CE ONLINE

Premier OR Grade Surgical Instruments:

The Manufacturing Process

An Online Continuing Education Activity
Sponsored By

Pfiedler ENTERPRISES

Funds Provided By

AESCULAP ACADEMY

AESCULAP®

Welcome to

Premier OR Grade Surgical Instruments: The Manufacturing Process

(An Online Continuing Education Activity)

CONTINUING EDUCATION INSTRUCTIONS

This educational activity is being offered online and may be completed at any time.

Steps for Successful Course Completion

To earn continuing education credit, the participant must complete the following steps:

1. Read the overview and objectives to ensure consistency with your own learning needs and objectives. At the end of the activity, you will be assessed on the attainment of each objective.
2. Review the content of the activity, paying particular attention to those areas that reflect the objectives.
3. Complete the Test Questions. Missed questions will offer the opportunity to re-read the question and answer choices. You may also revisit relevant content.
4. For additional information on an issue or topic, consult the references.
5. To receive credit for this activity complete the evaluation and registration form.
6. A certificate of completion will be available for you to print at the conclusion.

   Pfiedler Enterprises will maintain a record of your continuing education credits and provide verification, if necessary, for 7 years. Requests for certificates must be submitted in writing by the learner.

If you have any questions, please call: 720-748-6144.

CONTACT INFORMATION:

Pfiedler ENTERPRISES

Pfiedler Enterprises, 2101 S. Blackhawk Street, Suite 220, Aurora, Colorado 80014
www.pfiedlerenterprises.com Phone: 720-748-6144 Fax: 720-748-6196

OVERVIEW

The selection and use of quality surgical instruments are key components in providing safe, efficient and cost effective patient care in the operating room (OR). Quality instrument manufacturing involves standards for various aspects of the manufacturing process, including the basic requirements for the quality of stainless steel used, as well as quality control inspections used at every step in the process. Despite the existence of these standards, perioperative professionals are still confronted with surgical instruments of varying quality levels, depending on the individual quality standards of the instrument manufacturer. Therefore, it is important that members of the Sterile Processing and perioperative teams involved in the selection and use of surgical instrumentation understand the variations in instrument manufacturing processes, in order to provide the best possible instruments for patient care. This continuing education activity will provide a review of the key considerations in the quality manufacturing process for premier OR grade surgical instruments. A brief overview of the historical evolution of surgical instruments will be presented. The key components of premier quality stainless steel used in the manufacture of surgical instruments will be discussed. The United States requirements for stainless steel surgical instrument package labeling will be outlined, including the definition of country of origin. The steps in the manufacturing process of high quality surgical instruments will be described in detail. The clinical considerations related to the selection and use of quality premier OR grade instruments, and the importance of the facility's water quality in maintaining quality surgical instruments, will be presented.

LEARNER OBJECTIVES

After completing this continuing education activity, the participant should be able to:

1. Identify key components of premier quality stainless steel used for manufacturing surgical instruments.
2. Define the stainless steel surgical instrument package labeling requirements in the United States.
3. Name five steps in the surgical instrument manufacturing process.
4. Outline the importance of your facility's water quality in maintaining quality surgical instruments.

INTENDED AUDIENCE

This continuing education activity is intended for perioperative nurses, sterile processing personnel, and other health care professionals who are interested in learning more about the manufacturing of premier OR grade surgical instruments.

CREDIT/CREDIT INFORMATION

State Board Approval for Nurses

Pfiedler Enterprises is a provider approved by the California Board of Registered Nursing, Provider Number CEP14944, for **2.0 contact hours.**

Obtaining full credit for this offering depends upon attendance, regardless of circumstances, from beginning to end. Licensees must provide their license numbers for record keeping purposes.

The certificate of course completion issued at the conclusion of this course must be retained in the participant's records for at least four (4) years as proof of attendance.

IAHCSMM

The International Association of Healthcare Central Service Materiel Management has approved this educational offering for **2.0 contact hours** to participants who successfully complete this program.

CBSPD

The Certification Board for Sterile Processing and Distribution (CBSPD) has approved this program for **2.0 contact hours**.

RELEASE AND EXPIRATION DATE

This continuing education activity was planned and provided in accordance with accreditation criteria. This material was originally produced in December 2015 and can no longer be used after December 2017 without being updated; therefore, this continuing education activity expires December 2017.

DISCLAIMER

Pfiedler Enterprises does not endorse or promote any commercial product that may be discussed in this activity

SUPPORT

Funds to support this activity have been provided by **Aesculap, Inc**

AUTHORS/PLANNING COMMITTEE/REVIEWER

Julia A. Kneedler, RN, MS, EdD **Aurora, CO**
Program Manager/Reviewer
Pfiedler Enterprises

Rose Moss, MN, RN, CNOR **Westcliffe, CO**
Nurse Consultant/Author
Moss Enterprises, LLC

Judith I. Pfister, RN, BSN, MBA **Aurora, CO**
Program Manager/Planning Committee
Pfiedler Enterprises

Joan M. Spear, RN, MBA, CNOR, CRCST, CSPDT **Center Valley, PA**
Clinical Consultant Marketing/Planning Committee
Aesculap, Inc.

DISCLOSURE OF RELATIONSHIPS WITH COMMERCIAL ENTITIES FOR THOSE IN A POSITION TO CONTROL CONTENT FOR THIS ACTIVITY

Pfiedler Enterprises has a policy in place for identifying and resolving conflicts of interest for individuals who control content for an educational activity. Information below is provided to the learner, so that a determination can be made if identified external interests or influences pose potential bias in content, recommendations or conclusions. The intent is full disclosure of those in a position to control content, with a goal of objectivity, balance and scientific rigor in the activity. For additional information regarding Pfiedler Enterprises' disclosure process, visit our website at: http://www.pfiedlerenterprises.com/disclosure

Disclosure includes relevant financial relationships with commercial interests related to the subject matter that may be presented in this continuing education activity. **"Relevant financial relationships"** are those in any amount, occurring within the past 12 months that create a conflict of interest. A **commercial interest** is any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients.

Activity Planning Committee/Authors/Reviewer

Julia A. Kneedler, RN, MS, EdD
No conflict of interest.

Rose Moss, RN, MSN, CNOR
No conflict of interest.

Judith I. Pfister, RN, BSN, MBA
No conflict of interest.

Joan M. Spear, RN, MBA, CNOR, CRCST, CSPDT
Employed by Aesculap who provides funds for this activity.

PRIVACY AND CONFIDENTIALITY POLICY

Pfiedler Enterprises is committed to protecting your privacy and following industry best practices and regulations regarding continuing education. The information we collect is never shared for commercial purposes with any other organization. Our privacy and confidentiality policy is covered at our website, www.pfiedlerenterprises.com, and is effective on March 27, 2008.

To directly access more information on our Privacy and Confidentiality Policy, type the following URL address into your browser: http://www.pfiedlerenterprises.com/privacy-policy

In addition to this privacy statement, this Website is compliant with the guidelines for internet-based continuing education programs.

The privacy policy of this website is strictly enforced.

CONTACT INFORMATION

If site users have any questions or suggestions regarding our privacy policy, please contact us at:

Phone:	720-748-6144
Email:	registrar@pfiedlerenterprises.com
Postal Address:	2101 S. Blackhawk Street, Suite 220 Aurora, Colorado 80014
Website URL:	http://www.pfiedlerenterprises.com

INTRODUCTION

The focus on providing safe, cost-effective care takes on even greater significance in the face of today's economic challenges. In the OR, the use of quality surgical instruments is a key factor in not only providing safe patient care, but also in protecting the facility's investment. Surgical instruments must be able to perform accurately and safely throughout a surgical procedure and also be able to withstand repeated processing and sterilization procedures. Two critical considerations in selecting premier OR grade surgical instruments are the quality of the stainless steel used in manufacturing, as well as the manufacturing process itself. As will be discussed, quality premier OR grade instruments are required for all surgical procedures because they are designed and manufactured to strict specifications from high-quality stainless steel; further, they are subjected to quality control inspections at every step during the manufacturing process. There is no agency that establishes standards for instrument quality in the United States; this is left to the manufacturer. Therefore, it is imperative that Sterile Processing and perioperative personnel understand the key quality aspects of the instrument manufacturing process in order to select premier grade OR surgical instruments from a quality manufacturer to provide safe and effective patient care.

HISTORICAL EVOLUTION OF SURGICAL INSTRUMENTS[1,2]

As far back as 10,000 BC, prehistoric man devised tools to cut human flesh either for inflicting wounds or repairing them. Early writings describe the use of various cutting tools, such as razor sharp flint, sharpened animal teeth, as well as blades made of reed or bronze. During the pre-Christian era, grasping tools designed for extracting items such as arrowheads were created; many of these tools were in the form of animal or bird heads. In the first century AD, the use of scalpel handles with blunt dissecting ends, knives, saws, forceps, and hooks for retraction was reported. These crude and heavy instruments were the armamentarium of medicine through the Dark and Middle Ages. Ambrose Paré was the first person to grasp blood vessels with a pinching instrument, which was the predecessor of the modern hemostat used today.

In the late 1700s, surgeons employed various skilled artisans, such as steelworkers, coppersmiths, and needle grinders, in order to equip themselves for their practice of surgery. At this time, the surgeon had to explain the mechanisms of the various instruments and also supervise the manufacturing process. Some of the instruments created during this time had exquisitely hand-carved handles, made of ivory, bone, or wood. Each artisan used hand labor exclusively and dedicated his time to make only one type of instrument; as a result, the instruments produced were crude, expensive, and time-consuming to make. This concept remains today in the production of specialty instruments by instrument craftsmen who specialize in one particular line of instruments.

In the mid-1800s, amputations were the trademark of the United States Civil War. Amputations were the result of as many as three or four operations and often took place on kitchen tables, performed with heavy, crude knives and instruments, and even table forks used for retraction. After the Civil War, the use of ether and chloroform initiated a demand for new ideas in regards to the practice of surgery, as well as the instrumentation

needed to support these new ideas. When sterilization became an accepted practice around the turn of the twentieth century, instruments composed of entirely metals, eg, carbon, steel, silver, and brass replaced those with handles composed of wood, ivory, and bone so that they could withstand repeated sterilization. The development of stainless steel in the 1900s further enhanced the art and craft of manufacturing quality surgical instruments.

ALL STAINLESS STEEL – AND INSTRUMENT MANUFACTURERS – ARE NOT CREATED EQUAL!

Overview of Stainless Steel[3,4]

Today, approximately 85% of all surgical instruments are made from stainless steel. Stainless steel is a compound of varying amounts of iron; carbon, which is added to give steel its hardness; and chromium, which makes steel resistant to corrosion, by combining with oxygen in the air to form a very adherent surface film that resists further oxidation. However, the term "stainless" is actually a misnomer; the degree to which the steel is "stainless" is also determined by the chemical composition of the metal, the heat treatment, and the final rinsing process.

Stainless steel may also contain other alloying elements such as nickel, magnesium, silicon, molybdenum, sulfur, and other elements to prevent corrosion or add to its tensile strength; because of this, stainless steel can be of varying quality in regards to its physical properties, ie, flexibility, temper, malleability, as well as corrosion resistance. Thus, there are over 80 different types of stainless steel; therefore, the American Iron and Steel Institute grades steel based on its various mechanical properties and composition using three-digit numbers, as described below. The mechanical properties of the various grades of stainless steel are outlined in Table 1; the benefits of stainless steel are listed in Table 2.

- **Stainless Steel Type 304.** The most popular grade of stainless steel is 304; it is sometimes referred to as 18-8. The 300 series designation tells one that the grade is composed basically of 18% chromium and 8% nickel. It cannot be hardened by heat treatment.
- **Stainless Steel Type 316.** The next most popular stainless for general corrosion resistance is type 316. It also consists of chromium (16%) and nickel (10%), but also contains 2% molybdenum. The additional alloying increases the resistance to salt corrosion.
- **Stainless Steel Type 430.** This is a straight chromium type stainless (no nickel) with 16% chromium. It has less corrosion resistance than the 300 series. As with the 300 series, 430 type steel cannot be hardened by heat treatment.
- **Stainless Steel Type 410.** 410 is a straight chromium grade with less chromium than 430 (about 11.5%). Because it has less chromium, it has somewhat less corrosion resistance than 430, but this grade can be hardened by heat treatment.
- **Stainless Steel Type 409.** This grade contains the lowest level of chromium at 10.5%.

Table 1 – Mechanical Properties of Various Grades of Stainless Steel[5]

Stainless Steel Grade	Hardness (Rb)	Tensile Strength (1000 Psi)	Yield Strength (0.2% 1000 Psi)	Elongation (% in 2 inches)
304/316	78-83	80-85	30-42	50-60
430	80-85	70-75	40-50	30-35
410	80-82	70-75	34-45	25-35
409	75	65	35	25

Table 2 – Benefits of Stainless Steel[6]

Property	Benefit/Description
Corrosion Resistance	Lower alloyed grades resist corrosion in atmospheric and pure water environments, whereas high-alloyed grades can resist corrosion in most acids, alkaline solutions, and chlorine.
Fire and Heat Resistance	Special high chromium and nickel-alloyed grades resist scaling and retain their strength, even at high temperatures.
Hygiene	The easy cleaning ability of stainless steel makes it the first choice for strict hygiene conditions, such as hospitals and kitchens.
Ease of Fabrication	Modern steel-making techniques results in stainless steel that can be cut, welded, formed, machined and fabricated as readily as traditional steels.
Impact Resistance	The microstructure of the 300 series provides a higher degree of toughness, from elevated temperatures to far below freezing.
Long Term Value	When the total life cycle costs are considered, stainless steel is often the most cost effective material option, because stainless steel products complete their service life. In addition, there is less concern about disposal since this material is 100% recyclable.

Stainless Steel Surgical Instruments: Making the Grade[7,8,9]

Both 300 and 400 series grade stainless steel are used in the manufacture of reusable, heat-stable surgical instruments, with 400 being the most common. Both 300 and 400 series stainless steel resist rust and corrosion, as noted above, have good tensile strength, and will provide a sharp edge with repeated use. The 300 series grade steel is typically used for non-cutting surgical instruments that require high strength; the 400 series grade steel is used in the manufacture of both cutting and non-cutting instruments.

While all stainless steel instruments may appear to be of equivalent quality when they are new, there are differences in grade quality of the metals used in their manufacture; therefore, surgical instruments are available in three grades: premier OR grade, intermediate OR grade and floor grade instruments. Both premier OR grade and intermediate OR grade instruments can be used in all surgical sets because they are

designed and manufactured to specifications from quality stainless steel. Premier OR grade instruments are made to strict specifications from high-quality stainless steel; furthermore, they are subjected to strict quality control inspections at several points throughout the steps of the manufacturing process. Instruments in this classification are less likely to fail after repeated uses; in addition, they should cause no tissue damage related to their construction and finishing. With proper care, handling, cleaning, and sterilization, premier OR grade instruments will provide years of useful life. In contrast, lower quality instruments may be of similar design, but their specifications for steel quality and manufacture are less stringent. Floor grade instruments are made from forgings of lower grade metals, have wide pattern variation, and are usually plated. As a result, the precision of the instruments' key features is less exact than those of the higher quality O.R. grade instruments. An inspection of these instruments when they are new may reveal nicks, burrs, and instrument tips and jaws that often do not meet perfectly. In addition, these instruments typically bend or break easily; because they are plated, they can scratch, chip, and rust relatively easier than the higher quality instruments; thus, they are considered disposable and cannot be reprocessed with OR grade instruments. Using floor grade instruments in a delicate surgical procedure can result in unintended tissue damage that, along with the need for tissue repair, increases the potential for impaired healing, infection, and increased costs of care associated with prolonged recovery. Moreover most of these instruments which may appear to be stainless steel can be of such poor quality that they are sold as "single use".

As noted, premier O.R. grade surgical instruments are made from 300-400 grade stainless surgical steel and are more resistant to corrosion and wear. It is important for perioperative personnel involved in instrument processing to remember that, if the facility uses lower, floor grade instruments, they should not be placed in an ultrasonic cleaner or included with OR grade instruments during processing or in instrument sets; doing so can cause changes in the metal, due to ion transfer. These changes, in turn, alter the reaction between the metal and chemicals used for instrument cleaning, disinfection, and sterilization; as a result, resistance to staining, pitting and rusting may also be compromised. Once these problems occur, even premier OR grade instruments can be compromised, and they will no longer be appropriate for use in surgical instrument sets.

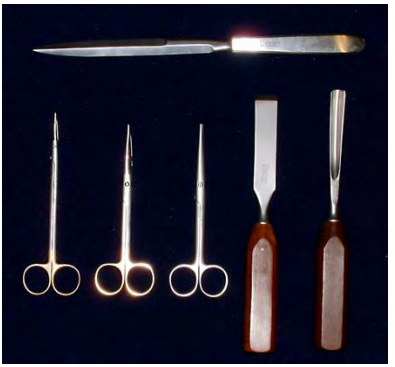
It is also important to note that, in the United States, there is no agency that sets standards for instrument quality; quality is determined by the manufacturer. For this reason, perioperative personnel should be aware of the differences in the manufacturing processes between various instrument manufacturers, how they define "quality", and what steps they take throughout the manufacturing process to ensure the quality of the end product.

HOW ARE QUALITY PREMIER OR GRADE SURGICAL INSTRUMENTS DEFINED AND MANUFACTURED?

Today, modern surgical instrumentation is critical to every surgical procedure performed in the OR. The general requirements for cutting and non-cutting surgical instruments are:

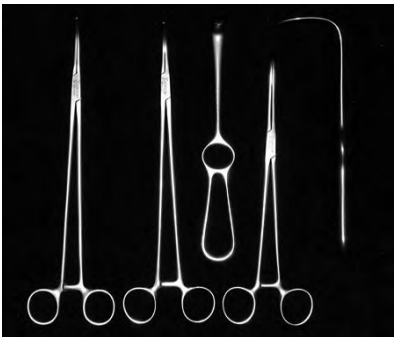
- Cutting instruments, eg, scissors, scalpels, chisels (see Figure 1):
    - o Corrosion resistant;
    - o Precise cutting;
    - o High hardness; and
    - o Highly resistant to wear; ie, the cutting surfaces stay sharp longer.

Figure 1 – Cutting Instruments



- Non-cutting instruments, eg, clamps, forceps, hooks (see Figure 2):
    - o Corrosion resistant;
    - o High elasticity;
    - o High stability; and
    - o Constant spring hardness.

Figure 2 – Non-Cutting Instruments



The performance of surgical instruments, which impacts patient care and optimal outcomes, is directly correlated to the quality of their manufacturing process. There are three principal prerequisites for manufacturing a quality instruments:

- High quality material for surgical instruments, defined in the DIN standards for surgical instruments;
- Reliable, well defined and documented production process; and
- Strategic quality testing to assure craftsmanship and minimal pattern variation.

Other aspects of the instrument manufacturing process that influence the quality of the end product are outlined below.

- The instrument's country of origin. Country of origin is defined by United States customs law as:
    - The country of manufacture, production, or growth of any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the "country of origin".[10] Unless excepted by law, every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit, in such manner as to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article, at the time of importation into the Customs territory of the United States.
    - Based on this definition, for surgical instruments, the country of origin is where forging takes place. For example, an instrument can be stamped "Made in Germany" if the forging is done in Germany; even if the remaining production steps, ie, 90% of the value, are done outside of Germany, the Country of Origin will still state Germany. Table 3 lists several examples of country of origin labeling.

Table 3 – Country of Origin Examples

Steel Origin	Place of Forging	Place of Production	Final Label
Germany	Malaysia	Germany	Malaysia
Germany	Malaysia	Malaysia	Malaysia
Japan	Germany	Pakistan	Germany
Germany	Germany	Pakistan	Germany

As noted above, in the United States, there is no agency that establishes standards for instrument quality; this is left to the manufacturer.

- **The manufacturing facility.** Instruments that are manufactured with high quality materials in one facility, where complete control of production from forging to finishing, with reliable production processes and strategic quality assurance and control testing, are typically of higher quality.

- **Pattern consistency.** Facilities that manufacture their own raw parts in their own forging department are able to carry out production consistently according to a drawing and master sample (see Figure 3), with thorough quality inspection carried out during the manufacturing process.

Figure 3 – Pattern Consistency

Pattern consistency is also facilitated when instruments are manufactured by experienced, master craftsmen. Today's technology and computer-assisted equipment have not total replaced the expertise of skilled craftsmen. Facilities that combine modern manufacturing technology with the expertise of master craftsmen produce every instrument to the same exact standards (see Figure 4). Typically, these craftsmen receive initial training by a certified master craftsman on the strict quality standards of the manufacturer for an average of 3.5 years; many craftsmen have over 15 years of experience in instrument manufacturing.

Figure 4 – Precision Craftsman

- **Types of standards.** The official standards used by most instrument manufacturers are the DIN/International Organization for Standardization (ISO) standards for pattern tolerances and consistency. (DIN is the acronym for the generally translated "Deutsche Institut fur Normung", a German standards and measurements organization.) Quality instrument manufacturers use tighter and narrower tolerances than DIN/ISO standards, that is, they require a greater number of defined measurements than those required by DIN/ISO. The differences between ISO, DIN and the higher quality manufacturer standards for tolerance range are outlined in Figure 5.

Figure 5 – Differences between ISO, DIN, and Quality Manufacturer Standards for Tolerance Range

Tighter measurement tolerances translate into higher precision and higher pattern consistency of an instrument. Figure 6 depicts the differences in measurement tolerances for a Mayo-Hegar needle holder 8" (205 mm). Figure 7 depicts the differences in the design and measurements of an Allis forceps made to DIN standards and then higher quality manufacturing standards.

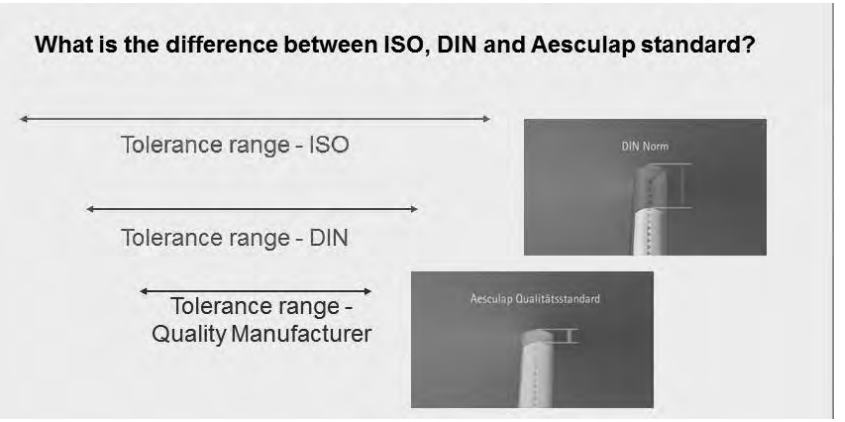


Figure 6 – Differences in Measurement Tolerances

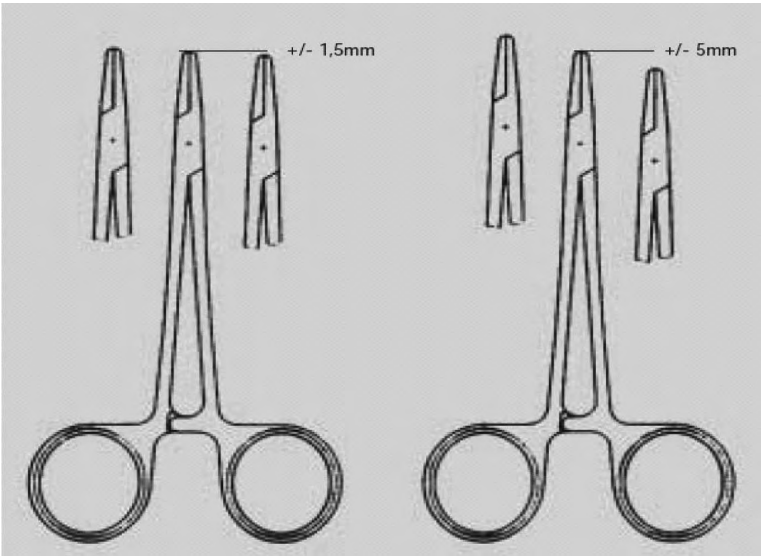


Figure 7 – Differences in the Design and Measurements of an Allis Forceps: DIN and Quality ManufacturerStandards

Another example of higher quality manufacturing standards are the materials used in scissors. Manufacturers that use materials with a higher carbon content produce a scissor that is sharper and more wear resistant; using higher chrome and molybdenum contents results in superior corrosion resistance.

THE QUALITY INSTRUMENT MANUFACTURING PROCESS

Premier grade surgical instruments go through numerous steps and quality checks before they are shipped to the end users. Before the instrument manufacturing process starts, however, it is important to that the expert craftsmen ensure that the right materials are being processed. At this time, the raw material stock is thoroughly examined in the manufacturing facility for shape and dimensions (see Figure 8), as well as mechanical properties (eg, hardness and forging properties).

Figure 8 – Examining Raw Materials for Shape and Dimensions

The use of high quality of the steel is essential for the manufacture of quality surgical instruments. The stainless steel used must meet the rigorous requirements of surgical instruments, specifically:

- Maximum corrosion resistance;
- Resistance to wear;
- Rigidity; and
- Elasticity.

The steps in the instrument manufacturing process are outlined below.

► ***Step1: Splitting.*** In this step, the unmatched part is cut from the steel, which is available in different forms (eg, square bars, round bars, or flat bars) in a splitting machine (see Figure 9).

Figure 9 – Splitting Machine and Unattached Part Cut from the Steel Strip

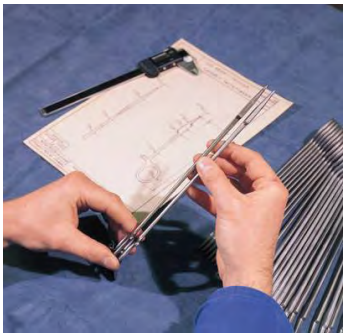
► ***Step 2: Forging.*** Forging, in which the die obtains the basic form of the instrument, is done with a drop hammer (see Figure 10). Forging is possible only in a heated condition (750-1050°C). Forging is done in three processing steps: bending, rough forging, and final forging.

Figure 10 – Drop Hammer

The forged raw parts are then deburred, in which the excess material is removed to round off sharp edges and dulled, ie, blasted with quartz sand in order to remove forging scale (see Figure 11). The raw parts are then inspected, based on comparison with the master sample or dimensioned control sheet (see Figure 12) and adjusted as needed.

Figure 11 – Deburring/Dulling of Forged Raw Parts

Figure 12 – Inspection and Comparison with Master Sample & Dimensioned Control Sheet



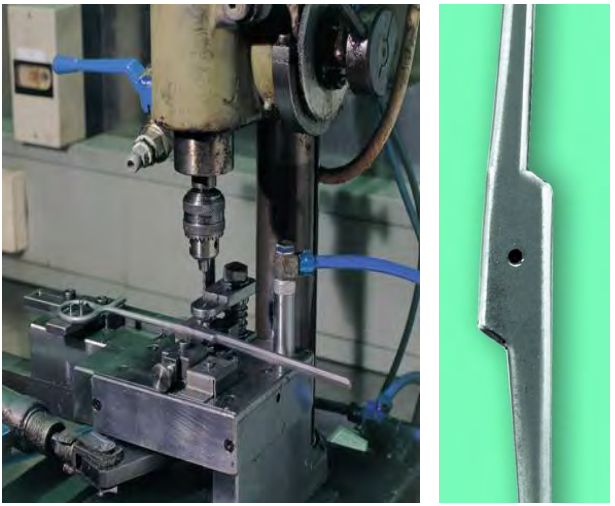
► ***Step 3: Annealing.*** Due to the extremely high temperatures in the forging process, the steel becomes hard. The next steps of drilling, milling, etc. are only possible with steel that is soft. Therefore, the forged parts must undergo an annealing process for machining. This is a rather slow process during which the forged parts are heated to a pre-determined temperature (see Table 4) and then allowed to cool slowly over a specified period of time. It is critical that the heat treatment process times for warm-up, holding time, and cooling time, are observed; if they are not, the parts are at increased risk for fracture and corrosion due to strutural damage.

Table 4 – Heat Treatment Temperatures

Process	Temperatures
Forging	750°C - 1050°C
Annealing	790°C
Hardening	1020°C - 1070°C

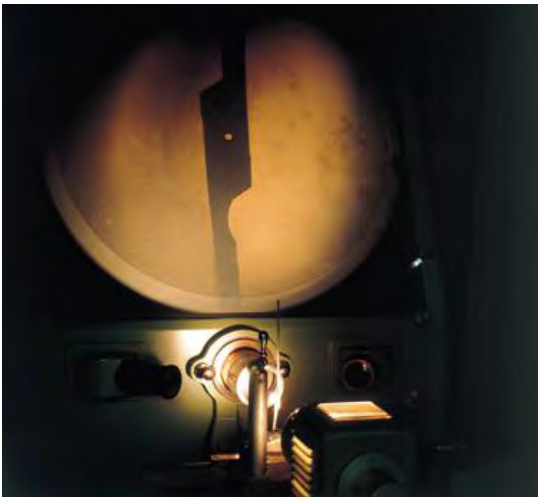
► ***Step 4: Drilling.*** The joint bore is then drilled into the annealed part (see Figure 13). The joint bore is the reference point for subsequent processing, that is, it is largely responsible for the dimensional accuracy of both parts of a clamp.

Figure 13 – Drilling



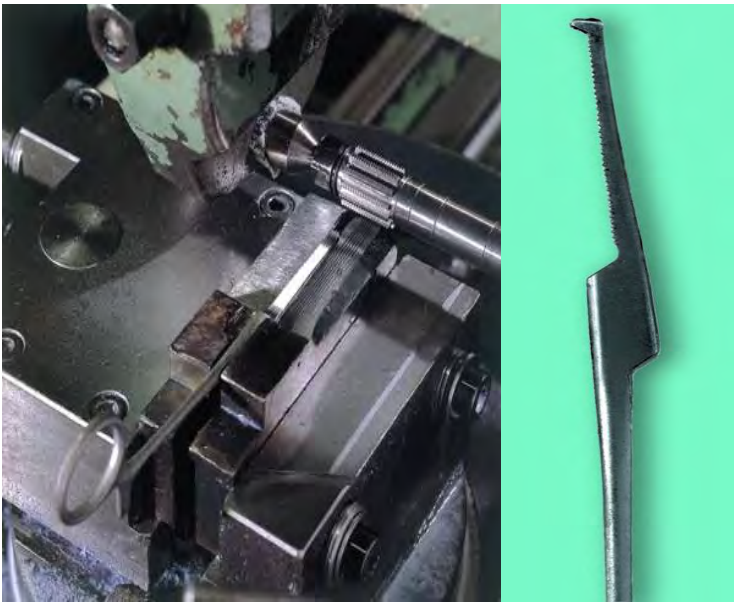
Shape and dimensional checks monitor the proper completion of this and all other processing steps (see Figuare 14).

Figure 14 – Test Projector



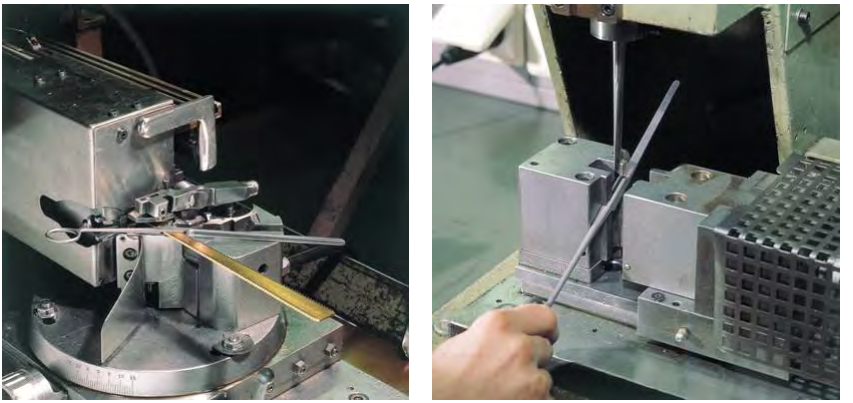
► ***Step 5: Jaw Tooth Milling.*** The annealed parts are then milled, based on the requirements of the final instrument design; this is done with special equipment that introduces teeth, serrations, etc. (see Figure 15).

Figure 15 – Jaw Tooth Milling



The female and the male components of the clamp and the latches are milled. The female component of the clamp joint is broached with a broaching tool and then expanded (see Figure 16).

Figure 16 – Broaching and Expanding the Female Component



The male component of the clamp joint is then inserted into the female component (see Figure 17).

Figure 17 – Inserting the Male Component of a Clamp Joint into the Female Component

The individual parts comprising a two-part instrument are inseparably connected at the joint by pressing them together and then riveting (see Figure 18).

Figure 18 – Pressing the Individual Parts of a Two-Part Instrument Together

► ***Step 6: Profile Grinding.*** After the forged parts are milled, they are next grinded on a rough stone grinding wheel (see Figure 19). This step removes any excess material that may be remaining after the forging process.

Figure 19 – Profile Grinding

A quality features in this step is to grind the part according to a template, which guarantees an exact profile accuracy of the jaw parts and the lock (see Figure 20).

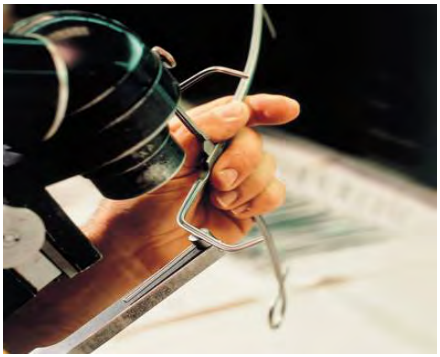
Figure 20 – Template for Profile Grinding

► ***Step 7: Bending***. Following profile grinding, bending is the next step. Figure 21 shows the mouth of an atraumatic clamp being bent after profile grinding.

Figure 21 – Bending the Mouth of an Atraumatic Clamp

► ***Step 8: Worker Self-Testing***. Quality instrument manufacturers require intermediate tests of all required instrument manufacturing steps; that is, the producers are verified and validated. A random sample test is conducted with respect to shape and dimensional accuracy, function, and surface quality.

Figure 22 – Worker Self-Testing



► ***Step 9: Cleaning.*** Cleaning in quality instrument manufacturing is done with two cleaning units. Cleaning Unit I is used before hardening and washes out oil, grease and foreign matter; Cleaning Unit II performs the final cleaning, which takes place after instrument production is completed (see Figure 23).

Figure 23 – Cleaning Units I & II

► ***Step 10: Vacuum Hardening***. Vacuum hardening improves an instrument's hardness, toughness and wear characteristics; this increases corrosion resistance. The advantages of using a vacuum hardening furnace (see Figure 24) for this process include no surface reactions; no cracking or embrittlement; and very little distortion of the instrument.

Figure 24 – Vacuum Hardening Furnace

► ***Step 11: Surface Treatment.*** This step consists of the processes described below.

- **Grinding and polishing.** The next step is grinding and polishing of the hardened surfaces of the instruments with mechanical "high gloss" processing to remove any scratches from the previous steps until the surface is smooth and flawless. Belt grinding (see Figure 25) of the outside of the rings, the branches and neck of the latch, the outside and inside of the jaws, and the side of the joint is done.

Figure 25 – Belt Grinding

Final grinding (see Figure 26), defined as a me*hanical-chemical abrasive process using plastic or ceramic chips to smooth the rough instrument surfaces, is performed next.*

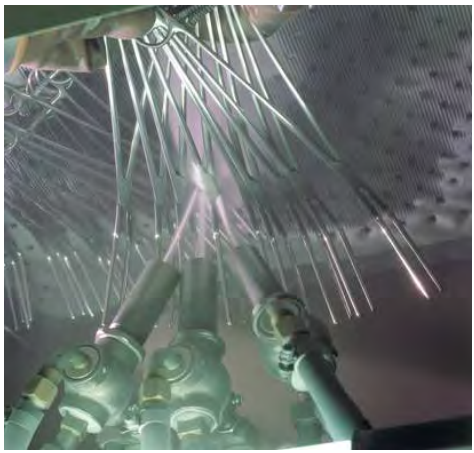
Figure 26 – Final Grinding

During electropolishing (see Figure 27), defined as *electromechanical material removal to smooth and passivate rough component surfaces*, the instruments are smoothed to a “high gloss”. At the completion of this step, the insturment have a uniform, corrosion resistant, “high gloss” surface.

Figure 27 – Electropolishing

- **Surface Dulling.** Surface dulling, defined as controlled roughening of the surface, is performed next (see Figure 28). In this process, a compressed-air treatment with very fine glass beads (ie, “silver dulling”) and fiber brushing (ie, “satin dulling”) are performed. This process results in a reduction of reflection from the “high gloss” surface.

Figure 28 – Surface Dulling

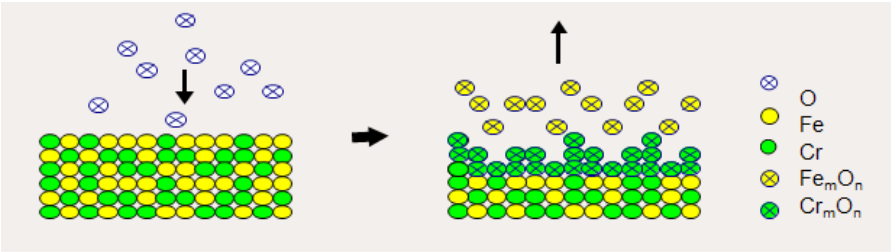


- **Passivation:** Chemical treatment to build up a “corrosion-protective” layer to perpetuate the instrument‘s corrosion resistance. In order to understand the importance of passivation, it is important to discuss how independently produced corrosion protection layers develop on metals (see Figure 29) and define the passivation process. Some metals, such as aluminum and titanium form their own passive/oxide coating, while others, such as iron/steel require chrome alloying.

Figure 29 – Passive/Oxide Coating

Passivation is the process of chemically treating or coating stainless steel to build up a corrosion-protective layer; it is a chemical reaction between the chromium in the stainless steel (ie, steel alloy) and oxygen. During this process (see Figure 30), organic acids react with iron through oxidation to create iron oxide (Fe_2O_3) and chromium oxide (Cr_2O_2). The iron oxide is solved from the surface, while the chromium oxide remains and builds a "passive" protective layer of iron/chromium oxide; the layer is usually 2-5 nm thick. The surface finish (ie, high gloss to matte) does not impact the effectiveness of this "passive" layer.

Figure 30 – Passivation



The formation of the "passive" layer is dependent on the following factors:

- Composition of alloy;
- Microstructure of the material;
- Surface condition, ie, the roughness or smoothness;
- Handling and reprocessing conditions; and
- Instrument life and frequency of use.

MAINTAINING QUALITY SURGICAL INSTRUMENTS: THE IMPORTANCE OF WATER QUALITY

Once a facility purchases premier OR grade surgical instruments, it is imperative that personnel maintain them properly in order to provide safe patient care, but also to protect the facility's investment. All perioperative personnel are well-aware of the importance of proper care and handling in maintaining an instrument's function and useful life; however, one key factor that is often not considered in these processes is the facility's water quality. The use of utility water for washing and critical water for final rinsing is recommended for instrument processing.[11] Water softeners are often used, but they add sodium salts; demineralizing the water removes these salts as well as other particles. It is important to note that steam requires the same attention to quality of water supply as well as proper filtration in the steam lines. Failure to provide quality steam for sterilization results in instrument spotting and/or surface breakdown.

Key aspects of water quality related to instrument cleaning are outlined in the Association of periOperative Registered Nurses' (AORN) Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment, as outlined below.[12]

- The type of water available for instrument cleaning should be consistent with the manufacturer's written instructions and intended use of the equipment and cleaning agent. Water quality is affected by conductivity; the presence of dissolved mineral solids, chlorides, and other impurities; and its acidity or alkalinity. Water quality also fluctuates over time. The optimum combination of chemicals used in a washer decontaminator is based on the hardness of the available water.
    - Potable water should be used for manual or mechanical (ie, automated) decontamination methods unless contraindicated by instrument manufacturers' instructions.
    - Softened or deionized water should be used for the final rinse. Softened or deionized water removes soil and detergent residues more efficiently. Water with a high chloride or chlorine content can damage surgical instruments and equipment. Water softeners remove the calcium and magnesium ions that cause spots on instruments. Deionizing water removes ionized salts and particles that could harm instruments.
    - A water quality assessment should be performed periodically and after major maintenance to the water source, as water quality varies seasonally and after water source maintenance. Periodic water testing can demonstrate if the chemical combination used to condition the cleaning and decontamination water should be adjusted. Water quality checks also indicate the hardness of the water and if any impurities are present. Impurities present in the water also can be a reflection of insufficient filtration. Based upon this testing, repairs or modifications in the filtration system should be performed.

WHY ARE QUALITY INSTRUMENTS IMPORTANT?

Operating room and sterile processing personnel use and handle hundreds of surgical instruments during the course of a normal work day. As a result, it is easy for perioperative personnel to take these instruments for granted and believe that they using high quality instrument to provide safe and effective care. But it is not that simple, as there are key clinical considerations related to the evaluation, selection, and use of quality surgical instruments. In this regard, patient and worker safety, quality, and cost containment are the primary considerations of perioperative personnel in the evaluation and selection of medical devices and products for use in the surgical practice setting.[13] One factor that contributes to both the useful life and performance of surgical instruments is their quality; therefore, it is important that perioperative personnel understand how surgical instruments are manufactured to assist them in the evaluation, selection, as well as proper use of all surgical instruments used for patient care in the OR.

Today, perioperative personnel may have experienced a drop in both the price and quality of surgical instrumentation, ie, the instruments that are less expensive buy, but need to be ordered more often.[14] While prices may have declined, the saying "you get what you pay for" holds true. All personnel responsible for the selection of surgical instruments should gain knowledge regarding instrument manufacturing and invest selectively in quality products in order to avoid the frequent replacement of instruments that are of sub-par quality. In addition to cost savings, purchasing high quality instruments will also improve surgeon and staff satisfaction.

An evaluation of the quality of surgical instruments reported in the literature demonstrated the importance of selecting high quality instrumentation.[15] For six months, all batches of new surgical instruments ordered by the central sterile supplies department at one hospital were assessed by three clinical engineers, with reference to the required manufacturing standards. Of the 4,800 instruments examined, 15% had potential problems. These problems included 116 with machining burrs and debris in the teeth of the tissue-holding regions, 71 with defects of the ratcheted instruments, 34 scissors with deficient cutting action, and 35 tissue forceps with protruding guide pins (see Table 5). In addition, 254 instruments did not have a visible manufacturer's mark.

Table 5 – Instrument Flaws

Principal Flaw	Number of Instruments
Machining burrs in teeth	116
Sharp burrs on handle grips	8
Soldering faults	47
Cracks	91
Failure of cutting action	34
Failure of correct meshing of ratchets	71
Failure of jaws of needle holders	36
Protruding tissue forceps guide pins	35
Corrosion	28
Deficient electrical insulation	10
Absent manufacturer's mark	254

The authors went on to describe the potential problems that could result from these flaws.

- Machining burr debris and surface imperfections:
    - Sharp burrs on instrument handles may contribute to previously unexplained surgical glove punctures.
    - Blood and tissue debris may collect in the surface imperfections. Clinicians have relied on various sterilization processes to render such debris inert; in today's increasingly hazard-conscious environment, the potential for transmission of blood borne and prion diseases remains a concern.
    - The metallic fragments may also wear off these surfaces and potentially remain as microscopic debris in the wound.
- Cracks and soldering faults may also provide niches for retention of blood and tissue, and serious defects may lead to instrument failure.
- Protruding tissue forceps guide pins may also be a source of glove puncture.

The authors concluded that the results of this study demonstrate the value of local quality control for surgical instruments. This is especially important in today's increasingly hazard-conscious environment, where there are concerns over instrument sterilization, surgical glove puncture and the potential for transmission of blood-borne and prion diseases. They also noted that no specific instance of harm to a patient or staff member occurred as a result of these defects.

Most surgical instruments were manufactured in Germany with German steel, as Germany has a long history of producing quality surgical instruments. However, today, instruments are manufactured in other countries such as Malaysia, Poland, and Pakistan. Pakistan has quite a large surgical instrument manufacturing base; however, it is important to note that many Pakistan instrument manufacturers compete on price alone and therefore usually produce lower grade instruments.[16] While instruments made in Pakistan will typically be the cheapest instruments available, and many times intended for limited use, they tend to rust or need replacement more frequently than instruments manufactured in other countries. In addition, some instruments are produced to be used once and are called single-use or disposable surgical instruments. Therefore, most surgical instrument manufacturers offer lower cost instruments that are *not* intended for repeated use in the surgical practice setting.[17]

Another report identifies problems associated with poorly manufactured surgical instruments.[19] Two-thirds of the world's surgical instruments are made in the city of Sialkot in northern Pakistan. While some of the larger companies operate state-of-the art facilities and have rigorous quality-control procedures in place, there is evidence that some of the smaller companies do not use magnifying glasses to inspect finished instruments before putting the required quality stamp on them. Other companies outsourced manufacturing to some of the 3,000 back-street workshops in the city, where undercover filming revealed a complete lack of hygiene or quality control.

Other strategies that perioperative personnel can take to ensure they are using premier OR grade instruments include:

- Know how and where surgical instruments are manufactured and who the manufacturer is; obtain this information from the supplier that you are purchasing instruments from.
- Become educated on quality in surgical instrumentation and the manufacturing process.
- Advocate for the selection and use of only premier OR grade instruments with perioperative managers, surgeons, materials management personnel, and product selection committees, as applicable. Do not be satisfied with inferior instrumentation for use in surgical patient care.
- Consult with manufacturer or supplier if instrument or patient care issues arise.

SUMMARY

The use of surgical instruments dates back to prehistoric times. The development of stainless steel in the 1900s enhanced the art of instrument manufacturing by providing a superior quality material to craft modern, more sophisticated surgical instruments. Today, the vast majority of surgical instruments are made of stainless steel.

Stainless steel is an alloy of iron, chromium, and carbon; it may also contain other alloying elements, such as nickel, magnesium, silicon, molybdenum, sulfur, and other elements to add to its tensile strength and also so that it will be resistant to corrosion when exposed to the atmosphere, blood and body fluids, cleaning solutions, and sterilization methods. For this reason, stainless steel can be of varying quality in regards to its physical properties. Because there are various types of stainless steel, the American Iron and Steel Institute grades stainless steel based on its various mechanical properties and composition. Both 300 and 400 series stainless steel are used in the manufacture of reusable, heat-stable surgical instruments, with 400 being the most common used.

It is important for perioperative personnel to keep in mind that the quality of today's premier OR grade surgical instruments is directly related to the quality of the steel used, as well as the quality of the manufacturing process. Because the manufacture of surgical instruments is a complex process, and there is no agency in the United States that sets standards for instrument quality, it is imperative that surgical instruments are obtained from a quality, reputable manufacturer or supplier, ie, one that incorporates quality control mechanisms throughout all steps of the manufacturing process and uses high-quality stainless steel. Another important consideration in the selection of quality instruments is the "country of origin." For surgical instruments, the country of origin labeled as "manufactured in…." only refers to the country in which forging takes place, which is less than 10% of an instrument's value.

Once the instruments are obtained, proper care and handling are essential in maintaining the instrument's quality, performance, and useful life. An important factor in maintaining an instrument's quality is the quality of the facility's water, as water quality fluctuates over time and is affected by various factors.

Today more than ever, it is important that perioperative personnel understand how premier OR grade surgical instruments are manufactured and consider the quality aspects of both the manufacturing process and end product when evaluating surgical instruments for use in the OR. Through this knowledge, the safety and effectiveness of surgical care can be enhanced, thereby promoting positive patient outcomes.

GLOSSARY

Annealing	A process which makes stainless steel soft for machining.
Corrosion Resistance	The capacity of a metal or alloy to resist the corrosive action (ie, gradual alteration, degradation) of a specific medium or the environment.
Country of Origin	The country of manufacture, production, or growth of any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the “country of origin”.
Critical Water	Water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, DI, and RO or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process. This water is mainly used for the final rinse or steam generation.
Deburring	Removal of excess material from a forged raw instrument part to round off the sharp edges.
Dulling	Blasting with quartz sand of a forged raw instrument part to remove forging scale; the controlled roughening of a surface.
Electropolishing	Electromechanical material removal to smooth and passivate rough component surfaces.
Elongation	A test to measure the ductility of steel. When a material is tested for tensile strength it elongates a certain amount before a fracture occurs; the two pieces are placed together and the amount of extension is measured against marks made prior to starting the test; elongation is expressed as a percentage of the original gauge length.

Final Grinding	A mechanical-chemical abrasive process using plastic or ceramic chips to smooth the rough instrument surfaces.
Forging	A process by which heated, pre-cut or fabricated lengths of stainless steel sheet or stock bars are hammered in the shape, size, and geometry of the instrument to be produced.
Malleability	The ability to be worked, hammered, or shaped under pressure without breaking.
Mechanical Properties	Various measured aspects of a material (eg, stainless steel) used to describe its elastic and inelastic reaction to applied force; these reactions may include tensile strength, yield strength, elongation, impact strength, and hardness.
Passivation	The process of chemically treating or coating stainless steel to build up a corrosion-protective layer.
PSI	Pounds per Square Inch; the common unit of measurement for pressure.
Rb	Abbreviation for Rockwell Hardness measured on the B scale; a designation of hardness of metallic materials measured by pressing a small rounded indenter against a clean prepared surface with a specific force.
Stainless Steel	Any of various steels alloyed with at least 10% chromium, which may also contain other elements and that are resistant to corrosion or rusting.
Temper	The degree of hardness and strength imparted to a metal, as by treatment with heat.
Tensile Strength	The resistance of a material to a force tending to tear it apart, measured as the maximum tension the material can withstand without tearing.
Tolerance Range	The permitted variation in a given measurement or dimension.

Useful Life	The length of time, as determined by the manufacturer, for which a product maintains acceptable safety and performance characteristics.
Utility Water	Water as it comes from the tap that might require further treatment to achieve the specifications. This water is mainly used for flushing and washing.
Yield Strength	The stress at which a predetermined amount of permanent deformation occurs.

REFERENCES

1. Fortunato N. Surgical instrumentation. In: *Berry & Kohn's Operating Room Technique*. 11th ed. St. Louis, MO: Mosby Elsevier; 2007: 328.

2. Guglielmi C, Hunger S. Sutures, needles, and instruments. In: JC Rothrock, ed. *Alexander's Care of the Patient in Surgery*. 14th ed. St. Louis, MO: Elsevier Mosby; 2011: 193.

3. Tighe, SM. Care and handling of surgical instruments. In: *Instrumentation for the Operating Room.* 6th ed. St. Louis, MO: Mosby; 2003.

4. Specialty Steel Industry of North America. Stainless steel primer. http:// www.ssina.com/download_a_file/primerupdatebroc.pdf. Accessed November 3, 2015.

5. Specialty Steel Industry of North America. Stainless steel primer. http:// www.ssina.com/download_a_file/primerupdatebroc.pdf. Accessed November 3, 2015.

6. Stainless steel grades explained. http://www.jamestowndistributors.com/userportal/document.do?docId=536. Accessed July 28, 2015.

7. Tighe, SM. Care and handling of surgical instruments. In: *Instrumentation for the Operating Room*. 6th ed. St. Louis, MO: Mosby; 2003.

8. Surgical instrumentation. http://www.storm2k.com/surgicalinstrumentation.pdf. Accessed July 28, 2015.

9. IAHSCMM. Lesson Plan CIS 219 instrument selection for surgical sets. https://www.distance.purdue.edu/training/cssp/cis/pdf/CIS219.pdf. Accessed July 28, 2015.

10. Title 19: customs duties – Part 134 – country of origin marking. http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=19:1.0.1.1.28. Accessed July 28, 2015.

11. ANSI/AAMI TIR34:2014 (Revision of AAMI TIR34:2007), Water for the reprocessing of medical devices, approved for August 2014 by Association for the Advancement of Medical Instrument, Arlington, VA;2014: 15.

12. AORN. Guidelines for cleaning and care of surgical instruments. In: *Guidelines for Perioperative Practice*. 2015 ed. Aurora, CO: AORN, Inc.; 2015:615-644.

13. AORN. Guidelines for cleaning and care of surgical instruments. In: *Guidelines for Perioperative Practice*. 2015 ed. Aurora, CO: AORN, Inc.; 2015:615-644.

14. Edelstein R. Top challenges to overcome when purchasing surgical instruments. http://www.beckersasc.com/asc-supply-chain-materials-management/7-top-challenges-to-overcome-when-purchasing-surgical-instruments.html. Accessed July 28, 2015.

15. Brophy T, Srodon PD, Briggs C, et al. Quality of surgical instruments. *Annals of the Royal College of Surgeons of England*. 2006; 88(4): 390-393.

16. Thorsfeldt HInstruments manufactured in Pakistan are not generally known for quality. Askville.com. http://askville.amazon.com/difference-stainless-steel-Pakistan-Germany-measure-quality/AnswerViewer.do?requestId=1455882. Accessed July 28, 2015.

17. Thorsfeldt HInstruments manufactured in Pakistan are not generally known for quality. Askville.com. http://askville.amazon.com/difference-stainless-steel-Pakistan-Germany-measure-quality/AnswerViewer.do?requestId=1455882. Accessed July 28, 2015.

18. Surgical tools used in NHS operations 'substandard.' http://www.bbc.com/news/uk-13894880. Accessed July 28, 2015.

Please click here for the Post-Test and Evaluation