must be eliminated.

Traceability:
There is always a lot number on the label of each Ortovia product. This lot number must be attached to the file of the patient in order to trace back production procedures. Because of traceability reason, distributional documents have to be maintained for 15 years.

Notification:
The following must be assured.

1. Delivery:
Particular requirement for active implantable medical devices and implantable medical device;
The supplier shall ensure that the name and address of the shipping package consignee is included in the quality records (see 2).

2. Lifetime and control of quality records:
Shelf life of Ortovia Product is defined as 10 years and lifetime of Ortovia is defined as expected treatment time. Particular requirements for all medical devices;
the supplier shall retain the quality records for 10 years and users are advised to retain the product records for 5 years.

3. Ordering Information:
Ortovia can be ordered from your distributor or Spinamer.

4. Removal:

Ortovia should be removed after bone healing and disposed as medical wast according to local regulations.

5. Symbols:

LOT	Batch code	NON STERILE	Non-Sterile
REF	Catalogue number		See the Instruction for Warning
	Do not reuse		Consult The Instructions for use
	Manufacturer		

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SPİNAMER Sağlık Ürünleri Sanayi ve Teknoloji LTD. ŞTİ.

Merkez : Metroport Busidence No 705, D100 Yanyol Sok N0 14B

34180 Bahcelievler-İstanbul

Fabrika : Sanayi Mah. 1715 Sk. No: 32-34

Esenyurt / İSTANBUL Tel: +90 212 441 64 44

Mail: info@spinamer.com, www.spinamer.com