BHH MIKROMED

BHH MIKROMED Sp. z o.o.
ul. Katowicka 11 42-530 Dąbrowa Górnicza POLAND

NIP 629-13-15-420 REGON 273123120 KRS 0000153283 www.mikromed.pl info@mikromed.pl **tel./fax +48 32 262-52-85 +48 32 264-68-85**

IMPORTANT INFORMATION FOR EXTERNAL STABILIZER USERS

NON STERILE PRODUCT.
STERILIZE DIRECTLY BEFORE USE AFTER UNPACKING.

BHH MIKROMED stabilizers are manufactured and supplied in compliance with the requirements of Directive 93/42/EEC as well as the Quality Management System in accordance with EN ISO 9001:2008 and EN ISO 13485:2012. The company has been certified by TÜV Rheinland, Cert. No. SX 60104809 0001, SY 6010810 0001, HD 60104808 0001.
The implants are marked with CE 0197.

INTENDED USE

External stabilizers including both simple constructions and complicated devices allowing dynamic fixations are sets of non-invasive elements allowing stabilization and fixation of implants inserted into bone fragments and thus:
- correcting of bone fragments position,
- fragments pressure,
- growing apart and transport of fragments for bone elongation,
- dynamisation or stiffening of the fixation.

Basic prerequisites for successful treatment outcome are listed below:
- proper selection of the method to the treated case,
- the surgeon has mastered the implantation technique at training workshops,
- good medical practices are duly performed,
- the surgeon, medical personnel and patient all follow the guidelines set out in **"Important information for external stabilizer users"** leaflet and the leaflets of **"Important information for implant users"** and **"Information on the use of surgical instruments"**.

DEVICE INFORMATION

A complete stabilizer consists of external supporting structure and bone implants.
The stabilizer supporting structure /support/ is made of stainless steel, titanium, aluminium alloys and synthetic materials in accordance with international standards.
Implants - bone grafts are made of stainless chrome-nickel-molybdenum steel in accordance with the international standard of ISO 5832-1, or, alternatively, of titanium, or of its alloy in accordance with ISO 5832-2,3.
Although the materials used show excellent properties, there are contraindication defined by modern medical practice. Allergic responses are also likely. **No implants may be reused.** Implants are supplied non sterile, their microbiological cleanliness is accepted. **Detailed information on implants** is included in the leaflet of **„Important information for implant users".**

The stabilizer and surgical instrument components are made of stainless steel, yet if they are not handled with proper care or in accordance with the suggested guidelines, they may be prone to corrosion traces, stains or damage.
Implants and other elements of the stabilizer are supplied **non sterile**.

CLEARING, STERILISATION AND STORAGE

Brand new and unpacked components of the supporting structure before first sterilization must be **carefully washed** with hot water and agents intended for medical applications.
Directly after components of the multiple use stabilizer have been used, they must be soaked with water solution of disinfecting agents and then manually washed with warm water and a plastic brush or with a special ultrasonic device. No wire brushes or scrubs may be used in manual cleaning. Cleaning must remove any blood, tissue, deposits and corrosion inhibiting fluids. Once the instruments have been cleaned and rinsed with distilled water, they should be carefully dried. After each washing, slipping surfaces of pins, wedges, clamps, articulations, threads must be lubricated with a thin layer of aseptic paraffin based substance and stored at the temperature of 15 – 30°C and relative humidity not exceeding 70%.

Clearing, disinfecting and sterilization procedure necessary to prepare a medical device for its intended application must meet requirements of the instruction based on the standard of EN ISO 17664:2004 „Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices".

Implants sterilization shall be carried out directly before use when removed from their packaging.

Following "Polish Pharmacopeia" it is recommend high pressure autoclaving at the temperature of 121°C and overpressure of 1 atm, for 20 minutes or, sterilization at the temperature of 134°C and overpressure of 2 atm for 10 minutes. These parameters should be considered minimal.

The sterilization procedure must be properly planned and carried out after being validated according to the EN ISO 17665-1:2006 standard ”Sterilization of heath care products – Moist heat. Part 1 Requirements for the development, validation and routine control of a sterilization process for medical devices”.
Validation must be carried out for all medical devices.

Sterile implants must meet requirements of the standard of EN 556-1:2001 ”Sterilization of medical devices. Requirements for medical devices to be designated STERILE. Part 1 Requirements for terminally sterilized medical devices” dealing with assurance of asepsis of 1/1000000 which means that probability of finding on a sterilized implant of microorganisms able to live does not exceed one millionth.

RECOMMENDATIONS

Before surgery commences, insure that all the components prepared for the procedure are in good condition and compatible. Subsequently, on the basis of a two-plane-x-ray image, plan the positioning of the implant, the number of required implants and the stabilizer - bone distance.
The stabilizer must be positioned as close to the bone as possible, but so as not to hinder dressing or other minor procedures in case they are required, or to irritate the skin should oedema occur. After relevant radiological images have been analyzed, initial repositioning of the bone fragments is required, while with an articular stabilizer installation, the position of the articulation in respect of the treated joint should be set with maximum precision. Before a stabilizer with implant components is used, it is imperative that the surgeon be familiar with the contents of the leaflet “Important information for implant users”.

WARNINGS

Metallic implants cannot withstand stresses caused by body weight bearing or excessive muscular activity associated with insufficient degree of union. Excessive or repeated stress may weaken the fixation, cause union delay, nonunion or implant breakage. Therefore it must be emphasized that implants will serve their function only when the guidelines listed below are observed:
- the implant has been correctly selected to match the patient’s body weight, lifestyle and the fixation type,
- every effort was made to minimize the loads to be transmitted by the implants,
- implant mechanical damage, scratch of its coating or its disfigurement was avoided,
- bending the implant was avoided. Should any deformation be necessary, it must be minimal, be made only once, and outside the implant hole area,
- forces applied throughout the implantation surgery should be minimal and match both the implant resistance and the bone,
- it was made sure that the implant - bone fragments fit is precise and firm,
- used implants show the same chemical composition and properties,
- **no implant was reused** as fatigue accumulation may result in early implant breakage,

It is necessary:
- not to ignore hazards caused by modern diagnostic and therapeutic technologies that generate electric and/or magnetic fields,
- to bear in mind that steel implants may cause interference in magnetic resonance /MR/ examinations,
- to use slow-speed drills with drilling site cooling,
- to bear in mind that any implant tips protruding through the skin pose injury risk,
- to provide the patient with adequate post-operative monitoring until the treatment is concluded,
- to advise each patient that no fixation will withstand excessive stress caused by the full body weight bearing or very active lifestyle,
- remove implants after the treatment is completed.

POSSIBLE ADVERSE EFFECTS

- metal sensitivity or foreign body allergies,
- shortening of the limb caused by the fractured bone compression,
- bone density reduction, fascial compartments,
- pain, discomfort or abnormal sensations caused by the implant presence,
- nerve damage caused by the surgical trauma, damage of blood vessels, nerves or tendons,
- bone necrosis, union delay, pseudoarthrosis, repeated fracture,
- inflammatory reaction in the implantation area.

PATIENT ADVICE

Successful treatment outcome is dependent on suitable post-operative procedures. The patient should be provided with adequate post-operative monitoring, periodical check-ups and x-ray examinations if necessary. Each patient should be advised that no fixation will withstand excessive stress caused by the full body weight bearing or very active lifestyle. Instruct the patient on proper fixation site hygiene and the necessity to notify the doctor of any changes noticed at the implantation site and any therapy linked events, even if the implant or the implantation site show no signs of injury. Ignoring of the above recommendations may cause damage or failure of the fixation, complications, medical incident or hazard for health and life.