

**USAF DENTAL INVESTIGATION SERVICE  
Detachment 1, USAF School of Aerospace Medicine  
Great Lakes, IL 60088**

**FINAL PROJECT REPORT**

**DioxiClear  
(Frontier Pharmaceutical, Inc.)  
1 May 2002**

**Project #01-70**

**OBJECTIVES:** To evaluate the ability of DioxiClear cleaner to produce dental unit water that meets the American Dental Association (ADA) recommended goal for microbial water quality. The handling, clinical acceptability, ease of use were also assessed.

**DATE OF EVALUATION:** February 2002 to April 2002

**EVALUATORS:** Col Joseph A. Bartoloni, USAF Dental Investigation Service, Great Lakes, IL; SSgt Paul A. Juergens, Laughlin AFB TX.

**PRODUCT DESCRIPTION:**

DioxiClear is a chlorine dioxide-based dental unit waterline cleaner marketed for use in units that have a self-contained water system. The product consists of two separate liquid concentrates that are placed in a dental units self-contained reservoir and then mixed with tap water. The mixing activates the active ingredients: chlorine dioxide and chlorous acid. For ideal waterline cleaning, the manufacturer recommends that DioxiClear be used in two steps: a twice-monthly flush with high concentrate solution for three minutes, and daily use of low concentrate solution (for continuous use). DioxiClear is supplied in one-gallon sets, including a measuring beaker and graduated cylinder to facilitate proper mixing concentrations.

**Manufacturer:**

Frontier Pharmaceutical, Inc.  
135 Spagnoli Road  
Melville, NY 11747  
(800) 767-3486  
(631) 777-1420  
(631) 777-1422 FAX  
[www.frontierpharm.com](http://www.frontierpharm.com)

**METHODS AND MATERIALS:**

The evaluation of DioxiClear consisted of clinic-user testing at a USAF dental clinic. All dental units involved in the evaluation of this product had been previously treated with other recommended waterline cleaners.

Clinical Evaluation: DioxiClear was provided to the Laughlin AFB TX dental clinic to evaluate its handling, clinical acceptability, and ease of use as well as its ability to achieve the ADA-recommended goal for microbial water quality for dental unit waterlines. Millipore HPC samplers (Millipore Corporation, Bedford, MA) were used to monitor water quality on a weekly basis for eight weeks. All water samples were taken from the same water exit port. A three-page, twenty-item questionnaire was used to obtain the evaluator's opinion regarding product features.

**RESULTS:**

Clinical Evaluation: The answers to the questionnaire items follow.

2. Number of years you have in dentistry:  
9 years
3. Indicate the length of time you evaluated this product:  
8 weeks
4. What is your source of water for use in the separate water system?  
Bottled sterile water
5. Does your clinic periodically disinfect the dental unit waterlines?  
Yes  
If "Yes," what product do you use, how long does the procedure take, and what frequency?  
Sterilex Ultra, overnight, once per week
6. Does your clinic periodically monitor the quality of the water in the dental units?  
Yes  
If "Yes," what culturing technique is used, how often do you do it, and what percentage of DTRs are monitored during each monitoring phase?  
Millipore HPC samplers, twice per month, all DTRs
7. Please rate the following features for DioxiClear by circling one of the available choices:

	Excellent	Good	Average	Fair	Poor
User-friendly instructions	(+2)	(-1) *	(0)	(-1)	(-2)
Ease of placement	(+2) *	(+1)	(0)	(-1)	(-2)
Ease of use	(-2)	(+1) *	(0)	(-1)	(-2)
Effectiveness	(+2)	(-1)	(0)	(-1)	(-2)

8. Did you notice any offensive odor from product use?  
Yes  
If "Yes," please describe.  
Strong bleach smell

9. Were there any patient complaints about after taste?  
No
10. Were there any clogging of the lines or signs of residue?  
No
11. Did you find the protocol to be time intensive?  
No
12. Did you find the protocol difficult to implement?  
No
13. Did you note any increased problems with the dental unit during the test period?  
No
14. Please list the monitoring results (Pass or Fail, using ADA goal of 200 cfu/ml).  
Week 1-Pass      Week 5-Pass  
Week 2-Pass      Week 6-Pass  
Week 3-Pass      Week 7-Pass  
Week 4-Pass      Week 8-Pass
15. Do you think this product has any advantages(s)?  
Yes  
If "Yes," describe the advantage(s):  
-"relatively easy to use"
16. Do you think this product has any disadvantage(s)?  
Yes  
If "Yes," describe the disadvantage(s):  
-"the strong bleach smell"
17. What changes, if any, would you recommend be made to this product to improve it?  
None
18. Please provide any other comments you have about this product: NA
19. How would you rate this product overall? (Please circle only one choice)
- |           |      |         |      |      |
|-----------|------|---------|------|------|
| Excellent | Good | Average | Fair | Poor |
|-----------|------|---------|------|------|
20. Would you purchase DioxiClear for your clinic?  
Yes

**DISCUSSION:**

Biofilms routinely form in dental unit waterlines due to the adhesion of planktonic (i.e., free-floating) bacteria found in the source water. This biofilm can then grow and proliferate if not treated by some means. The biofilm can range from 30 to 50 microns in thickness and can become dislodged during patient treatment, contaminating other areas of the dental unit and potentially exposing patients to opportunistic bacteria.

Several methods have been recommended to reduce microbial counts in dental unit water used for nonsurgical dental procedures. These methods include flushing, use of chemical germicides via an independent water system, filters, and sterile water delivery systems. Due to simplicity, many dental

clinics have opted to use chemical germicides placed into the separate water system to treat the waterlines. When selecting chemicals, it is essential that they be non-toxic, safe for patient treatment, non-corrosive to dental unit components, effective, and that are compatible with restorative materials. Several different types of chemicals have been shown to improve unfiltered output water. These include sodium hypochlorite, chlorine dioxide, hydrogen peroxide, citric acid, iodine, chlorhexidine gluconate, and commercial over-the-counter mouthwashes.

DioxiClear is a chlorine dioxide-based product that the manufacturer recommends be used at a high concentration biweekly for a three-minute contact time, and continuously at a lower concentration. The evaluator rated the handling properties as "Good to Excellent" and found the product easy to place. He also felt that DioxiClear was simple to implement, requiring minimal chair side time. During the eight-week testing period, no waterline clogging or detrimental effects were noted to the dental unit. Also, the patients did not complain of any bleach after-taste during the continuous use of the product. All water samples met the ADA goal for microbial water quality. The main disadvantage noted was a strong bleach smell when used for the biweekly flush. The evaluator stated he would purchase DioxiClear for his clinic due to its many advantages.

#### **ADVANTAGES:**

- + After treatment, dental unit water met ADA recommendations.
- + Easy to mix and use.
- + Simple protocol to implement.
- + No clogging of waterlines noted.
- + No detrimental effects noted to the dental unit.
- + Minimal amount needed for daily application.
- + Easy to dispense using provided spigot, beaker, and graduated cylinder.
- + No after-taste noted when used continuously at the recommended concentration.

#### **DISADVANTAGES:**

- More expensive than using diluted bleach for cleaning waterlines.
- Strong bleach smell when used for biweekly flush.
- Product requires mixing.

#### **SUMMARY AND CONCLUSIONS:**

DioxiClear is a two-part, chlorine dioxide-based dental unit waterline cleaner. It was rated "Good or Excellent" for its handling properties and clinical acceptability. During the eight-week test period, all tested water samples met the ADA goal for dental treatment water used for nonsurgical procedures. The product requires mixing two liquid concentrates with tap water in the dental unit's separate water bottle. Manufacturer instructions recommend a biweekly flush for three minutes using a high concentration solution, and a continuous, daily use of a low concentration solution. Patients did not complain of after-taste when the product was used continuously. The dental staff felt the product was easy to use and required minimal time to implement. Its relatively minor disadvantages were increased cost compared to using diluted bleach for waterline cleaning, a strong bleach smell when using the product for the biweekly flush, and the need for mixing before use. DioxiClear is rated Acceptable for use by the federal dental services.

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