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INFORMATION ON THE USE OF ROTARY SURGICAL INSTRUMENTS CE 0197

1. General informations

BHH Mikromed rotary surgical instruments: surgical drills, mills, screwdrivers, taps, wrenches connected to active medical device, manufactured in accordance with international standards, are made of stainless steel which generally shows magnetic properties.

Any instrument made of stainless steel may develop corrosion, stains or become damaged, if is handled without proper care or against the manufacturer's recommended guidelines. Rotary surgical instruments must only be used for their intended purpose**.**

2. Intended use

The rotary surgical instruments are reusable, operating in conjunction with a drill or any other active drive, serving for milling, drilling, screwing and tapping.

3. Description

The label placed on the implant unit package contains information identifying the product: catalogue number - REF, lot number – LOT and the implant name and dimensions.

The products may have been modified by manufacturer, it is imperative that their compatibility have been checked before the surgery begins.

4. Cleaning, desinfection and sterilization

Surgical instruments are supplied **non sterile**. When brand new instruments have been unpacked, prior to their first sterilization they must be washed with warm water with detergents intended for medical applications added. Sterilization must be carried out directly before use.

Directly after instruments have been used, they must be washed with water solution of disinfecting agents and then manually washed with warm water and a plastic brush or washed automatically. No wire brushes or scrubs may be used in manual cleaning. Cleaning must remove all postoperative biological contaminants. Use only cleaners and disinfectants which have been approved for medical applications and which contains corrosion inhibitors. Once the instruments have been cleaned and rinsed, they should be carefully dried – temperature cannot exceed 134°C. Multicomponent instruments which are not-integrally connected must be disassembled before cleaning and drying.

Clearing, disinfecting and sterilization procedure necessary to prepare a medical device for its intended application must meet requirements of the standard of PN-EN ISO 17664:2005 "Sterylizacja wyrobów medycznych. Informacje dostarczane przez wytwórcę w celu postępowania z wyrobami medycznymi przeznaczonymi do ponownej sterylizacji" (Sterilization of medical devices. Information provided by the manufacturer on handling the devices intended for repeated sterilization).

Sterilization: The recommended method is high pressure autoclaving at the temperature of 121°C and overpressure of 01013MPa (1atm.) for 20 minutes or alternatively, sterilization at the temperature of 134°C and overpressure of 0,2026MPa (2 atm.) for 10 minutes.

Sterile device must meet requirements of the standard of PN EN 556-1:2002 „Sterylizacja wyrobów medycznych. Wymagania dotyczące wyrobów medycznych określonych jako sterylne. Cz.1. Wymagania dotyczące finalnie sterylizowanych wyrobów medycznych" (Sterilization of medical devices. Requirements set for medical devices specified as sterile. Part 1 Requirements set for finally sterilized medical devices) dealing with assurance of asepsis on acceptable level.

Strictly observe the guidelines for the use all cleaning, disinfecting and sterilization equipment, as well as the temperature and operation time parameters. The sterilization procedure must be validated according to the standard of PN-EN ISO 17665-1:2008 „Sterylizacja produktów stosowanych w ochronie zdrowia – Ciepło wilgotne. Cz.1. Wymagania dotyczące opracowania, walidacji i rutynowej kontroli procesu sterylizacji wyrobów medycznych" (Sterilization of heath care products – Moist heat. Part 1 Requirements for working out, validation and routine control of the sterilization process of medical devices).

Validation must be carried out for all medical devices.

5. Storage

Packaged products should be stored in a clean, dry place, in conditions that ensure protection against direct sunlight, pests, extreme temperatures and humidity.

Every time before use the device must be controlled – it should be efficient, no postoperative biological contaminants and no residues of disinfection or sterilization may be revealed, no damages of the material structure are acceptable /blunt cutting edges, wear handle, breaks, bends, fractures, peels off/.

Remember that sterilization does not replace cleaning!

6. Warnings

The instruments must be used strictly with their intended purpose and in compliance with good medical practices, with special regard to the usage guidelines and following warnings:

- prior to surgery make sure that all the instruments necessary for the task have been prepared, and check whether all of the required implants and instruments are compatible;
- check that all instruments were correctly placed in driver of active medical device;
- use slow-speed drills;
- any force applied while the instruments are being handled must be proportional to the strength and condition of the bone;
- during use of the rotary surgical instrument connected to the driver, during surgery, suitable covers protecting eyes must be used;
- worn, disfigured, blunt or damaged instruments cannot be used;
- be aware of the effect of magnetic and electromagnetic fields, as the instruments show magnetic properties;

before the surgery is completed check whether all the instruments and their component parts have been removed from the surgical site.

The instruments can be used as long as their required properties allow to achieve the intended purpose. Observing of recommendations made by the manufacturer referring to cleaning, washing, sterilization, maintenance, proper use preventing mechanical damage, avoiding of contact with corrosion facilitating chemicals influence durability of instruments and quality of the operation.

Ignoring the recommendations significantly reduces durability of the instruments and shortens the time of their possible application, can cause hazard for health and life and can cause a medical incident.

The average life time of rotary surgical instrument shall be 20 full operating cycles (cleaning, disinfection, sterilization, use during operation) whereupon instrument is used and it is needed to replace it or give to regeneration.

In case of questions about use of instruments, please contact BHH Mikromed representative under the phone number which is specified in the header.

REF	Nr kat. / Catalogue no.		Producent / Manufacturer	NON STERILE	Niesterylny / Nonsterile
LOT	Nr serii / Serial no.		Data produkcji / Manufactured date	CE	Oznaczenie CE / CE Mark
	Zapoznaj się z instrukcją używania / Read the Instruction for use		Ostrzeżenie / Caution	0197	Numer jednostki notyfikowanej / Number of notified body