

ON PLUS OSTEO INTRODUCER / KIRSCHNER WIRE INSTRUCTIONS FOR USE

Product Description and Purpose of Use:

Kyphoplasty procedure is a percutaneous / minimally invasive procedure used to relieve pain, stabilize the fracture, correct angular deformation, maintain spine height, and provide decompression in patients with abnormal compression due to vertebral compression fractures due to tumor, trauma and osteoporosis. ON PLUS OSTEO INTRODUCER, which is used in kyphoplasty, enables the procedure to be performed within the spine over the kirschner wire applied for the purpose of fixation after entering the vertebral body with the first input needle. It acts as a cannula and bone filling is passed through this cannula to inject cement into the vertebral body.

Important Notes:

ON PLUS OSTEO INTRODUCER / KIRSCHNER WIRE may be used only by operating surgeons who are familiar with the general problems of spinal surgery and who are able to master the product-specific surgical techniques. For detailed usage information, please refer to the OSIMPLANT brochures and the related literature.

ON PLUS OSTEO INTRODUCER / KIRSCHNER WIRE is for single use only.

**** Our products do not contain human blood and its derivatives.*

**** Our products do not contain animal products and derivatives, they are not exposed to chemicals (e.g alcohol) in the clinical environment.*

**** Products whose surface is damaged should not be used and should be disposed of as medical waste.*

Indications:

- Osteoporotic Vertebral Fractures
- Traumatic Fractures
- Hemangiomas
- Multiple Myeloma
- Cancer
- Osteolyses / Metastases

Contraindications:

- Anatomical Damage of the Vertebrae, Preventing The Needle from Securely Accessing the Vertebral Body
- Vertebral Body Collapses Less Than 1/3 Of Vertebral Height
- Vertebra-Plana
- Vertebral Osteoporosis
- Malignant Vertebral Disease
- Fever or Leukocytosis
- Mental Illness
- Morbid Obesity
- Pregnancy
- Cement and/or Steel Allergy
- Local Infection or Inflammation

Patient Selection Criteria:

The corpus back wall must have the integrity on patient planned vertebroplasty or kyphoplasty. The fracture at the level to be treated should not be an old fracture.

Preoperative Warnings:

It is necessary to mention the risk of cement leakage in patients who will undergo vertebroplasty or kyphoplasty using ON PLUS OSTEO INTRODUCER / KISCHNER WIRE. It should be explained that in case of cement leakage, open surgery will be started.

Postoperative procedures:

The patient should be advised to stay away from work that requires heavy effort. The patient should be followed up with monthly checks. Patients with osteoporosis should be brought under control due to new fractures that may occur in the future.

Warning and Precautions:

- The usage of the ON PLUS OSTEO INTRODUCER / KISCHNER WIRE should be performed only by experienced spinal surgeons with specific training in the use of these products because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contraindications of this type of product.
- Proper product selection and patient compliance to postoperative precautions will greatly affect surgical outcomes.
- Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum product service life.
- The components of this system should not be used with components of any other system or manufacturer.
- The surgeon must ensure that all necessary products and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
- Postoperative care is important. The patient should be instructed in the limitations of his/her metallic product and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in loss of neurological functions.
- In order to increase the success of the surgery, the most suitable hand tools and imaging devices should be used.
- Prior to use, thoroughly read these Instructions for Use and become familiar with the surgical technique. Never use damaged or defective instruments.
- Sterilized products should not be touched without sterile gloves and clothing.
- Periodic X-ray films should be taken at least for the first six months to follow closely.
- The product must be carefully unpacked and checked for damage before use.
- Pre-operation systems and instruments must be well protected during storage.
- If a problem is found during storage or use, notify the manufacturer immediately and take corrective and preventive actions as necessary.
- Appropriate patient selection is extremely important.

- Before use, check the appearance of the product, avoid any deformation, damage, scratches and replace them with any other product.
- A large stock must be available during surgery.
- Allergies and reactions should be taken into consideration and tested.
- In addition to other measures for the success of the surgery, it is necessary to teach the patient to sit and get up and lie down without imposing inappropriate forces on his spine, and to teach him the appropriate restrictions to his daily life during the fusion period.
- ON PLUS OSTEO INTRODUCER / KISCHNER WIRE products should be treated as medical waste.
- Using the device without an instruction manual and using unsuitable products may cause more time for improvement, the need for revision, or further operations.
- Improper handling and storage can cause inflammation and infection.
- Using the device without the Surgical Instruction Manual may cause tissue or nerve damage, or gastrointestinal or urological problems.

Potential Adverse Effects:

- Infection
- Neurological dysfunction (paralysis, dysesthesia, hyperesthesia, paresthetic, drowsiness)
- Fracture, micro fracture, resorption, damage
- Herniated disc at the lower or upper level of the level where the surgical procedure is performed, disc degeneration
- Spinal mobility or loss of function
- Not being able to perform daily life activities
- Development of respiratory problems (pulmonary embolism, narrowing of the lungs, bronchitis, pneumonia)
- Risks associated with any surgical procedure such as injury to blood vessels, soft tissue damage, bleeding, pulmonary edema, heart attack, stroke, reactions to drugs or anesthetic agents used during and after surgery, and death.
- Tissue or nerve damage
- Vertebral fracture
- Pseudoarthrosis or delayed union
- Gastrointestinal or urological problems
- Hematoma
- Bursitis

MRI Information:

OSIMPLANT cannot make any claims regarding the safety of OSIMPLANT products with any specific MRI system.

Raw Material The handle part of our ON PLUS Osteo Introducer products is made of ABS HI121H (Injection Molding Grade) and the body part is made of AISI 304 Grade Stainless Steel.

Kishner Wire is produced from Stainless Steel according to is made of AISI 302 Grade.

Shelf life 60 months from production date

Sterilization Method:

ON PLUS OSTEO INTRODUCER / KISCHNER WIRE is offered to the market as a sterile product. ON PLUS OSTEO INTRODUCER / KISCHNER WIRE products are ethylene oxide sterilization. The sterilization method is presented to the user information on the product label.

Packaging and Labeling:

Products should only be accepted without loss of original packaging and labels. Products with damaged packaging or label with faintness should be returned to OSIMPLANT.

Storage and Maintenance:

- Damaged packages or products should never be used and should be returned to the manufacturer.
- Products should be stored without damaging the original surface.
- Damaged or defective instruments should not be used. Contact the manufacturer for repair or replacement instructions.
- Always store the product in the original protective packaging.
- Products must be stored according to maintenance instructions.
- To avoid unexpected scoring, deformation or damage, do not place anything heavy on the products and do not cover them.
- The products should be stored separately to prevent scratches and abrasion.

- Disposable products should not be reused. Reuse of the device due to it contacts blood, bone, tissue, or other body fluids may cause injury to the patient or user. Re-sterilizing a single-use device may cause damage or poor performance.
- Products should be stored separately from other materials that may cause wear or discolouration.
- All products should be stored in a clean and dry environment away from sunlight and extreme hot environments.
- The products should be stored at a temperature of 10-30°C and a humidity of 35%-60%rH.

Rules to be followed for sterile products:

- The product should be kept intact, sterilized and properly aligned, and should not be put together with other types of metal.
- Sterile products should be protected from moisture.
- The product should not be used if there are any scratches, tears or deformations on the sterile packaging.

Product Complaints:

If there is any complaint or dissatisfaction with the safety, durability, effectiveness, quality of the product by the health worker or the purchaser of the product and if there is a problem that may affect the correct operation of the product, Osimplant should be informed immediately. When reporting the complaint, the name of the product, the LOT number, the name of the person preparing the report and the nature of the complaint should be specified in detail.

For more information you can reach, OSIMPLANT Medical Materials and Medical Trade. Ltd.

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Importer: TR-IM-000017947

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Symbols:

Symbols which are used in this IFU generated in accordance with 93/42/EEC Medical Device Directive and EN ISO 15223-1¹ Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.

Symbol Representation	Explanation	Symbol Representation	Explanation
	Product reference number / catalog number		Do not use again
	Marking that Product Meets All Requirements of 93/42 / EEC MDD		Not Re-Sterilized
1984	KIWA Notified Body Code		Expiration date
	Lot number		Do not use if the packaging is damaged
	Sterilized with ETO		Keep Dry
	Attention		Humidity Limitation
	See User's Manual		Temperature Limit
	Production date		Keep Away From Sunlight
	Manufacturer Name and Address		

¹ The up-to-dateness of the standards is followed by the SV-A-3-9-1 Standards List.