



OHST Medizintechnik AG

Grünauer Fenn 3

14712 Rathenow

Deutschland / Germany / Allemagne /

Germania / Alemania / Duitsland /

Alemanha / Γερμανία / Niemcy /

Německo / Németország / Germania /

Германия / Алманыа / Німеччина /

Vokietija / Германия / 德国

Tel.: +49 (0)3385 - 54 20-0

Fax: +49 (0)3385 - 54 20-99

www.ohst.de

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IMPLANT

Flat-head screw

Before using the product, the user is under obligation to carefully study the following recommendations and information along with the information specific to the product.

The party introducing this product into circulation accepts no liability for direct or consequential damage or injury resulting from careless use or handling, particularly noncompliance with the following user instructions or improper care or maintenance. These implants may be used only by physicians with detailed knowledge, experience and the skills required for hip and knee arthroplasty. Familiarity with the surgical technique recommended for this system and its diligent application are indispensable in order to achieve the best possible result.

1. Product description and implant materials

The flat-head screws are designed for use as accessories with load-bearing implants.

The bone screws are made of Ti6Al4V alloy (ISO 5832-3). They have a head diameter of 8 mm and a cancellous bone screw thread with Ø 6.5 mm. The flat-head screws come in lengths of 15 mm to 60 mm with 5-mm increments.

Product, packaging contents and materials used are specified on the product label. The implant must be implanted using a suitable surgical technique familiar to the surgeon. In this regard, attention must be given to the explanations concerning the particular surgical technique.

1.1 Implant overview

Name	Material	Reference number
Flat-head Screw Ø 6.5 x 15 mm, self-tapping	ISO 5832-3 Ti6Al4V	000-290-15
Flat-head Screw Ø 6.5 x 20 mm, self-tapping	ISO 5832-3 Ti6Al4V	000-290-20
Flat-head Screw Ø 6.5 x 25 mm, self-tapping	ISO 5832-3 Ti6Al4V	000-290-25
Flat-head Screw Ø 6.5 x 30 mm, self-tapping	ISO 5832-3 Ti6Al4V	000-290-30
Flat-head Screw Ø 6.5 x 35 mm, self-tapping	ISO 5832-3 Ti6Al4V	000-290-35
Flat-head Screw Ø 6.5 x 40 mm, self-tapping	ISO 5832-3 Ti6Al4V	000-290-40
Flat-head Screw Ø 6.5 x 45 mm, self-tapping	ISO 5832-3 Ti6Al4V	000-290-45
Flat-head Screw Ø 6.5 x 50 mm, self-tapping	ISO 5832-3 Ti6Al4V	000-290-50
Flat-head Screw Ø 6.5 x 55 mm, self-tapping	ISO 5832-3 Ti6Al4V	000-290-55
Flat-head Screw Ø 6.5 x 60 mm, self-tapping	ISO 5832-3 Ti6Al4V	000-290-60

1.2 Instrument overview

The instruments of the OHST Medizintechnik AG listed below must be used exclusively for implantation:

Name	Reference number
Hexagonal Screwdriver SW 3.5mm grey with silicone handle, L=250 mm	250161-5
Cardan Screwdriver, SW 3.5mm with silicone handle grey, L= 273mm	00-092-10

1.3 Accessories

Name	Reference number
Screw gauge curved L=232mm, angle: 135°	367-115
Screw Holding Forcep	367-1021
Implant passport	50000572

2. Handling

2.1 General information

This implant is part of a system and must only be used with the appropriate original system components. Only the instruments of the system listed above must be used for implantation. Before using the instruments the attached instructions for use (50000354) must be considered.

Caution: Implants must always be kept in their complete, unopened protective packaging. The packaging containing the implant must not be exposed to direct sunlight. Before inserting the implant, the packaging must be examined for damage, as this could affect sterility.

When unpacking the implant, its conformity with the designation on the packaging (art. no. / serial no. / size) must be checked. Compliance is required with the appropriate hygiene regulations during removal of the implant from the packaging. Care must be taken to protect all implant surfaces against damage, since this could be decisive for possible failure. The prosthesis must not therefore come into contact with objects which could damage its surface. Before use, every implant must be visually inspected for damage. Machining an implant can not only reduce its service life, but can also lead to immediate or subsequent failure of the prosthesis under stress. The implant must therefore neither be mechanically nor otherwise processed. Implants from damaged packaging, unsterile, contaminated, damaged or carelessly handled implants or implants subjected to unauthorized machining must not be used.

Caution: Implants are intended for single use only! Individual loads on functional surfaces of an implant used for one patient modify the functional surfaces in a way that excludes any reuse. Detection of load-caused markings by visual methods only is not secured. Therefore, damage after explantation must be assumed which excludes any reuse.

2.2 Authorised component combinations

We guarantee compatibility of our products only in combination with our own CE-marked products and with the products we have approved for combined use and which have been authorised accordingly. In this regard, please note the instructions for use of the endoprosthesis manufacturers and the combination matrix approved by OHST.

Due to reasons relating the product safety and product liability, it is prohibited to use implants manufactured by OHST Medizintechnik AG in combination with components of other manufacturer that have not been approved by OHST.

2.3 Information for use

Caution: The application instructions of the implant system being used with the flat-head screws have to be observed.

Caution: Please be hereby explicitly advised that, in case of an intraoperative change or revision of the femoral head, only femoral heads without a ceramic cone are to be used. This is valid irrespective of the materials used in the previous cone pairing.

Caution: If a ceramic component is damaged or fractured, complete revision of the prosthetic components at the earliest possible date is recommended. In this case, the use of metal femoral heads is contraindicated in revision surgery, as this may lead to serious and partly life-threatening complications. In the rare event of a fracture of the ceramic component, thorough debridement with removal of all visible ceramic particles as well as careful wound irrigation is absolutely essential during surgery.

Before inserting the implant, the implant bed must be irrigated. During implantation, ensure that all loose particles (e. g. bone splinters, friction particles from the instruments) are removed from the prepared implant bed.

Caution: When using high-frequency surgical instruments (e.g. cautery knife), it must be ensured that they do not come into contact with the implants or instruments. This can cause such severe damage to the implants or instruments that failure (e.g. fracture) may ensue. If an implant has been damaged, it must not remain in the patient but needs to be replaced by a new, intact implant. Damaged instruments may only continue to be used if they can still perform their intended function without compromise.

2.4 Surgical technique

When using self-tapping flat-head screws, the bone has to be pre-drilled with a drill of diameter 3.2 mm according to the screw length being used. The depth of the drill-hole can be verified with the screw gauge. After that, the flat-head screws are inserted according to the surgical technique of the implant system being used.

Caution: The position of the screw holes of the implant/screw combination to be used, as well as the corresponding screw lengths, must be selected in a way that precludes damage to vessels and nerves or unintentional perforation of structures.

3. Packaging and sterility

Depending on the sterilisation method used, implants are packaged in a triple transparent pouch made of plastic laminated film (sterilisation by irradiation at least 25 kGy) or in a double transparent pouch made of Tyvek® (ethylene oxide sterilisation) with a carton. The instruments are supplied unsterile in protective packaging. They must be cleaned and sterilised prior to use in accordance with the respective instructions for use (50000354). The stated expiry date presumes that the packaging is intact and unopened and that the product is stored under suitable conditions.

Caution: The implants may not be resterilized! The reconditioning of components that have not been implanted but the packaging of which has been opened is permitted only at the manufacturer, because the components must pass through individual validated processes once again.

The outer pouch of the triple transparent pouch packaging is to be removed by the non-sterile personnel together with the carton. For the double transparent pouch packaging, only the carton is to be removed by the non-sterile personnel. The second pouch must be opened such that the sterility of the inner pouch is not compromised. The inner pouch is removed and opened by the sterile personnel. The implant must then be presented to the surgeon, who can then directly remove the sterile implant.

4. Preoperative planning and postoperative care

Preoperative planning by reference to X-rays, CT data and similar is indispensable and provides important information about suitable implants, placing and possible component combinations and enables the size of the implant to be used to be preselected. Surgery may only be performed once it has been established that the patient is able to tolerate the implant material. Use the X-ray templates for planning the operation. These are available for all sizes in a magnification of 1,15:1. In addition, X-ray templates with a 1:1 ratio are available in digital form. Trial prostheses for checking the correct seating (where applicable) and additional implants should be available should another size be required or the intended implant cannot be used. Recognized procedures must be used for postoperative care.

5. Indications

- Fixation of endoprotheses (e.g. hip cups, tibial components) within the scope of the anchorage authorised by the respective manufacturer
- Fixation of bone fragments in conjunction with hip or knee arthroplasty

Caution: The indications of the implant system being used with the flat-head screws must be observed.

6. Contraindications

- Acute or chronic infections, whether local or systemic
- Severe muscle, nerve or vascular diseases endangering the extremity concerned
- Missing bone substance or poor bone quality which threatens the stable fit of the implant
- Any underlying condition that can endanger the function of the implant
- Hypersensitivity to the material used
- Local bone tumours that preclude stable fixation of the implant

Caution: The contraindications of the implant system being used with the flat-head screws must be observed.

7. Risk factors and conditions that may affect the success of the surgery

Caution: Clinical experience has shown that the presence of one or more of the following concomitant circumstances (risk factors) may lead to shorter service lives, more frequent complications or an altogether poorer outcome of hip arthroplasty. This list is by no means exhaustive.

General risk factors and conditions:

- Overweight
- Alcohol or substance abuse
- Patient groups with mental disorders or addictions
- Pregnancy
- High-dose ingestion of cortisone or cytostatics

- Previous or threatening infectious diseases with possible joint involvement
- Deep vein thrombosis and/or history of pulmonary embolism
- All general surgical risks

Risk factors and conditions specific to hip and knee arthroplasty:

- Disorders of bone metabolism (osteoporosis, osteomalacia)
- Occurrence of fissures, in rare cases fractures
- Circulatory disorders of the affected limb
- Neurological disorders of the affected limb
- Muscle malfunction in the affected limb
- Growth in children and adolescents
- Anticipated extreme loading e.g. due to work and sport
- Epilepsy or other reasons for repeated trauma with an increased risk of fracture
- Joint deformities that make fixation of the implant difficult
- Weakening of the bearing structures by tumour

Caution: The risk factors of the implant system being used with the flat-head screws must be observed.

8. Possible negative effects

The negative effects listed below are among the most typical and commonly occurring consequences of a surgical procedure:

- Infection
- Venous thrombosis and pulmonary embolism
- Cardiovascular disorders
- Haematomas
- Paresthesia
- Numbness
- Swelling
- Nerve damage
- Oedem/fluids

The negative effects listed below are among the most typical and commonly occurring consequences of total hip replacement and knee arthroplasty:

- Change in position and loosening of the prosthesis
- Dislocation of the prosthesis

Caution: The adverse effects of the implant system being used with the flat-head screws must be observed.

9. Patient information, documentation

The serial numbers of the implants used must be recorded in the patient's records. Appropriate labels are included with the packaging of the sterile implants.

The patient must be informed of the advantages and risks of the procedure. If the implant is regarded as the best solution for the patient, although the contraindications described above partially apply to the patient, it is particularly important to point out to the patient the effects of these circumstances on the success. Patients undergoing hip or knee replacement surgery must be informed that the service life of the

implant will depend on the patient's weight and how active the patient is in everyday life. The patient has to be informed about activities with which he can reduce the effects of these aggravating circumstances. All the information given to the patient must be documented in writing by the surgeon. After surgery, the patient must be given an implant pass containing all necessary information concerning the implant. Adhesive labels are enclosed for documenting the implant used. Adverse effects that are harmful to patients can arise during MRI investigations. Artefacts, heating of implant, induction of electrical currents and implant loosening are among the possible effects. The equipment manufacturer's instructions should be carefully studied before use. In case of doubt, comparable implants should be checked for their specific MRI suitability as part of an individual risk assessment. Patients should be informed of the risks.

10. Key to label symbols

An explanation of the symbols used by OHST Medizintechnik AG can be found in the annex (p. 113).