Integra™ Distraction Screws

INDICATIONS FOR USE
Integra™ Distraction Screws are used in conjunction with orthopaedic retractors (distractors) for retraction of vertebral bodies during surgical procedures.

DESCRIPTION
Integra Distraction Screws are provided either sterile or non-sterile and are for single use only. The Distraction Screws are available in 12mm, 14mm and 16mm lengths. The proper surgical technique for the use of Distraction Screws is the responsibility of the surgeon.

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

WARNING
- 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.

CAUTION
Integra Distraction Screws are supplied sterile and non-sterile. All non-sterile Distraction Screws must be sterilized prior to use according to hospital protocol and the procedures outlined in this document. Failure to follow these procedures will invalidate the Distraction Screws’ warranty and can cause the Distraction Screws to fail.

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. Before a new non-sterile distraction screw is used it must be decontaminated and sterilized as described below. Inspect each Distraction Screw prior to use. 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.

INSTRUCTIONS FOR USE
1. Non-sterile products must be decontaminated and sterilized prior to use (see sterilization procedures below).

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

7. Ratchet distractor to desired distraction and perform necessary procedure. Avoid over-distraction of the vertebral bodies.

8. 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.

9. Remove Distraction Screw with provided screwdriver.

10. Dispose of Distraction Screws according to Hospital and State regulations.

Note: Distraction Screws are for single use only.

STERILIZATION PROCEDURES
TERMINAL STERILIZATION FOR NON-STERILE DISTRACTION SCREWS
Prior to use, all Non-Sterile Distraction Screws must be cleaned and sterilized. Independent laboratory testing, conducted according to the F.D.A. (21 CFR PART 58) and Good Laboratory Practice Regulations (G.L.P.), has validated steam sterilization as an effective process for reusable instruments. See also, “Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities”, ANSI/AAMI ST79:2006. AAMI standards recommend that the sterilizer manufacturer’s written instructions for cycle parameters should also be followed. Medical device manufacturer’s exposure times to sterilization temperature may need to be longer than the minimum indicated by the sterilizer manufacturer but must never be shorter.

1. CLEANING DISTRACTION SCREWS: Choose a cleaning solution appropriate for the Distraction Screws and follow the manufacturer’s instructions for use. The use of neutral pH detergents is vital to the maintenance of the screws. Contact with acidic or alkaline solution will remove the screws’ protective barrier of chromium oxide, often leading to corrosion, pitting, and breakage. The ideal cleaning agent is nonabrasive, low-foaming and free-rinsing. Using a small clean hand-held brush, remove soil from all surfaces of the screws while fully immersed in the solution. During manual cleaning, never use steel wool, wire brushes, scalpel blades or highly abrasive detergent or cleansers. These will damage the screws’ protective surface.

2. RINSE: Thoroughly rinse the Distraction Screw by immersing in tap water and wiping with a clean, soft cloth.

3. FINAL RINSE should be with “treated water”. Softened or deionized water should be used for the final rinse to better remove detergents etc.

- Softening water removes calcium and magnesium ions that cause water to be hard. Iron ions may also be removed by this treatment.
- Deionization removes ionized salts and particles from the water. Excessively hard water can spot or stain screws and excessive chlorine in water can cause pitting of the screws. Deionized water is preferred for the final rinse.

4. Decontaminate Clean Distraction Screws: Once screws have been cleaned they must be rendered safe for handling, inspection and assembly. They may be decontaminated using the steam sterilization parameters for unwrapped Items, found in this document.

5. Visual Inspection: Visually inspect the distraction screw for cleanliness and to ensure all parts are in proper working order. Inspection is a vital part of proper care and maintenance. DO NOT USE damaged distraction screws.

6. Drying: Before the distraction screw is wrapped for sterilization or storage, it must be thoroughly dry.

PREPARING DISTRACTION SCREWS FOR STERILIZATION
Prepare the Distraction Screw for sterilization using a wrapper, pouch or rigid sterilization container that is appropriate for the method of sterilization to be used. The Association for the Advancement of Medical Instrumentation (AAMI) and individual sterilizer manufacturers, as well as medical device manufacturers, provide guidance for the proper preparation of surgical instrument trays for sterilization.

DEcontamination Clean Distraction Screws:

1. Before the distraction screw is wrapped for sterilization or
   storage, it must be thoroughly dry.

2. Decontaminate Clean Distraction Screws: Once screws have
   been cleaned they must be rendered safe for handling, inspection
   and assembly. They may be decontaminated using the steam
   sterilization parameters for unwrapped Items, found in this
document.

3. Visual Inspection: Visually inspect the distraction screw for
   cleanliness and to ensure all parts are in proper working order.
   Inspection is a vital part of proper care and maintenance. DO NOT
   USE damaged distraction screws.

4. Drying: Before the distraction screw is wrapped for sterilization
   or storage, it must be thoroughly dry.

5. Prepare the Distraction Screw for sterilization using a wrapper,
pouch or rigid sterilization container that is appropriate for the method
of sterilization to be used. The Association for the Advancement of
Medical Instrumentation (AAMI) and individual sterilizer
manufacturers, as well as medical device manufacturers, provide
guidance for the proper preparation of surgical instrument trays for sterilization.
TERMINAL STEAM STERILIZATION

After following the decontamination recommendations, Integra Distraction Screws are ready for sterilization. Independent laboratory testing, conducted according to the F.D.A. (21 CFR PART 58) and Good Laboratory Practice Regulations (G.L.P.), has validated steam sterilization as an effective process for Integra reusable instruments. See also, AAMI Standards and Recommended Practice, “Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities”, ANSI/AAMI ST79:2006. AAMI standards recommend that the sterilizer manufacturer’s written instructions for minimum cycle parameters should also be followed.

Below are the recommended sterilization parameters:

<table>
<thead>
<tr>
<th>Sterilizer</th>
<th>Exposed Temperature</th>
<th>Exposed Time</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum (wrapped)</td>
<td>132° C (270°)</td>
<td>3 min</td>
<td>10 min</td>
</tr>
</tbody>
</table>

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 Integra. Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

PRODUCT INFORMATION DISCLOSURE

INTEGRA AND ITS SUBSIDIARIES (“INTEGRA”) AND MANUFACTURER EXCLUDE ALL WARRANTIES, EXCEPT INTEGRA’S APPLICABLE STANDARD WARRANTY WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NEITHER INTEGRA NOR MANUFACTURER SHALL BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. NEITHER INTEGRA NOR MANUFACTURER ASSUME NOR AUTHORIZE ANY PERSON TO ASSUME FOR THEM ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

MANUFACTURER:

Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227
Tel: 877-444-1114
Fax: 513-271-1915