d) The recommendations from the sterilizer’s manufacturer should be strictly adhered to. The sterilization process and adjustment of the autoclaves should be checked regularly. If there is residual dampness in the sterilization box after the sterilization cycle, proceed as follows:
- Usage of an FDA-cleared wrap is recommended to ensure that the device is sterile prior to implantation.
- Do not open the box immediately after use.
- Increase the drying time, unless tests show that the exposure time has been adequate, to obtain the required time for sterilization.
- Make additional box perforations to facilitate run-off of residual humidity.

e) The recommendations on sterilization are only given as a guideline. Under no circumstances can the manufacturer be held responsible for the sterility of devices sterilized within the hospital.

9 MR Compatibility Statement
The Diamond Orthopedic Bone Fixation Screws and Pins 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 artifact image 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.

10 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), AO Principles of Fracture Management, by T. P. Rueedi and W. M. Murphy (Publisher Thieme. Stuttgart, New York), Manual of Internal Fixation in the Craniofacial Skeleton by L. 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.

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.

12 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:

13 Label Symbol Legend

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
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</thead>
<tbody>
<tr>
<td>NONSTERILE</td>
<td>Nonsterile</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot number</td>
</tr>
<tr>
<td>Single Use</td>
<td></td>
</tr>
</tbody>
</table>

Note: Drying time is subject to variation depending on machine load.