Instructions for Use

Product: DTRAX Bone Screw

REF **PD-32-301**

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

PACKAGE CONTENTS:

Item #	Quantity	Description
1	1	Bone Screw
2	1	Detachable Handle Assembly

DESCRIPTION:

The DTRAX Bone Screw is a partially or fully threaded cortical screw offered in various diameters and lengths. All screws are manufactured from titanium alloy. The implants are single use only.

INDICATIONS FOR USE:

The DTRAX Bone Screw is intended for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

CONTRAINDICATIONS:

The DTRAX Bone Screw should not be used in any of the following instances:

- Patients with active or suspected infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone or neurovascular status
- Irreparable tendon system
- Possibility of conservative treatment
- Growing patients with open epiphyses

WARNINGS:

In any surgical procedure, the potential for complications exists. The risks and complications with the DTRAX Bone Screw include but are not limited to:

- Infection or painful, swollen or inflamed implant site.
- Fracture of the implant.
- Allergic reaction(s) to implant material(s).
- Bone resorption.
- Bone over-production.
- Loosening or dislocation of the implant requiring revision surgery.
- Histological responses possibly involving macrophages and/or fibroblasts.
- Migration of particle wear debris possibly resulting in a bodily response.
- Embolism.

PRECAUTIONS:

PRE-OPERATIVE:

- The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection. The surgeon must be thoroughly familiar with the implant, instruments, and surgical procedure prior to performing surgery.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The surgeon should also use medical devices in accordance with their labeled indications and the manufacturer's instructions for use.
- Patient selection should consider the following factors which may lead to increased risk of failure and can be critical to the eventual success of the procedure. The patient's:
  a) weight,
  b) activity level,
  c) occupation, and
  d) other patient conditions which may impact on the performance of the DTRAX system.

  Implant longevity and stability may be affected by these variables.
- The surgeon must consider the ability and willingness of the patient to follow instructions and to control their weight and activity level.

Additional conditions presenting increased risk of failure include:

a) Uncooperative patient or patient with neurologic disorders, incapable of following instructions;
b) Marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
c) Metabolic disorders that may impair bone formation;
d) Osteomalacia; and
e) Poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

INTRAOPERATIVE PRECAUTIONS:

- Do not mix instruments from different manufacturers. While rare, breakage of instruments may occur especially with extensive use or excessive force.
- Inspect devices prior to use for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Proper implant selection must consider design, fixation, patient weight, age, bone quality, size, activity level, preoperative level of health, and also the surgeon's experience and familiarity with the device. Implant longevity and stability may be affected by these variables. Surgeons should inform the patient about these factors.

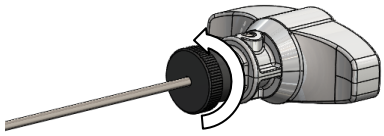
POSTOPERATIVE PRECAUTIONS:

- The patient must be advised of the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred.
- Periodic follow-up is recommended to monitor the position and state of the implant components, as well as the condition of the bone. Periodic post-operative x-rays are recommended for close comparison with early post-op conditions to detect long-term evidence of changes in position, loosening, bending, or cracking of components.

MRI WARNING
The DTRAX Bone Screw device has not been evaluated for safety or compatibility in the MR environment. MR risks, including heating, migration, and imaging artifacts next to the implant are known, but have not been evaluated for the DTRAX Bone Screw device.

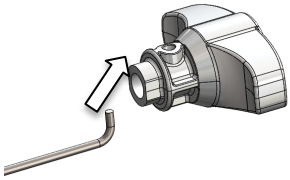
INSTRUCTIONS FOR USE:

1. DTRAX Bone Screws have a cutting tip and flute which make them self-drilling. In most cases, pre-drilling is not necessary. There may be circumstances, such as poor bone quality or very thin cortical bone, where it is advised to pre-drill.
2. Do not use a power tool to install the bone screw since this may produce extremely high insertion speed, local tissue heating, and resulting tissue damage.
3. Screw insertion should always be performed using a manual driver or the detachable Handle that is packaged with the Bone Screw implant.
4. Advance the screw by rotating it clockwise.
5. **NOTE:** DTRAX Bone Screw is packaged with the detachable Handle assembly pre-attached. If the Handle is to be detached, follow the procedure below:
   a) Unscrew the locking hub from the T-handle by turning the hub counter-clockwise.



   b) Remove the locking hub from the DTRAX Bone Screw by sliding it over the screw shaft.

   c) Remove the T-handle by un-hooking it from the bent proximal portion of the DTRAX Bone Screw shaft.



PACKAGING:

1. DTRAX Bone Screw is packaged in a protective sleeve and loaded to a backer card.
2. Unlock the T-handle from the backer card tabs, and pull the screw from the protective sleeve, leaving the sleeve on the backer card. Take care to not bend or damage the screw during removal.

BONE SCREW REMOVAL (If necessary):

1. Locate the implant with direct visualization or intra-operative imaging.
2. Palpate the screw head and remove surrounding soft tissue to gain exposure.
3. Engage the screw head with the appropriate driver and rotate counter-clockwise until the screw is removed.
4. If the screw head is stripped, engage the screw shaft under the head with a manual tool (ex: Korcher forceps), turning counter-clockwise while exerting upward pressure on the screw.
5. If there is bone overgrowth, core out with a trephine drill to expose the head of the screw.

CLEANING AND STERILIZATION:

DTRAX Bone Screws are provided **STERILE** and are **SINGLE-USE** devices.

CAUTION: The DTRAX Bone Screw should never be re-sterilized or reused after contact with body tissues or fluids, but rather should be discarded. Providence does not take any responsibility for the use of implants re-sterilized after contact with body tissues or fluids.

STORAGE CONDITIONS:

All implants must be stored in a clean, dry environment and be protected from sunlight and temperature extremes.

Verify package integrity prior to use. Do not use system components if packaging is damaged.

SYMBOLS USED ON THIS PRODUCT:

STERILE R	Sterilized using irradiation
	Do not use if package is damaged
	Do not reuse
	Caution
	Consult instruction for use
	Keep Dry
REF	Catalog Number
LOT	Lot code
	Use-By date
	Keep away from sunlight
	Manufacturer
EC REP	Authorized representative in the European Community
CE 0470	CE Mark by Notified Body number