Stain and Particulate Troubleshooting in Steam Sterilization

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The phone rings. *"Hi, this is OR 2 and we need another set right away. We just opened for our next case and there are brown stains and little black flecks in the tray. We caught it before we put it on the back table, so we don't have to replace all the trays. We just need another one of Dr. Wright's specialty trays right away."*

You open more cases, and there are black flecks in everything! What will you do? Contamination is always a bad outcome, and surgical instrument spotting, staining and corrosion pose significant challenges. Specks of debris or particles can lead to canceled procedures, effectively shutting down surgery. Even worse, they can jeopardize patient safety if their presence goes undetected and the devices are used during the procedure. These issues can be resolved by carefully considering the instrument processing process and having a thorough understanding of the potential causes of staining and particulates. This article provides a practical tutorial for analyzing stains, assessing the process, and identifying potential causes and remedies.

The diagram in **Figure 1** shows how all the pieces come together and converge on the steam sterilizer. Think about all the places these different items have been, particularly vendor representative sets and the wheels on case carts.

A two-step evaluation should be conducted for the stain or particle:

1. Identify it – Use magnification.
2. Analyze it – Focus on the process.

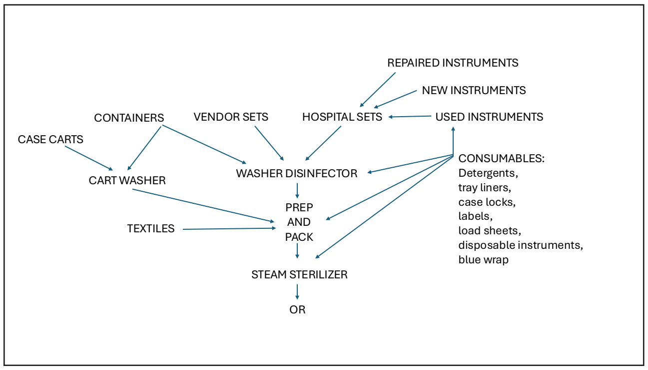
Steps for effective identification

It is essential to identify where and when the stain is occurring. Is it in the Operating Room (OR), decontamination area, the washer (this could be a cart washer or a washer-disinfector) or the sterilizer? **Figures 2** and **3** show a stain and indentation on blue wrap, which were identified by magnification with a jeweler's loupe or microscope. The brown stain in the blue wrap indentation was caused by a water softener failure. It is essential to inspect stains closely to ensure only one type of stain is present and seek to identify the cause. The stain in the example in Figures 2 and 3 occurred after steam exposure. Only after inspecting and identifying the stain can appropriate solutions be identified.

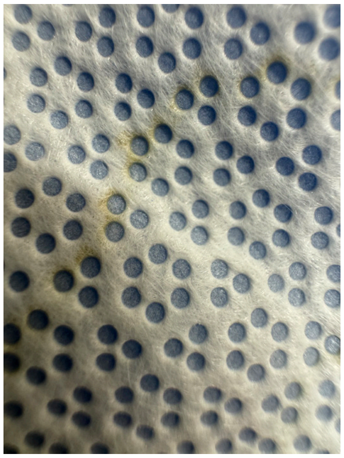
Water softeners replace calcium or magnesium with sodium (see example in **Figure 4**), and resin beads are inside the softener canister (see **Figure 5**). The beads can form a channel so that hard water can pass through the softener. They can fail, however, and the salt can also fail to regenerate the resin beads. The organization's Facilities department can conduct a simple water test to determine the hardness of wash water. Softener performance is one of the primary causes of brown stains on instruments, tray liners, and blue wrap.

ANSI/AAMI ST79:2017/(R)2022 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* recommends to "rinse with water of the quality specified by the device manufacturer. When the water quality is not specified by the device manufacturer, refer to the water standard." The new water standard, ANSI/AAMI ST108:2023 *Water for the processing of medical devices*, provides testing procedures and frequencies for testing the two types of water to be furnished to the washer. They are quarterly tests, but the softener's failure may not follow the quarterly schedule. Therefore, it is necessary to perform the test whenever an issue is identified or suspected.

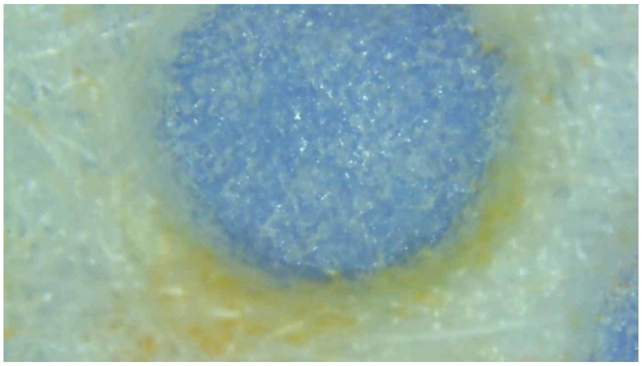
An example of a brown stain on a tray liner is shown in **Figure 6**. Under magnification (see **Figure 7**), the stain can be determined to be mostly particulate, which would require a different analysis than in the example of the water softener failure. One can clearly see how the magnification process makes it easier to focus on different causes of the brown stain. I recommend facilities purchase a microscope for the purpose of this identification; these are available for



1: How all pieces come together and converge on the steam sterilizer



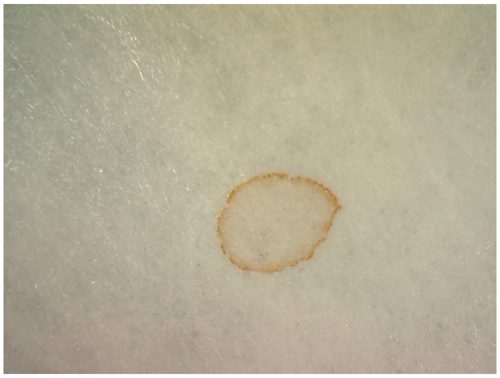
2: Stain and indentation on blue wrap



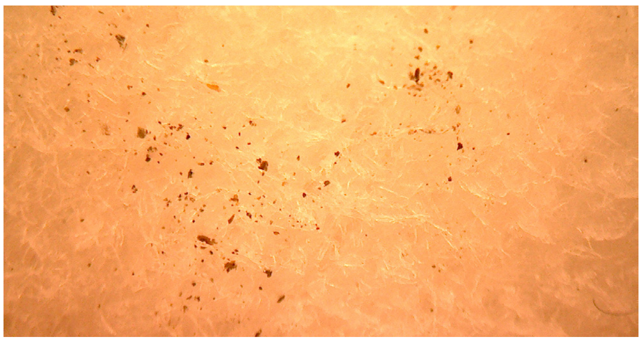
3: Stain and indentation on blue wrap under magnification

4: Water softener example

5: Resin beads that are inside softener canister



6: Brown stain on tray liner



7: Brown stain under magnification showing mostly particulate

$40 or less online (search for "digital microscope").

Steps for effective analysis

After identifying the stain or particle, the next step is determining which vendor the facility uses for water treatment and who is responsible for maintaining that relationship. It is critical to verify:

- Who inspects the softeners
- Who validates the critical water
- Who performs daily boiler water testing
- Who calibrates the detergent mix for the washer
- When all the inspection, validation, testing and calibration steps were last conducted

There are two typical ways a lab can analyze the stain or particle: inductively couple plasma (ICP) optimal emissions spectroscopy and Fourier transform infrared spectroscopy (FTIR). ICP measures the elemental composition of materials. It only provides the list of the elements (e.g., the tan stain on the wrap exhibits calcium with lower levels of silicon, magnesium phosphate, aluminum, zinc and copper). FTIR is a more sophisticated and expensive process. The brown stain on textile (see **Figure 8**) was submitted for FTIR analysis, and **Figure 9** shows the FTIR analysis output data. There are two curves; one is of the stain, and the chemist then matches the stain (as well as possible) to known compounds. In this case, the stain matched bacitracin.

We found that the surgeons were using liberal amounts of bacitracin when suturing the surgical site. It is important to remember that the steam sterilizer is a 270° final rinse. The OR cleaning and temperature of the wash water were not adequate to release the bacitracin from the hinges. The steam sterilizer was hot enough to "melt" it out of the hinges. The steam sterilizer appeared to cause the stain when it in fact originated in the OR.

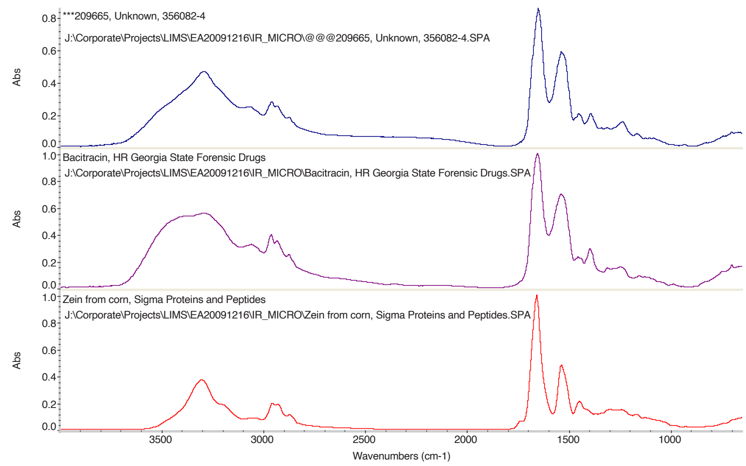
Figure 10 provides an example of a green particle that appeared on fabric in the OR. The FTIR analysis determined it was a phenolic resin (a plastic). It appeared after steam sterilization, but it was necessary to analyze and discover where it originated. **Figure 11** depicts the drain screen in a washer-disinfector. Note all the plastic bits and debris from the wash present on the screen. Now, visualize what happens to pieces of plastic that are smaller than the openings in the screen. They flow through the screen, down into the sump, and are then recirculated by the washer's spray arms, which can embed in the nooks and crannies of instruments. If they're not seen in the preparation and packaging process, they can be flushed out by the steam sterilization final rinse and make their way into the OR.

Another commonly seen discoloration is rust. **Figure 12** shows rust stains caused by a pit in the instrument. It is not rusting beneath the surface of the stain; instead, it is rust "bleeding" from the center of the pit. Rust can also emerge from welded pieces on the instrument as well as from laser etching used for instrument identification. **Figure 13** provides a good illustration of the small brown stain. When it was inspected under the microscope, we could see the pit in the center and how the rust bled out around the pit. *Note: To determine if a brown or orange discoloration on a device is a stain or rust, rub a pencil eraser over the discoloration; if the eraser removes the discoloration and the surface metal underneath is smooth and clean, it is a stain. If the eraser removed the discoloration, but a pit mark remains, this is corrosion, and the instrument will continue to rust.*[1]

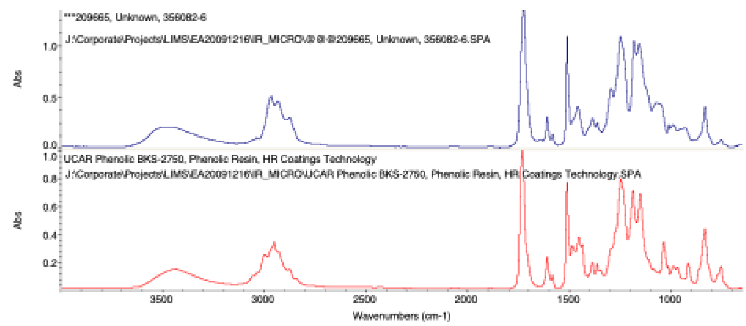
8: Brown stain on fabric

Why does rust form? The susceptibility of stainless steel to pitting depends on whether the metal is 300 or 400 series. There are 300-series stainless steel instruments used in sterile processing (basins are a prime example of this type of stainless steel, and some silverware is also manufactured with 300 series stainless steel—it is marked 18-8). The 300-series instruments can remain in moisture without staining (think of how 18-8 silverware does not stain when left in the dishwasher or sink overnight).

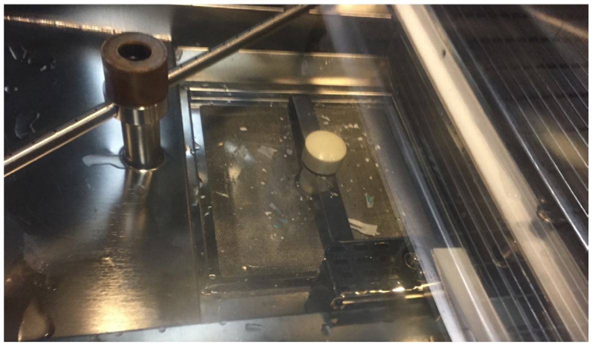
Stainless instruments in the 400 series are "hardenable" and may have a sharp edge or hinge (think of instruments that cut). These instruments can be identified by their magnetism (a magnet will stick to them). Chef knives used at home that are in the 400 series will rust if left wet overnight; therefore, it is recommended not to leave them in the dishwasher or water-filled sink. Chef knives also need periodic conditioning, cleaning and sharpening. Likewise, 400-series stainless steel instruments require conditioning known as passivation. This is either a nitric, citric or phosphoric acid bath that the instrument undergoes after reconditioning or when manufacturing removes the surface iron and rust by buffing or grinding. The acid removes surface iron and rust while sparing the chrome and nickel. Stains on 400-series stainless instruments



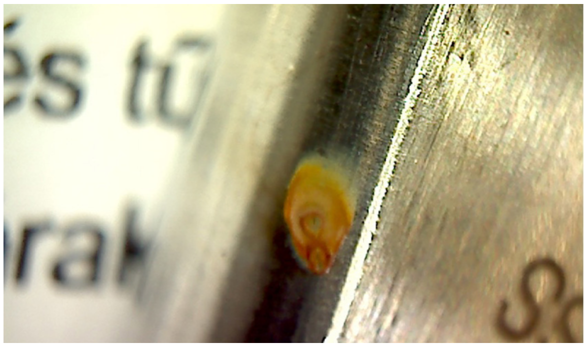
9: FTIR output analysis of brown stain



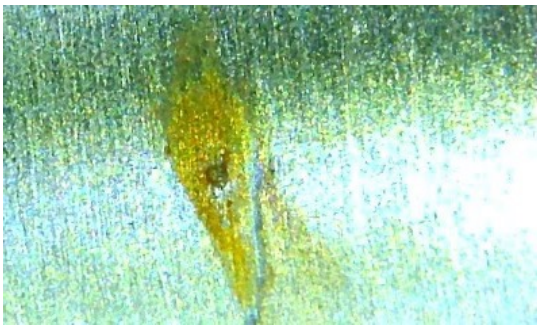
10: FTIR analysis of green particulate that appeared on fabric in OR



11. Phenolic Resin



12: Rust stain caused by a pit in the instrument



13: Small brown stain under microscope shows rust "bleeding" from the pit

will inevitably occur, so maintaining a good relationship with an instrument reconditioning service is an effective way to stay on top of proper repair reconditioning and passivation.

Understanding how steam sources can cause stains

Instrument stains can also occur from sources in the steam sterilizer and steam system. The steam delivery piping can rust, for example, and steam boilers can "carry over" if boiler water "burps" into the steam line. The boiler water might also foam. Chemicals can be injected into the boiler steam to prevent corrosion.

Wet steam is the most common way contaminants are carried into the sterilizer, which can cause staining or the presence of particulates. Annex O in ST79: 2017/(R)2022 includes a table identifying malfunctions that can affect the steam system's performance. The types of malfunctions include:

- Steam dryness not between 97% and 100% (i.e., excess water in the steam)
- Boiler feedwater containing too many noncondensable gases (i.e., air)
- Water treatment affecting the level of noncondensable gases [i.e., changed (seasonal, for example) or unusual or increased demands placed on the steam system]
- Boiler not properly maintained
- Improperly insulated steam lines
- Malfunctioning or absent trap in the steam line

Additionally, Annex L in ST79 includes another list of things to check. For example, if wet steam continues to be a problem, "priming" could be occurring in the boiler, causing water droplets to be delivered in the steam. Priming or foaming (which results in carryover of boiler water) can result from treating feedwater incorrectly, setting the boiler water level too high, forcing a boiler that needs internal cleaning, violent boiling under fluctuating load conditions, and/or a high level of total dissolved solids (typically 2,000 ppm).

Table 6 of ST108 states to check steam condensate at the sterilizer for conductivity and pH. These measurements are usually taken at the boiler or steam source already (the Facilities department can usually perform the measurement). In the case of a large boiler plant, these are typically taken daily. The Facilities department should be asked to take the same measurements in the Sterile Processing department. **Figure 14** shows a schematic of typical boiler steam outlet piping. The pipe design disengages water that could "burp" from the boiler and drains it as fast as possible. That is done by the steam trap, which is an automatic drain valve. Traps have very small discharge orifices and are subject to plugging, especially in the boiler outlet piping. If the trap plugs, staining is very likely because the boiler water contains dissolved solids. Without a functioning trap, the dissolved solids can flow to the sterilizer. **Figure 15** demonstrates what the piping looks like in actuality (the boiler is on the left, the header is at the top and the trap is in the upper right).

The importance of isolation

The third step of stain and particulate troubleshooting is to isolate the steam and wash process individually. To do this, it is necessary to identify the most likely instruments (is it a heavy orthopedic set, for example, or is the problem appearing on peel packs as well?). Make up two loads with the instruments most likely to present with issues. Sterilize one test load in house and have the other test taken elsewhere (across town at another facility that has a similar sterilizer setup. If the steam process caused the issue, it will show up in one set versus the other).

It can also be determined if the wash process is causing staining. Again, make up two test loads with the instruments most likely to experience staining. Run one set through the in-house washer and take the other set for washing at another facility with a similar washer setup. Then, bring both sets to the SPD and steam sterilize them (again, because one set will have been washed remotely and another washed in house, it can be determined whether the wash process caused the issue).

The wash process for textiles should also be investigated. Acquire either disposable or brand-new, preferably white, textiles and then identify the most likely stain. Make up two test loads, one with normal textiles that were pre-inspected for stains and one with the new or disposable test textiles. Sterilize them and see which one contains the stains or particulates.

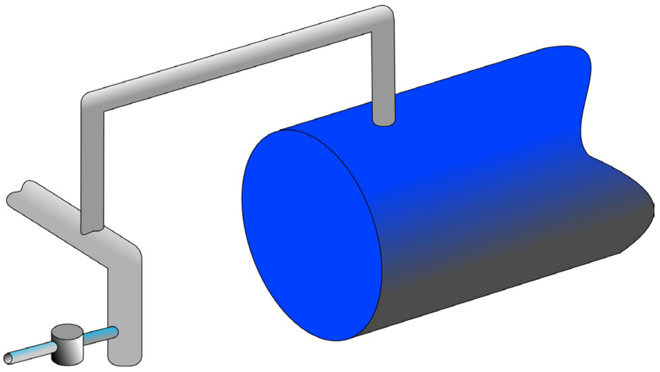
A word of caution: Once stains or particulate matter are identified as a problem, personnel often become hyper vigilant. In pursuit of a solution to these issues, it can be tempting to try many different things at once. This is a natural approach; however, it is important to identify current stains (those identified today and yesterday), not those that happened six weeks or even months ago.

Conclusion

It is vital to recognize that steam is not just used for sterilizing, but also for rinsing. It is a high-temperature final rinse that serves as a "final final" rinse. Ensure that all stages of sterile processing are assessed as well as the process for each stage. Work with the water treatment company, which usually has a lab for testing. Also, investigate third-party labs and consider washing at a partner facility, rely on the washer detergent vendor to recalibrate, and Facilities Engineering for assistance. Lastly, be sure to identify what is happening (defining the contamination and obtaining samples), analyze and have system testing for water, steam and air (onsite and in labs), isolate to determine whether the stain or particulates were caused by the washing or steam process, and implement the appropriate solution.

REFERENCE

HSPA. *Communiqué*. Sept/Oct. 2018. Schultz R. Instrument Whisperer column. “Do Your Surgical Instruments Look Ugly?” pp. 90–92.



14: Schematic of typical boiler steam outlet piping

15: Boiler steam outlet piping in actuality