



**INSTRUCTIONS FOR USE**  
**For**  
**INTRAFOCAL PIN PLATE**  
0010027 REV C

**CAUTION: Federal law restricts this device to sale by or on the order of a physician or hospital.**

**DEVICE DESCRIPTION**

This anatomically contoured plate system is made from stainless steel alloy (ASTM F-138) material. The plates are intended for fracture fixation of the distal radius. The distal head of the plate contains holes for use with 2.7mm screws. The screw holes are threaded or non-threaded and allow for fixed angle locking of the screws. The body of the device narrows from a slightly wider plate at the distal end to a rectangular cross section intramedullary section at the proximal end.

**INDICATIONS FOR USE**

This device is indicated for temporary or permanent fixation and stabilization of fractures and osteotomies involving the distal radius.

**CONTRAINDICATIONS**

This device is contraindicated in the following situations:

1. Lack of sufficient sound bone to seat the screws, including that due to skeletal immaturity or osteoporosis.
2. Metal allergies or sensitivity.
3. Infection at or near the site of implantation.
4. Distant infection.
5. Fractures exceeding the length of the device.

**WARNINGS AND PRECAUTIONS**

Do not re-use this device.

Do not use plates and screws of dissimilar materials.

**POSSIBLE ADVERSE EVENTS**

As with all implantable devices, risks can include bone resorption, poor bone formation, tissue or nerve damage as the result of surgical trauma, allergic reaction to the materials used in the implant, and/or infection.

**HOW SUPPLIED**

This device is supplied **NONSTERILE** and must be cleaned and sterilized prior to use. Steam sterilization at 121°C (250°F) for 30 minutes using gravity air displacement is recommended. Flash sterilization is not recommended.



**MANUFACTURER:**

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