Instructions for Use: Sterile Non-Reusable Orthopedic Surgical Instruments

Instructions for Use DMD-IFU-004 RevB Issue Date: March 2026

Caution: Carefully read all instructions 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 surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the parts, but must also be aware of their mechanical limitations. Diamond Orthopedic components should only be used with approved devices and accessories.

2 Description

a) The Diamond Orthopedic Single Use Instrumentation Kit contains screwdriver, drill bit, depth gauge and guidewire components. The screwdriver is manufactured from ABS thermoplastic and 455 stainless steel. Drill bits are manufactured from 17-4 or 455 stainless steel. The depth gauge is manufactured from 6061-T6 Aluminum conforming to ASTM B221. Guidewires are manufactured from 316LVM stainless steel conforming to ASTM F138.

b) The components of the kit are provided sterile and are intended for single use only. Do not use if the sterility of the components is potentially compromised. Never re-use or re-sterilize any component.

c) The instruments are designed for use with Diamond Orthopedic implants only.

3 Introduction

a) The surgical instrumentation can only be used by a qualified surgeon practicing in accordance with current data on progress in the science and art of surgery and with the manufacturer's recommendations available in the following documents: marketing leaflet, operating techniques, templates, etc.

b) Before use, the packaging should be removed, and a visual inspection conducted to ensure that all components are in good condition.

4 Maintenance, Storage, and Handling

Surgical components should be handled and stored with care in an appropriate, dry, clean environment in their original packaging. Instruments must not be stored in contact with, or close to, products that may have a corrosive effect.

5 Inspection and Function Testing

Diamond Orthopedic single-use components are designed to be used once and then discarded. Instruments should be inspected prior to use for any signs of deterioration, corrosion, discoloration, pitting, cracking, nicking of edges, or excessive deformation. Do not use an instrument that shows visual damage or wear.

6 Warnings for Implantable Devices

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.

7 Precautions for Implantable Devices

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. 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.

8 Notes about Implants

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.

9 Possible Adverse Effects for Implants

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.

10 Packaging and Sterilization

The Diamond Orthopedic Single Use Instrumentation Kit is packaged sterile. Devices are sterilized by gamma irradiation.

11 MR Compatibility Statement for Implants

Diamond Orthopedic implants have not been tested for MR conditions. Diamond Orthopedic Bone Fixation Screws and Pins made from stainless steel or titanium have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Diamond Orthopedic implants in the MR environment is unknown. Scanning a patient who has one or more of these devices may result in patient injury.

12 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.

13 Limited Warranty / Liability

Diamond Orthopedic products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other expressed 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 instruments should be used only by physicians having received appropriate training in orthopedic surgical techniques.

14 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
1669 Federal Ave
Gastonia, NC 28052
USA

15 Label Symbol Legend

Symbol	Meaning	Symbol	Meaning
LOT	Batch code		Consult instructions for use.
STERILE R	Sterilized using Gamma Radiation	Rx only	Federal law restricts this device to sale by or on the order of a licensed physician.
	Do not reuse		Caution, consult accompanying documents
	Use by date YYYY-MM-DD		Single sterile barrier with protective packaging
	Date of manufacture		Manufacturer
	The product must not be re-sterilized	REF	Reference number of the device.
	Do not use if damaged		