AESCULAP

Why Surgical Instrument Grade Is Important

BY PAUL MURPHY, PRODUCT MANAGER, CENTRAL STERILE PRODUCTS AND SERVICES—AESCULAP INC.

Certified Instrument Specialist (CIS) lessons provide members with ongoing education in the complex and ever-changing area of surgical instrument care and handling. These lessons are designed for CIS technicians, but can be of value to any CRCST technician who works with surgical instrumentation.

Earn Continuing Education Credits

Online: Visit www.iahcsmm.org for online grading.

By mail: For written grading of individual lessons, send completed quiz and $15 to:
Purdue Online – Central Service
Young Hall, Room 405
155 S. Grant St.
West Lafayette, IN 47907

Subscription series: Purdue Extended Campus offers an annual mail-in or online self-study lesson subscription for $75 (six specific lessons worth 2 points each toward CIS recertification of 6 hours). Call 765.494.0959 for details.

Scoring: Each quiz with a passing score is worth 2 contact hours toward your CIS recertification (6 hours) or CRCST recertification (12 hours).

More information: IAHCSMM provides online grading service for any of the Lesson Plan varieties. **Purdue University provides grading services ONLY for CRCST and CIS lessons.** Direct questions about online grading to IAHCSMM at 312.440.0078. Questions about written grading are answered by Purdue University at 765.494.0959.

LEARNING OBJECTIVES

1. Define surgical instrument grades
2. Understand how surgical instruments are made/manufactured
3. Determine how to optimize instrument selection for one's facility

In the Operating Room (OR), the use of high-quality surgical instruments is a critical factor in providing safe patient care and protecting the facility's surgical instrument inventory investment. Surgical instruments must be able to function accurately and safely throughout a surgical procedure, and they also must be able to withstand repeated reprocessing and sterilization.

Evidence of surgical instruments dates back as far as 2500 BC. Early materials available to make instruments included flints and animal teeth, which were durable and able to be sharpened. One military surgeon who advanced instruments and techniques during the 1500s focused on treating war wounds, including using a hemostat-type instrument. In the late 1700s, surgeons created and designed instruments as surgery evolved. Individual artisans developed expertise in making one specific instrument type, which marked the beginning of the concept of instrument craftsmanship and expertise that remains today.

Around the turn of the 20th century, the importance of sterilization was recognized, and new materials that could withstand sterilization were needed for instrumentation. Stainless steel was developed in the 1900s, providing material for instruments that could withstand the challenges of repeated cleaning and sterilization and making the manufacturing of high-quality surgical instruments possible.

The technology of modern instrument manufacturing developed in Europe. Master craftsman-level expertise and training for manufacturing surgical instruments are still found predominately in one area of Germany. Today, various steps in the manufacture of instruments are performed in many areas of the world. Identifying where all the manufacturing steps are done, the involvement of master craftsman in the manufacturing process, and the quality of raw materials is the challenge healthcare personnel face.

Quality instrument manufacturing includes quality controls when selecting raw materials and the type of stainless steel in addition to end-product quality control. Greater attention to quality throughout the design and manufacturing process translates into greater instrument performance and longevity. Understanding the critical quality aspects of instrument manufacturing and labeling is key for healthcare personnel involved in product selection and care.

Objective 1: Define surgical instrument grades

In the U.S., there is no universally accepted system or terminology to define surgical instrument quality. All stainless steel instruments may appear to be equivalent in quality when new; however, there are differences in the quality of stainless steel and the manufacturing process. These differences determine the "grade" of the surgical instrument. Three commonly seen grades are:

1. Premium OR-grade instruments
2. Mid-grade OR instruments
3. Floor-grade instruments

The overall quality of any surgical instrument is determined based upon a combination of the quality of craftsmanship used during the manufacturing process and the type and quality of metal composition, particularly the grade of stainless steel.

Grades of Stainless Steel

Approximately 85% of all surgical instruments are made from stainless steel. The physical properties of the steel vary in:

- Quality
- Flexibility
- Temper
- Hardness
- Malleability
- Corrosion resistance

For example, sharp instruments require more hardness (higher carbon content), while other instruments (such as clamps) require less hardness. Stainless steel is an alloy of iron, chromium and carbon. There are more than 100 different types of stainless steel, which are grouped by the American Iron and Steel Institute into sub-types based on mechanical properties and composition. Several types of stainless steel are used to produce surgical instruments; however, the two main types of are: 300 series and 400 series.

The 400 series stainless steel is hard and used for instruments that require a cutting surface. Examples of instruments made of 400 series stainless steel are scissors, osteotomes, chisels and rongeurs.

The 300 series stainless steel is not as hard as 400 series; it is more malleable. Examples of instruments made of 300 series stainless steel include retractors, cannulas and rib spreaders.

The "recipe" or combination of materials is determined by the attributes needed for the instrument type.

Instrument Grades

Premium OR-grade instruments differ from other grades of instruments in the following ways:

- Less pattern variation (e.g., jaw width, tip length)
- Greater quality control (QC) of raw materials
- QC inspections performed at several points during the manufacturing process

This classification results in more uniformity by instrument type and is less prone to failure after repeated use. With proper care, handling, cleaning, and sterilization, premium OR-grade instruments can provide years of useful life.

Mid-grade instruments (e.g., towel clamps, basins and blade handles) are comprised of lower-quality stainless steel than premium OR-grade instruments and were developed to meet hospitals' needs for less expensive, reusable stainless steel instruments. Mid-grade instruments typically have a greater variation in the pattern (e.g., tip length, jaw width) but are of similar design. For mid-grade instruments, the specifications for steel quality and manufacturing are less stringent. These differences can result in an instrument with less precision and durability.

Floor-grade instruments are generally intended for single/one-time use. Examples include suture kits used in the Emergency Department. Instruments in this category are made from forgings of lower-grade metals and have a wide pattern variation. As a result, the precision of the instruments' key features is less exact than those of a higher quality. New floor-grade instruments should be examined for nicks or burrs or tips or jaws that do not meet (if any of these issues are found during inspection, the instrument should not be used). Floor-grade instruments may bend or break easily and are at increased risk for staining and corrosion. Using floor-grade instruments to perform delicate surgical procedures may result in unintended tissue damage that may require repair and increase the risk for impaired healing, infection or other negative patient outcomes.

Floor-grade instruments should not be mixed with premium OR-grade instruments and should not be placed in an ultrasonic cleaner. When instruments of different grades are processed together, instrument corrosion can spread to other instruments. Instruments with corrosion present should never be used for surgical procedures.

Key attributes for all three surgical instrument grades include performance expectations, price points and useful life. There are no nationwide or international standards to clearly define the grades of surgical instruments, so it may be challenging for those using and/or purchasing surgical instruments to

	Premium OR Grade Surgical Instruments	Mid Grade Surgical Instruments	Floor Grade Instruments
Pattern Range	Over 10,000 patterns	Select patterns, under 1000, typically vendors provide less than 250 patterns	Select patterns, under 1000, typically vendors provide less than 250 patterns
Types of Patterns	Surgeon Specialty (eg, ENT, OB/GYN, Eye,Ortho, Neuro, Electro, Plastic, etc.) General Instrument (eg, scalpel blades, needle holders) Non-Surgeon Preference (eg, towel clamps, scalpel handles, retractors, curettes)	General Instruments Non-Surgeon Preference (eg, towel clamps, scalpel handles, basins, metal cup, tongue forceps) These patterns are typically less critical to the surgical outcome and in many cases are accidently discarded or lost prior to end of the useful life of the instrument	Similar to Mid Grade
Pattern Usage	Reusable	Reusable	Single-use, then dispose.
Delivery to OR	Reprocessed in central service departments (CSD)	Reprocessed in central service departments (CSD)	Typically come sterile and are single-use (eg, kit packers)
Typical Location of Forging	Germany, Malaysia, Poland	Pakistan, Germany	Pakistan
Typical Location of Product Finishing	Germany, Malaysia, Poland	Pakistan, Poland	Pakistan
Typical Level of Quality Control	High	Medium	Low
Typical Pattern Consistency	High	Medium	Low

Figure 1. Grades of Surgical Instruments: Common Market Understanding

Steel Origin	Place of Forging	Place of Production	Made In	Typical Grade of Instrument
Germany	Germany	Germany	Germany	OR Premium
Germany	Malaysia	Malaysia	Malaysia	OR Premium
Germany	Poland	Poland	Poland	OR Premium
Germany	Germany	Indonesia	Germany	OR Premium
Germany	Germany	Pakistan	Germany	Mid Grade
Pakistan	Germany	Pakistan	Germany	Mid Grade
Pakistan	Pakistan	Pakistan	Pakistan	Mid Grade, Floor

Figure 2. Examples of Country of Origin

understand the difference that surgical instrument grades have on patient care (see **Figure 1**).

Surgical instruments are labeled with a country of origin, which is defined by U.S. 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." Based on this definition, the country of origin for surgical instruments is where forging takes place (this is the second step in the manufacturing process). For example, an instrument can be stamped "Made in Germany" if the forging is done in Germany, even if the remaining production steps are done outside of Germany. **Figure 2** lists several examples of country of origin labeling.

Objective 2. Understand how surgical instruments are made/manufactured

Quality processes for manufacturing surgical instruments are provided by Deutsches Institut für Normung (DIN), which is the German Institute for Standardization. Master craftsmen generally follow DIN standards when producing surgical instruments. Manufacturers of premium OR-grade instruments may exceed the requirements of DIN.

Three principal prerequisites for producing premium OR-grade instruments are:

- Use of high-quality stainless steel
- Following or exceeding DIN standards for pattern consistency
- Incorporating defined QC testing during manufacturing

Like surgical instruments, stainless steel is manufactured in many parts of the world. Quality is determined by the manufacturing process and end product rather than the part of the world where it is produced. Stainless steel is the raw material used for most surgical instruments, and the raw materials are the first step in the production of premium

OR-grade surgical instruments.

Surgical instrument pattern consistency begins with master drawings and a master pattern for each individual instrument (e.g., catalog number or ID) that is cataloged and stored. Master craftsmen use both drawings and pattern samples to ensure pattern consistency when working on fine specialty instruments. Today's technology is computer-supported for mass production of general instruments; however, master craftsmen are still needed. Combining modern manufacturing technology with the expertise of master craftsmen supports the quality demanded by today's surgical procedures.

The numerous steps of the quality instrument manufacturing process are outlined below. For example, a hemostat requires 15 major steps in the manufacturing process.

Step 1: Splitting. This step results in an unmatched part cut from the steel by a splitting machine.

Step 2: Forging. The forge uses a die to "stamp" the shape of the instrument part.

Step 3: Deburring and Dulling. Deburring is the removal of excess material to round off sharp edges following the forging step.

Step 4: Annealing. Due to the extremely high temperatures in the forging process, the steel becomes hardened. The next steps of drilling, milling, etc. are only possible with soft steel; therefore, the forged parts must undergo an annealing process for machining.

Step 5: Drilling. The joint bore is then drilled into the annealed part. Shape and dimensional checks monitor the proper completion of this and all other processing steps.

Step 6: Jaw Tooth Milling. The annealed parts are then milled based on the requirements of the final instrument design. The individual parts comprising a two-part instrument are inseparably connected at the joint by pressing them together and then riveting.

Step 7: Profile Grinding. After the forged parts are milled, they are ground on a rough stone grinding wheel. This step removes any excess material that may be remaining after the forging process.

Step 8: Bending. The bending step involves the use of specialized tools to bend an instrument (i.e., the jaw of an atraumatic clamp) to ensure the correct shape is consistently achieved.

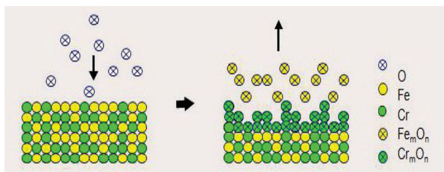
Step 9: Worker Self-Testing. Quality instrument manufacturers require intermediate tests of all required instrument manufacturing steps.

Step 10: 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.

Step 11: Vacuum Hardening. Vacuum hardening improves an instrument's hardness, toughness and wear characteristics, increasing corrosion resistance.

Step 12: Surface Treatment. This step consists of processes such as grinding and polishing.

Step 13: Passivation. Passivation is the process of chemically treating or coating stainless steel to construct a corrosion-protective layer (a chemical reaction between the chromium in the stainless steel and oxygen). During this process, organic acids react with iron through oxidation to create iron oxide (FeO) and chromium oxide (CrO). Iron oxide is dissolved from the surface, while the chromium oxide remains and builds a "passive" protective layer of iron/chromium oxide. The layer is usually 2nm to 5nm thick. The surface finish (e.g., high gloss to matte) does not impact the effectiveness of this passive layer.



Objective 3: Determine how to optimize instrument selection for one's facility

When selecting surgical instruments to be used in surgical sets, numerous considerations will impact those decisions. Among the most critical are:

- Quality and longevity of the instrument
- Surgeon preference
- Price
- Ease of care and cleaning
- Consistency and reliability of instrument performance
- Reputation of the supplier for quality, service, support and education
- Patient safety and comfort

When examining options for an instrument within a set, consider asking these questions:

- Will the instrument be similar or "cross" to existing patterns in the set?
- How easy or difficult is the instrument to clean? Can it be taken apart and easily reassembled?
- Does the instrument design provide a universal feel and ease of use for the surgeon?
- Will the instrument be easy to repair, so it will last longer?
- Does the supplier provide original equipment manufacturer (OEM) parts for repair/replacement?

Conclusion

It is important for perioperative personnel to understand that the quality of today's premium OR-grade surgical instruments is directly related to the quality of the steel used and the quality of the manufacturing process. Manufacturing of surgical instruments is a complex process, and there is no agency in the U.S. that sets standards for instrument quality; therefore, it is imperative that surgical instruments are obtained from a reputable manufacturer or supplier that uses high-quality stainless steel for their instruments and incorporates QC mechanisms throughout all stages of the manufacturing process.

RESOURCES

"The History and Evolution of Surgical Instruments." *Annals of The Royal College of Surgeons of England* 63, no. 4 (August 1981): 279–85. https://www.researchgate.net/publication/16181396_The_history_and_evolution_of_surgical_instruments_I_Introduction.

Specialty Steel Industry of North America. Stainless Steel Primer. Available at https://www.ssina.com/wp-content/uploads/2019/06/primerupdatebroc.pdf.

Title 19: Customs duties–Part 134–Country of origin marking. https://www.gpo.gov/fdsys/pkg/CFR-2012-title19-vol1/pdf/CFR-2012-title19-vol1-chapI.pdf.

U.S. Customs Ruling. https://www.customsmobile.com/rulings/docview?doc_id=561189&highlight=561189.

Deutsches Institut für Normung (German Institute for Standardization) https://www.din.de/en/about-standards/din-standards.

Association of periOperative Registered Nurses. "Guideline for Care and Cleaning of Surgical Instruments." *Guidelines for Perioperative Practice*, 2020 ed.