REUSABLE MEDICAL DEVICE STERILIZATION- ORGANIC BUILDUP IN LONG LUMENS

Application Note Med01-01

Complex designs and narrow lumen present obstacles for duodenoscope cleaning and sterilization. Bacteria and tissue residuals complicate the reprocessing of reusable medical devices. The Nova Process which uses NovaKill™ with supercritical CO_2 successfully inactivated bacterial endospores in both hard water and serum challenges inside long narrow lumen devices.

REPROCESSING AND STERILIZING RESUABLE MEDICAL DEVICES

Reusable medical devices have been repeatedly linked to numerous infectious outbreaks. The elevator chamber in duodenoscopes and long narrow lumen used in a variety of reusable medical devices pose specific challenges to cleaning, disinfection and/or sterilization. Failure to effectively remove and/or inactivate bioburden and completely dry lumen leads to a rapid biofilm buildup with insurmountable resistance to current disinfection treatments. Commonly used disinfectants such as glutaraldehyde or peracetic acid have been identified as causes of increased tolerance of proteins and biofilms to disinfection methods. Automatic washers used to clean these devices have been linked to infectious outbreaks. Additionally, microbial strains with increased tolerance to disinfectants have been isolated from such washers.

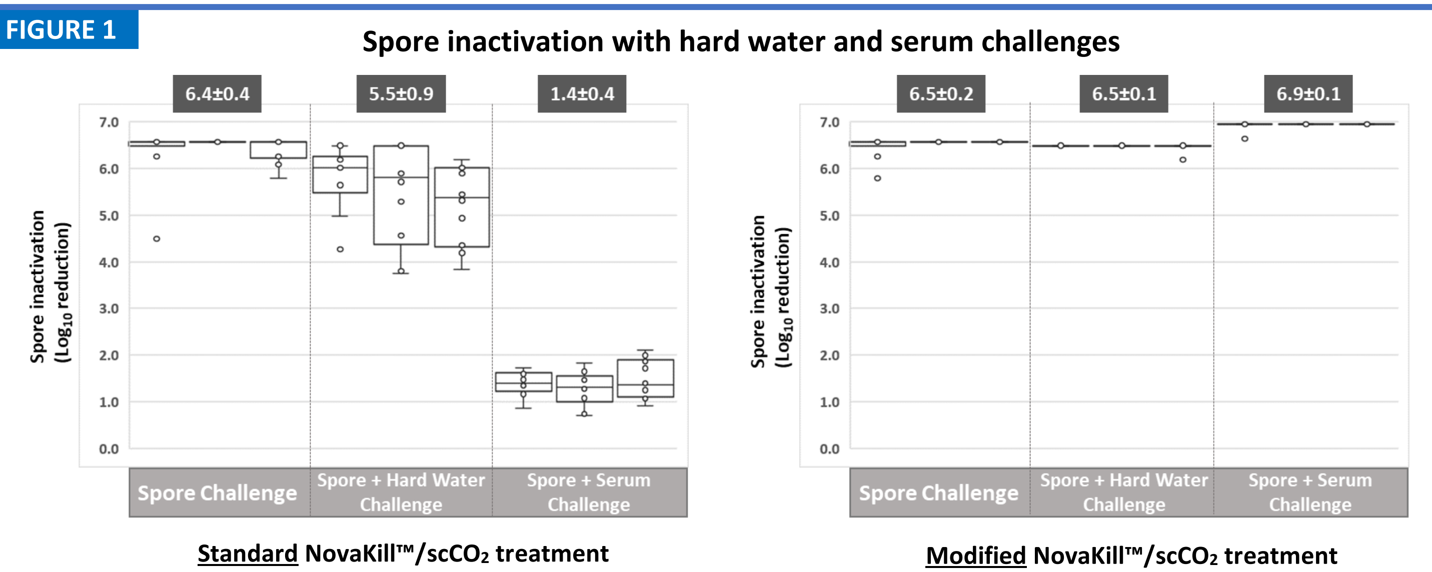
SPORE INACTIVATION WITH SUPERCRITICAL CO_2 STERILIZATION

A non-toxic sterilization modality capable of inactivating a broad array of micro-organisms, including endospores, viruses and biofilms, inside long narrow lumen of reusable medical devices is needed. The NovaSterilis sterilization process (“Nova Process”) has demonstrated very strong sporicidal, and virucidal properties (White *et al*., 2006; Qiu *et al.*, 2009, Setlow *et al.*, 2016). The Nova Process has been shown commercially to be an effective terminal sterilization solution in Tyvek™ medical packaging. The Nova Process has been successfully used as the sterilization process in a 510K cleared medical device that was double Tyvek pouched packaged so as to avoid any risk of contamination until opened in the OR.

OVERCOMING HARD WATER AND SERUM CHALLENGES

Bacillus atrophaeus spores (ATCC 9372) were used as the challenge organism. They were dried (>10^6cfu) onto stainless steel wires in the presence of hard water and then separately, 5% horse serum to create an inorganic and organic challenge to spore inactivation. The hard water and serum challenges were first tested and then measured after a 45-minute $scCO_2$ treatment with NovaKill™ additive by recovering and enumerating spores (**Figure 1, left**). Compared to spores dried onto wires without challenge, the hard water challenge reduced spore inactivation by an average of 0.9 log_{10}, and the hard water challenge reduced spore inactivation by an average of 5.0 log_{10}. However, both challenges were fully overcome when the 45-minute treatment utilized the Nova Process which includes a conditioning step, supercritical CO_2, and the proprietary additive, NovaKill (**Figure 1, right**).

FIGURE 1

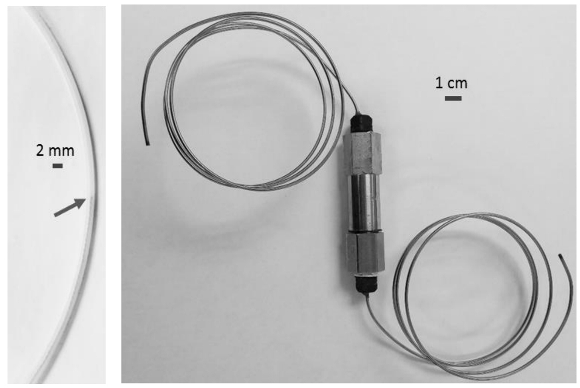


OVERCOMING ORGANIC BUILDUP INSIDE LONG NARROW LUMEN

In order to study spore inactivation inside long narrow lumen, *B. atrophaeus* spores in one condition were mixed with hard water and then in a second condition, mixed with 5% horse serum and then each were dried onto stainless-steel wires which were inserted to the mid-point of a 50-cm long flexible lumen with a 1mm internal diameter (**Figure 2, left**). A longer lumen challenge (2-meter total length) was then completed using a Process Challenge Device (PCD) (**Figure 2, right**) which contained commercial bioindicator spore strips (Mesa Labs, Omaha, NE).

When applying the Nova Process that successfully overcomes hard water and serum challenges (see Fig. 1) to wires inoculated with spores in the 50 cm lumen challenge (Fig. 2, left), both hard water and serum challenges reduce spore inactivation significantly (**Figure 3, left**) However, both the hard water and serum challenges are overcome inside a long narrow lumen when extending the Nova Process and increasing the amount of NovaKill by a factor of 2 (**Figure 3, right**).

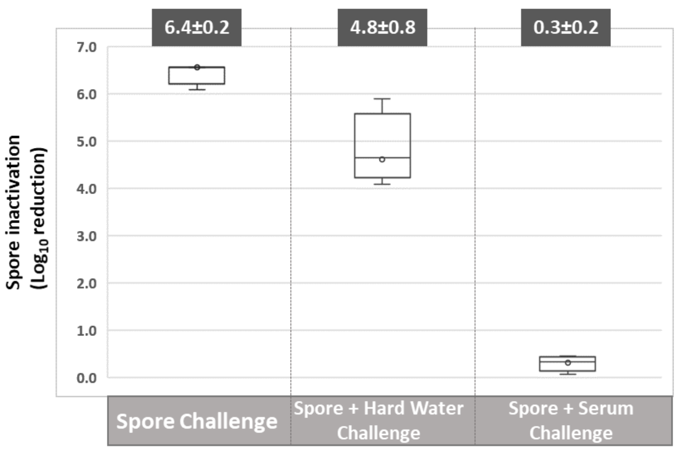
FIGURE 2 **Process Challenge Devices for Lumen Testing**



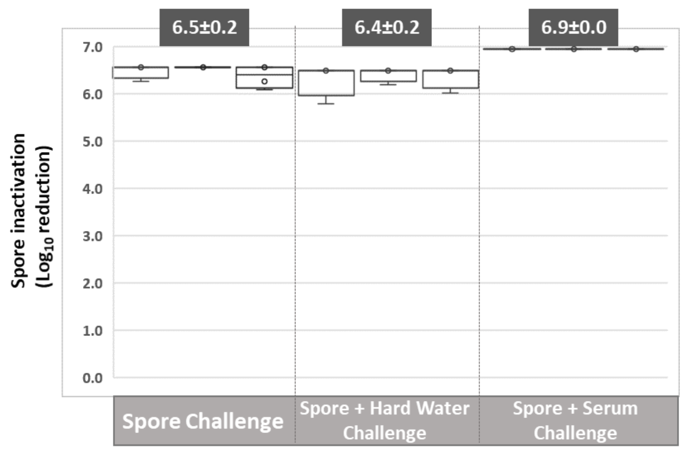
Left: **Stainless steel wire inserted inside a 50-cm flexible lumen (1 mm I.D.).**

Right: **Closed PCD with 1-meter rigid coiled lumens (1 mm I.D.) on each side.**

FIGURE 3 **Spore inactivation with hard water, serum and lumen challenges**



Modified NovaKill™/scCO₂ treatment



Long/Modified NovaKill™/scCO₂ treatment

When testing commercial bioindicator spore strips inside the 2-meter lumen condition, strips were dropped into bacterial broth post treatment to verify full inactivation. The Nova Process successfully sterilized bioindicators strip, without a need to extend time and/or increase the amount of NovaKill™. Sterility was also obtained when 100 µL hard water or 5% horse serum was first dried onto bioindicator strips prior to sterilization inside the 2-meter lumen challenge.

CONCLUSIONS

The Nova Process (pre-conditioning, NovaKill™ and supercritical CO_2) is an effective sterilization modality for spores in the presence of inorganic and organic contamination within long narrow lumen, which is a significant challenge facing the healthcare industry. This approach represents an encouraging path worthy of consideration by medical device companies developing new reusable instruments and devices. The emerging concerns around both young and mature biofilm buildup in reusable medical devices have the potential to be addressed by the Nova Process based on positive sterilization testing (refer to Technical Note Med01-02).

ADDITIONAL READING

Qiu *et al.*, *J Biomed Mater Res Pt B: Appl. Biomater*. 2009;91B:572-8.
Setlow *et al.*, *J. Appl. Microbiol.* 2016;120:57-69.
White *et al.*, *J. Biotechnol.* 2006;123:504-15.