ABHI

SURGICAL INSTRUMENT PURCHASE AND CARE GUIDE

Guidance for purchasing and caring for surgical instruments from ABHI's Surgical Instruments Group

THE PURPOSE OF THIS GUIDE

This booklet is designed to help healthcare providers achieve the best whole life value for money in their purchasing decisions.

Surgical instruments are a critical component of surgical procedures. It is important that purchasers are well informed, to ensure patient safety as well as best value. This Guide is an educational and training tool. It helps improve awareness and understanding of how surgical instruments are made, the standards which apply to them and the quality of the instruments.

By enabling effective procurement, we hope to help healthcare providers achieve the best return on their investment, while putting patients at the heart of decision-making. The Association of British HealthTech Industries (ABHI) is the UK's industry association for the HealthTech sector.

The companies we represent produce around 85% of the industry's total UK output. We promote the rapid adoption of HealthTech in the UK and key global markets to maximise patient outcomes, and support ethical procurement.

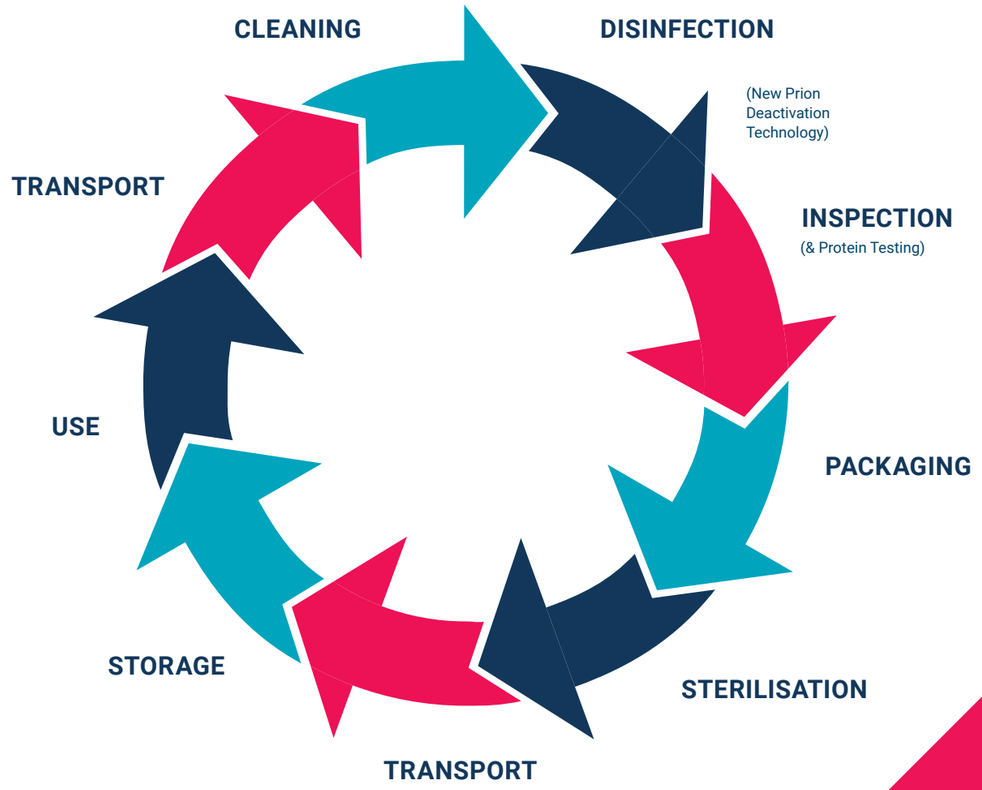
Contents

> **Quality is always top and non-negotiable**
> Lord Carter, Health and Care Show

UNDERSTANDING QUALITY

BUYING THE RIGHT INSTRUMENT IS A COLLECTIVE RESPONSIBILITY

Purchasing Surgical Instruments needs to be a co-ordinated process with input from the appropriate health professionals before and after purchase:



The surgeon, theatre staff, sterilisation and decontamination teams are all essential to surgical instrument purchasing decisions. Their feedback is critical in making the right decisions and ensuring continued patient safety.

Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care (or as appropriate)

UNDERSTANDING QUALITY

KNOW YOUR STANDARDS

Surgical instruments are governed by a number of standards including, but not limited to:

MDR - Medical Device Regulation, Regulation (EU) 2017/745

MDR – This regulation includes the general safety and performance requirements as affixing of CE Marks are necessary for European sales. manufacturers.

ISO 7153-1:2016; BS 5194-1:1991

The Standard for the composition of the different materials and steel grades used.

BS 5194-4:1985

For the specifications of scissors, shears, and other cutting instruments.

EN ISO 13485:2016

Requirements for a quality management system to be employed by manufacturers in the control of design, development, manufacturing, sales & maintenance of HealthTech.

BS 5194-2:1989

For the specifications of instruments with pivot points.

BS 5194-3:1986

For the specifications of dissecting forceps.

CE Marking

On every device, look for a CE mark, the name of the manufacturer and a traceability code. Be aware that a CE mark is a sign of compliance with MDR however and should not be taken as an automatic sign of quality.

UNDERSTANDING QUALITY

KNOW YOUR MATERIALS

Most surgical instruments start life as forgings or “blanks”. They are governed by two International Standards for material specification: DIN 17442 and DIN EN 10088-3 1995.

Surgical instruments are mainly made from two types of stainless steel: martensitic and austenitic. Some are made from titanium. The boxes on the right illustrate the types of instrument materials.

- **Martensitic is magnetic and contains up to 1% carbon which allows the instrument to be heat-treated**
- **Austenitic is the most common type of stainless steel and is highly versatile**

ISO 7153-1 has a full list of the suitable grades of stainless steel available.

Martensitic Grade B-420 S29

Used for non-cutting instruments, e.g. artery forceps

Hardness	40-48 HRC
Carbon content	0.16-0.25%
Chromium content	12-14%

Martensitic Grade C or D-420 S45

Used for cutting instruments, e.g. scissors & gouges

Hardness	50-58 HRC
Carbon content	0.35-0.45%
Chromium content	12-14%

Austenitic Grade 304 S15

Used for instruments which do not require hardening, e.g. dental tweezers and holloware

Hardness	40-48 HRC
Carbon content	0.07-0.15%
Chromium content	16-19%
Nickel content	8-11%

Titanium

Used for Ophthalmic & Microsurgery instruments

Ti-6Al-4V ELI or grade 23 titanium

MANUFACTURING PROCESSES

1. MACHINING

Metal cutters mill the forgings to create a box joint, serrations, teeth, or racks. This is a critical stage in ensuring the functionality of a deviceand making sure that it will perform as the surgeon expects.

2. FITTING AND ASSEMBLY

The various parts of an instrument are held with screws and rivets. Using a series of grindstones and lathes, the instrument is fashioned to the correct size, weight and dimensions of the intended pattern.

3. HARDENING

Before instruments are machined, they are annealed to soften them, prolonging the life of the cutters and helping form the instrument correctly. Then they are re-hardened, often using a vacuum hardening process.

4. FINISHING AND POLISHING

The hardening process creates a black oxide layer which must be removed. This is done by either rumbling the instruments or polishing and glazing them to a fine finish.

5. INSPECTION, MARKING AND TRACEABILITY

Before being placed on the market, instruments should be inspected for their functional and cosmetic qualities. A CE mark, the manufacturer's name, and a traceability code on every device.

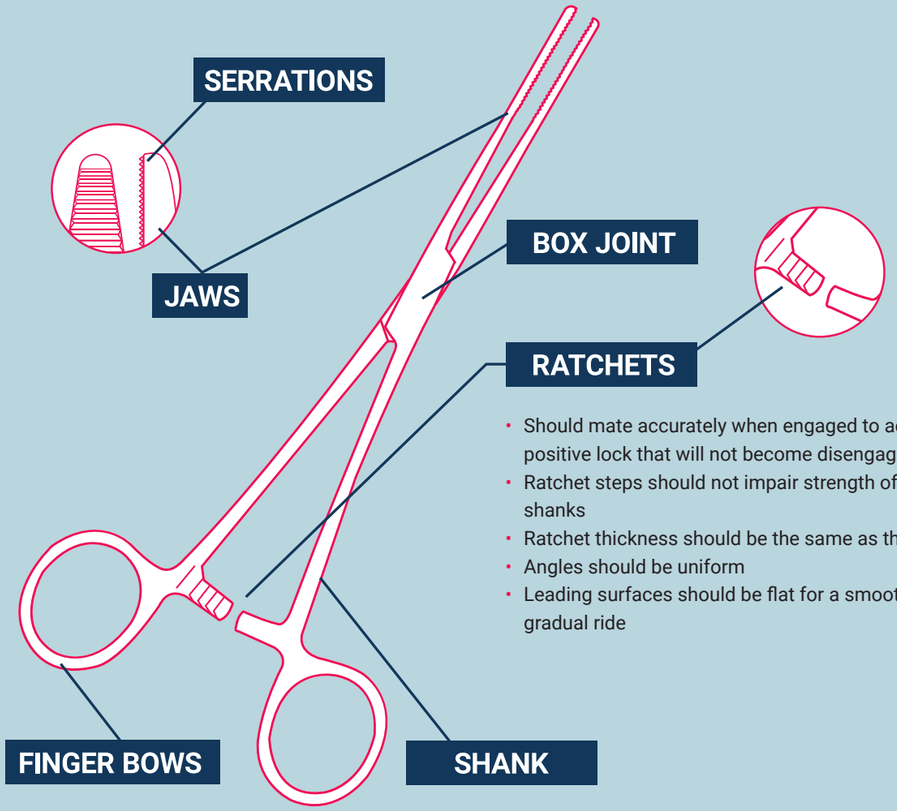
Although the manufacturer's name (etched) marked on a device is not a requirement of the MDR, we feel that this is the best way to ensure that the product guarantee can be maintained and enforced.

QUALITY INSTRUMENTS

COMMON FEATURES AND TERMINOLOGY

There are a huge variety of features which appear on reusable surgical instruments. Here are a few common features and what to look for in a quality item:

- Teeth and prongs should be sharp and mesh exactly when jaws close
- Serrations on both jaws should be identically shaped and mesh exactly
- When pressure is released, the teeth, prongs, and serrations should part freely without catching
- No slippage in Needleholder jaws
- Should be symmetrical
- Rectangular section should give maximum strength to the joint
- Should avoid unnecessary gaps
- Use of countersink prevents rivet from moving
- Joint should move smoothly, not too tight, not too loose
- It should be possible to open and close the joint easily with 2 fingers



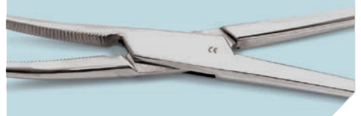
- Should mate accurately when engaged to achieve a positive lock that will not become disengaged in use
- Ratchet steps should not impair strength of the shanks
- Ratchet thickness should be the same as the shank
- Angles should be uniform
- Leading surfaces should be flat for a smooth and gradual ride

IDENTIFYING COMMON INSTRUMENT FEATURES

& WHERE THEY MAY BE SEEN

Box Joint

Found on:
- Spencer Wells artery forceps
- Halstead mosquisto artery forceps
- Crile artery forceps



Screw Joint

Found on:
- Mayo scissors
- Metzenbaum scissors
- McIndoe scissors
- Stevens scissors

Ratchet

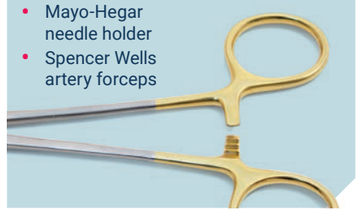
Found on:
- Norfolk and Norwich retractors
- Travers retractors
- West and Weitlander retractors

Teeth

Found on:
- Littlewoods tissue forceps
- Allis tissue tissue forceps
- Lanes tissue forceps

Rack

Found on:
- Mayo-Hegar needle holder
- Spencer Wells artery forceps



Scissor Blades

Found on:
- Mayo scissors
- Metzenbaum scissors
- Dressing scissors

Lumen

Found on:
- American, Adson, Magill & Zoellner suction tubes

Finish

- Bright polished or satin finished steel

Tungsten Carbide Tips

Found on:
- Needle holders for durability

Serrations

Found on:
- Artery forceps

Atraumatic Teeth

Found on:
- Debakey clamps and forceps
- Derra & Cooley vascular clamps

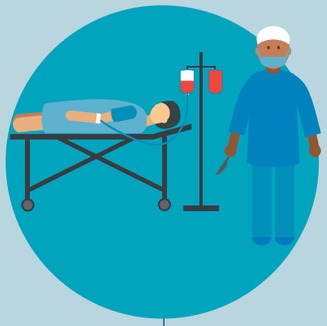
Bows

Found on:
- Scissors, needle holders & artery forceps

MAINTAINING HIGH QUALITY

A GUIDE TO REPROCESSING RE-USABLE SURGICAL INSTRUMENTS

IMPORTANT NOTE: This is not comprehensive. For a full, validated reprocessing guide, speak to your instrument supplier and follow current MHRA guidelines for reprocessing instruments.

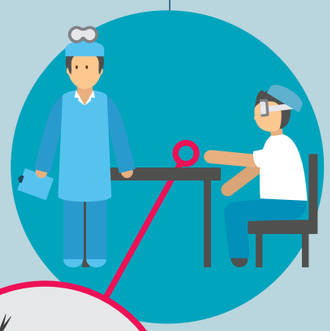


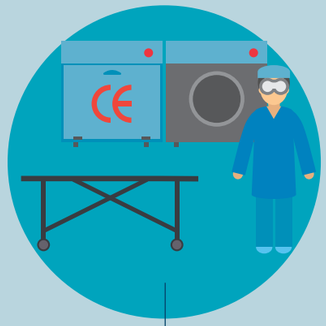
FROM POINT OF USE

Wherever possible, do not allow blood, debris or bodily fluids to dry on instruments. To prolong their life, reprocess immediately after use. If that's not possible, use an enzymatic foam spray to help prevent soil from drying

To prepare for decontamination, reprocess all instruments as soon as practicable following use. Disassemble only where intended, without the use of tools, unless specifically made available with the instrument and provided by the manufacturer.

PREPARATION





CLEANING

Automated Cleaning
Use CE marked or washer-disinfector machines and low-foaming, non-ionising cleaning agents and detergents. Follow the manufacturers' instructions for use, warnings, concentrations, and recommended cycles.

- Load instruments carefully, with box joints and hinges open, and so that any fenestrations can drain.
- Place heavy instruments with care in the bottom of containers. Do not overload wash baskets.
- Place instruments with concave surfaces facing down to prevent pooling of water.
- Use appropriate attachments to flush in side reamers, and devices with lumens or cannula.
- Ensure that soft, high purity water which is controlled for bacterial endotoxins is used in the final rinse stage.

Note Automated Cleaning may not be suitable for all lumens and cannula, in which case clean manually with a water jet gun, if available, and an appropriate brush and/or stilette that reaches the depth of the feature.

After manually cleaning, pass all devices through an automatic cleaning cycle to achieve disinfection.

INSPECTION

After cleaning, visually inspect all

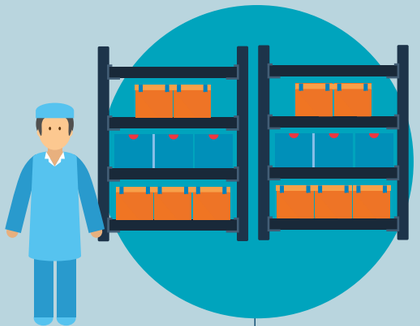
- Surfaces
- Cannulations
- Joints
- Ratchets
- Holes

Lumens for complete removal of soil and fluids. If any soil or fluid is still visible, return the instrument for repeat decontamination.

Ensure that instruments are dry before sterilisation. Always follow the instructions of the machine manufacturer. Use a CE marked or validated vacuum autoclave operating at 134-137oc 2.25 bar for 3 minutes minimum holding time.

When sterilising multiple instruments in one cycle, always make sure that the stated maximum load is not exceeded.

PACKAGING & STERILISATION



STORAGE

All instruments to be packed following local protocol in accordance with recognised standards.

MAINTAINING HIGH QUALITY

CARE & MAINTENANCE TIPS

For full guidance see www.a-k-i.org 'Red Brochure'

BROKEN/CRACKED BOX JOINTS

Tension stress

Cause
Heating and cooling in sterilisation process

Solution
Close instrument to first notch only during sterilisation

Forced stress

Cause
Overloading instruments

Solution
Ensure correct device and attachment is being used

NB: Also sutures and needle holders

General stress

Cause
Build up of blood and debris in box joint

Solution
Ensure instruments are cleaned in open position during washing and disinfection

DISCOLOURATION

Water spots

Light coloured, often with sharply defined edges

Cause
Final rinse or sterilisation water supply contains high concentration of minerals

Solution
Use demineralised water in final rinse, and pure steam in sterilisation

Yellow brown to dark brown spots

Cause
Debris has dried on the device before cleaning or hasn't been removed due to poorly performing detergents

Solution
Remove by thoroughly scrubbing with a good detergent, otherwise corrosive pitting will occur

Oxidisation spots

Light coloured, without sharply defined edges

Cause
Final rinse or sterilisation water supply contains high concentration of heavy metal ions and/or silicates

Solution
Use demineralised water in final rinse, and pure steam in sterilisation

Other causes of discolouration

- **Insufficient rinsing off detergents and disinfectants**
- **Chlorides**
- **Water droplets slowly condensing on instruments during sterilisation**
- **Inferior detergent**

CORROSION

Pitting corrosion

Cause 1
Excessive chloride concentrations

Solution
Use demineralised water

Cause 2
Prolonged exposure to saline solutions (blood, debris or contaminated disinfectant or detergent) where bacterial activity creates acidic residue

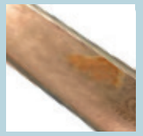
Solution
Clean instruments as soon as possible after use

Abrasion corrosion

Cause
Build up of debris stops devices from opening and operating smoothly, causing destruction of passivation layer at joints and crevices

Solution
Ensure instruments are cleaned in open position & lubricate regularly

Contaminated steam corrosion



Cause
Rusty steam in sterilisation process

Solution
Regular validation and maintenance of decontamination equipment

Surface corrosion

Cause
Damage to passivation layer

Solution
Avoid use of strong acid, alkaline or caustic solutions

NB: Aluminium is particularly susceptible

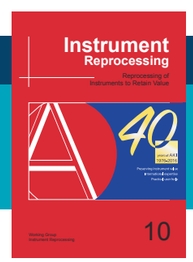
Spreading corrosion

Cause
Instruments sterilised with already rusty devices - rust is transferred through the detergent solutions

Solution
Separate rusty devices from "healthy" ones

The Red Brochure

The Instrument Reprocessing Working Group was set up in 1976. They have produced a Surgical Instrument guidance document for the past 40 years. This provides exhaustive guidance on all aspects of surgical instrument care and best practice. www.a-k-i.org



ETHICAL SUPPLY

Ethical Manufacturing & the NHS Supply Chain's Labour Standards Assurance System (LSAS)

ABHI has its own code of business practice and we support the ethical sourcing of products. The Surgical Instruments Group worked with NHS Supply Chain as part of the 2012 (and pending 2017) Surgical Instruments Framework Agreement to launch its Labour Standards Assurance System.

LSAS is a matrix of ethical requirements designed by NHS Supply Chain and the Department of Health, through which suppliers are audited and assessed by a third party notified body. The responsibility is with the supplier to ensure there is continual progress and regular risk assessment and review, to mitigate potential ethical and labour risks in the supply chain.

This has been embedded since 2012 and many of our members have improved to obtain level 2 and 3 on the framework.

ABHI is commited to promoting good ethical practice amongst members, we see this as integral and essential for improving labour standards in both single use and reusable surgery instrument manufacturing.

ABHI Code of Business Practice
At ABHI, we place ethical compliance at the heart of the HealthTech industry. Healthcare professionals and patients must feel they can be confident in our ethical standards at all times, so they can work with us to improve the innovations we develop.

We have been working hard for several years to help member and other companies reach the highest standards – both as organisations and as individuals at all levels.

It is a condition of ABHI membership that a company adheres to the ethical standards in the ABHI Code of Business Practice. The Code stipulates minimum standards for members' business practices in the UK, Europe and elsewhere.

More information can be found at **www.abhicodeofpractice.org.uk**

SUSTAINABILITY

The ABHI Surgical Instruments Group is committed to supporting the NHS on its net zero journey. The Group is dedicated to working collaboratively across stakeholders to support the best surgical solutions that will benefit patient, population and planet.

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