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# **ReLeaf RESTORATIVE Basic Setup Kit**



# **Specifications**

Material: Soft, flexible thermoplastic elastomer

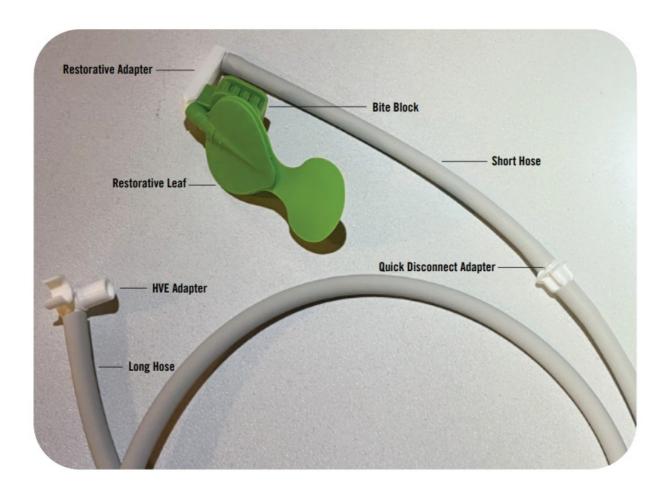
• 100% BPA and latex-free

• Intended Use: Restorative dental procedures

#### PRODUCT DESCRIPTION/INTENDED USE

ReLeaf® Restorative is a 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 comprises 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 comprise of a silicone rubber (silicone and silicon dioxide).



#### **INSTALLATION AND PATIENT USE**

- 1. Fold the two Leaf halves together by pushing together the small protruding knob into the opposing hole at the Restorative 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 Restorative Adapter on the Short Hose (8" Quick Disconnect Hose) with the smaller leaf face facing away from the hose. Ensure the Leaf is securely attached.
- 2. Insert the ReLeaf® Bite Block onto the peg closest to the Leaf on the Restorative Adapter. Making sure the concaved slope is in contact with the Restorative Leaf.

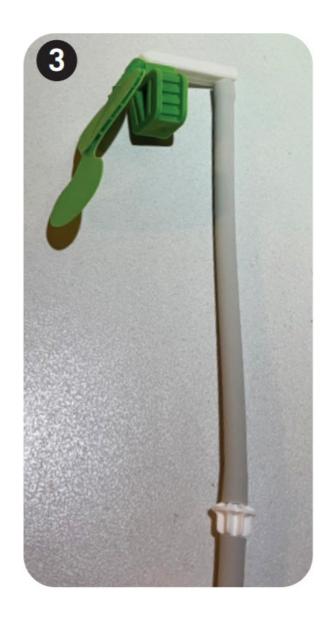




#### 3. Attach the free end of the

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 so the Adapter can slide in easily.
- 4. Place the ReLeaf® Bite Block on the opposing arch you are working on. While having the Leaf sweep in front of the tongue and wrap around the retromolar area to the opposing cheek side.
- 5. When transitioning between patients, a cleaned and sterilized Bite Block, Restorative Adapter, and Short Hose must be utilized before attaching a new Leaf.



#### **CONTRAINDICATIONS**

No known contraindications.

# **PRECAUTIONS**

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

# STERILIZATION, DISPOSAL AND 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.

#### • Bite Block, Restorative Adapter and Short Hose

100% Autoclavable and Reusable.

Before placement in an ultrasonic cleaner, rinse the Bite Block, Restorative Adapter and Short 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. Place in an ultrasonic unit filled with enzymatic cleaner. (note: follow instructions with enzymatic cleaner for proper mixing, exposure time, etc., per manufacturer instructions). Rinse with water, place in an autoclavable pouch. Run product through a wrapped / pouched cycle in the autoclave.

# Long Hose, Quick Disconnect Adapter and HVE Adapter

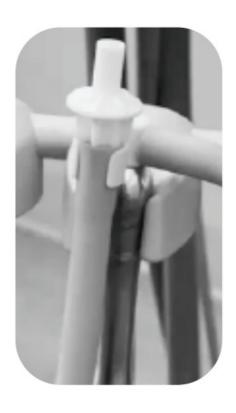
100% Autoclavable and Reusable.

The Long Hose should stay connected to the HVE until ready for routine evacuation cleaning with an enzymatic evacuation cleaner. Running evacuation cleaners through the hose to clean out any debris at least once per week is recommended. It is not necessary to run evacuation cleaners through the hose between each patient. If running through the autoclave, follow instructions listed above for Bite Block, Restorative Adapter & Short Hose.

#### **Storage**

Please ensure Releaf® is stored at room temperature.

The Long Hose and Short Hose are designed to be held in the HVE Adapter when unused. (See image)



# **VALIDATED STERILIZATION CYCLES**

# **Gravity Displacement Autoclave**

• TEMPERATURE: 121°C/250°F

• MINIMUM EXPOSURE TIME: 30 minutes

• MINIMUM DRY TIME: 30 min

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

# **TROUBLE SHOOTING**

# **Proper Releaf® Restorative Position**

Ensure the long end of the Restorative Leaf wraps around the retromolar area on the quadrant you are working on. To assist in evacuation, when a small amount of water and

saliva build up behind the Restorative Leaf, have the patient slowly push their tongue against the Leaf while closing down on the Bite Block.

This will evacuate any remaining water that flows behind the Leaf.

#### Loose connection

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

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



Innovative Product Brands Inc. TM

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#### **FAQ**

Are there any contraindications for using the ReLeaf Restorative system?

No known contraindications have been identified.

What precautions should be taken while using the product?
Risk of allergic reactions cannot be excluded for those predisposed to allergies.
How should loose connections be addressed?
If you find the coupler becoming loose, it may be necessary to replace the O-ring.
Documents / Resources
ReLeaf RESTORATIVE Basic Setup Kit [pdf] Instruction Manual RESTORATIVE Basic Setup Kit, RESTORATIVE, Basic Setup Kit, Setup Kit, Kit
References
• <u>User Manual</u>
<ul> <li>▶ Basic Setup Kit, Kit, ReLeaf, RESTORATIVE, RESTORATIVE Basic Setup Kit, Setup</li> <li>▶ ReLeaf</li> <li>Kit</li> </ul>
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