BRASSELER USA®

TotalVac™

IRRIGATION SYSTEM

INSTRUCTIONS FOR USE

KIT CONTENTS

1a - High Volume Evacuation

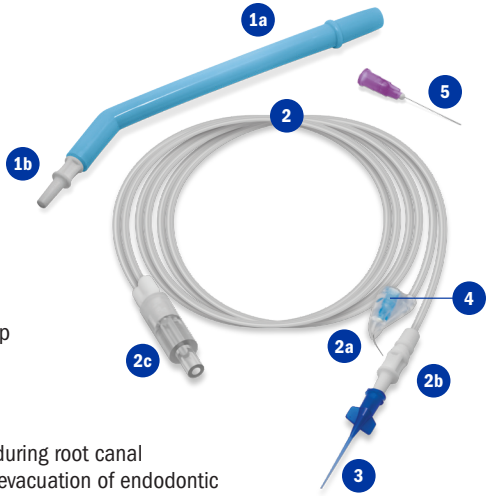
1b - Surgical Suction Adaptor

2 - TotalVac Tubing
- 2a - TotalVac Manifold
- 2b - TotalVac Handpiece
- 2c - HVE Fitting

3 - Plastic Suction Tip

4 - 25ga Short Delivery Tip

5 - 30ga Side Vented Long Delivery Tip



INDICATIONS FOR USE

The TotalVac kit is intended for using during root canal procedures, allowing for delivery and evacuation of endodontic irrigation solutions.

DESCRIPTION OF DEVICE

TotalVac's goal is to address the negative and positive pressure suction and irrigation needs of clinicians performing root canal therapy procedures. The TotalVac kit can be configured to perform both positive and negative pressure irrigation using the included tips, which vary in length and diameter.

CONTRAINDICATIONS

None known.

WARNINGS AND 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 the use of TotalVac, the use of a Rubber Dam (Primary Isolation) and a the addition of a caulking material to seal any seams (Secondary Isolation) is highly recommended.
- During Deep Irrigation Mode, pay attention to the length of the needle insertion relative to working length to avoid insertion beyond the apex and extrusion rate which could result in a hypochlorite accident.

CLEANING AND STERILIZATION

TotalVac is provided non-sterile and is single use only. All components should be properly disposed of after use.

WARRANTY

TotalVac is warrantied against defects in material and workmanship subject to proper usage. Defects caused by misuse, neglect, accident, or abuse are not covered. No liability is assumed for damage to TotalVac components, injuries to patients or users, or other problems resulting from improper use.

INSTALLATION

Open the kit and connect the high volume evacuation tube (1a) / Surgical suction adaptor (1b) assembly to one of the operatory's high evacuation suction inlets. The TotalVac Tubing (2) is then connected to a second high volume evacuation inlet by means of the HVE fitting (2c). The HVE Fitting (2c) later may also be connected directly to the surgical suction adaptor if two separate high speed evacuation inlets are not available as shown below. After these connections, the TotalVac tubing (2) may be laid to rest either on a tray over the patient's chest or directly on the patient's chest on a clean apron or waterproof bib for quick access during the procedure.

Note: Prior to the use of TotalVac, the use of a Rubber Dam (Primary Isolation) and a the addition of a caulking material to seal any seams (Secondary Isolation) is highly recommended.

ACCESS PREPARATION

The assistant can detach the surgical suction adaptor (1b) to operate the high volume evacuation during access preparation and in order to capture high volume of water and debris from the tooth and the high speed handpiece.

SURGICAL SUCTION

Once high access preparation with the high volume is over, the surgical suction adaptor (1b) can be reinserted into the high volume evacuation tube (1a) turning it into a conventional surgical suction for more precise suction in and around the operating field.

MODES OF OPERATION

The Positive and Negative pressure modes of TotalVac consist of two positive pressure irrigation modes and two negative pressure suction modes. These are based on their depth of irrigation and suction in the canal, referred to as Coronal and Apical irrigation and suction modes.

Irrigation Modes

Coronal Irrigation (Mode 1)

Used during the early phase of access and instrumentation

Attach the preassembled TotalVac manifold (2a)/short delivery tip (4) assembly to your irrigation solution of choice (we recommended NaOCl or Triton). Make sure the luer lock attachment is tight and secure to avoid any leakage! Insert the tip in the access preparation and irrigate. The manifold (2a) will suction the excess fluid from the site. Keep the manifold close to the cavosurface area of the access preparation to achieve effective suction. This assembly allows effective irrigation in the initial phase of access and instrumentation in the chamber and coronal portions of the root canals.

Apical Irrigation (Mode 2)

Used during the middle to the end of instrumentation

After apical patency has been achieved with a rotary instrument and working length has been established, the short delivery tip (4) may now be removed from the manifold (2a) and replaced with the long delivery tip (5) by inserting the needle through the manifold hole and adjusting the angle by bending it. The needle should be able to reach up to 17mm of depth for positive pressure irrigation with simultaneous suction using only one hand.

Note: pay attention to the length of needle insertion relative to working length to avoid insertion beyond the apex.

Suction Modes

Macro Suction (Mode 3)

May be used during the middle to the end of instrumentation

The large diameter plastic suction tip (3) is placed on the TotalVac handpiece (2b) and inserted into the root canal for suction. Achievable depth will depend on root preparation size. Insert the tip until it binds then retract slightly to allow fluid flow. The syringe manifold (2a) assembly is used to deposit solution inside the access while plastic suction tip is inserted deeper in the canal. The generated negative pressure generated carries the solution in the canal and up the plastic suction tube.

Micro Suction (Mode 4)

Used at the very end of instrumentation prior to obturation

If interested in achieving negative pressure deeper in the canal prior to obturation, The 30ga long delivery tip (5) is connected to the TotalVac handpiece (2b) and inserted closer to the working length. Irrigant is then added on top with the aid of the manifold syringe assembly. This can achieve safe, deep negative pressure close to the working length.

Note: Deep Suction should only be performed as the last step of the procedure after all macro debris has been removed. Otherwise, needle clogging by remaining macro debris may occur. Needle clogging generally indicates that macro debris removal had not been accomplished adequately and further agitation and irrigation is needed. Micro Suction can also be used to dry the canal prior to insertion of paper points for obturation.

These modes are elective and can be used based on clinician's preference and priorities during treatment. Certain modes may be preferred by some clinicians and others omitted if not required.

MODULARITY

TotalVac is a highly modular system and allows great versatility and access to a multitude of needles of different lengths and diameters based on your specific needs. WIth some experience, you will find the best sequence of use that best fits your style and workflow during root canal therapy.

TROUBLESHOOTING

The use of negative pressure modes through the application of the plastic and thin suction tips is not recommended until just prior to obturation of the procedure where all macro debris has already been removed. This helps prevent clogging of these tubes with debris and tissue. If any tip becomes clogged during this phase, remove from the tooth and attach to a syringe filled with NaOCl, distilled water, or alcohol and attempt to push fluid through the tip to clear the clog.

PRODUCT OFFERING

REF Number	Description
5027562U0	TotalVac Kit 25P
5027566U0	High Volume Evacuator and Surgical Suction Adaptor 20P
5027566U0	TotalVac Tubing* 20P
5027569U0	25GA Short Irrigation Tip 20P

**TotalVac Tubing should be used identically to the descripted instructions using the doctor's own tips of equivalent characteristics.*

PRODUCT SYMBOLS

Symbol	Title of the Symbol	Reference Number	Standard Containing the Symbol	Function/Description per Standard	Manufacturer Interpretation
	Manufacturer	3082	ISO 7000	To identify the manufacturer of a product. This symbol shall be used filled in all applications to differentiate it from ISO 7000-2497.	Manufacturer
	Catalogue number	2493	ISO 7000	To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.	Catalogue number
	Lot number	2492	ISO 7000	Indicates the manufacturer's batch code so that the batch or lot can be identified.	Lot number/ Batch code
	Quantity	N/A	N/A	Indicates the quantity contained in the packaging.	Quantity
	Non Sterile	2609	ISO 7000	Indicates a medical device that has not been subjected to a sterilisation process.	Non Sterile
 BrasselerUSA.com/eIFU	Consult instructions for use or electronic instructions for use	A15	ISO 15223-1	Indicates consult instructions for use for an electronic instruction for use (eIFU).	Follow the operating instructions for use

	Do not reuse	1051	ISO 7000	To indicate that the item is for single use only and must not be used more than once, for example, on packages of medical disposables.	Please contact your supplier for further information about the product disposal at the end of the product's lifetime
	Do not use if package is damaged	2606	ISO 7000	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	Do not use if seal or packaging is compromised
	Caution	0434B	ISO 7000	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	Consult the instructions for use for important cautionary information
Rx Only	Prescription Only	21 CFR 801.109	FDA Title 21	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.	Required if prescription device
	Medical device	5.7.7	ISO 15223-1	Indicates the item is a medical device.	Medical device

Glossary of Symbols can be found at Brasselerusadental.com/resources

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