



## INFORMATION FOR USE AND CLEANING AND STERILIZATION OF EMERGE DRILL BITS AND GUIDE WIRES

### FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

**DESCRIPTION:** These recommendations are for processing only non-sterile Emerge Instruments that are sold in the United States. Emerge instruments are provided clean but not sterile. The information provided below applies to unused and non-contaminated Emerge Medical instruments only. Any instrument that has not been used, but has become contaminated, should be handled according to hospital protocol. Emerge does not recommend the reprocessing of contaminated instruments. These recommendations are to be followed unless otherwise noted on specific packaging or inserts.

The Emerge Medical Drill Bit and Guide Wire instruments are manufactured from various medical grade stainless steels and nickel-cobalt-chromium alloys and are available in a variety of sizes.

**INFORMATION FOR USE:** The surgeon must select the type and size instrument that best meets the patient's surgical needs and the surgical procedure.

**INDICATIONS:** The Emerge Drill Bits and Guide Wires are intended to be used in orthopedic surgeries with standard instrument drivers. Always use the manufacturer recommended operating settings for drivers. Only medical professionals who are thoroughly familiar with the instrument's function, application and instructions for use should operate any Emerge instrument.

**WARNINGS:** For safe effective use of these instruments, the surgeon must be thoroughly familiar with the recommended surgical technique and the type of instrument. Application of excessive force to an instrument may cause damage to the instrument and/or injury to patient and/or operator. For optimum results, use new instrument for every procedure. Emerge instruments should not be lubricated.

Check instruments for damage before and during use. If instrument seems to be damaged, discontinue use. Never use a malfunctioning, damaged or suspected-to-be-damaged instrument.

There exists the possibility of the device failing as a result of improper use.

**CONTAINMENT AND TRANSPORT:** Emerge instruments should not be processed or transported with any type of contaminated materials. Soiled devices should be transported separate from non-contaminated devices to avoid contamination.

**INSPECTION:** Emerge instruments should be inspected after processing, prior to sterilization. Any instruments with corrosion, discoloration, scratches, flaws, residue or debris should be discarded.

**CLEANING:** Do not use steel wool or certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners. Long, narrow cannulations, blind holes and intricate parts require particular attention during cleaning. All devices must be thoroughly cleaned using established hospital methods.

**STERILIZATION METHODS:** Emerge does not recommend or support the use of flash sterilization of instruments. Emerge instruments are critical devices and must be terminally sterilized prior to use. The sterilization parameters are only valid for devices that are adequately cleaned. The following parameters are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment.

Pre-vacuum autoclave	
Minimum Temperature:	270° F (132° C) for 4 minutes
Minimum Dry Time:	20 minutes

- Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: 2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: 2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

**LIMITS ON REPROCESSING:** Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on Emerge instruments. Emerge instruments should be inspected for corrosion, damage such as scratches and notches, debris, discoloration or residue. Damaged instruments should be discarded.

**STORAGE INSTRUCTIONS:** Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering, or water contamination. Use oldest lots first.

**POINT OF USE CARE:** Wipe blood and/or debris from device throughout surgical procedure to prevent it from drying on the surface. Flush cannulated devices with sterile water to prevent the drying of soil and/or debris to the inside. Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings. Devices should be covered with a towel dampened with purified water to prevent blood and/or debris from drying.

**PREPARATION FOR DECONTAMINATION:** Any instrument contaminated with blood, tissue and/or bodily fluids/matter should be processed according to hospital protocol. Emerge does not recommend the reprocessing of contaminated instruments.

**ADDITIONAL INFORMATION:** Users should be trained on hospital policies and procedures along with current applicable guidelines and standards. Users should don appropriate personal protective equipment (PPE) when processing instruments.

**CAUTION: Federal Law (USA) restricts the product sale by or on the order of a physician or hospital.**

For more information about products, please visit [www.emergemedical.com](http://www.emergemedical.com) or contact Customer Service at (866) 553-0376

Manufactured and distributed by:



Emerge Medical, Inc.  
1530 Blake Street, Suite 204  
Denver, CO 80202