

## HARMONY ANTERIOR INSTRUMENTATION SYSTEM



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### System Contents:

- Non-Sterile Instruments – Reusable

**Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.**

Carefully read all instructions and be familiar with the surgical technique(s) prior to use of the system. Review the instructions for use associated with any Abbott Spine implant or instrument to be used in conjunction with the system. Use universal precautions when handling contaminated or biohazardous components.

### DESCRIPTION:

The Harmony Anterior instrumentation system is comprised of generic instruments and perforated instrument cases that are generally comprised of aluminum, stainless steel, and/or polymeric materials. The instrument cases may be multi-layered with various trays, holders and silicone mats to hold surgical instrumentation in place during handling and storage.

The perforated instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing a cleaning, sterilization, and drying cycle that has been validated by the user for the equipment and procedures employed at the user facility. Instrument cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap to maintain sterility.

### INSTRUMENT CARE AND HANDLING:

1. Failure to follow the instructions provided in this insert may result in instrument breakage and potential adverse effects on user or patient.
2. Use only instruments specifically designed for use with their associated devices.
3. Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. The following instructions should be followed to minimize damage:
  - Inspect the instruments and instrument case for damage when purchased and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair set aside for repair service or return to Abbott Spine.
  - Thoroughly clean and dry reusable instruments, whether or not they were used or were inadvertently contacted with blood or saline, to reduce corrosion and potential cross-contamination. Excessively acidic or alkaline solutions may corrode aluminum instruments or instrument cases.

4. Health care personnel should conduct testing in the health care facility to assure that the conditions essential to sterilization can be achieved and that specific configuration of the contents is acceptable for the sterilization process and for the requirements at the point of use.
5. AORN and ANSI/AAMI standards, practices and guidelines should be consulted for detailed guidelines for related to proper care, maintenance and handling of surgical instruments and container systems.

### MATERIALS:

Stainless Steel  
Aluminum  
Polymeric Materials

### CLEANING:

1. Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Loosen and/or disassemble instruments with removable parts.
2. Manual cleaning is recommended using a neutral pH detergent prepared in accordance with the manufacturers instructions and utilizing a mechanical aid such as a brush. Particular attention should be taken to remove all debris from instruments with cannulations and holes.
3. If ultrasonic cleaners and/or washer-decontamination equipment are used, follow equipment manufacturers recommended practices. Abbott Spine recommends performing manually cleaning prior to using automated cleaning equipment. Avoid excessively acidic or alkaline solutions.

### INSPECTION:

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure dissembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Abbot Spine representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Abbott Spine representative for a replacement.

### STERILIZATION:

Unless otherwise indicated, instruments are provided non-sterile and must be cleaned and sterilized prior to use. The following is a recommended minimum cycle for steam sterilization that has been laboratory validated:

Method:	Steam
Cycle:	Pre-Vacuum
Temperature:	270°F (132°C)
Exposure Time:	25 Minutes
Number of Pulses:	2
Wrap:	Double Wrap

Routine monitoring per AORN recommended practices for in-hospital sterilization should be followed. Instruments should be positioned to allow the sterilant to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be dissembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately re-sterilize all implant and instrument kits used in surgery as well as any unused kits that were in the surgical suite.

Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters provided in this insert.

### WARNINGS AND PRECAUTIONS:

Following are specific warnings, precautions, and adverse effects, which should be understood by the surgeon and explained to the patients. These warnings do not include all adverse effects, which can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Instruments must be thoroughly cleaned prior to sterilization. Instruments that are not clean may not be effectively sterilized.
2. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.
3. When handling sharp instruments, use extreme caution to avoid injury.
4. Unless otherwise indicated, instrument sets are provided non-sterile and must be sterilized prior to use.
5. Do not reuse instruments labeled for single use only. Reuse may adversely affect performance of the instrument.
6. Flash autoclaving should be avoided whenever possible. Instruments should never be flash autoclaved in an instrument case.

### LIMITED WARRANTY:

Abbott Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

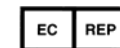
If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Abbott Spine for current information.

For product information or questions pertaining to sales and service, please contact your local sales representative or Abbott Spine customer service by calling toll free 800-326-0635.

Class I Instruments:



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