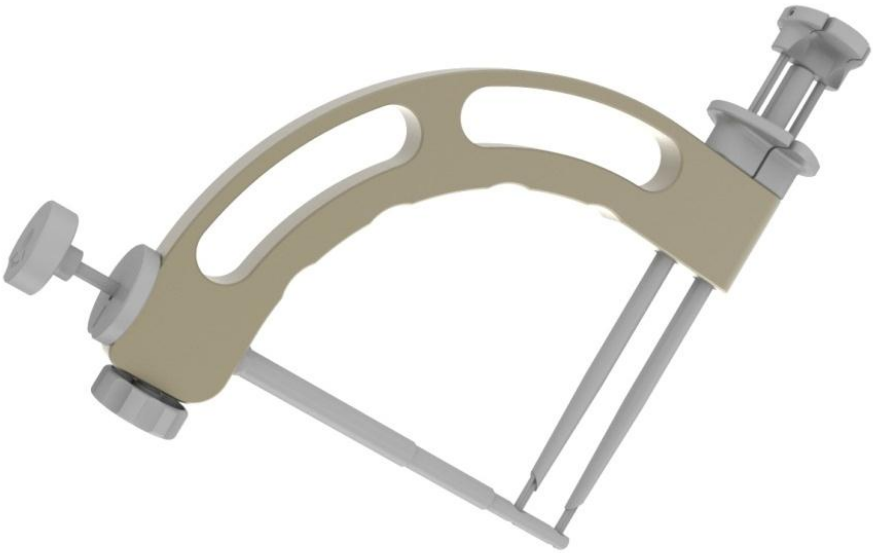
Adigo

Instrument Care and Maintenance

Introduction

Proper care and maintenance of any instrument is critical to its performance during surgery and also to cost containment efforts. An investment in a quality product can provide several years of satisfactory use but only if the operator utilises proper techniques during use, care, and handling. In an effort to reduce the cost and expenses associated with surgical instruments, many hospitals are experiencing that prevention is better than cure. Knowing and understanding basic facts about materials used to manufacture instruments, and their characteristics will result in a correct use - but most notably in a trouble free, long lasting life of your surgical instruments.

This manual is intended to facilitate such proper techniques and should be used in conjunction with the individual hospital policy for cleaning and sterilising.



Materials and Surface Quality

Modern surgical instruments may be made of several different materials. Some of the most important ones include:

- Martensitic Stainless Steel
- Austenitic Stainless Steel
- Titanium alloys
- Aluminium alloys

- Thermoplasts and Thermosetting plastics

- Ceramics

There are also lots of other materials used in surgical instrument manufacture, like Brass grade CZ121, Sterling Silver 95% Hallmark quality, superelastic nitinol wires etc.

About 75% of all surgical instruments are made of stainless steel. Actually, no steel is able to sustain each and every chemical, physical or other loads and no steel is absolutely »stainless«. During the manufacturing process a step known as passivation substantially improve corrosion resistance properties of the material. Passivation, which follows the final polishing steps, 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, also old instruments could be flawless protected by an effective layer of chromium oxides which have been strengthened by the repeated exposure to proper oxidising conditions achieved during reprocessing.

The steel used in most surgical instruments is a 400 series alloy that has several useful properties. It can be grinded to a sharp cutting edge and is able to hold sharp edge through continuous use. It has a high tensile strength. Chromium content of 12 - 18% gives the steel many of its stainless characteristics and the percentage of carbon gives the hardness required for maintaining sharp edges on instruments.

Austenitic stainless steels contain less carbon and higher level of chromium. Usually they are non-magnetic and are used in the manufacture of instruments where hardness is not so important. Lower level of carbon also means that this type is less susceptible to corrosion and staining. Grade 304 S12 sheet metal and grade 303 S21 rod are two most typical examples of material for the manufacture of instruments in this category.

Martensitic stainless steel contains a bit lower level of chromium and higher level of carbon. Usually it is magnetic and is used for the majority of hard instrument elements, like scissors, blades, forceps etc. This steel can be hardened by heat treatment to give strength and durability to the instrument. Some typical examples include:

- Grade 420 S29; used for dissectors, forceps, retractor blades etc.

- Grade 420 S37; screwdriver shafts, bone punches etc.

- Grade 420 S45; instruments with cutting edges, scissors, chisels, osteotomes etc.

Due to high carbon level martensitic steel type is more susceptible to corrosion and staining if careful adherence to percentage composition is not followed.

Quality Control and Standards

The stainless steel used in the manufacture of instrument meet the specifications set out in many standards, like EN ISO 5832-1, EN ISO9000:2000 and EN ISO13485. The microstructure, carbon content and impurity level must also comply with these standards.

During the manufacturing process the input material, individual elements and instruments undergo many rigorous measurements and quality assurance tests. All instruments made from Martensitic stainless steel are heat treated and hardened by the vacuum process. Once hardened each batch is tested for correct harness according to the Vickers and Rockwell scale.

Once the instruments have passed the final inspection stage they are ultrasonically cleaned to remove any final traces of manufacturing and polishing debris and finally lubricated as necessary.

Our production facilities adhere to the stringent criteria required by standards. Our instruments are manufactured by highly skilled craftsmen who strive to produce reliable instruments.

Instrument Care and Maintenance

Cleaning and Disinfection

Disinfection of soiled instruments preserves the instruments and also protects the persons responsible for their transportation and cleaning. Whenever possible, instruments should be disinfected and cleaned immediately after use. Any soiling left to dry will make eventual cleaning much more difficult.

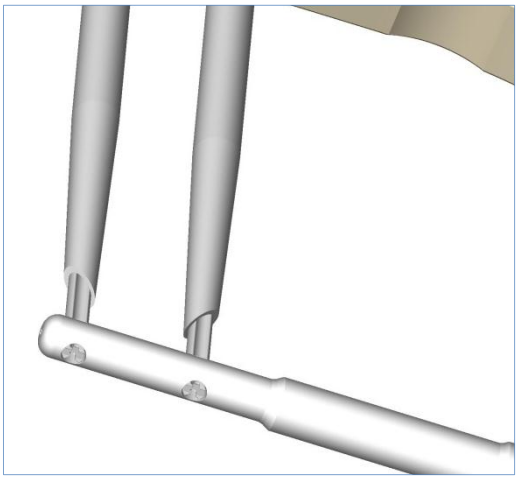


Figure: Detail of an Adigo pin and wire assembly for shoulder surgery. Cleaning of these elements is of utmost importance.

In operating rooms many caustic agents and medicines are used, e.g. iodine preparations, silver nitrate, mercury and chloride solutions. These agents are highly corrosive and should be removed from the instruments as soon as possible. Under no circumstances should

instruments be over exposed or stored in any physiological saline solution as prolonged contact causes pitting and rust.

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 manufacturer's instructions regarding compatibility of materials such as anodised aluminium otherwise corrosion of surfaces of the anodised item could occur.

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

- Corrosion due to soiling;

- Decrease in the effectiveness of disinfection agent due to excessive level of soiling;

- Corrosion due to increasing concentration of chemical caused by evaporation.

Powdered disinfecting products must be completely dissolved prior to immersing any instruments since undissolved particles may lead to clogging.

After chemical disinfection, instruments must be thoroughly rinsed in fresh running water to remove all residues. No metal brushes or scourers 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. The temperature of the inflowing water must never exceed 45°C as higher temperatures lead to protein coagulation.

Machine cleaning and disinfection is usually carried out with the instruments received for reprocessing in a dry state. If instruments are to be transported in a wet state then a low foaming chemical must be employed.

Again, the manufacturer’s instructions as to the concentration, temperature and exposure time, of the cleaning or disinfection agent must be strictly adhered to. 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:

- Ensure that cleaning trays/baskets are not overloaded;

-Hinged instruments must always be open to allow thorough cleaning of the joints;

- Any instruments with lumens must be placed so as to allow through flow of cleaning agents and rinse water;

- Ensure dissimilar metals are not in contact with each other which can cause contact corrosion;

- Place large instruments in such a way as to avoid ‘shadowing’ of other instruments.

The rinse phase is important. Any debris washed off the instruments must be removed during 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 low water quality is suspected then the temperature should be limited to between 70°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. Immediate drying, whether by machine or other means, is essential to avoid spotting and possible corrosion.

Lubrication

Even the most careful cleaning can 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 an instrument lubricant must be applied to all moving parts of instruments. Lubrication also prevents friction of metal on metal which would lead to fretting corrosion.

Ultrasonic cleaners remove 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 and it could be applied either manually or automatically during the final rinse stage of automated washers.

Inspection

Inspection has to be carried out in order to ensure that instruments still function as they should. If in any doubt, the manufacturer should be contacted to advise on suitable inspection methods.

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. Fine and delicate instruments should be inspected under an illuminated microscope.

Hinges should be checked for stiffness and to ensure the joints work smoothly. The tips of instruments should be of equal length, moving elements should close evenly. There should be no excess play in any joint and the ratchets – where applicable - should operate smoothly, hold firmly, even when knocked, and open easily. There should not be excessive fretting around the pivot pin which would lead to possible corrosion and breakage. There should also be no dull spots, chips or dents around or between the moving edges.

Sharp cutting edges should be inspected for sharpness and intact geometry on all the length. Blades should also be checked for burs.

Plated parts 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 pins and screws should be carefully checked and adjusted to make sure they are intact and safely located.

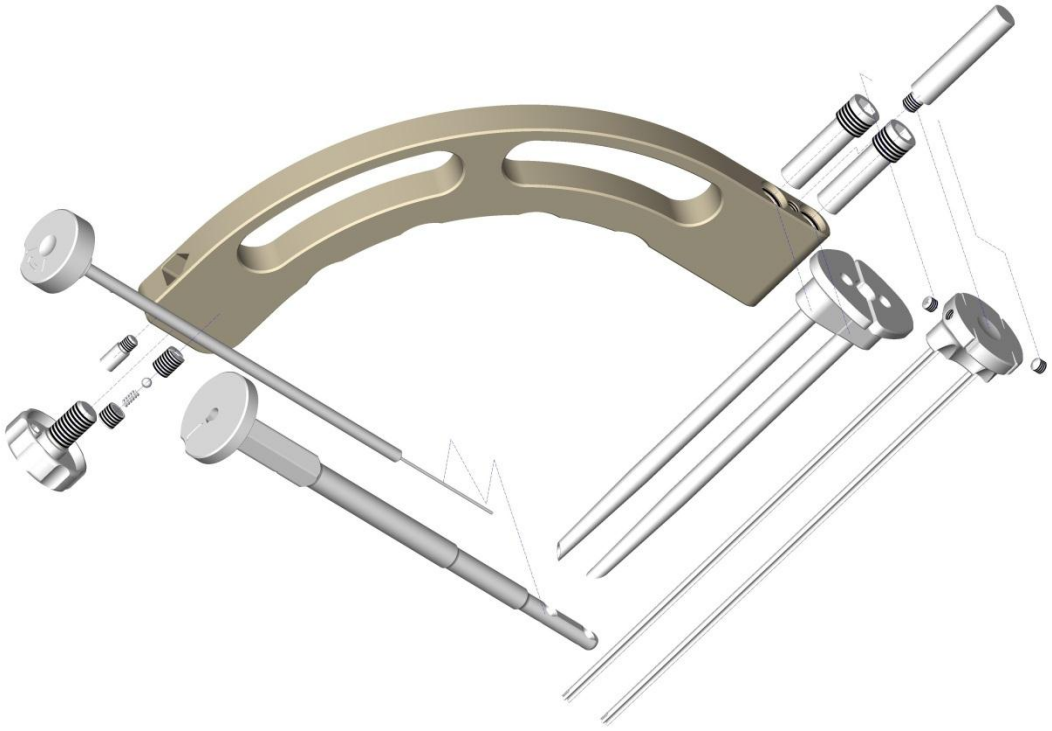


Figure: Instrument for fast surgical suturing is made of several pieces with different functions and made of different high-tech stainless materials.

Sterilization

There are many possible causes that can render an instrument non-sterile. Good cleaning and lubricating practises will help eliminate many of the problems.

There are however some critical points that need to be checked perpetually. If metallic ions or alkaline residues collect on the instrument during sterilization then staining and corrosion might result.

An impure water source, improperly maintained sterilizer or surgical wrappers are major sources of the impurities which can stain and corrode instruments. Most water sources are unsuitable for use in the generation of steam without pre-treatment. Rust particles from the conducting system may cause corrosion or too high a level of silicic acid may lead to discolouration of the instruments. In order to guarantee steam quality the recommendations of pr EN285 regarding the quality of water should be adhered to.

Different methods are usually employed to remove solids, lower hardness and control the presence of dissolved oxygen and carbon dioxide. The water is then further treated so that it can be used throughout the facility. 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 the instrument but also for the equipment.

Sometimes problems may be caused also 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 controlled and the best possible methods strictly applied.

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

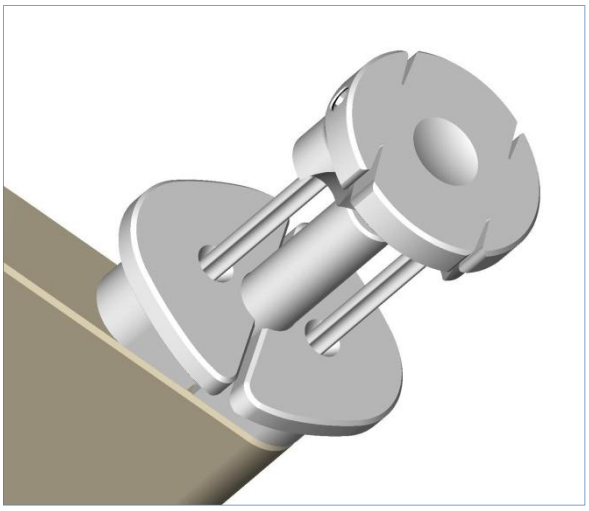


Figure: Detail of an Adigo instrument showing different pieces and materials in contact. Stain resistance is reached through the use of qualitative and certified materials, but may be maintained only by a proper use and handling techniques.

Trouble Shooting and Avoiding Problems

A written hospital procedure is the basis for the correct care and handling process of surgical instruments. Stated procedures should be clear but detailed for every step of the procedure including the equipment and supplies to be used.

Liaison between different departments is essential in preventing unnecessary troubles and mistakes. If a problem arises, first check to see that all procedures have been adhered to. These should include verification of quality and use of supplied water, steam, cleaning agents and other materials.

Never use short cuts when caring for instruments, the results could be costly and time-consuming.

Bear in mind that visible problem on one instrument could be a result of some other hidden problem elsewhere. 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, joints of different materials and between moving surfaces can be attributed to:

- Corrosive sterilizing solutions or too long an exposure to sterilizing solutions;

- Inadequate cleaning and drying immediately after use;

- Ordinary tap water rather than demineralised or distilled water in the cleaning and sterilizing process;

- Use of incorrect detergents;

- Hidden fault or rusty spot within the autoclave.

Some oxidation, i.e. rusting, may occur during autoclaving if 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 effect.

The mineral content of the water has important influence on the corrosion rate. In praxis this means that instruments may corrode more in one hospital than they do in another and sometimes even in one department more than another.

Surfaces which cannot be polished are usually more prone to corrosion. Typically, knurled or grooved handles may rust while the remainder of the instrument remains unaffected. Satin finish used to reduce light glare is more prone to discolouration than highly polished instruments. This kind of discolouration and marking may 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.

Possible Surface Defects like Spotting, Staining and Corrosion

Blue or Grey Stains

Source: Usually, cold or old sterilizing solutions.

Prevention: Changing the solution as frequently as recommended by the manufacturer. Prolonged use can make the solution to become corrosive. Use of distilled water and a rust inhibitor minimise this kind of discolouration but the manufacturer’s directions must be strictly adhered to.

Blue or Brownish Stains

Source: A chromic oxide film forming on the stainless steel when it is heated giving the instrument a dull blue cast. Brownish cast may 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.

Prevention: Try using other suitable compounds and ensure that quantities are accurately measured.

Light Coloured Spots

Source: Water droplets condensing on the surface of the instrument and evaporating slowly. Usually this can be traced to the mineral content of the water – particularly sodium, calcium and magnesium.

Prevention: Strictly follow the autoclave manufacturer's guide. The door should never be opened until all steam has been exhausted from the chamber. A leaky door or valve may cause water droplets to condense as a result of an improper drying cycle.

Dark Coloured Spots

Source: In most cases the source is the same as with light coloured spots.

Prevention: Ensure all solutions for cleaning, disinfecting, rinsing and sterilizing are prepared with distilled or demineralised water, free of any chlorides and with a pH value near 7.

Rust Coloured Film

Source: 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 piping systems or hospitals, foreign matters left inside steam pipes during installation can cause apparent rusting.

Prevention: Consult with hospital engineering staff.

Corrosion (Rust)

Once formed, rust cannot be just rinsed off. It is impossible to completely restore instruments after rusting or pitting has eroded the surface. Once the surface has been damaged by rust it becomes far more susceptible to further corrosion.

Source: 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.

Prevention: Check with the laundry service and ensure adequate rinsing of operating room linens.

Source: Dried blood in box joints, serrations and ratchets that appears like rust. It is usually baked on and if left untreated will lead to cracking of the box joint.

Prevention: Ensure adequate cleaning is made to box joints and pivoting instruments where blood and debris can be found.

Source: 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.

Prevention: Ensure 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.