



IMPORTANT INFORMATION FOR IMPLANT USERS (CE 0197) (CE 0044)

<p>1. General informations Implants manufactured by BHH Mikromed Sp. z o.o. are made of highly alloyed chrome-nickel-molybdenum highest purity stainless steel which meets all the requirements of the PN EN ISO 5832-1 standard, or, alternatively, of titanium, or its alloy in accordance with the international standards of ISO 5832-2 and ISO 5832-3.</p> <p>Implants are manufactured in accordance with international recommendations.</p> <p>2. Implant intended use The implant is designed to stabilise bone fragments temporarily. At the conclusion of the treatment the implants should be removed from the patient body. Specific guidelines for implant use are defined by current medical practices.</p> <p>Basic prerequisites for successful treatment outcome are listed below:</p> <ul style="list-style-type: none"> • the type and size of the implant as well as the surgical technique have been correctly selected and well matched with the case under treatment, • 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 this leaflet. <p>3. Description The label placed on the implant prepack contains information identifying the product: Reference number - REF, lot number - LOT and the implant name and dimensions.</p> <p>The products may have been modified, it is imperative that their compatibility have been checked before surgery initiates.</p> <p>4. Transport and storage Packaged products should be stored in a clean, dry place, in conditions that ensure protection against direct sunlight, pests, temperatures 15 -35°C and humidity 25% - 65%.</p> <p>5. Rules of use</p> <ul style="list-style-type: none"> • Implants are intended for single use only. Subsequent use will cause damage to outer layer and mechanical damage or failure. Repeated use can cause contamination of the human body. • Implants are supplied non sterile. • The products must be used before date announced on the label. • Implantation time /period, that implant is inside human body/ should not pass osteosynthesis time, not longer that 2 years, except important reasons related to patients treatment. • The lifetime of the product is 10 years. <p>6. Clearing, disinfection and sterilization</p> <ul style="list-style-type: none"> • Before using the implants should be removed from the wrapping, and subjected to cleaning and disinfection, and then the process of repackaging into the package refer to ISO 11607 in a room with supervised microbiological purity. Then they must be sterilized. • Clearing, disinfecting and sterilization procedure necessary to prepare a medical device for its intended application must meet requirements of the instruction based on EN ISO 17664:2022 "Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices". 	<ul style="list-style-type: none"> • The sterilization procedure must be properly planned, carried out and validated according to the EN ISO 17665-1:2006 standard "Sterilization of health 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. <p>Sterilization: it is recommend high pressure autoclaving at the temperature of 121°C and overpressure of 0,1013MPa (1 atm.), for 20 minutes or, alternatively, sterilization at the temperature of 134°C and overpressure of 0,2026MPa (2 atm.) for 10 minutes. These parameters should be considered minimal.</p> <p>Sterile device must meet requirements of the standard of PN EN 556-1:2002 „Steryliczacja 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.</p> <ul style="list-style-type: none"> • Implants can be sterilized max. 20 times, observing these rules. • The implant, which has been in contact with the tissues, blood or bodily fluids of a patient cannot be re-implanted due to the potential risk of cross-infection. <p>7. Contraindications States that may be associated with increased risk are the following:</p> <ul style="list-style-type: none"> • insufficient quantity or quality of bone (bone loss or weakening), • latent or active bone infection, internal or surface infections, compromised bone blood supply or earlier infections, • other conditions which make the patient incapable of following the treatment regime or postoperative treatment recommendations (mental or neurological conditions, etc.), • allergy to the implant, or other allergies which need to be excluded before the implantation procedure is initiated. <p>8. Warnings Metallic implants cannot withstand excessive forces involved in the implantation surgery, the stresses caused by body weight bearing or excessive activity associated with insufficient degree of union. Excessive or repeated stress may weaken the fixation, cause union delay, nonunion or implant breakage.</p> <p>Therefore it must be emphasised that implants will serve their function only if:</p> <ul style="list-style-type: none"> • the implant has been correctly selected to match the patient's body weight, lifestyle and the fixation type, • patient was advised that no implant will withstand stresses resulting from full body weight bearing or excessive activity, • every effort was made to minimise the loads to be transmitted by the implants, 	<ul style="list-style-type: none"> • 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. <p>It is necessary:</p> <ul style="list-style-type: none"> • not to ignore hazards caused by modern diagnostic and therapeutic technologies that generate electric and/or magnetic fields, • to keep safety during magnetic resonance /MR/ examinations in the reason that steel implants may cause interference in MR image or cause signal loss, • 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 remove implants from the body before 2 years after operation, except important reasons related to patients treatment do not allow. <p>9. Possible adverse effects</p> <ul style="list-style-type: none"> • metal sensitivity or foreign body allergies, • shortening of the limb caused by the fractured bone compression, • bone density reduction, • pain, discomfort or abnormal sensations caused by the implant presence, • nerve damage caused by the surgical trauma, damage of blood vessels or tendons, • bone necrosis, union delay, pseudoarthrosis, repeated fracture, • inflammatory reaction in the implantation area. <p>10. 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. 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, health state deterioration or any therapy linked events, even if the implant or the implantation site show no signs of injury. Leaflet important information for implant users should be delivered for patients.</p>
<p>REF Catalogue no.</p> <p>LOT Serial no.</p> <p> Do not use package if damaged</p> <p> Read the Instruction for use</p> <p> Storage temperature limitation 15°C - 35°C</p>	<p> Manufacturer</p> <p> Manufactured date</p> <p> Do not reuse</p> <p> CE Mark</p> <p> Storage humidity limitation 25% - 65%</p>	<p> Used by</p> <p> Nonsterile</p> <p> Caution</p> <p>0197 Number of notified body</p> <p>0044 Number of notified body for products manufactured before 01.10.2015</p>