Incus
SURGICAL LTD

A Guide to Instrument Care and Maintenance

Functionality and Visual Inspection Guide
for Reprocessed Surgical Instruments

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Introduction

Surgical Instruments represent a significant material asset within the overall investment of a hospital. The care and maintenance that these instruments receive is critical to their performance during surgery and to the cost containment efforts of each hospital authority.

Having made the investment in a quality product, the authority can expect several years of trouble-free use if the operator utilises proper techniques during use, care, and handling of its surgical instruments.

This guide has been produced based on the requirements of '**EN ISO 17664** – Sterilisation of Medical Devices – Information to be provided by the manufacturer for the processing of re-sterilisable medical devices', and is designed to help prolong the functional capability and value of these instruments and should be used in conjunction with the individual hospital policy for cleaning and sterilising.

The following instructions are to provide general guidance for the visual inspection and manual testing following reprocessing of reusable Class 1r, non-measurable, non-sterile surgical instruments manufactured by **Incus Surgical Limited** and is intended for use by persons with the required ***specialist knowledge and training.***

It is the responsibility of the re-processor to ensure that the reprocessing is performed using the equipment, materials and personnel in the reprocessing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the re-processor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

To help reduce the cost and expenses associated with surgical instruments, many hospitals are finding that prevention is better than cure. As a result, more and more healthcare institutions are developing specific standards and programs for proper instrument maintenance and care.

One such programme is **'Planned, Preventative Maintenance'** – a bespoke repair, refurbish or replace service that **Incus Surgical Limited** can tailor to meet your surgical instrument care needs.

For more information email: info@incus-surgical.com or call **01376 347300.**

An understanding of the materials used to manufacture instruments, and its characteristics, coupled together with a sound knowledge regarding correct reprocessing procedures will result in a trouble free, long lasting life for your Surgical instruments.

The myth about stainless steel:

Around 75% of all surgical instruments used today are made of stainless steel. It resists rust, can be honed to a fine point and retains sharp edges. Unfortunately, the term "stainless" steel is frequently taken too literally.

It does have its weaknesses, water spotting and staining to name but two. There is really no "stainless" type of steel. During the manufacturing process a step known as passivation provides the instrument with its corrosion resistance properties. Passivation, which follows the final polishing steps, is a chemical bath that creates an oxidised layer on the surface of the instrument.

Through routine hospital use and exposure to the air this oxidation process continues, effectively maintaining and even building up a barrier to most stains and corrosive elements. Therefore, we sometimes hear the remark "They don't make instruments like they used to; my old instruments don't seem to stain or mark like these new ones do!"

The fact is that the older instruments are extremely well protected by a very effective layer of chromium oxides which have been strengthened by the repeated exposure to oxidising conditions that exist during reprocessing.

Materials:

Stainless Steel:

The steel used in most surgical instruments is a 400 series alloy that has several useful properties. It can be brought to a very sharp cutting edge and will hold this edge through continuous use. It has a high tensile strength enabling it to maintain precisely set jaw approximations. The metal is often referred to as stainless because of its corrosion resistance qualities.

It usually has a Chromium content of 11.5% - 18% which gives the steel some of its stainless characteristics and the percentage of carbon gives the various hardness required for maintaining sharp edges on instruments.

The stainless steels used in the manufacture of surgical instruments can be divided into two main classes:

1: Austenitic (Non-magnetic)
2: Martensitic (Magnetic)

Non-magnetic stainless steel is used in the manufacture of instrument such as tongue depressors, Sims Speculum etc where hardness is not important. It contains less carbon steel and so is less susceptible to corrosion and staining. Grade 304 S12 sheet metal and grade 303 S21 rod are used in the manufacture of all instruments in this category.

Magnetic stainless is used for most of all other instrument manufacture. i.e. scissors, forceps, retractor blades etc.

Grade 420 S29 is used for forceps, dissectors, retractor blades etc.
Grade 420 S37 is used for screwdriver shafts, bone punches etc.
Grade 420 S45 is used for instruments with cutting edges, scissors, chisels, osteotomes etc.

Other Materials Used in Surgical Instrument Manufacture are:

Brass Grade CZ121, used for instruments such as uterine sounds and suction tubes.
Sterling Silver 95% Hallmark quality , used for items such as tracheostomy tubes and catheters etc.

A blackening process known by the term Ebanol Process is used to obtain a non-reflective finish of aural forceps and micro instrument and instruments used in laser surgery.

Quality Control

The stainless used in the manufacture of Incus instruments meet the specifications set out previously in British Standards and now in and **BS EN ISO 7153-1:2016 Part One – Surgical Instruments – Materials.** The carbon level also complies with these standards.

Throughout the manufacturing process the instruments undergo many rigorous quality assurance tests.

All forgings are inspected to ensure dimensional accuracy and that correct annealing has been achieved. Annealing is a process that brings the raw forging to the correct hardness for machinability and to minimise the grain size which enables better surface finishing of the instrument. This process is achieved by heat treatment bringing the forging to a correct temperature for a specific time usually within a vacuum furnace.

All instruments made from Martensitic stainless are heat treated and hardened by the vacuum process. Once hardened each batch is random tested for correct harness requirements according to the Rockwell scale.

Once the instruments have passed the final inspection stage, they are then etched with our company name, ultrasonically cleaned to remove all final traces of manufacturing and polishing debris and finally lubricated as necessary.

All our workshops adhere to the current criteria required by **BS EN 13485:2016** and additionally we have met the additional criteria set by the **MDR745:2017** for CE Marking our Class 1R Non-sterile, Non-measurable Surgical Instruments.

Incus Surgical Limited instruments are manufactured by highly skilled craftsmen who strive to produce reliable, durable instruments that surpass all expectations. We believe our adherence to stringent manufacturing and Quality Assurance procedures coupled with the use of high-grade conforming materials ensure that any instrument bearing the **Incus Surgical Ltd** name will meet the demand of even the most discerning operator.

Developing a Comprehensive Instrument Care Programme

The simple four step solution to instrument care:

1. Cleaning and Disinfecting
2. Lubrication
3. Inspection
4. Sterilisation

1. Cleaning and Disinfecting

Figure 1: Pitting and Corrosion

Disinfection of soiled instruments not only helps to preserve the instruments themselves but also serves to protect the persons responsible for their transportation and cleaning. Wherever possible, instruments should be disinfected and cleaned immediately after use. Any soiling left to dry will make eventual cleaning far more difficult and could result in damage to the instrument.

Caustic agents and medicines e.g. iodine preparations, silver nitrate, mercury and solutions high in chlorides can be used in operating rooms and other medical procedures. These agents are highly corrosive and should be removed as soon as possible from the surface of the instrument. Under no circumstances should instruments be over exposed or stored in any physiological saline solution as prolonged contact causes pitting rust. See figure 1.

If manual handling of instruments to be cleaned and disinfected has to be carried out then the instructions of the chemical manufacturer must be strictly adhered to regarding concentration, temperature and exposure time.

Special attention should be paid to the manufacturers instructions regarding compatibility of materials such as anodised aluminium otherwise corrosion of surfaces of the anodised item would occur. See Figure 2.

Figure 2: Corrosion of Anodised Aluminium

Cleaning and Disinfecting continued...

Always use fresh disinfecting and cleaning solutions as directed. Prolonged use of the same solution may cause:

- corrosion due to soiling
- corrosion due to increasing concentration of chemical caused by evaporation
- decrease in the effectiveness of disinfection agent due to excessive level of soiling

Powdered disinfecting products must be completely dissolved prior to immersing any instruments since undissolved particles may lead to clogging of narrow lumens and box locks and to discolouration of the instrument surface.

Following manual chemical disinfection, instruments must be thoroughly rinsed in fresh running water to remove all residues. No metal brushes or scouring products should be used. The final rinse should be in distilled or demineralised water to reduce the risk of water spots and finally, instruments should be thoroughly dried.

Machine cleaning and disinfection is usually carried out by the CSSD when the instruments are received for reprocessing in a dry state. If they need to be transported in a wet state then a low foaming chemical must be employed as high foam levels can influence the effectiveness of cleaning.

The temperature of the inflowing water must never exceed 45°C as higher temperatures lead to protein coagulation.

Again, the manufacturer's instructions as to the concentration, temperature and exposure time, of the cleaning or disinfection agent must be strictly adhered to. The popular belief of thinking that the more chemical is used then the more effective it must be should be immediately dispelled!

Using the correct dosage not only guarantees a proper disinfection and cleaning result but also protects the material of the instrument against excess alkaline or acidic pH levels. Corrosion and pitting can occur with imbalanced pH values.

When machine washing, special attention should be paid to the following:

Figure 3: Contact Corrosion

i) hinged instruments must always be open to allow thorough cleaning of the joints

ii) ensure that cleaning trays/baskets are not overloaded

iii) any instruments with lumens must be placed so as to allow through flow of cleaning agents and rinse water

iv) place large instruments in such a way as to avoid 'shadowing' of other instruments

v) ensure dissimilar metals are not in contact with each other which can cause contact corrosions.

See figure 3.

Cleaning and Disinfecting continued…

The rinse cycle phase is very important. Any debris washed off the instruments must be removed from the final rinse otherwise spotting and discolouration may occur.

Temperatures of between 70°C and 90°C has proved to give the best results but if bad water quality is suspected then the temperature should be limited to between70°C and 75°C.

The use of demineralised water in the final rinse stage will avoid water spots and discolouration and there would be no requirement to limit temperature of this stage. See Figure 4.

Immediate drying, whether by machine or other means, is essential to avoid further spotting and possible corrosion occurring due to evaporation of water on the surface of the instrument.

Figure 4: Discolouration

2. Lubrication

Even the most careful cleaning can sometimes still leave an instrument stiff or hard to work. Even if all blood and debris have been removed, mineral deposits and other impurities from the water system can collect on the instrument and may cause staining, rusting and corrosion.

To guard against the hazards endured during sterilization and storage a reputable instrument lubricant must be applied to all working surfaces and moving parts of all instruments.

Figure 5: Fretting Corrosion

Ultrasonic cleaners remove all traces of lubricants from an instrument and it is therefore particularly important to apply a lubricant during every recycling process.

The programme used for applying lubricant is up to the individual institution but it could be applied either manually or automatically during the final rinse stage of automated washers.

Lubrication helps prevent the friction of metal on metal which would lead to fretting corrosion.

See Figure 5.

3. Inspection

The importance of inspecting each instrument can not be overemphasised.

Each surgical instrument is designed for a specific purpose. Inspection has to be carried out to ensure that they still function as they should. If in any doubt, the manufacturer should be contacted to advise on suitable inspection methods.

Fine and delicate instruments should be inspected under an illuminated microscope. In order to avoid damage during handling at this stage place the instruments on specially designed racks and holders to prevent them knocking together, especially the tips of sharp instruments.

All hinged instruments such as clamps and forceps should be checked for stiffness and to ensure the joints work smoothly. The tips of instruments should be of equal length, jaws close evenly, approximate initially at the tips and be fully approximated when closed to the last ratchet.

There should be no excess play in any box joints and the ratchets should operate smoothly, hold firmly, even when knocked, and open easily.

The edges of sharp and semi sharp instruments such as scissors, ronguers, chisels, curettes etc should be inspected for sharpness.

Scissors should close smoothly with no 'grinding' around the pivot pin. There should also be no dull spots, chips or dents in the cutting edges.

Plated instruments must be checked for chips, as this would harbour debris, and also for sharp edges and worn spots. Sharp edges will damage tissue, surgeon's gloves and worn spots may be susceptible to rusting and corrosion during sterilization.

All instruments with pins and screws should be carefully checked to make sure they are completely intact and safely located.

A General Guide on How to Inspect Instruments

Forceps and Heamostats: A visual test would be to close the jaws lightly. If they overlap they are out of alignment and need re-aligning. If the forceps have serrated jaws they should be checked to see that they mesh fully.

There should be no play in the box joint of the instrument.

The ratchet should be closed and the instrument held by the box and tapped lightly on the other hand. If the ratchet springs open it is faulty and in need of repair. (this would not be ideal if the haemostat were on a vessel and sprung off when knocked by a hand or other instrument!)

Scissors: The standard test for all operating scissors should be applied. All Mayo and Metzenbaum type scissors should cut four layers of gauze at the tip of the blade.

Smaller scissors of less than 10cm in length should cut two layers in the same way.

Blades: These should be checked for burs and they should be in good approximation all the way down the length. There should not be excessive fretting around the pivot pin which would lead to possible corrosion and breakage.

Needle Holders: A needle should be clamped in the jaw and the instrument closed to the second ratchet. If the needle can be moved or turned easily then the instrument needs repairing.

4. Sterilization

Good cleaning and lubricating practises will help eliminate many of the problems that arise with surgical instruments but if metallic ions or alkaline residue collects on the instrument during sterilization then staining and corrosion will result.

An impure water source, improperly maintained sterilizer, or improperly processed surgical wrappers are all major sources of the impurities which can stain and corrode instruments. Most water sources are unsuitable for use in the generation of steam without some kind of pre-treatment.

In order to guarantee steam quality then the recommendations of pr EN285 regarding the quality of water in the tank, as well as the condensate, should be adhered to otherwise rust particle from the conducting system may cause corrosion or too high a level of silicic acid may lead to discolouration of the instruments.

Methods are usually employed to remove solids, alter hardness and control the presence of dissolved oxygen and carbon dioxide. The water is then further treated so that when it is turned into steam it can be used throughout the hospital for heating and returned to the boiler for reuse.

Unfortunately, unless these treatments are carried out very carefully the delivered steam may have unfavourable effect on both the instruments and the sterilizer itself.

Good quality steam at the correct pressure, as recommended by the manufacturer, is essential, not only for a long, trouble free life of the instrument but also that of the equipment.

Sometimes good quality steam is delivered to the sterilizer but staining and corrosion still develop. These problems may be caused by the linen wraps used in the preparation of trays for sterilization. The washing, rinsing and final treatment of linen used for this purpose must be understood and the best possible methods strictly adhered to.

Condensation is a necessary process for successful steam sterilization. If the instruments have not been completely rinsed so that no chemicals remain on their surfaces then staining and corrosion may occur as these residuals are altered in the presence of high temperature steam.

Proper drying cycles and strict adherence to the equipment manufacturers recommendations are essential to prevent the formation of excessive moisture and the resulting water spotting which will lead to staining and corrosion.

Trouble Shooting & Identifying Problems

A well written procedure will assure the correct care and handling process of surgical instruments. Procedures should be presented in as much detail as possible listing every step of the procedure and the equipment and supplies to be used.

Liaison with other departments is also essential, particularly the Maintenance Department – you should always know when there is any work being carried out on the water, or steam supply to your department as this could have impact on the cleaning and sterilizing process.

If a problem arises first check to see that all procedures have been adhered to.

Never use short cuts when caring for instruments, the result could be costly to put right when rusting, staining and corrosion happen as a result.

Be aware that rusting of one instrument doesn't necessarily identify your problem totally. There are many modern alloys and so called stainless steels in use today but even these can rust through the transfer of rust particles from non-stainless steel items.

Many instrument problems such as corrosion on blades, box joints and between two moving surfaces can usually be attributed to one or more of the following:

- inadequate cleaning and drying immediately after use
- corrosive sterilizing solutions or too long an exposure to sterilizing solutions
- ordinary tap water rather than demineralised or distilled water in the cleaning and sterilizing process
- incorrect detergents being used
- some fault within the autoclave

Surfaces which cannot be effectively polished are usually more prone to corrosion. Typically, knurled or grooved handled instruments may rust on the handle while the remainder of the instrument remains unaffected. Even the satin finish used to reduce operating light glare is more prone to discolouration than highly polished instruments.

This sort of discolouration and marking can be simply removed by scrubbing with a suitable instrument cleaning brush and appropriate detergent. If this is not effective the instrument can be re-polished and passivated by the manufacturer.

Some oxidation, i.e. rusting, may occur during autoclaving while the instrument is exposed to air, moisture and heat. Some of this rust can be attributed to water left in areas of an instrument that is difficult to dry. Always ensure thorough drying to alleviate this.

Be aware that instruments may corrode more in one hospital than they do in another indeed even in one department more than another. This can be traced to the mineral content of the water which varies from one area to another.

Recognising Spotting, Staining & Corrosion Problems

Light Coloured Spots:

Can be caused by water droplets condensing on the surface of the instrument and evaporating very slowly. Usually this can be traced to the mineral content of the water – particularly sodium, calcium and magnesium.

Can be rectified by following the autoclave manufacturers guide to the letter. The door should never be opened until all steam has been exhausted from the chamber. A leaky door gasket or valve may cause water droplets to condense as a result of an improper drying cycle.

Dark Coloured Spots:

Can be caused by – in most cases these are caused by the same situations as light coloured spots.

Can be rectified by ensuring all solutions for cleaning, disinfecting, rinsing and sterilizing are prepared with distilled or demineralised water, free of any chlorides and to a pH value near to 7.0.

Rust Coloured Film:

Can be caused by – some water softeners may cause rust coloured, dust like, film to occur under certain conditions. Also some areas have a high concentration of iron compounds in the water and this can be deposited on the surface of the instrument. In some new hospitals, foreign matters left inside steam pipes during installation can cause apparent rusting. Virtually nothing can be done about this but it is usually a temporary situation which should subside within two to three months.

Can be rectified by – consult with hospital engineering staff.

Bluish Grey Stains:

Can be caused by – in the main part—cold sterilizing solutions. rectified by – changing the solution as frequently as recommended by the manufacturer. Prolonged use will permit the solution to become corrosive.

Using distilled water and a rust inhibitor will minimise discolouration but the manufacturers directions must be strictly adhered to.

Brownish Stains:

Can be caused by a chromic oxide film forming on the stainless steel when it is heated giving the instrument a dull blue, but usually brownish, cast.

Frequently this discolouration can be traced to the instrument sterilizer. Many hospitals use dish washing compound compatible with their local water supply. However, many of these are polyphosphates which have a copper solubilizing action on parts of the sterilizer and this layer of copper is deposited on the surface of the instrument by electrolytic action.

Can be rectified by trying to use other suitable compounds and ensuring that quantities are accurately measured.

Corrosion (Rust):

Can be caused by – insufficient rinsing of operating room linens and wraps after the laundry has used caustic chemicals. Instruments wrapped in these linens may absorb these caustic residues during reprocessing.

Can be rectified by checking with the laundry service and ensuring adequate rinsing of operating room linens.

Recognising Spotting, Staining & Corrosion Problems continued...

Stiff Box Joints and/or Ratchets:

Can be caused by issues such as dried blood in box joints, serrations and ratchets that then appears like rust. It is usually baked on and, left untreated, will lead to cracking of the box joint.

Can be rectified by ensuring particular care is given to cleaning box joints and pivoting.

Instruments where blood and debris can be missed during cleaning.

Can be caused by excessive moisture left on the surface of the instrument, in box joints or crevices while wrapped in sterile packs. This can be due to a poor drying cycle or improper loading of the sterilizer.

Can be rectified by ensuring the sterilizer is preheated. Never compromise or shorten the drying stage of the cycle. Ensure the correct depth of vacuum is achieved and held for the correct period of time so that instruments are sensibly dry when they come to leave the sterilizer. Also have engineering check that there are no leaks from any part of the sterilizer.

Remember that rust cannot be rinsed off. It is impossible to completely restore instruments after rusting or pitting has eroded the hard surface. Once the surface has been compromised by pitting it is far more susceptible to further corrosion.

PREVENTION IS BETTER THAN CURE

Remember the four steps to Instrument Care & Maintenance

1. Clean and Disinfect

2. Lubricate

3. Inspect

4. Sterilise

If you would like to know more about **Incus Surgical Limited's** **'Planned, Preventative Maintenance'** – a bespoke repair, refurbish or replace service tailored to meet your surgical instrument care needs contact us today:

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T: **01376 347300.**

Illustrations of further examples of Corrosion, Spotting and Staining:

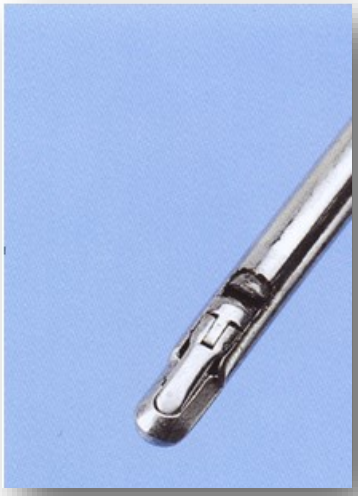

Figure 6: Chloride Induced Pitting

Figure 7: Chloride Induced Pitting

Figure 8: Staining due to a high Concentration of minerals.

Figure 9: Stress Corrosion Cracking

Figure 10: Stress Corrosion Cracking

Figure 11: Crevice Corrosion

Illustrations of further examples of Corrosion, Spotting and Staining—continued...

Figure 12: Crevice Corrosion

Figure 13: Silicate Coating

Figure 14: Black tints

Figure 15: Discolouration and Rusting due to poor cleaning

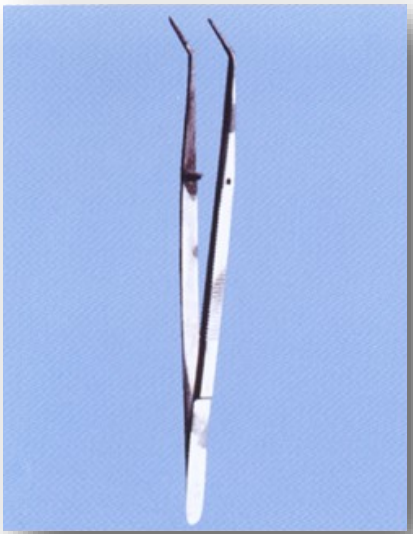

Figure 16: Pitting due to Caustic Solution

Figure 17: Pitting due to Caustic Solution—magnified

Illustrations of further examples of Corrosion, Spotting and Staining—continued...

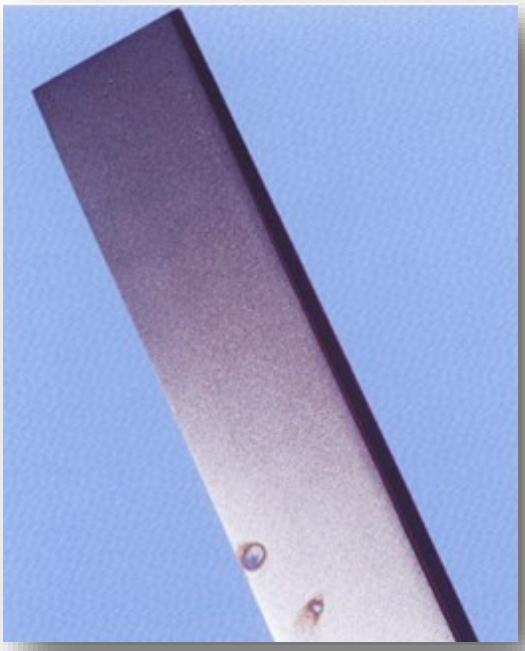

Figure 18: Pitting Corrosion

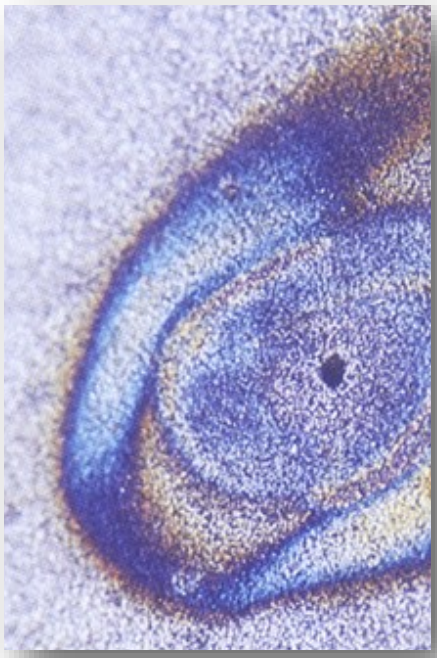

Figure 19: Pitting Corrosion—magnified

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