



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

February 14, 2024

Bob MacDonald
Agent for Crosstex International, Inc.
c/o Scientific & Regulatory Consultants, Inc.
Electronic Transmittal: bmacdonald@srcconsultants.com

Subject: Label Amendment – Update to Precautionary Statements and Claims.
Product Name: “Dentapure Microbiological Water Purification Cartridge”
EPA Registration Number: 74245-5
Received Date: October 23, 2020
Action Case Number: 00217328

Dear Mr. MacDonald:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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. Pursuant to 40 CFR 156.10(a)(6) 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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 Michael Varco by phone at (202) 566-0667, or via email at Varco.Michael@epa.gov.

Sincerely,

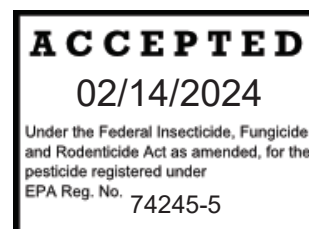
A handwritten signature in black ink, appearing to read 'D. Fuller', with a long horizontal stroke extending to the right.

Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Product master label

DentaPure™ Cartridge

EPA Registration No.: 74245-5



INSTRUCTIONS FOR USE
[[DentaPure] [Microbiological] [Dental Procedural] Water Purification
Cartridge]] [DENTAPURE™]
[For Use As A Microbiological Dental Unit Water Purifier]
[[Microbiological] [Dental Unit] Water Purification [Cartridge] [System]]

The DentaPure™ microbiological dental [procedural] water purification cartridge and System Models are for use on dental unit waterlines attached to dynamic instruments. Not intended for general consumption. Used according to labeling, this cartridge reduces microbial contamination from the procedural water supplied through the instruments to meet water quality having <10 CFU/mL. Once the cartridge and System Models are in place, procedural water will pass through the iodinated resin bed, which will continuously release low levels of antibacterial elemental iodine (I₂).

PLEASE SAVE THESE INSTRUCTIONS FOR FUTURE USE

Only selected information is contained on the cartridge packaging.

Active Ingredient: Iodine*	46 %
Other Ingredients	54 %
Total.....	100 %

*bonded to strong base anion exchange resin

FOR PROFESSIONAL USE ONLY

Keep Out of Reach of Children

CAUTION

For accidental exposure to resin:

In the remote event that the cartridge breaks causing exposure of iodinated resin pellets, use extreme caution.

If exposed to oral cavity, remove resin with evacuation tip. Oral exposure has not been shown to pose significant health risk.

FIRST AID:

IF IN THE 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 eye. Call poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes.

IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Have product container or label with you when calling a poison control center or doctor, or going for treatment.

See Instructions For Use for Directions, First Aid and additional Precautionary Statements

NET CONTENTS: 1 Cartridge

	Municipally Plumbed Cartridge	Bottle Cartridge	Bottle Cartridge	Centralized System Cartridge	Centralized System [Capable of receiving DentaPure Centralized System Cartridge]
Part Number	DP365M	DP365B	DP40B	DP365VC	CVV1000-DP
Iodinated Resin	38.0 cc	16.0 cc	4.0 cc	240.0 cc	N/A

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

CAUTION:

Causes moderate eye irritation. Avoid direct contact with eyes, skin and clothing. Wear protective eyewear and gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS: The exposed resin pellets are toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. For guidance, contact your state Water Board or regional office of the EPA.

DIRECTIONS FOR USE

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

Upon receipt, ensure that protective caps are in place and remove prior to installation. [Refer to enclosed installation instructions]

It is recommended to clean [shock] dental unit waterlines with an EPA registered dental unit waterline agent, or another product recommended by the dental equipment manufacturer prior to DentaPure Cartridge installation when possible. If cleaning [shocking] is necessary based on office protocol, or failed waterline testing following installation, remove the DentaPure Cartridge first. Never shock through a functional or depleted DentaPure Cartridge. For DP365B and DP40B cartridges, replace the cartridge with a temporary section of [included] tubing [DPBKIT] [or cartridge shock accessory], clean [shock] the lines per manufacturer's instructions, remove the temporary tubing [cartridge shock accessory] and reinstall the functional cartridge.

It is recommended to block or disconnect waterlines that are unused or extra such as low-speed handpieces, air-water syringes and ultrasonic scaler ports to avoid creating areas of stagnant water (dead legs) that are inaccessible to antimicrobial agents and can harbor biofilm that will continuously re-contaminate the water system.

It is recommended to disconnect water heaters.

Water pressure should be set between 40-50 psi. Consult your dental unit technical manual for calibration instructions.

The cartridge should be left in place during times that the dental unit is not used (weekends, holidays and vacations, etc). For extended periods of non-use, contact HuFriedyGroup for recommended protocols.

Bottle AND Municipal Cartridge Users: To maintain active iodine levels, perform a 2-minute morning flush each day patients are seen, on every line, every unit (include units/lines not used regularly to avoid dead legs). Adherence to CDC/ADA guidelines for aseptic procedures including, a 20-30 second flush of water and air after each patient, from any device connected to the dental water system that enters the patient's mouth and hand piece sterilization must be continued after the installation of the cartridge.

Bottle Cartridge Users (DP40B and DP365B): It is recommended to empty the residual water in reservoir bottle each night and either turn upside down to dry or return to manifold. Follow the bottle manufacturer's cleaning and maintenance schedule.

Best practice infection control protocol is to wipe down the DentaPure Cartridge with a clean, dry paper towel and inspect the cartridge intake end for obstruction. If bottle design provides a protective enclosure for the cartridge, but inhibits daily cartridge wiping, this step may be omitted.

Fill reservoir bottle with fresh, potable water each morning before starting patient treatment.

If practice protocol includes recording water usage, begin a new water check-off sheet. Discard depleted cartridge per Disposal instructions.

Optional Use of Iodine Test Strips: Iodine test strips use is suggested [especially for a very busy practice] to verify performance as the estimated end of cartridge life approaches. [Iodine Test strip sample[s] included.] See the chart below for suggested change intervals if iodine content is monitored.

To maintain a continuous iodine presence within the dental tubing, install a new cartridge immediately after removing a depleted cartridge.

To ensure water quality and confirm that the product procedures are effective, HuFriedyGroup supports [recommends following] industry, dental unit manufacturer, and state recommended/ required [monitoring] [testing] guidance. To ensure DentaPure Cartridge performance, follow Directions for Use.

*Centralized System Model incorporating DentaPure™ Microbiological Water Purification Cartridge carry the trade name of VistaClear™.

Current units are named:

- VistaClear™ DP Centralized Waterline Treatment System
- VistaClear™ DP System

Suggested use table:

DentaPure™ Cartridge Part Numbers	Centralized System Model [Capable of Receiving DentaPure DP365VC Cartridge]	If Water Usage Is Tracked	If Water Usage is NOT Tracked	If Iodine Content is Monitored
DP40B	N/A	40 Liters	60 Calendar Days	Change when iodine output falls below 0.5 ppm for All DentaPure Cartridge part numbers
DP365M DP365B	N/A	240 Liters	365 Calendar Days	
DP365VC	CVV1000-DP [System Treats up to 10 operatories]	2,400 Liters* *Treats [a system] up to 10 operatories at 240L per operatory	365 Calendar Days	

STORAGE: Store at room temperature in original packaging, away from direct sunlight. Avoid excessive heat. Do not allow cartridge to freeze. If the DentaPure Cartridge needs to be temporarily removed from installed position, place and seal in a zip top bag labeled and dated with [estimated] initial installation date and operator number/name. Store at room temperature until returned to manifold.

DISPOSAL: Securely wrap cartridge in paper toweling and discard in regular office trash.

TROUBLESHOOTING

- Slow or no water flows through cartridge/sputtering: Check the following:
 - Ensure new cartridge was installed properly
 - Luer fitting fully pushed in
 - Cartridge securely attached
 - Pick up tube securely attached to manifold and checked for cracks
 - Ensure air supply is turned on (40 - 50 psi).
 - Ensure cartridge is ¼" – ½" off of the bottom of the bottle
- Air leak from fitting: contact your dental dealer for replacement parts
- Discoloration of the waterline tubing from blue to green or black is normal
- Initial dark discoloration of water following installation of the DP365M Cartridge is normal [and is caused by release of activated carbon] [Operate water until flow appears clear.]

All company and product names are trademarks of Hu-Friedy Mfg. Co., LLC its affiliates or related companies, unless otherwise noted.

EPA Establishment No: xxxxx-xx-xxx



Manufactured for:
Crosstex International, Inc.
6789 W. Henrietta Road, Rush, NY 14543

For questions or technical assistance call: (800) 483-7433

©[Date] Crosstex International, Inc.
[Part#/Rev]

CROSSTEX

Optional language/logos that may appear on any panel of the carton label or in collateral literature in any combination

[(One) DentaPure Cartridge maintains water quality for 365 days or 240L of water]

(One) DentaPure Cartridge = 365 Days of dental procedural water that meets current microbiological water quality standards (DP365B, DP365M)

[Full Year] [365 days]

[Controls] [Reduces] [Inhibits] odor causing bacteria] microbial contamination in dental unit waterlines

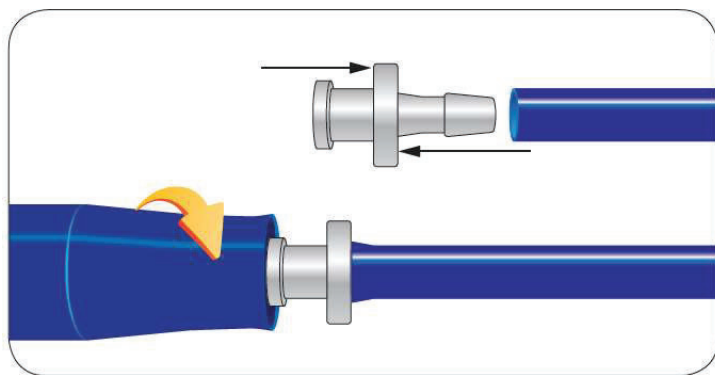
[Kills odor causing bacteria]

[For use on dental treatment waterline units only]

[For use with potable water]

[The DentaPure DP365VC Cartridge is included with the VistaClear™ DP Centralized Waterline Treatment System.]

[The DentaPure DP365VC Cartridge is available for use [included with the VistaClear DP Centralized Waterline Treatment System] with all VistaClear™ DP systems.]



1. For new installations, insert the barbed end of the luer fitting into the trimmed end of the pickup tubing.
2. Gently twist the DP365B cartridge onto the luer fitting. Take care not to over tighten – finger tighten only.
3. Ensure that there is at least ¼" of clearance between the bottom of the bottle and the end of the installed DP365B.
4. To replace a DP365B cartridge, simply untwist the old cartridge to remove and twist on the replacement.

[Refer to the enclosed installation document for step-by-step instructions]



[Register your DentaPure Cartridge online.]

[Warranty requirement. Please register your cartridge within two weeks from date of installation.]

[Have product lot#(s) available.] [Located on the original packaging and on the cartridge body.]

Optional language/pictures/diagrams that may appear in collateral literature in any combination

[effluent] [procedural water]

[DentaPure Cartridge treated water is not an appropriate coolant/irrigant for surgical procedures]

[Sterile water or sterile saline are the only appropriate coolants/irrigants for surgical procedures]

[Shut off water to the DentaPure Cartridge when not in use]

[An effective method of treating municipally plumbed dental units]

[As water passes through [the [DentaPure] cartridge], the resin releases 2 - 6 ppm of elemental iodine (I₂) during a typical dental procedure]

[Can use tap or distilled water]

[Compatible with bottle and municipal systems]

[Compatible with most commonly used dental tubing]

[Independent Water Bottle Cartridge DP365B [DP40B] Easily installed [by office staff] onto existing pick-up tube with included fitting]

[For use in healthcare facilities, dental offices, mobile units, hospitals, dental schools, clinics, community healthcare centers, military dental facilities and animal care facilities]

[For DP365B [and DP40B cartridges], replace the cartridge with a [the included] temporary section of tubing [Cartridge shock accessory]. [The included cleaning [shocking] [Cartridge shock accessory] tube twists onto the luer fitting already attached to the pickup tube]. Clean [shock] the lines per manufacturer's instructions, remove [untwist] the temporary tubing [Cartridge shock accessory] and reinstall the functional cartridge.]

[Optional Use of Iodine Test Strips: Iodine test strip use [sample[s] included] is suggested to verify performance as the estimated end of cartridge life approaches. See the chart below for suggested change intervals.]

[Installs in minutes]

[Dispose of used cartridges in the [your] regular [office] trash]

[Easy installation in minutes]

[Municipal Cartridge DP365M: For waterlines plumbed directly to city water. Installs onto incoming lines with included fittings]

[No routine shocking following installation]

[No routine shocking]

[Will not interfere with dental materials and bonding]

[No concerns with dental materials and bonding]

[No concerns with dental unit corrosion or etching]

[Reduces the possibility of human error]

[The DentaPure DP365B [40B] cartridge installs onto your dental unit's existing water bottle pickup tube]

[The DentaPure DP365B [40B] Cartridge is easily installed by dental office staff via included luer fitting onto your dental unit's existing pickup tube]

[The DentaPure DP365M Cartridge for units plumbed directly to city water. Installs in the Jbox [cabinet] via included poly-flo fittings. Service Technician installation recommended]

[While DentaPure Cartridges do not require monitoring, HuFriedyGroup supports all recommended/required monitoring guidance. Follow the DentaPure Cartridge IFU protocols to achieve results that meet current microbiological water quality standards]

[2–6 ppm of iodine is less than two slices of white bread or one cup reduced fat milk]

[The Elemental Iodine controls microbial contamination for 365 days or 240L [60 days, 40L]]

[The technology behind the DentaPure Cartridge: The DentaPure Cartridge is attached to the waterlines feeding into the dental unit equipment. As water passes through the cartridge, a small amount of elemental iodine is released into the water. This elemental iodine reduces the bacteria in the waterlines to deliver water to you during your dental procedure that meets current microbiological water quality standards]

[Choose the [DentaPure Cartridge] cartridge that's right for your office]

[Contact HuFriedyGroup for remediation support for [failed] dental waterline [monitoring] testing results [not meeting] [outside of] [current microbiological water quality standards.]]

[Daily waterline maintenance becomes a simple, annual routine]

[Discover [Understand] the problem that you may not realize you have]

[Do not clean [shock] or run anything other than [potable] water through a non-depleted DentaPure Cartridge]

[Do not use a depleted DentaPure Cartridge for cleaning [shocking] waterlines]

[HuFriedyGroup reminds you when it's time to change cartridges]

[Multi-Award Winning DUWL Treatment Cartridges]

[Reduce your daily DUWL treatment to a simple annual routine]

[Reduce your waterline treatment protocol to a simple annual routine]

[Revolutionize your [dental] waterline maintenance]

[How Do You Treat Your Patient Use [procedural] [treatment] Water?]

[How is your office treating DUWLs to minimize the potential for microbial growth?]

[How Often Are You Cleaning [shocking] Your Dental Unit Water Lines?]

[Impact of dental procedural [treatment] [patient treatment] water that does not meet current microbiological standards is too great to ignore]

[Impact of untreated procedural [treatment] [patient treatment] water is too great to ignore]

[Implications from improperly treated DUWLs are far too great to ignore]

[Is your office at risk?]

[Minimize [reduce] the potential for microbial growth]

[The challenge with dental unit waterlines]

[What you can't see may harm your patients, your staff and your practice's reputation]

[What's lurking in your waterline?]

[Simplifying DUWL maintenance protocols]

[Say Goodbye to Tedious Tablet Protocols]

[No More Tablets]

[No tablets/no tablet downsides [disadvantages]]

[Since 1997]

[For the love of your patients and your practice]

[For the love of your patients, staff and your practice]

[For the love of your patients]

[We care about our patient's]

[Treat your patients like family]

[Our practice uses DentaPure Cartridges for dental unit waterline treatment on each of our dental units [dental chairs]]

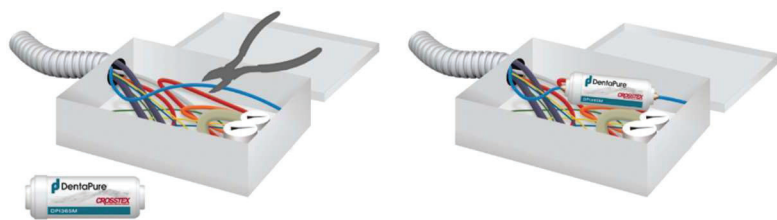
[Our patients are our first priority]

[The untreated dental procedural [treatment] water in your dental unit waterlines should not be used on patients]

[Water flowing through long and narrow dental unit waterlines can harbor bacteria. When untreated, or improperly maintained, these contaminated DUWLs can potentially harm your patients, your staff and your practice's reputation]



Independent water bottle systems
The DentaPure DP365B Cartridge is easily installed by office staff via included luer fitting onto your dental unit's existing pickup tube



Municipally plumbed systems
The DentaPure DP365M Cartridge for units plumbed directly to city water, installs in the Jbox via included poly-flo fittings. Service technician installation recommended

How the DentaPure Cartridge Works



The DentaPure Cartridge contains iodinated resin beads

As water passes through, the resin releases 2 – 6 ppm of elemental iodine (I_2) during a typical dental procedure

The elemental iodine controls the bacteria [microbial contamination], helping to produce water that meets current microbiological water quality standards [The Elemental Iodine controls microbial contamination for 365 days or 240L [60 days, 40L]

DentaPure™ Cartridge Installation Instructions

To ensure DentaPure™ Cartridge performance, refer to Directions for Use in the accompanying Instructions for Use document.

DP40B and DP365B Installation Instructions

REQUIRED TOOLS AND MATERIALS:

- DentaPure™ Cartridge
- Luer Fitting (Included in box)
- Scissors or sharp knife

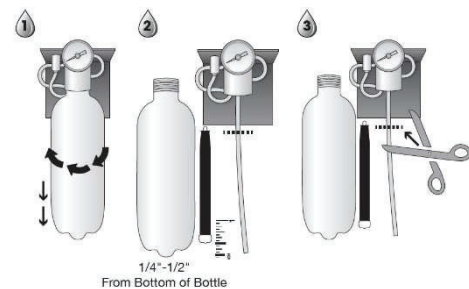
Installation Steps

Follow steps 1-3 for both the DP40B & DP365B cartridges.

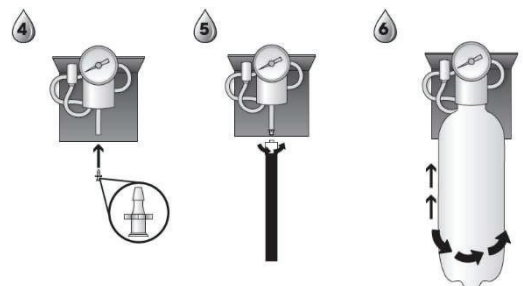
Continue to:

B1: steps 4-6 for DP40B

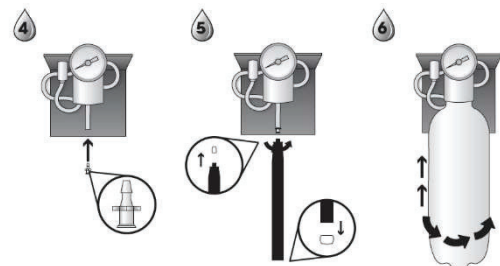
B2: steps 4-6 for DP365B



(B1) Steps 4-6 for
DP40B Installation



(B2) Steps 4-6 for
DP365B Installation



Following installation:

- Check air pressure to bottle: set between 40-50 psi.
- Operate dental unit instruments until all air is purged from the water system.
- If cleaning/shocking is necessary based on office protocol or failed waterline testing, remove the cartridge first. Never shock through a functional or depleted cartridge. Replace the

cartridge with a temporary section of [included] tubing [DPBKIT] [cartridge shock accessory], clean/shock the lines per manufacturer's instructions, remove the temporary tubing and reinstall a new or existing functional cartridge.

DP365M Municipal Cartridge Installation Instructions

REQUIRED TOOLS AND MATERIALS:

- Installation Kit: 2 polyflo fittings, 1x ¼" plastic union (barb to barb fitting), Teflon plumber's tape, 2x plastic clamps to secure tubing onto barb fittings, 1x Holding bracket
- Scissors or sharp knife • Adjustable wrench

- (1) Locate and turn off water supply. Identify placement of DP365M in or near junction box, immediately after the water pressure regulator. Ensure that there is enough space for the cartridge without kinking the tubing.
- (2) Set water regulator pressure between 40-50 psi.
- (3) Remove the blue plugs from the ends of the cartridge. Wrap Teflon tape around the fitting threads and install the included polyflo fittings onto each end of the cartridge.
- (4) Position the cartridge immediately after the water pressure regulator. Cut the water tube using scissors or a knife. **Note:** The DentaPure Cartridge should not treat the cuspidor/cup filler; this may require a bypass connection.
- (5) Unscrew the brass retainer portion of the polyflo fitting on the cartridge side closest to the junction. Slide the tubing through the retainer and slip the tubing onto the fitting on the cartridge. Tighten the retainer to the fitting.
 - Note: if tubing has fabric covering, ensure the fabric is captured within the plastic retainer. Ensure tubing does not kink after fitting to the cartridge.
- (6) Hold cartridge vertically. Turn on water, and let it flow to purge all air.
- (7) Repeat step 5 on the opposite side of the cartridge.
- (8) Install the holding bracket if desired and place cartridge in bracket.
- (9) Operate dental instruments to check water flow and purge air / carbon filter residues from the lines.

Optional: To install the bypass where iodinated water is not desired; ie: cuspidor cup configuration: turn water supply off and depressurize the water system by operating the air/water syringe. Install a "T" fitting before the cartridge.

Optional: If the DentaPure Cartridge needs to be removed for any reason, remove it by unscrewing the nut retainers, use the supplied plastic union fitting and clamps to secure waterlines together. Turn on water and purge the water system free of air using the air/water syringe and hand piece. Check for leaks. When treatment is completed, reinstall the cartridge following the instructions above. Check the re-installed cartridge for leaks before returning unit to operation.

For questions regarding DentaPure™ Cartridge installation for all models, please contact HuFriedyGroup Customer Care: (800) 483-7433

Manufactured for:

Crosstex International, Inc.

6789 W. Henrietta Road, Rush, NY 14543 (800) 483-7433

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CTXTEXDP-INSTALL REV C - xx/xxxx 50098-1029/x




Reminder sticker



Registration Card

Register your DentaPure™ Cartridge online




WARRANTY REQUIREMENTS

Please register your cartridge(s) within two weeks from date of installation. Have product Lot#(s) available. Located on the original packaging and on the cartridge body.

Following registration, you will receive a DentaPure™ Cartridge certificate of purchase*. Allow 4-6 weeks for delivery.

*Certificate availability restricted to the US and Canada.

00000CTX / REV A - 09/2023
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Crosstex is now a proud member of  **HuFriedyGroup**
The Best In Practice



EPA Reg. No. 74245-5

INSTRUCTIONS FOR USE

Advanced, Easy to Use and Cost Effective Clinical Water Treatment Technology

For use as a Microbiological Dental Unit Water Purification System

Keep Out Of Reach Of Children

CAUTION

PLEASE SAVE THESE INSTRUCTIONS FOR FUTURE USE. Only selected information is contained on the cartridge packaging, therefore you should keep this sheet for future reference.

Active Ingredient: Iodine* **46%**
Other Ingredients **54%**
Total **100%**

*Bonded to strong base anion exchange resin

Unit	DP365VC
Iodinated Resin	240.0 cc

IN THE REMOTE EVENT THE CYLINDER OR CARTRIDGE IS BROKEN AND THE IODINATED RESIN PELLETS ARE EXPOSED, USE EXTREME CAUTION.

FIRST AID:IF IN THE 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 eye. Call poison control center or doctor for treatment advise.

IF ON SKIN OR CLOTHING: Take off contaminate clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Have product container or label with you when calling a poison control center or doctor, or going for treatment.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

CAUTION: Avoid direct contact with eyes, skin and clothing. Wear protective eyewear (goggles) and gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Safety and effectiveness in children under the age of two has not been established.

ENVIRONMENTAL HAZARDS:

The exposed resin pellets are toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. For guidance, contact your State Water Board or regional office of the EPA.

It is a violation of federal law to use this product in any manner inconsistent with its labeling.

DIRECTIONS FOR USE

To obtain maximum bacteriological reduction, dental unit waterlines are to be cleaned with an approved dental unit waterline agent prior to initial installation of DentaPure™ Cartridges.

GENERAL PRECAUTIONS

USES: DentaPure™ Cartridge is for use on dental unit waterlines attached to the dynamic dental instruments. Used according to labeling, this cartridge reduces bacteria from the water supplied through the instruments to a level that will meet or exceed the current ADA recommendations for water quality having a maximum of 200cfu/ml.

IMPORTANT!

Use DentaPure Cartridge on dental unit waterlines only. Not for general consumption. While the unit will perform above these limits, it is recommended that the dental unit water have a pH level of less than 8 and not have a chlorine level greater than 1 ppm. Do not use heated water. Heated water will promote the growth of bacteria and the buildup of biological film in the water line leading to the DentaPure unit. Water pressure must not exceed 45 psi. If package seal is broken, or cartridge appears dry, wrap the cartridge in newspaper and dispose of it in the trash.

Once the cartridge is in place, the supply water will pass through the cartridge's iodinated resin bed, purifying the water delivered by the dental instrument. To maintain a continuous iodine presence within the dental tubing, install a new cartridge immediately after removing the used cartridge. The cartridge must be left in place during times that the dental unit is not used (weekends, vacations, etc).

Adherence to CDC/ADA guidelines for aseptic procedures including a 2 minute morning flush, a 20-30 second flush between patients, and hand piece sterilization must be continued after the installation of the cartridge.

Change the cartridge if the level of iodine output falls to less than 0.5 ppm. Use Iodine sensitive test strips to verify performance. See the chart below for suggested change intervals. To change cartridge, follow installation instructions. Remove the used cartridge and install the new

DentaPure™ Cartridge. Operate the dental instrument to check flow and verify that the unit is ready for use. Install a new water check-off sheet. Dispose of the old cartridge according to disposal instructions. Shut off water to dental unit when not in use.

STORAGE: Store at room temperature in original packaging, away from children, pets and direct sunlight. Avoid excessive heat. Do not allow cartridge to freeze. Do not store in open or unlabeled containers.

DISPOSAL: Securely wrap cartridge in newspaper and discard in trash.

TROUBLESHOOTING

Slow or no water flows through cartridge make sure new cartridge was installed properly. Make sure air supply is turned on (maximum 45 psi). Make sure cartridge is off the bottom of the bottle. Air leak from fitting, contact your dental dealer for replacement parts.

Discoloration of the tubing from blue to green or black is normal and is not a concern.

Initial dark discoloration of water is caused by release of activated carbon. Operate water until flow appears clear.

Suggested Use Table:

DENTAPURE Unit Size	If Water Usage Records Are Kept	If Water Usage Records are NOT Kept	If Iodine Content is Monitored
DP365VC	2400 Liters*	365 Calendar Days	Change when iodine output falls to less than 0.5 ppm

*Treats a system of up to 10 operatories at 240L/Operatory

QUESTIONS OR COMMENTS? Email: care@hu-friedy.com
or call 1.800.483.7433.



Manufactured for: Crosstex International, Inc.
6789 W. Henrietta Road, Rush, NY 14543 USA
800.483.7433

EPA Est No. 74245-AZ-1

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