



TOTAL JOINT ORTHOPEDICS, INC.
Drill and Pin Set, Sterile, and 3.2mm Drill
Tips, Sterile Instructions for Use (IFU)

Manufacturer:
Total Joint Orthopedics, Inc.
1567 East Stratford Ave.
Salt Lake City, UT 84106

CAUTION: Never re-use instruments designated for single-use, even if they appear to be in perfect condition, to prevent any risk of cross-contamination or a risk of reduced performance. Never re-sterilize instruments designated for single-use.

PRODUCT DESCRIPTION

Total Joint Orthopedics Sterile Drill Tips and Drill and Pin Sets are made of high-grade stainless steel and optimally suited for their surgical use. They are designed, constructed, and produced with utmost care. The following instructions for use and safety recommendations shall be observed.

INDICATIONS FOR USE

The Sterile Drill Tips and Drill and Pin Set is used by surgeons for the implantation and explantation of implants in orthopedic surgery. Do not modify these instruments.

INSTRUMENTS DELIVERED STERILE

All Sterile Drill Tips and Drill and Pin Sets are supplied sterile and are for single use only. Cleaning, re-sterilization or reuse of any kind is forbidden.

STORAGE AND HANDLING

The Sterile Drill Tips and Drill and Pin Sets are provided sterile and should always be stored unopened. Prior to use, inspect package for damage which may compromise sterility. If packaging has been opened or damaged, contact a manufacturer representative. When unpacking the Sterile Drill Tips and Drill and Pin Sets verify the labeling for the correct catalog number and size of each component and the expiration date to verify part has not expired. When removing the component from its packaging, the relevant aseptic protocols must be observed. Surgical instrumentation must be stored in an appropriate, clean and dry location to prevent any loss of sterility. Instrumentation must not be exposed to direct sunlight, ionizing radiation, extreme temperatures nor particulate contamination. Instruments must be handled with care to preserve package integrity. Instruments delivered sterile must be stored in the sealed packaging of origin; instruments delivered in convenience packs with multiple sterile packages in one box must be stored in the outer box.

PACKAGING AND STERILIZATION

- Instruments delivered sterile are sterilized by gamma irradiation. The expiration date for sterilization and integrity of the packaging must be checked. Any instrument whose packaging is open or damaged or whose expiration date has passed must not be used.
- Every precaution must be taken to ensure sterility when opening the packaging of the instruments.
- All Sterile Drill Tips and Drill and Pin Sets are supplied clean and sterile. Cleaning, re-sterilization or reuse of any kind is forbidden.

RETURN GOODS POLICY

For information on product returns and return authorization, contact Total Joint Orthopedics by calling 888.890.0102. All products returned to Total Joint Orthopedics must be accompanied by a Return Goods Authorization Number.

MEDICAL DEVICE REPORTING

Any potential adverse incident involving Total Joint Orthopedics products should be reported immediately by calling 888.890.0102.

WARRANTY AND LIMITATION OF LIABILITY

Total Joint Orthopedics, Inc., warrants that the product when delivered is free from defect in materials and workmanship and conforms to the manufacturer's product specifications. At its option, TJO will replace or provide a full refund for this product if it is found to be defective. The product must be returned to TJO in the original packaging with the catalog and lot numbers, or according to the return goods policy. TJO shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of, or inability to use, its product.

THE FOREGOING WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Total Joint Orthopedics neither assumes, nor authorizes any person to assume for it, any other additional liability or responsibility with respect to this product other than as set forth in writing herein.

CUSTOMER SERVICE INFORMATION

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For Symbol Glossary, please visit: tjoinc.com/ifu.