TORNIER

INSTRUCTIONS FOR USE
For
DORSAL INTRAMEDULLARY PLATE

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

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. Screw holes are cylindrical to allow for fixed angle locking of the screws or spherical to allow for variable angle orientation of the screws. K-wires may also be used for additional fixation. A sheath cover is attached to the distal head of the plate to cover the screws and lock in the fixed angle screws. The body of the device narrows from the wider plate at the distal end to a cylindrical 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. Do not use plates and K-wires of dissimilar materials. Use of internal fixation devices of dissimilar metals may result in electrolytic corrosion at the interface of the devices.
Do not overbend or rebend the plate. Overbending or rebending the plate will reduce its mechanical strength and may result in device breakage.

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, infection, screw pullout, device fracture, device loosening, and/or fracture nonunion. Adverse events are more likely if the device is not removed after healing occurs.

DIRECTIONS FOR USE

The Surgical Technique for the Dorsal IM Plate should be reviewed prior to use of the device. The Surgical Technique can be obtained by contacting DVO Extremity Solutions, LLC.

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.

Manufactured for Tornier:
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IFU Number: 2005-02
Dwg. Number: 0010100 R C 5/27/08