Parc ESTER - 1, rue Columbia - 87068 Limoges (France)
TELI. +33 5 55 69 12 12 - FAX. +33 5 55 35 06 50

CE 1014

INSTRUCTIONS FOR USE *ENGLISH*

NT/BR/02/2017-10 18(Last revision : October 2017)

This device must be used by qualified and trained staff, and who have read carefully these instructions and assimilated the surgical technique. This device is sterile and for single use.
For additional information, please contact us or consult documentation available at our website www.iceram.fr

BIRDIE Spinal System

1. Description of the device

The **BIRDIE Spinal System** is in titanium alloy (ISO 5832-3 Standard) or in stainless steel (ISO 5832-9 Standard), it includes:
- Stems of 5.5 and 6 mm diameter and of different lengths
- Universal clips
- Transverse fixations
- Laminar, pedicle and thoracic hooks
- Pedicle screws of 5.5 and 6 mm diameter, of length from 30 to 50 mm.

All the components of the **BIRDIE System** enables the realization of variations provided that the dimensional compatibility of the parts and the materials is respected. These variations must be realized with components manufactured or expressly approved by I.CERAM.

The Birdie® spinal system is a spinal fusion system used for posterior spinal arthrodesis in neuromuscular or idiopathic scoliosis. This system is also intended for adults in severe cases of scoliosis.

2. Packaging – Sterilization – Resterilization

Components of the **BIRDIE System** are packed, as the case may be, in double or triple pack (example: peelable bag, tough blister).
The sterilization of each of these components is done by Gamma radiation at the minimum dose of 25 kGy. A sterilization mark, red if sterile, is on the box and another one is appended on the pack closest to the implant.
I.CERAM guarantees the implants' sterility providing that the pack is neither open nor damaged.
Each I.CERAM implant is for single use and cannot be sterilized again**.** I.CERAM's responsibility is not involved in the case of the resterilization of one or several implants by the user. The re-use or resterilization of a single-use medical device is likely to induce undesirable clinical reactions from the patient (infection, embolism, poisoning). Desterilized implants are sent back to I.CERAM.
The sterilization of test implants and instrumentation is mandatory and under the responsibility of the health care facility, in conformity with the ISO 17665-2.

3. Storage

The I.CERAM implants must be stored in their original packaging, in a dry place and away from the light so as to preserve the integrity of their packaging.

4. Marking

Each implant has the batch number linked with its fabrication. This batch number is also on all the tags that allow the implant's designation, information on the different files, including the patient's.
The communication of this batch number enables to trace back each implant's fabrication in its entirety, from raw material to sterilization.

5. Instructions (usage instructions) and precautions

For an optimal implantation of the **BIRDIE System**, it is necessary to use the I.CERAM instrumentation dedicated to this system.
For the implantation recommendations and the appropriate use of the instrumentation, the surgeon will refer to the surgical technique written by I.CERAM.
Before any use, it is necessary to control dates and sterilization markings as well as the integrity of the pack to check the implants' sterility. Each component, sterile and for single use, will be taken off its packaging, at the time of the implantation, aseptically and handled with caution by qualified staff so it is not damaged and so its sterility is protected.
The assembly surfaces must imperatively be kept clean to ensure the perfect adjustment of the components.

6. Indications

The implantation's indication for the **BIRDIE System** is decided by the surgeon and under their responsibility. Likewise, the components' assembly is for the surgeon(s) discretion.

The **BIRDIE System** is especially indicated for skeletal deformities, neuromuscular scoliosis, lumbar fractures, degenerative joint disease, tumors (1).

7. Contraindications and limiting factors

The implantation of the **BIRDIE System** is especially contraindicated in cases of recent infection, pronounced atrophy, bone deficiency, allergic reaction, of any concomitant illness likely to affect the implant's function (1).

Severe osteoporosis, infectious illness, overweight, smoking, drug addiction, alcoholism, mental disorder, intense physical activity, exposure to excessive loads, risk of conflict with another implant: these are the most common factors among those likely to limit the implant's lifespan (1).

8. Complications or adverse reactions

Bruising, late healing, cardiovascular disease, infection;
Those are the most common complications or adverse reactions (1).

9. Post-operatory precautions

Advise the patient of the precautions to be followed as part of post-operative development,
- Carry out radiological surveillance (frequency and protocol determined by surgeon).
- Be attentive to any signs of pain.

The surgeon is to decide on authorising free movement of the patient and to define any limits on patient activity after implantation. However, excessive activity is strongly discouraged.

10. Ablation of device

The surgeon makes the final decision concerning ablation of an implant.

11. Handling - Storage

Follow the required precautions for asepsis instructions when removing from packaging. Some products have sharp components that could injure the handler. The packaging of products delivered sterile
is not to be opened until time of use. Store products in their packaging

12. Advice for the patient

To guarantee the implant's lifespan, it is extremely important that the surgeon informs the patient about the device's limits, the acceptable weight, the movements, the allowed activity levels and the postoperative aftercare to which they have to agree to.
Cases of senility, of mental disorders or alcoholism can lead the patient to ignore these recommendations, and provoke postoperative complications.
(1) : These lists are not exhaustive

13. Meaning of the symbols

Limit date for use (Before YYYY-MM)	See the user instructions
LOT Lot code	REF Catalogue's reference
Do not use if damaged packaging	Manufacturer address
For single use	STERILE R Sterilized by Irradiation