Manufacturer: **Gobble Surgical**

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1. SCOPE:

Device(s): All re-useable surgical & Dental instruments supplied by Gobble Surgical Sialkot–Pakistan, comprising fixed/moveable assemblies and simple hinged assemblies, excluding those containing Aluminum alloys.

FOR PROFESSIONAL USE ONLY:
Do not use instrument other than the intended procedure

2. INFORMATION TO BE PROVIDED BY THE MANUFACTURER:

2.1 Reprocessing Instructions:

WARNINGS:	Aluminum based instruments are damaged by alkaline (pH > 7) detergents and solutions. Long narrow cannulations and blind holes require particular attention during cleaning.
2.2- Limitation on processing:	Don't exceed 150 °C Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

INSTRUCTIONS:	
2.3- Preparation at the Point of use:	Remove excess soil with disposable cloth/paper wipe.
Containment and Transportation:	No particular requirement It is recommended that:- • Immediately after use, rinse instruments under warm (not hot) running water. Rinse should remove most blood, body fluids and tissues. • Instruments are reprocessed as soon as is reasonably practical following use.
2.4 DOCUMENTATION:	
2.4.1- Preparation for cleaning:	Instruments should be submerged in al solution of water and neutral pH (7) detergent for 15 minutes.
2.4.2- CLEANING: **2.4.2.a- Cleaning: Manual**	Most instruments manufacturers recommend ultrasonic cleaning as the best and most effective way to clean surgical / dental instruments particularly those with hinges, locks and other removing parts. If Ultrasonic cleaning is not available observe the following steps. • Rinse excess soil from instrument (Temp < 30 °C) • Use stiff plastic cleaning brushes • Do not use steel wool or wire metal brushes for instruments serrated areas or on bone files, burs or on stained areas in knurled handles. • Use only neutral pH (7) detergents, because if not rinsed off properly low pH (acidic – less than 6 pH) detergents will cause breakdown of stainless protective surface (pitting) and black staining. High pH detergents (alkaline–more than 8pH) will cause surface deposit of brown stain (phosphates), which will also interfere with smooth operation of the instrument. Most brown stains are not rusting – but merely a high pH surface (phosphate) deposit and can easily be removed with ordinary

	surgical instrument stain remover. • Brush delicate instruments carefully and if possible rinse clean these instruments totally separate from General instruments. • Make sure the entire instruments surface is perfectly clean. • After scrubbing, rinse instrument thoroughly under clean running water for 3 minutes. Ensure that running water passes through cannulations and that blind holes are repeatedly filled and emptied. • While rinsing instruments to also make sure the hinge areas are rinsed out, as well as outside of the instruments.
	ULTRASONIC CLEANING. Instruments should be processed in the ultrasonic cleaner for the full-recommended cycle time - usually 5-10 minutes. • A lid should cover the ultrasonic cleaner during operation to avoid splashing. • Place instruments with hinges, locks and other moving parts in open position into ultrasonic cleaner, make sure that the sharp blades of scissors, gingivectomy, Knives; curettes etc do not touch other instruments. • All the instruments have to be fully submerged into the cleaning solution. • Do not place instruments made of dissimilar metal (Stainless, Chrome plated copper etc) in the same cleaning cycle. • Change solution frequently – at least as often as manufacturer recommends. • Rinse carefully instruments after Ultrasonic cleaning under running water to remover Ultrasonic cleaning solution. • Surgical instrument cleaner may be used with all ultrasonic cleaners.
2.4.2.b- Cleaning: Automatic	**Automatic Washer / Sterilizer** Follow manufacturer's commendations but make sure that your process is well validated before applying on our products.
2.4.3- Disinfection:	To protect medical personal from accident during cleaning. • To avoid blood and other proteins from sticking to instruments surfaces, an enzymatic cleaner bath (soak) should be used on all instruments. After soaking for at least 10 minutes, rinse instruments under running tap water. • Immerse instruments completely in an EPA approved disinfectant for another 10 minutes or more. Then rinse again. • Never expose stainless instrument to bleach or other corrosive chemicals for the purpose of disinfection. Exposure to bleach will result in severe pitting of instruments and void manufacturers guarantees.
2.4.4- Drying & Lubrication:	Immediately after cleaning and rinsing, instruments should be carefully air-dried. All instruments with hinges, locks and other moving parts (Metal to metal action). Such as scissors, homeostatic, needle holders, extracting forceps etc. should be lubricated. Surgical lubricants only are recommended. Do not use industrial lubricants. This is good time to inspect each instrument for proper function and condition
Maintenance:	Apply a small quantity of surgical grade lubrication oil to hinges. Discard blunt or damaged instruments.
2.5- Inspection & Function Testing:	Immediately after cleaning and rinsing, instruments should be carefully air-dried. All instruments with hinges, locks and other moving parts (Metal to

	metal action). Such as scissors, homeostatic, needle holders, extracting forceps etc. should be lubricated. Surgical lubricants only are recommended. Do not use industrial lubricants. This is good time to inspect each instrument for proper function and condition Check and make sure that:- • Scissor blades glide smoothly all the way (they must not be loose when in closed position). Test scissor by cutting into thin gauze or surgical glove material. Three quarters of length of blade should cut all the way to the scissor tips, and not hang up. • Forceps (pickups) have properly aligned tips. Teeth must meet properly – without catching action. • Hemostats and needle holders should not show light between the jaws – when closed in the first ratchet position (hemostats may show a small open space – half way in form the closed tips), lock and unlock easily and joints are not loose. Check needle holders for wear on jaws surface. • Suction tubes are clean inside. • Biopsy punches – punch a clean hole into tissue paper. • Retractors function properly. • Cutting Instruments and Knives have sharp, undamaged blades.
2.6- Packaging:	**Singly:** A standard polyethylene pouch may be used. Ensure that the pack is large enough to contain the instrument with out stressing the seal. **In Sets:** Instruments may be loaded into dedicated instrument trays, or general-purpose sterilization trays. Ensure that cutting edges are protected, and not exceed 12 Kg per tray. Wrap the trays.
2.7- Sterilization: (Autoclaving)	**Vacuum autoclave, minimum of 5 minutes at 134 °C.** **Don't exceed 150 °C.** • Lubricate all instruments, which have any "metal to metal" action such as scissors hemostats, needle holders and self-retaining retractors, etc. Use non-silicon, water-soluble surgical lubricant. Don't use industrial lubricants. • Put instruments up for sterilization either individually or in sets. **Individual Instruments:** - Disposable paper or plastic pouches are ideal. Make sure use of a wide enough pouch (4" or wider) for instruments with ratchets locks such as hemostats and needle holders so the instrument can be sterilized in an open (unlocked) position. Locking instruments during autoclave will cause cracked hinges (box locks) and other defects because of heat expansion. If the instruments are wrapped make sure that towels do not contain detergent residue (which can stain the instruments) and are neutral pH (7) if immersed in water. **Instrument Sets:** - Unlock all instruments and sterilize them in an open position. Place heavy instruments on bottom of set (when two layers are required). • Never Lock an Instrument during Autoclaving It will not be sterilized as steam can not reach the metal to metal surfaces. The instrument will develop cracks in hinge (box lock) areas

	because of heat expansion during sterilization cycle. • Don't overload autoclave chamber as pockets may form that do not permit steam penetration. • Place towel on bottom of pan to absorb excess moisture during autoclaving. This will reduce the chances of getting "wet Packs". **Caution:** • With most portable tabletop autoclaves, at the end of the autoclave cycle – before the drying cycle – unlock the door and open it no more than a crack about 4" (6.4mm). Then run dry cycle for the period recommended by the autoclave manufacturer. If the autoclave door is opened fully before the drying cycle, cold room air will rush into the chamber, causing condensation on the instrument. This will result in water stains on instruments and also cause wet packs. • Make sure autoclave filters and chambers are cleaned periodically. • Use Surgical Instrument stain remover to clean the autoclave
2.8- Storage:	Instruments to be stored, let them air dry and store them in a clean and dry environment.

Additional Information:	When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer manufacturer's stated maximum load is not exceeded.
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