

## TZ Medical Distraction Screws

### INDICATIONS FOR USE

TZ Distraction Screws are used in conjunction with orthopaedic retractors (distractors) for retraction of vertebral bodies during surgical procedures.

### DESCRIPTION

TZ Distraction Screws are provided sterile and are for single use only. The Distraction Screws are available in 12mm, 14mm, 16mm and 18mm lengths. The proper surgical technique for the use of Distraction Screws is the responsibility of the surgeon.

### CONTRAINDICATION

TZ Distraction Screws should not be used for anything other than their intended use.

### WARNING

- Reuse of sterile product could lead to cross-contamination.
- Sterility is not guaranteed for sterile product, if package is opened or damaged.
- Do not reuse products. Distraction Screws are for single use only.
- Excessive torque may cause screws to break.
- Use of inappropriate size of screw may cause damage to vertebral body.

### INSPECTION OF ALL DISTRACTION SCREWS

All Distraction Screws are carefully inspected before shipment. Because damage may occur during transit, the Distraction Screws should be thoroughly inspected upon receipt. All Distraction Screws must be inspected prior to use.

Handling and Operating Distraction Screws: Distraction Screws should be handled and operated by personnel completely familiar with their use, assembly and disassembly.

Failure to make a complete inspection to assure the proper operation and function of the Distraction Screws may result in unsatisfactory performance.

Do not use if the Distraction Screw does not appear to be functioning properly. Use of Distraction Screws for a task other than that for which it is intended could result in injury to the patient, damaged or broken Distraction Screws, or one which provides unsatisfactory performance. TZ Medical Distraction Screws







### INSTRUCTIONS FOR USE

1. Choose screw size appropriate for patient's anatomical site. The screws should be long enough so that they will penetrate cortical bone on the posterior wall of the vertebral body, but not so long as to pass through the wall entirely.
2. The Distraction Screws are self-drilling; however, pre-drilling can be chosen for patients with poor bone quality. Use only drills appropriate for spinal applications.
3. Use provided screwdriver to insert one screw in the center of each vertebral body adjacent to the affected site. Insert screw parallel to the end plates of the vertebral bodies to ensure proper distraction. Drill guide may be utilized to assure proper placement of Distraction Screws.
4. Screws should be inserted completely so the flange at the base of the posted section is snug with the anterior wall of the vertebral body. Do not overtighten or damage can occur to the vertebral body.
5. Attach appropriate distractor so its arms slide completely over the posted sections of both distraction screws. Left and right distractors are available, depending on the side of the exposure site on the patient.
6. Ratchet distractor to desired distraction and perform necessary procedure. Avoid over-distraction of the vertebral bodies.
7. After completion of the intervertebral procedure, release the distractor by lifting the thumb latch on the ratchet mechanism. Lift the distractor off of the screws.
8. Remove Distraction Screw with provided screwdriver.
9. Dispose of Distraction Screws according to Hospital and State regulations. Note: Distraction Screws are for single use only.

### RETURNED GOODS POLICY

Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Determination of a product defect will be made by TZ Medical. Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

### SYMBOLS USED ON LABELING


-  Manufacturer
-  Catalog number
-  Lot number
-  Manufacture date
-  Expiration date
-  Single Use Only

**Rx ONLY** Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner.


 Method of sterilization: ethylene oxide

 Sterile Barrier System

 Medical Device

 Do not use if package is damaged

 Store at Room Temperature

 Caution or Warnings

 Consult instructions for use

[www.tzmedical.com](http://www.tzmedical.com)

Not made with natural latex rubber.

 Manufacturer:

TZ Medical inc.  
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Portland, OR 97224 USA



**EU Authorized Representative:**  
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