

Absolute Sterility of Omnicam Sleeves after
Intermediate Level Disinfection vs Dry Heat Sterilization

A Thesis

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In Partial Fulfillment of the Requirements for the Degree of
Master of Science in Oral Biology

By

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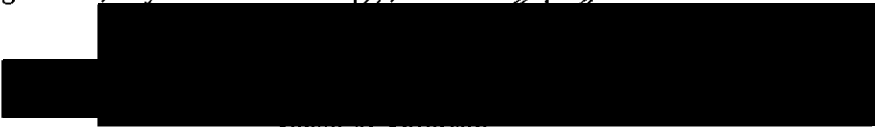

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Absolute Sterility of Omnicam Sleeves after
Intermediate Level Disinfection vs Dry Heat Sterilization

A REPORT ON

Research project investigating the effectiveness of intermediate level disinfection vs dry heat
sterilization of the Omnicam mirror sleeve

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ABSTRACT

Background: The Omnicam is an intraoral scanning device used by Army Dental Treatment Facilities (DTFs). The Army's protocol for the sterilization of the Omnicam mirror sleeve recently changed (in 2016) due to an update in the manufacturer's instructions for use. This change cost the military productivity, time and additional financing. The purpose of this study was to compare intermediate level disinfection of the Omnicam mirror sleeve to dry heat sterilization.

Methods: The Omnicam mirror sleeves were swabbed after dry heat sterilization (DHS), no treatment immediately after intraoral use (NT) and following intermediate level disinfection (ILD). These swabs were then transferred into thioglycolate broth and incubated for 24h. The sample groups were analyzed for bacterial growth by Optical Density (OD) readings at 24h and 48hr, and colony forming units (CFU)/ml on tryptic soy agar plates at 24h.

Results: Three samples for each treatment group (DHS, NT, ILD) were obtained from 31 intraoral scans. One sampled group was thrown out due to contamination, leaving a total of 30 sample groups. All samples in both the DHS and ILD sample groups showed zero OD readings at 24h and 48h and zero CFU/ml after 24h indicative of complete bacterial disinfection. With a 95% confidence interval these findings showed no difference between DHS and ILD. In contrast, all 30 samples from NT group showed OD readings ranged from 0.07-0.71 at 24h-48h and CFU/ml ranged from $5.9-102 \times 10^6$ CFU/ml demonstrating bacterial growth of the Omnicam sleeve after intraoral use in all 30 samples.

The NT was positive for growth in all 30 samples. OD readings at 24h-48h ranged from .07-.71. CFU/ml ranged from $5.9-102 \times 10^6$ CFU/ml.

Conclusions: Within the limitations of this study, intermediate-level disinfection proved to be as effective as dry heat sterilization on the absolute sterility of the Omnicam mirror sleeve. However, CDC guidelines and Omnicam manufacturer's instructions recommend dry heat sterilization of the Omnicam mirror sleeve. Despite this project's findings, the author recommends maintaining DHS until further studies are conducted.

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Disclaimer

This thesis was prepared or accomplished by the author in his personal capacity. The opinions expressed in this project are the author's own and do not reflect the view of the Department of Defense, the Uniformed Services University of the Health Sciences, or the Advanced Education in General Dentistry Two-Year Program.

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INTRODUCTION

Digital workflow technology obtained through intraoral scanning (IOS) and computer-aided design and manufacturing (CAD/CAM) technologies has revolutionized the dental industry. IOS captures a digital impression by projecting light onto the dental arches, to include hard and soft tissue, which is then reflected and recorded by imaging sensors creating point clouds. These point clouds are triangulated by the scanning software and processed into a 3D surface model or mesh. This 3D surface model is the digital alternative to conventional dental impressions. Complete dental arches, prepared teeth, and implant scan bodies are a few examples of the objects that IOS can obtain.

IOS has many benefits when compared to conventional impressions. Among these are the reduction of patient's stress, discomfort, and gag reflex. In addition, optical impressions are time-efficient, eliminate plaster models, trays, and materials, while saving time and space. Moreover, IOS has proven to be reliable (in trueness and precision) for creating single tooth restorations and fixed dental prostheses (1). This is also true for implant restorations (2). Finally, IOS can improve communication with patients and the dental laboratory (1). Despite these benefits, IOS lack accuracy to conventional impressions on dual arch and full arch scanning or when used to fabricate long span fixed prosthesis over 5 units (3, 4). However, with new and better scanners becoming available, and more research being conducted, these limitations may soon be overcome.

The process of IOS presents with similar challenges that obtaining conventional impressions possess. Like conventional impressions, the object must have good isolation from saliva and blood. The margin must be exposed, and the use of retraction cord or hemolytic

agents may be indicated. In addition, IOS has its own inherent unique challenges. These challenges include; unwanted alternative light sources from reflective materials such as metal and polished surfaces, maintaining a relative distance and speed while scanning for the tracking of software, software interface competency, and maintaining data integrity across file types throughout the digital workflow (5, 3). The disinfection process for the IOS sleeve is also a unique challenge inherent with IOS. The method of disinfection has the potential to compromise the durability of the IOS sleeve and alter the reliability of the optics to produce an accurate scan.

According to the 2003 Center for Disease Control and Prevention (CDC) Guidelines for Infection Control in Dental Health Care Settings, intraoral scanners fall into the category of semicritical devices. These are any item that contacts mucous membranes or non-intact skin. These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are permissible (6). Placement in this category creates challenges to the practitioner in sterilizing the IOS without damaging the equipment. Due to the categorization of the IOS as a semicritical device, the CDC requires heat sterilization or high level Disinfection (HLD) with specialized chemical solutions. The Military tends to discourage HLD due to the safety issues surrounding the handling and disposal of these agents. The CDC also acknowledges that some devices such as digital radiography sensors and other high-technology instruments like, intraoral cameras, electric perio probes, and lasers, are affected by sterilization or HLD. It states these semicritical items that cannot be reprocessed by heat sterilization or high-level disinfection should, at a minimum, be barrier protected and after

removing the barrier, the device should be cleaned and disinfected with an EPA-registered hospital disinfectant (intermediate-level) after each patient.

The main challenge in the military is the preference to sterilize items utilizing autoclave. However, autoclaving the CEREC Omnicam mirror sleeve, due to the use of steam and pressure, tends to be corrosive to the IOS device and degrades the accuracy of the optics. Additionally, utilization of a barrier is not recommended by the manufacturer because they introduce distortion during the scan due to the barrier trapping in moisture and folding in on itself. To overcome this issue, barriers that only cover the scanning mirror sleeve and not the glass window were proposed. However, this partial barrier technique is not suggested due to the ledged interface between the mirror sleeve and the glass window potentially being the most likely place to harbor transmitted bacteria.

It was because of these challenges presented by sterilization that IOS manufacturers traditionally recommended to merely wipe the camera after each use utilizing an ILD. Many IOS cameras did not have detachable sleeves separate from the camera housing and optics, making sterilization or high-level disinfection not possible. ILD of instruments with wipes, such as Caviwipes™, allow the elimination of vegetative bacteria, including tubercle bacilli, lipid and some non-lipid viruses, and fungi, but not bacterial spores. For this reason, wiping the IOS device after each use with ILD was the accepted practice for many years. However, due to the rising numbers of corporate and federal dental clinics, the practices of sterilization and disinfection have had more oversight during recent years. As a result, there is more scrutiny of the standardization and implementation of the recommended CDC guidelines. This increased

oversight with the desire to best protect our US Military's personnel and family members led to a drastic and expensive overhaul of how the military sterilized its IOS devices.

The military uses the Omnicam IOS device with the Chairside Economical Restoration of Esthetic Ceramics (CEREC) system manufactured by Sirona Dental Systems. The Omnicam IOS device is a powder free full-color continuous capture scanner. It has a stainless steel removable intraoral mirror sleeve with a sapphire glass window that is detachable from the camera and optics housing. When this system was first implemented into military clinics worldwide the detachable mirror sleeve was cleaned between patients using ILD wipes (Figure 1).

In 2016 Sirona Dental Systems updated their U.S. instructions for cleaning, disinfection and sterilization. The updated manufacturer's instruction recommended that the Omnicam mirror sleeve be dry heat sterilized or high-level disinfected (7). Soon after, the dental directorates of each military branch became aware that their ILD protocol of the Omnicam IOS device was no longer compliant with the CDC guidelines for semicritical items or the manufacturer's recommendations. The U.S. Army quickly sent out a Dental Patient Safety Directive to all dental treatment facilities (DTF) to halt all intraoral use of the Omnicam system until protocol compliant with recommendations could be established (Appendix 1). The option of high-level disinfection was rejected due to safety hazards without proper ventilation and the man hours required for proper HAZMAT training and protocol implementation. Another contributing factor against high-level disinfection was that the internal compartment of the sleeve housing would also be submerged, creating difficulties in removing smears off the internal mirror potentially creating irreparable damage to the mirror sleeve. In most DTFs these mirror sleeves are used from 2-5x per day, by providers and techs, with varying levels of

knowledge of the scanner and or the high-level disinfection process. The decision to implement high-level disinfection of the Omnicam mirror sleeve would have most likely led to increased cost and unnecessary risk. As a result, Sirona Dental Systems also created its own alternative to sterilization releasing the Omnicam disposable mirror sleeve. This is a clear, hard, plastic housing that covers the entire mirror sleeve and sapphire glass window. It would be disposed of after each patient use thus eliminating the need for sterilization of the scanning device. Unfortunately, it is a cost-prohibitive option due to cost at this time.

After many months with the CEREC systems in DTFs worldwide going unused, the Army's DTFs were able to acquire the manufacturer recommended dry heat sterilization units, such as the COX 6000 RapidHeat Sterilizer (Figure 2). With the months of lost productivity time and a price tag of \$4,000 per sterilizer, the decision to change the protocol to dry heat sterilization from the previous protocol of using ILD at 8 cents per wipe was a very costly one.

The Cox 6000 RapidHeat Sterilizer allows for complete sterilization of the mirror sleeve, when wrapped in a sterilization pouch, in 12 minutes at 190°C. It accomplishes this without the corrosive or damaging effects of steam, pressure or chemicals. These units have also proven themselves to be easy to operate and have minimal maintenance requirements. Although dry heat sterilization seems to be an effective solution to the 2016 Sirona Dental Systems policy, many DTFs are seeing unwanted effects after long term dry heat cycling of the mirror sleeves. These effects include a color change of the mirror sleeve, and the presence of artifacts on the sapphire glass coated window due to residue from wiping with ILD or alcohol and not allowing it to dry prior to placement in the dry heat sterilization bag (Figure 3). Although many are small, these artifacts become apparent while scanning resulting in inaccuracies of the

processed 3D image (Figure 4). These inaccuracies could create potential discrepancies in scan integrity. Despite the manufacturer's acknowledgement of the color changes effect that occurs after dry heat cycling, they claim that it "will not have any negative impact upon the mirror sleeve's durability" (7).

The Omnicam IOS device and the CEREC system is attractive to military DTFs for the already stated benefits. The military has a patient population that is moving quickly and constantly, either for deployment, change of duty station or discharge. Digital fabrication of restorations with chairside mills enable providers to deliver a definitive prosthesis without the lengthy wait of sending conventional impressions by mail to the Army Dental Laboratory and waiting upwards of 4+ weeks for its return. It also decreases the need to deploy soldiers with provisional restorations. Digital workflows also streamline the lab aspect of restoration fabrication by eliminating the need for impressions, model work and then scanning of the cast or waxing the restoration prior to fabrication. The addition of the updated dry heat sterilization protocol for the IOS sleeve may limit some of the efficiency afforded the provider. Although the integration of DHS came with a large initial cost, additional long-term concerns include maintenance, downtime during repairs or replacement of unserviceable/expired units.

For many years ILD has proven to be an effective alternative to dry heat sterilization without adding costs, maintenance, or servicing required for sterilization. In addition, ILD does not have the potential damaging heat cycling artifacts created by bioburden. Without the restrictions of costly and bulky DHS equipment, the Omnicam IOS is a lightweight, portable scanner that can be a useful asset in the deployed remote setting. Although it is best to follow the CDC recommendations, if proven effective, the military may find it advantageous in these

austere environments to permit the use of ILD. This study aims to determine if U.S. Military providers can use ILD as an alternative to dry heat sterilization on the Omnicam IOS, while still upholding current guidelines and maintaining a safe and healthy environment for his patients.

HYPOTHESES

The objective of this study is to compare the absolute sterility of the Omnicam mirror sleeve after dry heat sterilization (DHS), no treatment after intraoral use (NT), and intermediate level disinfection (ILD).

Null Hypothesis #1: There will be no difference in mean optical density (OD) readings or mean CFU/ml between DHS and ILD.

Study Hypothesis #1: There will be a significant difference in mean OD readings and mean CFU/ml readings between DHS and ILD.

Null Hypothesis #2: There will be no difference in mean OD readings or mean CFU/ml between ILD and NT.

Study Hypothesis #2: There will be a significant difference in mean OD readings or mean CFU/ml readings between ILD and NT.

MATERIALS AND METHODS

Sample Collection:

A total of 93 sample specimens were obtained from 31 patient encounters requiring the use of the CEREC Omnicam scanner (Sirona Dental, Inc. Charlotte, NC) at Billy Johnson Dental Clinic, located in Fort Hood, Texas. PII was not documented or recorded in any way for the purpose of

this study. A total of three samples were obtained from each patient encounter. These three samples were comprised of an initial swab of the Omnicam mirror sleeve immediately after unpacking from dry heat sterilization (DHS), a swab of the Omnicam mirror sleeve after intraoral use (NT), and a swab following intermediate level disinfection (ILD).

All swabs from the Omnicam sleeves were obtained by a single provider in the same manner while wearing appropriate personal protective equipment as follows. A BBL CultureSwab Collection and Transport System (BD Diagnostics, Sparks, MD) was used to swab the Omnicam mirror sleeve methodically starting with the sapphire glass window and then circumferentially swabbing the top 2/3rds of the mirror sleeve. The bottom 1/3rd intentionally remained unswabbed to allow space to grip the sleeve. Each swab was then immediately placed into the swab transport system containing liquid Amies Transport Medium and sealed. Each sealed swab was then labeled as belonging to either DHS, NT, or ILD. The vials of Amies Transport Medium were transported within 24hrs for incubation and data collection (Figure 5). This study was approved as research not involving human use by the Clinical Investigation and Research Office, Carl R. Darnall Army Medical Center (Appendix 2).

Sterilization and Disinfection:

Dry heat sterilization of the Omnicam sleeves was obtained using the Cox 6000 Rapid Dry Heat Sterilizer (CPAC Environmental Solutions, Leicester, NY) at 190°C for 12 minutes. Chemical indicators were used to verify the performance of the Omnicam sleeve package sterilization process prior to opening. After validation of the sterilization process each sample

was collected using a new pair of sterile gloves using the swabbing method described above. For the DHS sample, the sterilized Omnicam sleeve sample was collected immediately after the package was open. For NT, the sample was collected immediately after intraoral use of the Omnicam mirror sleeve. For ILD, the sample was collected after a new PDI Sani-Cloth AF3 (Professional Disposables International, Inc. Orangeburg, NY) was used to wipe down the complete Omnicam mirror sleeve to ensure that the whole surface was covered. All ILD swabs were obtained after 3-minute contact with the PDI Sani-Cloth.

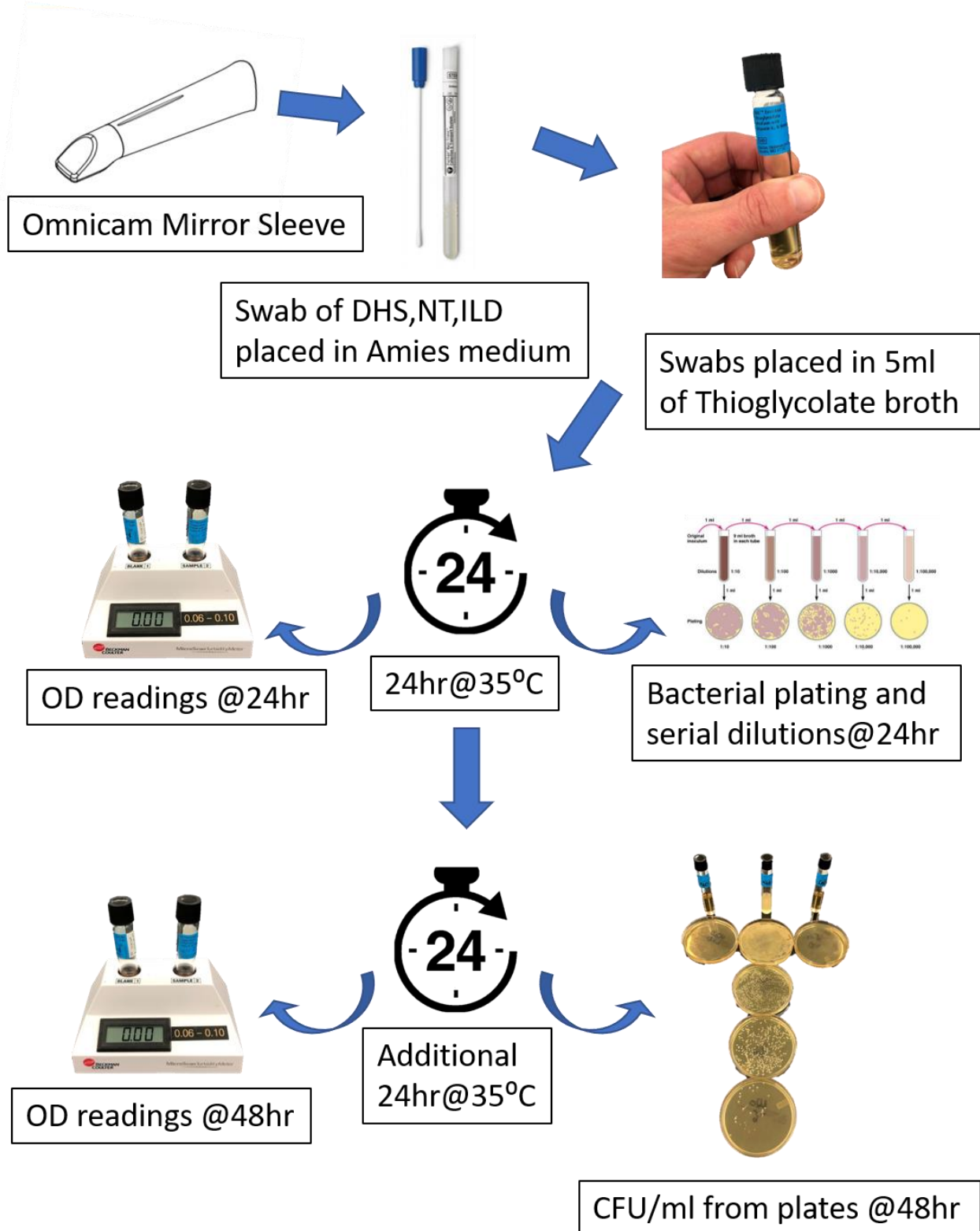
Bacterial Culture and Colony Counting:

The samples were taken to the Carl R. Darnall Army Medical Center (CRDAMC) Laboratory Services for incubation within 24hrs of being obtained. Each sample was placed into a 5ml vial of thioglycolate medium enriched with dextrose, hemin and Vitamin-K (ThermoFisher Scientific, Waltham, MA) and incubated for 24 hours at 35 °C. Optical Density (OD) readings were recorded after 24 hours of incubation. These were acquired by vortexing each vial and collecting an OD reading using the MicroScan Turbidity Meter (Beckman Coulter Inc., Atlanta, GA) calibrated against a new unused thioglycolate broth vile (Figure 6).

All samples were also plated at 24 hours onto Tryptic Soy Agar (Hardy Diagnostic, Santa Maria, CA) plates without dilution. In addition, serial 1:10 dilutions were prepared for samples that showed any turbidity and plated at dilutions of 10^{-4} , 10^{-5} , and 10^{-6} . The Thioglycolate vials and the Tryptic Soy Agar (TSA) plates were then incubated for an additional 24 hours at 35 °C. At 48 hours new OD readings were obtained for all sample vials. The TSA plates were removed and colony forming units (CFU/ml) were recorded for each plate. To standardize our findings;

any CFU/ml count >200 was deemed too numerous to count (TNC), any count <20 was deemed too few to count, and a count of zero was given to the plates that showed no visual growth. Serial dilutions of 10^{-4} , 10^{-5} , and 10^{-6} were chosen to be plated based on our pilot study results which demonstrated counts between 20-150 CFU/ml allowing a more accurate counting.

Protocol Synopsis



Statistical Analysis:

A Paired T-Test was the intended method of statistical analysis. This method was selected because each sample group was coming from the same person, allowing us to compare the mean result from one test condition to the mean result of another condition within the same sample. The independent variable is the method of sterilization/disinfection: Dry Heat sterilization (DHS), Intermediate Level Disinfection (ILD). The dependent variables are the bacterial levels, as measured using two methods: OD readings and the CFU/ml.

In the event that all DHS and ILD samples do not show evidence of any bacterial growth, then the Paired T-Test is not necessary because we know there is no difference between the test conditions. However, we can calculate our confidence interval (CI) to better contextualize the results. To calculate our confidence interval (CI) we will use the statistical *Rule of Three* (8).

Rule of Three:

$$P \approx 3/n \times 100$$

Where P is the % probability of the event, in our case that ILD or DHS sample will show no growth. N represents the number of samples in the tested groups.

RESULTS

Optical Density Readings:

The optical density (OD) reading was used as an indicator of the concentration of bacteria in the thioglycolate broth suspension at 24 and 48 hours after inoculation with study samples.

Table A shows the OD reading results for the 31 sample groups included in this study. The NT samples showed turbidity readings from 0.06-0.71 at both 24 and 48 hours. These results are expected since this group represented samples collected directly after the Omnicam was removed from the oral environment. Of note, each NT sample OD readings at 48 hours was greater than the OD reading determined at 24 hours indicating the growth of bacteria over this period. These findings verify that the Omnicam mirror sleeve was indeed contaminated before dry heat sterilization and intermediate level disinfection.

In contrast, all the DHS and the ILD samples showed OD readings of zero or no growth at 24 hours (Figure Broth). At 48 hours, except for ILD-21, all the DHS and ILD samples showed OD 0.00 readings indicative of no bacterial growth. Sample ILD-21 showed an OD reading of 0.48. This sample was plated on TSA after 48 hours of incubation showing no bacterial growth. This unexpected result was attributed to an error during sample processing. Consequently, this treatment group was excluded from the study analysis. The most probable cause being that when plating the NT-21 sample at 24hrs, the pipet tip was not discarded and the ILD-21 was inadvertently inoculated.

TABLE A: Optical Density Readings for Test Groups after 24 and 48 hours

Sample Groups	OD @ 24hrs	OD @ 48hrs	Sample Groups	OD @ 24hrs	OD @ 48hrs
DHS – 1	0	0	DHS – 17	0	0
NT – 1	0.58	0.68	NT – 17	0.37	0.43
ILD – 1	0	0	ILD – 17	0	0
DHS – 2	0	0	DHS – 18	0	0
NT – 2	0.55	0.64	NT – 18	0.42	0.52
ILD – 2	0	0	ILD – 18	0	0
DHS – 3	0	0	DHS – 19	0	0
NT – 3	0.61	0.66	NT – 19	0.55	0.63
ILD – 3	0	0	ILD – 19	0	0
DHS – 4	0	0	DHS – 20	0	0
NT – 4	0.53	0.59	NT – 20	0.64	0.68
ILD – 4	0	0	ILD – 20	0	0
DHS – 5	0	0	DHS – 21	0	0
NT – 5	0.58	0.63	NT – 21	0.61	0.68
ILD – 5	0	0	ILD – 21	0	*0.48
DHS – 6	0	0	DHS – 22	0	0
NT – 6	0.51	0.59	NT – 22	0.56	0.65
ILD – 6	0	0	ILD – 22	0	0
DHS – 7	0	0	DHS – 23	0	0
NT – 7	0.07	0.53	NT – 23	0.62	0.70
ILD – 7	0	0	ILD – 23	0	0
DHS – 8	0	0	DHS – 24	0	0
NT – 8	0.65	0.71	NT – 24	0.56	0.60
ILD – 8	0	0	ILD – 24	0	0
DHS – 9	0	0	DHS – 25	0	0
NT – 9	0.33	0.53	NT – 25	0.24	0.58
ILD – 9	0	0	ILD – 25	0	0
DHS – 10	0	0	DHS – 26	0	0
NT – 10	0.53	0.58	NT – 26	0.06	0.6
ILD – 10	0	0	ILD – 26	0	0
DHS – 11	0	0	DHS – 27	0	0
NT – 11	0.31	0.50	NT – 27	0.62	0.7
ILD – 11	0	0	ILD – 27	0	0
DHS – 12	0	0	DHS – 28	0	0
NT – 12	0.55	0.63	NT – 28	0.48	0.58
ILD – 12	0	0	ILD – 28	0	0
DHS – 13	0	0	DHS – 29	0	0
NT – 13	0.32	0.46	NT – 29	0.07	0.65
ILD – 13	0	0	ILD – 29	0	0
DHS – 14	0	0	DHS – 30	.0	0
NT – 14	0.38	0.55	NT – 30	0.40	0.51
ILD – 14	0	0	ILD – 30	0	0
DHS – 15	0	0	DHS – 31	0	0
NT – 15	0.35	0.55	NT – 31	0.62	0.71
ILD – 15	0	0	ILD – 31	0	0
DHS – 16	0	0			
NT – 16	0.44	0.48			
ILD – 16	0	0			

DHS= Dry heat sterilization NT= No treatment after intraoral use ILD= Intermediate level disinfection

*all 21 group results thrown out due to ILD-21 at 48hrs being contaminated after plating

Colony Counting:

Table B showed the CFU/ml counts for all test groups. All the NT samples showed growth on undiluted plates with CFU/ml that was too numerous to count (TNC). After serial dilution of the included 30 groups, the final TSA plate growth ranged from $5.9-102 \times 10^6$ CFU/ml. The variable growth on the NT TSA plates verifies that the Omnicam mirror sleeve was seeded with bacteria from the oral cavity before dry heat sterilization and intermediate level disinfection.

All the 31 sample groups of undiluted TSA plates from both DHS and ILD showed no growth after 24hr of incubation and all NT samples showed positive growth too numerous to count (TNC) (Figure 7). With a 95% CI these findings showed no difference between DHS and ILD.

TABLE B: Colony Counting Results at 24 hours After Plating

Test Group	CFU UD	CFU 10 ⁴	CFU 10 ⁵	CFU 10 ⁶
DHS – 1	0	-	-	-
NT – 1	TNC	*TNC	*TNC	*TNC
ILD – 1	0	-	-	-
DHS – 2	0	-	-	-
NT – 2	TNC	*TNC	*TNC	*96
ILD – 2	0	-	-	-
DHS – 3	0	-	-	-
NT – 3	TNC	TNC	141	TFC
ILD – 3	0	-	-	-
DHS – 4	0	-	-	-
NT – 4	TNC	TNC	TNC	50
ILD – 4	0	-	-	-
DHS – 5	0	-	-	-
NT – 5	TNC	TNC	TNC	37
ILD – 5	0	-	-	-
DHS – 6	0	-	-	-
NT – 6	TNC	TNC	103	TFC
ILD – 6	0	-	-	-
DHS – 7	0	-	-	-
NT – 7	TNC	TNC	TNC	102
ILD – 7	0	-	-	-
DHS – 8	0	-	-	-
NT – 8	TNC	TNC	TNC	46
ILD – 8	0	-	-	-
DHS – 9	0	-	-	-
NT – 9	TNC	TNC	TNC	65
ILD – 9	0	-	-	-
DHS – 10	0	-	-	-
NT – 10	TNC	TNC	TNC	40
ILD – 10	0	-	-	-
DHS – 11	0	-	-	-
NT – 11	TNC	TNC	TNC	28
ILD – 11	0	-	-	-
DHS – 12	0	-	-	-
NT – 12	TNC	TNC	TNC	24
ILD – 12	0	-	-	-
DHS – 13	0	-	-	-
NT – 13	TNC	TNC	75	TFC
ILD – 13	0	-	-	-
DHS – 14	0	-	-	-
NT – 14	TNC	TNC	59	TFC
ILD – 14	0	-	-	-
DHS – 15	0	-	-	-
NT – 15	TNC	TNC	TNC	29
ILD – 15	0	-	-	-
DHS – 16	0	-	-	-
NT – 16	TNC	TNC	67	TFC
ILD – 16	0	-	-	-

Test Group	CFU UD	CFU 10 ⁴	CFU 10 ⁵	CFU 10 ⁶
DHS – 17	0	-	-	-
NT – 17	TNC	TNC	98	TFC
ILD – 17	0	-	-	-
DHS – 18	0	-	-	-
NT – 18	TNC	TNC	TNC	41
ILD – 18	0	-	-	-
DHS – 19	0	-	-	-
NT – 19	TNC	TNC	TNC	38
ILD – 19	0	-	-	-
DHS – 20	0	-	-	-
NT – 20	TNC	TNC	TNC	36
ILD – 20	0	-	-	-
**DHS – 21	0	-	-	-
**NT – 21	TNC	TNC	TNC	43
**ILD – 21	0	-	-	-
DHS – 22	0	-	-	-
NT – 22	TNC	TNC	TNC	38
ILD – 22	0	-	-	-
DHS – 23	0	-	-	-
NT – 23	TNC	TNC	TNC	30
ILD – 23	0	-	-	-
DHS – 24	0	-	-	-
NT – 24	TNC	TNC	TNC	26
ILD – 24	0	-	-	-
DHS – 25	0	-	-	-
NT – 25	TNC	TNC	TNC	64
ILD – 25	0	-	-	-
DHS – 26	0	-	-	-
NT – 26	TNC	TNC	TNC	26
ILD – 26	0	-	-	-
DHS – 27	0	-	-	-
NT – 27	TNC	TNC	TNC	47
ILD – 27	0	-	-	-
DHS – 28	0	-	-	-
NT – 28	TNC	TNC	TNC	54
ILD – 28	0	-	-	-
DHS – 29	0	-	-	-
NT – 29	TNC	TNC	TNC	30
ILD – 29	0	-	-	-
DHS – 30	0	-	-	-
NT – 30	TNC	TNC	61	TFC
ILD – 30	0	-	-	-
DHS – 31	0	-	-	-
NT – 31	TNC	TNC	TNC	90
ILD – 31	0	-	-	-

DHS= Dry heat sterilization NT= No treatment after intraoral use ILD= Intermediate level disinfection

TNC= Too numerous to count TFC= Too few to count

*Serial dilutions for N-groups 1 and 2 were rejected due to contamination

**Group 21 was thrown out due to contamination during the plating process

DISCUSSION

Our experimental goal of comparing the absolute sterility of the Omnicam mirror sleeve after intraoral use, dry heat sterilization (DHS) and intermediate level disinfection (ILD) was achieved within the parameters of this study (Figure 8).

We accept our Null hypothesis #1 and reject our Study hypothesis #1: With a 95% CI there was no difference between DHS and ILD on the Absolute sterility of the Omnicam mirror sleeve. The 30 included sample groups after DHS and ILD showed zero turbidity on OD readings at 24 and 48hrs of incubation. All 30 included sample groups of DHS and ILD showed zero growth (CFU/ml) after 24hrs of incubation.

We reject our Null hypothesis #2 and accept our Study hypothesis #2: With a 95% CI there was a significant difference between ILD and NT. All included samples after ILD showed zero OD readings and zero CFU/ml. All NT samples showed turbidity on OD readings and variable quantities of CFU/ml in OD readings or CFU/ml.

There are many limitations to this study that must be acknowledged for our results to hold value. Chief among these being that the oral cavity is host to more than 700 bacterial species (9). Of these, facultative anaerobes predominate over aerobic bacteria and constitute from 60-75% of the total oral microflora (10). In addition to bacteria, other organisms to include fungi and viruses also reside in the oral cavity.

Cultivating this diverse flora is complicated by many variables. These include avoidance of exposure to oxygen, duration of collection time, a transport medium that supports a heterogeneous mixture of organisms, and a growth plate that has a nonselective nutrient source.

The choice to use OD readings as a source for data collection allowed us to gather and test for a mixture of both anaerobic and aerobic bacteria, reflective of the oral microflora. This was achieved using the Amies Transport Medium and thioglycolate broth.

The vials of Amies Transport Medium contain a nutrient enhanced semisolid gel that keeps the sample locked in, hydrated and buffered for transport to the incubation location. It is approved for the transport of aerobic and anaerobic bacteria. Integral to maintaining the vitality of anaerobic species was the immediate sample collection following intraoral use of the Omnicam sleeve and subsequent sample obtained immediately following 3 minutes of ILD.

All samples were placed into 5ml vials of thioglycolate broth enriched with hemin and Vitamin-K. This is a non-selective general-purpose medium used in qualitative procedures of microorganisms including aerobic and anaerobic bacteria. Sodium thioglycolate in the medium consumes oxygen and permits the growth of obligate anaerobes, the enriched hemin and Vitamin-K also support obligate and facultative anaerobic growth. Obligate anaerobes cultivate at the bottom of the vials, facultative anaerobes occupy the upper 2/3rds of the vial, while aerobic species survive at the top. The collection of both aerobic and anaerobic specimen was evident on visual inspection of our sample vials (Figure 9). Although all samples varied, most N-group vials showed organisms growing somewhere between the top and bottom, an indication of facultative anaerobic bacteria. Although not as predominant, growth at both the top and bottom of the vials were also present. This represents a positive cultivation of both aerobic and obligate anaerobic bacteria respectively. This highlights that our data is non-selective for specific organisms and allows use to determine the overall heterogeneous growth reflective of the true oral environment.

The use of CFU/ml as an additional data set has its own set of limitations. Whatever nutrient agar you choose as a growth source will be selective for only certain types of bacteria. In this study, we choose to use TSA plates. TSA is a relatively inexpensive non-differential nutrient source for gram-positive or gram-negative bacterial species, however it is favorable for aerobes. The selection of TSA would allow us to quantify the growth of a variety of species. As with the thioglycolate broth, we are attempting to quantify as wide a spectrum of species as possible to better reflect the conditions of the oral cavity. The quantities of colonies obtained from the NT samples reflects what is found in the oral cavity and indicates whether treatment was or was not successful. The varying CFU/ml data we obtained is based on a myriad of technical variables to include, age of patient, pH, salivary flow, and hygiene. However, it is very possible that one patient may have a dominant species that could not thrive in any of our nutrient mediums. This would result in a lower number of CFU/ml and not be representative of the total CFU/ml at any time in that individual's oral cavity.

The data sets resulting in no growth in either the OD readings or CFU/ml after DHS and ILD is not surprising within the parameters of this study. DHS describes a process that destroys or eliminates all forms of microbial life. When executed appropriately, our protocol follows CDC and Omnicam manufacturer recommendations, it is anticipated that all organisms represented in our data sets would be non-existent when sampled. Chemical indicators verified each packages sterility before opening. It is for this reason that DHS was our reference for absolute sterility that ILD would be compared to. The effectiveness of DHS was evident in our research outcomes and validates our current sterilization protocol. ILD describes a process that eliminates most pathogenic microorganisms, except for bacterial spores. Our ILD protocol

using the PDI Sani-cloth AF3 is EPA-registered as bactericidal, tuberculocidal, virucidal and according to manufacturer is effective against bloodborne pathogens and pathogenic fungi. If proper protocol was followed within the parameters of our study, ILD would be expected to return the negative growth results seen in our data sets.

There is a strong argument for the use of ILD for the Omnicam mirror sleeve: minimal damage is done to the structures of the oral cavity, the oral cavity can tolerate small numbers of spore forming bacteria, areas containing the most pathogenic bacteria such as the gingival crevice and plaque are not contacted, the mirror sleeve shape is inherently atraumatic, and the surface is simple to clean and disinfect. Taking into account the limitations of our study, our results give strength to this argument.

CONCLUSION

In conclusion, Intermediate-level disinfection demonstrates equal effectiveness as dry heat sterilization on the absolute sterility of the Omnicam mirror sleeve. Based on this finding, ILD may be a viable adjunct to dry heat sterilization between patients, especially in a deployed environment.

To better substantiate the results, further testing and research are required to prove the efficacy of ILD against spore forming organisms and viruses. Until further testing is completed and evaluated, DHS, in accordance with CDC guidelines should remain the sterilization method of choice.

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Figure 1 – Intermediate-level disinfectant (ILD), a quaternary ammonium compound PDI Sani-Cloth™AF3 Germicidal Disposable Wipe used in this study



Figure 2- COX 6000 RapidHeat Sterilizer



Figure 3 – Left, Omnicam mirror sleeve in sterilization pouch after DHS. Center and Right, Unwanted effects after long term dry heat cycling of the mirror sleeves, to include bioburden on sleeve and sapphire-coated glass.

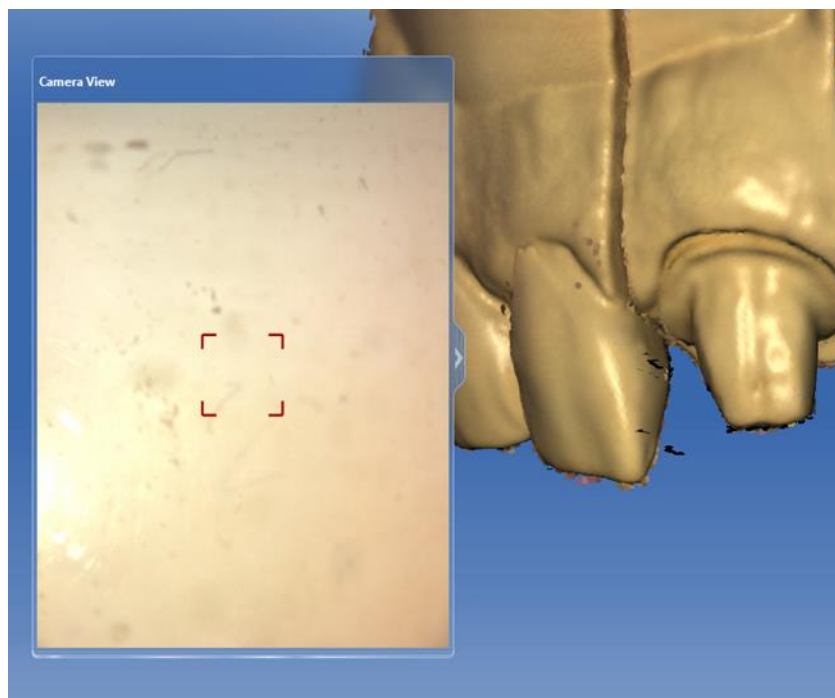


Figure 4 – Irregularities on mirror sleeve create artifacts on scanned 3D surface model

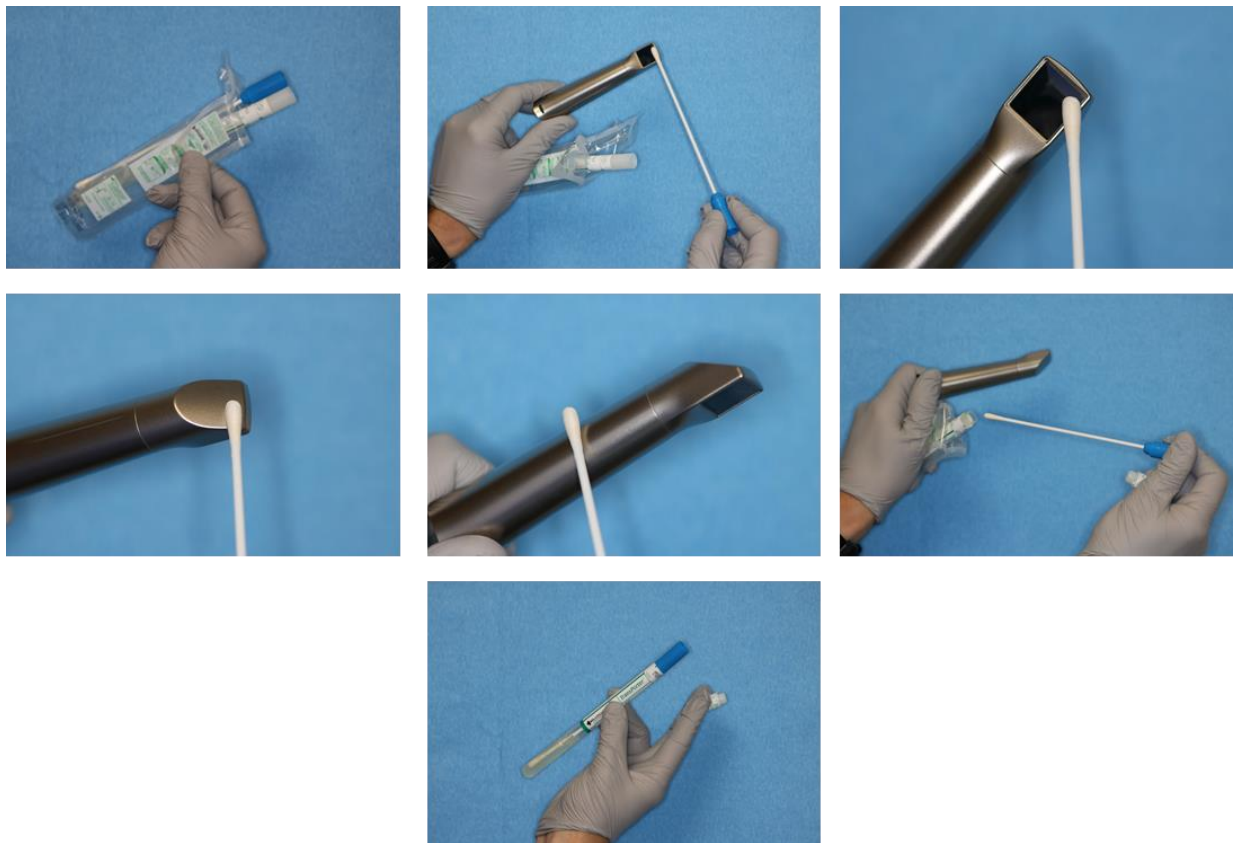


Figure 5 – Sample collection of Omnicam mirror sleeve. Start upper left; unpack swab, start at sapphire glass, glass crevice, back of sleeve head, upper 2/3rds of sleeve, place into the swab transport system containing liquid Amies Transport Medium and seal



Figure 6 - MicroScan Turbidity Meter (Beckman Coulter Inc., Atlanta, GA) for recording OD readings, seen here is a DHS sample in a thioglycolate broth vile (right) calibrated against a new unused vile (left).

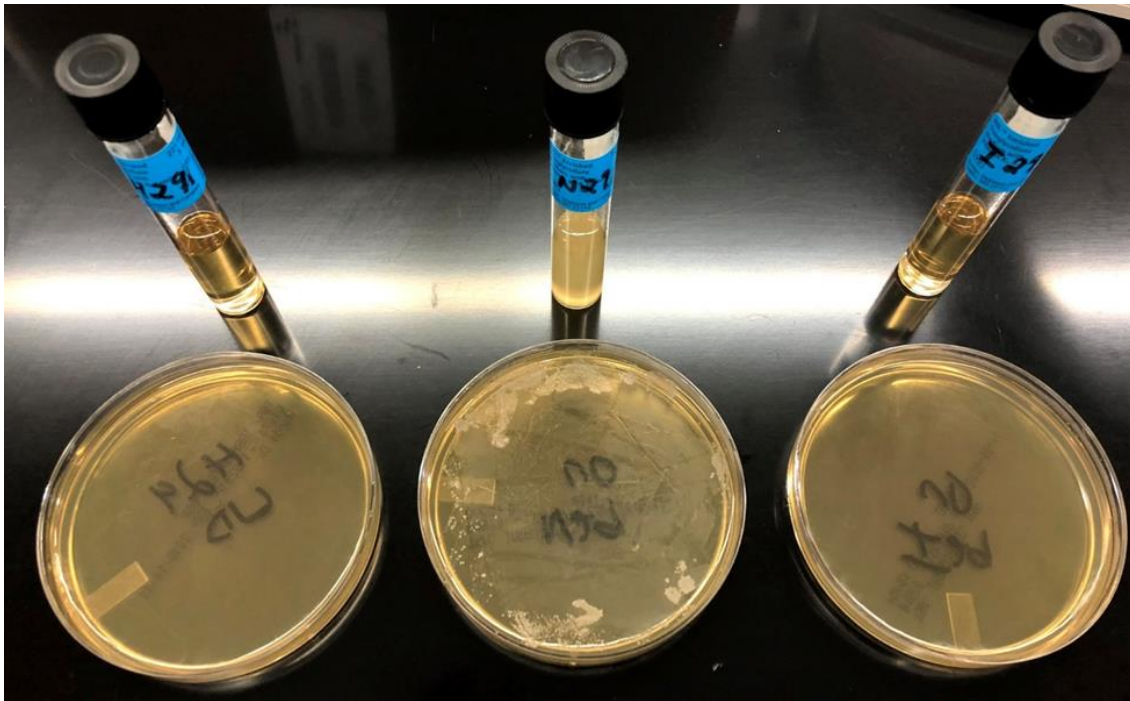


Figure 7 – Thioglycolate broth vials and undiluted TSA plates at 48 hours. No growth is seen on either the DHS or ILD vials or plates (left and right samples). The NT sample in the center shows visual turbidity in the vial and growth too numerous to count (TNC) on the plate.

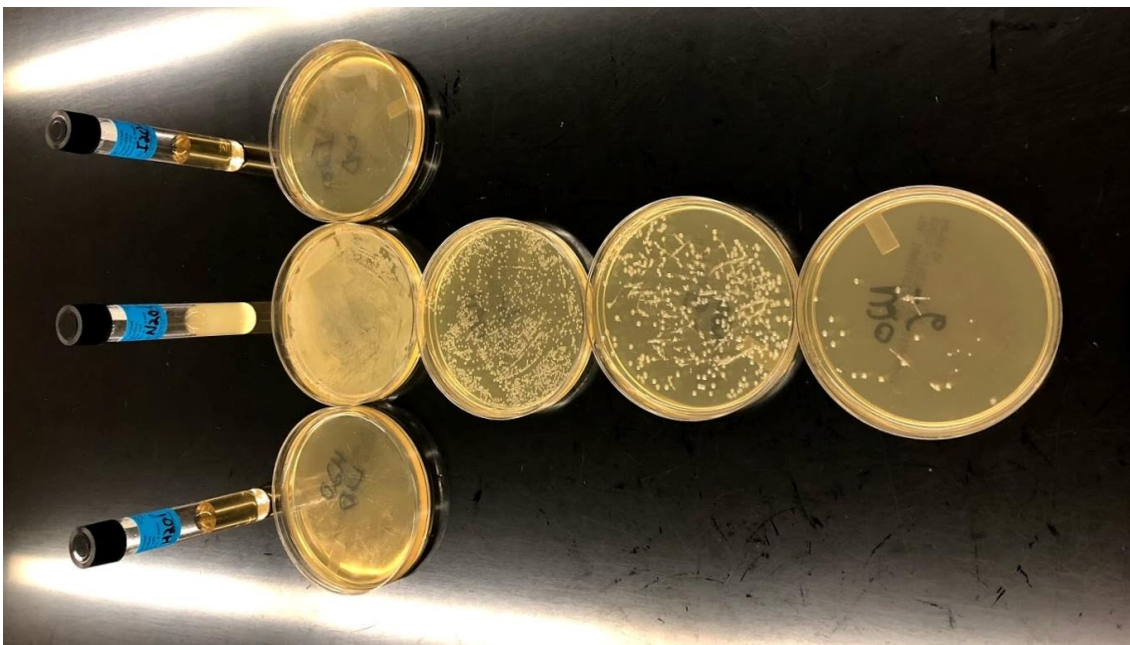


Figure 8 – An example of DHS (bottom), NT (center) and ILD (top) samples from the same treatment group. Pictured are the thioglycolate broth vials and undiluted TSA plates at 48 hours, to include the NT serial dilutions of 10^4 , 10^5 , 10^6 . This highlights the consistent pattern of no growth in the DHS and ILD samples and variable growth within the NT samples.



Figure 9 – The Enriched Thioglycollate is a non-selective medium. Obligate anaerobes cultivate at the bottom of the vials, facultative anaerobes occupy the upper 2/3rds of the vial, while aerobic species survive at the top. The DHS (left) and ILD (right) have no growth at 24h, the NT (center) shows most colony growth in the upper 2/3rds indicative of facultative anaerobes.

DENCOM Infection Control Message #04-16

Initial Guidance for Installation and Use of the Cox Rapid Heat Dry Heat Sterilizer

Purpose: Beginning this month, the Army Dental Directorate will reauthorize the limited use of dry heat sterilization in selected Army DTFs. This action will result in some significant changes to the standardized sterilization policies and protocols that we use in the Dental Corps. The purpose of this message is to provide all ICOs with information on how we got to this point, and what will be required to implement this new IC policy.

Background: When considering the types of sterilization that are available for use in Army DTFs today, steam sterilization remains the primary method of reprocessing dental instruments and devices. The use of high-level disinfectants (HDL), historically known as “cold sterilization”, has been prohibited for use in Army DTFs (as well as the other Federal Dental Services) for over a decade, due to their limited application and toxic health effects when being used. Other sterilization methods such as “gas sterilization” (e.g., ethylene oxide gas and hydrogen peroxide gas plasma sterilizers) are not also authorized for use in Army DTFs due to their high cost and limited application in dentistry.

Dry heat sterilization has very limited application in modern dentistry as well, being used only for those dental instruments that cannot be steam sterilized and cannot use a barrier, but are otherwise heat tolerant. In the past, such items included carbide burs, diamond burs, endodontic files, and orthodontic pliers and instruments, all of which were susceptible to corrosion when steam sterilized. However, with improved technology in metallurgy and improved manufacturing techniques for these dental devices in the past two decades, only selected orthodontic instruments remained on this list of items that were authorized to be dry heat sterilized. In 2014, dry heat sterilization was no longer authorized for use in Army DTFs, due primarily to low utilization, but also due to an increasing number of sentinel events stemming from their use.

However, a situation has recently emerged that has prompted the Federal Dental Services to reintroduce the use of dry heat sterilization. Early in 2016, the Air Force Dental Evaluation and Consultation Service (DECS) brought to light a rather stunning revelation involving the Sirona CAD/CAM system. Specifically, it had been discovered that the Sirona IFU stated that the mirror sleeve (the “semi-critical” part of the Omnicam that is used intraorally) could simply be wiped down with an intermediate-level disinfectant ILD (such as a Cavi-wipe) between patients, and did not have to be sterilized between patients. The Air Force DECS pointed out that not only was this IFU not in compliance with the CDC guidelines on sterilization for semi-critical devices, it also noted that the FDA had never validated or approved the use of ILD for the reprocessing of the mirror sleeve. Due to the unique characteristics of the Sirona Omnicam mirror sleeve lens, it is relatively heat tolerant, but cannot be steam sterilized,

cannot be immersed in any liquid (ruling out use of HLD), and cannot be protected with a barrier sleeve during use. This rare combination of circumstances permits only one FDA-approved method for reprocessing the Omnicam mirror sleeves in the U.S., which is dry heat sterilization. More specifically, these mirror sleeves must be reprocessed using a “forced-air” dry heat sterilizer at a very specific time and temperature cycle, and cannot use the more commonly used “static-air” dry heat sterilizer.

In May of 2016, after months of investigation and collaboration between the Federal Dental Services, Sirona, and the FDA, the decision was made to reauthorize the limited use of dry heat sterilization only in those military DTFs that utilize the Sirona CAD/CAM system. Further, it was decided that the only dry heat sterilizer that is authorized for use in military DTFs is the Cox Rapid Heat, forced-air dry heat sterilizer, using a 90°C (134°F), 12-minute “wrapped” sterilization cycle. Each of the three military Dental Services made a central purchase of these Cox Rapid Heat sterilizers, along with additional mirror sleeves for each of their affected DTFs. It is anticipated that all of these DTFs will receive their Cox dry heat sterilizers and extra mirror sleeves by the end of July 2016.

In preparation for receiving and operating these new Cox dry heat sterilizers, all affected Army DTFs have been provided with information from the Dental Directorate regarding what they will need to purchase in the way of dry heat sterilization supplies in order to support this method of sterilization (e.g., dry heat instrument pouches, dry heat internal chemical indicators, and dry heat spore test kits.). In addition, the Dental Directorate will send out an official Information Paper during the week of 11 July 16 that describes how to set up, operate, and maintain these new sterilizers. Army DTFs will use this Information Paper as official “interim command policy guidance” on the use of dry heat sterilization until this can be reflected in updated versions of DENCOM Policy Letters 6-2 (Dry Heat Sterilization) and 6-6 (Sterilization Standardization), as well as DENCOM Pam 40-5-1, Appendix J (Sterilization).

The purpose of this Infection Control Message is to merely highlight the information that will be contained in the official Dental Directorate Information Paper that is being sent down through command channels. It is also being provided in response to many inquiries that have been sent in from various ICOs who have requested initial guidance on the “start-up” requirements for installing and operating the new Cox sterilizers. The following information and guidance is therefore being provided to all ICOs in order to ensure a smooth transition to the reintroduction of dry heat sterilization in these selected Army DTFs:

1. **Actions to take prior to the delivery of the Cox dry heat sterilizer to your DTF:**

a. **Order dry heat sterilization supplies.** Order the dry heat supplies that will be needed, so that they are on-hand and available when your Cox sterilizer arrives. A supply list of these items, to include DMLSS item numbers and costs, was provided to each affected DTF. This list includes three items:

- 1) Dry heat nylon instrument pouches, Item #400636, Nylon Pouches 2" x 10"
- 2) Dry heat internal chemical indicator strips, Item #400635, 100/box
- 3) Dry heat "In-Office" Biological Monitoring System, Item #400640.

Critical note: *These dry heat sterilization supplies are NOT compatible with steam sterilization, and vice versa.* All of the sentinel events that have occurred in the past have stemmed from dental personnel mixing these supply items between dry and steam sterilization protocols. ***Dry heat and steam sterilization supplies and spore test systems are not interchangeable!***

b. Conduct didactic training. Require all Sterilization technicians (and alternate technicians), ICOs, OICs, and NCOICs to complete a self-paced "didactic training" on the Cox Rapid Heat sterilizer. This includes providing them with a copy of the Cox Rapid Heat Operator's Manual, the dry heat "in-house" spore test IFU, the IFU for the dry heat internal chemical indicators, the IFU for the dry heat nylon instrument pouches, as well as a copy of the Sirona CAD/CAM Operator's manual.

Critical note: Your sterilization technicians and management personnel should *only read the Sirona IFU section on pre-cleaning of the Omnicam body and mirror sleeves*, but should ***ignore the erroneous IFU information regarding use of HLD and dry heat sterilization, as this information is incorrect.*** Despite this information being in the IFU, the use of HLD is prohibited (IAW recent FDA guidance on this particular device), and the time/temperature settings that are listed for dry heat sterilization are not applicable to the Cox sterilizer.

c. Select the proper location for the Cox sterilizer. The Cox sterilizer should be located in the clean side of your Sterilization Room, just like your steam sterilizers, where they will be operated and maintained only by certified sterilization technicians, under the supervision of the ICO and NCOIC. They cannot be located in any patient treatment areas or dental laboratories. If for any reason the Cox sterilizer cannot fit in the Sterilization Room, a suitable room or area must be selected that is as close to the Sterilization Room as possible, and satisfies the requirements for a "clean sterilization area", IAW applicable policies and guidelines from the CDC, The Joint Commission, ANSI/AAMI, and the Dental Directorate.

d. Separate dry heat and steam sterilization operations. Keep dry heat sterilization operations (the sterilizer itself and all dry heat supplies) completely separate from steam sterilizers and supplies! Keep these two systems as far apart as possible. Use signs and drawer/cabinet labels that clearly state that dry heat and steam sterilization supplies and spore test systems are not interchangeable.

e. Create a new "Dry Heat Sterilization Log". The ICO and primary Sterilization technician must design a separate sterilization log to document all dry heat sterilization

loads and dry heat spore test results. Do not use the same sterilization log that you use for steam sterilization. Keep these records completely separate.

2. Actions to take prior to placing your new dry heat sterilizer in service. When your Cox Rapid Heat sterilizer arrives, everyone will want you to immediately start using it to sterilize their mirror sleeves without delay. Don't do this! There are several critical actions that must be completed **before** you can start using your new Cox dry heat sterilizer for routine sterilization operations:

a. First, your Medical Maintenance technicians must conduct an initial T.I. (technical inspection) of the sterilizer to ensure that it is working properly. They will then apply the required ECN label to the sterilizer, and will provide this information to your Property Book Office so that it can be assigned to a hand receipt holder. Note: During the T.I. process, the Medical Maintenance technicians often keep the Operator's Manual for themselves. Although they certainly need a copy of this IFU (or the manufacturer's Service Manual), so do you! As such, ensure that you get a copy to keep on file.

b. Second, as with all medical devices, the Cox sterilizer must undergo appropriate "function testing" (either by the Medical Maintenance technicians during the T.I., or by the ICO) prior to being put into service. In the case of the Cox sterilizer, you must run three consecutive B.I. (spore) tests using the dry heat "in-house" spore test kit and incubator that was purchased. Note: This means that you run three dry heat sterilization cycles back-to-back on the same day, and place the spore tests in the incubator all at the same time. Carefully follow the spore test IFU for conducting the spore test and incubation procedure! The incubation period is seven days, during which time you may **NOT** use the sterilizer. At the end of the 7-day incubation, all three tests should read "negative", and the control test should read "positive". If all three are negative, you may then place the sterilizer in service and begin normal operations. However, if any of the spore tests are positive, then repeat the 3-test protocol. (Most positive results are due to human error.) If the second set of spore tests all come out negative, you may place the sterilizer in service. However, if any of the tests are still positive, contact Medical Maintenance and place a work order to resolve the problem.

c. Critical note on the in-house dry heat spore test. This spore test is not like the one used for steam sterilization. The dry heat spore test requires you to remove the sterilized test strips from its sleeve and aseptically transfer it into the growth medium prior to placing it in the incubator. Warning: if you do this incorrectly and inadvertently contaminate the sterilized test strip during this transfer, this will result in a "false positive" result. Use a strict aseptic technique!!

d. Conduct hands-on training for Sterilization technicians. During the seven-day incubation period for your three spore tests, you will not be allowed to use the Cox sterilizer. Use this time to conduct formal "hands-on training" for all of your Sterilization technicians and managers. Invite your Medical Maintenance technicians to this training if possible to lend their expertise and guidance on the operation and maintenance of the Cox sterilizer. Practice your dry heat sterilization protocol, using the nylon pouches and

dry heat internal chemical indicators on “test instruments” (but don’t release these for actual use).

e. Conduct basic “pre-cleaning” training for all clinic personnel during this 7-day period as well, especially those dental auxiliaries and dentists who will be using the Omnicam mirror sleeves. Provide them with written instructions on how to clean the mirror sleeves IAW the Sirona IFU (e.g., wiping them with a Cavi-wipe, but being careful to wipe the actual lens with alcohol IAW the IFU) before turning them in to the Sterilization Room for reprocessing. Remind all clinic personnel that they are not allowed to operate the Cox sterilizer, and that only the Sterilization technicians may do so.

3. Dry heat sterilization operations. Once you have completed all of the above actions, your Cox dry heat sterilizer is ready to put into regular service. Below are some important items to follow:

a. The OIC, NCOIC, and ICO must develop an efficient dry heat sterilization protocol that will ensure rapid turnaround of the mirror sleeves. This protocol will be based on the number of mirror sleeves that are available to use, and the number of scheduled patient appointments there are on any given day. The Sterilization technicians must be advised that they must give the mirror sleeves a priority for sterilization throughout each duty day, and must make the rapid turnaround of these devices a part of their daily routine.

b. Managers (OIC, NCOIC, and ICOs) must provide frequent oversight of this new dry heat sterilization protocol in the first 30 to 60 days of operation to ensure that all Sterilization technicians are following the correct procedure. This is when human errors are most likely to occur with a new piece of equipment.

c. The Dental Directorate will permit orthodontic instruments to be reprocessed in the Cox dry heat sterilizer in those DTFs that also have a Sirona CAD/CAM system. However, the mirror sleeves will always have priority over orthodontic instruments in the sterilization schedule. In addition, all dental instruments that are dry heat sterilized must be wrapped. To reiterate, the only types of dental instruments that may be dry heat sterilized are Omnicam mirror sleeves and selected orthodontic instruments.

d. Dry heat sterilization logs and the results of weekly spore tests will be kept on file in a separate section of the DTF Sterilization Manual.

4. Special considerations.

a. Spore testing and the release of dry heat sterilization loads. Please be advised that you do **NOT** have to obtain the results of the weekly spore test in order to release dry heat sterilization loads. Like steam sterilization, knowing the results of any spore test is **NOT** a requirement for releasing sterilization loads, with only one exception.

When a steam sterilization load contains an *implantable device*, you must obtain the results of the spore test before you can release the load. (FYI – implantable devices must never be dry heat sterilized.)

b. Expiration dates for wrapped instruments using the dry heat nylon pouches.

Please be advised that the dry heat nylon pouches that have been recommended for use by the Federal Dental Services **have an expiration date of 30 days**. As such, dry heat sterilization Load Control Labels must provide the following information on these nylon instruments pouches:

- 1) Sterilizer number.
- 2) Sequential load number for that sterilizer on the day of sterilization.
- 3) Date of sterilization.
- 4) Date of expiration (e.g., 30 days from the date of sterilization).

This “time-related sterilization” is different from the “event-related sterilization” method that is currently being used for most steam sterilized instrument packs. OICs, NCOICs, and ICOs must ensure that “time-related” sterilization is used for all dry heat loads, and that a 30-day expiration date is clearly indicated on all load control labels. Although it is unlikely that any mirror sleeve will ever be in sterile storage for anywhere close to this expiration period, ICOs must be vigilant in checking the expiration dates of reprocessed mirror sleeves. Similarly, any orthodontic instruments that have been dry heat sterilized must be checked regularly to ensure that none have gone past their 30-day expiration date. Any instrument that exceeds this expiration date must be reprocessed.

b. Flash sterilization will **not** be performed using dry heat sterilization. Reason: given the exceptionally short dry heat sterilization cycle for wrapped instruments (12 minutes), there is virtually no reason not to wrap a dental instrument or device for dry heat sterilization. Also, having an instrument wrapped for sterilization eliminates the problem of transporting an unwrapped flash-sterilized instrument in a sterile manner from the sterilizer to the point of use.

c. Remove any high-level disinfectant from all DTFs. During the past few months, Army DTFs were ordered to cease all intraoral use of the Omnicam until the new Cox dry heat sterilizers could be purchased and put into service. All DENTACs, DCC’s, and DTFs were also forbidden from using “interim” methods of disinfection and from using makeshift barriers for the mirror sleeves. Unfortunately, the loss of so much productivity and the inability for DTFs to keep up with the demand for deliver single crowns caused many DTFs to use these well intentioned, but improper methods to reprocess their mirror sleeves. Some individuals justified their use of HLD solutions (e.g., Cidex OPA) by stating that the Sirona IFU included the use of HLD as an accepted method of reprocessing the mirror sleeves. However, it was made patently clear to all DENTAC and DCC commanders that using HLD for reprocessing mirror sleeves was NOT

authorized in DENCOM Pam 40-5-1, and (more importantly) has not been validated and approved by the FDA for use with these mirror sleeves.

Please be advised that if your DTF is using HLD for this (or any other) purpose, it is in violation of command directives, and is also violating a directive from the FDA to the Federal Dental Services to not use HLD to reprocess the Omnicam mirror sleeve. Now that the Cox sterilizers are expected to arrive to all affected DTFs by the end of this month, the “interim use” of HLD should become a moot point. However, all ICOs are advised to collect all HLD in their DTFs immediately, and turn it in to their local hospital Hazardous Waste collection point or their local installation DRMO.

d. Please be advised that the initial guidance on which dry heat supplies should be purchased for use with the Cox Rapid Heat sterilizer incorrectly listed a “mail-in” dry heat spore test kit (e.g., Item #400634, Spore Test Kit – 52 tests/box). You are advised NOT to purchase this type of spore test kit, since the Army DTFs will only be using the “in-office biological monitoring system (Item #400640) listed above in paragraph 1-a-3). Please know that this in-office spore test kit includes both the test strips and the incubator required to perform this test.

Conclusion: Whenever a new sterilization device or protocol is introduced to DTFs, there is always an initial period of confusion on how it is supposed to be utilized. The purpose of this IC message is to merely augment the official guidance from the Dental Directorate, and to serve as interim implementation guidance until Dental Directorate policies on this subject can be updated. Still, since each DTF is unique in some way, attempts to implement this new sterilization protocol will likely cause some level of confusion that will require additional guidance to resolve. Please feel free to contact me with any questions that you may have at telephone (706) 787-4466, or email at david.l.carr10.civ@mail.mil.

Appendix 2 – IRB Approval Letter



DEPARTMENT OF THE ARMY
HEADQUARTERS, CARL R. DARNALL ARMY MEDICAL CENTER
36065 SANTA FE AVENUE
FORT HOOD, TEXAS 76544-5060

MCXI-QCD

DATE: 24 May 2018

MEMORANDUM THRU

CPT(P) Anthony Hackett, MC, Director, Clinical Investigation and Research Office
(CIRO), Carl R. Darnall Army Medical Center (CRDAMC)

FOR: Jesse Thietten and Richard Low, Principal Investigators (PI)

SUBJECT: Research – Not Involving Human Subjects (RNIHS) Status Determination

PROJECT TITLE: Absolute Sterility of Omnicam Sleeves After Intermediate Level
Disinfection vs Dry Heat Sterilization

REFERENCE #: CRDAMC 18-19

ACTION: RNIHS STATUS DETERMINATION

DETERMINATION DATE: 24 May 2018

1. This letter is in response to your request to Carl R. Darnall Army Medical Center (CRDAMC) for review of the above-referenced project.
2. A CRDAMC Determination Official (DO) has reviewed the study. The DO concluded that the study is Research Not Involving Human Subjects (RNIHS) and is not subject to review by the Institutional Review Board (IRB). The DO also determined that the HIPAA privacy rule is not applicable to this study.
3. This opinion is based on the regulation 32 CFR 219 and associated guidance. Federal regulation 32 CFR 219.102(f) defines a human subjects as a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. In accordance with the regulation and associated guidance, the study does not meet the criteria above and would therefore not be considered human subjects research.
4. Because the study investigators will not see, use, record, or disclosure any individually identifiable health information or protected health information (PHI) as part of this study, HIPAA regulations do not apply (DoD 6025.18-R DL1.1.20 and DL1.1.28).
5. At the completion of your study, you are required to submit a study closure report in accordance with CRDAMC policies.

MCXI-QCD

SUBJECT: Research – Not Involving Human Subjects Status Determination

6. You are reminded that publication clearance is required for all materials submitted for presentation or publication outside of the institution.

7. POC for this action is the undersigned at larissa.a.schmersal.civ@mail.mil or (915) 742-6075.

5/24/2018

X Larissa A. Schmersal

Larissa A. Schmersal, PhD

Determination Official

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