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THE EFFECTIVENESS OF CLEANING AND STERILIZING RECIPROCAL ORTHODONTIC INTERPROXIMAL REDUCTION STRIPS FOR PATIENT RE-USE: A COMPARATIVE STUDY

DISCLAIMER

The opinions or assertions contained herein are the private ones of the authors and are not to be construed as official or reflecting the view of the Department of Defense or the Uniformed Services University of the Health Sciences.

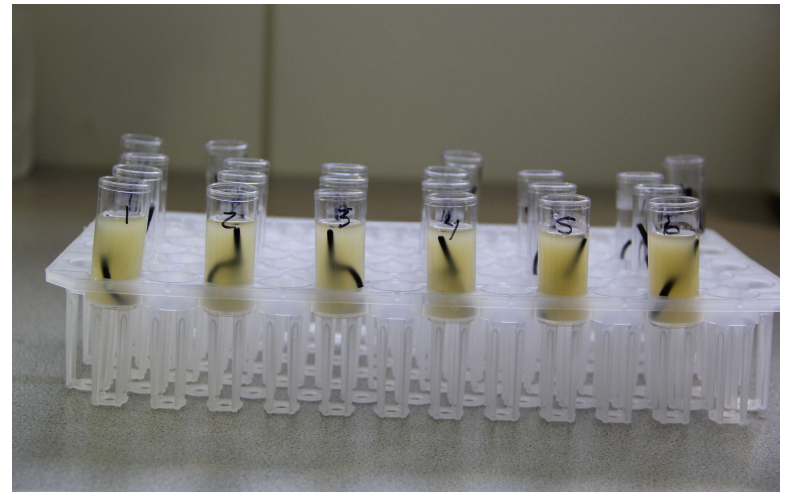
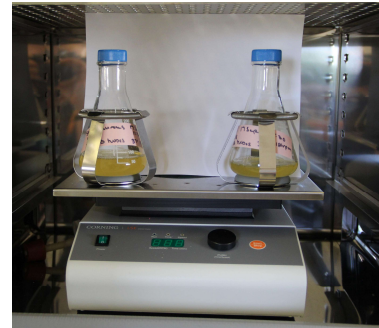
BACKGROUND AND PURPOSE

Diamond coated IPR strips are used for the incremental removal of enamel between teeth. Infection control research has sparked a national debate about cross-contamination through medical devices and the need to limit them to single use. Proponents cite patient safety while opponents cite the costs and waste of such policies. In 2003 the FDA regulated that all manufacturers label diamond coated dental instruments as “single use” citing a lack of research by manufacturers on the subject. While there are limited studies on cylindrical burs, there are none on IPR strips. Additionally, there is a lack of investigation into how variables such as diamond grit and methods of cleaning relate to sterilizability and removal of debris on these instruments. The purpose of this study was to eliminate the uncertainty about the safety of IPR strip re-use, and by extension, the re-use of dental diamond coated instruments.



MATERIALS AND METHODS

178 sterile IPR strips (half extra-course and half extra-fine) were used to strip enamel from sterile bovine teeth. Each IPR strip was then immersed in 5ml bacterial suspension of staph aureus and psuedomonas aeruginosa (approx. 1.5×10^8 colony forming units/ml) for 30 seconds. The samples were removed from the inoculation and left in a sterile container for 4 hours. Samples were randomly divided into 4 groups investigating varying cleaning methods as seen on the following slides.

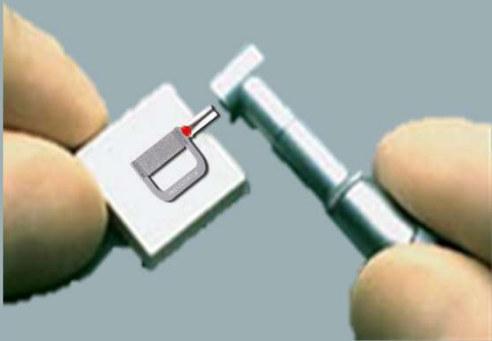


CLEANING PROTOCOLS

Cleaning Stone

Initial bioburden removal with cleaning stone

10 sec runtime of IPR strip over stone with handpiece



Sonication

Sonicate IPR strips in Quantrex 360 for 15 minutes

Ultradose germicidal cleaning solution and disinfectant



Washing

Wash IPR strips in BeliMed WD 250 washer

PI enzymatic normal cycle

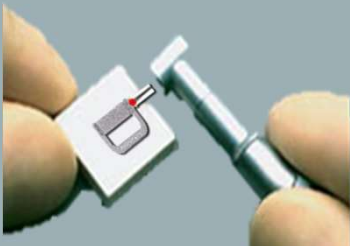
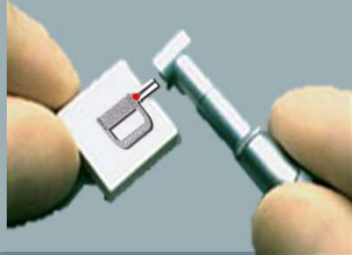












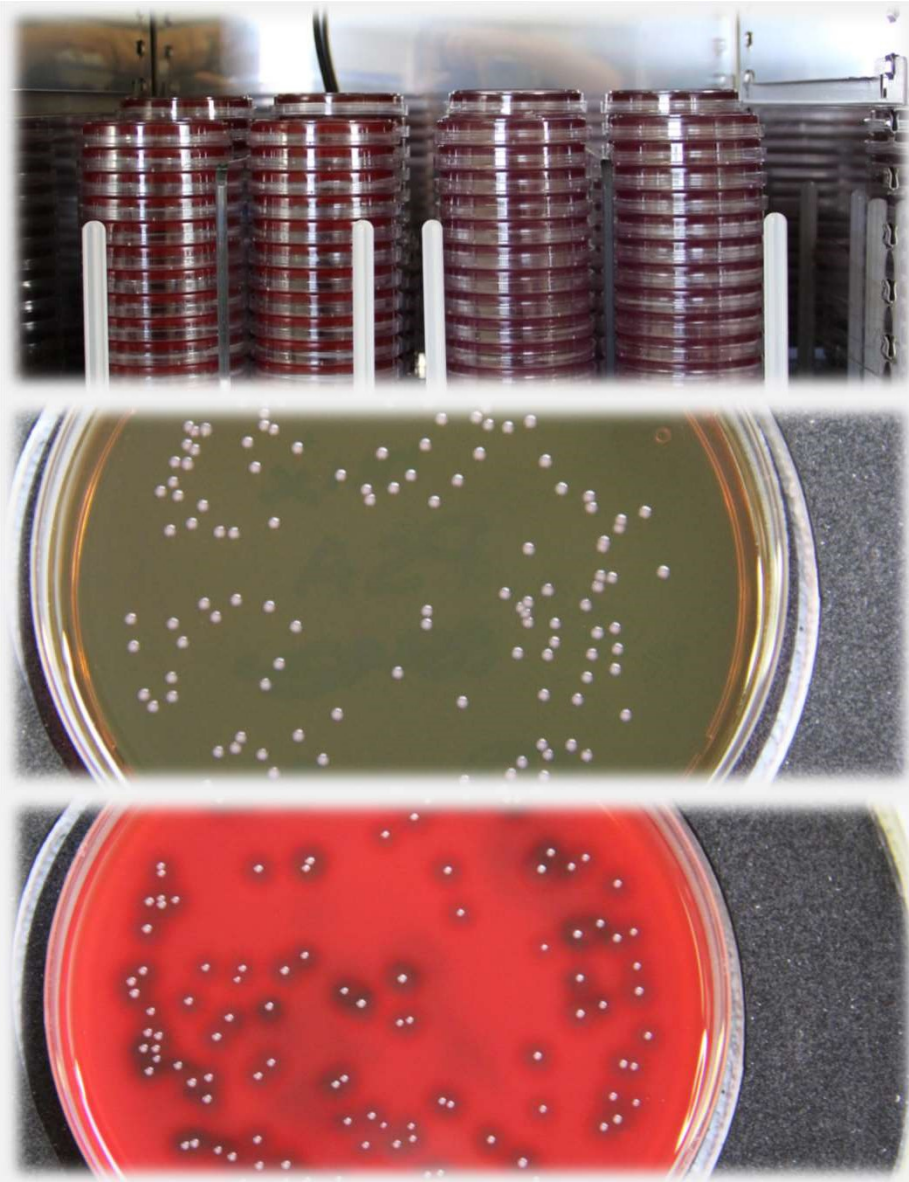
Sterilization

Pack IPR strips in self-sealing pouches

Autoclave in Getinge 553LS steam sterilizer at 274°, 30 psi for 10 minutes



Method	Group 1	Group 2	Group 3	Group 4
Cleaning Stone				
Ultrasonic				
Machine Washer				
Autoclave				



MATERIALS AND METHODS

Additionally, each group had positive controls with inoculated IPR strips that were not cleaned and negative controls with clean IPR strips out of the package that were sterilized. All IPR strips were immersed in 5ml sterile saline and vortex mixed to remove organisms. The saline was plated on two types of agar growth mediums specific for staph aureus and pseudomonas aeruginosa. The plates were incubated for 24 hours and the resulting colony forming units were counted.

MATERIALS AND METHODS

16 IPR strips were set aside from the following: Out of the package, after enamel stripping but before inoculation and cleaning, and one from each test group. These strips were investigated under scanning electron microscope to determine the amount of debris on each sample.



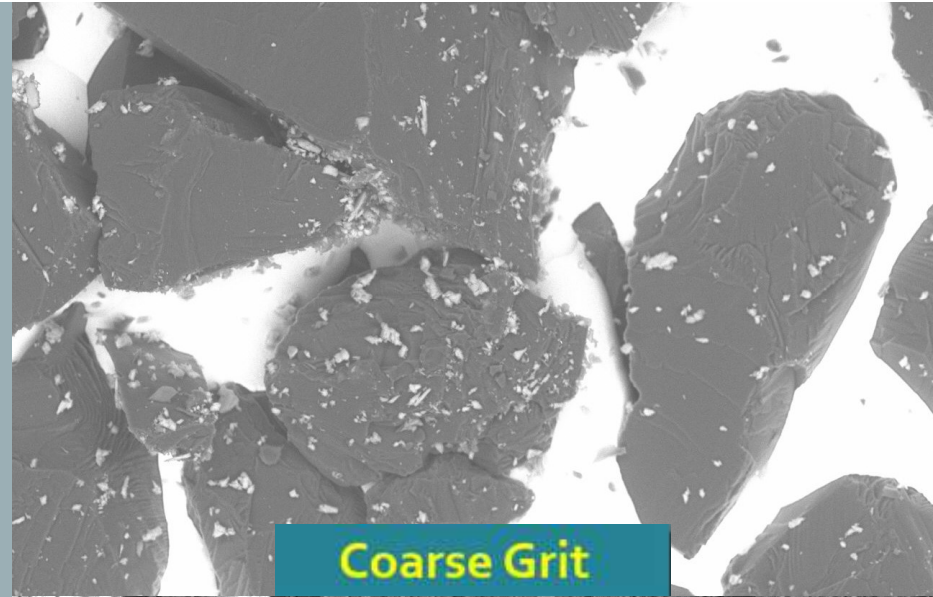
RESULTS: MICROBIOLOGY

Results were reported as a percentage of the kill rate from the positive controls. Most of the groups had a bacterial kill rate of 100%. Those that did not had at least a bacterial load reduction of 7 log₁₀.

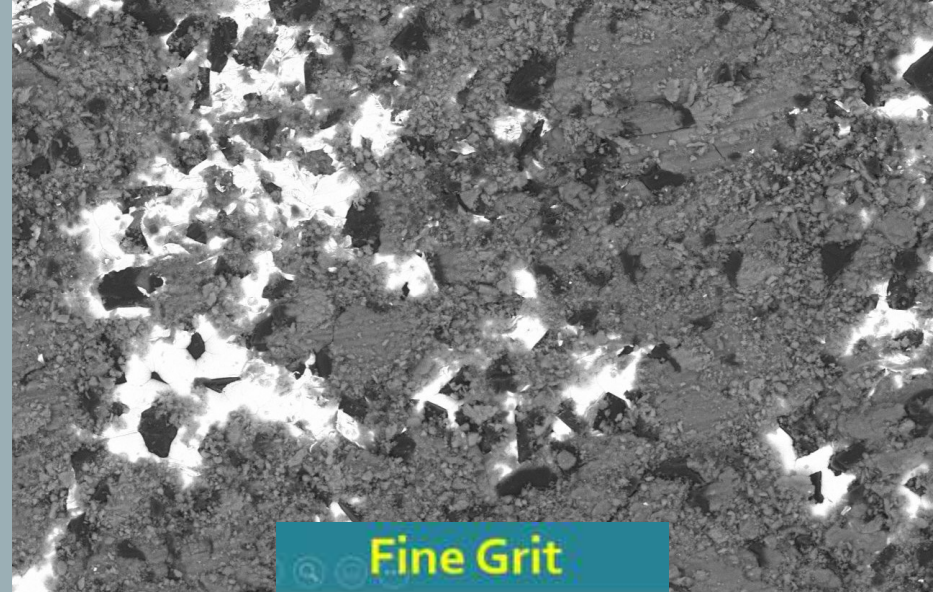
White (Fine) IPR Strip % Reduction From Positive Control	Black (Coarse) IPR Strip % Reduction From Positive Control
Group 1 100.00000000%	Group 1 99.99999531%
Group 2 100.00000000%	Group 2 100.00000000%
Group 3 100.00000000%	Group 3 99.99999812%
Group 4 100.00000000%	Group 4 99.99999718%
Neg. Control 100.00000000%	Neg. Control 100.00000000%

RESULTS: SCANNING ELECTRON MICROSCOPE

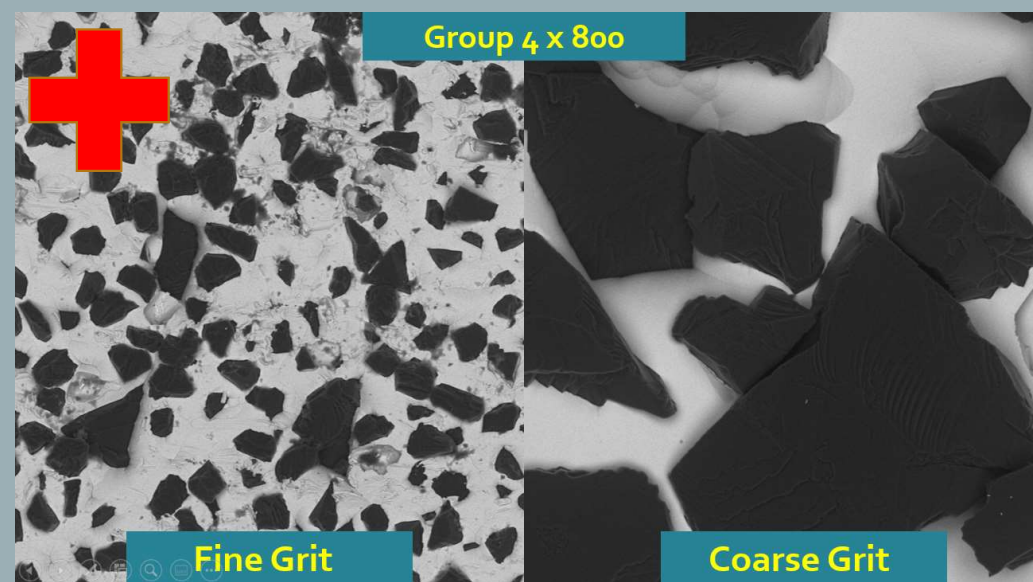
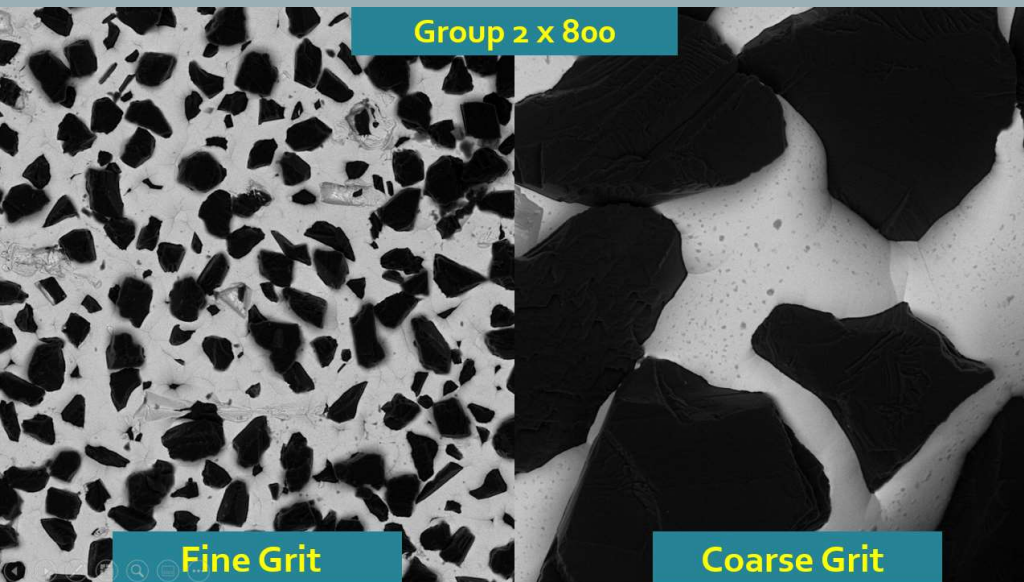
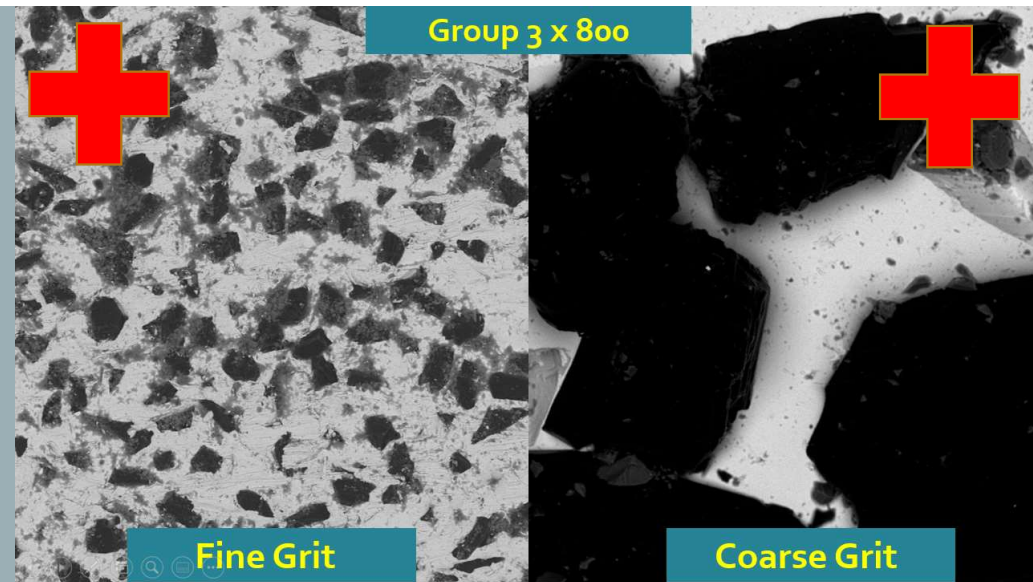
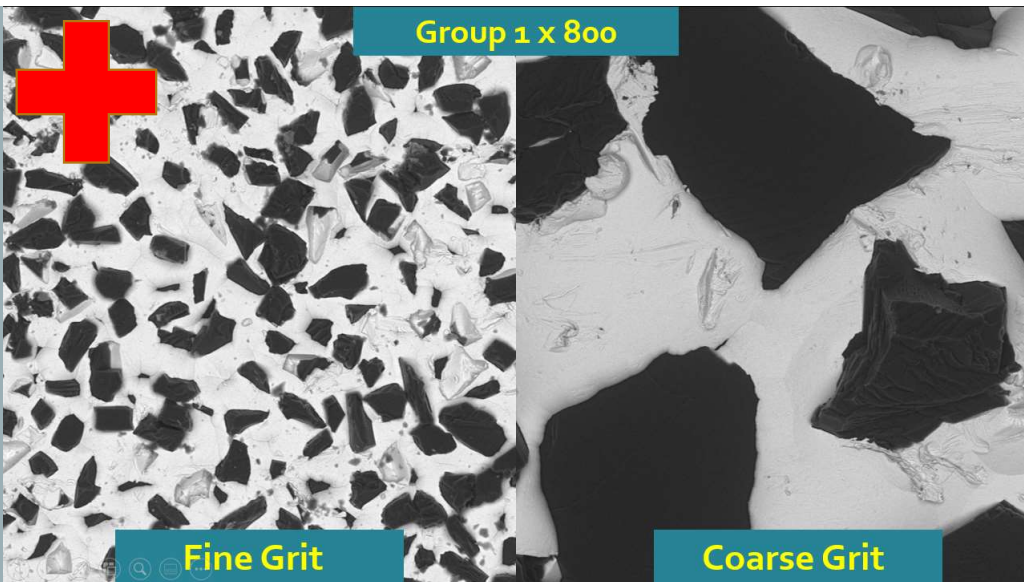
For the baseline enamel stripping, the fine IPR strip had significantly more debris than the coarse IPR strip. Only group 3 had visual debris remaining on the coarse IPR strips. Of the fine IPR strips, groups 1,3 and 4 all had remaining debris as can be appreciated on the following slide.



Coarse Grit



Fine Grit



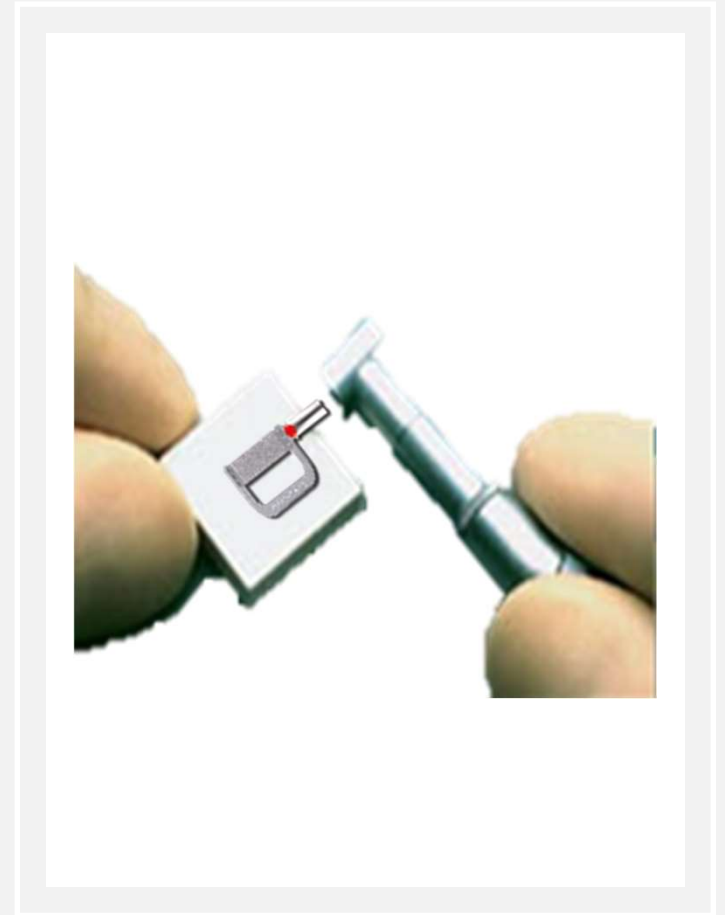
DISCUSSION

The FDA sterilization standard for reprocessing instruments is a 6 log₁₀ reduction which is a kill rate of 99.9999% of microbes. As all groups within this study had at least a 7 log₁₀ reduction, all samples fell within the sterility range. This finding was different than other findings within the literature. The use of an ultrasonic cleaner and autoclave have been well established in the literature as the best methods for cleaning and sterilizing, yet all studies showed less than sterile/debris free results. The glaring difference between this study and all others was the use of a machine washer. Thus, a washer prior to autoclave appears to be critical for sterility.



DISCUSSION

The difference in debris between the coarse and fine diamond coated IPR strips can likely be explained by the ease of access for cleaning between the coarse diamond particles and the difficulty of access between the fine diamond particles. In the fine diamond IPR strip groups, all samples cleaned without a washer had remaining debris. If there were remaining debris on samples cleaned with the washer, it was because they were first cleaned with a cleaning stone which tended to produce more debris than enamel stripping. The use of a cleaning stone does not appear to contribute to sterility but does appear to increase the chance of remaining debris on processed instruments which are most likely debris from the stone itself.



CONCLUSION

Based on the data, it appears that used extra course and fine diamond coated IPR strips can be effectively re-processed for patient re-use. In order to effectively remove all debris and sterilize, it is recommended that strips undergo sonication, machine washing and steam sterilization after patient use. Use of a cleaning stone does not appear necessary and may increase remaining debris.

BIBLIOGRAPHY

1. Charatan F. Controversy erupts over reuse of "single use" medical devices. *West J Med* 2000;172:58-59.
2. Dunn D. Reprocessing single-use devices--the ethical dilemma. *AORN J* 2002;75:989-999; quiz 1000-1004.
3. Laheij AM, Kistler JO, Belibasakis GN, Valimaa H, de Soet JJ, European Oral Microbiology W. Healthcare-associated viral and bacterial infections in dentistry. *J Oral Microbiol* 2012;4.
4. Al-Jandan BA, Ahmed MG, Al-Khalifa KS, Farooq I. Should Surgical Burs Be Used as Single-Use Devices to Avoid Cross Infection? A Case-Control Study. *Med Princ Pract* 2016;25:159-162.
5. Morrison A, Conrod S. Dental burs and endodontic files: are routine sterilization procedures effective? *Tex Dent J* 2010;127:295-300.
6. Gul M, Ghafoor R, Aziz S, Khan FR. Assessment of contamination on sterilised dental burs after being subjected to various pre-cleaning methods. *J Pak Med Assoc* 2018;68:1188-1192.
7. Sajjanshetty S, Hugar D, Hugar S, Ranjan S, Kadani M. Decontamination methods used for dental burs - a comparative study. *J Clin Diagn Res* 2014;8:Zc39-41.
8. Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data. In: Food and Drug Administration H, editor. *National Register* 2003: p. 23139-23148.
9. Penel G, Iost A, Libersa JC. [Cleaning implantation burs. Observations using scanning electron microscopy]. *Bull Group Int Rech Sci Stomatol Odontol* 2001;43:11-13.
10. Javanmardi F, Emami A, Pirbonyeh N, Keshavarzi A, Rajaei M. A systematic review and meta-analysis on Exo-toxins prevalence in hospital acquired *Pseudomonas aeruginosa* isolates. *Infect Genet Evol* 2019;75:104037.
11. Mekviwattanawong S, Srifuengfung S, Chokepaibulkit K, Lohsiriwat D, Thamlikitkul V. Epidemiology of *Staphylococcus aureus* infections and the prevalence of infection caused by community-acquired methicillin-resistant *Staphylococcus aureus* in hospitalized patients at Siriraj Hospital. *J Med Assoc Thai* 2006;89 Suppl 5:S106-117.
12. Administration USFD. Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration 2015; Center for Devices and Radiologic Health:28.