



Instructions for Use

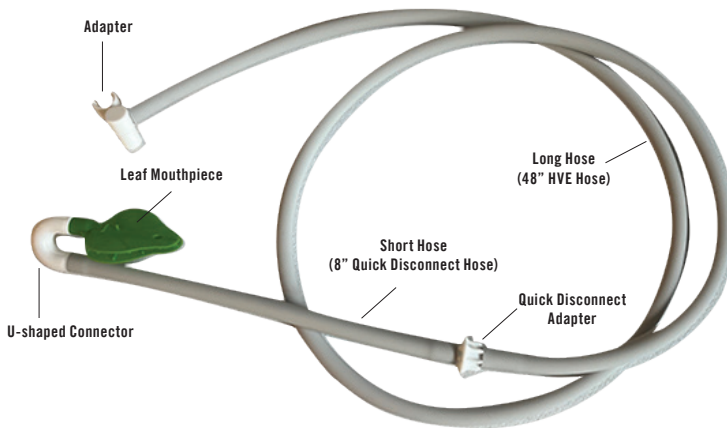
PRODUCT DESCRIPTION/INTENDED USE

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.

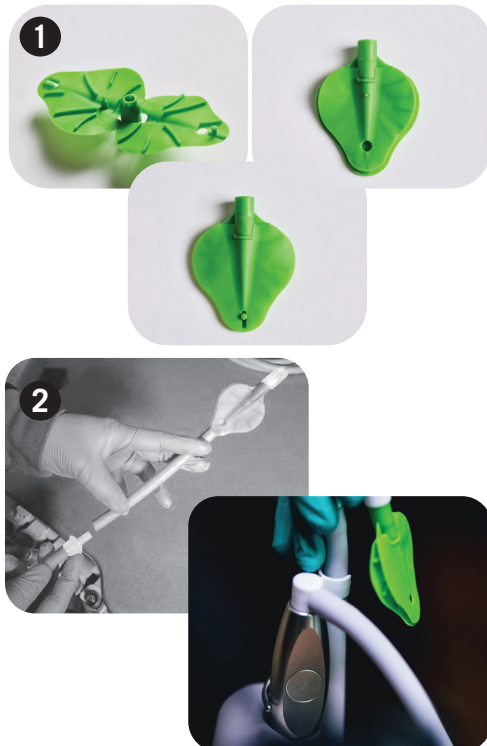
The Leaf Mouthpiece is composed of a soft, flexible thermoplastic elastomer that is 100% BPA and latex free. No health hazards have been identified with the use of this material.

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



INSTALLATION AND PATIENT USE

1. Fold the two Leaf halves together by pushing together the tiny protruding knob into the opposing holes at the Leaf base. Insert the larger knob into the opposing hole at the Leaf tip. Squeeze the two halves of the Leaf together to ensure each side securely attaches to the other. Attach the Leaf to the "U-shaped Connector" on the Short Hose (8" Quick Disconnect Hose) with the Calculus portal (lower suction hole) facing away from the hose. Ensure the Leaf is securely attached.
2. Attach the free end of the Short Hose to the Quick-Disconnect Adapter on the Long Hose (48" HVE Attachment Hose). Insert the coupler at the other end of the Long Hose securely into an open HVE port. It may be necessary to wet the O-ring inside the unused port for the adapter to slide in easily.
3. Place Releaf® into the patient's oral cavity with the Leaf positioned between the teeth and cheek and the Calculus portal (lower suction hole) facing towards the patient's teeth
4. When transitioning between patients, a cleaned and sterilized U-Shaped Connector and Short Hose must be utilized prior to attaching a new Leaf.



CONTRAINDICATIONS

No known contraindications.

PRECAUTIONS

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

STERILIZATION, DISPOSAL & 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 disposable Leaves are meant for **single use only**. Due to the nature of the material and design of the Leaves, they should not be sterilized and reused. Leaf mouthpieces must be properly discarded in a clinical waste container to prevent transmission of infectious pathogens.

U-Shaped Connectors

Rinse the U-Shaped Connectors with water and brush both external and lumen surfaces with a soft bristle brush for the exterior surface and a soft bristle lumen brush or pipe cleaner for the interior surfaces. The U-Shaped Connectors may also be placed in an ultrasonic bath for additional cleaning. Ensure the tubing and internal channels are filled with water before placing them in the ultrasonic bath to prevent floating. After cleaning, rinse with water, place in an autoclavable pouch, and process through a wrapped cycle in the autoclave (See Sterilization Cycle Table).

Short Hose (8" Quick-Disconnect Hose): 100% Autoclavable and Reusable

Rinse the Quick-Disconnect Hose with water and brush both external and lumen surfaces with a soft bristle brush for the exterior surface and a soft bristle lumen brush or pipe cleaner for the interior surfaces. The hose may also be placed in an ultrasonic bath for additional cleaning. Ensure the tubing is filled with water before placing it in the ultrasonic bath to prevent floating. After cleaning, rinse with water, place in an autoclavable pouch, and process through a wrapped cycle in the autoclave.

Long Hose (48" HVE Attachment Hose with Quick-Disconnect Adapter): The Long Hose should stay connected to the HVE until ready for routine evacuation cleaning with an enzymatic evacuation cleaner.

Running evacuation cleaner through the hose to clean out any debris at least once per week is recommended. It is not necessary to run evacuation cleaner through the hose between each patient.



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)



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 devices is prohibited for any other purpose than recommended by the manufacturer.

Manufactured by



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