WHITE PAPER ON

Light-Based Rapid Sterilization of Dental and Surgical Instruments

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Executive Summary

Oral health has a major impact on overall health, medical costs, and quality of life. To provide quality oral care, the instrument sterilization process is critical to ensuring patient safety and driving efficiencies in the dental office. Steam sterilization in autoclaves (moist heat in the form of pressurized, saturated steam) is a widely used sterilization method in the dental industry. Advances and innovation in sterilization technologies have provided a unique sterilization process that uses specific slices of the electromagnetic spectrum to effectively sterilize instruments in significantly shorter time periods with lower energy consumption and without the use of any water, thus, eliminating instrument drying and corrosion. This whitepaper will demonstrate the powerful impact to oral health by Lumaegis' novel device (RadBox) and method (GUVIR…Germicidal Ultraviolet and Infrared) to sterilize medical and dental instruments in a fast, efficient, and thorough manner delivering cost savings and dramatically extend instrument lifetime. These benefits lead to significant instrument savings for dental practices.

Today's Challenges in Sterilization

Millions of invasive surgical procedures are performed per year and each of these procedures involves contact by a medical device or surgical instrument with a patient. A major risk of all such procedures is the introduction of pathogenic microbes, which can lead to infection. For example, failure to properly disinfect or sterilize equipment may lead to person-to-person transmission via contaminated devices [1,2]. Steam sterilization in autoclaves (moist heat in the form of pressurized, saturated steam) is a widely used sterilization method in the dental industry. The heat that an autoclave delivers via pressurized steam kills bacteria and other microorganisms by causing the organisms' structural proteins and enzymes to denature in an irreversible way making them nonfunctional. However, there are multiple challenges with steam sterilization.

- The typical duration for the sterilization process could exceed more than one hour affecting instrument turnaround time.
- Heat can damage some materials over multiple cycles. It can melt acrylics, distort PVC, and corrode metal tools.
- An instrument that is wet after steam sterilization can be a source for recontamination.
- Added safety concerns when not operating and maintaining the pressure vessel device per recommended instructions. See FDA MAUDE reports on steam sterilization system [3].

Also, steam sterilizers require de-ionized or steam distilled water and significant amounts of electricity to operate — all of which add up over the lifetime operation of the unit. The cost of de-ionized water alone can reach as high as $100,000 annually ($10,000s per sterilizer for steam distilled) for a medium-sized dental clinic. In steam sterilization, energy and equipment costs have risen and have become an increasing economic burden on oral and medical care. In addition, productivity requirements for dental clinics continue to increase where procedural timing and delicate instrumentation are required for an efficient and successful practice. This is only being accelerated by the burgeoning Dental Service Organization (DSO) trend, where the practitioner is now an employee, not an owner, and where ownership is increasingly of the private equity sort.

Other alternatives to steam sterilization in dentistry include dry heat sterilization or chemical sterilization e.g., ethylene oxide and hydrogen peroxide plasma [4]. Dry heat is a practical way to sterilize surgical instruments. An oven with forced hot air can be used to increase the heat transfer rate but this is a longer process than steam sterilization. Traditional dry heat sterilization is difficult to facilitize and is logistically not easy in the clinical setting. In case of chemical sterilization options, the sterilization time, the toxicity of the chemical, and potential corrosiveness makes it a not viable alternative.

Innovation of RadBox

Lumaegis' solid-state based microbicidal platform eliminates all forms of microbial life and enables the next generation of sterilization devices for healthcare facilities based on modern semiconductor technology. The anti-microbial properties of UV-C radiation are well-established and with intensity and exposure time, UV-C light can break bonds in the DNA and/or RNA strands of pathogens rendering them unable to reproduce [5, 6, 7]. In addition, thermal treatment is widely used for the inactivation of pathogens [8]. Thermal mechanisms to inactivate viruses is accomplished by denaturing the secondary structures of proteins, resulting in damage [9].

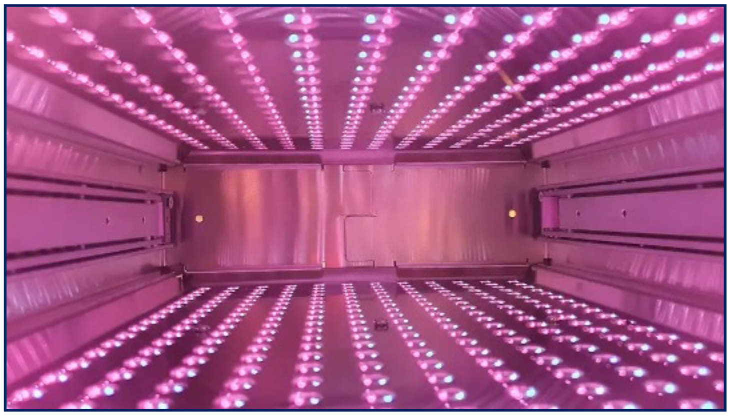

Figure 1: Pre-production RadBox sterilizer.

Lumaegis innovative sterilization solution RadBox (Figure 1), combining germicidal UV-C radiation with raising the temperature of the irradiated surface to increase the killing efficacy has been proven based on 3rd party laboratory results. It has the unique design that, in addition to UV-C light, it uses Infrared (IR) light to increase the temperature of the illuminated surface and hence, improves the effectivity and speed of sterilization. This approach works in close proximity to the target surface (e.g., irradiance is four times higher when bringing the target surfaces closer by half the distance…$1/r^2$). This proximal architecture enables delivery of the required lethal germicidal ultraviolet (UV-C, wavelength ~275 nm) with thermal infrared (IR, wavelength ~800 nm) irradiation (GUVIR) dose in <180 seconds. By using targeted slices of electromagnetic spectrum to attack DNA and RNA — critical ingredient for breaking the covalent bonds and denaturing protein molecules — Lumaegis' device sterilizes surgical tools in minutes, while overcoming many of the limitations and safety concerns of other devices. Time-temperature profiles have been established for bioindicator strips to deliver a Sterility Assurance Level (SAL) representing a microbial inactivation level of twelve logs of Bacillus pumilus spores [10].

Benefits to Practitioners

1. Instrument compatibility and turnaround

Ultraviolet radiation and temperature compatibility with all intrinsic instrument components is imperative. For a RadBox sterilizer, most instruments and their components are constructed of materials that would not be subjected to damage. Standard hand pieces, pliers, and cutters are typically stainless steel do not corrode, dull, pit, or crack under GUVIR radiation. For those instruments that contain plastic or other non-metal components there may be susceptibility to repeated exposure although most non-metal components compatible with a steam sterilization process are also compatible. Changes in color, cracking, or other alteration in physical appearance are visible indicators that the UV-C exposure is affecting the material and could affect the instrument's performance. However, recent innovations in radiation-tolerant materials (e.g., UV resistant fluoropolymers and silicones) used in medical devices have significantly reduced the number of instruments that are intolerant to UV-C.

RadBox sterilizes in hot, dry conditions that minimize or eliminate instrument corrosion. In comparison, chemical or steam sterilization methods, chemical and/or steam react with metals to corrode. Corrosion shortens the lifetime of an instrument due to micro-pitting and dulling. RadBox GUVIR sterilization is a water-free process that is devoid of the conditions necessary to promote corrosion, thus providing practitioners another added benefit in extending tool lifetime. As an example: A single periodontist's drill kit, costing ~ $5,000 per, will only last 15-20 cycles through a steam sterilizer before requiring replacement. RadBox does no such damage and extends tool lifetime an estimated >2X.

A quick turnaround of instruments from one patient to the next results in reduction of expensive instrument inventory and efficient instrument use. Some dentists schedule their procedures based on instrument availability. All steam and chemical sterilization processes are temperature and time dependent and shortening sterilization times to expedite the process is not possible. Total time required of the sterilization consists of (1) the time necessary to achieve the required temperature and pressure or chemical dwell time, (2) the sterilization cycle time, and (3) instrument drying cycle time.

Three types of sterilizers are typically found within dental practices: traditional vacuum-assist autoclave (e.g., Midmark M11), cassette autoclave (e.g., Statim G4 2000) or H_2O_2 plasma (e.g., Sterlink FPS-15). The steam sterilizers take ~17 minutes to achieve the required temperature and pressure before initiating the sterilization cycle. For the vacuum-assist sterilizers (at 270^0F), the sterilization time ranges from 4 to 8 minutes for unwrapped and wrapped instruments, respectively. However, the time required for instrument drying is ~30 minutes for the vacuum-assist autoclave and ~60 minutes for the cassette autoclave (per the sterilizer's FDA 510k). Total instrument turnaround time, therefore, is considerable with vacuum-assist units taking from 48 to 52 minutes and cassette autoclaves taking from 46 to 70 minutes.

RadBox GUVIR sterilization does not require a drying cycle. Complete processing time includes the time required to deliver the microbicidal dose. For unwrapped instruments, the RadBox sterilization cycle time is 6 minutes.

A comparison of total treatment times between sterilization technologies is shown in Table 1 below.

Table 1: Comparison of total treatment times between sterilizers

Sterilizer Type	Sterilant	Pre-Cycle Heating Time (Min)	Sterilizing Time (Min) – Unwrapped	Drying Time (Min)	Total Process Time (Min)
Vacuum-Assist Autoclave (e.g., MidMark M11)[1]	Steam	17	3	60	80
Cassette-Type Autoclave (e.g., Statim G4 5000)[2]	Steam	4	4	40	48
Plasma Type (e.g., Sterlink FPS-15s Plus)[3]	H_2O_2 Plasma	21	15	0	36
Light Radiation RadBox GUVIR[4]	Germicidal UV-C and IR	0	6	0	6

1 - Midmark M11 technical specifications; 2 – Statim G4 2000 specifications; 3 –Sterlink FPS- 15s Plus 14 L technical specifications; 4 – RadBox GUVIR estimates based on 3rd party BI tests

2. Operational Requirements and Workflow

The RadBox will increase throughput of medical and dental tools so that practitioners become more productive. Based on a survey with dental practitioners, they schedule many of their procedures based on cleaning cycles, usually due to one-of-a-kind or limited supply of instruments [11]. Imagine the increased patient throughput with getting tools back in clean working order in 6 minutes vs 75 minutes and the increased revenue.

The workflow of the device is envisioned. All tools first must endure a simple, ultrasonic cleaning and drying procedure, as in any sterilization process. Our simple, 6-minute sterilization cycle improves overall productivity by 2X over the four-tray Midmark M11 steam sterilizer, drastically reducing needed inventory per clinic and enabling more efficient capital spend. Combined with the increased tool lifetime, we conservatively estimate a 4X reduction in needed tool inventory.

RadBox is also ¼ the size of the M11 unit, enabling simple stacking when more capacity is needed. The device plugs into a standard 120V outlet and requires no dedicated breakers or circuitry, meaning installation is simple. The training is a simple 15-minute video, mostly on the operation of the controls and pad messages. Once the technician places the tools in the custom, re-usable FEP tray, seals the top and places the loaded tray in the receiving support, closes the system and hits “go”, the RadBox takes it from there. After six minutes, the technician removes the sterilized tray, scans the barcode for inventory control and delivers the tray for immediate use or into “clean” tool inventory.

Perhaps the most important benefit the RadBox delivers is the on-going costs savings conveyed to the practitioner. As detailed in the Table 2 below, when compared with the four-tray Midmark M11, RadBox saves over $25,000 per unit annually due to no water being used, 1/20th of the power consumption and other consumable and labor savings. For a mid-size dental clinic using four Midmark’s, that’s $100,000 savings per year. System lifetime is designed for 3+ years and can then be re-furbished with new, higher power and more efficient LED panels, thus extending the units lifetime indefinitely.

Table 2: Maintenance, repair and operations (MRO) cost comparison between sterilizers

	Midmark m11** Steam	Statim G4 2000*** Steam	Sterlink FPS-15s **** H_2O_2	RadBox Light	Comments
Average tray size, cm²	755	500	1000	507	Average size of each tray
Run time fully loaded, min.	75	40	36	5-6	12x longer time for Midmark m11
Total tray area, cm²	3,019	500	1000	507	4 trays for Midmark m11, 1 for Radbox
Area sterilized / fully loaded run, cm²/min	40.4	12.5	27.8	101.5	RadBox 2-3x better
Damage to assets	Yes	Yes	Yes	No	Steam/Plasma sterilization deforms tools
Power used per run, Wh	1600	1450	1000	80	RadBox 20x lower power consumption
Water/H_2O_2 used, gallon	2	0.1	0.001 H_2O_2	0	RadBox no water, steam or chemicals
Running cost per annum*, $	33,000.00	29,575.00	44,000.00	7,000.00	MRO costs for 400 tool/day, 8 hour/day & 260 days/year

* Based on 8-hour shift, 260 days/year; ** Midmark M11 technical specifications; *** Statim G4 2000 specifications; **** Sterlink FPS- 15s Plus 41 L technical specifications

Bottom Line

The RadBox GUVIR sterilization method using UV-C and IR radiation provides a safer and more effective solution for sterilizing dental instruments. Its fast cycle times, reduced maintenance requirements and lower environmental impact make it a disruptive alternative to traditional methods. It pays for itself in 4 months saving the practitioner $25,000/yr vs. steam sterilizers and has the potential to increase tool turnaround time by 2X while improving tool lifetime. The benefit to the dental office is reduced inventory per clinic by estimated 4X and reducing the need for capital investment.

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