Inter Links

All kinds of Medical instruments we manufacture

Instruction for Use

This instructions manual applies to all reusable Inter Links Dental and surgical instruments for the Care, Cleaning, Maintenance, Identification and Sterilisation and should be read carefully. This information also applies to disposable medical instruments. Instruments are supplied NON-STERILE and must be inspected, cleaned and sterilized before each use. The user should adhere to the local laws and regulations in countries with stricter recycling requirements.

Warranty:

Inter Links products are warranted to be free from defects in material and workmanship when used under normal condition for its intended purpose for 5 years. Any instrument that proves to be defective during this period, Inter Links will, at its sole discretion, either repair or replace the defective product at no charge. This limited warranty is null and void if an Inter Links product is repaired or modified in any way by any party that is not explicitly Inter Links authorized. Inter Links shall not be held responsible for consequential or indirect damage arising from the sale or use of any product. Inter Links instruments are reusable and meet AAMI standards for sterilization. All our products are designed and manufactured to meet the highest quality standards.

Warning and Precautions:

- Inter Links recommends thorough manual and automated cleaning of medical devices prior to sterilization. Automated methods alone may not adequately clean devices.
- Devices should be reprocessed as soon as possible following use. Instruments must be cleaned separately from cases and trays.
- All cleaning agent solutions should be replaced frequently before becoming heavily soiled.
- Prior to cleaning, sterilization and use, all instruments should be inspected to ensure proper function and condition. Do not use instruments if they do not perform satisfactorily.
- Risk of damage: The surgical instrument is a precision device. Careful handling is important for the accurate functioning of the product. Improper external handling can cause product malfunction.
- Instruments with points or sharp edges should be handled with caution.
- When dealing with contaminated or potentially contaminated materials, instruments and products, appropriate personal protective equipment should be worn. This includes a gown, a mask, goggles or visors, gloves and shoe covers.
- In the case of manual cleaning, no metal brushes or abrasive cleaning materials are permitted. These materials result in damage to the surface and coating of the instruments. It is advisable to use nylon brush with soft bristles.
- During the manual cleaning process, detergent with low-foaming surfactants should be used to ensure that the instruments are visible in the detergent solution. When scrubbing by hand using brushes, the instruments should always remain below the surface of the cleaning solution, so as to avoid creating particulate material and spray, thereby potentially spreading contaminating substances. Cleaning agents must be gently yet thoroughly rinsed off from the product surfaces to prevent the accumulation of detergent residues.
- Heavy objects should not be placed on sensitive products.
- Do not allow contaminated instruments to dry prior to reprocessing. All of the steps for cleaning and sterilisation described below are facilitated if blood, body fluids, bone and tissue residues, saline solution and disinfectants are not allowed to dry on used instruments.
- Saline solutions, cleaning agents and disinfectants which contain aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and must not be used. Instruments must not be immersed or placed in Ringer's solution.
- Mineral oil and silicone lubricant should not be used as they:
  1) coat microorganisms.
  2) prevent the direct contact of steam with the surface and
  3) are difficult to remove.
- No descaling agents containing morpholine should be used in steam sterilisers. This agent leaves residues that may cause damage to instruments made from polymer over time.
- Fading of color-anodized aluminum instruments may be accelerated if cleaning and sterilization recommendations below are not followed. Remove all protective caps and sheaths carefully. Before beginning to use the instrument, the instrument must be cleaned, lubricated, decontaminated, sterilized, and inspected before use in surgery.
- Many electrosurgical accidents have been caused by faulty accessories, by failure to check for and identify these accessories prior to each procedure, and by careless use. The use of the device with safely functioning and compatible handles, cords, generators, and accessories is the user's responsibility. Read and understand all precautions and instructions before attempting to use any electrosurgical device.
- With proper care and use, these devices can last a lifetime. Normal repeated use has minimal effect on these instruments. End of life is normally determined by wear and damage due to use. Dispose of at end of life in accordance with national regulations and approved hospital practices for surgical instrumentation disposal.
- Use of these instruments for any purpose, or in any manner other than those described here may cause instrument damage or failure which could result in serious patient injury or death. If needed, all metal instruments or fragments thereof can be located by means of an X-Ray.

Cleaning Instructions:

Please note for preparation of cleaning:

1) When applicable, instruments should be cleaned in the open or unlocked position. Large, non-delicate instruments may be soaked in a corrosion inhibiting detergent (like Alconox) when other cleaning methods are not practical. Rinse and dry your instruments after soaking them.

2) Black coated and color anodized components may be negatively affected if aggressive cleaning mediums or appliances (e.g. extreme acidic/alkaline, abrasives) are used. A pH neutral cleaner, which may or may not contain enzymes is recommended. Exposure to chlorides or hydrogen peroxide may negatively affect the coatingor colorization of components.

Please note:

Steel/Metal instruments without cannulated holes/lumen or non-metal/polymer handles or other components (e.g. compressors, distractors, etc.). These instruments can tolerate alkaline detergent as long as the cleaning process includes neutralisation with acid and thorough rinsing. In the presence of rust or corrosion, these instruments can be cleaned using rust remover approved for use on surgical instruments.

Steel/Metal instruments with cannulated holes/lumen, but without non-metal/polymer handles or other components (e.g. polyaxial screwdriver, approximator, etc.). These instruments can tolerate alkaline detergent as long as the cleaning process includes neutralisation with acid and thorough rinsing. In the presence of rust or corrosion, these instruments can be cleaned using rust remover approved for use on surgical instruments. Cannulas and cavities must be cleaned by hand.

Instruments made from or using Polymers without cannulated holes: Instruments made from polymers or metal instruments with polymer components (e.g. awl, pedicle probe, etc.). These instruments can tolerate alkaline detergent as long as the cleaning process includes neutralisation with acid and thorough rinsing.

Instruments made from or using Polymers with cannulated holes: Instruments with cannulated holes made from polymers or metal instruments with polymer components (e.g. T- handle, straight handle, etc.). These instruments can tolerate alkaline detergent as long as the cleaning process includes neutralisation with acid and thorough rinsing. Cannulas and cavities must be cleaned by hand.

Instruments made from Titanium or Aluminium alloys: Instruments made from Titanium or Aluminium alloys for assembly or disassembly or with other reprocessing aids (e.g. instrument containers, trays and sterilisation containers). These instruments should be cleaned in accordance with the manual or combined manual/automated cleaning procedures in this manual. These instruments should not be exposed to alkaline cleaning agents.

Manual Cleaning Instructions:

1) Rinse and/or flush under warm flowing tap water to remove all blood, bodily fluids, and tissue immediately after use for a minimum of 30 seconds.
2) Ultrasonically clean using a detergent solution prepared accordingto the manufacturer's instructions for a minimum of 10 minutes.
3) Completely immerse the instruments in a detergent solution prepared according to the manufacturer's instructions.
4) Scrub all instruments with an appropriately sized soft nylon bristle brush for a minimum of one minute, paying particular attention to crevices and hard to clean areas.
5) For applicable instruments, such as suction tubes, insert the supplied wire mandrel to dislodge potentially trapped soil.
6) Scrub cannulations with an appropriately sized soft nylon bristlebrush for a minimum of 30 seconds.
7) Flush instruments with cannula by inserting a cleaning cannulaand attaching appropriately sized syringe filled with cleaning solution. Flush cannula two times with approximately 50 ml of cleaning solution each time.
8) Flush suction tubes by inserting syringe with appropriately sized needle into lumen near thumb grip. Flush lumen three times with approximately 1 ml each time with cleaning solution.
   Please note: Remove wire mandrel from within suction tube lumen and process alongside suction tube.
9) Rinse with flowing Critical Water for a minimum of 30 seconds.
10) Dry the instruments using absorbent, low-lint wipes to remove excess water.
11) Use a spray/surgical instrument lubricant in the hinges to improve the function of the instrument.
    CAUTION: Do not use WD-40, oil or other industrial lubricants.

Automated Cleaning Instructions:

1) Use only washer/disinfector machines that have been validated inaccordance with ISO 15883.
2) Perform pre-cleaning to remove gross contaminants as follows:
   a. Submerge and soak in a pH neutral detergent solution prepared according to the manufacturer's instructions fora minimum of 1 minute.
   b. Flush any cannulations that may be present.
   c. While still submerged, remove visible soil by scrubbing with an appropriately sized soft nylon bristle brush for a minimum of 3 minutes.
   d. Rinse with flowing Critical Water for a minimum of 30seconds.
3) Load instruments into washer/disinfector in accordance with the manufacturer's instructions.
4) Arrange instruments with curved surfaces and cannulations facingdownward to prevent pooling of water.
5) Operate the washer/disinfector cycle according to themanufacturer's instructions.
   a. Recommended minimal washer/disinfector parameters:
      i. Heated Wash at 140°F (60°C) for 2 minutes
      ii. Heated Tap Water Rinse at 140°F (60°C) for 20 seconds
      iii. Heated purified Water Rinse at 180°F (82°C) for 1 minute
      iv. Forced Air Drying at 240°F (116°C) for 9 minutes

Note: Automated cleaning may not be suitable for instruments with long lumens, ball joints, or stainless steel cables (e.g. suction tubes and surgical arms). Such instruments should undergo a manual cleaning prior to sterilization.

Manual cleaning instructions for articulating and flex arms:

1) Turn tightening knob counter-clockwise to loosen the internal cable to enable movement of the surgical arm beads to allow fluid to flow between each link prior to placing arm in sonicator.

2) Ultrasonically clean arms using a detergent solution prepared according to the manufacturer's instructions for a minimum of 10minutes.
3) Completely immerse the instruments in a detergent solution prepared according to the manufacturer's instructions.
4) Scrub all instrument surfaces with an appropriately sized soft nylon bristle brush for a minimum of 1 minute.
5) Rinse surgical arm with flowing Critical Water for a minimum of 30seconds.
6) Manually dry surgical arm using clean, absorbent, low-lint wipes toremove excess water.

Surgical arm inspection before use:

1) Inspect entire assembly for damage.
2) Hold arm assembly at column and tighten central tightening knob clockwise.
3) Check to make sure that arm is rigid at all three joints.
4) Insert column into rail clamp, tighten column-tightening lever andmake sure that it holds securely.

Sterilization Instructions:

Lubricate: For instruments with moving parts, lubricate joints with asteam-permeable, water-soluble instrument lubricant prior to sterilization.

Sterilize:

1) Instruments should be sterilized in the open, loosened, or unlocked position. CAUTION: Never lock an instrument during autoclaving. This will prevent the steam from reaching and sterilizing the metal-to-metal surfaces. Heat expansion during autoclaving could cause cracks in hinge areas. Place a towel on bottom of the sterilization tray to absorb excess moisture during autoclaving. Arrange the instruments in the trays. Load the autoclave chamber, but do not overload it. Overloading may hinder steam penetration. Run your autoclave according to the manufacturer's directions. At the end of the autoclave cycle (before the drying cycle) unlock autoclave door and open it no more than a crack (about 3/4"). Run the 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 instruments. This will result in water stains on instruments and also cause wet packs.
2) Instruments should be sterilized by standard process parameters using steam with established procedures.
3) The following sterilization process parameters have been validated to be effective.

Gravity:

- The Gravity Displacement autoclave process is to sterilize theinstruments at 250°F (121°C) for 30 minutes and 30 minute dry time.

Prevacuum:

- A Prevacuum autoclave process is to sterilize the instrumentsat 270°F (132°C) for 4 minutes and 30 minute dry time.
- A Prevacuum autoclave process is to sterilize the instrumentsat 273°F (134°C) for 3 minutes and 30 minute dry time.

Autoclave temperatures should not surpass 280°F (137°C), as handles, insulation or other non-metallic parts may be affected. (Note: Contact your steam autoclave manufacturer to confirm appropriate temperatures and sterilization times.)

Storage:

To guarantee instrument sterility up to the time of use on the patient, germ-tight packaging is absolutely essential. The sterilized instruments should be stored in dry, clean, dust-free and protected from direct sunlight condition at moderate temperatures of 5°C to 40°C.

Transportation and storing should not adversely affect the features of the reprocessed medical device. Please examine instrument for wear and tear prior to use for functionality and damage. Proper examination, care and handling may also be guided by the ASTM Standard F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" or using reference manuals such as the "Instrument Reprocessing, Reprocessing of Instruments to Retain Value"(availablefrom www.a-k-i.org).

Checking / Functional testing / Maintenance:

Visual inspection for cleanliness, assembling and functional testing according to instructions of use. If necessary perform reprocessing process again until the instruments are visibly clean. Follow the described maintenance below and the functional testing as described.

Stained instruments are the results of faults in the preparation. Causes of these stains could be:

- Insufficient automatic and manual cleaning.
- Unsuitable cleaning agents, disinfectants and care agents.
- Non-observance of the dosage instruction of cleaning agents, disinfectants and care agents or residues.
- Influences from the water, e.g. by foreign ions such as iron or silicate.
- Residues of drugs, sign pens or chemical indicators.
- Process error (e.g. non cleaning of brand new surgical instruments before sterilisation)

After cleaning or cleaning/disinfection check all instruments for loose parts, corrosion, damaged surfaces, splitting, distortion, movability/operation, hairline cracks in the joint areas etc. Damaged, distorted or otherwise worn instruments must be replaced immediately. Properly inspection of set screw, if screw is loose, please tighten at your own technical evaluation. Instrument oil should only be used when explicitly specified. If oiling is desired, however, it should be ensured that only instrument oil, which are approved for sterilization, are used, taking into account the maximum sterilisation temperature applied and which have been proven biocompatible. Instruments with joints, locks and sliding shaft instruments (Forceps, Scissors, Rongeurs, Punches, etc.) must be treated in the joints with instrument oil to avoid fretting corrosion. Distribute the lubricant uniformly in the joint by opening and closing the instrument several times. Only moving parts must be oiled; instruments must not be given a complete coating of oil and, in particular, plastic components should not be oiled.

Prior to every use, the instruments shall be checked for fractures, cracks, deformations, damage and for proper functionality. It is especially essential to check areas, such as blades, points, ends, stops and snaps as well as movable parts. Worn,

corroded, deformed, porous or otherwise damaged instruments shall be sorted out. The stainless steels (non-corroding), used for instrument production, create - based on their alloy technology - specific passive layers as protective layers. These steels only resist the effects of chloride ions and aggressive media and fluids conditionally! In addition to the efforts that have been undertaken by the manufacturer through the selection of proper materials and careful processing, the user of instruments shall carry out professional and continuous maintenance and proper reprocessing.

Gouge, Osteotome and Knife

The cutting edges shall not indicate any notches.

Tweezers

- Inspect the working tips for integrity.
- In a closed state, the working tips shall perfectly lie on top of each other.
- The spring section shall be inspected for cracks.

Screwdriver

- Screw driver blades shall be inspected for proper profile Screws.

Punch

- The shank shall be oiled.
- The punches shall be inspected for fracture sites.
- The punches shall easily open and close.
- The cutting edges shall be checked for integrity.
- A cutting test shall be carried out with a silicone strip.

Retractors

- Inspect the working tips for integrity.

Forceps

- The spanner shall be oiled.
- The lock joints shall be inspected for fracture sites.

Intended User Profile

The instruments shall be exclusively applied for the purpose for which they have been intended in the medical fields and used by educated and qualified personnel. The attending physician or user shall be responsible for the selection of instruments for specific applications or for surgical procedures, proper training and information, as well as for having the adequate experience in handling of the instruments. Consult medical literature relative to techniques, complications and hazards prior to performance of any surgical procedure. Before using the product, all instructions regarding its safety features must be read carefully.

Warning: If any device or instrument is/was used in a patient with or suspected of having Creutzfeldt-Jakob Disease (CJD), Bovine spongiform encephalopathy (BSE) (so-called mad cow disease), Transmissible spongiform encephalopathy (TSE) the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!

Stain Guide For Stainless Steel: Although stainless steel is corrosive resistant, it can still rust and/or stain if it is handled improperly. To determine if a discoloration is rust or just a stain, erase the discoloration with a pencil eraser. If there is pitting in the metal under the discoloration, it is corrosion. If the discoloration is removed, it was just a stain.

Stain Table

Stain color	Cause
Brown/Orange	High pH
Dark Brown	Low pH
Bluish/Black	Reverse plating due to mixed metals during cleaning process
Multicolor	Excessive heat
Light/Dark Spots	Water droplets drying on the surface
Black	Contact with ammonia
Gray	Excessive use of rust remover solution
Rust	Dried-on blood or bio-debris

Symbols used on Labeling:

REF	Reference Number		Manufacturer
MD	Medical Device		Manufacturing Date
	Warning /Instructions for use/Attention/Precautions	EC REP	Authorized Representative in the European Union
	Instructions for Use	QTY	Quantity
	Temprature Limitations		Do not re-use
	Keep in a dry place	STERILE	Has a Sterilization process
LOT	Lot Number/Batch Code	STERILE EO	Sterilized using Ethylene Oxide
CE	CE-MARK (Complies with European Medical Devices Directive 93/42/EEC updated Directive 2007/47/EC).	STERILE R	Sterilized using Irradiation
UDI	Unique Device Identification	STERILE	Sterilized using Steam or Dry heat
SN	Serial Number	2 STERILIZE	Not to be re-sterilized
	Protect from Sunlight	NON STERILE	Packaged Non-Sterile
	Expiration date/Use by date (Format: yyyy/mm)		Do don't use if Package is Damaged

NON STERILE **CAUTION:** These reusable devices are packaged non-sterile and are steam sterilizable too. sterilize before use.

Products

These instructions are valid for all instruments manufactured by Inter Links as listed below products and groups categories:

Dental Instruments:

Burs, Drills and Trephine	Boley Gauge	Miscellaneous Products
Ivory	Rigid Stainless Steel Spatula	Mixing & Separating Spatulas
Anisworth	Apical Fragment Ejectors	Mouth Gags & Retractor
Silver Point Stieglitz Forceps	Applicator and Amalgam Carriers	Needle Holders
Self Aspirating Dental Syringe	Articulators	Operating Scissors
Band Seater Stainless Steel Sterilizа	Black's Cutting Instruments	Orthodontic Instruments
Band Seater, Nylon, Sterilizable	Bone Curettes	Periodontia Instruments
Band Pusher Mershon, 5 - Sided	Bone Files	Pertotomes and Papilla Elevators
Distal End Cutter With Wire Safety	Bone Rongeurs	Plastic Filling Instruments
Ortho Heavy - Duty Wire Cutter	Calibrated Probes	Plastic Filling Instruments, Excavators
Mathieu Needle Holder	Caliper Rulers	Orthodontics Pliers & Prosthetics
Bird Beak Plier	Cavity Preparation	Pliers
Arrow Clasp Forming Bending Plier	Cement & Mixing Spatulas	Mixing Spatulas
Niti Cinch Back Plier	Chisels and Gouges	Plaster Cutting Knives
Posterior Band Remover Plier	Cotton Plier & Dressing Tweezers	Probes & Explorers
Separating Plier, Spring Back Actio	Crown Removers	Root Elevators
Step Plier With A Double Sided	Dental Syringes	Root Splinter Forceps
Universal Pin Binding Plier	Endodontic Instruments	Rubber Dam Punch Clamp Forceps
Tweed Arch Forming Plier	Excavators	Scalers
Tweed Ribbon Arch Forming Pliers	Filling Instruments	Spreaders
Cap Removal Tool Plier	Forceps For Children	Tooth Extracting Forceps (Americar
Band Seating Removing Instrument	Gracey Curettes	Tooth Extracting Forceps (British)
Goldman Fox Bone/Soft Tissue Nipper	Gum Scissors	Universal Curettes
Micro Surgical Scissors Microsuturing	Haemostatic Forceps	Wax and Modelling Carvers
Micro Surgical Needle Holder	Impression Trays Stainless Steel	Wax Knives Bone Files and Curette
Crown Remover Morrel (3 Inserts)	Matrix Retainers	Wisdom Extracting Forceps

Surgical Instruments:

Anaesthesia	Intestinal & Stomach	Scalpels
Artery Forceps	Maxillo-Facial	Scissors
Asepsis	Neuro Surgery	Self-Retaining Retractors
Bone Surgery	Obstetrics	Sterilization
Cardiovascular	Oral Instruments	Suture
Cotton Swab Forceps	Otology	TC Instruments
Dermatology	Plaster	Thoracic & Lung Surgery
Diagnostics	Probes, Applicators & Spatulas	Tonsil
Dressing & Tissue Forceps	Rectum	Tracheotomy
Gall Bladder	Retractors	Trocars & Suction Tubes
Gynecology	Rhinology	Urology

Quality Statement, Standards and Directives:

Inter Links is dedicated to providing innovative high quality specialty dental and surgical instrumentation. Inter Links guarantees that all of our products have been manufactured by skilled instrument craftsmen, using only quality materials. Every effort is made to manufacture the finest quality surgical instruments at exacting specifications.

Applicable standards and directives:

Inter Links (dental and surgical instruments) is certified by **ISO 9001**, **ISO 13485** and Complies with European Medical Devices Directive 93/42/EEC updated Directive 2007/47/EC (Class I) and bear the **CE Mark**.

Company Information:

Inter Links

All kinds of Medical instruments we manufacture

Inter Links

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