



AMEDICA CORPORATION
1885 West 2100 South
Salt Lake City, Utah 84119 USA
(801) 839-3500
www.amedicacorp.com

Rx CAUTION: Federal (USA)
Law Restricts This Device To
Sale By Or On The Order Of A
Physician.

EC REP Emurgo Europe
Molenstraat 15
2513 BH The Hague
The Netherlands

AMEDICA® Instrumentation Sets

Caution: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Instructions for Use/Intended Use

Amecica® cases/trays and instruments are intended to provide a convenient, secure, sterilizable system for use with Amecica® orthopedic implant devices. They are designed to facilitate the sterilization process when used in conjunction with a specified filtered sterilization container system. Filtered containers are designed to allow air removal, steam penetration/evacuation (drying) and maintain the sterility of the internal components.

Recommendations for Care, Cleaning and Sterilization of Amecica® Cases/Trays and Instruments

Always inspect cases/trays and instruments for cleanliness or damage before use. Make sure all latches and handles are secure and in working order.

Ensure that cutting instruments are sharp and undamaged and articulating instruments operate smoothly. If the instruments are damaged, replace them with sterile, undamaged instruments.

Both physical and chemical (detergent) processes may be necessary to clean soiled items. Chemical (detergent) cleaners alone cannot remove all soil and debris.

Immediately after the completion of the surgical procedure, soak the disassembled instruments in a mild enzymatic detergent in luke warm water following the detergent manufacturer's instructions.

Carefully clean each item manually with a soft sponge or cloth for maximum decontamination. For difficult access areas, a clean soft bristled brush is recommended. Once the items have been cleaned, thoroughly rinse them with clean water to remove any detergent or chemical residue before sterilization. Amecica® recommends the use of a mild enzymatic detergent with a near neutral pH. Do not use solvents, abrasive cleaners, metal brushes or abrasive pads. Cases/trays and instruments may be placed in mechanical cleaning equipment.

Balance contents uniformly within the container and arrange to allow steam to come in contact with all objects in the container.

Amecica® recommends that the delivery systems (cases and trays) and instruments be processed according to the filtered container manufacturer's instructions prior to sterilization to maintain sterility of internal components/items and for proper aseptic presentation to the surgical field.

For steam autoclaves, Amecica® has verified product performance in the following cycles. Our testing was done with common surgical appliances such as reamers, drills, hammers, rasps, drivers, chisels, awl, handpieces, rongeurs, blades and bits, including short lumened devices. Complex instruments may require disassembly and extended sterilization times. If using other manufacturer's instruments with the case/tray, follow instrument manufacturer instructions if their sterilization or drying recommendations exceed these guidelines.

Filtered Sterilization Container Systems

Amecica® cases/trays and instruments have been validated for placement inside Aesculap filtered sterilization container systems and exposed to the following parameters:

Follow the recommendations of the manufacturer of the filtered sterilization containers for the proper placement and use of cases and trays inside the container. Use of an outer wrap is not recommended for this case configuration.

Cycle 1 Gravity	Temperature: 134°C
	Cycle: 60 min Dry: 40 min

Cycle 2 Prevacuum	Pre Pulses: 3
	Temperature: 132°C Cycle: 16 min Dry: 40 min

Contraindications

Amecica® cases and trays have NOT been validated for use with flexible endoscopes, or devices with lumens or working channels longer than four inches (3mm ID). Always refer to instrument manufacturer instructions.

Stacking of delivery systems (cases and trays) and overloading of the units may adversely effect sterilization and drying effectiveness. DO NOT STACK cases and trays in autoclave chamber.

Deviations from the cleaning or sterilization procedures described in this document should be validated by qualified personnel within the user facility.

Precautions:

- DO NOT LOAD CASES with their contents into sterilizer on sides or upside down with lid side on the shelf or cart. Load cases on cart or shelf, so that the lid is always facing upward. This will allow for proper drying. Amecica® cases and trays are designed to drain in this position.
- AFTER THE AUTOCLAVE DOOR IS OPENED, allow all cases to cool thoroughly. Place cases on a rack or shelf with linen cover until cooling is complete. The potential for condensation may increase if the case is not allowed to cool properly.
- IF CONDENSATION IS OBSERVED, check to ensure steps 1 and 2 were followed. In addition, verify that the steam which is being used for sterilization processing has a quality of more than 97%. Also confirm that the sterilizers have been inspected for routine maintenance in accordance with manufacturer recommendations.



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