Artemamed

Spinal Punches Indications for Use:

Artemamed spinal punches are manually operated instruments intended for cutting or biting bone, cartilageand tissue during surgery involving the skull or spinal column.

Contraindications

Instruments should not be used for anything other thantheir intended use.

Precautions

• Check screws on instruments after ultrasonic cleaning.Vibration from ultrasonic cleaning may cause them to loosen or fall out.
• Inspect punch tips before use to ensure cutting surfaces meet evenly; ensure that bone ejector is not bent. Unevenmeeting or bent bone ejector may indicate a weakened tipand may lead to tip failure.
• Spinal punches are supplied non-sterile and must be cleaned, lubricated and sterilized prior to use. Failure todo so can cause instrument malfunction.
• Inappropriate use of instruments will lead to damage thatis usually not repairable and/or under warranty.

Inspection of All Instruments

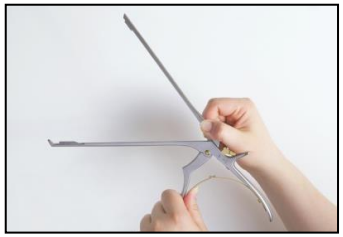
Instruments must be thoroughly inspected upon receipt and prior to use to ensure proper functioning. Failure to perform a complete inspection to ensure proper operationand function of instruments may result in unsatisfactory performance.

Handling and Operating of Instruments

Instruments should be handled and operated by personnelcompletely familiar with their use, assembly and disassembly.
• Before instruments are used and prior to each surgical procedure, instruments must be decontaminated, lubricated, and sterilized.
• Do not use instruments if they do not appear to be functioning properly. Use of instruments for anything otherthan which they are intended could result in damaged or broken instruments, or unsatisfactory performance.

Directions for Easy2Clean Kerrison Spinal PunchesTo open:

a) Squeeze handle together and hold.
b) While holding handle together, push down on the levertoward the handle horn.
c) Release hold on handle.
d) Pull back slider and lift up to open.



To close:

a) Align and engage slider in grooves on main body.
b) Squeeze handle together and hold.
c) While holding handle together, push up on the leverto original position.
d) Release hold on handle and check instrument functionto ensure slider is engaged properly.

The instruments used to implant orthopedic prostheses do not have an indefinite functional life. These instruments are subjected to repeated stresses related to bonecontact, impaction and routing, cleaning, and sterilizationprocesses.

Most instrument systems include inserts/trays and a container(s). Many instruments are intended for use with a specific implant. It is essential that the surgeon and operating room staff are fully conversant with the appropriate surgical technique for the instruments and associated implant, if any.

CAUTION: These instructions DO NOT APPLY to single-use devices sold as sterile.

These reprocessing instructions are capable of preparing Artemamed instruments for use and are provided to the best of our knowledge at the time of issue. It is the responsibility of the reprocessor to ensure that the reprocessing's actually performed using appropriate equipment, materials, and personnel to achieve the desired result.
This normally requires validation and routine monitoringof the process. Any deviation by the reprocessor from these instructions should be evaluated for effectivenessand potential adverse consequences.

Warnings:

• Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents andequipment used.
• Do not exceed 140° C [284° F] during reprocessingsteps.
• Highly alkaline conditions can damage products withaluminum parts.
• Complex devices, such as those with tubes, hinges,

Recommendations for Decontamination andSterilization of Artemamed Instruments

These reprocessing instructions apply to:

• Non-sterile, reusable surgical instruments supplied by Artemamed
Reusable instruments definition: Instruments intended for repeated use on different patients, with appropriate decontamination and other processing between uses.
• Instruments intended for reprocessing in a health carefacility setting.
• Single-use medical devices supplied by Artemamed thatare supplied non-sterile but are intended to be used in a sterile state. These devices are single-use but can be reprocessed if not used.

Note: “not used” refers to those single-use components that have not been in contact with blood, bone, tissue other body fluids. Any unused, single-use devices that have beenexposed to blood, bone, tissue or body fluids must not be reprocessed or reserialized and must be discarded.
retractable features, mated surfaces, and textured
surface finishes, require special attention during cleaning. Mangalore-cleaning of such
device featuresis required before automated cleaning processing.

- Avoid exposure to hypochlorite solutions, as thesewill promote corrosion.
- Scratches or dents can result in breakage.
- For instruments produced by another manufacturer, reference the manufacturer’sinstructions for use.
- Care should be taken to remove any debris, tissue or bone fragments that may collect on theinstruments.

Limitations on Reprocessing

- Repeated processing has minimal effects on instrument life and function.
- End of useful life is generally determined bywear or damage in surgical use.
- Carefully inspect instruments between uses toverify proper functioning.
- Damaged instruments should be repaired or replaced to prevent potential patient injury such asloss of metal fragments into the surgical site.

Decontamination ConsiderationsCreutzfeldt-Jakob Disease (CJD)

Under certain classifications of risk, the World Health Organization (WHO), or local regulatory authorities recommend special CJD (Creutzfeldt-Jakob Disease) inactivation processing procedures. Consult WHO andlocal regulations for further information.

Reprocessing Instructions

Step 1. Care at the Point of Use

• Clean instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in a compatible detergent solution or water to prevent dryingand encrustation of surgical soil.
• Avoid prolonged exposure to saline to minimize thechance of corrosion.
• Remove excessive soil with a disposable wipe.

Step 2. Containment and Transportation

Reprocess instruments as soon as is reasonably possibleafter use.

Step 3. Preparation for Cleaning
For instruments that require disassembly for cleaning,perform disassembly for that instrument.

Step 4. Manual Cleaning - See Sections A-C
Section A: ALL INSTRUMENTS
• Clean delicate (microsurgical) instruments separatelyfrom other instruments.
• Disassemble instruments that are intended to come apartfor cleaning.
• Prepare an enzymatic cleaning solution in accordancewith the manufacturer's instructions.
• Soak soiled instruments for 5 minutes in the enzymaticsolution.
• Follow the additional instructions in Manual Cleaning Sections B, or C, based on the category that most closelymatches the type of instrument.
• Use a soft bristle brush to remove all traces of blood anddebris; pay close attention to any hard-to-reach areas, textured surfaces, or crevices.
• Rinse instruments thoroughly with warm tap water.
• Dry instruments immediately after final rinse.
Section B: Instruments with Cannulations or Lumens(i.e. tubes), or Holes
• Follow the steps in Section A: ALL INSTRUMENTS.
• When cleaning, use a tight-fitting, soft, non-metallic cleaning brush or pipe cleaner to scrub the cannula, lumen, or hole. Push in and out, using a twisting motionto remove debris. Use a syringe filled with enzymatic cleaning solution to flush hard-to-reach internal areas.
• Ultrasonically clean instruments in fully opened position for 10 minutes in neutral pH detergent, preparedin accordance with the manufacturer's instructions.
• When rinsing, pay particular attention to flush the cannulations, lumens, or holes with warm tap water.
• Dry internal areas with filtered compressed air.
Section C: Articulating Instruments (those with move-able parts)
• Follow the steps in Section A: ALL INSTRUMENTS.

When cleaning, fully immerse instruments in the clean- ing solution to avoid aerosol generation. Brush with a soft non-metallic bristle brush to remove all traces of blood and debris. Pay close attention to threads, crevices, seams, and any hard-to-reach areas. Actuate any moveable mechanisms, such as hinged joints, box locks, or spring- loaded features, to free trapped blood and debris. If instrument components can be retracted, retract or open the part while cleaning the area. For instruments with flexible shafts, bend or flex instruments under the cleaningsolution while brushing the flexible areas.

• Ultrasonically clean instruments in fully opened position for 10 minutes in neutral pH detergent, prepared in accordance with the manufacturer's instructions.
• When rinsing, pay particular attention to internal areas and moveable parts. Actuate moveable parts while rinsing.If instrument components can be retracted, retract or openthe component while rinsing the area. For instruments withflexible shafts, flex instruments under the rinse solution.
• Dry internal areas with filtered compressed air.

Step 5. Automated Cleaning
• For instrument types with complex design features, such as those described in Step 4: Manual Cleaning Sections B and C, it is necessary to manually clean prior to automatedprocessing to improve the removal of adherent soil. Followinstructions in Step 4: Manual Cleaning Sections B and C. Brush instrument actuate mechanisms, agitate and/or irrigate under the surface of the cleaning solution to pre- vent the creation of aerosols.
• Load instruments so that hinges are open and cannulations and holes can drain.
• Place heavier instruments on the bottom of containers.Do not place heavy instruments on top of delicate instruments.
• For instruments with concave surfaces, such as curettes,place instruments with the concave surface facing down- ward to facilitate draining.
• Run the automatic wash cycle – minimum cycleparameters:
- five minute cold prewash
- five minute enzyme wash at 43° C [110° F] minimumtemperature
- five minute detergent wash at 55° C [131° F] minimumtemperature
- one minute rinse at 45° C [113° F] minimum temperature

Step 6. Cleaning Inspection
• Inspect all instruments before sterilization or storage toensure the complete removal of soil from surfaces, tubesand holes, moveable parts.
• If areas are difficult to inspect visually, check for blood by immersing or flushing the instrument in a 3% hydrogenperoxide solution. If bubbling is observed, blood is present.
• Rinse instruments thoroughly after using hydrogenperoxide solution.

- If soil is still present, reclean the instruments.

Step 7. Disinfection
Instruments must be terminally sterilized prior to surgicaluse. See Step 11: Sterilization instructions.

Step 8. Lubrication
Before instruments are used and prior to each surgical procedure, instruments must be decontaminated,lubricated, and sterilized. Lubricate moving parts with a water-soluble lubricant in accordance with the Manufacture's instructions.

Step 9. Inspection and Functional Testing
- Visually inspect instruments and check for damage andwear.
- Cutting edges should be free of nicks and have acontinuous edge.
- Jaws and teeth should align properly.
- Moveable parts should have smooth movement withoutexcessive play.
- Locking mechanisms should fasten securely and closeeasily.
- Long, thin instruments should be free of bending anddistortion.

Step 10. Packaging
- If desired, use instrument trays to contain instrumentsthat are provided in sets.
- Biological or Chemical Indicators (BIs or CIs) used for monitoring the performance of sterilization processes should be placed in the middle racks within wrapped trays.They should be tested according to the BI or CI manufacturer's directions.
- Double wrap instruments in accordance with local proceduress, using standard wrapping techniques such as thosedescribed in ANSI/AAMI ST46-1993.
- Label the contents of the wrapped tray using an indeliblemarker or other sterilization compatible label system.

Step 11. Sterilization
- Use a validated, properly maintained and calibratedsteam sterilizer.
- Effective steam sterilization can be achieved using thefollowing cycles:

Dynamic Air Removal (Prevacuum) Steam Exposure Temperature	Minimum exposure time	Minimum drying time
4 pulse - 132°C [270°F] or 3 pulse - 135°C [275°F]	3 minutes	Wrapped instruments: 15 minutes Wrapped containment devices: 30 minutes

Step 12. Storage
Store sterile packaged instruments in a manner that provides protection from dust, moisture, insects, vermin,and extremes of temperature and humidity.

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