PS | SYSTEM

A MULTI-CANNULAR NEGATIVE PRESSURE IRRIGATION DEVICE

PulpSucker Instructions for Use

A Multi-Cannular Negative Pressure Irrigation Device

503800-I-DL (3)

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Indications for Use

The PS System is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.

Description of Device

The PS System presents a clinically effective way to irrigate the entire canal space during root canal treatments. The PS System is a closed system negative pressure irrigation apparatus that draws fluid through the distal ends of individually placed cannulas then out through the pulp chamber by way of evacuation that is controlled independently through the dental chair vacuum system, eliminating the risk of apical irrigant extrusion during root canal procedures. The PS procedure creates a closed system by establishing an airtight seal between the tooth and stage via a light-curable barrier. The PS System is designed to accommodate the full range of tooth and root canal anatomy and is offered in three specific procedural kits based on the type of tooth to be treated: anterior, premolar, and molar.

Contraindications

None Known

Warnings & Precautions

- CAUTION: Federal law restricts this device to sale by, or on the order of a dentist
- The manufacturer assumes no liability for any damage arising from any other or improper use of this device.
- Product is single use only.
- Product is NOT for injection use.
- Prior to PS System irrigation, the Clinician must take every precaution necessary to ensure the integrity of the rubber dam seal and any potential communication from the pulp chamber to the oral cavity are isolated.

• Always protect the patient's eyes and face with proper personal protective equipment (PPE) from irrigant splatter or spill. Safety glasses, and protective drapes to cover their clothing are recommended.

• The PS System supports every instrumentation technique. After instrumentation, adequate fluid flow will need to be confirmed prior to operation. File size will determine maximum cannula depth. Reference cannula drawing (Fig. 5) for fitment constraints.

• Always use the PS System in the sequence described herein. Skipping or deviating from the following steps can cause the PS System's operational efficacy to be reduced.

• Do not mix or try to use the provided irrigants simultaneously. NaOCl and EDTA are known to be incompatible with one another. Sequential use of SmearOff (EDTA) and Chlor-Xtra (8% NaOCl) in copious volumes is required for clinical efficacy.

• Do not place the cannulas beyond working length (WL) and/or have the cannula opening placed at, or extend beyond, the apical foramen. Failure to properly establish cannula depth could result in a hypochlorite accident.

• Do not use solutions other than those provided.

• The PS System is designed to work with a vacuum minimum of 7.5"HG. Check the vacuum reading on your system before proceeding.

Clinical Considerations

• The PS System's fluid mechanics depend on the dental chair vacuum being able to supply at least 7.5"Hg. If your system provides less than the recommended vacuum even after cleaning the trap and any other maintenance, it is highly recommended to purchase an auxiliary vacuum that meets this criteria.

• The PS System's fluid mechanics depend on an air and fluid-tight seal between the tooth in treatment and the stage. If the tooth in treatment has a crown that is compromised, or walls missing from decay, create a temporary replacement wall using a suitable temporary material to fabricate the missing structure.

Troubleshooting

Unclogging the Cannula(s)

Adequate use of SmearOff (EDTA) during instrumentation to remove the gross debris will minimize clogging. Once the clinician gains proficiency in clinical use, clogging becomes a non-issue and happens infrequently. If any cannula should become clogged, (Cannula ends can scrape debris off of dentin walls as they move through canal curvatures) unclog it by attaching the SmearOff (EDTA) syringe to the center stem of the 3-way Flow Valve attached to the cannula fluid line and turn the Flow Valve "Off" lever toward the Irrigant Bag, then press the SmearOff syringe plunger and in most cases the cannula(s) will be immediately cleared.

Retreatment

In the case of retreatment, all pulp canals must be fully prepared, cleared and dried of gutta percha solvent as much as possible before proceeding to PS System irrigation. Still, clogging may occur as this is the very nature of retreatment. When this occurs, unclog as noted above. In anticipation of excessive clogging during retreatment, adequate clearing of the canal before evacuation reduces the chances of this happening.

Failure to Initially Draw Irrigant

Check each cannula supply line to visually confirm if fluid is flowing through the small tubing supplying each cannula. Failure to achieve flow can occur if the stage and tooth do not have an air and fluid-tight seal. Audible suction noise may be present in the event of a leak, which can be fixed as follows: disconnect the vacuum line from the chairside evac, place additional VacuSeal at all possible leakage points, light-cure, reconnect the vacuum line and listen for persistent leaks. Fluid flow is also stopped or limited when cannula ends bind smaller canal walls or the cannula has been taken to length in larger canals. In this case, carefully–with a hemostat–pull the cannula(s) back 1-2 mm and check fluid flow again with the EDTA syringe. Careful retraction of cannula(s) will usually maintain the air-seal, however, if leakage can be heard after retraction, simple repeat the routine above.

Cleaning & Sterilization

The PS System is provided non-sterile and has been designed for single-use only. All PS System components should be properly disposed of after use, and no components should be reused or reprocessed.

Warranty

PlanB Dental warrants certain components of the PS System against defects in material and workmanship for 12 months from the date of purchase, subject to proper usage. During that twelve-month period, PlanB Dental will replace:

- Cannula(s) and fluid line, if received clogged.
- Stage/Top Plate/placement tool, if received in unusable condition.
- Vacuum line, if received in unusable condition.
- Reagents (Chlor-Xtra™ (NaOCl), SmearOff™ (EDTA) and VacuSeal™), if received in unusable condition.

Defects caused by misuse, neglect, accident, or abuse are not covered by this warranty. PlanB Dental assumes no liability resulting from improper use, damage, or breakage due to misuse of these components by the purchaser. PlanB Dental assumes no liability for damage to the PS System components, injuries to patients or users or other problems resulting from improper use of accessories or other materials not supplied by PlanB Dental.

PulpSucker Instructions for Use

Included in kit:

Fig. 1

Fig. 1. PS System kits have everything you need for endodontic irrigation procedures, including empty aeration syringe (1), irrigating cannula set with supply line, 3-way valve, and HVE/surgical vacuum line (2), VacuSeal™ light-cure material and delivery tip (3), SmearOFF™ EDTA plus CHX and 30ga side vented tip (4), mini irrigant bag of 8% Chlor-Xtra™ Plus Enhanced NaOCl (5), and PulpSucker™ staging assembly with top plate (6).

Preparing Teeth and Securing the Stage

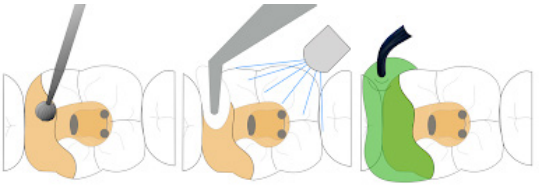

Fig. 2A Fig. 2B Fig. 2C

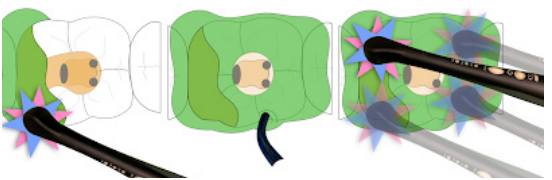

Fig. 2D Fig. 2E Fig. 2F

Fig. 2A. Defective restorations are removed and all caries excavated to sound tooth structure.

Fig. 2B. After scrubbing with alcohol cotton pellets, the isolated teeth are rinsed with water spray and dried COMPLETELY with the air/water syringe.

Figs. 2C and D. If tooth has missing wall(s), use suitable temporary material to fabricate missing tooth structure. Using a slit dam will expose adjacent tooth surfaces, allowing VacuSeal to be placed on their interproximal surfaces will add stability to the stage/tooth interface.

Figs. 2E and F. It is critical that a thorough coating of VacuSeal be placed on all isolated coronal tooth surfaces and be light-cured before place-ment of the VacuSeal-loaded stage, as the VacuSeal material on tooth structure will not completely cure through the Stage Skirt.

Fig. 3A Fig. 3B Fig. 3C Fig. 3D

Figs. 3A–D. Placement Tool and Premolar stage. Placement Tool helps center the Stage over MIE (minimally invasive endodontics) access cavities.

Fig. 4A

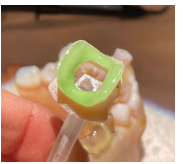

Fig. 4B

Fig. 4C

Fig. 4D

Fig. 4E

Fig. 4A. Insert the Placement Tool into the PS Stage.

Fig. 4B. Load the inside surfaces of the flexible Stage Skirt, being certain to syringe a good rope of VacuSeal onto the mesial and distal edges of the skirt.

Fig. 4C. Place the stage on the tooth light and cure all sides of the Stage Skirt for 3-5 secs.

Fig. 4D. Carefully retrieve the Placement Tool while holding the stage with a cotton pliers and cure the through center of the stage opening for 10-15 secs.

Fig. 4E. Add VacuSeal as needed to fill any gaps between the stage and tooth, being careful not to place the VacuSeal in cannula grooves in the cannula fence. Cure each surface for 3-5 secs.

Catheterization of Canals

All Premolar and Molar PS Cannulas are the same so it doesn't matter which ones go in each canal.

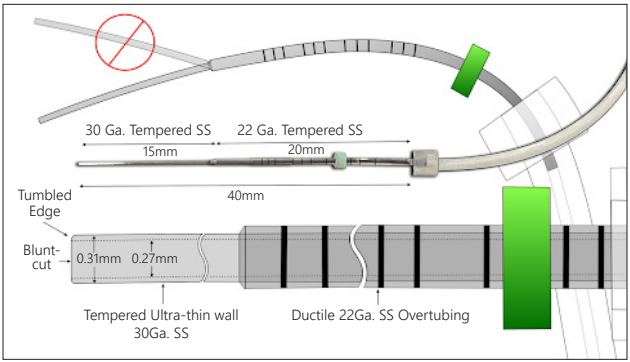

Fig. 5

Fig. 5. Avoid acutely bending 30 ga. PS Cannula portions at its intersection with the 22ga portion as they can separate.

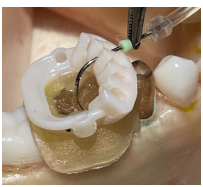

Fig. 6A

Fig. 6B

Fig. 6C

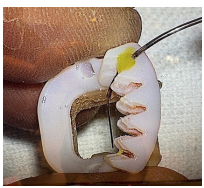

Fig. 6D

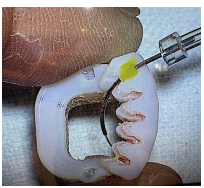

Fig. 6E

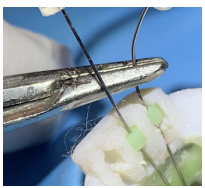

Fig. 6F

Fig. 6A. In small roots drop the 30 ga. PS Cannula to its binding point in the canal.

Fig. 6B. Lay the cannula in the Stop Hold groove and slide the stop forward into the Cannula Fence.

Fig. 6C. Tack the Stop into the Stop Hold with a drop of VacuSeal. Cure 3-5 secs.

Figs. 6D–F. Once the stop has been tacked in place with VacuSeal, the 22 ga. cannula can be easily adjusted in or out to extend or retract the 30 ga. cannula in the canal. Hemostats work better than cotton pliers for this.

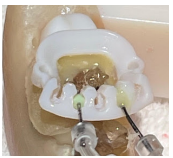

Fig. 7A

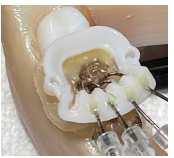

Fig. 7B

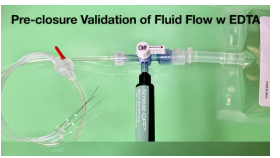

Fig. 7C

Figs. 7A and B. In molars place PS Cannulas in the mesial root first, then the distal or palatal canals.

Fig. 7C. Fluid flow is checked with the included syringe of SmearOff EDTA + CHX solution after threading it onto the middle stem of the Fluid Flow Valve. The Fluid Flow Valve lever (this lever indicates "OFF" is turned away from (opposite) the manifold line, opening the fluid passageway between the middle and manifold stems of the Fluid Flow Valve. With a suction tip held next to the stage, SmearOff is carefully syringed into the manifold and out the ends of cannulas to remove any debris from Cannula ends (this is 100% safe, while watching the clear tubing for air bubble signs of fluid flow. Any cannula with little or no fluid flow should be retracted a millimeter and tested again. Once fluid flow is confirmed, staging is nearly complete.

Fig. 8A

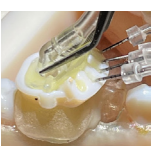

Fig. 8B

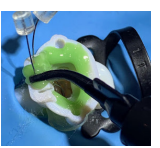

Fig. 8C

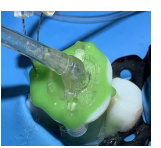

Fig. 8D

Figs. 8A and B. VacuSeal is syringed onto the underside of the Top Plate, the top plate is placed on the stage, positioned by its outrigger pegs fitting into the positioning sockets on the sides of the stage. Cure thoroughly.

Figs. 8C and D. Syringe VacuSeal over the PS Cannula Fence, filling any vacant Stop Holds and covering the Cannulas they exit the Cannula Fence.

Fig. 9A

Fig. 9B

Figs. 9A and B. After VacuSeal has been cured, plug the Vacuum Line to the chairside evacuation system. *Do not connect Vacuum Line to the Stage until all sealant is cured.*

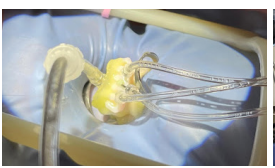

Fig. 10A

Fig. 10B

Fig. 10C

Fig. 10A. Once Staging and cannula placement have been completed, attach the luer connector to the Top Plate Vacuum Port, turn on the evacuation valve, and listen for air leakage. Check fluid flow with the included SmearOff syringe and adjust and seal Cannulas as described above.

Figs. 10B and C. Using the empty syringe included in the kit, add two syringefuls of air into the Chlor-Xtra Plus bag, shake it for a full 5 seconds to foam and aerate the irrigant, and connect it to the third stem (opposite the PS Manifold line) of the Fluid Flow Valve. Turn the Fluid Flow Valve "OFF" lever toward the middle stem, and watch to confirm fluid low from the NaOCl bag, watching for air bubbles traveling through the individual Cannula lines. Run PulpSucker irrigation until the IV bag of NaOCl is emptied.

Drying Canal Systems with PS Vacuum Line

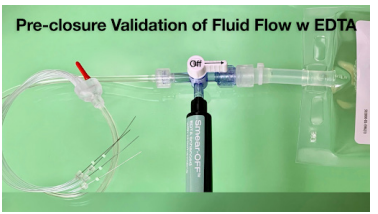

Fig. 11A

Fig. 11B

Figs. 11A and B. Before removing the PS Stage and Cannulas, turn the "Off" lever of the Fluid Flow Valve toward the IV bag, detach the Vacuum Line from the Vacuum Port on the Top Plate, re-attach it to the middle stem of the Fluid Flow Valve, and let the vacuum draw all the irrigant present inside the root canal system and lines through the Cannulas for 10-15 seconds. This reduces the number of paper points needed to dry the canals and also reduces the chance of any NaOCl leakage when the device is removed from the tooth in treatment.

Removing PS Stage and Cannulae

Fig. 19A

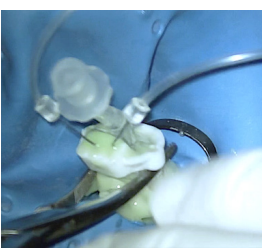

Fig. 19B

Figs. 19A and B. The PS Stage is removed from the tooth by grasping it with a pair of hemostats and simply rolling it off the tooth, picking VacuSeal particles from undercuts with an explorer tine.

Symbols

	Caution		Manufacturer
LOT	Lot number / batch code	REF	Part number
	Product is not sterile		Manufacturing Date
	Keep dry		Use-by-date; expiration date
	Follow instructions for use		Temperature limitation
	Do not reuse; single use only		Corrosive
	Do not use if seal or packaging is compromised		Keep away from sunlight
Rx ONLY	**CAUTION:** US Federal law restricts this device to sale by or on the order of a dental professional		Irritant (skin and eye); acute toxicity

Manufactured for:
PlanB Dental
315 Bollay Drive
Suite 150
Goleta, CA 93117 USA
Call (805) 899-4529
or visit planbdental.com

Inter-Med, Inc.
2200 South St.
Racine, WI 53404 U.S.A.

Rx ONLY