



Instructions for Use

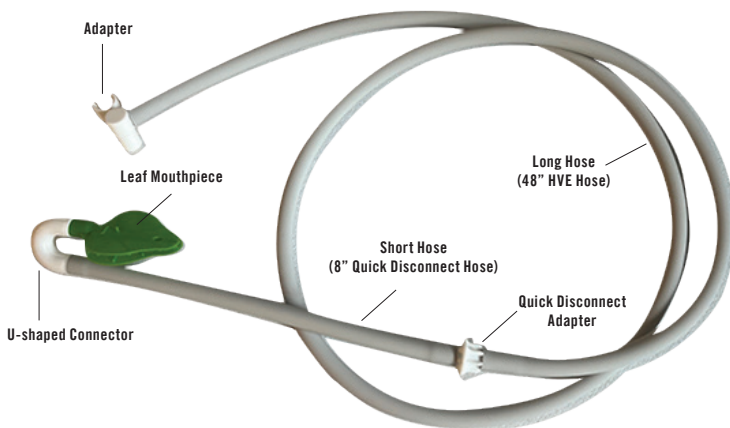
PRODUCT DESCRIPTION/INTENDED USE

ReLeaf® is hands free, high volume dental suction device that assists practitioners with evacuation, isolation, retraction and maintaining a dry field during general dentistry, restorative and hygiene procedures.

ReLeaf® is for clinical use by dental professionals.

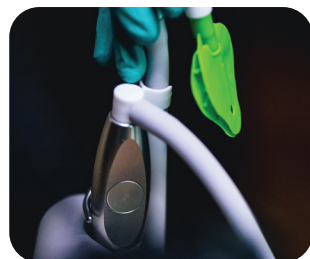
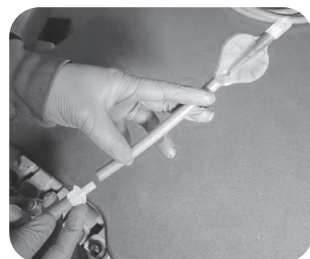
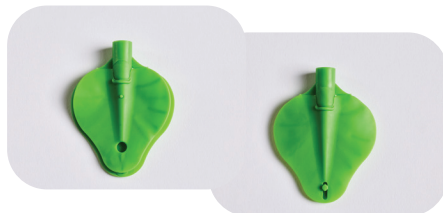
The Leaf Mouthpiece is composed of a soft, flexible thermoplastic elastomer that is 100% BPA and latex free. No health hazards have been identified with the use of this material.

The ReLeaf® Hoses are composed of a silicone rubber (silicone and silicon dioxide).



INSTALLATION AND PATIENT USE

1. Attach the disposable Leaf to the U-Shaped Connector on one end of the Short Hose (8" Quick-Disconnect Hose). Attach the other end of the Short Hose to the Quick-Disconnect Adapter on the Long Hose. Ensure that all connections are secure.
2. Insert the HVE Adapter at the other end of the Long Hose securely into an open HVE port. If needed, lightly wet the O-ring inside the HVE port with water to facilitate insertion of the HVE Adapter. (If the connection is loose, refer to the troubleshooting section).
3. Before patient use, inspect the Leaf and reusable components for damage, cracks, tears, deformation, or deterioration. Confirm that all connections are secure and that the Leaf is properly attached.
4. Place the ReLeaf disposable Leaf between the vestibules on the buccal surface, similar to the positioning of a dry angle. The U-shaped bend of the Leaf should fit comfortably outside or into the commissure of the patient's mouth. The Calculus Portal (lower suction hole, larger on one side) should face towards the lingual.
5. Confirm that the patient is comfortable and that the Leaf is properly positioned before beginning the procedure.
6. When transitioning between patients, a cleaned and sterilized U-Shaped Connector and Short Hose must be utilized before attaching a new Leaf.



CONTRAINDICATIONS

No known contraindications.

PRECAUTIONS

Risk of allergic reactions can not be excluded for those predisposed to allergies.

DISPOSAL, STERILIZATION & STORAGE

All gray and white components of the ReLeaf™ system are compatible with standard dental sterilization protocols. These parts can be: wiped with dental-approved disinfectant wipes or sprays, run through dental atomizer, processed through an ultrasonic bath, run through a thermal washer, and run through autoclave cycle per sterilization cycle table.

Leaves: One Time Use, Disposable

The ReLeaf™ disposable Leaf is intended for single use only. Due to the material and design of the Leaf, it must not be cleaned, sterilized, or reused.

After each patient use, discard the Leaf in accordance with applicable dental office, clinical waste, and local disposal requirements.

U-Shaped Connector: Autoclavable and Reusable

The U-Shaped Connector is a reusable component and must be cleaned and sterilized by autoclave after each use on a patient.

Rinse the U-Shaped Connector with water. If needed, brush the external surfaces using a soft-bristle brush and the internal/ lumen surfaces using a soft-bristle lumen brush or pipe cleaner. Brushing may be performed before or after processing in an ultrasonic bath, instrument washer, or washer-disinfector.

Rinse thoroughly with water. Place the U-Shaped Connector in an autoclavable pouch and process through an appropriate wrapped autoclave sterilization cycle after each patient use. (See Sterilization Cycle Table.)

Short Hose (8" Quick-Disconnect Hose): Autoclavable and Reusable

The Short Hose is a reusable component and must be cleaned and sterilized by autoclave after each patient use.

Rinse the Short Hose with water. If needed, brush the external surfaces using a soft-bristle brush and the internal/lumen surfaces using a soft-bristle lumen brush or pipe cleaner. Brushing may be performed before or after processing in an ultrasonic bath, instrument washer, or washer-disinfector.

Rinse thoroughly with water. Place the Short Hose in an autoclavable pouch and process through an appropriate wrapped autoclave sterilization cycle after each patient use. (See Sterilization Cycle Table.)

NOTE: Place the Short Hose and U-Shaped connector on the top shelf of the autoclave. Do not place directly on top of cassettes or instruments, as excessive heat may cause the product to melt or deform.

Long Hose (48" HVE Attachment Hose with Quick-Disconnect Adapter and HVE adapter): Autoclavable and Reusable

The Long Hose is treated as an extension of the existing HVE evacuation system and should remain connected to the HVE system during routine use.

After each patient use, wipe the Long Hose at the routine cleaning area with dental-approved disinfectant wipes or sprays.

For routine evacuation cleaning, run an appropriate enzymatic evacuation cleaner through the Long Hose according to the cleaner manufacturer's instructions. It is not necessary to run an evacuation cleaner through the hose between each patient; flushing with water is adequate.

Routine cleaning and sterilization of the Long Hose may be performed nightly, weekly, or monthly, based on the dental practice's established infection prevention and equipment maintenance protocols.

When sterilizing the Long Hose in an autoclave, place it in an appropriate autoclavable pouch and process through the validated autoclave cycle. (See Sterilization Cycle Table.)

NOTE: Place the Long Hose, quick disconnect and HVE adapter on the top shelf of the autoclave. Do not place directly on top of cassettes or instruments, as excessive heat may cause the product to melt or deform.

VALIDATED STERILIZATION CYCLES	
Gravity Displacement Autoclave	Pre-vacuum Autoclave
TEMPERATURE: 121°C/250°F	TEMPERATURE: 132°C/270°F
MINIMUM EXPOSURE TIME: 30 minutes	MINIMUM EXPOSURE TIME: 4 minutes
MINIMUM DRY TIME: 30 min	MINIMUM DRY TIME: 20 minutes



STORAGE

Please ensure ReLeaf® is stored at room temperature.

The Short Hose (8" Quick Disconnect Hose) is specifically designed to be placed in the HVE adapter holder clamp when not in use. (See image)

The adapter can hold the long hose as well, when the short hose is being autoclaved.



TROUBLE SHOOTING

Proper ReLeaf® Position

By placing the Leaf in the location shown here in the picture, the Leaf will be in the prime location to deliver a consistent and comfortable suction during the dental procedure. Ensure that ReLeaf® is positioned on the same side where work is being performed and ensure that the patient tilts their head towards the working side for optimal performance.

To assist in evacuation, when a small amount of water and saliva build up, have the patient slowly close down when needed (teeth before lips is recommended). When the patient closes their jaw or occludes their teeth together, it pushes the tongue away from ReLeaf®. Fluid is then forced to the cheeks where ReLeaf® can evacuate the remaining fluid.



Large Oral Cavity

When placing ReLeaf® into a large oral cavity, please direct patient to close down slightly to ensure that the sides of ReLeaf® fit comfortably into the vestibule area. Some patients can open wider than ReLeaf®'s designed maximum width. This causes ReLeaf® to dislodge out of place towards the midline. The solution is to inform patients with a large max opening to relax their jaw until the sides of ReLeaf® begin to enter the buccal area. ReLeaf® is designed to allow as much working space as possible. The designed width of ReLeaf®, with the combination of a large max opening, still allows the practitioner plenty of room to perform the necessary treatments.

Loose Connection

If you find the coupler becoming loose, it may be necessary to replace the O-ring in your HVE valve.

ReLeaf® is a registered trademark of Innovative Dental Technologies, Inc. Must be sold by or on the order of a dental professional only. Use of this device is prohibited for any other purpose than recommended by the manufacturer.

Manufactured by



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