

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 25, 2023

Michael Overmyer COO Anodia Systems, LLC 109 Larrimore Lane Danville, KY 40422

Subject: Label Amendment – Updating the previously approved dental unit Cabriton

waterline language throughout the label and the Directions for Use language for

the different types of dental units that are connected to the city water.

Product Name: Mint-A-Kleen

EPA Registration Number: 85298-2 Application Date: July 04, 2022 Action Case Number: 00377236

Dear Mr. Overmyer:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Page 2 of 2 EPA Reg. No. 85298-2 Action Case No. 00377236

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Lorena Rivas via email at rivas.lorena@epa.gov.

Sincerely,

Steven Snyderman, Product Manager 33

Regulatory Management Branch II Antimicrobials Division (7510M)

Office of Pesticide Programs

Steven Inyderman

Enclosed: Stamped label

MINT-A-KLEEN® EPA FINAL MASTER LABEL

Front Panel

[MINT-A-KLEEN®] [SHOCKING®] [BottleX®]

[DENTAL] [UNIT] [CAVITRON] [SCALER] [WATERLINE] [WATER LINE] [&] [WATER] [BOTTLE] [MEDICAL DEVICE] [CPAP] [SLEEP APNEA MACHINE[S]] [AND] [OR] [FOR] [OTHER SLEEP APNEA MACHINES] [OTHER PRESSURIZED ASSISTED BREATHING MACHINES] [LIQUID] [TREATMENT] [CLEAN[S]] [CLEANING] [SOLUTION] CLEANER

[PATENTED FORMULA & PROTOCOL FOR DENTAL UNIT [WATER BOTTLE] [&] [WATERLINE] [WATER LINE] CLEANING TREATMENT [BY ANODIA SYSTEMS, LLC].] [PATENTED CLEANING FORMULA & PROTOCOL FOR CPAP SLEEP APNEA MACHINES & OTHER PRESSURIZED ASSISTED BREATHING MACHINES BY ANODIA SYSTEMS, LLC.] [PATENTED CLEANING SOLUTION]. [For Use in any [CPAP] [Sleep Apnea Machine].] [For Use in any [Dental] [Unit] [&] [Water Bottle] [Scaler] [Cavitron].] [Cleans [contaminated] CPAP [and] [other] [sleep apnea machine[s]].] [Cleans [contaminated] dental unit [waterlines] [water lines].] [Cleans [contaminated] dental water bottle[s].] [Shock and maintenance cleaning treatment].

ACTIVE INGREDIENTS

Chlorhexidine Gluconate 0.12% OTHER INGREDIENTS 99.88% TOTAL 100.00%

[[CLEAN] [FRESH] [REFRESHING] [MINT SCENT] [PEPPERMINT SCENT] [SPEARMINT SCENT] [MINT FRAGRANCE] [PEPPERMINT FRAGRANCE] [SPEARMINT FRAGRANCE]]

See carton insert for additional [Precautionary Statements], [First Aid], [Directions for Use], [and] [Container Handling]. READY TO USE | DO NOT DILUTE | DO NOT FILTER [MINT-A-KLEEN®] [NO MIXING REQUIRED] [DO NOT ATTACH MINT-A-KLEEN® BOTTLE TO DENTAL UNIT.] [ADD MINT-A-KLEEN INTO DENTAL UNIT'S EMPTY WATER BOTTLE. NO WATER.][[Pour Mint-A-Kleen into empty dental water bottle to clean water bottle] [and] [to dispense Mint-A-Kleen into the dental unit for [waterline] [water line] cleaning].] [DO NOT USE BLEACH IN [DENTAL UNIT] [WATER LINES] [WATERLINES] [&] [DENTAL WATER BOTTLE] [CAVITRON] [SLEEP APNEA MACHINE] [CPAP].] [CLEANING SOLUTION] NOT FOR HUMAN CONSUMPTION]. [DO NOT DRINK] [FOR EQUIPMENT USE ONLY].

Net Contents: OZ (ML)

[4 FL OZ (118ML)]; [8 FL OZ (236 ML)]; [12 FL OZ (355 ML)]; [16 FL OZ (473 ML)]; [20 FL OZ (591 ML)]; [32 FL OZ (946 ML)]; [64 FL OZ (1.9 L)]; 1 GALLON (3.8 L)]

[CAUTION] [KEEP OUT OF REACH OF CHILDREN]



Watch our Online Instructional Video at www.AnodiaSystems.com PATENTED Product by Anodia Systems, LLC, Protected by U.S. Patent: [10,785,998] [&] [10,849,999]. [Mint-A-Kleen] is Developed, Patented, Bottled & Owned by Anodia Systems, LLC.

MADE IN USA [Made in the United States of America] Questions? Please contact us directly:

Anodia Systems, LLC [Dental Manufacturer] [Healthcare Manufacturer] 109 Larrimore Lane Danville, KY 40422 P: 866.246.2548

E: info@AnodiaSystems.com www.AnodiaSystems.com

EPA Reg. No. 85298-2 EPA Establishment No. 85298-KY-001

ACCEPTED

04/25/2023

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 25000 0

85298-2

- [Cleans any dental unit: [Closed] [Independent] [Self-Contained] and [Open] [Directly Plumbed] [City Water] [Municipal Water Supply] [dental units] [dental unit water delivery systems] [systems].]
- [Cleaning solution for [dental unit] [scaler] [cavitron] [waterlines] [water lines] [dental water bottle].]
- [Cleaning solution for [CPAP] [sleep apnea machine].]
- [For the cleaning of dental unit [waterlines] [water lines] [and] [water bottles].]
- [For the cleaning of [CPAP] [sleep apnea machine] [&] [other pressurized assisted breathing machines].]
- [PATENTED CLEANING FORMULA]
- [PATENTED CLEANING PROTOCOL]
- [Cleans all dental equipment containing dental unit [waterlines] [water lines] including cavitron's [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]
- [Maintains dental unit water quality by cleaning contaminated dental unit [waterlines] [water lines].]
- [Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & [Dental] [Waterlines] [water lines].]
- [Cleans dental unit [waterlines] [water lines] [and] [water bottles].
- [Mint-A-Kleen's patented cleaning formula and protocol cleans contamination in dental unit [waterlines] [water lines] [and] [water bottles].]
- [Maintains sleep apnea machine's air quality by cleaning the sleep apnea machine once per week.]
- [ONCE PER WEEK CLEANING TREATMENT.]
- [NOT FOR CONTINUOUS USE.]
- [Does not corrode scaler [cavitron], dental unit and dental equipment's [waterlines] [water lines], valves, reservoirs and bottles.]
- [Does not clog [waterlines] [water lines].
- [Non-staining]. [Water soluble.] [Does not stain the dental unit [waterlines] [water lines] and dental bottle.] [Does not affect dental bonding]. [No impact on bonding].
- [Cleans any dental unit: [Closed] [Independent] [Self-Contained] and [Open] [Directly Plumbed] [City Water] [Municipal Water Supply] [dental units] [dental unit water delivery systems] [systems].]
- [Cleaning solution for [dental unit] [scaler] [cavitron] [waterlines] [water lines] [dental water bottle].]
- [Cleaning solution for [CPAP] [sleep apnea machine].]
- [For the cleaning of dental unit [waterlines] [water lines] [and] [water bottles].]
- [For the cleaning of [CPAP] [sleep apnea machine] [&] [other pressurized assisted breathing machines].]
- [PATENTED CLEANING FORMULA]
- [PATENTED CLEANING PROTOCOL]
- [Cleans all dental equipment containing dental unit [waterlines] [water lines] including cavitron's [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]
- [Maintains dental unit water quality by cleaning contaminated dental unit [waterlines] [water lines].]
- [Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & [Dental] [Waterlines] [water lines].]
- [Cleans dental unit [waterlines] [water lines] [and] [water bottles].
- [Mint-A-Kleen's patented cleaning formula and protocol cleans contamination in dental unit [waterlines] [water lines] [and] [water bottles].]
- [Maintains sleep apnea machine's air quality by cleaning the sleep apnea machine once per week.]
- [ONCE PER WEEK CLEANING TREATMENT.]
- [NOT FOR CONTINUOUS USE.]
- [Does not corrode scaler [cavitron], dental unit and dental equipment's [waterlines] [water lines], valves, reservoirs and bottles.]
- [Does not clog [waterlines] [water lines].
- [Non-staining]. [Water soluble.] [Does not stain the dental unit [waterlines] [water lines] and dental bottle.] [Does not affect dental bonding]. [No impact on bonding].

BACK PANEL MINT-A-KLEEN® EPA FINAL MASTER LABEL

[<u>Set 1 of 8</u> Master Label Directions for Use: Closed Dental Unit Water Bottle System Mint-A-Kleen Dental Unit Waterline & Dental Water Bottle Cleaning Instructions]

[DENTAL [UNIT] [WATERLINE] [WATER LINE] [&] [WATER] [BOTTLE] [SCALER] [CAVITRON] [CLEANER] [LIQUID] [CLEANING] [SOLUTION]

- [Cleaning solution] [used] [For the cleaning of contamination in dental unit [waterlines] [water lines] and [dental water] bottles.] [For use in any dental unit [,] [scaler] [cavitron] [and] [dental water bottle].]
 - [Mint-A-Kleen Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & Dental [Waterlines] [water lines].]
 - [Mint-A-Kleen cleans by removing contamination in dental unit [waterlines] [water lines] [and] [water bottles].
 - [Mint-A-Kleen's patented cleaning formula and protocol cleans contamination in [contaminated] dental unit [waterlines] [water lines] [and] [water bottles].]

[Mint-A-Kleen cleans all dental equipment containing dental unit [waterlines] [water lines] including [cavitron's] [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]

[Refer to the additional Mint-A-Kleen® Sets of Cleaning Instructions on Carton Insert] [or] [Download Cleaning Instructions Carton Insert on our Website, www.AnodiaSystems.com.]

 [Additional Mint-A-Kleen Sets of Instructions provides how to use Mint-A-Kleen with dental unit [waterline] [water line] cleaning accessories, how to clean scaler [cavitron], [Closed] [Independent] [Self-Contained] [and] [Open] [City Water] [Municipal Water Supply] [Directly Plumbed] [dental units] [dental unit water delivery systems].]

[BEFORE YOU [START] [BEGIN] [DENTAL UNIT] [WATER LINE] [WATERLINE] CLEANING TREATMENT] [BEGINS] :

- [Remove handpieces and insert from scalers to prevent clogging of the instruments' dental unit water lines.]
- [Remove insert from scaler before removing water from dental unit or scaler [cavitron].] [If not removed, the insert, the scaler and handpiece can become clogged.]
- [Disconnect handpieces for sterilization and leave handpiece hoses for [waterline] [water line] cleaning treatment.]
- [[Disconnect Water Purifying Filter Cartridges] [:] [remove inline water filter cartridge from dental [waterline] [water line] that treats dental water before using Mint-A-Kleen®.] [Do not filter Mint-A-Kleen's ingredients.] [Do not filter Mint-A-Kleen.] [through [iodine] [silver] cartridge]. [Mint-A-Kleen is a ready to use formula that should not be [filtered][,] [diluted] [or] [altered].]
 - [IF Dental Unit has Water Purifying Filter Cartridge [(Purifying Dental Water)]:
 - [Remove Chemical (Iodine, Silver, etc.) Filter Cartridge for Dental Unit Water Purifying Treatment from the Dental Unit Manifold's Pick-Up Tube.]
 - [After Dental Water Treatment Filter Cartridge is <u>removed</u> from the Dental Unit Manifold's [Waterline] [water line] Pick-Up Tube] [–] [Extend this Dental Waterline Pick-Up Tube by Connecting DentaLINE® Connector (Item #: MAK-1277).]
 - [DentaLINE® Connector is an Élongated Pick-Up Tube that Connects where the Water Treatment Filter Cartridge was attached to the Original Dental Unit Manifold's [Waterline] [water line] Pick-Up Tube.]
 - [DentaLINE® Connector Pick-Up Tube <u>contacts</u> MINT-A-KLEEN® from inside the Dental Water Bottle and Dispenses MINT-A-KLEEN® into the Dental Unit's [Waterlines] [water lines].]

- [After MINT-A-KLEEN's Cleaning Treatment is Completed, the User will Disconnect DentaLINE®.]
- [Rinse DentaLINE® with Water for Future MINT-A-KLEEN® Dental [Waterline] [water line] Cleaning Treatments.]
- [Re-Connect Dental Water Treatment Filter Cartridge to the Original Dental Unit Manifold's [Waterline] [water line] Pick-Up Tube.]
- [User will Re-Connect the Water Treatment Filter Cartridge to the Dental Unit Manifold's Pick-Up Tube and <u>Begin Dental Procedures</u>.]
- [TURN OFF DENTAL UNIT HOT WATER HEATER:]
 - [When emptying a heater, turn heater off and air purge.]
 - o [When removing Mint-A-Kleen from heater, air purge and then flush with water.]
 - [After MINT-A-KLEEN's Cleaning Treatment is Completed, Turn Heater ON.]
 - [Dental Unit Hot Water Heaters are reservoirs for bacteria.]
 - [If a Tank Type Water Heater is in use, Turn Water Heater OFF.] [This Prevents Heating Element Failure when Cleaning Dental Unit [Waterlines] [water lines].]
- [Dental units directly [plumbed] [connected] to [city] [municipal] water must clean dental unit [waterline] [water line] at the dental unit's [utility] [junction] box.] [This cleaning treatment can be achieved by using Anodia Systems' city [waterline] [water line] cleaning systems: DentaKLEEN® (Item #: MAK-1900), PRO-KLEEN® (Item #: MAK-1910) and VELOCITY WATER® (Item #: MAK-1805).]
- [*Note:] [For best results,] [air purge and clean all instruments and dental equipment containing dental unit waterlines using the following cleaning protocol, including but not limited to: handpiece, air/water syringe, scaler, quick disconnect line.] [Examples of dental equipment with dental water lines that contain water are the dental unit and cavitron.] [Allow Mint-A-Kleen® to remain in the dental waterlines [water lines] while the dental office is closed for the weekend, holiday break or vacation. Dental Schools that use Mint-A-Kleen® leave Mint-A-Kleen® in their dental waterlines for up to 3 months during their summer breaks.]

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. [FOLLOW ONLY MINT-A-KLEEN'S DENTAL UNIT WATER BOTTLE & [WATERLINE] [WATERLINE] CLEANING PROTOCOL INSTRUCTIONS, STEP BY STEP.]

[[NEW [MINT-A-KLEEN] USER] [1st Month] [INITIAL] [SHOCK] CLEANING [TREATMENT] [SCHEDULE]

[*Note: Each week allow Mint-A-Kleen® to remain in the dental unit [waterlines] [water lines] and bottle overnight [and] [or] over the weekend.]

Week 1: Use Mint-A-Kleen® at the end of every business day.

Weeks 2-4: Use Mint-A-Kleen® twice per week at the end of the business day.

After [week 4] [1st Month]: Use Mint-A-Kleen® once per week.]

[WEEKLY ROUTINE CLEANING [TREATMENT] [SCHEDULE]

- Use Mint-A-Kleen® [at least] once per week.
- Use Mint-A-Kleen® at the end of the last business day of the week.
- Leave Mint-A-Kleen[®] in dental unit [waterlines] [water lines] and bottle overnight and over the weekend.
- On Monday morning before dental procedures begin, Air Purge [waterlines] [water lines]
 again then Flush [Waterlines] [water lines] with Water.]

[DENTAL UNIT] [WATERLINE] [WATER LINE] AND BOTTLE CLEANING [FOR USE WITH CLOSED DENTAL UNIT DELIVERY SYSTEM] DIRECTIONS:







STEP 2: ADD MINT-A-KLEEN



STEP 3: AIR PURGE WATERLINES



STEP 4: FLUSH WATERLINE:

STEP 1: AIR PURGE: REMOVE DENTAL UNIT WATER FROM DENTAL UNIT [WATERLINES] [WATER LINES] AND [DENTAL UNIT] [WATER] BOTTLE

- After the last patient leaves at the end of the business day, turn dental unit OFF.
- Empty [dental unit] water bottle. Now attach this empty water bottle to dental unit.
- Turn dental unit ON.
- Air purge [waterlines] [water lines] by activating handpiece hoses and air/water syringes until
 water is eliminated.

STEP 2: ADD MINT-A-KLEEN®

- Turn dental unit OFF. Remove [dental unit] water bottle, pour 4 ounces of Mint-A-Kleen® into [dental unit's] empty [dental] water bottle.
- Place [sterile] [clean] 2x2 gauze on dental water bottle's opening. Turn dental water bottle upside down 3 times with gauze in place. [This allows Mint-A-Kleen® to coat this dental water bottle's interior walls.]
- Using the same 2x2 gauze, wipe down the pick-up tube.
- Attach dental water bottle to dental unit.
- Turn dental unit ON. Activate handpiece hoses and air/water syringes until Mint-A-Kleen[®] exits.
- Turn dental unit OFF. Allow Mint-A-Kleen® to treat [waterlines] [water lines] and bottle for at least 8 hours before proceeding to the next step.

STEP 3: (REPEAT STEP 1: AIR PURGE DENTAL UNIT [WATERLINES] [WATER LINES])

- Turn dental unit OFF. Remove water bottle, dispose of any excess Mint-A-Kleen[®]. Empty Idental water bottle. Now attach this empty water bottle to dental unit.
- Turn dental unit ON.
- Air purge [waterlines] [water lines] by activating handpiece hoses and air/water syringes until NO liquid comes out.

STEP 4: FLUSH DENTAL UNIT [WATERLINES] [WATER LINES] AND [DENTAL] WATER BOTTLE

- Turn dental unit OFF. Remove water bottle from dental unit, dispose of any excess Mint-A-Kleen[®].
- Rinse dental water bottle with water. Fill water bottle with water source.
- Turn dental unit ON. Flush [waterlines] [water lines] with water for 30 seconds to remove any
 excess Mint-A-Kleen[®].
- Begin dental procedures.]

[Set 2 of 8 Master Label Directions for Use: BottleX Dental Water Bottle Cleaning Instructions]

[Mint-A-Kleen® DENTAL WATER BOTTLE [CLEANER] [LIQUID] [CLEANING] [SOLUTION] For the Cleaning of Contamination in Dental Water Bottles. For Use in [any] Dental Water Bottle. DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. [FOLLOW ONLY [MINT-A-KLEEN'S] DENTAL UNIT WATER BOTTLE CLEANING PROTOCOL INSTRUCTIONS, STEP BY STEP.]

[ROUTINE CLEANING [TREATMENT] [SCHEDULE]

- Use Mint-A-Kleen[®] every business day.
- Use Mint-A-Kleen[®] at the end of the business day.
- Leave Mint-A-Kleen® in dental water bottle overnight and over the weekend.
- Monday morning before dental procedures begin, rinse dental water bottle with water [source].

DIRECTIONS FOR BOTTLE CLEANING:

STEP 1: REMOVE WATER FROM DENTAL WATER BOTTLE

- After the Last Patient Leaves at the End of the Business Day, Turn Dental Unit OFF.
- Empty Water Bottle.

STEP 2: ADD Mint-A-Kleen®

- Pour 4 ounces of Mint-A-Kleen® into Empty Dental Water Bottle.
- Place Sterile 2x2 Gauze on Dental Water Bottle's Opening. Turn Dental Water Bottle Upside Down 3 Times with Gauze in Place. This Allows Mint-A-Kleen® to Coat this Dental Water Bottle's Interior Walls.
- Using the Same 2x2 Gauze Soaked in Mint-A-Kleen[®], Wipe Down the Pick-Up Tube.
- Attach Dental Water Bottle to Dental Unit.
- Allow Mint-A-Kleen[®] to Treat Bottle for at Least 8 hours Before Proceeding to the Next Step.

STEP 3: RINSE DENTAL WATER BOTTLE

- Remove Water Bottle. Empty Water Bottle and Dispose of Any Excess Mint-A-Kleen[®].
- Rinse Dental Water Bottle with Water. Fill Water Bottle with Water Source.
- Attach Dental Water Bottle to Dental Unit. Turn Dental Unit ON.
- Begin Dental Procedures.]

[<u>Set 3 of 8</u> Master Label Directions for Use: Shocking Closed Dental Unit Water Bottle System Mint-A-Kleen Dental Unit Waterline & Dental Water Bottle Cleaning Instructions]

[MINT-A-KLEEN® DENTAL UNIT [WATER LINE] [waterline] CLEANER [SHOCK] [CLEANING SOLUTION] [LIQUID] [TREATMENT]

- [Cleaning solution] [used] [For the cleaning of contamination in dental unit [waterlines] [water lines] and [dental water] bottles.] [For use in any dental unit [,] [scaler] [cavitron] [and] [dental water bottle].]
 - [Mint-A-Kleen Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & Dental [Waterlines] [water lines].]
 - [Mint-A-Kleen cleans by removing contamination in dental unit [waterlines] [water lines] [and] [water bottles].
 - o [Mint-A-Kleen's patented cleaning formula and protocol cleans contamination in [contaminated] dental unit [waterlines] [water lines] [and] [water bottles].]

[Mint-A-Kleen cleans all dental equipment containing dental unit [waterlines] [water lines] including [cavitron's] [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]

[Refer to the additional Mint-A-Kleen® Sets of Cleaning Instructions on Carton Insert] [or] [Download Cleaning Instructions Carton Insert on our Website, www.AnodiaSystems.com.]

• [Additional Mint-A-Kleen Sets of Instructions provides how to use Mint-A-Kleen with dental unit [waterline] [water line] cleaning accessories, how to clean [scaler] [cavitron], [Closed] [Independent] [Self-Contained] [and] [Open] [City Water] [Municipal Water Supply] [Directly Plumbed] [dental units] [dental unit water delivery systems].]

[BEFORE YOU [START] [BEGIN] [DENTAL UNIT] [WATER LINE] [WATERLINE][SHOCK] CLEANING TREATMENT] [BEGINS] :

- [Remove handpieces and inserts from scalers to prevent clogging of the instruments' dental unit water lines.]
- [Remove insert from scaler before removing water from dental unit or scaler [cavitron].] [If not removed, the scaler, insert and handpieces can become clogged.]
- [Disconnect handpieces for sterilization and leave handpiece hoses for [waterline] [water line] cleaning treatment.]
- [[Disconnect Water Purifying Filter Cartridges] [:] [remove inline water filter cartridge from dental [waterline] [water line] that treats dental water before using Mint-A-Kleen®.] [Do not filter Mint-A-Kleen's ingredients.] [Mint-A-Kleen is a ready to use formula that should not be altered.]]
- [[Turn off dental unit hot water heater] [:] [dental unit hot water heaters are reservoirs for bacteria.] [When emptying a heater, turn heater off and air purge.] [When removing Mint-A-Kleen from heater, air purge and then flush with water.]]
- [Dental units directly [plumbed] [connected] to [city] [municipal] water must clean dental unit [waterline] [water line] at the dental unit's [utility] [junction] box.] [This cleaning treatment can be achieved by using Anodia Systems' city [waterline] [water line] cleaning systems: DentaKLEEN® (Item #: MAK-1900), PRO-KLEEN® (Item #: MAK-1910) and VELOCITY WATER® (Item #: MAK-1805).]
- [*Note:] [For best results,] [air purge and clean all instruments and dental equipment containing dental unit water lines using the following cleaning protocol, including but not limited to: handpiece, air/water syringe, scaler, quick disconnect line.] [Examples of dental equipment with dental water lines that contain water are the dental unit and cavitron.] [Allow Mint-A-Kleen® to remain in the dental [water lines] [waterlines] while the dental office is closed for the weekend, holiday break or vacation. Dental Schools that use Mint-A-Kleen® leave Mint-A-Kleen® in their dental [water lines] [waterlines] for up to 3 months during their summer breaks.]

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. [FOLLOW ONLY MINT-A-KLEEN'S DENTAL UNIT [WATER BOTTLE] & [WATERLINE] [WATERLINE] [CLEANING] [SHOCK] [TREATMENT] PROTOCOL INSTRUCTIONS, STEP BY STEP.]

[[NEW [MINT-A-KLEEN] USER] [1st Month] [INITIAL] [SHOCK] [CLEANING] [TREATMENT] [SCHEDULE]

[*Note: Each week allow Mint-A-Kleen® to remain in the dental unit [water lines] [waterlines] and bottle overnight [and] [or] over the weekend.]

Week 1: Use Mint-A-Kleen® at the end of every business day.

Weeks 2-4: Use Mint-A-Kleen® twice per week at the end of the business day.

After [week 4] [1st Month]: Use Mint-A-Kleen® once per week.]

[WEEKLY ROUTINE [SHOCK] [CLEANING] [TREATMENT] [SCHEDULE]

- Use Mint-A-Kleen® [at least] once per week.
- Use Mint-A-Kleen® at the end of the last business day of the week.
- Leave Mint-A-Kleen® in dental unit [water lines] [waterlines] and bottle overnight and over the weekend.
- On Monday morning before dental procedures begin, Air Purge [waterlines] [water lines] again then Flush [water lines] [waterlines] with Water.]

[DENTAL UNIT] [WATERLINE] [WATER LINE] AND BOTTLE CLEANING [FOR USE WITH CLOSED DENTAL UNIT DELIVERY SYSTEM] DIRECTIONS:







STEP 2: ADD MINT-A-KLEEN



STEP 3: AIR PURGE WATERLINES



STEP 4: FLUSH WATERLINE: WITH WATER

STEP 1: AIR PURGE: REMOVE DENTAL UNIT WATER FROM DENTAL UNIT [WATER LINES] [WATERLINES] AND [DENTAL UNIT] [WATER] BOTTLE

- After the last patient leaves at the end of the business day, turn dental unit OFF.
- Empty [dental unit] water bottle. Now attach this empty water bottle to dental unit.
- Turn dental unit ON.
- Air purge [water lines] [waterlines] by activating handpiece hoses and air/water syringes until
 water is eliminated.

STEP 2: ADD MINT-A-KLEEN®

- Turn dental unit OFF. Remove [dental unit] water bottle, pour 4 ounces of Mint-A-Kleen® into [dental unit's] empty [dental] water bottle.
- Place [sterile] [clean] 2x2 gauze on dental water bottle's opening. Turn dental water bottle upside down 3 times with gauze in place. [This allows Mint-A-Kleen® to coat this dental water bottle's interior walls.]
- Using the same 2x2 gauze, wipe down the pick-up tube.
- Attach dental water bottle to dental unit.
- Turn dental unit ON. Activate handpiece hoses and air/water syringes until Mint-A-Kleen[®] exits.
- Turn dental unit OFF. Allow Mint-A-Kleen® to treat [water lines] [waterlines] and bottle for at least 8 hours before proceeding to the next step.

STEP 3: (REPEAT STEP 1: AIR PURGE DENTAL UNIT [WATER LINES] [WATERLINES])

- Turn dental unit OFF. Remove water bottle, dispose of any excess Mint-A-Kleen[®]. Empty [dental] water bottle. Now attach this empty water bottle to dental unit.
- Turn dental unit ON.

 Air purge [water lines] [waterlines] by activating handpiece hoses and air/water syringes until NO liquid comes out.

STEP 4: FLUSH DENTAL UNIT [WATER LINES] [WATERLINES] AND [DENTAL] WATER BOTTLE

- Turn dental unit OFF. Remove water bottle from dental unit, dispose of any excess Mint-A-Kleen[®].
- Rinse dental water bottle with water. Fill water bottle with water source.
- Turn dental unit ON. Flush [water lines] [waterlines] with water for 30 seconds to remove any
 excess Mint-A-Kleen[®].
- Begin dental procedures.]

[<u>Set **4 of 8**</u> Master Label Directions for Use: Cavitron Dental Equipment

Mint-A-Kleen Dental Unit Waterline & Dental Water Bottle Cleaning Instructions]

[DENTAL [UNIT] [WATERLINE] [WATER LINE] [&] [WATER] [BOTTLE] [SCALER] [CAVITRON] [CLEANER] [CLEANING SOLUTION]

- [Cleaning solution] [used] [For the cleaning of contamination in dental unit [waterlines] [water lines] and [dental water] bottles.] [For use in any dental unit [,] [scaler] [cavitron] [and] [dental water bottle].]
 - [Mint-A-Kleen Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & Dental [Waterlines] [water lines].]
 - [Mint-A-Kleen cleans contamination in dental unit [waterlines] [water lines] [and] [water bottles].
 - [Mint-A-Kleen's patented cleaning formula and protocol cleans contamination in dental unit [waterlines] [water lines] [and] [water bottles].]

[Mint-A-Kleen cleans all dental equipment containing dental unit [waterlines] [water lines] including [cavitron's] [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]

[Refer to the additional Mint-A-Kleen® Sets of Cleaning Instructions on Carton Insert] [or] [Download Cleaning Instructions Carton Insert on our Website, www.AnodiaSystems.com.]

 [Additional Mint-A-Kleen Sets of Instructions provides how to use Mint-A-Kleen with dental unit [waterline] [water line] cleaning accessories, how to clean [scaler] [cavitron], [Closed] [Independent] [Self-Contained] [and] [Open] [City Water] [Municipal Water Supply] [Directly Plumbed] [dental units] [dental unit water delivery systems].]

[BEFORE YOU [START] [BEGIN] [DENTAL UNIT] [WATER LINE] [WATERLINE] CLEANING TREATMENT] [BEGINS] :

- [Remove handpieces and insert from scalers to prevent clogging of the instruments' dental unit water lines.]
- [Remove insert from scaler before removing water from dental unit or scaler [cavitron].] [If not removed, the insert, the scaler and handpiece can become clogged.]
- [Disconnect handpieces for sterilization and leave handpiece hoses for [waterline] [water line] cleaning treatment.]
- [[Disconnect Water Purifying Filter Cartridges] [:] [remove inline water filter cartridge from dental [waterline] [water line] that treats dental water before using Mint-A-Kleen®.] [Do not filter Mint-A-Kleen's ingredients.] [Mint-A-Kleen is a ready to use formula that should not be altered.]
- [[Turn off dental unit hot water heater] [:] [dental unit hot water heaters are reservoirs for bacteria.] [When emptying a heater, turn heater off and air purge.] [When removing Mint-A-Kleen from heater, air purge and then flush with water.]]
- [Dental units directly [plumbed] [connected] to [city] [municipal] water must clean dental unit [waterline] [water line] at the dental unit's [utility] [junction] box.] [This cleaning treatment can be achieved by using Anodia Systems' city [waterline] [water line] cleaning systems: DentaKLEEN® (Item #: MAK-1900), PRO-KLEEN® (Item #: MAK-1910) and VELOCITY WATER® (Item #: MAK-1805).]
- [*Note:] [For best results,] [air purge and clean all instruments and dental equipment containing dental unit water lines using the following cleaning protocol, including but not limited to: handpiece, air/water syringe, scaler, quick disconnect line.] [Examples of dental equipment with dental water lines that contain water are the dental unit and cavitron.] [Allow Mint-A-Kleen® to remain in the dental waterlines [water lines] while the dental office is closed for the weekend, holiday break or vacation. Dental Schools that use Mint-A-Kleen® leave Mint-A-Kleen® in their dental waterlines for up to 3 months during their summer breaks.]

[Mint-A-Kleen cleans any dental [waterlines] [water lines] that supply water to a dental instrument such as a scaler. [Below is how to clean a cavitron with Mint-A-Kleen:]

[Air Purge Scaler [Cavitron]: Remove Water

- Remove insert from scaler before removing water from scaler [cavitron].
- Air purge water from scaler [cavitron]. Remove all water before adding Mint-A-Kleen to scaler [cavitron].]

[How to Add Mint-A-Kleen to Scaler [Cavitron]

- [How is the dental unit water supplied to the scaler?]
 - [Water from dental unit water bottle system or water from the scaler [cavitron] reservoir?]
- 1. [If scaler [cavitron] does not have a water reservoir then follow Mint-A-Kleen's attached instructions.] [4 oz of Mint-A-Kleen is added into empty dental unit water bottle then supplied to the scaler [cavitron] by the dental unit's quick disconnect.]
- 2. [If scaler [cavitron] does have a water reservoir then pour 4 oz of Mint-A-Kleen into empty scaler [cavitron] reservoir.]
- [Once Mint-A-Kleen is added into scaler [cavitron] then follow the attached instructions. Allow Mint-A-Kleen to treat the scaler [cavitron] overnight or over the weekend.]
- [After Mint-A-Kleen Treatment, then Air Purge to remove Mint-A-Kleen and contamination.]
- [Flush the scaler [cavitron] with water.]
- [Begin Dental Procedures.]]

[<u>Set **5 of 8**</u> Master Label Directions for Use: Directly Plumbed City Water Dental Units Velocity Water® and DentaKLEEN® Systems

Mint-A-Kleen Dental Unit [Waterline] [water line] & Dental Water Bottle Cleaning Instructions]

[INDICATIONS FOR USE: With the Flip of a Toggle Switch – Clean your Dental [Waterlines] [water lines] while Remaining on City Water. [[Waterline] [water line] Cleaning System for Dental units on city water.]]

[[DentaKLEEN] [Velocity Water] is Designed to Clean Dental Unit [Waterlines] [water lines] for Dental Units Connected to City Water without a Bottle System. [DentaKLEEN] [Velocity Water] is a City Water Delivery Bottle System that uses Dual Toggle Switches. Toggle Switch #1: Controls City Water Flowing into Dental Unit. Toggle Switch #2: Air Purges Dental Unit or Adds Mint-A-Kleen into Dental Unit. SIZE: 1 Liter [DentaKLEEN] [Velocity Water] BOTTLE SYSTEM]

IGENERAL DENTAL PROCEDURES:

***Please Read and Follow [DentaKLEEN's] [Velocity Water's] Installation Instructions Prior to Operation.]

- [1). After Installation is Completed, Turn City Water's Toggle Switch to ON.]
- [2). Begin Dental Procedures.]

[[DentaKLEEN's] [Velocity Water's] Dental [Waterline] [water line] Cleaning Directions using MINT-A-KLEEN®]

- [1. Turn Dental Unit OFF and [DentaKLEEN's] [Velocity Water's] Master Switch OFF.]
- [2. Remove [DentaKLEEN's] [Velocity Water's] Bottle.]
- [3. Fill the Empty Bottle with MINT-A-KLEEN®.]
- [4. Attach [DentaKLEEN's] [Velocity Water's] Bottle Filled with MINT-A-KLEEN® onto the [DentaKLEEN's] [Velocity Water's] System.]
- [5. Turn Dental Unit ON and [DentaKLEEN's] [Velocity Water's] Master Switch ON.]
- [6. Turn "CITY WATER" Toggle Switch to OFF.]
- [7. Turn Toggle Switch to "AIR".]
- [8. Air Purge Dental Unit [Waterlines] [water lines] by Activating Handpiece Hoses and Air/Water Syringes until Dental Unit Water is Eliminated.]
- [9. Turn Toggle Switch to MINT-A-KLEEN®. Activate Handpiece Hoses and Air/Water Syringes until MINT-A-KLEEN® Exits.]
- [10. Turn Dental Unit OFF and [DentaKLEEN's] [Velocity Water's] Master Switch OFF. Allow MINT-A-KLEEN® to Treat [Waterline] [water lines] for at least 8 Hours (Preferably Over the Weekend Before Proceeding to the Next Step).]
- [11. Turn Dental Unit ON and [DentaKLEEN's] [Velocity Water's] Master Switch ON.]
- [12. Confirm "CITY WATER" Toggle Switch is OFF.]
- [13. Turn Toggle Switch to "AIR".]
- [14. Air Purge Dental Unit [Waterlines] [water lines] by Activating Handpiece Hoses and Air/Water Syringes until MINT-A-KLEEN® is Eliminated.]
- [15. Turn "CITY WATER" TOGGLE SWITCH to ON.]
- [16. Flush [Waterlines] [water lines] with Water for 30 Seconds to Remove Any Remaining [Waterline] [water line] Waste.]
- [17. Begin Dental Procedures.]

[* NOTE – For Optimal Cleaning, Air Purge and Clean All Instruments and Tubing that Contain Water using MINT-A-KLEEN® and its Cleaning Protocol. Please use the included DEAD ENDS® Drain Tube to Drain & Remove the Dental Unit's Water (Instructions Included). Water Heaters Must Be Cleaned as They Increase the Amount of Bacteria in the Dental [Waterlines] [water lines]. If a Tank Type Water Heater is in Use, Please Consider the Following Important Information. Most Water Heaters of this Style Cannot Be Run Dry When Turned On. They Must Be Shut Off Prior to Being Drained During Air Purging. Also After the Use of Mint-A-Kleen or Any Liquid Dental Unit [Waterline] [water line] Cleaner, the Unit Must be Air Purged First to Remove the Solution from the Water Heater and Then Flushed with Water for 30 Seconds. Remember Water Heaters Must Be Turned ON After the Dental Unit [Waterlines] [water lines] Are Cleaned. FAILURE TO TURN TANK TYPE WATER HEATERS OFF DURING THE PROCESS OF CLEANING THE [WATERLINES] [WATER LINES] COULD CAUSE THE WATER TANK ELEMENT TO FAIL.]

[<u>Set 6 of 8</u> Master Label Directions for Use: PRO-KLEEN Portable Dental Waterline Cleaning Mint-A-Kleen Dental Unit Waterline & Dental Water Bottle Cleaning Instructions]

[[INDICATIONS FOR USE:

PRO-KLEEN® SYSTEM is a Portable, Pressurized Dental Unit [Waterline] [water line] Cleaning System Designed to Dispense Mint-A-Kleen®, Dental Unit [Waterline] [water line] Cleaner, to Dental Units without Bottle Systems that are Connected to City Water. Now offices on City Water without Bottle Systems Do Not have to Invest in Bottle Systems in order to Treat and Maintain Clean Dental Unit [Waterlines] [water lines]. Administering Mint-A-Kleen using PRO-KLEEN is a Safe, Affordable, Convenient and Effective Cleaning System for Offices on City Water that are Committed to Dental Unit [Waterline] [water line] Infection Control.]

[DIRECTIONS FOR USE

IMPORTANT

- Please Read and Follow the PRO-KLEEN Installation Guide Prior to Operation.
- Read Mint-A-Kleen®, Dental Unit [Waterline] [water line] Cleaning Instructions Prior to using PRO-KLEEN®.
- Check Mint-A-Kleen Fluid Level in PRO-KLEEN and Replace/Refill Bottle if necessary.
- Ensure Dental Unit's Master Toggle Switch is in the 'ON' Position.
- Prior to Dental Unit [Waterline] [water line] Cleaning Treatment, Remove Handpieces, Scaler Insert and Syringe Tips.
- Notice Regarding Low-Speed Handpieces: If the Dental Unit's Low-Speed Handpiece is Dry, Ensure that the Handpiece Tubing [Waterline] [water line] is Disconnected from the Control Block and that the appropriate Barb Fitting is Removed and Replaced with the provided Plug.]

[HOW TO USE PRO-KLEEN® WITH MINT-A-KLEEN®]

- 1. [Attach a Full Mint-A-Kleen Bottle to PRO-KLEEN's Manifold.]
- 2. [Turn the Dental Unit's Utility Box's Toggle Switch to the **OFF** Position.]
- 3. [Insert PRO-KLEEN's **YELLOW** and **BLUE** Male Quick Connects into like colored Female Quick Connects on Dental Unit's Utility Box. **YELLOW** is 'AIR SUPPLY' and **BLUE** is 'FLUID CONNECTION'.]
- 4. [Turn PRO-KLEEN Toggle Switch to the **AIR PURGE** Position.]
- 5. [Turn Dental Unit's Utility Box's Toggle Switch to the **ON** Position and Run Handpieces, Syringe, Scaler and any other Oral Cavity Water-Consuming Device until <u>only</u> Air is Expelled.]
- 6. [Turn the PRO-KLEEN Toggle Switch to the **Mint-A-Kleen** Position and Run Handpieces, Syringe, and Scaler any other Oral Cavity Water-Consuming Device until Mint-A-Kleen is Visible.]
- 7. [Remove PRO-KLEEN's **YELLOW** and **BLUE** Quick Connects from the Dental Unit's Utility Box.]
- 8. [Turn Dental Unit's Utility Box's Toggle Switch to the **OFF** Position.]
- 9. **[DO NOT** use Dental Unit for Dental Procedures when Mint-A-Kleen is Inside Treating the Dental Unit [Waterlines] [water lines].]
- 10. [Allow Mint-A-Kleen to Treat Dental Unit [Waterlines] [water lines] for at Least 8 hours before Flushing with Water.]
- 11. [FLUSH DENTAL [WATERLINES] [WATER LINES] AFTER A MINIMUM OF 8 HOUR MINT-A-KLEEN TREATMENT]
- 12. [FLUSH Handpieces, Syringe, Scaler and any other Oral Cavity Water-Consuming Device with WATER for 30 Seconds.]
- 13. [Begin Dental Procedures.]

IMPORTANT NOTICE REGARDING WATER HEATERS

If a tank type water heater is in use, the following important information must be considered. Most water heaters of this style cannot be run dry when turned on. Water Heaters must be shut **OFF** prior to being drained. As both the [PRO-KLEEN] and bottle systems purge air through the [waterlines] [water lines] prior to adding MINT-A-KLEEN, it is critical that the water heater be turned OFF during this process.

FAILURE TO TURN TANK TYPE WATER HEATERS OFF DURING THE PROCESS OF ADMINISTERING MINT-A-KLEEN COULD CAUSE WATER TANK ELEMENT FAILURE.]]

[<u>Set **7 of 8**</u> Master Label Directions for Use: Dental Waterline Cleaning Accessories Mint-A-Kleen Dental Unit Waterline & Dental Water Bottle Cleaning Instructions]

[DENTAL [UNIT] [WATERLINE] [WATER LINE] [&] [WATER] [BOTTLE] [CAVITRON] [CLEANER] [CLEANING SOLUTION]

- [Cleaning solution] [used] [For the cleaning of contamination in dental unit [waterlines] [water lines] and [dental water] bottles.] [For use in any dental unit [,] [cavitron] [and] [dental water bottle].]
 - [Mint-A-Kleen Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & Dental [Waterlines] [water lines].]
 - [Mint-A-Kleen cleans contamination in dental unit [waterlines] [water lines] [and]
 [water bottles].
 - [Mint-A-Kleen's patented cleaning formula and protocol cleans contamination in dental unit [waterlines] [water lines] [and] [water bottles].]

[Mint-A-Kleen cleans all dental equipment containing dental unit [waterlines] [water lines] including cavitron's [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]

[Refer to the additional Mint-A-Kleen® Sets of Cleaning Instructions on Carton Insert] [or] [Download Cleaning Instructions Carton Insert on our Website, www.AnodiaSystems.com.]

• [Additional Mint-A-Kleen Sets of Instructions provides how to use Mint-A-Kleen with dental unit [waterline] [water line] cleaning accessories, how to clean cavitron, [Closed] [Independent] [Self-Contained] [and] [Open] [City Water] [Municipal Water Supply] [Directly Plumbed] [dental units] [dental unit water delivery systems].]

[BEFORE YOU [START] [BEGIN] [DENTAL UNIT] [WATER LINE] [WATERLINE] CLEANING TREATMENT] [BEGINS] :

- [Remove handpieces and scalers to prevent clogging of the instruments' dental unit water lines.]
- [Remove insert from scaler before removing water from dental unit or cavitron.] [If not removed, the scaler and handpiece can become clogged.]
- [Disconnect handpieces for sterilization and leave handpiece hoses for [waterline] [water line] cleaning treatment.]
- [[Disconnect Water Purifying Filter Cartridges] [:] [remove inline water filter cartridge from dental [waterline] [water line] that treats dental water before using Mint-A-Kleen®.] [Do not filter Mint-A-Kleen's ingredients.] [Mint-A-Kleen is a ready to use formula that should not be altered.]
- [[Turn off dental unit hot water heater] [:] [dental unit hot water heaters are reservoirs for bacteria.] [When emptying a heater, turn heater off and air purge.] [When removing Mint-A-Kleen from heater, air purge and then flush with water.]]
- [Dental units directly [plumbed] [connected] to [city] [municipal] water must clean dental unit [waterline] [water line] at the dental unit's [utility] [junction] box.] [This cleaning treatment can be achieved by using Anodia Systems' city [waterline] [water line] cleaning systems: DentaKLEEN® (Item #: MAK-1900), PRO-KLEEN® (Item #: MAK-1910) and VELOCITY WATER® (Item #: MAK-1805).]
- [*Note:] [For best results,] [air purge and clean all instruments and tubing dental equipment containing dental unit water lines using the following cleaning protocol, including but not limited to: handpiece, air/water syringe, scaler, quick disconnect line.] [Examples of dental equipment with dental water lines that contain water are the dental unit and cavitron.] [Allow Mint-A-Kleen® to remain in the dental waterlines [water lines] while the dental office is closed for the weekend, holiday break or vacation. Dental Schools that use Mint-A-Kleen® leave Mint-A-Kleen® in their dental waterlines for up to 3 months during their summer breaks.]

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. [FOLLOW ONLY MINT-A-KLEEN'S DENTAL UNIT

WATER BOTTLE & [WATERLINE] [WATERLINE] CLEANING PROTOCOL INSTRUCTIONS, STEP BY STEP.]

[[NEW [MINT-A-KLEEN] USER] [1st Month] [INITIAL] [SHOCK] CLEANING [TREATMENT] [SCHEDULE]

[*Note: Each week allow Mint-A-Kleen® to remain in the dental unit [waterlines] [water lines] and bottle overnight [and] [or] over the weekend.]

Week 1: Use Mint-A-Kleen® at the end of every business day.

Weeks 2-4: Use Mint-A-Kleen® twice per week at the end of the business day.

After [week 4] [1st Month]: Use Mint-A-Kleen® once per week.]

[WEEKLY ROUTINE CLEANING [TREATMENT] [SCHEDULE]

- Use Mint-A-Kleen® [at least] once per week.
- Use Mint-A-Kleen® at the end of the last business day of the week.
- Leave Mint-A-Kleen® in dental unit [waterlines] [water lines] and bottle overnight and over the weekend.
- On Monday morning before dental procedures begin, Air Purge [waterlines] [water lines] again then Flush [Waterlines] [water lines] with Water.]

[DENTAL UNIT] [WATERLINE] [WATER LINE] AND BOTTLE CLEANING [FOR USE WITH CLOSED DENTAL UNIT DELIVERY SYSTEM] DIRECTIONS:







STEP 2: ADD MINT-A-KLEEN



STEP 3:



STEP 4: FLUSH WATERLINE WITH WATER

STEP 1: AIR PURGE: REMOVE DENTAL UNIT WATER FROM DENTAL UNIT [WATERLINES] [WATER LINES] AND [DENTAL UNIT] [WATER] BOTTLE

- After the last patient leaves at the end of the business day, turn dental unit OFF.
- Empty [dental unit] water bottle. Now attach this empty water bottle to dental unit.
 - [Remove Stagnant Water from Dental Unit.]
 - [If Dental Unit has a Quick Disconnect Water Outlet (Scaler [Cavitron]/Hydrocolloid), utilize the Dental Unit [Waterline] [water line]
 Cleaning Accessory called, DEAD ENDS® DRAIN TUBE (Item #: MAK-1919), this will help Drain Stagnant Water from Dental Unit.]
 - o [Insert the DRAIN TUBE's Open-End Clear Tubing into the Saliva Ejector.]
 - [Connect DRAIN TUBE's Male Quick Connect Fitting into the Dental Unit's Female Quick Disconnect Water Outlet.]
 - [Turn Saliva Ejector ON.]
- Turn dental unit ON [to Pressurize Empty Dental Water Bottle.]
 - [Observe Water Expel from the Dental Unit Water Outlet through the DRAIN TUBE's Clear Tubing into the active Saliva Ejector.]
 - [After <u>no</u> water is visible in the DRAIN Tube's Clear Tubing, Turn Saliva Ejector **OFF.**]
 - [Disconnect DEAD END's DRAIN TUBE from the Dental Unit.]
 - [Use MINT-A-KLEEN ASSISTANT®, a Suction Funnel for Expelled [Waterline] [water line] Waste (Item #: MAK-1380), a Dental Unit [Waterline] [water line] Cleaning Accessory.]
 - [Insert MINT-A-KLEEN ASSISTANT's Male Base into the High-Speed Suction's Opening.][The High-Speed Suction serves as a holder.] [Note: the high-speed suction remains off.] [No liquid is being transported into the high-speed suction during Mint-A-Kleen's cleaning treatment.]
 - [Insert Handpiece Hoses & Air/Water Syringe Tips into MINT-A-KLEEN ASSISTANT's Top Openings.]

- [Turn Foot Control Water Toggle Switch ON.]
- [Activate Foot Control until Water is Completely Expelled from Handpiece Hoses.]
- [Activate Air/Water Syringe's Water Button until Water is Completely Expelled from Syringes' Tips.]
- [Air Purge Step is Completed when Water is <u>no longer exiting</u> Syringe Tips & Handpiece Hoses.]
- [Leave the MINT-A-KLEEN ASSISTANT™ Connected to the High-Speed Suction with Handpiece Hoses & Syringe Tips <u>remaining</u> inside.]
- [Air purge [waterlines] [water lines] by activating handpiece hoses and air/water syringes until water is eliminated.]
- [***NOTE*** For Dental Units with an "AIR PURGE" Toggle Switch, Activate AIR PURGE
 Feature and Purge Water <u>out</u> of the Dental Unit until <u>ALL</u> of the Dental Unit Water is
 removed.]

STEP 2: ADD MINT-A-KLEEN®

- Turn dental unit OFF. Remove [dental unit] water bottle [from dental unit]. Pour 4 ounces of Mint-A-Kleen® into [dental unit's] empty [dental] water bottle.
- Place [sterile] [clean] 2x2 gauze on dental water bottle's opening. Turn dental water bottle upside down 3 times with gauze in place [to Clean inside of Dental Bottle]. [This allows Mint-A-Kleen® to coat and clean this dental water bottle's interior walls.]
- [For Cleaning of Dental Water Bottle's Pick-Up Tube:] [Using the same 2x2 gauze [Saturated with MINT-A-KLEEN®], wipe down the pick-up tube['s External Surface.]]
- [Attach dental water bottle [containing MINT-A-KLEEN®] to [the] Dental Unit.]
- Turn dental unit ON [to Pressurize Dental Water Bottle with MINT-A-KLEEN®].
- [Handpiece Hoses & Air/Water Syringe Tips should still <u>remain</u> in MINT-A-KLEEN ASSISTANT's Top Openings.]
- [Press Foot Control with Water Toggle Switch **ON**.]
- [Activate handpiece hoses and air/water syringes until Mint-A-Kleen® exits.]
- [Leave the MINT-A-KLEEN ASSISTANT® connected to High-Speed Suction with Handpiece Hoses and Air/Water Syringe Tips remaining inside.] [The connected MINT-A-KLEEN ASSISTANT® serves as a <u>Visual Reminder</u> to Dental Staff that MINT-A-KLEEN® is inside in the Dental Unit Water Bottle and Waterlines.]
- Turn dental unit OFF. [For Cleaning Purposes,] [Allow Mint-A-Kleen® to treat dental water bottle and [waterlines] [water lines] for at least 8 hours or over the weekend before proceeding to the next step.]

STEP 3: (REPEAT STEP 1: AIR PURGE DENTAL UNIT [WATERLINES] [WATER LINES])

- [Turn dental unit OFF.] [Remove water bottle, dispose of any excess Mint-A-Kleen® [that is remaining in dental water bottle].]
- [Attach this empty water bottle to dental unit.]
- [Re-insert DEAD ENDS® DRAIN TUBE's Open-End Clear Tubing into the Saliva Ejector.]
- [Reconnect DRAIN TUBE's Male Quick Connect Fitting into the Dental Unit's Female Quick Disconnect Water Outlet to remove MINT-A-KLEEN and Contaminants from the Dental Unit Waterlines.]
 - [Turn Saliva Ejector ON.]
- [Turn dental unit ON [to Pressurize Empty Dental Water Bottle.]
 - o [Observe MINT-A-KLEEN Expel from the Dental Unit Water Outlet through the DRAIN TUBE's Clear Tubing into the active Saliva Ejector.]
 - [After <u>no</u> MINT-A-KLEEN is visible in the DRAIN Tube's Clear Tubing, Turn Saliva Ejector **OFF.**]
- [Disconnect DEAD END's DRAIN TUBE from the Dental Unit.]
- [Handpiece Hoses & Air/Water Syringe Tips should still <u>remain</u> in MINT-A-KLEEN ASSISTANT's Top Openings.]
- [Confirm Foot Control Water Toggle Switch is **ON**.]
- [Activate Foot Control until MINT-A-KLEEN® is Completely Expelled from Handpiece Hoses.]
-]Activate Air/Water Syringe's Water Button until MINT-A-KLEEN® is Completely Expelled from Syringes' Tips.]

- [Air Purge Step is Completed when Water is no longer exiting Syringe Tips & Handpiece Hoses.]
- [Air purge [waterlines] [water lines] by activating handpiece hoses and air/water syringes until NO liquid comes out.]

STEP 4: FLUSH DENTAL UNIT [WATERLINES] [WATER LINES] AND [DENTAL] WATER BOTTLE

- [Turn dental unit OFF. Remove water bottle from dental unit.]
- [Rinse dental water bottle with water. Fill water bottle with water source. Attach dental water bottle to dental unit.1
- [Turn dental unit ON.]
- [Handpiece Hoses & Air/Water Syringe Tips should still remain in MINT-A-KLEEN ASSISTANT's Top Openings.]
- [Confirm Foot Control Water Toggle Switch is still **ON**.]
- [Flush [waterlines] [water lines] with water for 30 seconds to remove any excess Mint-A-Kleen®.1
- [Remove the MINT-A-KLEEN ASSISTANT when MINT-A-KLEEN's Dental Unit [Waterline] [water line] Cleaning Treatment is completed.]
- [Remove Handpiece Hoses & Air/Water Syringe Tips from MINT-A-KLEEN ASSISTANT®.]
- [Remove the MINT-A-KLEEN ASSISTANT® from High-Speed Suction.]
- [Rinse MINT-A-KLEEN ASSISTANT® with Water. <u>Do Not Autoclave</u>. <u>Do Not use Bleach.]</u> [Allow MINT-A-KLEEN ASSISTANT® to Air Dry before the <u>next MINT-A-KLEEN®</u>, Dental Unit Water Bottle and [Waterline] [water line] Cleaning Treatment.]
- Begin dental procedures.]

[Set 8 of 8 Master Label Directions for Use: Shocking® CPAP Sleep Apnea Machine Cleaning Instructions]

[[INDICATIONS FOR USE:

[Mint-A-Kleen is a [liquid] cleaning solution that helps maintain CPAP sleep apnea machine and other pressurized assisted breathing machine's air quality by cleaning the sleep apnea machine on a once-per-week routine basis.] [Mint-A-Kleen cleans the sleep apnea machine's components: sleep apnea machine tubing, sleep apnea machine breathing mask, sleep apnea machine reservoir and sleep apnea machine reservoir's seal.] [Mint-A-Kleen Cleaner is for cleaning any sleep apnea machine, namely CPAP Continuous Positive Airway Pressure) machine, BiPAP (Bi-level Positive Airway Pressure) and APAP (Automatic Positive Airway Pressure) for people in need of treatment for obstructive sleep apnea.] [Do not get the sleep apnea machine's headgear wet.]]

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

[WEEKLY ROUTINE CLEANING:]

- [Use Mint-A-Kleen once per week.]
- [Mint-A-Kleen Cleaning Treatment is used for a minimum of 8 hours.]
- [Mint-A-Kleen's once-through weekly cleaning treatment is performed <u>intermittently</u>, not continuously.]
 - [Mint-A-Kleen intermittent once-per-week treatment is only used when the sleep apnea machine is <u>not</u> being used as a positive airway pressure therapy device.]
 - [Do <u>not</u> use Mint-A-Kleen Cleaner while the sleep apnea machine is being used as a positive airway pressure therapy device.]
 - [For example, if the sleep apnea machine user uses the CPAP machine at night, then the Mint-A-Kleen Cleaning Treatment will be performed during the day.]
- [Mint-A-Kleen Cleaning Protocol's Final Step is a Flush & Rinse with Water through the sleep apnea machine to remove contaminants and Mint-A-Kleen Cleaner.]
 - [This removal process helps prevent patient exposure to Mint-A-Kleen and contaminants.]

[BEFORE YOU BEGIN MINT-A-KLEEN CLEANING TREATMENT:]

- [Unplug the sleep apnea machine from the electrical power source.]
- [Remove the following Sleep Apnea Machine's Components from Machine:]
 - [Remove sleep apnea machine's water reservoir.]
 - [Remove sleep apnea machine's air filter. Place air filter on a dry flat surface near a sink.]
 - [Disconnect sleep apnea machine's tubing and mask from headgear.] [Place headgear aside.]
- [Read the entire Directions for Use (see below).]

DIRECTIONS FOR USE:

STEP 1: PURGE: REMOVE WATER FROM SLEEP APNEA MACHINE

• [Dispose water from the sleep apnea machine's reservoir and empty into sink.]

STEP 2: ADD MINT-A-KLEEN

CLEAN EMPTY RESERVOIR'S INTERIOR:

- o [Saturate a clean cloth with Mint-A-Kleen and wipe the empty reservoir's interior.]
- o [If there is film inside the reservoir, clean film from reservoir.]

CLEAN MASK:

- o [Disconnect mask from headgear and sleep apnea machine's tubing.]
- [Saturate a new cloth with Mint-A-Kleen and wipe the sleep apnea machine's breathing mask internally and externally.]
- [Place clean mask inside empty clean reservoir.]

CLEAN TUBING:

- [Take the end of the tubing that was connected to the sleep apnea machine and plug that tubing's opening with a rubber plunge stopper or cloth.]
- [Take the other end of the tubing and pour Mint-A-Kleen Cleaner into this tubing's opening.]
- [After Mint-A-Kleen Cleaner is poured, plug that tubing's opening.]
- o [The plugged ends of the tubing should be held in each hand.]
- [Move each hand up and down 3 times so the cleaner coats the entire inside of the tubing's inner walls.]
 - [This cleaning motion is achieved by lowering one end of the tubing and raising the other end of the tubing, simultaneously.]
 - [Alternating this movement moves the cleaner throughout the tubing.]
- [After completing this coating, place the plugged tubing on a flat surface, such as a bathtub or hang off of a showerhead. Allow the cleaner to stay inside the tubing over the next 8 hours.]

CLEAN FILTER:

- o [Remove the filter from the sleep apnea machine.]
- [Saturate the filter with Mint-A-Kleen.]
- [Immediately squeeze dry the air filter.]
- [Place the air filter back into the sleep apnea machine.]

STEP 3: FLUSH & RINSE MACHINE'S TUBING WITH WATER

REMOVE MINT-A-KLEEN FROM TUBING

- [After 8 hours of cleaning treatment is completed, Drain Mint-A-Kleen from tubing into a sink.]
- [Flush and Rinse the tubing with water: Place one tubing opening in the sink and then place the tubing's other opening to the sink faucet's opening.]
 - [Gradually turn the sink faucet ON then flush tubing with water for 30 seconds to remove any Mint-A-Kleen.]
 - o [After rinsing the tubing with water is completed, turn water OFF.]
 - [Disconnect the tubing from the sink and raise this tubing's end to remove the water into the sink.]
- o [Rinse sink with water.]

REMOVE MASK FROM RESERVOIR

o [Fill reservoir with water from preferred water source.]

RE-CONNECT MACHINE'S COMPONENTS TO MACHINE

- o [Turn ON the machine.]
 - [If you hear gurgling noise in the tubing, allow the air to push any remaining water from the tubing.]
 - o [Begin sleep apnea machine use.]]

BACK PANEL MINT-A-KLEEN® EPA FINAL MASTER LABEL

[All 8 sets of Directions for Use will provide the following Container information on label:]

CONTAINER HANDLING: Do not contaminate water, food or feed by storage and disposal. **Storage:** store in a cool dark room away from heat or open flame. **Disposal:** wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. **Container:** non-refillable container. Do not reuse or refill container. Rinse with water and place in trash or offer for recycling if available.

[PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals. CAUTION: Causes moderate eve irritation. Harmful if inhaled or swallowed. Avoid contact with eves or clothing or breathing vapor. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. FIRST AID: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For non-emergency information on this product, call Anodia Systems, LLC (1-866-246-2548), Monday through Friday, 9 a.m. to 5 p.m. EST. For medical emergencies, call the poison control center at 1-800-222-1222. IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice. IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person. PHYSICAL OR CHEMICAL HAZARDS. Combustible. Do not use or store near heat or open flame.]

[Anodia Systems, LLC Phone:866.246.2548 www.AnodiaSystems.com] [EPA Reg. No. 85298-2

[Developed, Patented & Bottled By Anodia Systems LLC]

EPA Establishment No. 85298-KY-001]

FINAL MASTER CARTON INSERT UPDATES

[MINT-A-KLEEN®] [SHOCKING®] [BottleX®]

[DENTAL] [UNIT] [CAVITRON] [SCALER] [WATERLINE] [WATER LINE] [&] [WATER] [BOTTLE] [MEDICAL DEVICE] [CPAP] [SLEEP APNEA MACHINE[S]] [AND] [OR] [FOR] [OTHER SLEEP APNEA MACHINES] [OTHER PRESSURIZED ASSISTED BREATHING MACHINES] [LIQUID] [TREATMENT] [CLEAN[S]] [CLEANING] [SOLUTION] CLEANER

- [For Use in any [Dental] [Unit] [&] [Water Bottle] [Scaler] [Cavitron].]
- [Cleans any dental unit: [Closed] [Independent] [Self-Contained] and [Open] [Directly Plumbed] [City Water] [Municipal Water Supply] [dental units] [dental unit water delivery systems] [systems].]
- [For Use in any [CPAP] [Sleep Apnea Machine].]
- [Cleaning solution for [dental unit] [cavitron] [waterlines] [water lines] [dental water bottle].]
- [Cleaning solution for [CPAP] [and] [other] [sleep apnea machine[s]].]
- [For the cleaning of contamination in dental unit [waterlines] [water lines] [and] [water bottles].]
- [For the cleaning of [CPAP] [sleep apnea machine] [&] [other pressurized assisted breathing machines].]
- [PATENTED FORMULA & PROTOCOL FOR DENTAL UNIT [WATER BOTTLE] [&]
 [WATERLINE] [WATER LINE] CLEANING TREATMENT [BY ANODIA SYSTEMS,
 LLC].]
- [PATENTED CLEANING FORMULA]
- [PATENTED CLEANING SOLUTION]
- [PATENTED CLEANING PROTOCOL]
- [PATENTED CLEANING FORMULA & PROTOCOL FOR CPAP SLEEP APNEA MACHINES & OTHER PRESSURIZED ASSISTED BREATHING MACHINES BY ANODIA SYSTEMS, LLC.]
- [Cleans all dental equipment containing dental unit [waterlines] [water lines] including cavitron's [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]
- [Cleans [contaminated] dental unit [waterlines] [water lines].]
- [Cleans [contaminated] dental water bottle[s].]
- [Cleans [contaminated] [CPAP] [and] [other] [sleep apnea machine[s]].]
- [Maintains dental unit water quality by cleaning contaminated dental unit [waterlines]
 [water lines].]
- [Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & [Dental] [Waterlines] [water lines].]
- [Cleans by removing contamination in dental unit [waterlines] [water lines] [and] [water bottles].
- [Cleans by removing contamination in CPAP [and] [other] [sleep apnea machine[s]].]
- [Mint-A-Kleen's patented cleaning formula and protocol cleans contamination in dental unit [waterlines] [water lines] [and] [water bottles].]
- [Cleaning the sleep apnea machine helps maintain the sleep apnea machine's air quality.]
- [Maintains sleep apnea machine's air quality by cleaning the sleep apnea machine once per week.]
- [ONCE PER WEEK CLEANING TREATMENT.]
- [NOT FOR CONTINUOUS USE.]
- [Shock and maintenance cleaning treatment].
- [Does not corrode cavitron, dental unit and dental equipment's [waterlines] [water lines], valves, reservoirs and bottles.]
- [Does not clog [waterlines] [water lines].
- [Non-staining]. [Water soluble.] [Does not stain the dental unit [waterlines] [water lines] and dental bottle.] [Does not affect dental bonding]. [No impact on bonding].
- [CLEANING SOLUTION] NOT FOR HUMAN CONSUMPTION].
- [DO NOT DRINK] [FOR EQUIPMENT USE ONLY].

[ACTIVE INGREDIENTS

Chlorhexidine Gluconate 0.12%
OTHER INGREDIENTS 99.88%
TOTAL 100.00%]

[MINT SCENT] [PEPPERMINT SCENT] [WINTERGREEN SCENT] [SPEARMINT SCENT] [MINT FRAGRANCE] [FRESH MINT FRAGRANCE] [REFRESHING MINT FRAGRANCE] [FRESH MINT FRAGRANCE] [PEPPERMINT FRAGRANCE] [SPEARMINT FRAGRANCE] [WINTERGREEN FRAGRANCE] [Clean Mint Scent]

READY TO USE | DO NOT DILUTE | DO NOT FILTER [MINT-A-KLEEN®] [NO MIXING REQUIRED]

[DO NOT ATTACH MINT-A-KLEEN® BOTTLE TO DENTAL UNIT.] [ADD MINT-A-KLEEN INTO DENTAL UNIT'S EMPTY WATER BOTTLE. NO WATER.]

[DO NOT USE BLEACH IN [DENTAL UNIT] [WATER LINES] [WATERLINES] [&] [DENTAL WATER BOTTLE] [CAVITRON] [SLEEP APNEA MACHINE] [CPAP]]

Net Contents: OZ (ML)

[4 FL OZ (118ML)]; [8 FL OZ (236 ML)]; [12 FL OZ (355 ML)]; [16 FL OZ (473 ML)]; [20 FL OZ (591 ML)]; [32 FL OZ (946 ML)]; [64 FL OZ (1.9 L)]; 1 GALLON (3.8 L)]

[CAUTION] [KEEP OUT OF REACH OF CHILDREN]

Watch our Online Instructional Video at www. AnodiaSystems.com
PATENTED Product By Anodia Systems, LLC, Protected by U.S. Patent: [10,785,998] [&]
[10,849,999]. [Mint-A-Kleen] is Developed, Patented, Bottled & Owned by Anodia Systems, LLC.

[<u>DENTAL [UNIT] [WATERLINE] [WATER LINE] [&] [WATER] [BOTTLE] [SCALER]</u> [CAVITRON] [CLEANER] [LIQUID] [CLEANING] [SOLUTION]

[Cleaning solution] [used] For the cleaning of contamination in dental unit [waterlines] [water lines] and [dental water] bottles. For use in any dental unit [,] [scaler] [cavitron] [and] [dental water bottle].

[Mint-A-Kleen cleans all dental equipment containing dental unit [waterlines] [water lines] including [cavitron's] [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]

[Refer to the [Greater] <u>Detailed</u> Mint-A-Kleen[®] Instruction Carton Insert] [or] [Download Instruction Carton Insert on our Website, <u>www.AnodiaSystems.com</u>.]

• [[Greater] Detailed Mint-A-Kleen Instructions provides how to use Mint-A-Kleen with dental unit [waterline] [water line] cleaning accessories.] [Additional Mint-A-Kleen Instructions provided describes how to clean [scaler] [cavitron][,] [Closed] [Independent] [Self-Contained][,] [Open] [City Water] [Municipal Water Supply] [Direct[ly] Plumbed] [dental unit[s]] [dental unit water delivery systems].]

[[Recommended] [ANODIA SYSTEMS'] [DENTAL [UNIT] [WATER LINE] [WATERLINE] [&] [WATER] [BOTTLE] [SCALER] [CAVITRON] [CLEANER] [CLEANING SOLUTION] [OPTIONS:]

- 1. **[MINT-A-KLEEN®**, Dental Unit Water Bottle & [Waterline] [water line] [cleaning solution] [cleaner].]
 - a. [MINT-A-KLEEN] 1 Gallon Jug ([Anodia Systems] Item #: MAK-OZ-GAL).]
 - b. [MINT-A-KLEEN] [10 PACK Ten 16 oz. BOTTLES ([Anodia Systems] Item #: MAK-OZ).]
 - c. [MINT-A-KLEEN] [6 PACK Six 16 oz. BOTTLES ([Anodia Systems] Item #: MAK-OZ-6).]
 - d. [[MINT-A-KLEEN] [1 PACK One 16 oz. BOTTLE ([Anodia Systems] Item #: MAK-OZ-1).]
- 2. [SHOCKING®, CPAP [Sleep Apnea Machine] or Dental Unit [Water Bottle] [&] [Waterline] [Water Line] Cleaner [Cleaning Solution].]
 - a. [[SHOCKING][1 Pack 32 oz Bottle ([Anodia Systems] Item # MAK-SHOCK)]]
 - b. [[SHOCKING] [1 Pack 16 oz Bottle ([Anodia Systems] Item # MAK-SHOCK-16)]]
- 3. [BottleX®, Dental Unit Water Bottle [cleaner] [cleaning solution].]
 - a. [BottleX®] [1 Pack 32 oz Bottle ([Anodia Systems] Item # MAK-BTX)].]

[[Recommended] [ANODIA SYSTEMS'] [WATERLINE] [WATER LINE] CLEANING ACCESSORIES FOR CLEANING [DENTAL UNIT] [SCALER] [CAVITRON] [WATERLINES] [WATER LINES]:]

- 1. **[MINT-A-KLEEN ASSISTANT®** ([Anodia Systems] Item #: MAK-1380), a Funnel for Expelled Aerosols & [waterline] [water line] Waste Removal During [Waterline] [water line] Cleaning Treatment.]
- 2. **[DEAD ENDS® Drain Tube**, ([Anodia Systems] Item #: MAK-1919) Drains [Stagnant] [Contaminated] Water from [Dental Unit] [scaler] [cavitron] during [Waterline] [water line] Cleaning Treatment.]
- 3. **[DentaLINE**® Connector Pick-Up Tube ([Anodia Systems] Item #: MAK-1277) is a pick-up tube [waterline] [water line] that replaces the Water Purifying Filter Cartridge so that MINT-A-KLEEN is NOT Filtered During Mint-A-Kleen's Treatment.]
 - [***NOTE: MINT-A-KLEEN Users that have a Water Purifying Filter Cartridge installed in the Dental Bottle's Pick-Up Tube, must *Disconnect* the Water Purifying Filter Cartridge and *Remove* the Cartridge so that MINT-A-KLEEN's Formula is NOT Filtered.]

[[Recommended] [ANODIA SYSTEMS'] WATERLINE CLEANING SYSTEMS FOR [DIRECT[LY] PLUMBED] DENTAL UNITS CONNECTED TO [CITY WATER] [MUNICIPAL WATER SUPPLY]:]

- [DentaKLEEN® ([Anodia Systems] Item #: MAK-1900), an FDA Registered 510 K023815 [waterline] [water line] Cleaning System that Cleans Dental Units Connected to City Water.]
- 2. **[PRO-KLEEN®** ([Anodia Systems] Item #: MAK-1910), <u>Portable</u> Dental Unit [waterline] [water line] Cleaning System that Cleans Dental Units without a Bottle System.]
- 3. **[VELOCITY WATER**® ([Anodia Systems] Item #: MAK-1805), a versatile FDA Registered 510 K023815 City Water Delivery Bottle System allowing the User to stay [Connected] [directly plumbed] to [City Water] [municipal water] *or* use Any Preferred Dental Water Source using the System's Contained Water Bottle.]

[[ANODIA SYSTEMS'] Recommended [CLOSED] [Independent] [Self-Contained] DENTAL UNIT WATER BOTTLE DELIVERY SYSTEM:

- [WaterlineX[®] ([Anodia Systems] Item #: MAK-1806), FDA Registered 510 K023896 [Independent] Closed Bottle System, Delivers [any] Preferred Dental Water Source using the System's Contained Water Bottle.]
 - [<u>Set 1 of 8</u> Master Label Directions for Use: Closed Dental Unit Water Bottle System Mint-A-Kleen Dental Unit Waterline & Dental Water Bottle Cleaning Instructions]

[DENTAL [UNIT] [WATERLINE] [WATER LINE] [&] [WATER] [BOTTLE] [SCALER] [CAVITRON] [CLEANER] [LIQUID] [CLEANING SOLUTION]

• [Cleaning solution] [used] [For the cleaning of dental unit [waterlines] [water lines] and [dental water] bottles.] [For use in any dental unit [,] [scaler] [cavitron] [and] [dental water bottle].]

- [Mint-A-Kleen Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & Dental [Waterlines] [water lines].]
- o [Mint-A-Kleen cleans dental unit [waterlines] [water lines] [and] [water bottles].
- [Mint-A-Kleen's patented cleaning formula and protocol [contaminated] dental unit [waterlines] [water lines] [and] [water bottles].]

[Mint-A-Kleen cleans all dental equipment containing dental unit [waterlines] [water lines] including [cavitron's] [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]

[Refer to the additional Mint-A-Kleen[®] Sets of Cleaning Instructions on Carton Insert] [or] [Download Cleaning Instructions Carton Insert on our Website, www.AnodiaSystems.com.]

 [Additional Mint-A-Kleen Sets of Instructions provides how to use Mint-A-Kleen with dental unit [waterline] [water line] cleaning accessories, how to clean scaler [cavitron], [Closed] [Independent] [Self-Contained] [and] [Open] [City Water] [Municipal Water Supply] [Directly Plumbed] [dental units] [dental unit water delivery systems].]

[BEFORE YOU [START] [BEGIN] [DENTAL UNIT] [WATER LINE] [WATERLINE] CLEANING TREATMENT] [BEGINS] :

- [Remove handpieces and inserts from scalers to prevent clogging of the instruments' dental unit [waterlines] [water lines].]
- [Remove insert from scaler before removing water from dental unit or scaler [cavitron].] [If not removed, the insert, the scaler and handpiece can become clogged.]
- [Disconnect handpieces for sterilization and leave handpiece hoses for [waterline] [water line] cleaning treatment.]
- [[Disconnect Water Purifying Filter Cartridges] [:] [remove inline water filter cartridge from dental [waterline] [water line] that treats dental water before using Mint-A-Kleen®.] [Do not filter Mint-A-Kleen's ingredients.] [Do not filter Mint-A-Kleen] [.] [through [iodine] [silver] cartridge]. [Mint-A-Kleen is a ready to use formula that should not be [filtered][,] [diluted] [or] [altered].]
 - [IF Dental Unit has Water Purifying Filter Cartridge [(Purifying Dental Water)]:
 - [Remove Chemical (Iodine, Silver, etc.) Filter Cartridge for Dental Unit Water Purifying Treatment from the Dental Unit Manifold's Pick-Up Tube.]
 - [After Dental Water Treatment Filter Cartridge is removed from the Dental Unit Manifold's Waterline [water line] Pick-Up Tube] [–] [Extend this Dental Waterline Pick-Up Tube by Connecting DentaLINE® Connector (Item #: MAK-1277).]
 - [DentaLINE® Connector is an Elongated Pick-Up Tube that Connects where the Water Treatment Filter Cartridge was attached to the Original Dental Unit Manifold's Waterline [water line] Pick-Up Tube.]
 - [DentaLINE® Connector Pick-Up Tube <u>contacts</u> MINT-A-KLEEN® from inside the Dental Water Bottle and Dispenses MINT-A-KLEEN® into the Dental Unit's [Waterlines] [water line].]
 - [After MINT-A-KLEEN's Cleaning Treatment is Completed, the User will Disconnect DentaLINE®.]
 - [Rinse DentaLINE® with Water for Future MINT-A-KLEEN® Dental Waterline Cleaning Treatments.]
 - [Re-Connect Dental Water Treatment Filter Cartridge to the Original Dental Unit Manifold's Waterline Pick-Up Tube.]
 - [User will Re-Connect the Water Treatment Filter Cartridge to the Dental Unit Manifold's Pick-Up Tube and Begin Dental Procedures.]
- [TURN OFF DENTAL UNIT HOT WATER HEATER:]
 - o [When emptying a heater, turn heater off and air purge.]
 - [When removing Mint-A-Kleen from heater, air purge and then flush with water.]
 - [After MINT-A-KLEEN's Cleaning Treatment is Completed, Turn Heater ON.]
 - [Dental Unit Hot Water Heaters are reservoirs for bacteria.]

- [If a Tank Type Water Heater is in use, Turn Water Heater OFF.] [This Prevents Heating Element Failure when Cleaning Dental Unit [Waterlines] [water lines].]
- [Dental units directly [plumbed] [connected] to [city] [municipal] water must clean dental unit [waterline] [water line] at the dental unit's [utility] [junction] box.] [This cleaning treatment can be achieved by using Anodia Systems' city [waterline] [water line] cleaning systems: DentaKLEEN® (Item #: MAK-1900), PRO-KLEEN® (Item #: MAK-1910) and VELOCITY WATER® (Item #: MAK-1805).]
- [*Note:] [For best results,] [air purge and clean all instruments and dental equipment containing dental unit water lines using the following cleaning protocol, including but not limited to: handpiece, air/water syringe, scaler, quick disconnect line.] [Examples of dental equipment with dental [water lines] [waterlines] that contain water are the dental unit and scaler [cavitron].] [Allow Mint-A-Kleen® to remain in the dental waterlines [water lines] while the dental office is closed for the weekend, holiday break or vacation. Dental Schools that use Mint-A-Kleen® leave Mint-A-Kleen® in their dental waterlines [water lines] for up to 3 months during their summer breaks.]

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. [FOLLOW ONLY MINT-A-KLEEN'S DENTAL UNIT WATER BOTTLE & [WATERLINE] [WATERLINE] CLEANING PROTOCOL INSTRUCTIONS, STEP BY STEP.]

[[NEW [MINT-A-KLEEN] USER] [1st Month] [INITIAL] [SHOCK] CLEANING [TREATMENT] [SCHEDULE]

[*Note: Each week allow Mint-A-Kleen® to remain in the dental unit [waterlines] [water lines] and bottle overnight [and] [or] over the weekend.]

Week 1: Use Mint-A-Kleen® at the end of every business day.

Weeks 2-4: Use Mint-A-Kleen® twice per week at the end of the business day.

After [week 4] [1st Month]: Use Mint-A-Kleen® once per week.]

[WEEKLY ROUTINE CLEANING [TREATMENT] [SCHEDULE]

- Use Mint-A-Kleen[®] [at least] once per week.
- Use Mint-A-Kleen® at the end of the last business day of the week.
- Leave Mint-A-Kleen[®] in dental unit [waterlines] [water lines] and bottle overnight and over the weekend.
- On Monday morning before dental procedures begin, Air Purge [waterlines] [water lines] again then Flush [Waterlines] [water lines] with Water.]

[DENTAL UNIT] [WATERLINE] [WATER LINE] AND BOTTLE CLEANING [FOR USE WITH CLOSED DENTAL UNIT DELIVERY SYSTEM] DIRECTIONS:



STEP 1: AIR PURGE WATERLINES



STEP 2: ADD MINT-A-KLEEN



STEP 3: AIR PURGE WATERLINES



STEP 4: FLUSH WATERLINES WITH WATER

STEP 1: AIR PURGE: REMOVE DENTAL UNIT WATER FROM DENTAL UNIT [WATERLINES] [WATER LINES] AND [DENTAL UNIT] [WATER] BOTTLE

- After the last patient leaves at the end of the business day, turn dental unit OFF.
- Empty [dental unit] water bottle. Now attach this empty water bottle to dental unit.
- Turn dental unit ON.
- Air purge [waterlines] [water lines] by activating handpiece hoses and air/water syringes until
 water is eliminated.

STEP 2: ADD MINT-A-KLEEN®

- Turn dental unit OFF. Remove [dental unit] water bottle, pour 4 ounces of Mint-A-Kleen® into [dental unit's] empty [dental] water bottle.
- Place [sterile] [clean] 2x2 gauze on dental water bottle's opening. Turn dental water bottle upside down 3 times with gauze in place. [This allows Mint-A-Kleen® to coat this dental water bottle's interior walls.]
- Using the same 2x2 gauze, wipe down the pick-up tube.
- Attach dental water bottle to dental unit.
- Turn dental unit ON. Activate handpiece hoses and air/water syringes until Mint-A-Kleen[®] exits.
- Turn dental unit OFF. Allow Mint-A-Kleen® to treat [waterlines] [water lines] and bottle for at least 8 hours before proceeding to the next step.

STEP 3: (REPEAT STEP 1: AIR PURGE DENTAL UNIT [WATERLINES] [WATER LINES])

- Turn dental unit OFF. Remove water bottle, dispose of any excess Mint-A-Kleen[®]. Empty [dental] water bottle. Now attach this empty water bottle to dental unit.
- Turn dental unit ON.
- Air purge [waterlines] [water lines] by activating handpiece hoses and air/water syringes until NO liquid comes out.

STEP 4: FLUSH DENTAL UNIT [WATERLINES] [WATER LINES] AND [DENTAL] WATER BOTTLE

- Turn dental unit OFF. Remove water bottle from dental unit, dispose of any excess Mint-A-Kleen[®].
- Rinse dental water bottle with water. Fill water bottle with water source.
- Turn dental unit ON. Flush [waterlines] [water lines] with water for 30 seconds to remove any excess Mint-A-Kleen®.
- Begin dental procedures.]

[Set 2 of 8 Master Label Directions for Use: BottleX Dental Water Bottle Cleaning Instructions]

[Mint-A-Kleen® DENTAL WATER BOTTLE [CLEANER] [LIQUID] [CLEANING SOLUTION]

For the Cleaning of Dental Water Bottles. For Use in [any] Dental Water Bottle.

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. [FOLLOW ONLY [MINT-A-KLEEN'S] DENTAL UNIT WATER BOTTLE CLEANING PROTOCOL INSTRUCTIONS, STEP BY STEP.]

[DAILY ROUTINE CLEANING [TREATMENT] [SCHEDULE]

- Use Mint-A-Kleen[®] every business day.
- Use Mint-A-Kleen[®] at the end of the business day.
- Leave Mint-A-Kleen® in dental water bottle overnight and over the weekend.
- Monday morning before dental procedures begin, rinse dental water bottle with water [source].

DIRECTIONS FOR BOTTLE CLEANING:

STEP 1: REMOVE WATER FROM DENTAL WATER BOTTLE

- After the Last Patient Leaves at the End of the Business Day, Turn Dental Unit OFF.
- Empty Water Bottle.

STEP 2: ADD Mint-A-Kleen®

- Pour 4 ounces of Mint-A-Kleen® into Empty Dental Water Bottle.
- Place Sterile 2x2 Gauze on Dental Water Bottle's Opening. Turn Dental Water Bottle Upside Down 3 Times with Gauze in Place. This Allows Mint-A-Kleen® to Coat this Dental Water Bottle's Interior Walls.
- Using the Same 2x2 Gauze Soaked in Mint-A-Kleen[®], Wipe Down the Pick-Up Tube.
- Attach Dental Water Bottle to Dental Unit.
- Allow Mint-A-Kleen[®] to Treat Bottle for at Least 8 hours Before Proceeding to the Next Step.

STEP 3: RINSE DENTAL WATER BOTTLE

- Remove Water Bottle. Empty Water Bottle and Dispose of Any Excess Mint-A-Kleen[®].
- Rinse Dental Water Bottle with Water. Fill Water Bottle with Water Source.
- Attach Dental Water Bottle to Dental Unit. Turn Dental Unit ON.
- Begin Dental Procedures.]

[<u>Set 3 of 8</u> Master Label Directions for Use: Shocking Closed Dental Unit Water Bottle System Mint-A-Kleen Dental Unit Waterline & Dental Water Bottle Cleaning Instructions]

[MINT-A-KLEEN® DENTAL UNIT [WATER LINE] [WATERLINE] [CLEANER] [SHOCK] [CLEANING SOLUTION] [LIQUID] [TREATMENT]

- [Cleaning solution] [used] [For the cleaning of dental unit [waterlines] [water lines] and [dental water] bottles.] [For use in any dental unit [,] [scaler] [cavitron] [and] [dental water bottle].]
 - [Mint-A-Kleen Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & Dental [Waterlines] [water lines].]
 - o [Mint-A-Kleen cleans dental unit [waterlines] [water lines] [and] [water bottles].
 - o [Mint-A-Kleen's patented cleaning formula and protocol cleans [contaminated] dental unit [waterlines] [water lines] [and] [water bottles].]

[Mint-A-Kleen cleans all dental equipment containing dental unit [waterlines] [water lines] including [cavitron's] [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]

[Refer to the additional Mint-A-Kleen[®] Sets of Cleaning Instructions on Carton Insert] [or] [Download Cleaning Instructions Carton Insert on our Website, <u>www.AnodiaSystems.com</u>.]

[Additional Mint-A-Kleen Sets of Instructions provides how to use Mint-A-Kleen with dental unit [waterline] [water line] cleaning accessories, how to clean [scaler] [cavitron] [Closed] [Independent] [Self-Contained] [and] [Open] [City Water] [Municipal Water Supply] [Directly Plumbed] [dental units] [dental unit water delivery systems].]

[BEFORE YOU [START] [BEGIN] [DENTAL UNIT] [WATER LINE] [WATERLINE][SHOCK] CLEANING TREATMENT] [BEGINS] :

- [Remove handpieces and inserts from scalers to prevent clogging of the instruments' dental unit water lines.]
- [Remove insert from scaler before removing water from dental unit or cavitron.] [If not removed, the inserts, the scaler and handpieces can become clogged.]
- [Disconnect handpieces for sterilization and leave handpiece hoses for [waterline] [water line] cleaning treatment.]
- [[Disconnect Water Purifying Filter Cartridges] [:] [remove inline water filter cartridge from dental [waterline] [water line] that treats dental water before using Mint-A-Kleen®.] [Do not filter Mint-A-Kleen's ingredients.] [Mint-A-Kleen is a ready to use formula that should not be altered.]
- [[Turn off dental unit hot water heater] [:] [dental unit hot water heaters are reservoirs for bacteria.] [When emptying a heater, turn heater off and air purge.] [When removing Mint-A-Kleen from heater, air purge and then flush with water.]]
- [Dental units directly [plumbed] [connected] to [city] [municipal] water must clean dental unit [waterline] [water line] at the dental unit's [utility] [junction] box.] [This cleaning treatment can be achieved by using Anodia Systems' city [waterline] [water line] cleaning systems: DentaKLEEN® (Item #: MAK-1900), PRO-KLEEN® (Item #: MAK-1910) and VELOCITY WATER® (Item #: MAK-1805).]
- [*Note:] [For best results,] [air purge and clean all instruments and dental equipment containing dental unit water lines using the following cleaning protocol, including but not limited to: handpiece, air/water syringe, scaler, quick disconnect line.] [Examples of dental equipment with dental water lines that contain water are the dental unit and cavitron.] [Allow Mint-A-Kleen® to remain in the dental [water lines] [waterlines] while the dental office is closed for the weekend, holiday break or vacation. Dental Schools that use Mint-A-Kleen® leave Mint-A-Kleen® in their dental [water lines] [waterlines] for up to 3 months during their summer breaks.]

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. [FOLLOW ONLY MINT-A-KLEEN'S DENTAL UNIT [WATER BOTTLE] & [WATERLINE] [WATERLINE] [CLEANING] [SHOCK] [TREATMENT] PROTOCOL INSTRUCTIONS, STEP BY STEP.]

[[NEW [MINT-A-KLEEN] USER] [1st Month] [INITIAL] [SHOCK] [CLEANING] [TREATMENT] [SCHEDULE]

[*Note: Each week allow Mint-A-Kleen® to remain in the dental unit [water lines] [waterlines] and bottle overnight [and] [or] over the weekend.]

Week 1: Use Mint-A-Kleen® at the end of every business day.

Weeks 2-4: Use Mint-A-Kleen® twice per week at the end of the business day.

After [week 4] [1st Month]: Use Mint-A-Kleen® once per week.]

[WEEKLY ROUTINE [SHOCK] [CLEANING] [TREATMENT] [SCHEDULE]

- Use Mint-A-Kleen[®] [at least] once per week.
- Use Mint-A-Kleen[®] at the end of the last business day of the week.
- Leave Mint-A-Kleen[®] in dental unit [water lines] [waterlines] and bottle overnight and over the weekend.
- On Monday morning before dental procedures begin, Air Purge [waterlines] [water lines] again then Flush [water lines] [waterlines] with Water.]

[DENTAL UNIT] [WATERLINE] [WATER LINE] AND BOTTLE CLEANING [FOR USE WITH CLOSED DENTAL UNIT DELIVERY SYSTEM] DIRECTIONS:







STEP 2: ADD MINT-A-KLEEN



STEP 3: AIR PURGE WATERLINES



STEP 4: FLUSH WATERLINES WITH WATER

STEP 1: AIR PURGE: REMOVE DENTAL UNIT WATER FROM DENTAL UNIT [WATER LINES] [WATERLINES] AND [DENTAL UNIT] [WATER] BOTTLE

- After the last patient leaves at the end of the business day, turn dental unit OFF.
- Empty [dental unit] water bottle. Now attach this empty water bottle to dental unit.
- Turn dental unit ON.
- Air purge [water lines] [waterlines] by activating handpiece hoses and air/water syringes until
 water is eliminated.

STEP 2: ADD MINT-A-KLEEN®

- Turn dental unit OFF. Remove [dental unit] water bottle, pour 4 ounces of Mint-A-Kleen® into [dental unit's] empty [dental] water bottle.
- Place [sterile] [clean] 2x2 gauze on dental water bottle's opening. Turn dental water bottle
 upside down 3 times with gauze in place. [This allows Mint-A-Kleen® to coat this dental water
 bottle's interior walls.]
- Using the same 2x2 gauze, wipe down the pick-up tube.
- Attach dental water bottle to dental unit.
- Turn dental unit ON. Activate handpiece hoses and air/water syringes until Mint-A-Kleen[®] exits.
- Turn dental unit OFF. Allow Mint-A-Kleen® to treat [water lines] [waterlines] and bottle for at least 8 hours before proceeding to the next step.

STEP 3: (REPEAT STEP 1: AIR PURGE DENTAL UNIT [WATER LINES] [WATERLINES])

- Turn dental unit OFF. Remove water bottle, dispose of any excess Mint-A-Kleen[®]. Empty [dental] water bottle. Now attach this empty water bottle to dental unit.
- Turn dental unit ON.
- Air purge [water lines] [waterlines] by activating handpiece hoses and air/water syringes until NO liquid comes out.

STEP 4: FLUSH DENTAL UNIT [WATER LINES] [WATERLINES] AND [DENTAL] WATER BOTTLE

- Turn dental unit OFF. Remove water bottle from dental unit, dispose of any excess Mint-A-Kleen®.
- Rinse dental water bottle with water. Fill water bottle with water source.
- Turn dental unit ON. Flush [water lines] [waterlines] with water for 30 seconds to remove any excess Mint-A-Kleen®.
- Begin dental procedures.]

[<u>Set **4 of 8**</u> Master Label Directions for Use: Cavitron Dental Equipment

Mint-A-Kleen Dental Unit Waterline & Dental Water Bottle Cleaning Instructions]

[DENTAL [UNIT] [WATERLINE] [WATER LINE] [&] [WATER] [BOTTLE] [SCALER] [CAVITRON] [CLEANER] [CLEANING SOLUTION]

- [Cleaning solution] [used] [For the cleaning of dental unit [waterlines] [water lines] and [dental water] bottles.] [For use in any dental unit [,] [scaler] [cavitron] [and] [dental water bottle].]
 - [Mint-A-Kleen Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & Dental [Waterlines] [water lines].]
 - o [Mint-A-Kleen cleans dental unit [waterlines] [water lines] [and] [water bottles].
 - [Mint-A-Kleen's patented cleaning formula cleans dental unit [waterlines] [water lines]
 [and] [water bottles].]

[Mint-A-Kleen cleans all dental equipment containing dental unit [waterlines] [water lines] including [cavitron's] [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]

[Refer to the additional Mint-A-Kleen® Sets of Cleaning Instructions on Carton Insert] [or] [Download Cleaning Instructions Carton Insert on our Website, www.AnodiaSystems.com.]

[Additional Mint-A-Kleen Sets of Instructions provides how to use Mint-A-Kleen with
dental unit [waterline] [water line] cleaning accessories, how to clean [scaler] [cavitron]
[Closed] [Independent] [Self-Contained] [and] [Open] [City Water] [Municipal Water
Supply] [Directly Plumbed] [dental units] [dental unit water delivery systems].]

[<u>BEFORE YOU [START] [BEGIN] [DENTAL UNIT] [WATER LINE] [WATERLINE] CLEANING TREATMENT</u>] [BEGINS] :

- [Remove handpieces and inserts from scalers to prevent clogging of the instruments' dental unit water lines.]
- [Remove insert from scaler before removing water from dental unit or cavitron.] [If not removed, the scaler, inserts and handpieces can become clogged.]
- [Disconnect handpieces for sterilization and leave handpiece hoses for [waterline] [waterline] cleaning treatment.]
- [[Disconnect Water Purifying Filter Cartridges] [:] [remove inline water filter cartridge from dental [waterline] [water line] that treats dental water before using Mint-A-Kleen®.] [Do not filter Mint-A-Kleen's ingredients.] [Mint-A-Kleen is a ready to use formula that should not be altered.]]
- [[Turn off dental unit hot water heater] [:] [dental unit hot water heaters are reservoirs for bacteria.] [When emptying a heater, turn heater off and air purge.] [When removing Mint-A-Kleen from heater, air purge and then flush with water.]]
- [Dental units directly [plumbed] [connected] to [city] [municipal] water must clean dental unit [waterline] [water line] at the dental unit's [utility] [junction] box.] [This cleaning treatment can be achieved by using Anodia Systems' city [waterline] [water line] cleaning systems: DentaKLEEN® (Item #: MAK-1900), PRO-KLEEN® (Item #: MAK-1910) and VELOCITY WATER® (Item #: MAK-1805).]
- [*Note:] [For best results,] [air purge and clean all instruments and dental equipment containing dental unit water lines using the following cleaning protocol, including but not limited to: handpiece, air/water syringe, scaler, quick disconnect line.] [Examples of dental equipment with dental water lines that contain water are the dental unit and cavitron.] [Allow Mint-A-Kleen® to remain in the dental waterlines [water lines] while the dental office is closed for the weekend, holiday break or vacation. Dental Schools that use Mint-A-Kleen® leave Mint-A-Kleen® in their dental waterlines [water lines] for up to 3 months during their summer breaks.]

[Mint-A-Kleen cleans any dental [waterlines] [water lines] that supply water to a dental instrument such as a scaler. [Below is how to clean a scaler [cavitron] with Mint-A-Kleen:]

[Air Purge Scaler Cavitron]: Remove Water

Remove insert from scaler before removing water from scaler [cavitron].

• Air purge water from scaler [cavitron]. Remove all water before adding Mint-A-Kleen to scaler [cavitron].]

[How to Add Mint-A-Kleen to Scaler [Cavitron]

- [How is the dental unit water supplied to the scaler?]
 - [Water from dental unit water bottle system or water from the scaler [cavitron] reservoir?]
- 3. [If scaler [cavitron] does not have a water reservoir then follow Mint-A-Kleen's attached instructions.] [4 oz of Mint-A-Kleen is added into empty dental unit water bottle then supplied to the scaler [cavitron] by the dental unit's quick disconnect.]
- 4. [If scaler [cavitron] does have a water reservoir then pour 4 oz of Mint-A-Kleen into empty scaler [cavitron] reservoir.]
- [Once Mint-A-Kleen is added into scaler [cavitron] then follow the attached instructions. Allow Mint-A-Kleen to treat the scaler [cavitron] overnight or over the weekend.]
- [After Mint-A-Kleen Treatment then Air Purge to remove Mint-A-Kleen.]
- [Flush the scaler [cavitron] with water.]
- [Begin Dental Procedures.]]

[<u>Set **5 of 8**</u> Master Label Directions for Use: Directly Plumbed City Water Dental Units Velocity Water® and DentaKLEEN® Systems

Mint-A-Kleen Dental Unit [Waterline] [water line] & Dental Water Bottle Cleaning Instructions]

[INDICATIONS FOR USE: With the Flip of a Toggle Switch – Clean your Dental [Waterlines] [water lines] while Remaining on City Water. [[Waterline] Water Line] Cleaning System for Dental units on city water.]

[[DentaKLEEN] [Velocity Water] is Designed to Clean Dental Unit [Waterlines] [water lines] for Dental Units Connected to City Water without a Bottle System. [DentaKLEEN] [Velocity Water] is a City Water Delivery Bottle System that uses Dual Toggle Switches. Toggle Switch #1: Controls City Water Flowing into Dental Unit. Toggle Switch #2: Air Purges Dental Unit or Adds Mint-A-Kleen into Dental Unit. SIZE: 1 Liter [DentaKLEEN] [Velocity Water] BOTTLE SYSTEM]

[GENERAL DENTAL PROCEDURES:

***Please Read and Follow [DentaKLEEN's] [Velocity Water's] Installation Instructions Prior to Operation.]

- [1). After Installation is Completed, Turn City Water's Toggle Switch to ON.]
- [2). Begin Dental Procedures.]

[[DentaKLEEN's] [Velocity Water's] Dental [Waterline] [water line] Cleaning Directions using MINT-A-KLEEN®]

- [1. Turn Dental Unit OFF and [DentaKLEEN's] [Velocity Water's] Master Switch OFF.]
- [2. Remove [DentaKLEEN's] [Velocity Water's] Bottle.]
- [3. Fill the Empty Bottle with MINT-A-KLEEN®.]
- [4. Attach [DentaKLEEN's] [Velocity Water's] Bottle Filled with MINT-A-KLEEN® onto the [DentaKLEEN's] [Velocity Water's] System.]
- [5. Turn Dental Unit ON and [DentaKLEEN's] [Velocity Water's] Master Switch ON.]
- [6. Turn "CITY WATER" Toggle Switch to OFF.]
- [7. Turn Toggle Switch to "AIR".]
- [8. Air Purge Dental Unit [Waterlines] [water lines] by Activating Handpiece Hoses and Air/Water Syringes until Dental Unit Water is Eliminated.]
- [9. Turn Toggle Switch to MINT-A-KLEEN®. Activate Handpiece Hoses and Air/Water Syringes until MINT-A-KLEEN® Exits.]
- [10. Turn Dental Unit OFF and [DentaKLEEN's] [Velocity Water's] Master Switch OFF. Allow MINT-A-KLEEN® to Treat [Waterlines] [water lines] for at least 8 Hours (Preferably Over the Weekend Before Proceeding to the Next Step).]
- [11. Turn Dental Unit ON and [DentaKLEEN's] [Velocity Water's] Master Switch ON.]
- [12. Confirm "CITY WATER" Toggle Switch is OFF.]
- [13. Turn Toggle Switch to "AIR".]
- [14. Air Purge Dental Unit [Waterlines] [water lines] by Activating Handpiece Hoses and Air/Water Syringes until MINT-A-KLEEN® is Eliminated.]
- [15. Turn "CITY WATER" TOGGLE SWITCH to ON.]
- [16. Flush Waterlines with Water for 30 Seconds to Remove Any Remaining [Waterline] [waterline] Waste.]
- [17. Begin Dental Procedures.]

[* NOTE – For Optimal Cleaning, Air Purge and Clean All Instruments and Tubing that Contain Water using MINT-A-KLEEN® and its Cleaning Protocol. Please use the included DEAD ENDS® Drain Tube to Drain & Remove the Dental Unit's Water (Instructions Included). Water Heaters Must Be Cleaned As They Increase the Amount of Bacteria in the Dental Waterlines. If a Tank Type Water Heater is in Use, Please Consider the Following Important Information. Most Water Heaters of this Style Cannot Be Run Dry When Turned On. They Must Be Shut Off Prior to Being Drained During Air Purging. Also After the Use of Mint-A-Kleen or Any Liquid Dental Unit [Waterline] [water line] Cleaner, the Unit Must be Air Purged First to Remove the Solution from the Water Heater and Then Flushed with Water for 30 Seconds. Remember Water Heaters Must Be Turned ON After the Dental Unit Waterlines Are Cleaned. FAILURE TO TURN TANK TYPE WATER HEATERS OFF DURING THE PROCESS OF CLEANING THE WATERLINES COULD CAUSE THE WATER TANK ELEMENT TO FAIL.]

[<u>Set 6 of 8</u> Master Label Directions for Use: PRO-KLEEN Portable Dental Waterline Cleaning Mint-A-Kleen Dental Unit Waterline & Dental Water Bottle Cleaning Instructions]

[[INDICATIONS FOR USE:

PRO-KLEEN® SYSTEM is a Portable, Pressurized Dental Unit [Waterline] [water line] Cleaning System Designed to Dispense Mint-A-Kleen®, Dental Unit [Waterline] [water line] Cleaner, to Dental Units without Bottle Systems that are Connected to City Water. Now offices on City Water without Bottle Systems Do Not have to Invest in Bottle Systems in order to Treat and Maintain Clean Dental Unit [Waterlines] [water lines]. Administering Mint-A-Kleen using PRO-KLEEN is a Safe, Affordable, Convenient and Effective Cleaning System for Offices on City Water that are Committed to Dental Unit [Waterline] [water line] Infection Control.]

[DIRECTIONS FOR USE

IMPORTANT

- Please Read and Follow the PRO-KLEEN Installation Guide Prior to Operation.
- Read Mint-A-Kleen®, Dental Unit [Waterline] [water line] Cleaning Instructions Prior to using PRO-KLEEN®.
- Check Mint-A-Kleen Fluid Level in PRO-KLEEN and Replace/Refill Bottle if necessary.
- Ensure Dental Unit's Master Toggle Switch is in the 'ON' Position.
- Prior to Dental Unit Waterline Cleaning Treatment, Remove Handpieces, Scaler Insert and Syringe Tips.
- Notice Regarding Low-Speed Handpieces: If the Dental Unit's Low-Speed Handpiece is Dry, Ensure that the Handpiece Tubing Waterline is Disconnected from the Control Block and that the appropriate Barb Fitting is Removed and Replaced with the provided Plug.]

[HOW TO USE PRO-KLEEN® WITH MINT-A-KLEEN®]

- 14. [Attach a Full Mint-A-Kleen Bottle to PRO-KLEEN's Manifold.]
- 15. [Turn the Dental Unit's Utility Box's Toggle Switch to the **OFF** Position.]
- 16. [Insert PRO-KLEEN's **YELLOW** and **BLUE** Male Quick Connects into like colored Female Quick Connects on Dental Unit's Utility Box. **YELLOW** is 'AIR SUPPLY' and **BLUE** is 'FLUID CONNECTION'.]
- 17. [Turn PRO-KLEEN Toggle Switch to the AIR PURGE Position.]
- 18. [Turn Dental Unit's Utility Box's Toggle Switch to the **ON** Position and Run Handpieces, Syringe, Scaler and any other Oral Cavity Water-Consuming Device until <u>only</u> Air is Expelled.]
- 19. [Turn the PRO-KLEEN Toggle Switch to the **Mint-A-Kleen** Position and Run Handpieces, Syringe, and Scaler any other Oral Cavity Water-Consuming Device until Mint-A-Kleen is Visible.]
- [Remove PRO-KLEEN's YELLOW and BLUE Quick Connects from the Dental Unit's Utility Box.]
- 21. [Turn Dental Unit's Utility Box's Toggle Switch to the **OFF** Position.]
- 22. **[DO NOT** use Dental Unit for Dental Procedures when Mint-A-Kleen is Inside Treating the Dental Unit Waterlines.]
- 23. [Allow Mint-A-Kleen to Treat Dental Unit Waterlines for at Least 8 hours before Flushing with Water.]
- 24. [FLUSH DENTAL [WATERLINES] [WATERLINES] AFTER A MINIMUM OF 8 HOUR MINT-A-KLEEN TREATMENT]
- 25. [FLUSH Handpieces, Syringe, Scaler and any other Oral Cavity Water-Consuming Device with WATER for 30 Seconds.]
- 26. [Begin Dental Procedures.

[IMPORTANT NOTICE REGARDING WATER HEATERS

If a tank type water heater is in use, the following important information must be considered. Most water heaters of this style cannot be run dry when turned on. Water Heaters must be shut **OFF** prior to being drained. As both the [PRO-KLEEN] and bottle systems purge air through the waterlines prior to adding MINT-A-KLEEN, it is critical that the water heater be turned OFF during this process.

FAILURE TO TURN TANK TYPE WATER HEATERS OFF DURING THE PROCESS OF ADMINISTERING MINT-A-KLEEN COULD CAUSE WATER TANK ELEMENT FAILURE.]]

[<u>Set **7 of 8**</u> Master Label Directions for Use: Dental Waterline Cleaning Accessories Mint-A-Kleen Dental Unit Waterline & Dental Water Bottle Cleaning Instructions]

[DENTAL [UNIT] [WATERLINE] [WATER LINE] [&] [WATER] [BOTTLE] [SCALER] [CAVITRON] [CLEANER] [CLEANING SOLUTION]

- [Cleaning solution] [used] [For the cleaning of dental unit [waterlines] [water lines] and [dental water] bottles.] [For use in any dental unit [,] [scaler] [cavitron] [and] [dental water bottle].]
 - [Mint-A-Kleen Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & Dental [Waterlines] [water lines].]
 - o [Mint-A-Kleen cleans dental unit [waterlines] [water lines] [and] [water bottles].
 - [Mint-A-Kleen's patented cleaning formula and protocol cleans contamination in dental unit [waterlines] [water lines] [and] [water bottles].]

[Mint-A-Kleen cleans all dental equipment containing dental unit [waterlines] [water lines] including [cavitron's] [waterlines] [water lines] for dental scalers (Electrical & Air Powered Dental Scalers), the dental unit water bottles' pick-up tube [waterline] [water line], and veterinary dental equipment.]

[Refer to the additional Mint-A-Kleen® Sets of Cleaning Instructions on Carton Insert] [or] [Download Cleaning Instructions Carton Insert on our Website, www.AnodiaSystems.com.]

 [Additional Mint-A-Kleen Sets of Instructions provides how to use Mint-A-Kleen with dental unit [waterline] [water line] cleaning accessories, how to clean scaler [cavitron], [Closed] [Independent] [Self-Contained] [and] [Open] [City Water] [Municipal Water Supply] [Directly Plumbed] [dental units] [dental unit water delivery systems].]

[BEFORE YOU [START] [BEGIN] [DENTAL UNIT] [WATER LINE] [WATERLINE] CLEANING TREATMENT] [BEGINS] :

- [Remove handpieces and inserts from scalerto prevent clogging of the instruments' dental unit water lines.]
- [Remove insert from scaler before removing water from dental unit or cavitron.] [If not removed, the scaler, insert and handpiece can become clogged.]
- [Disconnect handpieces for sterilization and leave handpiece hoses for [waterline] [waterline] cleaning treatment.]
- [[Disconnect Water Purifying Filter Cartridges] [:] [remove inline water filter cartridge from dental [waterline] [water line] that treats dental water before using Mint-A-Kleen®.] [Do not filter Mint-A-Kleen's ingredients.] [Mint-A-Kleen is a ready to use formula that should not be altered.]]
- [[Turn off dental unit hot water heater] [:] [dental unit hot water heaters are reservoirs for bacteria.] [When emptying a heater, turn heater off and air purge.] [When removing Mint-A-Kleen from heater, air purge and then flush with water.]]
- [Dental units directly [plumbed] [connected] to [city] [municipal] water must clean dental unit [waterline] [water line] at the dental unit's [utility] [junction] box.] [This cleaning treatment can be achieved by using Anodia Systems' city [waterline] [water line] cleaning systems: DentaKLEEN® (Item #: MAK-1900), PRO-KLEEN® (Item #: MAK-1910) and VELOCITY WATER® (Item #: MAK-1805).]
- [*Note:] [For best results,] [air purge and clean all instruments and tubing dental equipment containing dental unit water lines using the following cleaning protocol, including but not limited to: handpiece, air/water syringe, scaler, quick disconnect line.] [Examples of dental equipment with dental [waterlines] [water lines] that contain water are the dental unit and cavitron.] [Allow Mint-A-Kleen® to remain in the dental waterlines [water lines] while the dental office is closed for the weekend, holiday break or vacation. Dental Schools that use Mint-A-Kleen® leave Mint-A-Kleen® in their dental waterlines for up to 3 months during their summer breaks.]

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. [FOLLOW ONLY MINT-A-KLEEN'S DENTAL UNIT WATER BOTTLE & [WATERLINE] [WATERLINE] CLEANING PROTOCOL INSTRUCTIONS, STEP BY STEP.]

[[NEW [MINT-A-KLEEN] USER] [1st Month] [INITIAL] [SHOCK] CLEANING [TREATMENT] [SCHEDULE]

[*Note: Each week allow Mint-A-Kleen® to remain in the dental unit [waterlines] [water lines] and bottle overnight [and] [or] over the weekend.]

Week 1: Use Mint-A-Kleen® at the end of every business day.

Weeks 2-4: Use Mint-A-Kleen® twice per week at the end of the business day.

After [week 4] [1st Month]: Use Mint-A-Kleen® once per week.]

[WEEKLY ROUTINE CLEANING [TREATMENT] [SCHEDULE]

- Use Mint-A-Kleen[®] [at least] once per week.
- Use Mint-A-Kleen[®] at the end of the last business day of the week.
- Leave Mint-A-Kleen[®] in dental unit [waterlines] [water lines] and bottle overnight and over the weekend.
- On Monday morning before dental procedures begin, Air Purge [waterlines] [water lines] again then Flush [Waterlines] [water lines] with Water.]

[DENTAL UNIT] [WATERLINE] [WATER LINE] AND BOTTLE CLEANING [FOR USE WITH CLOSED DENTAL UNIT DELIVERY SYSTEM] DIRECTIONS:







STEP 2: ADD MINT-A-KLEEN



STEP 3:



STEP 4: FLUSH WATERLINES

STEP 1: AIR PURGE: REMOVE DENTAL UNIT WATER FROM DENTAL UNIT [WATERLINES] [WATER LINES] AND [DENTAL UNIT] [WATER] BOTTLE

- After the last patient leaves at the end of the business day, turn dental unit OFF.
- Empty [dental unit] water bottle. Now attach this empty water bottle to dental unit.
 - [Remove Stagnant Water from Dental Unit.]
 - [If Dental Unit has a Quick Disconnect Water Outlet (Scaler [Cavitron]/Hydrocolloid), utilize the Dental Unit [Waterline] [water line] Cleaning Accessory called, DEAD ENDS® DRAIN TUBE (Item #: MAK-1919), this will help Drain Stagnant Water from Dental Unit.]
 - o [Insert the DRAIN TUBE's Open-End Clear Tubing into the Saliva Ejector.]
 - [Connect DRAIN TUBE's Male Quick Connect Fitting into the Dental Unit's Female Quick Disconnect Water Outlet.]
 - o [Turn Saliva Ejector ON.]
- Turn dental unit ON [to Pressurize Empty Dental Water Bottle.]
 - [Observe Water Expel from the Dental Unit Water Outlet through the DRAIN TUBE's Clear Tubing into the active Saliva Ejector.]
 - [After <u>no</u> water is visible in the DRAIN Tube's Clear Tubing, Turn Saliva Ejector **OFF.**]
 - [Disconnect DEAD END's DRAIN TUBE from the Dental Unit.]
 - [Use MINT-A-KLEEN ASSISTANT®, a Suction Funnel for Expelled [Waterline] [waterline] Waste (Item #: MAK-1380), a Dental Unit Waterline Cleaning Accessory.]
 - [Insert MINT-A-KLEEN ASSISTANT's Male Base into the High-Speed Suction's Opening.][The High-Speed Suction serves as a holder.] [Note: the high-speed suction remains off.] [No liquid is being transported into the high-speed suction during Mint-A-Kleen's cleaning treatment.]
 - [Insert Handpiece Hoses & Air/Water Syringe Tips into MINT-A-KLEEN ASSISTANT's Top Openings.]
 - [Turn Foot Control Water Toggle Switch ON.]
 - [Activate Foot Control until Water is Completely Expelled from Handpiece Hoses.]

- [Activate Air/Water Syringe's Water Button until Water is Completely Expelled from Syringes' Tips.]
- [Air Purge Step is Completed when Water is <u>no longer exiting</u> Syringe Tips & Handpiece Hoses.]
- [Leave the MINT-A-KLEEN ASSISTANT™ Connected to the High-Speed Suction with Handpiece Hoses & Syringe Tips <u>remaining</u> inside.]
- [Air purge [waterlines] [water lines] by activating handpiece hoses and air/water syringes until water is eliminated.]
- [***NOTE*** For Dental Units with an "AIR PURGE" Toggle Switch, Activate AIR PURGE
 Feature and Purge Water <u>out</u> of the Dental Unit until <u>ALL</u> of the Dental Unit Water is
 removed.]

STEP 2: ADD MINT-A-KLEEN®

- Turn dental unit OFF. Remove [dental unit] water bottle [from dental unit]. Pour 4 ounces of Mint-A-Kleen® into [dental unit's] empty [dental] water bottle.
- Place [sterile] [clean] 2x2 gauze on dental water bottle's opening. Turn dental water bottle upside down 3 times with gauze in place [to Clean inside of Dental Bottle]. [This allows Mint-A-Kleen® to coat and clean this dental water bottle's interior walls.]
- [For Cleaning of Dental Water Bottle's Pick-Up Tube:] [Using the same 2x2 gauze [Saturated with MINT-A-KLEEN®], wipe down the pick-up tube['s External Surface.]]
- [Attach dental water bottle [containing MINT-A-KLEEN®] to [the] Dental Unit.]
- Turn dental unit ON [to Pressurize Dental Water Bottle with MINT-A-KLEEN®].
- [Handpiece Hoses & Air/Water Syringe Tips should still <u>remain</u> in MINT-A-KLEEN ASSISTANT's Top Openings.]
- [Press Foot Control with Water Toggle Switch ON.]
- [Activate handpiece hoses and air/water syringes until Mint-A-Kleen® exits.]
- [Leave the MINT-A-KLEEN ASSISTANT® <u>connected</u> to High-Speed Suction with Handpiece Hoses and Air/Water Syringe Tips <u>remaining</u> inside.] [The connected MINT-A-KLEEN ASSISTANT® serves as a <u>Visual Reminder</u> to Dental Staff that MINT-A-KLEEN® is inside in the Dental Unit Water Bottle and Waterlines.]
- Turn dental unit OFF. [For Cleaning Purposes,] [Allow Mint-A-Kleen® to treat dental water bottle and [waterlines] [water lines] for at least 8 hours or over the weekend before proceeding to the next step.]

STEP 3: (REPEAT STEP 1: AIR PURGE DENTAL UNIT [WATERLINES] [WATER LINES])

- [Turn dental unit OFF.] [Remove water bottle, dispose of any excess Mint-A-Kleen® [that is remaining in dental water bottle].]
- [Attach this empty water bottle to dental unit.]
- [Re-insert DEAD ENDS® DRAIN TUBE's Open-End Clear Tubing into the Saliva Ejector.]
- [Reconnect DRAIN TUBE's Male Quick Connect Fitting into the Dental Unit's Female Quick Disconnect Water Outlet to remove MINT-A-KLEEN and Contaminants from the Dental Unit [Waterlines] [water lines].]
 - [Turn Saliva Eiector ON.]
- [Turn dental unit ON [to Pressurize Empty Dental Water Bottle.]
 - [Observe MINT-A-KLEEN Expel from the Dental Unit Water Outlet through the DRAIN TUBE's Clear Tubing into the active Saliva Ejector. 1
 - [After <u>no</u> MINT-A-KLEEN is visible in the DRAIN Tube's Clear Tubing, Turn Saliva Ejector **OFF.**]
- [Disconnect DEAD END's DRAIN TUBE from the Dental Unit.]
- [Handpiece Hoses & Air/Water Syringe Tips should still <u>remain</u> in MINT-A-KLEEN ASSISTANT's <u>Top</u> Openings.]
- [Confirm Foot Control Water Toggle Switch is **ON**.]
- [Activate Foot Control until MINT-A-KLEEN® is Completely Expelled from Handpiece Hoses.]
-]Activate Air/Water Syringe's Water Button until MINT-A-KLEEN® is Completely Expelled from Syringes' Tips.]
- [Air Purge Step is Completed when Water is **no longer exiting** Syringe Tips & Handpiece Hoses.]

• [Air purge [waterlines] [water lines] by activating handpiece hoses and air/water syringes until NO liquid comes out.]

STEP 4: FLUSH DENTAL UNIT [WATERLINES] [WATER LINES] AND [DENTAL] WATER BOTTLE

- [Turn dental unit OFF. Remove water bottle from dental unit.]
- [Rinse dental water bottle with water. Fill water bottle with water source. Attach dental water bottle to dental unit.]
- [Turn dental unit ON.]
- [Handpiece Hoses & Air/Water Syringe Tips should still remain in MINT-A-KLEEN ASSISTANT's <u>Top</u> Openings.]
- [Confirm Foot Control Water Toggle Switch is still **ON**.]
- [Flush [waterlines] [water lines] with water for 30 seconds to remove any excess Mint-A-Kleen®.]
- [Remove the MINT-A-KLEEN ASSISTANT when MINT-A-KLEEN's Dental Unit Waterline Cleaning Treatment is completed.]
- [Remove Handpiece Hoses & Air/Water Syringe Tips from MINT-A-KLEEN ASSISTANT®.]
- [Remove the MINT-A-KLEEN ASSISTANT® from High-Speed Suction.]
- [Rinse MINT-A-KLEEN ASSISTANT® with Water. <u>Do Not Autoclave</u>. <u>Do Not use Bleach</u>.]
- [Allow MINT-A-KLEEN ASSISTANT® to Air Dry before the <u>next MINT-A-KLEEN®</u>, Dental Unit Water Bottle and Waterline Cleaning Treatment.]
- Begin dental procedures.]

[Set 8 of 8 Master Label Directions for Use: Shocking® CPAP Sleep Apnea Machine Cleaning Instructions]

[[INDICATIONS FOR USE:

[Mint-A-Kleen is a [liquid] cleaning solution that helps maintain CPAP sleep apnea machine and other pressurized assisted breathing machine's air quality by cleaning the sleep apnea machine on a once-per-week routine basis.] [Mint-A-Kleen cleans the sleep apnea machine's components: sleep apnea machine tubing, sleep apnea machine breathing mask, sleep apnea machine reservoir and sleep apnea machine reservoir's seal.] [Mint-A-Kleen Cleaner is for cleaning any sleep apnea machine, namely CPAP Continuous Positive Airway Pressure) machine, BiPAP (Bi-level Positive Airway Pressure) and APAP (Automatic Positive Airway Pressure) for people in need of treatment for obstructive sleep apnea.] [Do not get the sleep apnea machine's headgear wet.]]

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

[WEEKLY ROUTINE CLEANING:]

- [Use Mint-A-Kleen once per week.]
- [Mint-A-Kleen Cleaning Treatment is used for a minimum of 8 hours.]
- [Mint-A-Kleen's once-through weekly cleaning treatment is performed <u>intermittently</u>, not continuously.]
 - [Mint-A-Kleen intermittent once-per-week treatment is only used when the sleep apnea machine is <u>not</u> being used as a positive airway pressure therapy device.]
 - [Do <u>not</u> use Mint-A-Kleen Cleaner while the sleep apnea machine is being used as a positive airway pressure therapy device.]
 - [For example, if the sleep apnea machine user uses the CPAP machine at night, then the Mint-A-Kleen Cleaning Treatment will be performed during the day.]
- [Mint-A-Kleen Cleaning Protocol's Final Step is a Flush & Rinse with Water through the sleep apnea machine to remove contaminants and Mint-A-Kleen Cleaner.]
 - [This removal process helps prevent patient exposure to Mint-A-Kleen and contaminants.]

[BEFORE YOU BEGIN MINT-A-KLEEN CLEANING TREATMENT:]

- [Unplug the sleep apnea machine from the electrical power source.]
- [Remove the following Sleep Apnea Machine's Components from Machine:]
 - [Remove sleep apnea machine's water reservoir.]
 - [Remove sleep apnea machine's air filter. Place air filter on a dry flat surface near a sink.]
 - [Disconnect sleep apnea machine's tubing and mask from headgear.] [Place headgear aside.]
- [Read the entire Directions for Use (see below).]

DIRECTIONS FOR USE:

STEP 1: PURGE: REMOVE WATER FROM SLEEP APNEA MACHINE

• [Dispose water from the sleep apnea machine's reservoir and empty into sink.]

STEP 2: ADD MINT-A-KLEEN

CLEAN EMPTY RESERVOIR'S INTERIOR:

- o [Saturate a clean cloth with Mint-A-Kleen and wipe the empty reservoir's interior.]
- o [If there is film inside the reservoir, scrub film from reservoir.]

CLEAN MASK:

- o [Disconnect mask from headgear and sleep apnea machine's tubing.]
- [Saturate a new cloth with Mint-A-Kleen and wipe the sleep apnea machine's breathing mask internally and externally.]
- [Place clean mask inside empty clean reservoir.]

CLEAN TUBING:

- [Take the end of the tubing that was connected to the sleep apnea machine and plug that tubing's opening with a rubber plunge stopper or cloth.]
- [Take the other end of the tubing and pour Mint-A-Kleen Cleaner into this tubing's opening.]
- [After Mint-A-Kleen Cleaner is poured, plug that tubing's opening.]
- o [The plugged ends of the tubing should be held in each hand.]
- [Move each hand up and down 3 times so the cleaner coats the entire inside of the tubing's inner walls.]
 - [This cleaning motion is achieved by lowering one end of the tubing and raising the other end of the tubing, simultaneously.]
 - [Alternating this movement moves the cleaner throughout the tubing.]
- [After completing this coating, place the plugged tubing on a flat surface, such as a bathtub or hang off of a showerhead. Allow the cleaner to stay inside the tubing over the next 8 hours.]

CLEAN FILTER:

- o [Remove the filter from the sleep apnea machine.]
- [Saturate the filter with Mint-A-Kleen.]
- [Immediately squeeze dry the air filter.]
- [Place the air filter back into the sleep apnea machine.]

STEP 3: FLUSH & RINSE MACHINE'S TUBING WITH WATER

REMOVE MINT-A-KLEEN FROM TUBING

- [After 8 hours of cleaning treatment is completed, Drain Mint-A-Kleen from tubing into a sink.]
- [Flush and Rinse the tubing with water: Place one tubing opening in the sink and then place the tubing's other opening to the sink faucet's opening.]
 - [Gradually turn the sink faucet ON then flush tubing with water for 30 seconds to remove any Mint-A-Kleen.]
 - [After rinsing the tubing with water is completed, turn water OFF.]
 - [Disconnect the tubing from the sink and raise this tubing's end to remove the water into the sink.]
- o [Rinse sink with water.]

REMOVE MASK FROM RESERVOIR

o [Fill reservoir with water from preferred water source.]

RE-CONNECT MACHINE'S COMPONENTS TO MACHINE

- o ITurn ON the machine.1
 - [If you hear gurgling noise in the tubing, allow the air to push any remaining water from the tubing.]
 - o [Begin sleep apnea machine use.]]

BACK PANEL MINT-A-KLEEN[®] EPA FINAL <u>MASTER LABEL</u>

[All 8 sets of Directions for Use will provide the following Container information on label:]

CONTAINER HANDLING: Do not contaminate water, food or feed by storage and disposal. **Storage:** store in a cool dark room away from heat or open flame. **Disposal:** wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. **Container:** non-refillable container. Do not reuse or refill container. Rinse with water and place in trash or offer for recycling if available.

[PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals. CAUTION: Causes moderate eye irritation. Harmful if inhaled or swallowed. Avoid contact with eyes or clothing or breathing vapor. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. FIRST AID: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For non-emergency information on this product, call Anodia Systems, LLC (1-866-246-2548), Monday through Friday, 9 a.m. to 5 p.m. EST. For medical emergencies, call the poison control center at 1-800-222-1222. IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice. IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person. PHYSICAL OR CHEMICAL HAZARDS. Combustible. Do not use or store near heat or open flame.]

[Anodia Systems, LLC Phone:866.246.2548 www.AnodiaSystems.com] [EPA Reg. No. 85298-2

[Developed, Patented & Bottled By Anodia Systems LLC]

EPA Establishment No. 85298-KY-001]



Watch our Online Instructional Video at www.AnodiaSystems.com

If you have any questions, please contact us directly.

Anodia Systems, LLC

109 Larrimore Lane | Danville, KY 40422 | P: 866.246.2548 | F: 866.926.8246

E: info@AnodiaSystems.com | www.AnodiaSystems.com

MINT-A-KLEEN®
EPA FINAL MASTER CARTON INSERT UPDATES
Additional Educational Facts & FAQ Section CARTON INSERT

[Facts for][Dental Unit [Waterline] [water line] cleaning with MINT-A-KLEEN:]

[DENTAL [WATERLINE] [WATER LINE] [&] [WATER BOTTLE] CLEANING FACTS:

- [Treated, Distilled or Purified Water Does Not Clean Contaminated Dental Unit [Waterlines] [water lines].]
- [All Water including Treated & Purified Water is Susceptible to Contamination.]
- [Treated & Purified Dental Water will become Contaminated when Supplied to Contaminated Dental Unit [Waterlines] [water lines].]
- [Dental Offices need Mint-A-Kleen® to Clean their [water line] [waterlines] in order to Maintain the Dental Unit Water Quality.]
- [Water Purifying Treatment Products (Tablets, Cartridges & Water Filters) require an additional cleaning product, a [waterline] [water line] cleaner, referred to as "shocking" the [waterlines] [water lines] also known as cleaning the [waterlines] [water lines] to help clean the dental unit [waterlines] [water lines].]
- [All Water (Treated, Filtered, Distilled and Purified Water) does not maintain the cleanliness of the dental unit [water bottle] [and] [waterlines] [water lines].]
- [Mint-A-Kleen Maintains the Dental Unit Water Quality by Cleaning the Contaminated Dental Unit Water Bottles & Dental [Waterlines] [water lines].]
- [Mint-A-Kleen cleans dental unit [waterlines] [water lines] [and] [water bottles].
- [Mint-A-Kleen's patented cleaning formula and protocol cleans dental unit [waterlines] [water lines] [and] [water bottles].]
- [Air purging is a process of removing water from the dental unit waterlines via activating the dental unit's foot control to expel the water from within the handpiece and 3-way syringe waterlines by the dental unit's pressurized air.] [Removal of dental unit water from the dental unit waterlines prevents dilution of Mint-A-Kleen[®].][Also, the removal of water from the dental unit allows Mint-A-Kleen[®] to come in direct contact with the inner walls of the dental unit waterlines.]
- [Mint-A-Kleen's Instructions recommends using only 4 ounces of Mint-A-Kleen per dental unit, once-per-week after dental business hours (when NO patients are present in the dental operatory).]
 - o [Mint-A-Kleen is used at night, intermittently in the dental office.]
 - [Mint-A-Kleen's is <u>not</u> used continuously during operative procedures in the dental office.]
- [NO dental patients are exposed to Mint-A-Kleen.]
 - [Mint-A-Kleen's 1st Protocol Step: Air Purge, removes the existing dental unit water so Mint-A-Kleen is never mixed with the patient's dental unit water.]
 - [Mint-A-Kleen is then added into the empty dental unit to ensure Mint-A-Kleen's formula coats the inner walls of the dental unit waterline tubing.]
 - [Mint-A-Kleen is a ready-to-use formula that should never be diluted or mixed with a patient's consumable dental unit water.]
 - [After the once-through Mint-A-Kleen treatment is completed, Mint-A-Kleen's Final Protocol Step is a Flush/Rinse of the dental unit water system so that it will not result in patient exposure to the Mint-A-Kleen product and contaminants.]
 - [Mint-A-Kleen does not go in the patient's mouth.]

[Mint-A-Kleen's pH Level Alters Before being indirectly Disposed into Sewer]

- [Mint-A-Kleen is <u>not</u> being disposed directly into the sewer.]
- [Mint-A-Kleen's pH alters during Mint-A-Kleen's cleaning protocol.]
- Clarification on [Waterline] [water line] Cleaners and Water Treatment products:
 - Dental water quality and contaminated dental [waterlines] [water lines] are two separate issues. Mint-A-Kleen is a dental unit [waterline] [water line] cleaner that treats dental unit [waterlines] [water lines] only, not the water. The following water treatment products: tablets, filters, and irrigants treat water with the false assumption that clean water equals clean dental unit waterlines. [This is an important distinction.] [Clean water does not equal clean dental unit [waterlines] [water lines].] [Treated water does not remove contamination.] [A

dental office can have clean treated water and still have contaminated dental unit [waterlines] [water lines].]

- [The following causes contaminated dental [waterlines] [water lines] and [bottles]:]
 - [Small Diameter of [waterline] [water line] tubing.]
 - > [Water Source.]
 - [Slow water flow through [waterlines] [water lines].]
 - [Stagnant water] [in] [waterlines] [water lines].]
 - [Warm water temperatures in [waterlines] [water lines].]
 - Patient back flow of oral fluids] [from high-speed handpiece vacuum during dental operative procedures.]

[Again, improving dental unit water quality is an important step to infection control in the dental office; however, it does **not** replace the need for Mint-A-Kleen, a dental [waterlines] [water lines] cleaner.]

- [After Mint-A-Kleen cleans the dental unit and before Mint-A-Kleen's diluted formula contacts the sewer, Mint-A-Kleen's pH level is affected by the dental unit water's minerals, contaminated dental unit's debris and the dilution from Mint-A-Kleen's Final Step: flushing/rinsing with dental unit water.]
- [When Mint-A-Kleen's cleaning solution is diluted with dental unit water, the concentration of hydrogen ions alters and the pH of the solution changes.]
- [Question: Why is it important to air purge before adding Mint-A-Kleen?]
 - [Answer: Air purging removes all of the water from the dental unit [waterlines] [water lines] and ensures that only Mint-A-Kleen comes in direct contact with the inner walls of the [waterlines] [water lines].] [Products that do not air purge become diluted and less effective.] [If water is not removed then it weakens Mint-A-Kleen's formula. Mint-A-Kleen is ready to use; no dilution and no mixing.]
- [Question: Is it necessary to use Mint-A-Kleen with other products: tablets, filters, powders, irrigants, or cartridges?]
 - [Answer: No, Mint-A-Kleen is the only cleaning product a dental office needs to clean their dental unit [waterlines] [water lines]. Mint-A-Kleen is a once per week [waterline] [water line] treatment and does not require the use of multiple products: tablets, powders, cartridges, filters, or irrigants.]
- [Question: Should I air purge my [waterlines] [water lines] at night to decrease the levels of bacteria in the waterlines?]
 - O [Answer: No. Studies have shown that the time of day and length of time spent air purging does not reduce bacteria in [waterlines] [water lines].][* Air purging is important because it prepares the [waterlines] [water lines] for the Mint-A-Kleen cleaning phase and ensures that there is no water left in the [waterlines] [water lines], which would dilute the Mint-A-Kleen treatment.] [*Ref: "The effect of ultrafiltration on the quality of water from dental units." Dr. Associate Professor T. Larsen. International Dental Journal. 10.2956/indj.2006.56.6.352.]
- [Question: Is it recommended that Mint-A-Kleen remain in the waterlines over the weekend?]
 - <u>[Answer:</u> The once-per-week Mint-A-Kleen treatment can occur at any time during the week—whatever is convenient for your dental staff and office.] [Many of our customers prefer treating the [waterlines] [water lines] on the last day of their business week (i.e., Friday) and allowing Mint-A-Kleen to remain in the waterlines and bottles over the weekend for a longer treatment.] [We recommend a minimum of 8 hours for treatment and certainly a weekend treatment is optimal as well.]
- [Question: Why do I have to flush dental unit [waterlines] [water lines]?]
 - [Answer: Flushing your [waterlines] [water lines] removes any excess Mint-A-Kleen along the [waterline] [water line] and bottle walls.] [Following our cleaning protocol as outlined in the Directions for Use ensures clean [waterlines] [water lines] and bottles][—][your equipment is now ready for general dental procedures].
- [Question: What are Dental Unit [waterlines] [water lines]?]
 - [Answer: Dental Unit [waterlines] [water lines] [(DUWLs)] are narrow-bore tubing used to deliver water for high-speed dental handpieces, air-water syringes, and

dental unit water quick disconnects.] [Regardless of the dental unit water that offices choose to use as their source, all dental water is susceptible to bacteria growth, which adhere to the inner tubal walls and water bottle interiors and form a slime layer, which can cause odors and other equipment malfunctions.] [Supplying purified treated dental water to contaminated dental unit [waterlines] [water lines] will impact the dental unit water quality]. [Mint-A-Kleen cleans the contaminated dental unit [waterlines] [water lines] to maintain the dental unit water quality.]

- [Question: What causes bacteria growth in Dental Unit [waterlines] [water lines]?]
 - [Answer: A combination of any of the following causes contaminated dental [waterlines] [water lines] and bottles:]
 - [Small diameter of [waterline] [water line] tubing.]
 - [Water source.]
 - [Pick-up tube in water bottle becomes contaminated when staff touches the pick-up when filling the water bottle.]
 - [Unclean water bottles—not cleaning the inside of the water bottle on a weekly basis before filling it with water source.]
 - [Handpiece connectors—high-speed handpiece disconnects that are exposed.]
 - [Slow water flow through tubing such as high-speed handpieces.]
 - [Stagnant water in [waterlines] [water lines].]
 - [Warm water temperature in water heaters.]
 - [Patient backflow of oral fluids.]
 - [Poor infection control by dental office staff—Not following protocols, not wearing gloves, not washing hands properly, etc.]
 - ["Dead-ends" on dental unit—these are a reservoir for bacteria unless an office is using a Dead Ends® Drain Tube.] [A 'dead-end' on a dental unit is a point at which water does not continuously flow and is stopped by a valve.] [Most dental units have a water quick-disconnect outlet that is a 'dead-end'—meaning it is a reservoir for bacteria if not properly cleaned using a drain tube and Mint-A-Kleen®.]