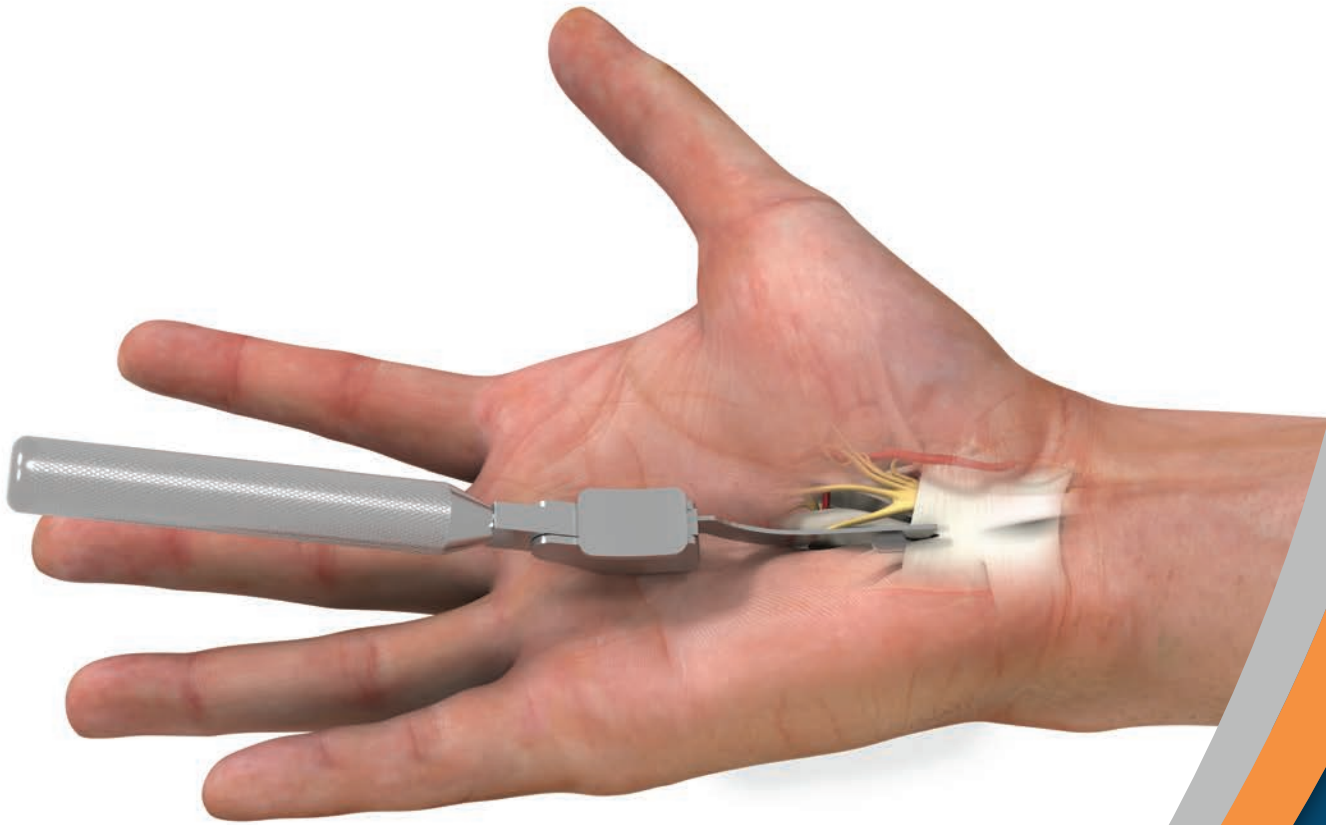


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S2S CTR INSTRUMENTS IFU INSTRUCTIONS

VERSION 2.3

Point of Use

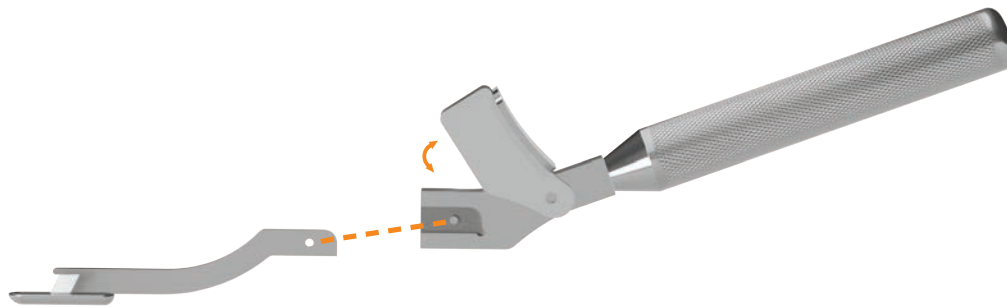
MANUAL DECONTAMINATION

PRECLEANING: Remove gross debris from surgical instruments with a lap sponge and sterile water routinely during the procedure to prevent drying on of blood and body fluids, etc. It is important to rinse instruments that have been exposed to blood in saline solution before the substances dry. Blood and body fluids as well as saline solutions are highly corrosive. In addition, blood can produce a stain that is difficult to remove.

Step 1. Maintain moisture: Immediately after the carpal tunnel procedure, place the instruments in an instrument tray/container and cover with a towel moistened with sterile distilled water. Foam, spray or gel products, specifically intended for use with surgical instruments, are available to keep the soil moist. Transport tray of soiled instruments in an impervious plastic bag or container with a tight lid to the decontamination environment (keep the outside of the containment clean).

DISASSEMBLY

Open locking assembly of the CTR blade holder (20-105) by rotating the locking cover upwards. This will expose the blade holder pocket, and guidepost. Remove and discard the single use CTR blade in appropriate sharps container.



CLEANING/DECONTAMINATION

Step 2. Enzymatic soak: Immerse fully opened and/or disassembled instruments in an enzymatic solution, specific for use with surgical instruments. Prepare the solution and use per enzyme manufacturer's recommendations, paying special attention to instructions for correct dilution, temperature and soaked time.

Step 3. Rinse: Remove from enzymatic soak after the time period recommended by the enzymatic manufacturer in rinse thoroughly with tap water.

Step 4. Cleaning Instruments: Choose a cleaning solution appropriate for surgical instrument and follow the manufacturer's instructions for use. The use of neutral pH detergents is vital to the maintenance of surgical instruments. Contact with acidic solution will remove the instruments 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 instrument while fully immersed in the solution. During manual cleaning, never use stiff wool, wire brushes, scalpel blades or highly abrasive detergent or cleansers to remove soil from surgical instruments. These will damage the instruments protective surface and lead to corrosion. Remove the soil from the tips, box lock, and hinge mechanism. The box lock and hinge portion of the instrument must be thoroughly clean after each use. A buildup of soil, debris, lubricants, etc. in these areas, will make it difficult to use the instrument and eventually irreparably damage it. Manual cleaning should remove all visible residue. It is essential to keep the box locks and hinges open during any manual or automated cleaning process.

Step 5. Rinse: Thoroughly rinse instruments by immersing in tap water and wiping with a clean, soft cloth.

Step 6. Ultrasound Cleaning and Rinsing: Follow the recommendations of the ultrasonic manufacturer regarding cycle times, detergents, proper placement of the instrument tray, and conditioning ("degassing") of the cleaning solution, etc. Use an ultrasound cleaner to remove soil from hard to reach surfaces after gross soil has been removed. Open instruments as appropriate (CTR blade holder (20-105)). Place instruments in a mesh bottom stainless steel instrument tray. Place the tray into the ultrasonic cleaner.

Step 7. 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. Deionization removes ionized salt and particles from the water. Excessively hard water can spot or stain instruments and excessive chlorine in water can cause pitting of the instrument. Deionized water is preferred for the final rinse.

MECHANICAL DECONTAMINATION

Instruments may be processed in a washer sterilizer or washer decontaminator/disinfector. Some of these processes include an enzyme application phase and a lubrication phase that is designed into the cycle. Follow the manufacturer's specifications when using automatic washer-sterilizers or washer decontaminators/disinfectors. The usually required the use of a low foaming, free rinsing detergent with a neutral pH (7.0). A high-foaming detergent may clean effectively but will often leave residual deposits on the instruments and do harm to mechanical washers.

ASSEMBLY

CLEANING:

Step 8. Lubricate: The use of an instrument lubricant, that is compatible with the method of sterilization to be use, is recommended before instruments are sterilized. Be certain that the instrument lubricant is diluted and maintained properly, according to the manufacturer's instructions. This type of lubricant, referred to as "instrument milk "is usually applied by spraying into the box locks and hinges or by dipping the opened instrument into a solution. Lubricants that are too concentrated or too heavily applied will result in slippery instruments that will also be mistaken as wet after sterilization. Routine use of lubricating agents, on thoroughly clean instruments, will prevent hinged parts from sticking.

Step 9. Drying: The instruments must be thoroughly dry before wrapping for sterilization or storage. If the set of instruments is wet when wrapped for sterilization it is likely to come out of the sterilizer wet. "Wet packs "are not suitable for use after sterilization because they may be easily contaminated when handled. Repair instrument sets for sterilization using wrapper, pouch or rigid sterilization container that is appropriate for the method of sterilization to be used.

STERILIZATION

Terminal Sterilization

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.

Below are the recommended sterilization parameters:

	Sterilizer	Exposure Temperature	Exposure Time	Minimum Dry Time
S2S Carpal tunnel Instruments	Pre-vacuum Standard cycle	270° F/275° F	10 min	40 min
S2S Carpal tunnel Instruments	Pre-vacuum Short load Cycle (Minimum cycle Parameters)	270° F/275° F	4 min	20 min

Source Document: S2S_Surgical_Carpal_Tunnel_Instruments_r2_2019.pdf

Disclaimer: The information in this document is for reference only and includes only a portion of the manufacturer's labeling/instructions. The manufacturer's labeling/instructions contain(s) other important information that must be considered in order to properly process these items.