CARE AND MAINTENANCE Reference Guide

SCANLAN® Instruments

Since 1921, Scanlan International, Inc. has worked diligently to fulfill its promise to make the highest quality surgical instrumentation. All SCANLAN® instruments are handcrafted by artisans who have acquired their skills from earlier generations. This Old-World craft utilizes the expertise found in the hand and eye of the artisan, who is doing much more than simply following a detailed blueprint.

Instrument design is constantly evolving as refinements and new procedures are achieved and older procedures are perfected or set aside. By continually asking how processes may be improved, Scanlan International has always been an active participant in this evolution. This commitment to excellence means much more to us than making the finest instruments in the world. We are also committed to what these instruments are meant to do -- save lives.

Our Scanlan family name, proudly placed on each instrument, guarantees not only the highest quality surgical instruments, but also represents a tradition of excellence.

ONE SCANLAN PLAZA • SAINT PAUL, MINNESOTA 55107 • USA
800-328-9458 • 651-298-0997 • FAX 651-298-0018 • www.scanlaninternational.com

Your Quality Instrumentation Investment

Begin By Purchasing the Best

High quality surgical instrumentation is an investment that can lead to better surgical outcomes, shorter surgery time and happier surgeons. With appropriate care and handling, purchasing high quality instruments will also lead to long term savings through less frequent replacement and less down time for repair and sharpening.

Since 1921, Scanlan International has designed and manufactured the highest quality surgical instrumentation by paying strict attention to minute details. As each instrument passes through its manufacturing process, experienced master artisans scrutinize it at every step. Continual monitoring of metallurgical, biotechnical, and surgical advances allows Scanlan International to meet the ever-changing needs of the surgeon and, ultimately, the patient. Innovation is not a luxury at Scanlan International – it is a necessity.

Be Sure to Utilize Your Investment Appropriately

Most surgical instruments are designed and manufactured to accomplish a specific task. Use of an instrument for a purpose other than its intended use could compromise the integrity of the instrument, affecting its performance and longevity.

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Design and Manufacture of Surgical Instrumentation

Better Understanding, Greater Success

Understanding how an instrument is designed and manufactured will complement your ability to meet the requirements of the surgeon, as well as affect the surgical outcome for the patient.

The Evolution of Instrument Design

As surgical knowledge and technology advances, surgical instrumentation must also be designed to meet these rapidly changing needs. At Scanlan International, we work with surgeons, nurses, surgical technologists, engineers, and other experts worldwide to develop new instrument designs as well as refine existing ones. Our design engineers translate these ideas to reality using state-of-the-art processes.

Care and Maintenance of Surgical Instrumentation

Caring For Your Long-Term Investments

SCANLAN® instruments are handcrafted from the highest quality materials available. The unique craftsmanship behind each SCANLAN® instrument will provide years of service, if properly cared for. To extend the service life of your SCANLAN® instrument, follow the Scanlan Cleaning and Sterilization Instructions, document #FRMRA007-EN. These instructions provide valuable pre, intra, and post-operative care information for your SCANLAN® instruments.

This reference guide provides general information to help you care for and maintain your investment in your SCANLAN® instruments.

Making Appropriate Use of Your Instruments

Use instruments only for their intended purpose. For example, a micro needle holder designed for use with a delicate 7-0 suture needle cannot withstand the stress of a heavier 3-0 suture needle. Similarly, a hemostat is not designed to withstand the stress of being clamped on surgical tubing. Inappropriate use of instrumentation may damage or impair its precision design.

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Pre-Operative Care

Hygiene and Maintenance Prior To Initial Use

- Reuseable instruments are delivered non-sterile.
- Packaging materials the instruments are shipped in are not sterilizable. Do not sterilize in the packaging materials.
- Clean, inspect, lubricate, and sterilize instruments as instructed in the Scanlan Cleaning and Sterilization Instructions, document #FRMRA007-EN.

Intra-Operative Care

Soiling (blood, medication, saline, etc.) encountered with the normal use of a surgical instrument can cause corrosion. Therefore, remove gross soiling as soon as possible after use. Do not allow soil to dry on the instrument.

Gross soiling can be removed by submerging the instrument in cold water as soon as possible after use. However, do not allow instruments to stand in water for a prolonged period. Air bubbles formed in standing water will cling to the instrument surface, which can stain. Keep a soiled instrument moist by placing it in a towel dampened with sterile water until it can be properly cleaned.

Do not use a fixating detergent or hot water as these can cause fixation of soiling and hinder the effectiveness of processing. If enzymatic or presoak solutions are used, the instrument can be rinsed or immersed for a short period before reaching the decontamination area.

Safe storage and transportation in a closed container to the reprocessing area is advised for safety, to avoid instrument damage, and to minimize contamination of the clinical environment.

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Post-Operative Care

Clean Thoroughly

Thoroughly clean instruments after each use cycle to ensure they remain safe and effective. Scanlan Cleaning and Sterilization Instructions are validated to international standards. Manually pre-clean instruments per the instructions prior to automated cleaning and thermal disinfection.

Note: Prepare detergent solution according to manufacturer recommendation

Certain instruments must be disassembled prior to cleaning (see the Scanlan Cleaning and Sterilization Instructions for a list of instruments that can be disassembled). Brushes or stylets must be used when cleaning the interior surfaces of suction instruments.

Rinse Properly

After washing, the instruments should be thoroughly rinsed. A good water filter at the rinse source can help diminish the effects of chemicals and minerals found in most tap water. Thorough rinsing removes detergent and residue, assuring a stain-free instrument. The use of a neutralizer may also be necessary per the washing detergent instructions for use. After Rinsing, always check to ensure all visible contamination is removed.

Dry Thoroughly

Instruments should not be allowed to drip dry, as this may cause spotting or a buildup of minerals on the surface of the instrument. A dry instrument will reduce spotting and allow lubrication to adhere.

Dry the instrument through the drying cycle of the automated washer-disinfector following parameters in the cleaning instructions.

If needed, manual drying can be performed with a non-linting cloth. Bores or lumens of instruments can be dried by using instrument air (reference ANSI /ISA–7.0.0–1996). Instrument air is preferable when drying delicately tipped microsurgical instruments, to prevent breakage should tips be caught in the cloth.

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Inspect Carefully

To ensure the performance and longevity of your SCANLAN® instrument perform the recommended inspection, maintenance, and testing after each use cycle per the Scanlan Cleaning and Sterilization Instructions.

Carefully inspect instruments for visible soil, flaws, damage, detergent residue, and contamination.

Functionally test instruments for smooth actuation, cutting, and gripping performance, etc., as intended. Inadequate function may be an indication of improper cleaning or wear.

Visually inspect accessory items such as identification or color coding systems for wear. Color coding systems wear out with use and may need to be removed and replaced.

If necessary, perform reprocessing procedures again until the instruments are clean. Look for residual soil, proper functioning, and damage. If an instrument does not function properly or is damaged, remove it from service and send it to the Scanlan-authorized facility for reconditioning.

Repair and Refurbishment

To ensure your SCANLAN® instrument continues to perform as intended, have it repaired and refurbished by a Scanlan authorized facility.

To send your SCANLAN® instrument in for repair and refurbishment, please ship your product to:

Scanlan International, Inc.
c/o Scanlan Group Logistics Center
285 Florida Street
St. Paul, MN 55107

Please make sure all items are DECONTAMINATED and affix a Certificate of Decontamination to the outside of the shipping package in a clear plastic packing list holder. SCANLAN® instrument that has been processed per the Scanlan Cleaning and Sterilization Instructions is considered decontaminated. The latest instructions may be obtained at: www.scanlaninternational.com.

If for whatever reason, the instrument cannot be fully decontaminated, it must be handled in a safe manner to prevent the spread of possible infection. Appropriate Personal Protective Equipment (PPE), (e.g. gloves, gown, and face shield), are to be worn. The instrument is to be placed in a leak and puncture proof container and labeled as biohazard. Items must be shipped in accordance with applicable local, national, and international regulations.

For additional help please contact the Scanlan Customer Service team for assistance at 1-651-298-0997 or email us at info@scanlangroup.com

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Lubricate

An instrument should be dipped or sprayed, never soaked, in an antimicrobial, water-soluble instrument lubricant per lubricant label directions. The lubricant forms a thin, protective film over the instrument. The film is both steam- and gas-permeable and does not interfere with sterilization. The lubricant can help prevent soil from bonding to the instrument. This protective lubricant will extend the life of the instrument.

Sterilize

Scanlan's cleaning and sterilization instructions are validated to international standards. Ensure instruments are clean, inspected, and functioning correctly before sterilizing. Be certain the sterilizer is in proper working order. Instruments should be gently and carefully placed into the sterilizer. Instruments should always be sterilized and stored in an "open" and unlocked position. This increases the life of the instruments, prevents possible breakage, and is recommended by established standards.

Marking Instruments for Identification and Storage

Marking instruments has become a standard system to aid in sorting instrument sets and to help identify instruments against possible loss.

Mechanical engravers are not recommended for stainless steel instruments, as they scratch the instrument surface, penetrating the rust-resistant chromium oxide surface and prompting corrosion in the area. In addition, if a mechanical engraver is used on the box lock (hinge) area of an instrument, it can cause small cracks in this crucial area. This can eventually cause a complete break in the box lock, rendering the instrument useless.

If you wish to permanently mark your instruments, using a laser marking system is recommended. This method is safe when accomplished by professional technicians, a service provided by Scanlan International.

Another efficient and completely safe way to mark your instruments is through color coding. The Surg-I-Band® color coding system is used throughout the world. This Scanlan product has been tested to international standards for safe use through normal reprocessing cycles. Inspect color coding for wear or coming loose after each use cycle. Replacing Surg-I-Band® is quick and easy with the use of the Surg-I-Band® Remover, Surg-I-Band® Dispenser, and the Surg-I-Band® Carousel. Refer to the Surg-I-Band® IFU.

Proper Protection of Instruments

Protect sharp or delicate instruments during sterilization and storage by covering the tips with Tip-Guard™ instrument protectors and by utilizing SCANLAN® sterilization trays. These lightweight containers are designed to hold and protect delicate and "special" instruments during sterilization and storage. When using a sterilization tray, arrange instruments neatly. Larger instruments must never be stacked on smaller, more delicate ones. Never toss instruments into pans or containers.

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Note: Scanlan Sterilization Trays are intended to be used with appropriate packaging for sterilization according to one or more of the following applicable standards: ISO 17665-1, ISO 11607-1, and EN 868.

Proper Care for Your Cleaning and Sterilization Equipment

Dirty or improperly functioning equipment may not effectively clean or sterilize your instrumentation. Follow the equipment manufacturers instructions for periodic preventative maintenance and cleaning.

Write and Follow Procedures

The Scanlan Cleaning and Sterilization Instructions have been validated to international standards as being capable of processing reusable Scanlan surgical products. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials, and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the processes.

Make sure your health care facility has written policies and guidelines for the care of your surgical instrumentation. Providing proper training for all staff handling surgical instruments will make them experts in instrument care and maintenance, and thereby extend the life and quality of your surgical instrument investment.

For Further Information

Following Scanlan's Cleaning and Sterilization Instructions will help maintain your instruments in excellent working order and provide years of trouble-free service.

SCANLAN INTERNATIONAL, Inc.
U.S. & Canada: 800-328-9458
International: 651-298-0997
FAX: 651-298-0018
email: info@scanlaninternational.com

Troubleshooting Guide for Surgical Instrumentation

Corrosion and Pitting

Corrosion is a gradual wearing away of a surface, generally by chemical reaction. Corrosion on surgical instrumentation is caused by a chemical reaction between the stainless steel and the chemicals, minerals and soiling that the instrument comes into contact with on a daily basis (i.e., detergents, blood and other body fluids, medications, saline, water, etc.). High concentrations of chlorides cause significant corrosion, which can lead to pitting and possible stress fractures. Damage caused by these substances accelerates when combined with the heat, humidity, and pressure of sterilization.

When corrosion breaks through the passive layer of stainless steel, a pit will appear. Pitting (depressions, scars, or cavities) occurs when corrosion is allowed to progress unchecked. An extreme chemical reaction can also cause pitting. Chemicals on sterilization or biological indicators are extremely corrosive to stainless steel and can even cause pitting on an instrument in a single sterilization cycle.

Pitting disrupts the integrity of the instrument, changing the way it functions and leading to eventual breakage. When pitting is noted on an instrument, it should be immediately returned to a Scanlan-authorized facility to prevent further damage.

Corrosion commonly first appears on non-smooth surfaces of instruments, such as box locks, fulcrums, serrations, or knurling, and indicates improper cleaning and care procedures. Early forms of corrosion can be scrubbed away (using only a soft bristle brush). If the corrosion cannot be easily removed, the instrument should be returned to Scanlan for repair or restoration to original specifications whenever possible.

Magnetized Surgical Instruments

Stainless steel instruments are made of martensitic steel, a type of steel that can be heat hardened, but which can also become magnetized. Magnetization is especially troublesome for needle holders and tissue forceps, as small needles can cling to instrument tips, creating frustration and hampering the surgical procedure.

General processing, handling, and ultrasonic cleaning of instruments can create a magnetic charge. Instruments commonly become magnetic by touching them to another magnet, such as magnetized needle boards and instrument mats used during surgical procedures to keep instruments from falling to the floor.

Note: Because titanium instruments are produced from a non-ferrous alloy, they cannot become magnetized. Due to this fact, the Scanlan line of titanium surgical instrumentation has gained much popularity over the years.

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Instrument Discoloration and Staining

Staining and discoloration of surgical instruments generally suggests problems with their cleaning and care. Extensive or abnormal deposits on the surface of the instrument may impair function or sterilization and could lead to instrument failure. Understanding how staining and discoloration occur will allow identification and correction of the underlying problem.

Stainless Steel Instrumentation

Some surface discoloration of stainless steel surgical instruments may be caused by day-to-day usage and processing, and can even be beneficial to the instrument. Below are some of the most common stains found on stainless steel instrumentation.

Light Brown Veneer:

An even, light brown tint on the instrument (more evident on instruments with a satin finish) indicates the formation of a protective chromium oxide layer. This thin, hard layer forms naturally with normal processing, and results in a smooth, protective surface for the instrument, performing much like the original passivation layer found on brand new instruments.

Brown/Orange Stains:

This color suggests a chemical stain, generally from phosphates, or may actually be rust. If the stain is found to be rust, pitting will often be found when it is rubbed away.

Possible causes of these types of stains include:

- Water source or steam supply containing minerals and/or metals;
- Instrument cleaning detergents with high alkalinity and/or containing phosphates;
- Surgical wrapping washed in a phosphate detergent and not rinsed properly;
- Cold sterilant solutions (which have a high pH) were not rinsed thoroughly away;
- Inadequate cleaning, rinsing and/or drying.

Black Stains:

This color suggests an acid reaction with another stainless steel instrument.

Possible causes of these types of stains include:

- Detergents with low pH (less than 6);
- Water Contact with a sterilization indicator.

Bluish-Gray Stains:

Result from plating, which occurs when dissimilar metals (for example, chrome-plated instruments and those made of aluminum) are mixed in either an ultrasonic cleaner or autoclave. Surgical titanium and stainless steel instrumentation can be processed with no threat of staining or damage. If used improperly, chemical sterilizing or disinfecting solutions can also cause this type of stain.

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Multi-Color Stains:

Excessive heat will cause an instrument to display rainbow colors, set on an overall background of blue or brown.

Water Spot Discolorations:

Light and dark spots suggest water spotting. This may be caused by a faulty drying cycle in an autoclave, which may be the result of a defective valve or gasket. Another possibility is that water drops with a high mineral content (such as tap water) may have slowly dried by air drying on the instrument and left a mineral “stain.”

Purplish-Black Stains:

These colors are usually caused by detergents or solutions that contain ammonia or amines. To help avoid this type of staining, all detergent (especially those with a high alkaline content) used to clean autoclaves and steam lines must be completely flushed from the system before autoclaving instruments.

Titanium Instrumentation

SCANLAN® titanium instruments are made from an alloy containing three major ingredients: titanium, aluminum, and vanadium. This makes our titanium instrumentation strong, lightweight, flexible, nonmagnetic and, because these are non-ferrous metals, extremely corrosion resistant.

These inherent characteristics make the SCANLAN® line of titanium instruments of special value to surgeons. The light weight of titanium produces less fatigue for surgical teams during long procedures, as well as providing better control of pressure and weight applied to vessels and tissue. As titanium is nonmagnetic, small needles will not stick to tips of needle holders and thumb forceps. Titanium instrumentation is being used increasingly often in surgical procedures utilizing Magnetic Resonance Imaging (MRI).

Color Variations:

Slightly different shades of the blue oxide layer may be noticed on our anodized titanium instrumentation. This is not a defect, but is a phenomenon caused by slight variations in the manufacturing technique or alloy composition. This is a cosmetic characteristic only and does not compromise the high quality of your SCANLAN® instrumentation.

Staining Or Discoloration:

The oxide layer (blue finish) of titanium instrumentation is extremely stable and unaffected by temperature and normal environmental factors. The color of your titanium instrumentation can be affected in three ways. Abrasion may wear away the thickness of the oxide, which would change the color. Contact with chlorides, fluorides, halocarbons, and other chemicals may reduce the oxide thickness and change the color. Coatings of other chemicals and oils may build up on the surface, distorting the light and changing the apparent color. This condition is cosmetic only and does not compromise the high quality of your SCANLAN® instrumentation. If requested, the titanium instrument may be re-anodized to restore its original surface appearance.

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SCANLAN® titanium instrumentation should be cleaned and maintained with the same procedures used for stainless steel instruments. Refer to Scanlan Cleaning and Sterilization Instructions, FRMRA007-EN.

When you see a problem with:

- Staining
- Pitting
- Corroding
- Instrument malfunctions

Ask Yourself

1. Were the instruments sterilized in a steam sterilizer? Were they “flash” or “immediate use” sterilized (which often has no drying cycle)?
2. What type of water was used to clean and sterilize the instruments (i.e., city water supply, or softened water)?
3. If city water was used, was the sterilizer equipped with an appropriate filter? When was the filter last replaced?
4. Was the health care facility following recommended care and maintenance of the surgical instruments? Were instruments washed properly and rinsed thoroughly? Lubricated? Dried quickly? Protected during sterilization and storage?
5. What was the pH of the detergent used to wash the instruments? Was it too acidic? Too alkaline?
6. How was the instrument used? Was it for something other than the purpose for which it was designed?
7. What detergent was used for cloth surgical wrappers? Was it thoroughly rinsed away?
8. Were the instruments soaked in water or enzyme prerinse? For how long?
9. Does the health care facility have a written policy and guidelines for the care of surgical instruments? Does each staff member follow the same procedures when caring for surgical instruments?

When in doubt as to the cause of the staining, send the instrument to a Scanlan-authorized facility for analysis of the problem and reconditioning.

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Sterilization of Surgical Instrumentation

Sterilization Defined

Sterility is achieved when a substance or object is completely free of all living microorganisms and is incapable of producing any form of life. Aseptic conditions are defined as the absence of any infectious agents (pathogens). To achieve asepsis, an environment or object must be cleaned and disinfected. Terminal disinfection renders all articles, materials, and their immediate physical surroundings incapable of conveying infectious agents.

Sterilization Techniques

In hospitals, sterility can generally be achieved through several methods, such as steam sterilization, liquid chemical sterilization, or gaseous chemical sterilization. Inappropriate use of any of these sterilization methods can cause serious damage to surgical instruments. Guidelines for correct sterilization methods can be obtained through the Association of periOperative Registered Nurses (AORN) and/or the Association for Advancement of Medical Instrumentation (AAMI). Strict adherence to manufacturer instructions, periodic preventative maintenance, and monitoring the quality of water and steam supply will help to ensure the proper functioning of your sterilizer.

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SCANLAN®

CARE AND MAINTENANCE

SCANLAN® Scanturian® MIS Instruments

Scanlan International, Inc. takes pride in providing the finest surgical instruments made from the highest quality materials available. With proper care and maintenance, these instruments will provide years of excellent performance.

Please see the Scanturian® MIS Instruments addendum to SCANLAN® Cleaning and Sterilization Instructions (FRMRA007-EN) for complete details. Information contained in this guide is presented here for convenience only.

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Intra-Operative Instrument Care

Proper care during an operation must be taken to prevent debris from drying on Scanturian® MIS Instruments, which may result in improper functioning during procedure and long-term damage to instruments.

Wipe

• Wipe instruments with sterile gauze after each use in a procedure.

Soak

• After wiping, store instruments in sterile water during operation.

Flush

• Periodically flush instruments with sterile water using luer connection on handle.

Post-Operative Instrument Care

Proper inspection, lubrication, and testing during reprocessing are critical to proper functioning and longevity of Scanturian® MIS Instruments. Examination for excessive wear is necessary on all instruments during reprocessing to ensure proper performance. Scissors will require periodic sharpening and DIAMOND DUST™ may require periodic reapplication. Both should be performed by a Scanlan® authorized repair facility. *Refer to Scanturian® MIS Instruments addendum to SCANLAN® Cleaning and Sterilization Instructions FRMRA007-EN, available from Scanlan International, Inc. for details specific to each topic below..*

Cleaning

Refer to Scanturian® MIS Instruments addendum to SCANLAN® Cleaning and Sterilization Instructions FRMRA007-EN, available from Scanlan International, Inc.

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Maintenance

Inspection and Lubrication

- Inspect instruments for cleanliness. Repeat cleaning if necessary.
- Inspect each device for excessive wear and damage. If damage or excessive wear is observed, sterilize instruments, and return to a Scanlan authorized repair facility for assessment, refurbishment, or replacement.
- Use an antimicrobial water-soluble lubricant on hinged/moving components at both ends of instruments where indicated below. Actuate instruments repeatedly to allow lubricant to flow into hinge mechanisms.

Testing

Verify that instruments actuate smoothly. Rough actuation may indicate damage, excessive wear, insufficient lubrication, or incomplete cleaning.

Sterilization

Refer to Scanturian® MIS Instruments addendum to SCANLAN® Cleaning and Sterilization Instructions FRMRA007-EN, available from Scanlan International, Inc.

Storage

- Store instruments in an open/unlocked position inside sterile packaging.
- Storage area should be protected from dust, moisture, pests, and temperature/humidity extremes.

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