Instructions for Use: Sterile Implants

Instructions for Use DMD-IFU-003 RevA Issue Date: February 2018

Caution:
Carefully read all the instruction and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions for use.
U.S. Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

1 General Instructions

The Diamond Orthopedic Bone Fixation Screws and Pins are intended to be used as fixation implants for bone fractures, joint fusion, bone reconstruction, or as guide pins for insertion of other implantable devices. Diamond Orthopedic implants should only be used with approved devices and accessories.

The use of metallic surgical implants has given the surgeon a means of bone fixation and helps generally in the management of fracture and reconstructive surgery; however, these implants are intended only to assist healing and run intended to replace normal body structures. Metallic bone fixation devices are internal splints which align the fracture while normal healing occurs. The size and shape of bones and soft tissue place limitations on the size and strength of implants. If there is delayed union or nonunion of bone in the presence of weight bearing or loadbearing, the implant could eventually break due to metal fatigue. Therefore, it is important that immobilization of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. All metallic surgical implants are subject to repeated stresses in use, even in the absence of direct weight-bearing, which can result in metal fatigue. Factors such as the patient's weight, activity level, and adherence to weight-bearing or load-bearing instructions have an effect on the stresses to which the implant is subjected, and therefore on the life the implant. It is important to note that these implants may break at any time if they are subjected to sufficient stresses.

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant but also must be aware of the mechanical and metallurgical aspects of surgical implants. Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instructions could lead to loosening or breakage of the implant, and/or possibly migration, requiring revisional surgery.

2 Device Description

a) Implants made from titanium in accordance with ASTM F-136 Ti6Al4V alloy manufactured by Diamond Orthopedic, LLC. The surface of these implants is chemically passive.
These implants can be combined with the standardized material provided that its composition lies within the analysis stipulated in the ASTM F-136 standard and the required specifications. Alloyed titanium is biocompatible and prevents a so-called chrome-nickel allergy by its nature.

b) Implants made from stainless steel in accordance with ASTM F-138 stainless steel manufactured by Diamond Orthopedic, LLC. The surface of these implants is chemically passive.
These implants can be combined with the standardized material provided that its composition lies within the analysis stipulated in the ASTM F-136 standard and the required specifications. Material alloys with chrome-nickel (implant steel) components can trigger a so-called chrome-nickel allergy by their nature; there are no other known biocompatible hazards.

3 Indications

Diamond Orthopedic Bone Fixation Screws and Pins are intended to be used as fixation implants for bone fractures, joint fusion, bone reconstruction, or as guide pins for insertion of other implantable devices).

4 Warnings

a) **Correct selection of the implant is extremely important.** The potential for success of fracture fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand activity levels and/or loads equal to those placed on normal healthy bone as **these devices are not designed to withstand the unsupported stress of full weight-bearing or load-bearing.**

b) **These devices can break when subjected to the increased loading associated with delayed union or nonunion.** Internal fixation appliances are load-sharing devices which hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, the implant could eventually break due to metal fatigue. Loads produced by weight-bearing and activity levels will dictate the longevity of the implant. The patient should understand that stress on an implant can involve more than weight-bearing. In the absence of solid bony union, the weight of the limb alone, muscular forces associated with moving a limb, or repeated stresses of apparent relatively small magnitude, can result in failure of the implant. Notches or scratches put in the implant during the course of surgery may also contribute to breakage.

c) **Corrosion.** Implanting metals and alloys in the human body subjects them to an aggressive chemical environment of salts, acids, and proteins, which can cause corrosion. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects.
Additionally, mixing of implant components from different manufacturers is not recommended, for metallurgical, mechanical and functional reasons.

d) Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

5 Contraindications

a) Presence of fever or infection (systemic or localized).

b) Patients with metal sensitivity or allergies to the implant materials.

c) Patients unwilling or unable to follow post-operative care instructions.

d) Any medical or surgical condition which would preclude the potential benefit of implant surgery.

6 Precautions

a) **Surgical implants must never be reused.** An explanted metal implant must never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

b) **Correct handling of the implant is extremely important.** Contouring of metallic implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

c) **Removal after fracture healing.** Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients.
While the surgeon must make the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management to avoid refracture.

d) **Adequately instruct the patient.** Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful fracture healing. This is particularly important should the device be used to treat an unstable fracture, such as intertrochanteric or subtrochanteric. The patient must be made aware of the limitations of the implant and that physical activity and full weight-bearing or load-bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and will fracture under normal weight-bearing or load-bearing in the absence of complete bone healing. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

7 Notes

The user should record and keep all information provided to the patient. It should be checked before use whether the patient tolerates the material to be implanted. The implants described in these instructions for use may only be used (implanted) by surgeons with the appropriate experience.

8 Possible Adverse Effects

a) Nonunion or delayed union which can lead to breakage of the implant.
b) Metal sensitivity or allergic reaction to a foreign body.
c) Limb shortening due to compression of the fracture or bone resorption.
d) Decrease in bone density.
e) Pain, discomfort, or abnormal sensations due to the presence of the device.
f) Nerve damage due to surgical trauma.
g) Necrosis of bone.
h) Vascular changes.

9 Packaging and Sterilization of Sterile Implants

a) The Diamond Orthopedic Bone Fixation Screws and Pins are packaged sterile.
b) Devices are sterilized by gamma irradiation.

10 MRI Safety Information

This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

11 Implant Usage

The use of Diamond Orthopedic surgical implants has given the surgeon a means of stable internal fixation in the management of fractures and reconstructive surgery. However, the surgeon should be fully aware that Diamond Orthopedic implants are intended for Use in internal fixation in accordance with techniques of the AO group. The products should not be used unless the surgeon is thoroughly familiar with the fracture repair techniques including but not limited to the AO method as described in the latest editions of the Manual of Internal Fixation by M.E. Miller, et. Al (Publisher Springer-Verlag. New York, Heidelberg, Berlin), AD Principles of Fracture Management, by T.P. Ruedi and W.M. Murphy (Publisher Thieme. Stuttgart, New York), Manual of Internal Fixation in the Craniofacial Skeleton by L.A. Assael, et. Al (Publisher Springer-Verlag. New York, Heidelberg, Berlin), and the Small Fragment Set Manual by U. Helm and K. M. Pfeiffer (publisher Springer-Verlag. New York, Heidelberg, Berlin). It is also recommended that surgeons utilizing these instruments and implants attend one of the various AO/ASIF instructional courses offered periodically in North America and around the world. Additional information regarding specific devices may be obtained from Diamond Orthopedic LLC.

12 Limited Warranty / Liability

Diamond Orthopedic products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.
Diamond Orthopedic shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Diamond Orthopedic neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Diamond Orthopedic intends that these implants should be used only by physicians having received appropriate training in orthopedic surgical techniques.

13 Contact Information

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate Diamond Orthopedic location for current information. For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Diamond Orthopedic location as listed below:

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14 Label Symbol Legend

Symbol (reference number):	Meaning:	Standard of Origin:
LOT (5.1.5)	Batch code, indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
STERILE (5.2.1)	Sterile, indicates a medical device that has	ISO 15223-1:2016 Medical device – Symbols to be used with medical device

	been subjected to a sterilization process	labels, labelling and information to be supplied – Part 1: General requirements
 (5.4.2)	Do not re-use, indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
 (5.1.4)	Use-by-date, indicates the date after which the medical device is not to be used	ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
 (5.1.3)	Date of manufacture, indicates the date when the medical device was manufactured	ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
 (5.4.3)	Consult instructions for use, Indicates the need for the user to consult the instructions for use	ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements