



TECHNICAL ANALYSIS

Stainless Steel Maintenance Tools: Reducing Process Contamination Risks

Executives in industries such as electronics, biotechnology, pharmaceuticals, food processing and other fields should recognize that general industrial carbon steel tools introduce unacceptable risk of contamination from iron oxide (rust) and chrome particles.

An ordinary screwdriver or wrench is likely to undermine elaborate steps ensuring sterility and environmental integrity for sensitive production operations. Using appropriate hand tools to install and maintain sterile processing line machinery is an essential element of current good manufacturing practice (cGMP) in critical areas.

Mechanics using standard shop floor pliers to repair stainless steel production apparatus subvert standard operating procedures to assure quality control and regulatory compliance.

This report summarizes risks from introducing general-purpose tools into aseptic or cleanroom settings, and shows why professional-grade stainless steel maintenance tools are the accepted standard for industries that also include health care, semiconductors, chemicals, aerospace, avionics and nuclear energy.

Introduction: Critical operations require purpose-designed tools

Ferrous contamination of production line parts and equipment occurs through neglect or ignorance of best-practice maintenance methods for sterile processing situations, which require different tools than general manufacturing. Though the carelessness is unintended, the significant, costly impact can include:

- Interrupted production for replacement or rusted parts and sanitizing.
- Quality control rejection of pharmaceutical, culinary, semiconductor or biomedical product batches because of compromised environmental sterility.
- Negative evaluation report references by inspectors from the FDA, state health department or accreditation commission.

A common source of process contamination is the use of ordinary carbon steel tools on stainless steel fasteners and production equipment. The integrity of critical machinery that meets regulatory standards can be compromised by routine cleaning or maintenance with incompatible wrenches, pliers, cutters, awls, nut drivers or other hand tools.

Here's the risk: A sterilized carbon steel screwdriver is still a ferrous tool that should *never* touch non-ferrous (stainless steel) materials. Free iron migrates naturally to the surface of carbon steel. So even the hardest chrome-plated tools leave tiny iron particles on stainless surfaces as equipment is installed, fasteners are turned, edges are smoothed or parts are repaired. Even in low-humidity cleanrooms, the exposed steel dust reacts with oxygen (oxidation) to form iron oxide or pitting corrosion that becomes visible much later. At that point, environmental sterility is compromised.

Some production engineers and maintenance technicians proceed with a false sense of protection because they autoclave general industrial tools between uses in a sterile setting. While this is effective initially, each successive sterilization cycle degrades the electroplated coating applied to carbon steel or chrome-vanadium steel for corrosion resistance.

After as few as 20 autoclave cycles, the plating may chip, flake and peel – a second source of airborne particulates that compromise any process requiring a sterile site. Tiny chrome particles from repeatedly autoclaved carbon tools contaminate sterile processes, either directly from the tool or from a technician's hands, hairnet or lab coat. This contamination potential is particularly troublesome for food processing, hospitals, biotech labs, scientific research, microchip production or other high-tech fabrication.

Moreover, extra time and labor is diverted to sanitize autoclaves tainted by tools with degraded plating.

➔ **Key point:** Sterilization alone is insufficient to ensure the efficient operations and long-term integrity of hand tools. Instead, the solution is provided by stainless steel tools that have become standard for risk-monitored industry processes.

Solution: Stainless steel brings multiple benefits



Durability, hardness and corrosion resistance are the main advantages of stainless steel hand tools for sensitive production areas. They also bring notable cost savings over their working lifespan, which extends significantly longer than for frequently sterilized carbon counterparts.

A key advance of stainless steel for critical operations is that it's a **homogeneous material** – with no plating that can separate from the steel. As a result, hand tools don't compromise sanitation or sterility.

Stainless steel is a low-carbon alloy that contains at least 10 percent chromium to resist corrosion. Contact with oxygen forms a passive (non-reactive) chromium-oxide surface film lacking iron content – unlike chrome plating's ferrous surface.



A protective process called passivation often is used after fabrication to maximize the **natural corrosion resistance**. Under ideal conditions, the original oxide film completely covers all workpiece surfaces. In actual practice, however, microscopic iron particles from cutting tools may be transferred during machining.

For a maximum safeguard against corrosion, newly fabricated stainless steel devices are immersed in a passivating bath of citric acid or nitric acid. The result is superior endurance in all environments, including salt spray exposure during marine industry applications.

As an added benefit, the invisible chromium-oxide layer is **self-repairing**. If a tool is scratched, nicked or chemically damaged, chromium in the steel reacts again with oxygen – even in small amounts – to renew the rust protection. This immediate self-sealing is indispensable for two reasons:

1. It averts any interaction between free iron and oxygen.
2. It's accomplished without plating, which means stainless instruments tolerate frequent sterilization through thousands of autoclave cycles without deterioration.

These quality control assurances are as essential in delicate industrial environments as they are in hospitals and dental offices, where stainless hand tools have been the standard for decades. Applying the same technology for other sterility-critical applications led to stainless steel tools for industries that are regulated or that monitor interior environments rigorously, such as:

- Pharmaceutical production
- Life sciences research
- Food preparation
- Semiconductor clean rooms
- Avionics and aerospace
- Nuclear energy

In addition to longevity and safety, tools designed for the rigors of daily maintenance also share other characteristics with their medical-grade counterparts. Each variety generally is fabricated from "400 series" stainless steel, valued for resistance to stress cracks and other wear.

Type 420 is a martensitic alloy typically used by leading manufacturers, such as Athlet. for industrial-strength tools such as screwdrivers, nut drivers, wrenches, pliers, cutters, awls and interchangeable bits. A multi-level hardening process provides outstanding tensile strength and torque capability.

Martensitic steels are distinguished from other stainless steels in their ability to achieve high hardness by a heat treatment that produces martensite, a supersaturated solid solution of iron.

The Aven AntiCor® line, for example, delivers exceptional performance in critical applications.

To preserve the nonferrous integrity of specialized hand ware, storage apart from ferrous tools is essential. Technicians use a stainless steel toolbox, plastic tray or other carrier that fits in a sterilization unit.



Cost-effective ROI: Extended lifespan earns savings

Reducing contamination vulnerability is accompanied by measurable financial benefits during the first year of using stainless steel maintenance equipment, which has an **ROI of 100 to 200 times** that of equivalent carbon steel hand tools that fail prematurely.

While carbon models have lower purchase costs, they become unusable in critical areas within about month of daily sterilizing and must be replaced. Chrome plating can begin to deteriorate after roughly two dozen autoclave cycles, creating airborne particles and ferrous contamination on contact.

The return on investment in stainless tools can be realized in as soon as nine or 10 months. And over years of production usefulness though thousands of sterilizations, stainless steel workpiece savings accumulate dramatically – particularly for multi-location companies.

Conclusions

- Stainless tools are a GMP standard in critical processes.
- Strength, hardness, torque capacity are industrial-grade.
- ROI achieved in less than a year by avoiding frequent tool replacement.

→ **Key point:** A one-time upgrade to the **most appropriate hand tools** for critical operations is a good manufacturing practice (GMP) in terms of process protection and cost containment.

- - -

© 2014, Aven, Inc.