

## ENGLISH

### INSTRUCTIONS FOR USE - INSTRUMENTS medical devices for orthopaedic surgery

This product must be handled by WELL-TRAINED and  
QUALIFIED PERSONS.

AWARE of these INSTRUCTIONS FOR USE.

#### 1. Description of the medical device

The medical instruments covered by this INSTRUCTIONS FOR USE are sterile single use instruments and non-sterile instruments.

Instruments manufactured by In2Bones® and instruments for 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.

These instruments do not contain phthalates unless this is indicated on the label.

#### 2. Indications

These instruments intended for use in orthopedic surgery.

These instruments should only be used in association with the implantation of associated In2Bones® products.

None of the instruments shall be implanted.

#### 3. Warnings and precautions

Physician must determine if the use of the instruments is appropriate for patients who have any of the following conditions:

- Acute or chronic systemic inflammations;

- Active infections;

- Sensitivity/allergies to the instruments materials or implants;

- Lack good general physical condition;

- Use of steroid derivatives, chemotherapy, etc... Drug and/or alcohol and/or smoke addition and/or abuse;

- Obesity;

- A patient unwilling or unable to comply with postoperative instructions;

May include, but are not limited to:

- Pain; discomfort or abnormal sensations;

- Wound healing problems;

- Nerve injury;

- Adhesions;

- Infections;

- Hematoma, thrombosis, pulmonary embolism;

Complications linked to damage or breakage of the instrument.

#### 4. Safety / Active surgical instruments

These instruments are recommended when using any active surgical instrument.

The cannulated surgical instruments should not be used without the appropriate corresponding instruments and inside containers.

The Kirschner wire must be removed for each procedure.

The surgeon and the surgical instrument are responsible for the safe operation of the instrument as well as any accessories or equipment, including power equipment that may be necessary for the use of the active surgical instrument.

Avoiding excessive force, twisting, or bending of the surgical instrument in any unsterile or unintended way.

The instrument must be properly inserted and securely locked into the power device before it is turned on.

The surgical instrument must be properly inserted, sealed and locked before turning on and/or engaging the active surgical instrument.

#### 5. Cleaning / Sterilization

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#### 6. Readiness for cleaning and sterilization

These instruments are recommended for sterilization / Product sold not sterile

These instruments are intended for products sold non-sterile. Disinfection, debridement, packaging in compliance with current regulations to resterilize non-sterile products. The users should only use the sterilization cycles, validated by In2Bones®, as recommended, following section (d) handling and reprocessing.

#### 6.2 Handling and reprocessing / Product sold sterile

Check the integrity of the packaging and labeling before use. Remove all the products from the package. Remove all the products from the tray, transfer them to their packaging prior to sterilization. All products should be cleaned, decontaminated, and sterilized before use. Always immediately clean and decontaminate all devices that have been soiled. Reprocessing after reprocessing has little effect on these products.

#### 6.3 Reprocessing limits

These instruments do not define a maximum number of uses for any medical devices. The lifetime of these devices is undefined and depends on many factors (method of treatment, cleaning agents used, handling...).

The lifetime of a medical device depends on the sterility of the instrument and the damage caused by the use.

**Cautions:**

Some cleaning solutions such as those that contain bleach, formaldehyde or sodium hydroxide (NaOH), can damage specific components and should be avoided.

#### • Manual cleaning process

Device preparation:

Remove gross soil present on the instruments using the appropriate technique. For instruments with cavities, it is mandatory to irrigate any channels to clean them as soon as they have been used.

Do not use fitting products which would cause the binding of residues and affect the outcome of the cleaning. After cleaning, dry the instruments by soaking the instruments in a disinfectant solution as soon as their use is ended.

Devices with unacceptable deterioration should be returned to the manufacturer or disposed of.

Warning: when the instruments have been used in a surgery with a risk of contamination by TSE agents, the instruments should be properly disposed of.

**Pre-cleaning:**

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