

# OstomyVac™ User's Manual

# DOC001R03

# THIRD EDITION

MANUFACTURED BY:

# **OSTO INNOVATIONS**

2633 LANTANA RD BUILDING 1301 / SUITE 46 LANTANA FL 33462 PHONE: 561-601-8838 <u>CUSTOMERSUPPORT@OSTOUSA.COM</u>

**IMPORTANT: READ MANUAL BEFORE USE** 

OstomyVac<sup>™</sup>User's Manual



# **Table of Contents**

1.0	INTRODUCTION1
2.0	WARNINGS
3.0	OstomyVac <sup>TM</sup> KIT COMPONENTS
3.1	BREAKDOWN OF OstomyVac <sup>™</sup> KIT 4
4.0	OstomyVac <sup>™</sup> OVERVIEW
5.0	OVAC <sup>TM</sup> OVERVIEW
5.7	$OVAC^{TM} LOGIC \dots 11$
5	.7.1 <i>OVACTM</i> ON/OFF 11
5	.7.2 VACUUM PUMP CONTROLS 11
5	.7.3 VIBRATION MOTOR CONTROLS
5	.7.4 HEARTBEAT
6.0	INSTRUCTIONS FOR USE
6.1	PREPARATION AND ATTACHMENT OF YOUR
OST	OMYVAC <sup>TM</sup>
6.2	DAILY BATTERY REPLACEMENT14
6.3	BATTERY CHARGING14
6.4	CONNECTING YOUR TETHER FOR BATHING 15
6.5	CONNECTING YOUR DRYBOX FOR SHOWERING AND
SWI	MMING 15
7.0	DAILY ACTIVITIES16
7.1	SHOWERING 16
7.2	BATHING 16
7.3	SWIMMING16
7.4	SLEEPING17
8.0	SECURING YOUR OVAC <sup>TM</sup>
8.1	POUCH COVER 18
8.2	BELT
9.0	TROUBLESHOOTING
10.0	WARRANTY STATEMENT 20



# **1.0 INTRODUCTION**

Osto Innovations LLC has developed and patented an ostomy appliance that utilizes vacuum to supplement the attachment of Coloplast ostomy pouches to the body. The OstomyVac<sup>™</sup> appliance is made of soft, highly flexible, medical grade silicone which provides an interface between a Coloplast ostomy pouch and the user's stoma.

The vacuum that supplements attachment to skin is provided by a fully automated,  $Ovac^{TM}$  vacuum pump module.

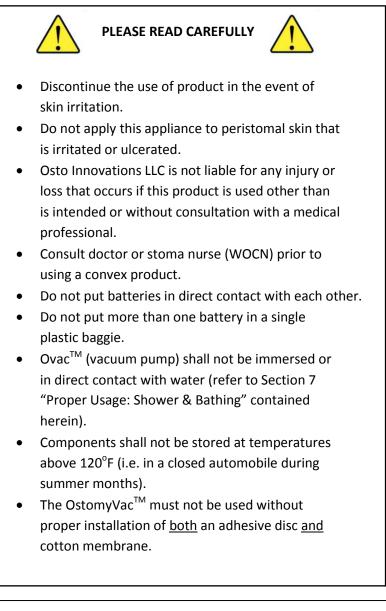
The OstomyVac<sup>TM</sup> appliance and  $Ovac^{TM}$  vacuum pump operate as a single system and must not be used independent of each other.

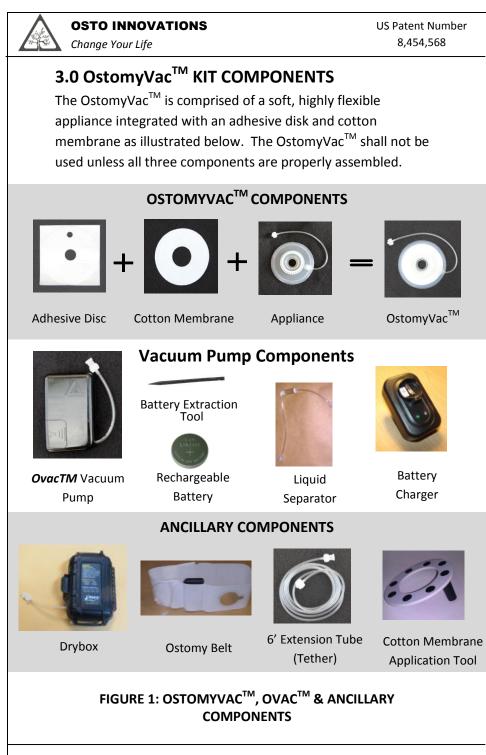


Change Your Life

### 2.0 WARNINGS

It is important that the following warnings are carefully read and understood prior to using the OstomyVac<sup>™</sup> appliance.





OstomyVac<sup>™</sup>User's Manual

**3** | Page



Change Your Life

## 3.1 BREAKDOWN OF OstomyVac<sup>™</sup> KIT

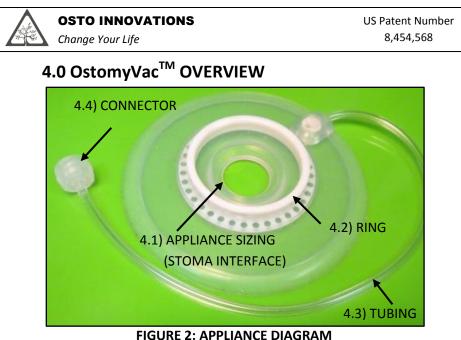
EXCEPT FOR DISPOSABLES, each kit contains components that are designed to provide reliable performance for a period of one year. The kit is delivered with two months' worth of disposables (adhesive and membranes). Disposables should be reordered monthly.

COMPONENT	ТҮРЕ	KIT QUANTITY	# OF SPARES
Adhesive Disc	Disposable	40	Maintain a reserve stock
Cotton Membrane	Disposable	40	of 5 sets at all times.
Appliance	Reusable	2	1
Ovac <sup>™</sup> Vacuum Pump	Reusable	2	1
Battery Extraction Tool	Standalone 1		0
Battery	Rechargeable/ Reusable	4	3
Liquid Separator	Standalone	2	0
Battery Charger	Standalone	1	0
Drybox	Standalone	1	0
Ostomy Belt	Standalone	2	0
Extension Tube (Tether)	Standalone	1	0
Cotton Membrane Application Tool	Standalone	1	0

### TABLE 1: OstomyVac<sup>™</sup> KIT BREAKDOWN



COMPONENTS THAT ARE NOT IN USE SHALL BE STORED IN THEIR ORIGINAL PLASTIC PACKAGAING

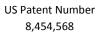


(Shown without Adhesive Disc or Cotton Membrane)

The appliance is the device that is the interface between the stoma and the pouch. The appliance is attached to the user's body using adhesive and vacuum. The vacuum does <u>not</u> assist with, or effect stoma output. The appliance is made of soft, highly flexible, medical grade silicone and is configured for optimizing comfort while minimizing adhesive contact area with peristomal skin.

### **APPLIANCE FEATURES:**

4.1) <u>APPLIANCE SIZING:</u> The OstomyVac<sup>™</sup> is available in thirteen standard sizes and shapes to accommodate most stoma configurations, as listed in Table 2. OstomyVac<sup>™</sup> is also available as a custom-made appliance that precisely conforms to each individual user's unique stoma. For added comfort all edges and surfaces that contact the peristomal skin area are soft and complaint (no sharp edges or rigid surfaces).



Change Your Life

CIRCULAR							
	CONFIG	DIAMETER (D)		COLOPLAST SIZE*			
	#	INCHES	MM	COLOR			
	1	0.50″	13mm	Green			
	2	0.625″	16mm	Green			
	3	0.75″	19mm	Green			
	4	0.875″	22mm	Green			
	5	1.00"	25mm	Green			
	6	1.125″	29mm	Red*			
	7	1.25″	32mm	Red*			
	8	1.375″	35mm	Red*			
	9	1.50″	38mm	Red			
	10	1.625	41mm	Red			
		OVAL					
	CONIFIC	LENGTH (L) x HEIGHT (H)		COLOPLAST			
	CONFIG #			SIZE*			
	#	INCHES	MM	COLOR			
	11	1.5" X 0.75"	38mm x 19mm	Red			
	12	1.5" x 1.0"	38mm x 25mm	Red			
	13	2.25" x 1.25"	57mm x 32mm	Yellow*			
<ul> <li>TABLE 2: APPLIANCE SIZE STANDARD CONFIGURATIONS</li> <li>* It is important to note that OstomyVac<sup>™</sup> sizing is inconsistent with Coloplast sizing. Please follow the chart above.</li> <li>4.2) <u>RING</u>: The OstomyVac<sup>™</sup> is designed to be used exclusively with standard, "Click to Lock", Coloplast Ostomy pouches.</li> <li>4.3) <u>TUBING</u>: The vacuum line between the OstomyVac<sup>™</sup> and the Ovac<sup>™</sup> is comprised of medical grade tubing. It is through this tubing that the vacuum level is drawn.</li> </ul>							
OstomyVac <sup>TM</sup> User's Manual $6 \mid P \mid P \mid g \mid e$							



<u>Note 1:</u> If moisture does happen to collect in this line, IGNORE IT. Moisture is potentially caused by perspiration forming under the OstomyVac<sup>™</sup> and then traveling down into the vacuum line. A liquid separator is provided to prevent liquid from reaching the pump. Liquid that may accumulate in the OstomyVac<sup>™</sup> Tubing (Ref. Figure 2, Item 4.3) poses no problem as long as a liquid separator is in use.

When changing out the OstomyVac<sup>™</sup>, any moisture that may have accumulated in the vacuum line can be removed using the syring provided in every kit. The pamphlet "OstomyVac<sup>™</sup> Service Procedure" provides instructions on how to use the syringe to remove the moisture.

4.4) <u>CONNECTOR</u>: The connector is the joint to connect the OstomyVac<sup>™</sup> to the Liquid Separator. Ensure that the two pieces are fully engaged by twisting clockwise until firmly connected (<u>HAND TIGHT ONLY</u>). A loose connection could cause a vacuum leak (not good).



Change Your Life

US Patent Number 8,454,568



### FIGURE 3: OSTOMYVAC<sup>™</sup> DIAGRAM

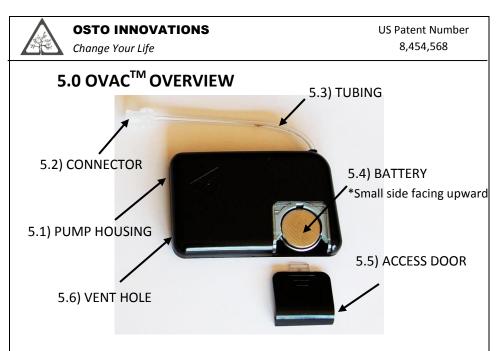
4.5) <u>ADHESIVE DISC:</u> The primary purpose of the adhesive disc is to secure the OstomyVac<sup>™</sup> device to the body. The appliance cannot be worn without the adhesive disc and cotton membrane. The adhesive disc and cotton membrane should be changed every three days.

<u>COTTON MEMBRANE</u>: The purpose of the cotton membrane is to distribute vacuum over the peristomal skin for adhesion enhancement. The OstomyVac<sup>™</sup> will not work properly if the adhesive disc <u>and</u> cotton membrane are not installed.

Detailed step-by-step instructions for installing the adhesive disc and cotton membrane are provided in the "OstomyVac<sup>™</sup> Service Procedure". This pamphlet is contained in the shipping box.



DISCONTINUE THE USE OF PRODUCT IN THE EVENT OF ANY SKIN IRRITATION.



### FIGURE 4: OVAC<sup>™</sup> VACUUM PUMP MODULE

The primary function of the  $Ovac^{TM}$  is to maintain the vacuum level over the peristomal skin. The  $Ovac^{TM}$  is merely a 'black box' autonomously controlled by the internal electronics. The only interaction required with the  $Ovac^{TM}$  is opening the access door to replace the battery. Besides the access door, the  $Ovac^{TM}$  enclosure shall NOT be opened to avoid damage.

### OVAC<sup>™</sup> FEATURES:

- 5.1) <u>OVAC<sup>™</sup> HOUSING</u>: The Ovac<sup>™</sup> housing is a black plastic enclosure that is NOT water tight. <u>Putting in water will damage the Ovac<sup>™</sup></u>, voiding warranty.
- 5.2) <u>CONNECTOR</u>: The connector is the joint to connect the OvacTM to the Liquid Separator. Ensure that the two matching pieces are fully engaged by twisting clockwise (hand tight only) until firmly connected. A loose connection could cause a vacuum leak (not good).



- 5.3) <u>TUBING</u>: The Ovac<sup>™</sup> vacuum tubing is comprised of medical grade tubing. It is through this line that the vacuum level is drawn. Note: If Moisture happens to accumulate in this tube, ignore it. <u>DO NOT</u> attach a syringe to this section of tubing as it will damage the Ovac<sup>™</sup>.
- 5.4) <u>BATTERY</u>: A lithiom ion battery (3.6 Volts) powers the Ovac<sup>™</sup>. The battery is sized to last for three days before replacement is necessary. In spite of that, it is highly recommended to change the battery daily to avoid the possibility of low battery charge. See Section 6.3 for the battery replacement procedure.

The  $Ovac^{TM}$  has the ability confirm a full battery charge at start-up (the moment when battery is installed). If the inserted battery is fully charged, a lamp inside the  $Ovac^{TM}$  will illuminate for 2-seconds at start-up. If the battery is installed and the lamp does not illuminate for 2-seconds, the battery is not fully charged and requires replacement.

<u>NOTE</u>: As shown in Figure 4, the smaller side of the battery faces upward. The side marked with an "+" faces downward.



BATTERIES NOT IN USE, SHALL BE STORED IN THEIR OWN **INDIVIDUAL** PLASTIC CONTAINER

- 5.5) <u>ACCESS DOOR:</u> This is a sliding door that provides access to the battery compartment at the time of battery replacement.
- 5.6) <u>VENT HOLE</u>: The vacuum pump outlet is vented to the outside of the Ovac<sup>™</sup> case through this hole.

OstomyVac<sup>™</sup>User's Manual

**10** | Page



# 5.7 OVAC<sup>™</sup> LOGIC

The Ovac<sup>™</sup> vacuum pump module is a rather simple device that controls the operation of the vacuum pump, vibration motor, and heartbeat.

### 5.7.1 OVACTM ON/OFF

The ON/OFF function is controlled by installing and removing the battery. There is no ON/OFF switch, only the battery. When the battery is INSTALLED the vacuum pump turns ON. When the battery is REMOVED the vacuum pump turns OFF.

You can expect the vacuum pump to turn ON as soon as the battery is installed. The  $Ovac^{TM}$  has a built-in safety feature that will automatically shut the unit OFF in a safe manner, in the event the battery is inadvertently left installed.

### 5.7.2 VACUUM PUMP CONTROLS

The Ovac<sup>™</sup> uses a vacuum sensor to precisely measure vacuum level over the peristomal skin area. A micro-vacuum pump is automatically turned on and off to precisely maintain the proper vacuum level.

The pump is typically on for less than half a second (0.5 second) when vacuum is needed to maintain normal adhesion. This is consistent for every user.

The time interval between pump ON can range from every fifteen minutes to hours depending on the user.

### **5.7.3 VIBRATION MOTOR CONTROLS**

The  $Ovac^{TM}$  incorporates a feature for detecting leakage of the OstomyVac<sup>TM</sup>. In the event the vacuum pump runs for more than two seconds (consistent with a leak), a vibration motor will turn on. It will shake the  $Ovac^{TM}$  box, similar to a cell



Change Your Life

phone vibration mechanism. Once the vacuum is restored (depressing the appliance onto the body), the vibration motor will turn off. The vibration motor will run until the leak has been restored.

<u>Note</u> – When a battery is installed in the Ovac<sup>™</sup>, the unit will continue to run until sufficient vacuum level is attained in the OstomyVac<sup>™</sup>. So as to maximize battery life after charging, the battery should not be installed until all vacuum lines are connected and the OstomyVac<sup>™</sup> is fully attached to the body. Under this condition, the vacuum pump will normally run less than two seconds to establish adequate vacuum level.

If vacuum is not established within two seconds after inserting the battery, you can expect the vibration motor to start vibrating and continue to run until adequate vacuum level has been established.

### 5.7.4 HEARTBEAT

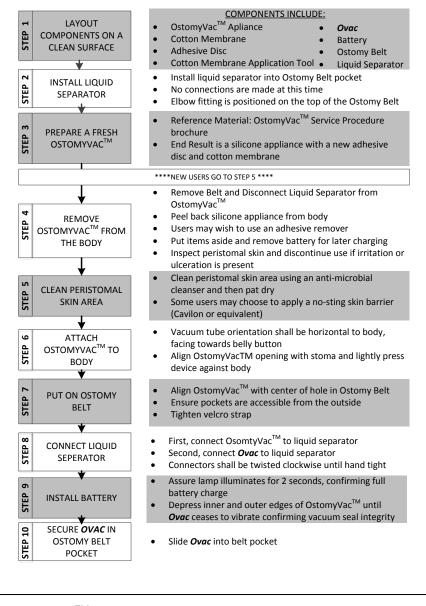
The OstomyVac<sup>™</sup> has a built-in 'heartbeat'. The 'heartbeat' is a blinking light that illuminates every ~12 seconds assuring normal operation. If the 'heartbeat' ceases to blink, the unit is not operating and the user should replace the battery.



Change Your Life

### 6.0 INSTRUCTIONS FOR USE

# 6.1 PREPARATION AND ATTACHMENT OF YOUR OSTOMYVAC<sup>TM</sup>



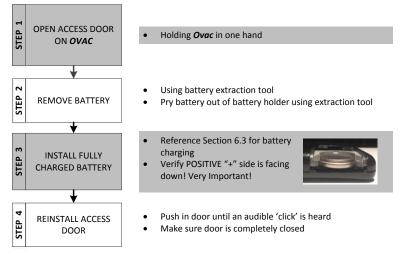
OstomyVac<sup>™</sup>User's Manual

**13** | Page

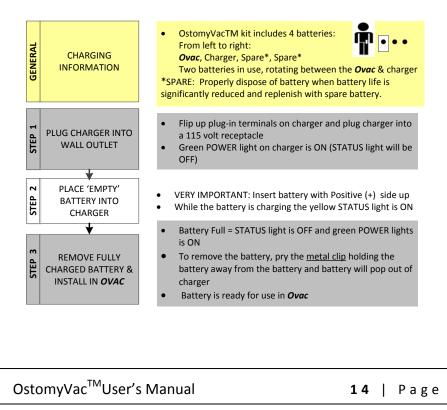


Change Your Life

### 6.2 DAILY BATTERY REPLACEMENT



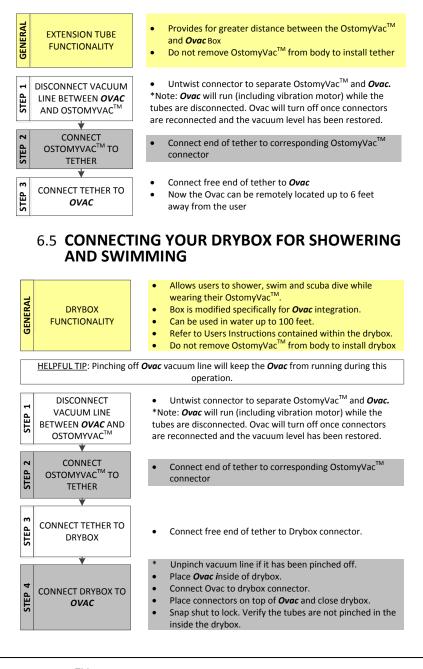
### 6.3 BATTERY CHARGING





Change Your Life

### 6.4 CONNECTING YOUR TETHER FOR BATHING



OstomyVac<sup>™</sup>User's Manual

**15** | Page



# 7.0 DAILY ACTIVITIES

### 7.1 SHOWERING

There are two options available for protecting the  $Ovac^{TM}$  from water damage during showering. The first option is to hang the  $Ovac^{TM}$  by its tether out of direct contact with water (refer to Section 6.4 for tether installation instructions). The second option is to enclose the  $Ovac^{TM}$  in the water-tight Drybox and let it lay on the shower floor (refer to Section 6.5 for Drybox installation instructions). This option allows the user more mobility during showering.

After showering is an ideal time to do the daily battery replacement to maximize battery life.

### 7.2 BATHING

While bathing, the user should connect the tether so as to keep the  $Ovac^{TM}$  out of direct contact with water. Refer to Section 6.4 for tether installation instructions.

After bathing is an ideal time to do the daily battery replacement to maximize battery life.

### 7.3 SWIMMING

The Drybox shall be used whenever the user is swimming so as to protect the  $Ovac^{TM}$  from water damage. Refer to Section 6.5 for Drybox installation instructions.

Before swimming in public pools, confirm below, to maintain hygiene at pool, protecting all.

- 1.) Correct Battery use, Section 5.4.
- OstomyVac<sup>™</sup> has a good seal against the body. If a good seal has <u>not</u> been achieved, the user can expect the vibration motor to turn on. Section 6.7.3



If while swimming, the user notices a breach in the seal, the user should place their hand on the OstomyVac<sup>TM</sup> (securing it in place) and exit the pool.

Osto Innovations is not liable for any contamination to a public or private swimming pool.

### 7.4 SLEEPING

The user will determine their individual preference as to what the best configuration is for sleeping. A pouch cover or belt is preferred since they provide secure attachment of the  $Ovac^{TM}$ to the body. The user may also allow the  $Ovac^{TM}$  to merely reside in bed since damage will not occur to the plastic case if slept on top of. There is slight risk of pulling the OstomyVac<sup>TM</sup> from the body using this configuration which would result in leakage.



# 8.0 SECURING YOUR OVAC<sup>™</sup>

There are several options available for securing your  $Ovac^{TM}$  during bathing, showering, swimming, along with normal use. Accessories such as pouch covers, belts and a drybox allow for use of the OstomyVac<sup>TM</sup> during these activities.

### 8.1 POUCH COVER

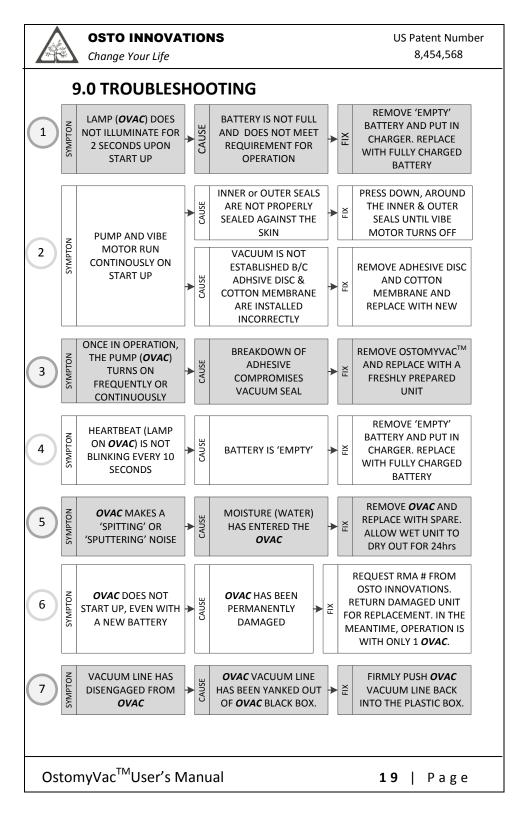
The pouch cover is made from high quality, durable fabrics and serves the dual purpose of adding stylish accent while securing the  $Ovac^{TM}$ .

The pouch cover can be purchased from C&S Ostomy Pouch Covers. Upon ordering, be sure to order the pouch cover designated for Osto Innovations.

> C&S Ostomy Pouch Covers www.cspouchcovers.com 941-429-8030

### 8.2 BELT

A large-width cotton-spandex belt is available to enhance OstomyVac<sup>™</sup> security while providing a pocket to hold the Ovac<sup>™</sup>. The large width helps to prevent skin folds and is not visible through loose-fitting clothing. Belts can be purchased directly from Osto Innovations.





Change Your Life

# **10.0 WARRANTY STATEMENT**

Osto Innovations LLC warrants all products to be free of defects in material and workmanship of OstomyVac<sup>™</sup> (Appliance) and/or Ovac<sup>™</sup> (Vacuum Pump) for a period of one year commencing from date of shipment.

Osto Innovations will issue a Return Material Authorization (RMA) Number to any user who wishes to return defective products for warranty consideration. An RMA number must be issued before any materials are returned.

Warranty consideration is subject to review of returned items (see Limitations and Exclusions) and application of warranty is to be determined by Osto Innovations, LLC, in its sole discretion.

Osto Innovations, LLC, reserves the right to make design changes in appliance and accessories, without incurring obligation to incorporate these changes in products previously shipped.

At original purchaser's discretion items determined to be defective will be subject to either:

- 1. A refund of the purchase price (minus a 10% restocking fee) or,
- Replacement of defective parts with new materials (the original warranty expiration date will remain in force). Replacements are shipped at the expense of Osto Innovations, LLC.

### SATISFACTION GUARANTEE

Osto Innovations, LLC, guarantees customer satisfaction. If for any reason (see Limitations and Exclusions) the user is not completely satisfied with our products:



Change Your Life

OstomyVac<sup>™</sup> (Appliance) and/or Ovac<sup>™</sup> (Vacuum Pump), they may be returned within 60 days of the date of shipment for a full refund (minus a 10% restocking fee).

### LIMIATIONAS AND EXCLUSIONS

User neglect, user modification, and mishandling nullify any consideration for refund.

### LIABILITY WAIVER

Osto Innovations, LLC is not liable for any injury or loss that occurs because this product is used other than is intended or without consultation with a medical professional.

### **RETURN INSTRUCTIONS**

- For safety and health reasons please return all used OstomyVac<sup>™</sup> appliances in sealed zip lock bags.
- 2. For warranty consideration or refund, please ship items in original boxes (if possible) to:

Osto Innovations, LLC.

2633 Lantana Road, Building 1301 /Suite 46 Lantana, Florida 33462.

3. Shipping costs of returned materials are the customer's responsibility. We recommend returns be shipped via UPS or Fed Ex, with an assigned tracking number, to validate receipt. Ensure RMA number is documented somewhere ON or IN the package. Please allow 5 business days for warranty consideration and notification (by phone, email, or mail).