Implant. While proper selection can help minimize risks, the size and shape of human 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 sound bone union, the weight of the limb alone, muscular forces associated with moving a limb, or repeated stresses of apparent relatively small magnitude, could result in failure of the implant. Nuthces 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. Due to the 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 new hole. The operating surgeon should avoid any nothing 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. Frequent and adequate postoperative care by the patient is expected while the patient's postoperative healing is taking place.

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 allergy 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 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. Ruessi 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, 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 reserves the right to modify 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). 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.

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:

Diamond Orthopedic, LLC
1600 Camden Road
Charlotte, NC 28203
USA

14 Label Symbol Legend

<table>
<thead>
<tr>
<th>Symbol (reference number):</th>
<th>Meaning:</th>
<th>Standard of Origin:</th>
</tr>
</thead>
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<tr>
<td>LOT (5.1.5)</td>
<td>Batch code, indicates the manufacturer’s batch code so that the batch or lot can be identified</td>
<td>ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements</td>
</tr>
<tr>
<td>STERILE (5.2.3)</td>
<td>Sterile, indicates a medical device that has been sterilized by gamma irradiation</td>
<td>ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements</td>
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<tr>
<td>Symbol</td>
<td>Description</td>
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<tr>
<td><img src="5.4.2" alt="2" /></td>
<td>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</td>
<td>ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements</td>
</tr>
<tr>
<td><img src="5.1.4" alt="6" /></td>
<td>Use-by-date, indicates the date after which the medical device is not to be used</td>
<td>ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements</td>
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<td><img src="5.1.3" alt="1" /></td>
<td>Date of manufacture, indicates the date when the medical device was manufactured</td>
<td>ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements</td>
</tr>
<tr>
<td><img src="5.4.3" alt="3" /></td>
<td>Consult instructions for use, indicates the need for the user to consult the instructions for use</td>
<td>ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements</td>
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