INSTRUCTIONS FOR USE
IN2BONES® - STERILE SINGLE USE INSTRUMENTS

In accordance with the directive 93/42/EEC relative to medical devices and its amendments, this product must be handled by WELL-TRAINED and QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

1. Description of the medical device

The surgical instruments covered by this INSTRUCTIONS FOR USE are sterile single use instruments.
Instruments manufactured by In2Bones® and sold sterile have been sterilized by gamma radiation.
The sterilization method is specified on the packaging. Components sterilized by radiation are exposed to a minimum of 25 kGy of gamma irradiation.

2. Indications

These instruments are intended for use in surgery, and should be used only for the introduction of associated In2Bones® products. None of the instruments shall be implanted.

3. Use of the instrument

Only medical professionals who are thoroughly familiar with the instruments function, application, and use should use them in surgery. Only a surgeon qualified to perform the orthopedic surgery required by the particular patient should use the surgical instruments.

3.1. Preoperative – packaging of sterile products

Check packaging and labeling integrity before use. The sterility is guaranteed as long as the packaging has not been damaged (film scratched, label missing, questionable packing…) and before the end of the sterility validity. Do not use any product for which the packaging has been opened or damaged outside the operating theatre. Inner packaging should be handled under sterile conditions (persons/instruments).

3.2. Peroperative - examination of instruments

Instruments must always be examined by the user prior to use in surgery.
Sharp instruments should be inspected to confirm that sharp edges are not blunt and that the cutting properties of the instrument are intact.
Examination of instruments should be thorough, and in particular should take into account the presence of any cracks, bending, or distortion, and that all components of the instrument are complete.
Never use instruments with obvious signs of damage, incomplete or otherwise unfunctional. Any instrument with evidence of corrosion, discoloration, crack, pitting must not be used.
Instruments with unacceptable deterioration should be returned to the manufacturer or properly disposed.
Under any circumstances should the surgical instrument be modified.

3.3. Instruments connected to a power driver

Safety glasses are recommended when using any active surgical instrument. The cannulated surgical instruments should not be used without the appropriate corresponding In2Bones® K-wire inside the cannulated part.
The K-wire must be renewed for each procedure.
The surgeon using a surgical instrument connected to a power driver is responsible for the proper operation of the instrument as well as any accessories or equipment, including power equipment. Avoid using excessive force, twisting, or bending of the surgical instrument in any unnatural or unintended way.
The surgical instrument must be properly inserted and securely locked into the power driver before it is turned on and/or operated. All accessories must be properly inserted, sealed, and locked before turning on and/or engaging the active surgical instrument.
The surgical instrument connected to a power driver may become hot from friction and the surgeon should take appropriate care to ensure that the patient is not harmed.
Minimize the tissue contact to avoid possibility of burns.
Contact with other metal objects could cause damage to the surgical instrument and may necessitate replacement.

3.4. Measuring instruments

Some surgeries require the use of instruments which incorporate a measuring function. Ensure that these are not worn, that any surface engravings are clearly visible. Except if another specific indication is indicated on the instrument itself, the measures provided by these instruments with a measuring function, have the following characteristics:
Measure of a length: Unit: millimeter (mm) - Accuracy: length read +/- 1mm.
Measure of an angle: Unit: angle (°) - Accuracy: angle read +/- 1°.

3.5. Re-use / re-sterilisation

Products intended for single use must not be re-used (see symbols). Re-use may compromise the structural integrity of the device and/or lead to device failure, that may result in patient injury, illness or death. Furthermore, re-use of single use device may create risks of contamination from one patient to another or the user.
Please note that a single use device which comes into contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed. The company declines all responsibility in the event of such re-use.

Re-sterilization is prohibited for products sold sterile.

3.6. Surgical technique / Responsibility of the Surgeon

In2Bones® does not practice medicine and does not recommend any specific surgical technique.
It is the surgeon's responsibility to select the appropriate surgical technique and instruments for each individual patient, in accordance with the surgeon's practice, experience, training, standard of care and knowledge of the relevant medical literature. In2Bones® is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.
Criteria for patient selection are the responsibility of the surgeon. The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and device being implanted in the surgical procedure. The surgeon should refer to the instructions for use accompanying the device.
Information contained within this document should be taken into consideration during the selection process.
Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon.
Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience.

4. Storage

Store in dry place

5. Information on the products / Responsibility

In2Bones® has taken reasonable precautions in the selection of materials and in the manufacture of these products. However, In2Bones® excludes any legal guarantee, whether express or implicit, including but not limited to, any implicit guarantee of the marketable quality or suitability for a specific use. In2Bones® cannot under any circumstances be held responsible for any loss, damage or related costs or incidents, directly or indirectly linked to the use of this product.
In2Bones® does not assume, and does not authorize any third party to assume on its behalf, any other responsibilities relating to these products. The intention of In2Bones® is that this device should be used only by doctors having received appropriate training in techniques of orthopaedic surgery for its use.

Caution: US Federal law restricts this device to sale by or on the order of a physician

Information

Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.

CE 0499

Last revision: 07/2015

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IFU006 – Revision 03 – Date 07/2015

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