LASCHAL SURGICAL INSTRUMENTS

INSTRUCTIONS FOR USE

Intended Uses

Laschal Scissors are Intended for cutting or trimming of dental surgical materials such as matrix bands, bleaching tray material, titanium mesh or sutures. Laschal Surgical Scissors are intended to cut tissue or suture at the surface or inside the human body.

Includes the following Laschal Scissor products: LA-1, LA-1-15 , LA-1B, LA-1C, LA-1CB, LA-2, LA-206XF, LA-2B, LA-2BC, LA-2C, LA-2CB, LA-3, LA-3B, LA-3B-STR, LA-3B/4C-SET, LA-3BC, LA-4, LA-4B, LA-4C, LA-4CB, LA-4CXF, LA-4XF, LA-5, LA-6, N-4CXF, N-4CXF-7, N-4XF

Laschal Needle holders are used for wound management during a surgical procedure. The instrument grasps the surgical needle to aid in performing the suturing procedure. Used in any procedure where a doctor needs to close a wound.

Includes the following Laschal Needle Holder products: 6-10L, 6-10L/C, 6-10LC/TL, 6-10RL, 6-10RL/C, 6-10RL/TL, 6-10RLC/TL, 7-10L, 7-10L/C, 7-10RL, 7-10RL-M, 7-10RL/C, 7-10RL/TL, 7-10RLC/TL, 7-COMP, 7-TCLC/R, 7-TCL, 7-TCL/R, 7-TCL/TL, 7-TCLC, 7-TCLC/R, 7-TCLC/TL, 7-TCLCR/M, 7-TCLCR/TL, 7-TCLR/M, 7-TCLR/TL, 7TC/R, 7TCLCR/M, 7TCLCR/M/TL, 7TCLCR/MM, 7TCLCR/MM/TL, 7TCLR/M, 7TCLR/M/TL, 7TCLR/MM, 7TCLR/MM/TL, FNH-C, FNH-C6, FNH-S, FNH-S6, FNH-SM, TCL, TCL/R, TCL/TL, TCLC, TCLC/R, TCLC/TL, TCLCR/TLTCLR/TL, 2-331-12, 2-331-15, 2-331-20, 2-332-12, 2-332-20, 2-333-20, 2-335-20

Laschal Forceps are used to grasp a surgical instrument such as an endodontic file, post, or suture. It maty also be used to hold, carry or deliver a implant screw or abutment to the surgical site.

Includes the following Laschal Forcep products: 7-LM-2.5-B, 75-S/L, 75-SP, 75-SP/L, 75CHF/L, 75SL/M, 75SPL/M, CORN, PLAF/R/1X2, PLAF/R/1X2/L, PLAF/R/F, R-PLAF, SRF-6, 90S/L, 90SL/M, 90SPL/M, BBF-7, CDF, CORN/45, CORN/45B, D-45SL/M, D-45SPL/M, D-75SL/M, D-75SPL/M, D-90SL/M, D-90SPL/M, FBF, LN/L, LW/L, LW/L-ST, 45-CCR/L, 45-S, 45-S/L, 45-SM, 45CCR, 45CCR/L, 45END, 45END/L, 45ENMD/L, 45SL/M, 45SPL/M, 90AHF/L, EF-1, EF-1-7, HAF/75, HAF/75-7, HAF/90, HEX/75, IP-1, TF-L, TF-R, TF-S, TF-S-M, LA-CERAM, LA-F, LA-H75SP, LA-H75SP-C/L

Intended User

For use by a dentist or surgeon. Any surgical procedures should be performed by licensed healthcare professional trained and familiar with surgical techniques. This instruction for use alone does not provide sufficient background for direct use of the Device.

Patient Target Group

Person receiving treatment as part of a dental or surgical procedure.

CONTRADITIONS

- Surgical & Dental Instruments should not be used for anything other than their intended use.
- Instruments should not be used with patients that have allergies to the specific materials used including stainless steel and tungsten carbide.

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Precautions and Warnings

- Devices shall be used in accordance with these instructions for use. Read all sections of this insert prior to use. Improper use of this device may cause serious injury. In addition, improper care and maintenance of the device may render the device non-sterile prior to patient use and cause a serious injury to the patient or health care provider.
- Inappropriate use of instruments may result in patient injury, damaged or broken instruments.
- Proper cleaning, handling, sterilization and standard routine maintenance (such as sharpening, lubrication if applicable) will ensure that the instruments perform as intendedand will extend their useful life.
- Delicate surgical/dental instruments require special handling to prevent damaging the tips.Use caution during cleaning and sterilization.
- For instruments with Tungsten Carbide inserts (hemostats, scissors, needle holders-also identified by a gold handle) we do not recommend cold sterilizations or solutions containing Benzyl Ammonium Chloride, which will deteriorate the Tungsten Carbide inserts.
- Do not expose instruments to phenols or iodophors.
- Do not apply excessive stress or strain at joints; misuse will result in misalignment or cracksat the box locks or jaws.
- Rongeurs and bone cutting forceps should only be used to cut bone, never wire or pin. Donot twist or apply excessive stress during use.
- Before use, inspect the instruments for possible damage, wear or non-functioning parts. Carefully inspect the critical, inaccessible areas, joints and all movable parts.
- Damaged or defective instruments should not be used or processed.
- Improper cleaning may lead to inadequate sterilization. Failure to completely dry instruments during autoclaving may leave moisture and cause discoloration and oxidation. The use of hydrogen peroxide or other oxidizing agents will damage the surface of the instruments. Periodic testing, cleaning, and calibration of the autoclave equipment is recommended to ensure the unit remains in proper working order.
- Instruments are supplied non-sterile and must be cleaned and sterilized before the first use and before each subsequent use. It is important that instruments be well cleaned before the sterilization process.

Directions for Use

Proper surgical procedures and restorative techniques are the responsibility of the medical professional. Each clinician must evaluate the appropriateness of the procedure used based on personal medical training and experience as applied to the patient case.

Laschal instruments may be sterilized in any conventional manner and are guaranteed to be capable of all high level sterilization procedures.

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CLEANING & MAINTENANCE

DECONTAMINATION: **MANUAL**	**A) Immediately after use** Directly after surgery, rinse instruments under warm (hot) running water. Rinsing should remove the majority of blood, body fluids, and tissue. **B) Ultrasonic Cleaning and rinsing** • To avoid blood and other proteins from sticking to instruments surfaces, an enzymatic cleaner bath (soaking) should be used on all instruments. After soaking for a minimum of 10 minutes, rinse all instruments in running tap water. • Immerse instruments completely in any approved disinfectant for another 10 minutes or more, then rinse again. • Never expose stainless steel instruments to bleach or other chemicals for the purpose of disinfection. Exposure to bleach will result in severe pitting of your instruments and will void all manufacturer's guarantees. **Ultrasonic** Follow the recommendations of the ultrasonic manufacturer regarding cycle times, detergents, proper placement of the instrument tray, and conditioning (degassing) of the cleaning solutions, etc. Use an ultrasonic cleaner to remove soil from hard to reach surfaces such as grooves, crevices, lumens, instruments with moving parts, etc., after gross soil has been removed. Open or disassemble instruments as appropriate. Place instruments in a mesh bottom stainless steel instrument tray. Place the tray into the ultrasonic cleaner. Flush air out of lumens and fill them with the ultrasonic cleaning solution (under the solution level in the chamber) for effective removal of soil from that inner surface by the ultrasonic activity. **C) Final rinse 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. Iron ions may also be removed by this treatment. Deionization

removes ionized salts 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.

D) Decontaminate clean instruments

Once instruments have been cleaned, they must be rendered safe for handling, inspection and assembly. They may be steam sterilized without a wrapper or disinfected following the instructions from the instrument, sterilizer and disinfectant manufacturers.

E) Visual inspection and instrument set assembly

Visually inspect the instrument for cleanliness and to ensure all parts are in proper working order, as the set is assembled. Inspection is a vital part of proper care and maintenance. Instruments in need of repair will not perform accurately in surgery and breakage is likely to occur. Do not use damaged instruments. Worn ratchets, loose box locks and misaligned jaws can be repaired at a fraction of the cost of new instruments.

Contact your local representative or visit our website for information regarding an instrument repair program.

F) Lubricate Instruments

The use of an instrument lubricant, that is compatible with the method of sterilization to be used, 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 is referred to as "instrument milk" and is usually applied by spraying into the box locks and moving parts or by dipping the opened instruments 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.

G) Drying Instruments

Before instruments are wrapped for sterilization or storage, they must thoroughly dry. If a 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. In addition, remaining moisture, particularly in box locks and hinges may result in corrosion that will weaken the instrument and lead to breakage during use. Prepare instrument sets for sterilization using a wrapper, pouch or rigid sterilization

	container that is appropriate for the method of sterilization to be used. The Association for the Advancement of Medical Instrumentation (AAMI) and individual sterilizer manufacturers provide guidance for the proper preparation of surgical instrument trays for sterilization. Some sterilizer manufacturers can also provide information regarding wet pack problem solving. See also, "Sterilization for the Healthcare Facility, 2nd Edition", Reichert, M.; Young J., "Wet Pack Problem Solving", Lee, S. (Frederick, MD: Aspen, 1997).
MECHANICAL DECONTAMINATION	General surgical instrumentation 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. They usually require 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. Automated washer sterilizers and washer decontaminator/disinfectors usually have adjustable wash and rinse times. Some washers enable the user to customize extra cycles to process heavily soiled surgical instruments more effectively. Check with a Technical Service representative for questions regarding processing delicate, complex and/or multipart instruments by this method.
TERMINAL STERILIZATION	After following the decontamination recommendations, reusable instruments are ready for sterilization. Independent laboratory testing, conducted according to the F.D.A. (21CFR PART 58) and Good Laboratory Practice Regulations (G.L.P.), has validated steam sterilization as an effective process for reusable instruments. See also, AAMI Standards and Recommended Practices, "Steam Sterilization and Sterility Assurance in Health Care Facilities, " ANSI/AAMI ST46:2002; "Flash Sterilization Steam Sterilization of Patient Care Items for Immediate Use.". ANSI/AAMI ST37: 3ED. AAMI standards recommend that the sterilizer manufacturer's written instructions for cycle parameters should also be followed. Steam sterilization of lumened instruments requires that they be flushed with sterile water just prior to wrapping and

sterilization. The water generates steam within the lumen to move air out. Air is the greatest enemy to steam sterilization, preventing steam contact if not eliminated. Medical device manufacturer's exposure times to sterilization temperature may need to be longer than the minimum indicated by the sterilizer manufacturer but never shorter.

Sterilizer	Exposure Temperature	Exposure Time	Minimum Time
Pre-Vacuum (wrapped)	121°C (250°F) 132°C (270°F) 134°C (273°F)	20 minutes 4 minutes 3 minutes	20 minutes 20 minutes 15 minutes
Pre-Vacuum (unwrapped)	132°C (270°F)	4 minutes	
Gravity Steam (unwrapped)	132°C (270°F)	18 minutes	

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