DAI 500.40.28 Attachment B - DentaPure Instructions for Use Effective Date: 06/08/15



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

INSTRUCTIONS FOR USE

DentaPure Microbiological Water Purification System

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Active Ingredient:							
lodine*		46%	Unit	DP365M	DP90M	DP365B	DP40B
Other Ingredients		54%	Iodinated Resin	38.0 cc	12.0 сс	16.0 cc	4.0 cc
	TOTAL	100%				·	

^{*}Bonded to strong base anion exchange resin

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 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.

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, or using tobacco. 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 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.

NOTE: USED, UNDAMAGED CARTRIDGES AND CYLINDERS ARE NOT CONSIDERED HAZARDOUS AND MAY BE WRAPPED IN NEWSPAPER AND DISPOSED OF IN THE REGULAR TRASH.

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

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

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 200 cfu/ml.

IMPORTANT! Use DentaPure® cartridge on dental unit waterlines only, not for general consumption. While the unit will preform 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

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and the buildup of biological film in the water line leading to the DentaPure unit. Water pressure should 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.

The bottle in water bottle systems must be emptied each night and the empty bottle replaced on the manifold. Prior to daily use, wash the inside of the bottle and rinse thoroughly. Wipe down the outside of the cartridge, and make sure the intake end is not obstructed. Fill with fresh water each morning before its first use. The DentaPure® DP40B cartridge must be changed after 40 liters of water usage, or if records of usage are not kept, after 60 calendar days of installation.

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.

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	
DP40B	40 Liters	60 Calendar Days	Change when iodine output falls	
DP90M	60 Liters	90 Calendar Days	to less than 0.5 ppm	
DP365M & DP365B	240 Liters	365 Calendar Days		

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INSTALLATION: Effective Date: 06/08/15 DentaPure® DP40B & DP365B

TOOLS AND MATERIALS REQUIRED:

- Installation Kit-Includes one female and one male fitting
- Scissors or sharp knife

To obtain maximum bacteriological reduction, dental unit waterlines should be cleaned with an approved dental unit waterline agent prior to initial installation.

- 1. Remove white shipping caps from both ends of the unit.
- 2. (Optional) Disconnect dental unit water heating system, if installed.
- 3. Remove bottle from manifold.
- 4. Install female fitting, from installation kit into male fitting which is attached to the cartridge.
- 5. Place the DentaPure® cartridge against the bottle pickup tube, aligning the bottoms of the

- pick up tube and the new unit, allowing enough space (about 1/4") so that cartridge will not touch the bottom of the bottle.
- 6. Push female fitting into the remaining short section of pickup tube projecting from the manifold and attach the unit.
- 7. Attach the male fitting from the installation kit into the cut end of the removed portion of pickup tubing. Save this for future dental unit cleaning or purging.
- 8. Check air pressure to bottle, set at 45 psi.
- 9. Operate dental unit instruments until all air is purged from the water system.

NOTE: If the unit has a cuspidor and cup filler, bypass these using a "T" fitting on the supply line before the water bottle.

INSTALLATION:

TOOLS AND MATERIALS REQUIRED:

- Installation Kit--Includes attachment bracket(s),
 2 polyflo fittings, 1 union
- Scissors or sharp knife
- Teflon plumber's tape
- 1. Turn off water supply. Locate placement of DP365 or DP90 in or near junction box.
- Arrange to install the DentaPure Cartridge immediately after the water pressure regulator. Set water regulator pressure to 45 psi.
- 3. Remove the shipping plugs from the end of the cartridge. Install the 1/4" or 5/8" (determined by the size of your water line) polyflo fittings on each end of the DentaPure cartridge. Make watertight with Teflon tape wrap around the fitting threads.
- 4. Cut the water tube and attach to the polyflo fittings on each end of the DentaPure cartridge. Push tubing through the retainer in the fitting nut, slip tube onto fitting and tighten nut. NOTE: if tubing has fabric covering, make sure the fabric

DentaPure® DP365M & DP90

- is captive within the plastic retainer. Make sure the tubing will not kink after it is fitted to the DentaPure cartridge.
- 5. Install the holding bracket(s).
- 6. Hold cartridge vertically, turn on water, and operate dental instrument(s) to check water flow and purge unit free of air. Place cartridge in bracket(s).
 - To install the bypass splice (to be used where iodinated water is not desired; ie: cuspidor/cup configuration): turn water supply off and depressurize the water system by operating the syringe. Install a T fitting before the cartridge.

If treatment of the line is desired, turn off the water source. Remove the DentaPure cartridge by unscrewing the nut retainers. Reinstall on the splice fitting. Turn on water and purge the water system free of air using the syringe and hand piece. When treatment is completed, reinstall the DentaPure cartridge.

Studies show that water heaters can be a source of increased biological contamination. For optimal biological purity DentaPure® recommends not using water heaters.

QUESTIONS OR COMMENTS? Visit our website at www.dentapure.com or e-mail us at dentapure@dentapure.com.

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