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CE 1639 (Pour/For instruments classe/class IIa)
CE

Réf. : ni_Anc
Édition : 24
2020-07

Directive 93/42/CEE
Année marquage CE : 1997

Instructions for the attention of the surgeon and the operating room personal

NON STERILE

ORTHOPAEDIC SURGICAL INSTRUMENTS
RE-USEABLE MEDICAL DEVICES

EN

1. DESCRIPTION

These instructions are applicable to the instruments provided by BIOTECHNI for use with BIOTECHNI orthopedic implants.
Three categories of instruments are marketed by BIOTECHNI: 1) instruments connected to an active medical device (IRDA), 2) trial prostheses, and 3) reusable surgical instruments (Class I).
The raw materials used for the instruments manufacturing are: stainless steel, PEEK, Polypropylene, Silicone, Titanium alloy (TA6V-ELI).

1. INTENDED PURPOSE

- The instruments are designed for transient use, normally intended to be used continuously for less than 60 minutes.
- The list and the description of the instruments are given in the operating technique of the associated implants as well as in the documents attached to the products. BIOTECHNI can also provide them upon request.
- Class I instruments are intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device.
- IRDA instruments are intended for surgical use in cutting, drilling, reaming, or similar procedures, with a connection to an active device.
- Trial prostheses are intended for surgical use simulating the final implant.
- Surgical instruments may also be used to facilitate the insertion of surgical implants.

The use of an instrument for tasks other than those for which they are indicated may result in instrument damaging or breakage.

2. USE

The instrumentation is intended to be used on **adult patients.**
The instruments are designed for the following total number of uses: 80 times for calcar reamers, 30 times for acetabular reamers and 100 times for drills and trial prostheses. **Over this frequency, BIOTECHNI can't ensure the performance of the devices.**
All IRDA instruments must be used with and connected to an appropriate active medical device compliant with ISO 60601-1 in the sterile operating environment. The type of connection for each reference is indicated in the following table. The IRDA instruments performances have been verified with the motor rotation speed for 250 rpm, and the effort applied 150 N.

Reference	Type of connection

A042-0400; A042-0401; A042-9213; C4A/190; C4A/310	Triangle shank
A042-2027; A042-2035; A042-2135; C0423001037	Straight shank
A32-03; CA4002; C4A/280	Mini AO
CA4005; CA4009; CA4010	Twist straight shank with pin
C15A-132; C15A-132A; PFRC312x26; C15A-160	AO
FRCXX (XX:38 to 76)	Cross (with the PFRC312x26)

3. SIDE EFFECTS

The use of surgical instruments can lead to the potential side effects identified in the following non-exhaustive list:

- Lengthening of the operational time due to, among other, instrument breakage or damaging, difficulty of assembly, loss in the patient's body (trial femoral heads)
- Pain, discomfort for the patient, physical harm to the patient or the operating staff
- Perioperative bone fracture, poor final implant stability or malpositioning, re-intervention
- Allergy to the materials, infection of the surgical site, from but not limited to: corrosion, unsuitable sterilization or cleaning,
- Contamination from incorrect management of a contaminated device
- Infections, peripheral neuropathies, vascular damages, nerve damages.

4. HOW SUPPLIED

BIOTECHNI's surgical instruments are supplied NON-STERILE. If the instruments are part of a full set necessary for the implantation of a particular implant, they are supplied with a protective container including trays. This document provides instructions for cleaning, decontamination and sterilization of instruments before use, the effectiveness of which has been validated by BIOTECHNI. Other validated reprocessing methods not covered by this document may be used but are under full responsibility of the health facility.

5. INSPECTION

Before use, it is required to inspect the instruments for possible damage, wear or dysfunction. Carefully inspect the critical, inaccessible areas, joints and all movable parts. Damaged or defective instruments should not be used or processed. Contact your local sales representative or BIOTECHNI for repair or replacement.

6. PRECAUTIONS

- The instruments must be handled by well-trained, qualified persons aware of these instructions for use and having detailed knowledge and experience of the appropriate operative technique for the instruments and associated implant, and of the potential risks associated to the operation to be performed.
- Before surgery, the surgeon must inform the patient on all potential allergies to materials.
- The surgeon must use the instrumentation recommended in accordance with the relative surgical technique provided by the manufacturer.
- Handle the instruments with care, without contact and shock, all through the different phases of use and treatment (cleaning and sterilization).

7. WARNINGS

- Do not use an instrument damaged, stained, contaminated or handled not correctly.
- Do not implant the instruments.
- Use an instrument only for its intended use to avoid any damaging, compromising of its strength and causing its immediate or premature failure.
- BIOTECHNI advises expressly against use of instruments manufactured by a third party in association with the BIOTECHNI implants and accepts no liability for possible damages and consequences resulting of a such use.
- Do not store the instruments in contact or in the vicinity of products which could have a corrosive action.
- The transport containers provided by BIOTECHNI are not for sterilization purposes.

8. CARE AND HANDLING

The procedures outlined below should be followed to ensure safe handling of biologically contaminated surgical instruments. All instruments must be sterilized before use.

CLEANING

- Put in soak the instruments immediately after use (it is imperative to avoid the drying of stains on the instruments). Open the articulated instruments as indicated in the Annex. Immerse fully in the decontamination bath; eliminate any substance which could obstruct the liquid penetration inside the hollow or cannulated instruments. BIOTECHNI recommends the use of the disinfectant Neodisher® Septo Preclean ZP 1% diluted for 15 minutes at environmental temperature.
- Brush all the surfaces of the instrument with non-metallic brushes.
- Visually inspect the instrument to verify that no soil remains on the device.
- Perform an automatic cleaning and disinfection in a validated washer-disinfector (compliant with the ISO 15883 series), following a standard cycle of the washer-disinfector. BIOTECHNI recommends the use of Neodisher® SeptoClean et Neodisher® MediKlar special as chemicals. In any case, refer to the recommendations of chemicals manufacturers.

STERILIZATION

- Sterilize before use by saturated steam autoclaving according to the regulations in force in the health-care organizations (suggested method: wet steam at 134°C during at least 18 minutes).
- The container in which are placed the instruments can be steam sterilized either by wrapping the container itself in a double layer of paper or pouch conform to EN868-2 to 10, or by placing it inside a sterilization container agreed by the health-care organization.

CAUTION: the transport containers provided by BIOTECHNI must not be used for the sterilization. These containers may be damaged during the transport, they are only provided to improve the protection and the handling of the ancillary.

9. STORAGE

Storage conditions must be such as to maintain the integrity of the equipment. Instruments should be stored in a clean, dry place. The maximum allowable storage time between uses for sterile instruments must be defined by the health care facility.

10. MAINTENANCE AND REPAIR

If an instrument requires repair or maintenance, return the instrument to:
BIOTECHNI SAS, 178 avenue du Serpolet, 13600 La Ciotat (France).

Instruments returned to BIOTECHNI for repair must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

BIOTECHNI expressly advises against the instrument's reparation or maintenance by a third party. In such case, BIOTECHNI declines all responsibility regarding the performance of the instrument and possible consequences for the patient's health.

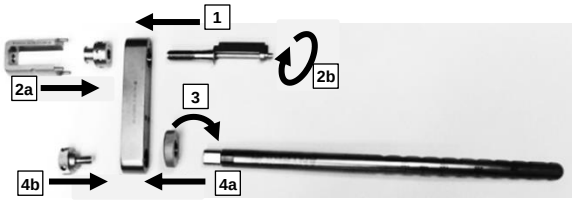
11. WASTE MANAGEMENT

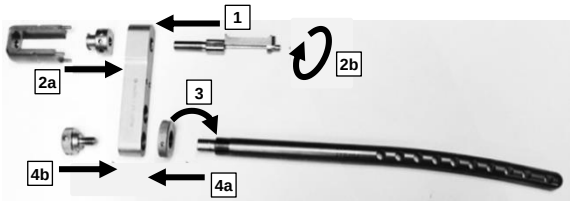
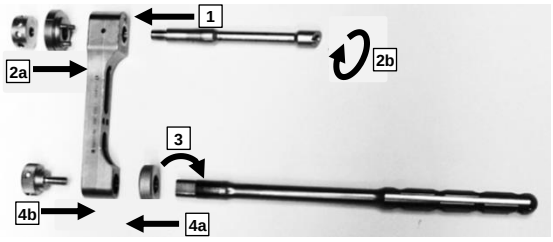
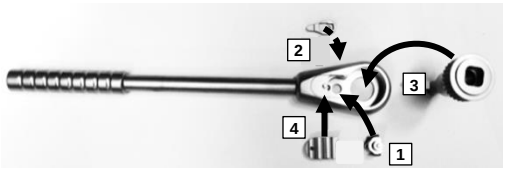
Surgical instruments to eliminate and packaging wastes must be handed over to a specialized service for environmentally safe disposal in compliance with strict hygiene rules under the responsibility of the medical center, and according to the local applicable regulations.
A defective instrument must be returned to the manufacturer after decontamination.

ATTENTION: Any serious incident occurring in relation with an instrument must be reported to the manufacturer and competent authority of the pertinent Member State.

For any additional information, please contact your sales representative or the manufacturer (info@biotechni.com).

The reference text is the French text.

ANNEX INSTRUCTIONS FOR THE ASSEMBLY	
A042-0401 	
C4A/190 	
C4A/100 	

C4A/600 	
A042-9200 	
C8A-PC450 	

	Non sterile
	Manufacturer
	Fragile; handle with care
	Date of manufacture
REF	Reference
	Keep away from rain
LOT	Batch number