Technical Data Monograph

Prolystica® Ultra Concentrate HP Neutral Detergent
Ability to Handle Hardness and Metal Ions in Water

STERIS

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1 Background

Water Impurities

Water can contain a number of chemical contaminants that have potential negative implications on surgical instrumentation functionality and useful life. These same contaminants can affect the operation of the washer disinfectors and the effectiveness of the products used to clean these instruments. Water hardness ions, calcium (Ca^{2+}) and magnesium (Mg^{2+}), can precipitate with the alkalinity ion carbonate ($CO3^{2-}$) to form hard water scale or deposits. **Image 1** shows the results of scale deposition in a washer. Visible scale in a washer is an indication that the instruments washed in that washer will have scale deposits as well (just not as visually apparent).

Image 1. Scale Deposits in a Reliance® 444 Washer from STERIS.

Common metals such as copper (Cu^{2+}), iron (Fe^{2+} or Fe^{3+}) and zinc (Zn^{2+}) can deposit on instruments and washers/disinfectors without needing alkalinity or other driving force to do so. The deposits are seen as red to brown (iron), green (copper), or black (iron or zinc) stains. Additionally, once the metals have deposited on the surface, they can cause galvanic corrosion of the stainless steel, which may be seen as a rainbow effect. **Image 2** shows a hemostat which has this type of staining.

Image 2. Rainbow Staining on a Hemostat

Water hardness and transition metal impurities are a concern when cleaning surgical instruments because of the damage they can cause to the appearance and functionality of the instruments. Water hardness is defined as the concentration of calcium and magnesium in water. Hardness deposits, or scale, are caused by the precipitation of calcium and/or magnesium carbonate. These carbonates are very insoluble in water and can form rapidly when conditions are conducive. Scale deposits on instruments can

accelerate corrosion, harbor and protect microorganisms from sterilization processes, and are visually unappealing. Scale formation is most likely when high hardness levels (>150 ppm hardness as $CaCO_3$) are present. However, scale can form in lower hardness waters when the water is heated, as during a wash cycle in a washer/disinfector, or if the alkalinity is increased, as is the case with the use of alkaline cleaning chemistries.

Most potable water contains a blend of carbonate and bicarbonate. The amounts of carbonate and bicarbonate are often referred to as the carbonate alkalinity and bicarbonate alkalinity, respectively. The amounts of each are important because the carbonate ion combines with calcium and magnesium to form hard water scale. The total alkalinity is defined as the sum of the carbonate, bicarbonate and hydroxide alkalinity. The hydroxide alkalinity in potable water is generally very small relative to the total alkalinity and is not important for our purposes. The amount of carbonate and bicarbonate present in water is determined by the pH and total alkalinity of the water. Even in cases where the potable water is naturally lower in pH, when the pH is increased, as when an alkaline detergent is added, bicarbonate is converted to carbonate. Since calcium and magnesium carbonate are very insoluble, the carbonate salt usually precipitates, forming hard water scale. Chelants or sequestrants interfere with this reaction, preventing scale formation.

One area where water hardness may be beneficial to the operation of washer disinfectors is in the reduction of foaming of some cleaning chemistries. Foaming in automated washer disinfectors can interfere with the operation of the spray, slowing and even stopping arm movement in extreme cases. The hardness cations (Ca^{2+} and Mg^{2+}) interact with some surfactants, reducing their foam in high pressure washers. In softened or deionized water, the hardness cations have been removed. This may exacerbate foaming problems.

Preventing Scale and Stains (metal deposits)

STERIS cleaning chemistries contain chelants and sequestrants that prevent scale and metal deposits from forming on surgical instruments or equipment. Chelants work by combining with metals including calcium and magnesium to form a chelate. That is, one molecule of the chelant combines with one or more ions of calcium, or another metal, to form a new complex. This complex prevents the calcium or magnesium cations from interacting with the carbonate anions preventing scale formation. They also prevent metals such as zinc, copper or iron from depositing on an instrument or washer surface where they could cause staining or corrosion.

Sequestrants work in a different manner. One sequestrant molecule may interact with many metal ions and salts. Sequestrants do not prevent the formation of calcium or magnesium carbonate. Rather, they interact with the small calcium and magnesium carbonate particles preventing them from aggregating into a hard scale deposit. The particles repel each other and remain suspended in the water, or form loose aggregates which may settle. These loose aggregates are easily rinsed away and will not form a deposit.

To compensate for poor scale prevention performance of the cleaning chemistry product, some companies might recommend using softened or deionized water throughout the wash cycle to remove the water hardness cations. If metal deposits are a problem, deionized or reverse osmosis (RO) water might be recommended throughout the wash cycle, to not only remove the hardness ions, but also the metal ions. The cost of using softened or deionized/reverse osmosis water throughout is expensive and can add significant cost to each load of instruments processed. Bracketing the possible scenarios (Highest water usage and lowest water usage) with a standard instrument cycle in a Reliance® 444 Single Chamber Washer/Disinfector using deionized water, instead of tap water as the makeup water, would cost $2.62 per cycle. A Vision® Single Chamber Washer/Disinfector running a Standard Instrument Cycle (not a cycle using Prolystica Ultra Concentrate Cleaning Chemistries) would cost $0.91 per cycle running deionized water only. These water costs can exceed the cost of the cleaning chemistry used. (See Appendix 1 for these and additional calculations). Utilizing a cleaning chemistry that allows for the use of “untreated” tap water in the wash phase and softened water or deionized (or RO) water only for the final rinse could result in significant cost savings. There is a cost to using a cleaning chemistry with poor ability to handle hard water or metal ions in water.

Purpose

The set of experiments below explored the ability of the chelant-sequestrant package in the Prolystica Ultra Concentrate HP Neutral Detergent to prevent precipitation of calcium carbonate in 200 ppm concentration of calcium and equivalent carbonate concentration. This represents the ability of the product to handle hardness and metal ions in potable water sources and prevent discoloration and damage to instruments and washer equipment. A concentration of 200 ppm calcium would represent fairly hard water.

Calcium was chosen because it is the more abundant of the two hardness ions in most water sources and has lower solubility with carbonate than magnesium. In other words, calcium is the worst case for scale formation. Prolystica Ultra Concentrate HP Neutral Detergent performed well at all use dilutions with improved effectiveness as the use concentration increased.

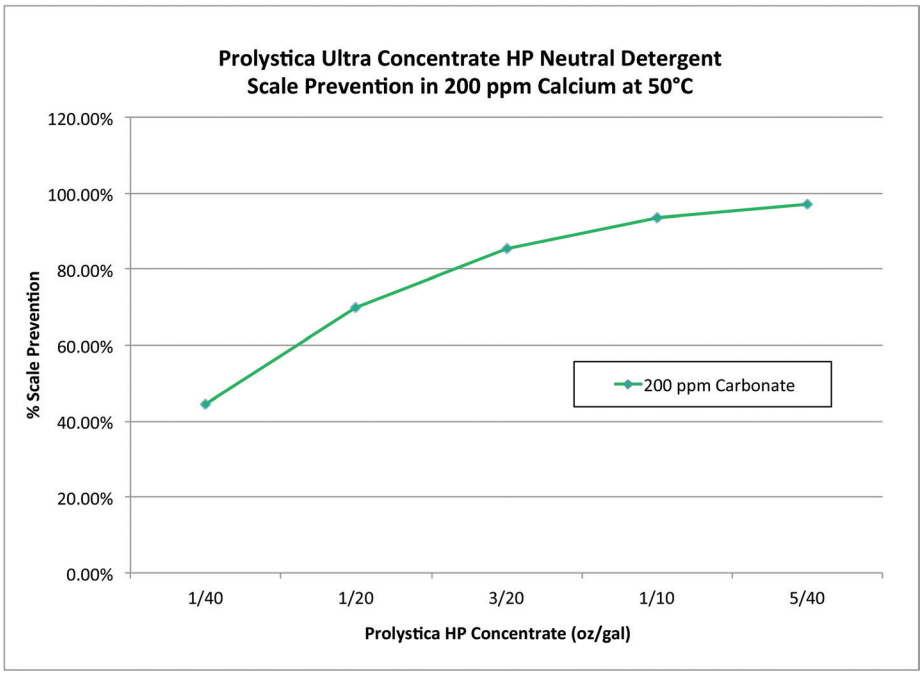
Method

Solutions of calcium (200 ppm as $CaCO_3$) were dosed with different amounts of Prolystica Ultra Concentrate HP Neutral Detergent. These solutions were then stressed by adding carbonate and heating to 50°C for at least 20 hours. Each solution was then filtered to remove any precipitated calcium carbonate (scale deposits). Finally the filtered solutions were analyzed for calcium. From this data the percent calcium in solution was calculated. **Figure 1** shows the results for the 200 ppm Ca as $CaCO_3$. The Competitive chemistries were run across their use dilution ranges. The Asepti-Solid™ Neutral Detergent was dissolved manually according to the stated claim that two 2.5 pound bricks is equivalent to 15 gallons of a normal detergent. The OptiPro™ Neutral Detergent was dissolved manually according to the stated claim that two 2.8 pound bricks is equivalent to 15 gallons of a normal detergent.

Results and Discussion

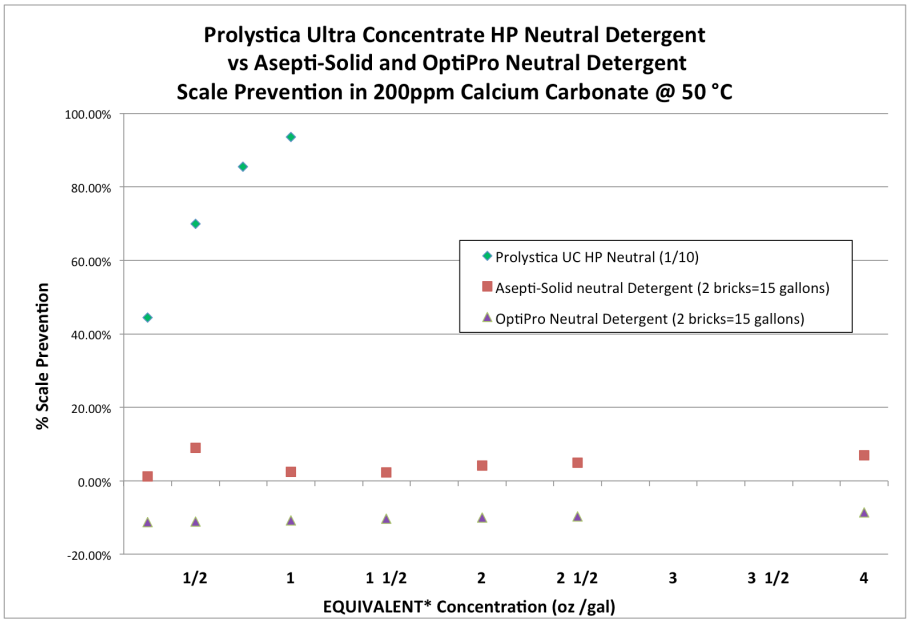
The 200 ppm carbonate conditions are a very difficult case for scale formation. However, the data generated is very useful in showing the increased effectiveness of the chemistries as the concentration of the cleaner is increased. Prolystica Ultra Concentrate HP Neutral Detergent was able to keep 100% of the calcium from precipitating under the most aggressive 200 ppm calcium and carbonate conditions.

Figure 1. Prolystica Ultra Concentrate HP Neutral Detergent Performance in 200 ppm Hard Water.



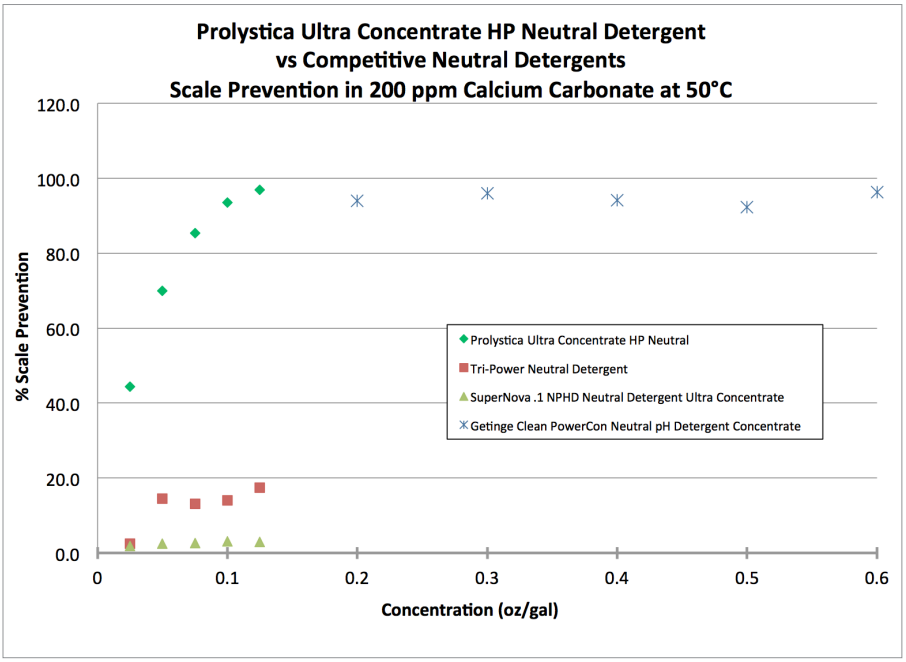
In comparison, a sample of Asepti-Solid Neutral Detergent (Huntington Brand/Ecolab®) and OptiPro Solid Neutral Detergent (Ecolab) were tested using the 200 ppm calcium – 200 ppm carbonate condition. **Figure 2** shows the performance of the solid neutral detergents in comparison with the Prolystica Ultra Concentrate HP Neutral Detergent at equivalent use dilutions. The lack of any increased performance with concentration of the Asepti-Solid Neutral Detergent and the actual decrease in the performance of the OptiPro Solid Neutral Detergent indicates that these chemistries will not control water scale formation or prevent metal deposits from forming on surgical instruments or equipment.

Figure 2. Prolystica Ultra Concentrate HP Neutral Detergent Performance vs Competitive Solid Neutral Detergent Chemistries.



Other competitive liquid neutral chemistries were also tested in comparison to Prolystica Ultra Concentrate HP Neutral Detergent to evaluate their ability to inhibit scale formation across their use dilution ranges. None were able to match the performance of Prolystica Ultra Concentrated chemistry at the low concentrations of use. The only product that appeared to have at least close activity was PowerCon™ Neutral pH Detergent Concentrate (Getinge). It has a significantly higher usage (dilution) range for the product listed on the label. Tri-Power Neutral Detergent (United Biotech) and SuperNova®.1 NPHD Neutral Detergent Ultra Concentrate (Case Medical) were tested but demonstrated no scale inhibition activity.

Figure 3. Prolystica Ultra Concentrate HP Neutral Detergent Scale Prevention Performance in 200 ppm Calcium with 200 ppm Carbonate vs Other Neutral Detergents.



Once metal deposits have formed on instruments or equipment, they can be very difficult to remove. In fact, if corrosion occurs near or under the deposits, then the metal surface may be permanently damaged and may not be able to be returned to its original condition. Prevention of metal deposits and corrosion is the best approach to maintaining instruments allowing deposits to occur costs time and money in refurbishing and/or replacing instruments.

Conclusion

Prolystica Ultra Concentrate HP Neutral Detergent is formulated with chelants and sequestrants to protect instruments and equipment from hard water scale formation and metal deposits. Use of cleaning chemistries that do not contain chelants or sequestrants put instruments and equipment at risk of damage and may reduce their longevity. Using softened, deionized, or reverse osmosis water for entire wash cycles is an expensive alternative to choosing chemistries that effectively clean and protect medical devices against the negative effects of water.

Appendix 1. Cost Calculation of Deionized Water Use in Washer/Disinfectors from STERIS Corporation.

The estimate of capital equipment purchase and ongoing operational costs was based on assumptions given to an outside water treatment company. These assumptions were for a facility operating one Reliance 444 Washer and two Vision Washers, each running an average of ten instrument cycles per day, five days per week. The defined washer equipment and numbers of daily and weekly cycles resulted in the following system requirements:

- Average Flow Rate = 6-8 GPM
- Max Flow Rate = 10-12 GPM
- Annual Usage = 560,000 Gallons
- Desired Resistivity (purity) = 1 Mega Ohm

The estimated first year cost and the anticipated reoccurring costs are shown below in **Tables 1 and 2** (Reoccurring cost includes mixed bed and carbon filters but does not included sanitization costs).

Table 1. First Year Cost

Capital Equipment	$24,500
Maintenance Cost	$15,500
Cost per gallon	$0.071/gallon

Table 2. Reoccurring Cost

Capital Equipment	$0
Maintenance Cost	$14,960
Cost per gallon	$0.026/gallon

The cost of deionized water used in standard instrument cycles in both the Reliance 444 Washer and the Vision Washer is shown below.

Table 3. Calculations for Reliance 444 and Vision Washers, Standard Instrument Cycle.

Washer	Reliance 444 Washer	Vision Washer
Gallons per cycle	100.8	35
Cost of DI water (per gallon)		
First Year	$ 0.071	$ 0.071
2+ Years	$ 0.026	$ 0.026
DI Water Cost Per Cycle		
First Year	$ 7.16	$ 2.49
2+ Years	$ 2.62	$ 0.91

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