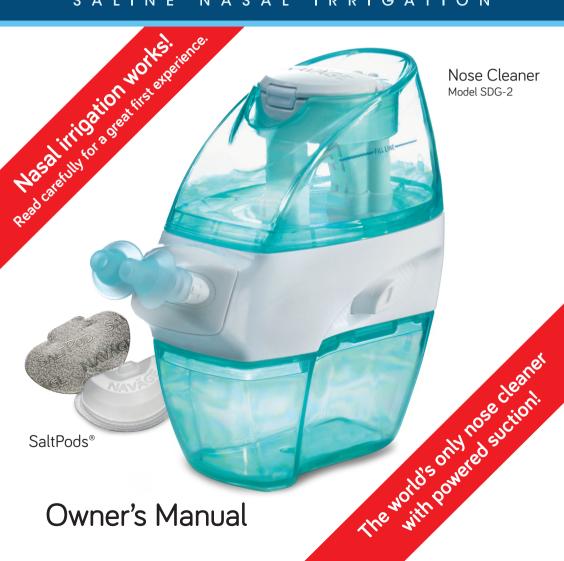
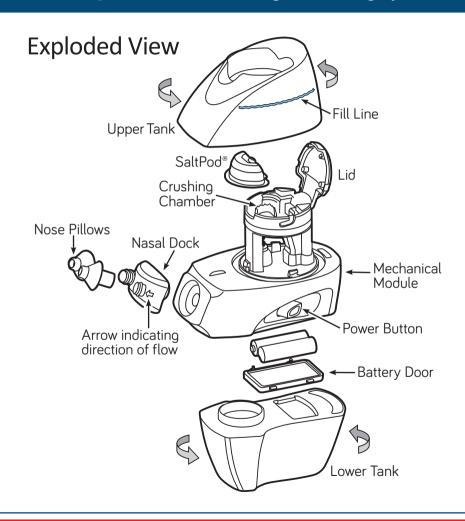
## NAVAGE NASAL SALINE NASAL IRRIGATION



# Take the Naväge Challenge!

# Use Naväge twice a day for two weeks and experience how clear nose-breathing can change your life!



#### STEP BY STEP INSTRUCTIONS

- 1. Attach the nasal dock to the mechanical module, taking care that the blue O-Rings remain snug in their channels (Fig. 1). The nasal dock rotates 360° allowing rinse to flow in either direction. Note the arrows indicating the direction of flow (Fig. 2).
- 2. Fill the upper tank to the Fill Line with warm water (Fig. 3). See page 6 for important information about water.
- **3.** Place a new, unused SaltPod capsule in the crushing chamber, **foil-side down** (Fig. 4).
- **4.** Close the lid firmly until you hear it click shut, **and do not reopen it** (Fig. 5).
- **5.** Gently shake the device for a second or two to mix the SaltPod contents with the water in the upper tank.
- 6. Locate the two-stage power button. Gently push the button in half-way and the pump will start. You can actually feel the suction: cover both nose pillows with your finger tips and press the button in half-way. You will feel a light suction from only one of the pillows because the rinse gets pulled in one pillow and exits the other. Firmly push the button in all the way and the drain valve will open, allowing the rinse to flow out of the other nose pillow. Be sure to do this over a sink!
- 7. Arrows on the nasal dock indicate the direction of flow (Fig. 2). Again, note that the rinse goes **into the nose** through one nose pillow, and **out of the nose** through the other.
- **8.** Run a little water over the nose pillows to make them easier to slip into your nostrils.

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The power button only works with a new SaltPod in the crushing chamber and the lid clicked shut.

If you reopen the lid after loading a SaltPod, the device will not work.

No Peeking!







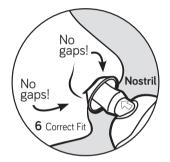


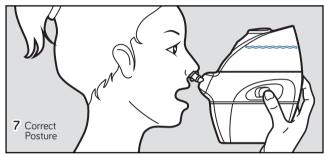


### STEP BY STEP INSTRUCTIONS (CONT.)

9. Insert and center the nose pillows in your nostrils, making sure not to block the tips. They should be in snug, but not too snug. You can bend the flexible pillow stems to obtain a centered, comfortable fit (Fig. 6). For the best first experience, take time to adjust the nose pillows correctly.

First, press the pillows in firmly to create the seal. Then, once the cycle is initiated, back off a little to increase the flow. With the nose pillows it's all about correct **positioning** (keeping the tips centered and unblocked), and **pressure** against the nostrils (just enough to make a seal). **If one or both of the pillow tips are blocked, suction will decrease or stop and you may get water down your throat, slow flow, or no flow at all.** Wiggling the Nose Cleaner around a little can also help you get a good seal.





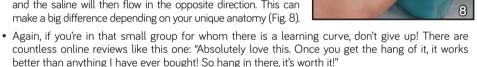
- 10. Relax... Stand up straight (Fig. 7). Look ahead and don't bend over. Smile and breathe normally through your mouth. Now push the power button in half-way for a second or two and feel the suction. Or you can push it in all the way right from the start (press hard). Experiment and you'll find what works best for you.
- 11. Naväge uses powered suction. Keeping the power button pushed in half-way in the suction-only mode for more than a second or two may cause minor ear discomfort in some users. This condition typically resolves on its own similar to riding in an elevator or airplane, and it is harmless. To avoid this completely, you can firmly press the power button in all the way right from the start. You must press all the way in so that it is flush with the side of the unit. This will eliminate any suction buildup and allow the saline to flow into your nose immediately.
- 12. Nasal irrigation is safe and effective, and it can be practiced as often as you wish. While you're learning, we recommend using your Naväge several times in a row to quickly get the hang of it. If you need assistance, please call Customer Service at (800) 248-7550. Our reps are daily Naväge users themselves, and they are caring, knowledgeable, and eager to help!
- 13. A Naväge cycle can last from 10 seconds to a minute, depending on your personal anatomy (such as a deviated septum), and how congested you are (the more congested, the longer the cycle). Most cycles last from 20 to 30 seconds. The cycle is complete when the upper tank is empty.
- **14.** Release the power button and remove the pillows from your nostrils. Most users will have a little saline remaining. Gently blow your nose.
- **15.** Twist off the bottom tank and empty it. Clean your device following the instructions on page 6.

#### **TROUBLESHOOTING**

#### 1. Problem: I'm getting water down my throat!

The key to successful nasal irrigation is to make your nasal cavity into a closed system, completely separate from the oral cavity. That's why the rinse can go in one nostril and out the other, and not down your throat. This is done by closing the soft palate. For most new users this happens naturally effortlessly, and spontaneously. What follows are some tips if you are having trouble. But for many it may be easier to chat with our awesome customer service reps—they are daily Naväoe users themselves and can be reached at 800-248-7550.

- Relax, be confident, and smile. It really helps. The more relaxed you are, the easier it is! Nasal lavage is safe and effective, but for some new users there's a learning curve. It may take 3 or 4 or 5 tries. but be assured that just like millions of daily users, you'll master it too!
- The nose pillows should be in snug, but not too snug. Press the pillows in firmly to create a seal. Once the cycle is initiated, back off a little to increase the flow. Don't block the tips against the inside walls of your nose. Less pressure often results in more flow.
- Breathe normally through your mouth.
- Press your tongue up firmly against the roof of your mouth.
- While irrigating, say Ähh... Seriously. Take a deep breath and say or sing "ahh" just like you would for a doctor examining your throat. Then take another breath and sing it again!
- Reverse the direction of flow. Rotate the nasal dock 180 degrees. and the saline will then flow in the opposite direction. This can make a big difference depending on your unique anatomy (Fig. 8).

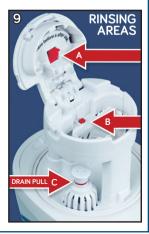


#### 2. Problem: Power button won't push in. Part 1.

For the power button to operate, a new Naväge SaltPod must be placed in the crushing chamber foil-side down and the lid clicked shut. The device operates only when loaded with a genuine, unused SaltPod capsule. This is an important safety feature to avoid the painful stinging and burning that is caused by running plain, unsalted water through your nose. It is also super convenient and eliminates the uncertainty and mess of mixing and measuring. This is critical: If you reopen the lid, the power button will no longer work with that particular SaltPod—even if you re-close the lid. The button will be locked out, and impossible to push in. That's why we say No Peeking!

#### 3. Problem: Power button won't push in, Part 2.

Rinse the device with very hot water for at least 30 seconds in each of the three places marked A, B, and C (Fig. 9). This will eliminate salt crystal buildup that can interfere with device operation. Make sure you time it; 30 seconds is the magic number and it's longer than you think! After rinsing, lift the Drain Pull (C) to verify that it is not stuck.



### **TROUBLESHOOTING (CONT.)**

- 4. Problem: The button pushes in, but the pump doesn't start.
  - a. Rinse the device with very hot water as described in #3 on page 5.
  - **b.** Visually reconfirm that the batteries are installed in the correct direction. Fresh AA batteries should last at least 3 months of daily use.
- 5. More help, instructional videos, and additional tips are available at navage.com. You can also email support@navage.com or call us at (800) 248-7550 during normal business hours. Our customer support reps are daily Naväge users themselves, and they are caring, knowledgeable, and eager to help!

### **CLEANING INSTRUCTIONS**

- Underside of the white mechanical module: Wipe with a damp cloth. Do not rinse the underside with running water, as this may damage the pump and force water into the battery compartment. Do not immerse the mechanical module; it is not water proof.
- Crushing chamber lid: See Fig. 9, page 5 and rinse areas A and B with very hot water for 30 seconds to melt any dry salt crystals.
- Upper and lower tanks, nose pillows, and nasal dock: Detach and wash after use with anti-bacterial dishwashing soap or diluted white vinegar (half-water, half-vinegar).





- **Drain pipe:** Put antibacterial dishsoap or diluted white vinegar on the included cleaning swab, and insert as shown in Fig. 10 and Fig. 11. To rinse, lift the Drain Pull and run hot water through the drain pipe (see Fig. 9, page 5).
- The Naväge Nose Cleaner is not dishwasher safe. Exposing the tanks to dishwasher heat will warp them and prevent them from sealing to the mechanical module. Running the Nose Cleaner through a dishwasher voids the warranty.

#### **CAUTIONS**

- If you experience pain during use, stop immediately. If the pain continues, consult a health care professional.
- ABOUT WATER. The University of Wisconsin Department of Family Medicine advises that in North America, luke warm tap water from municipal water systems, or intact wells deeper than 40 feet, is safe for saline solution preparation. If these criteria are not met or if water safety is in doubt, distilled water or tap water boiled and then cooled to room temperature is recommended. The US FDA advises using filtered, distilled, or previously boiled water for nasal irrigation, and that water "passed through a filter with an absolute pore size of 1 micron or smaller" is safe for nasal irrigation.
- Most users prefer to warm their water prior to use. Do not overheat the water. It should be lukewarm to the touch and not hotter than about  $85^{\circ}$   $90^{\circ}$  F ( $29^{\circ}$   $32^{\circ}$  C).
- Rinsing your nasal passages with plain, unsalted water will cause a painful burning sensation.
- Consult your doctor before use if you have had ear or nose surgery in the past 6 months.
- Nose bleeds are a rare but known side effect of saline nasal irrigation. Consult your physician if you
  experience a nose bleed after use.
- Do not use if your nasal passages are completely blocked and it is impossible to breathe through your nose.
- Do not use if you have an ear infection or if your ears are blocked.

- Ear popping and ear fullness are rare but known side effects of nasal irrigation that typically resolve on their own in a short time. Discontinue use and consult your physician if the condition persists.
- Holding the power button in the suction-only mode (pressed in half-way) for more than a few seconds may
  cause minor ear discomfort. To avoid this, press the power button in all the way, right from the start. This will
  prevent suction buildup and allow the saline to flow immediately into your nose.
- Consult your health care practitioner if you are using the Naväge Nose Cleaner to relieve congestion due to a nasal illness and there is no improvement after use; if your symptoms persist or worsen; if you have a persistently thick and yellow or green discharge; or if skin at the base of the nostrils becomes raw or crusted.
- Terminate use if no saline appears in the lower tank after 60 seconds.
- Do not use continuously for longer than five minutes.
- To prevent cross infection between users, the Naväge Nose Cleaner should not be shared.
- Not for use by children under the age of twelve.
- Clean the nose pillows and device after each use according to the cleaning instructions.
- Using the product with illegal drugs, alcohol, or prescription drugs except when prescribed by a physician is prohibited, may damage the device, voids the warranty, and may cause serious injury.
- Use only as indicated in these instructions or as directed by a health care practitioner.

#### FREQUENTLY ASKED QUESTIONS

#### What actually happens during a nasal lavage cycle?

Saline enters one nostril and flows to the back of the nose where there is a gap between the back edge of the nasal septum and the back wall of the nasal cavity. The rinse flows from one side of the nasal cavity, through the gap and into the other side, and then returns to the front of the nose where it exits through the other nostril, flushing out allergens, mucus, dust, and germs, and moisturizing the nasal passages with saline, Nature's Decongestant.<sup>®</sup> In short, in one nostril, around the back of the nasal cavity, and out the other nostril.

#### How is the Naväge system different from other nasal irrigators?

Naväge® is the only nasal irrigation system—in the world—that uses powered suction. It **pulls** saline through the nose while other devices like the neti pot and nasal squeeze bottle **push**. It's like the difference between a vacuum cleaner and a broom. As a result, there's nothing as neat and convenient as Naväge!

#### What is in a Naväge SaltPod®?

Naväge SaltPods contain sea salt and water. The salt is a super-purified pharmaceutical grade that contains over 99.95% sodium chloride. With zero additives and no fillers, this is the purest sea salt available. The water goes through a sophisticated, 5-stage purification process consisting of carbon filtration, double deionization, ultraviolet sterilization, and a sub-micron finishing filter. The result is seriously clean water.

#### How often should I irrigate?

As often as you wish because Naväge and saline nasal irrigation are completely drug-free! We suggest you use Naväge twice a day, morning and evening, but doctors advise that it's safe to use more often. Find out what's best for you: Use it regularly for a couple of weeks and judge for yourself!

#### I leak saline – sometimes hours after I irrigate! What's happening?

During an irrigation cycle, sometimes a small amount of saline can flow into a sinus cavity, remain, and flow out later. This can be annoying and even embarrassing, but it is completely harmless. To avoid it, try this: After completing a cycle, bend over at the waist and bring your chin to your chest. Keeping your chin on your chest, turn your head to the left as if looking over your shoulder. Now turn your head to the right and look up over your right shoulder. If there's any residual saline, this usually lets it flow out. Gently blow your nose.

#### How long will the batteries last?

The batteries will provide enough power for several months of twice daily use. If you notice the motor is running at a lower pitch or if there is less suction than you're used to, it's time to change the batteries.

#### Naväge Nose Cleaner Limited Warranty

The Naväge Nose Cleaner is covered by a limited, one-year parts and labor warranty. We will repair or replace any product that malfunctions due to a manufacturing defect within a year of purchase. For service, contact us at support@navage.com, or call (800) 248-7550. Please note that the Naväge Nose Cleaner is not water-proof. The limited warranty does not cover damage caused by:

- Placing the Nose Cleaner in a dishwasher;
- Using the Nose Cleaner without a new, unused, genuine Naväge SaltPod capsule;
- The use of harmful additives such as tea tree oil, that can cause irreparable damage to plastic:
- Submerging the Nose Cleaner in water;
- Not fully tightening the screws on the battery door;
- Dropping and other accidents.

#### Disposal and Recycling

Please recycle. Naväge SaltPods are made from HDPE, recycling code #2. The SaltPod packaging tray is made from recycled PET (RPET), recycling code #1. The Naväge system is completely BPA-free.

#### RhinoSystems is the manufacturer of the Naväge Nose Cleaner and SaltPod® Capsules.

The Navage Nose Cleaner is designed in the USA and made in China. Navage SaltPods are manufactured in our Cleveland, Ohio facility which is certified to comply with ISO 13485:2003, certificate number 32908-00. ISO 13485 is the internationally recognized quality standard for medical device manufacturing.

RhinoSystems is registered with the United States Food and Drug Administration (USFDA). The Naväge Nose Cleaner is approved by the USFDA for use in the United States. Naväge SaltPods are licensed by Health Canada's Natural Health Product Directorate, Natural Product License Number 80035721. RhinoSystems is committed to continually improving our products through ongoing research and development. We strive to maintain the highest quality in everything we do.

#### Electromagnetic Compatibility

The Naväge Nose Cleaner has been built and tested to comply with the applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2 for residential, commercial and light industry environments. For further details, see "Guidance and Manufacturer's Declaration – Electromagnetic Emissions and Immunity" as follows.

#### Guidance and Manufacturer's Declaration - Electromagnetic Emissions and Immunity

The Naväge Nose Cleaner is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that it is used only in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR11	Group 1	The Naväge Nose Cleaner uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The Naväge Nose Cleaner is a direct-current battery-powered medical device that is suitable for use in all establishments. It is not intended or suitable to be directly connected to the public low-voltage alternating-current power supply network.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Cautions: Medical devices need special precautions with respect to EMC, and the Naväge Nose Cleaner should be installed and put into service according to the EMC information provided herein. The device can be affected by portable and mobile RF communications equipment. It should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, it should be observed to verify normal operation in the configuration in which it will be used. The product has been found to have no Essential Performance and does not require immunity testing.