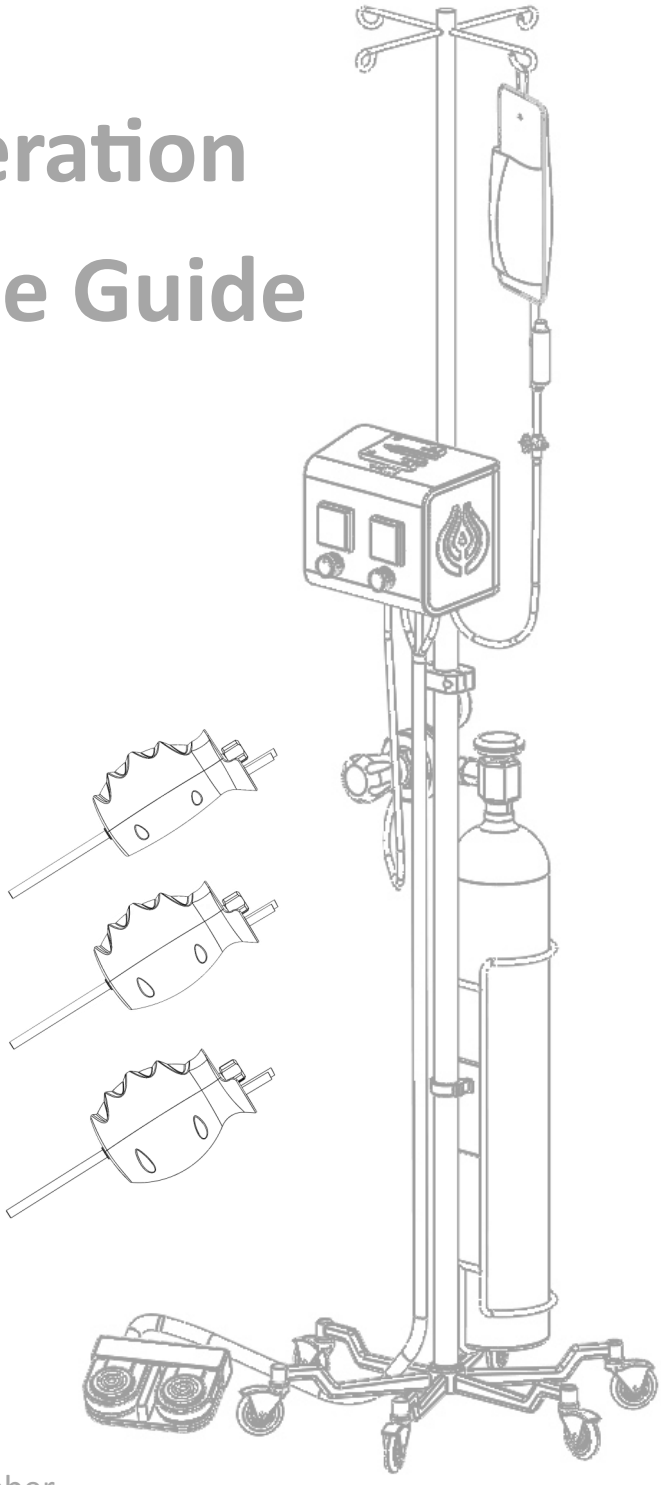
POSEIDON
LENS CLEANING SYSTEM

Installation, Operation and Maintenance Guide

Instructions for Use

R_x ONLY

REF	SCI-CTRLTWR
REF	SCI-LV-S
REF	SCI-LV-M
REF	SCI-LV-L



This product not made with dry natural rubber.

SCI-IFU-QSG Rev 1.0.0

IMPORTANT INFORMATION

The words WARNING, CAUTION, and NOTE have special meaning and should be reviewed.

WARNING: Disregarding WARNING information may compromise the safety of the patient and/or health care staff and may result in injury.

CAUTION: Disregarding CAUTION information may compromise product reliability and may result in damage.

NOTE: NOTE information supplements and/or clarifies procedural information.

A triangle with an exclamation point alerts the health care professional to read and understand the accompanying instructions, especially the operating, maintenance and safety information

DEVICE DESCRIPTION

The Poseidon Lens Cleaning System is a pneumatically controlled system consisting of a Control Tower, Foot Switch, and disposable Lens Cleaning Sheaths with Line and Valve sets. The system provides irrigation and suction functionality designed to keep the lens of a rigid endoscope clear during surgical procedures, particularly in endoscopic sinus surgery. This allows the surgeon to maintain clear visualization of the surgical site without having to remove the endoscope from the nasal cavity.

INDICATIONS FOR USE

Intended to clear the end of a rigid rod endoscope in order to maintain clear visualization of endoscopic procedures without having to remove the scope from the surgical site. The device is indicated for use during routine diagnostic procedures and during endoscopic sinus surgery. The Poseidon Control Tower is intended to be used in the operating room, surgical center and doctor's office to provide irrigation and suction during endoscopic sinus surgery. System is meant for use in the sinonasal cavity.

CONTRAINDICATIONS

There are no known contraindications.

POSSIBLE ADVERSE EFFECTS

The possible adverse effects, which may be associated with Lens Cleaning Sheath are identical to those associated with any commonly used sheath. These include the possibility of infection, recurrent or persistent bleeding, necessitating medical attention, trauma to intranasal tissues and/or nasal septal and surrounding structures. Surgeon should exercise the same clinical judgement and safe technique as required in any endoscope sinus procedure.

WARNINGS

- **DO NOT** use this product without first reading and understanding the instructions contained in this booklet. If you are unable to understand the Warnings, Cautions, or Instructions, contact a healthcare professional., dealer or technical personnel before use—otherwise serious bodily injury or product damage may occur.
- **DO NOT REUSE** any device after exposure to any patient. ****DO REUSE, REPURPOSE OR RESTERILIZE THIS DEVICE** . This device is intended for **SINGLE USE ONLY.**
- These products are for single use only. **It is **NOT DESIGNED FOR REUSE OR RESTERILIZATION.** Reprocessing may lead to damage of the device and compromise device performance. Reusing and/or reprocessing single-use devices can also cause cross contamination leading to patient infection. These risks may potentially affect patient safety.
- Poseidon Lens Cleaning Sheath, Line and Valve Sets and Foot Switch are designed to connect only to the Poseidon Controller. Do not attempt to connect these devices with any other console. Failure to comply may result in damage to equipment and voids warranty.
- The physician must exercise their own medical judgement in determining specific techniques and procedures appropriate for using Lens Cleaning Sheath.
- Only trained and experienced health care professionals should use this equipment. Before using any system component, or any component compatible with this system, read and understand the instructions. Become familiar with the system components prior to use.
- Each physician must evaluate the appropriateness of the use of Lens Cleaning Sheaths and the suggested directions for use are based on their own medical training, experience, and specific needs of the patient.
- **DO NOT** exceed the maximum weight capacity of 28lbs attached to the pole and 9lbs on each hook. (It is recommended that all added weight be evenly distributed amongst the top hooks to maintain stability.)
- All wheels must be in contact with the floor at **ALL TIMES**.
- **DO NOT** use the I.V. pole while walking backwards, down gradients, or climbing stairs, curbs or to go over obstacles. Serious risk of fall or injury may occur.
- **DO NOT** use in MRI areas.
- **DO NOT** lift the pole by the top half of the pole.
- Perform recommended maintenance as indicated in these instructions. Only trained and experienced health care professionals should maintain this equipment.

ENDOSCOPE COMPATIBILITY

The Poseidon Lens Cleaning Sheath is compatible with endoscopes with an outer diameter of 4mm and lengths of 170mm to 185mm in length.

DISPOSABLE INFORMATION

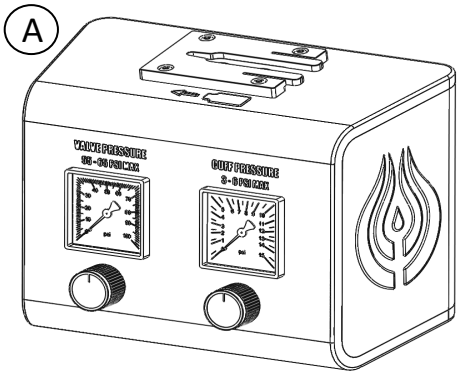
Use only approved components unless otherwise specified. Do not attempt to connect Poseidon devices with any other console. Using other components may result in equipment damage and voids warranty.

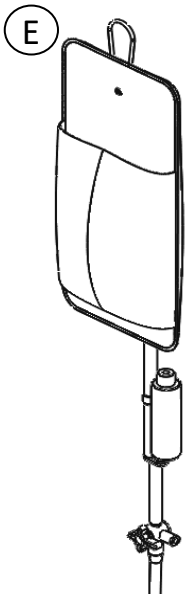
Description	REF
WaveGrip, Small	SCI-LV-S
WaveGrip, Medium	SCI-LV-M
WaveGrip, Large	SCI-LV-L
Pressure Cuff	SCI-CUFF
Foot Switch	SCI-FTSWTCH

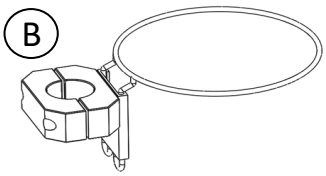
If you need more information or a complete list of accessory information, contact your Huck Medical Technologies sales representative or call Huck Medical Technologies customer service at 1-903-339-1257.

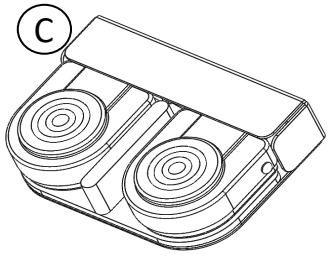
CONTROL TOWER COMPONENTS

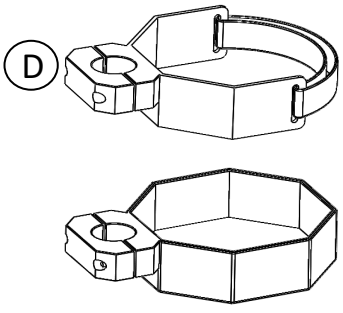
A. Controller
B. Suction Canister Mount
C. Foot Switch
D. Gas Cylinder Mount
E. Pressure Cuff
F. IV Pole with 6 Casters (not pictured)









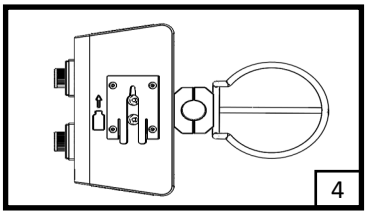


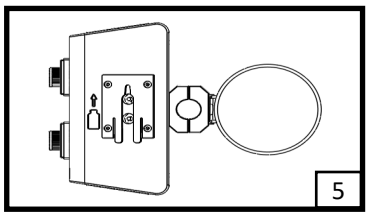
CONTROL TOWER ASSEMBLY INSTRUCTIONS

1. Assemble IV Pole following manufacturer's instructions. Retain Allen Wrenches to be used for Control Tower Assembly.
2. Remove all parts of Control Tower from packaging.
3. Affix Controller to IV Pole at comfortable working height utilizing allen wrench.

   Note: Gages should be visible during use.
4. Affix CO2 Gas Cylinder Lower Mount at bottom of IV Pole Base utilizing allen wrench then affix CO2 Gas Cylinder Upper Mount 12 inches (305 mm) above Lower Mount.

   Note: Position CO2 Gas Cylinder Mounts opposite of Controller to counterbalance weight on IV Pole.



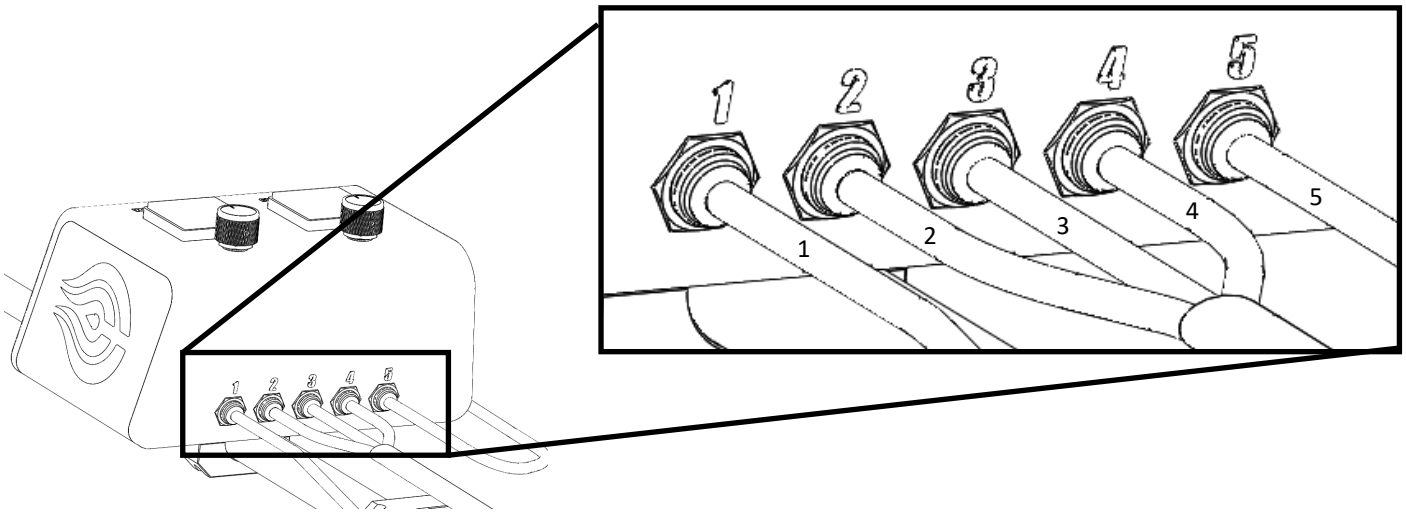


5. Affix Suction Canister Mount to IV Pole approximately 9 inches (230 mm) below Controller utilizing allen wrench.

   Note: Position Suction Canister Mount opposite of Controller to counterbalance weight on IV Pole.

> **NOTE:** Ensure gas cylinder regulator is closed and in the OFF position prior to proceeding to step 6.

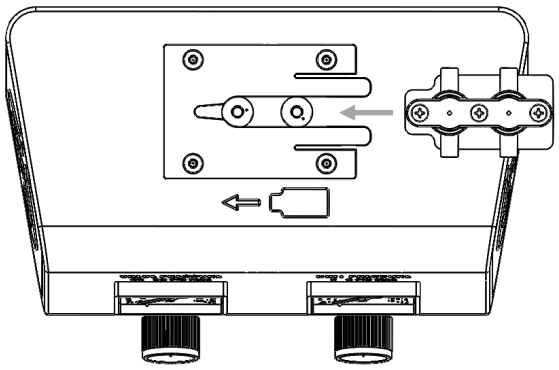
6. Connect one end of pneumatic line #1 into CO2 gas cylinder regulator. Connect opposite end of pneumatic line #1 into port #1 on bottom of Controller.
7. Insert and seat foot switch pneumatic line #2 into port #2 on bottom of controller.
8. Insert and seat foot switch pneumatic line #3 into port #3 on bottom of controller.
9. Insert and seat foot switch pneumatic line #4 into port #4 on bottom of controller.
10. Hang pressure cuff from hooks of IV Pole. Insert pneumatic line #5 of pressure cuff into port #5 located on bottom of Controller.



INSTRUCTIONS

To Prepare Valve Cartridge For Use:

1. Place the Control Tower on a flat surface in a convenient location within the operating room.
2. Insert IV fluid bag into pressure cuff sleeve and secure fluid bag on built-in hook of pressure cuff.
3. Insert suction canister into suction canister mount and attach house vacuum to vacuum port of suction canister.
4. Remove the WaveGrip and valve cartridge from the protective packaging.
5. Orientate valve cartridge according to diagram located on top of controller and insert valve cartridge into valve cartridge bracket.



NOTE: An audible click is heard when valve cartridge is fully seated into valve cartridge bracket.

6. Connect female connector of suction tubing attached to the valve cartridge to the patient port of the suction canister.
7. Remove IV spike cap attached to valve cartridge and insert spike into IV fluid bag.

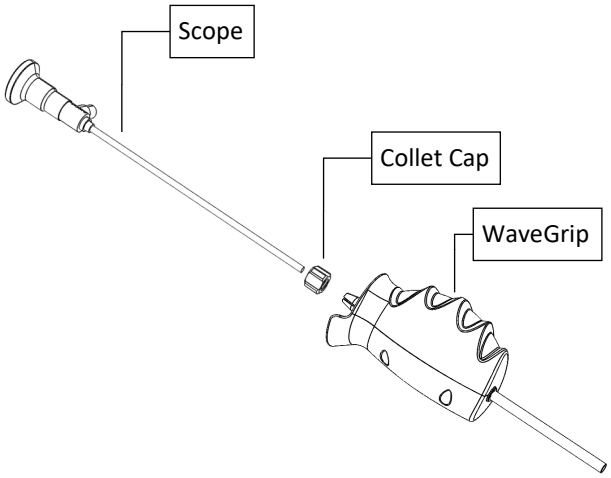
INSTRUCTIONS

To Prepare WaveGrip for Use:

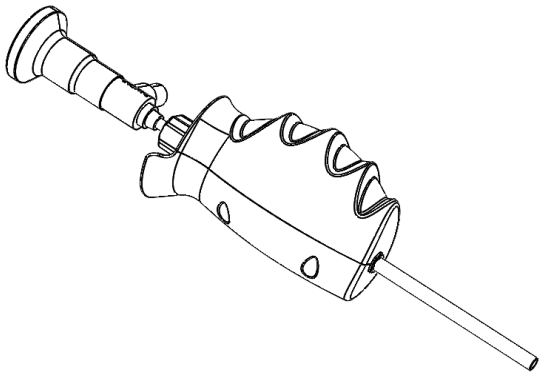
1. Remove the WaveGrip from the protective packaging then remove the red protective cap on the distal end of sheath.

NOTE: Ensure to dispose of red cap appropriately and/or account for at the end of the procedure.

2. Loosen collet cap, insert scope into collet cap then insert scope into open port of collet valve located in the WaveGrip.



3. Position and orientate scope in the collet valve then tighten collet cap onto collet valve until scope is secured.



INSTRUCTIONS

Control Tower Preparation—

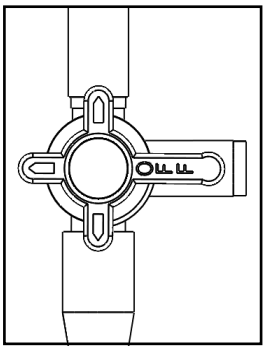
Valve Pressure Initialization:

1. Set CO2 gas cylinder regulator to 100 PSI MAX and open gas cylinder.
2. Turn left knob on controller to the right to increase valve pressure and set valve pressure to 55 PSI.

Note: If valve does not operate when foot switch is engaged, gradually increase valve pressure by turning left knob to the right until valve operates when foot switch is engage, 65 PSI MAX.

Cuff Pressure Initialization:

1. Turn stopcock on pressure cuff to the inflate position, shown below.



2. Turn right knob on the controller slowly to the right to increase cuff pressure, allowing the pressure cuff to start to inflate.
3. Once pressure cuff fully inflates, adjust the pressure to 3 PSI .

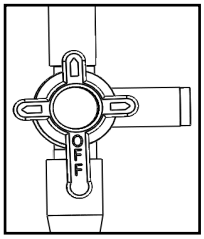
INSTRUCTIONS

System Operation Verification:

1. With foot switch orientated towards operator, verify system operation by activating both foot switches separately ensuring that the valve cartridge moves independently when each foot switch is depressed.

To Prepare Control Tower for Relocation after Use

1. Turn Valve Pressure knob to the left until depressurized and verify gage reads 0 PSI.
2. Turn Cuff Pressure knob to the left until depressurized and verify gage reads 0.
3. Turn gas cylinder regulator off.
4. Turn stopcock to the deflate position to depressurize the pressure cuff.



5. Remove IV fluid bag from pressure cuff.
6. Remove valve cartridge from bracket by gently lifting bracket fingers and sliding cartridge to the right.
7. Disconnect suction tubing from patient port of suction canister.
8. Loosen Collet Cap and remove scope from WaveGrip.
9. Dispose of WaveGrip, valve cartridge and line-set according to facility's hazardous waste disposal guidelines.

INSTRUCTIONS

To Prepare Control Tower for Relocation after Use (cont'd)

10. Coil foot switch pneumatic tubing and secure foot switch to hook located on the IV Pole.

CLEANING RECOMMENDATIONS

1. Wipe the external surfaces of the Control Tower with a soft cloth dampened with a non-abrasive, hospital disinfectant.
2. Inspect the Control Tower. See *Periodic Maintenance.*

STORAGE AND HANDLING—

CONTROL TOWER

To ensure longevity, performance and safety of this equipment, use the original packaging when storing or transporting this equipment.

LENS CLEANING SHEATH

The Poseidon Lens Cleaning Sheath should be stored at normal room temperature conditions within original packaging.

PERIODIC MAINTENANCE

INTERVAL	ACTIVITY
Prior to each use and after each cleaning	Inspect the level of available gas in cylinder, the valve cartridge bracket for cracks, pneumatic tubing and connections for cuts and/or leaks.
As required	Replace the gas cylinder as required

DISPOSAL OF DEVICE

Unused device cannot be disposed of in ordinary trash. Dispose of the product in accordance with the hospital's procedures for contaminated medical waste and in compliance with applicable government regulations regarding medical devices.

SERIOUS INCIDENT REPORTING PROCESS

Report any serious incident relating to the use of this product to Huck Medical Technologies and to the health authority of the country in which it occurred. This applies to any incident where a shortcoming in the performance, usability, or labeling of this product has led, might have led or could lead to the death, permanent or temporary deterioration in the state of health of the patient, user, or others. It also applies to any incident that indicates that a serious public health threat exists.

RETURNED GOODS POLICY

Product returns or exchanges to be arranged by contacting Huck Medical Technologies distributor or Huck Medical Technologies customer service.

PRODUCT ORDERING

To order a device, or for additional product information, please contact:

Huck Medical Customer Service

111 Cash Street

Jacksonville, Texas 75766

Phone: 903-312-1259

Email: customerservice@huckmedtech.com

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