



Vante®

**INSTRUCTION
MANUAL**

MODEL 4105

Hand-Held Sealing Head

This page intentionally left blank

Vante®

3480 E. Britannia Dr., Suite 120
Tucson, AZ 85706 USA

Telephone (520) 881-6555
Fax (520) 323-9055
Toll Free (877) 565-5557

Part No. 41050810-01 Rev. D

This page intentionally left blank

Preliminary Information

Document Scope

This manual is intended as a guide for the operation, care and maintenance of the Vante® Model 4105 Hand-Held Sealing Head. The information contained herein is based upon technical data that have been validated by Vante® and is believed to be appropriate for the intended use of the product.

Intended Audience

This manual is intended for use by personnel with technical skills and a thorough understanding of the products, procedures, and safety requirements for processing and handling of biopharmaceutical products.

Application

The Model 4105 Hand Held Sealing Head is part of a system and cannot be used independently. When used in conjunction with a Vante® radio frequency (RF) Power Source, it is the instrument used to make seals on tubing made of RF-reactive thermoplastic materials typically used in biopharmaceutical manufacturing. Tubing utilized in the handling of biopharmaceutical products are typically made from thermoplastic vinyl, namely polyvinylchloride, (PVC) or ethylene vinyl acetate (EVA), and it is this application for which this product is specifically intended.

Exclusions and Limits of Liability

Vante® makes no warranties, expressed or implied, and assumes no liability in connection with any use of this information. If the Sealing Head or its related procedures are used for purposes other than those stipulated herein, validation of the specific application should be obtained, otherwise Vante® assumes no liability or obligation nor guarantees product performance. Personnel using the Sealing Head do so at their own discretion and risk.

Proprietary Information

All rights are reserved. Copying of the protected designs associated with the Model 4105 Sealing Head is strictly prohibited without the prior written consent of Vante®.

User Alerts

Throughout this document WARNINGS, CAUTIONS and NOTES are employed to notify the user of important and/or critical information.

WARNING: A Warning indicates a condition or procedure that could result in improper tube sealing or possible injury to the user. A Warning is enclosed with a bold-line box.

CAUTION: A Caution indicates a condition or procedure that could result in damage to the unit. A Caution is enclosed with a single-line box.

NOTE: A Note indicates important and/or useful information.

Safety Symbols



Caution, risk of electric shock



Caution



Protective Earth (P.E.)



Fuse



On



Off



WEEE – Indicates electronic equipment requiring proper recycling (EU only)

CE Mark Information

For inquiries related to the CE marking of this product, please contact Vante® at 3480 E. Britannia Dr, Suite 120, Tucson, Arizona 85706 U.S.A., 520-881-6555, 520-323-9055 (fax).

Table of Contents

Preliminary Information.....	v
Document Scope	v
Intended Audience	v
Application.....	v
Exclusions and Limits of Liability.....	v
Proprietary Information.....	vi
User Alerts	vi
Safety Symbols.....	vi
CE Mark Information.....	vi
Table of Contents.....	vii
Table of Figures	viii
Table of Tables	viii
1. Sealing Head Description.....	1
1.1 Product Overview	1
1.2 Theory of Operation.....	1
1.3 Component Identification	1
1.4 Environment.....	3
2. Sealing Head Operation	5
2.1 Setup	5
2.2 Splash Guard Installation	5
2.3 Sealing Procedure	7
2.4 Seal Spacing.....	10
3. Cleaning the Sealing Head.....	11
3.1 Topical Cleaning of the Sealing Region	12
3.2 Disassembly of the Sealing Head.....	15
3.3 General Cleaning of the Sealing Head.....	18
3.4 Reassembly of the Sealing Head.....	18
4. Repair.....	23
4.1 Troubleshooting	23
4.2 Spring Replacement	24
4.3 Returning a Unit for Repair	25
5. Radio Frequency System Safety Considerations.....	27
5.1 General Information	27
5.2 RF Effects On Human Tissue	27
5.3 RF Effects On Pacemakers	27
5.4 Electrical Safety	27
5.5 RF Effects On Electronic Equipment.....	27
5.6 RF Effects In Potentially Explosive Atmospheres.....	28

Table of Figures

Figure 1.1	Model 4105 Hand Held Sealing Head	2
Figure 2.1	Tab and Sides A & B of Splash Guard	5
Figure 2.2	Splash Guard Tab	6
Figure 2.3	Final Attachment of Splash Guard	6
Figure 2.4	Correct Technique for Holding the Sealing Head	7
Figure 2.5	Incorrect Technique for Holding the Sealing Head	8
Figure 2.6	Maintaining Compression During the Entire Sealing Process	8
Figure 2.7	Releasing the Sealing Head Lever at Seal Completion	9
Figure 3.1	Incorrect Cleaning Technique.....	11
Figure 3.2	Correct Lever/Sealing Body Gap.....	12
Figure 3.3	Cleaning the Sealing Region	13
Figure 3.4	Drying the Sealing Region.....	13
Figure 3.5	Cleaning Ground and RF Jaw Surfaces	14
Figure 3.6	Drying Ground and RF Jaw Surfaces	14
Figure 3.7	Releasing Spring Tension in Sealing Head	16
Figure 3.8	Removing the Lever and Ground Jaw	17
Figure 3.9	Sealing Head Components.....	17
Figure 3.10	Cleaning Individual Sealing Head Components.....	18
Figure 3.11	Installation of Ground Jaw onto RF Jaw/Tube Assembly	19
Figure 3.12	Installation of Lever on to Sealing Head	19
Figure 3.13	Installation of Lever into Pivot Slots	20
Figure 3.14	Final Assembly of Sealing Head	21

Table of Tables

Table 1.1	Sealing Head Component Functions.....	2
-----------	---------------------------------------	---

1. Sealing Head Description

1.1 Product Overview

The Vante® Model 4105 Hand-Held Sealing Head (“the Sealing Head”) is part of a system which employs radio frequency (RF) to make uniform, quality seals on a variety of tubing sizes. A Vante® Power Source (Model 4380 or 4600) provides RF power to the Sealing Head and controls RF power and sealing time. The manually-activated Sealing Head forms a seal with its jaws in such a way as to make segment separation easy and uniform. The Sealing Head is equipped with a splash guard for operator protection from inadvertent contact with biopharmaceutical products in the unlikely event of tubing rupture.

1.2 Theory of Operation

The physical properties of PVC plastic tubing (and other RF-reactive thermoplastic materials) cause it to dielectrically heat at a molecular level in the presence of RF energy. This energy causes the plastic to soften due to the friction of the vibrating molecules. In this softened condition, the plastic becomes weldable because the molecules are free to intermingle under the application of external forces, such as compression. If allowed to cool while the forces are applied, the material will be permanently reshaped.

The Sealing Head receives a controlled amount of RF energy from the generator while mechanically compressing the tubing across its diameter during the dielectric sealing and forming process. When the energy is removed and the tubing is allowed to cool under compression, a permanent seal is produced.

1.3 Component Identification

Table 1.1 indicates the function of each component included with the Sealing Head.

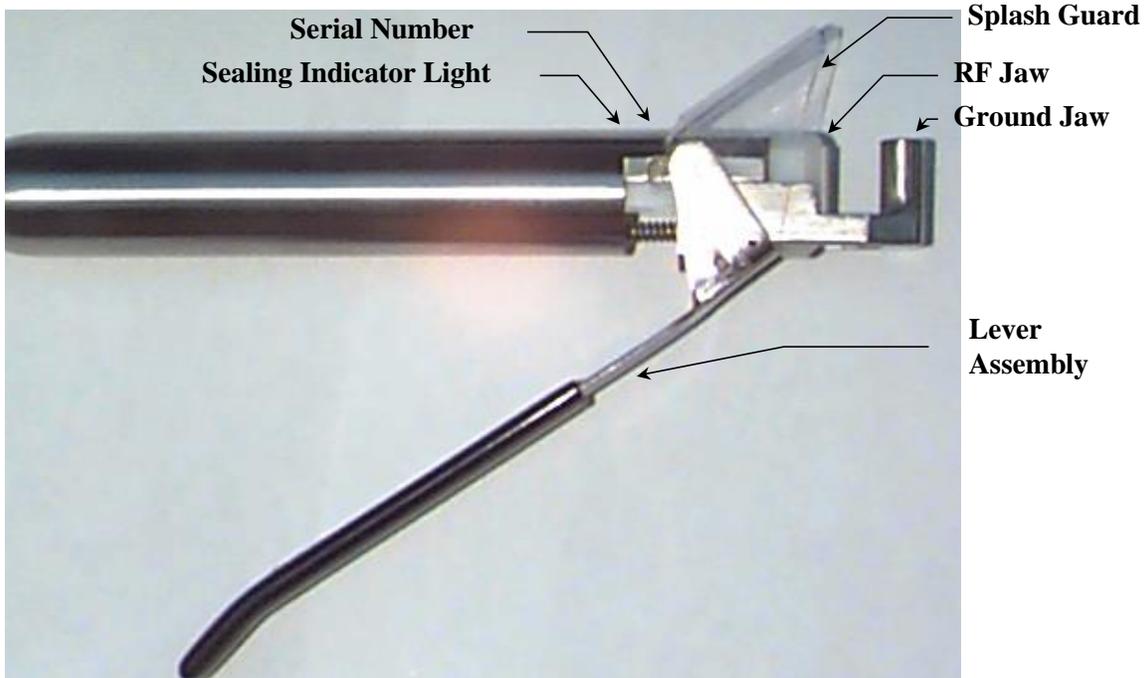


Figure 1.1 Model 4105 Hand Held Sealing Head

Component	Function
Lever Assembly	Compresses the tubing between the jaws and activates the sealing process.
RF Jaw	Compresses tubing with ground jaw while applying RF.
Ground Jaw	Grounds RF as it is applied and molds tubing.
Splash Guard	Attached to the lever of the Model 4105. Protects the operator from accidental exposure to biopharmaceutical products in the unlikely event of a tubing rupture.
Sealing Indicator Light	Light on Sealing Head that indicates duration of RF power. The Sealing Head jaws <i>must</i> remain closed until <i>two seconds after</i> the indicator light turns completely off.
Serial Number	Indicates the serial number. Please make note of this number when calling the Vante® Customer Service Department.

Table 1.1 Sealing Head Component Functions

1.4 Environment

The Sealing Head will perform effectively when used in a typical biopharmaceutical processing facility or environment. Variations in actual environmental conditions of the facility and/or the level of contamination and/or moisture on the ground and RF jaws and/or tubing type, size and exterior may affect actual performance. Users are advised that when temperature and humidity conditions seem less than what might be considered comfortable for humans, it is best to slow the rate of repetitive sealing, to be certain the Sealing Head and tubing are clean and dry, and to frequently check the quality of seal being produced.

Mechanical

Dimensions (Lever compressed):	8.0 in. L x 1.5 in. W x 1.0in. H (20.3cm L x 3.8cm W x 2.5cm H)
Operating weight	0.6 lb (0.3 kg)
Shipping weight (Boxed system):	2.0 lb (0.9 kg)

This page intentionally left blank.

2. Sealing Head Operation

2.1 Setup

Remove the components from their protective shipping containers and visually inspect them for obvious damage. Contact an authorized Vante® service center if any damage is found.

NOTE: If possible, retain shipping containers and packing materials for future use.

2.2 Splash Guard Installation

NOTE: The Sealing Head assembly comes with a clear plastic splash guard to provide operator protection in the event of a tubing rupture during sealing. Extra splash guards are provided with each shipment and are available for purchase from Vante.®

Ensure the RF power cable is disconnected from the Sealing Head.

WARNING: Failure to separate the Sealing Head from the power source prior to removing or attaching the splash guard may result in an RF burn.

Fold tab and sides A & B at perforations of the new splash guard. Remove plastic cutout opposite of tab and discard. See Figure 2.1.

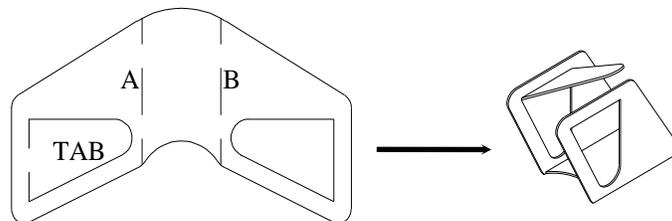


Figure 2.1 Tab and Sides A & B of Splash Guard

Close lever and place around head of sealer. Insert tab into the splash guard opening on opposite side. See Figure 2.2.

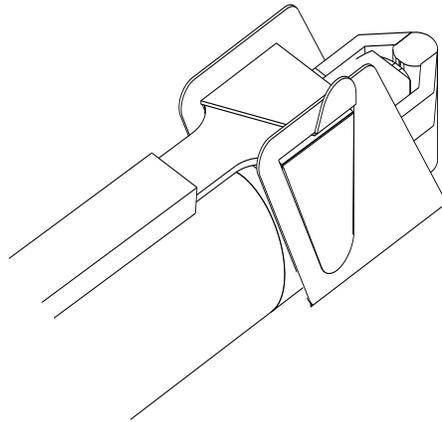


Figure 2.2 Splash Guard Tab

Position splash guard so sides of lever protrude through openings. Bend end of tab to lock into position.



Figure 2.3 Final Attachment of Splash Guard

See the Generator Instruction Manual for proper setup.

2.3 Sealing Procedure

For sealing and segmenting tubing, hold the Sealing Head in the palm of either hand with the fingers on the moveable lever so that the splash guard and sealing indicator light face the operator, as shown in Figure 2.4. In this position, the tubing can be easily placed into the space (“sealing region”) between the RF and ground jaws, sealed, and *pushed* through the region to the next sealing position by the operator's free hand.

WARNING: The sealing region *must* open facing upward so the operator may ensure that the tubing or bag is fully seated between the RF jaw and ground jaw and clearly observe the sealing indicator lamp on the Sealing Head.

WARNING: Do NOT pull the tubing or bag through the sealing region. Under *no* circumstances should the tubing be pulled at the instant of sealing. An opening in the tubing could occur which will subject the product or media to non-sterile conditions and the user to potentially hazardous fluids. In addition, the Sealing Head may become damaged by arcing caused by contamination of the sealing region.

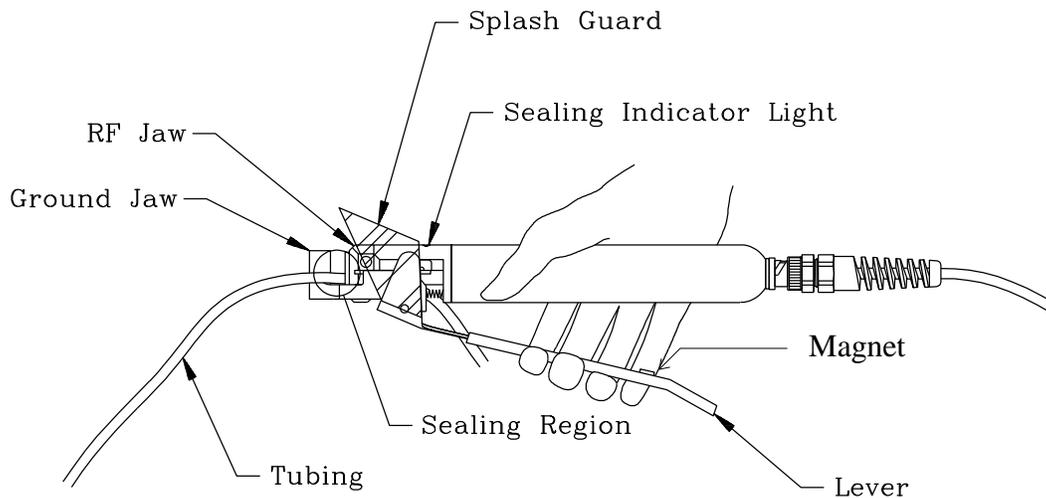


Figure 2.4 Correct Technique for Holding the Sealing Head

WARNING: Do not place fingers in close proximity to the sealing region while sealing. Doing so will subject the operator to a radio frequency burn hazard and will not allow for good magnet-Sealing Head body contact, resulting in poor or ruptured seals.

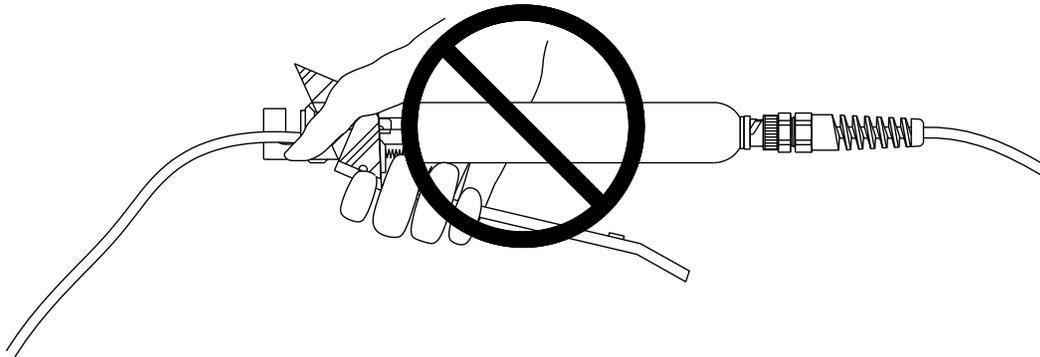


Figure 2.5 Incorrect Technique for Holding the Sealing Head

To make a seal, squeeze the lever until the magnet on the lever touches the Sealing Head body, and hold it there (Figure 2.6). This action compresses the tubing and activates the sealing energy, visually indicated by the illumination of the sealing indicator light. *Continue to squeeze the lever for two seconds after the sealing indicator light goes completely out.*

WARNING: Dimming of the indicator light will occur, but do not release the lever until two seconds *after* the indicator light is completely off! Premature lever release will cause incomplete sealing and/or ruptured tubing. Holding the lever closed will *not* cause overheating or burn-through of the tubing.

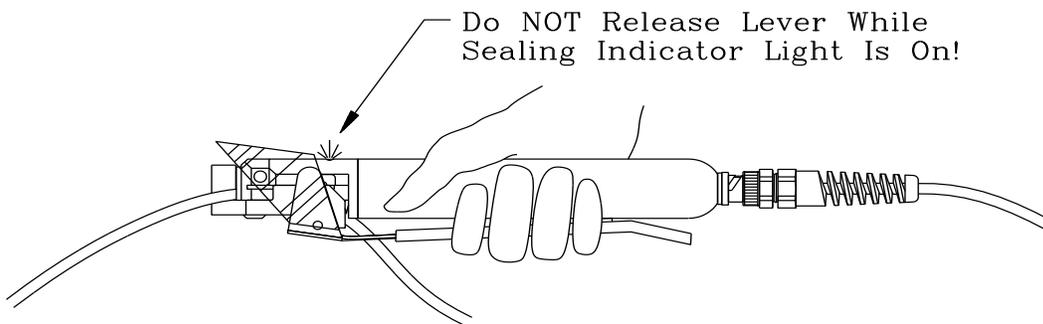


Figure 2.6 Maintaining Compression During the Entire Sealing Process

CAUTION: Never squeeze the lever when non RF-reactive materials are in the sealing region, or if the RF power source is not connected and turned on. Damage to the lever and poor Sealing Head operation may result.

Although RF remains on for approximately one second, as indicated when the light on the Sealing Head goes out, the lever should not be released until two seconds after the RF light goes out. *Another seal cannot be made until the moveable lever has been fully opened.* See Figure 2.7. At this time the tubing segments can be easily separated by manually turning and pulling with a slight snap.

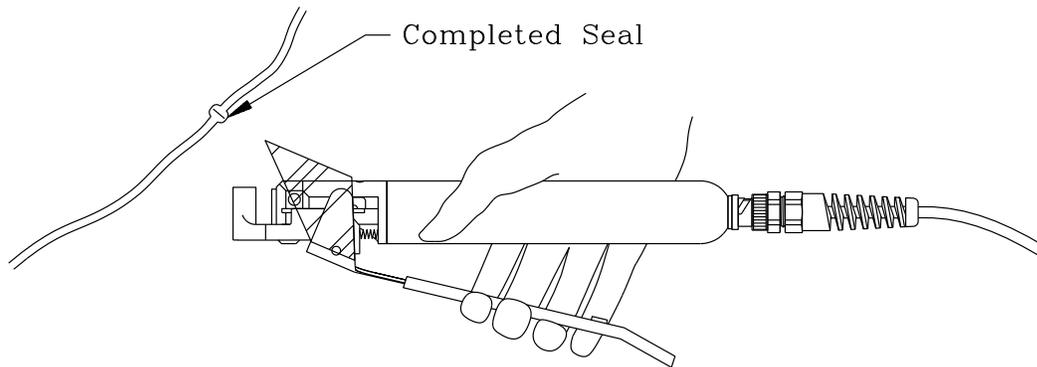


Figure 2.7 Releasing the Sealing Head Lever at Seal Completion

NOTE: Seals on large tubing may require an additional lever hold down time after the indicator light goes out to ensure formation of the best seal.

WARNING: Under *no* circumstances should the tubing or bag be separated by pulling it while the indicator light is illuminated. This action may cause an opening in the tubing, which will subject the product or media to non-sterile conditions and the user to potentially hazardous fluids. In addition, the Sealing Head may become damaged by arcing due to contamination of the sealing region.

WARNING: If you observe arcing while making a seal, follow the instructions in the Troubleshooting Guide under “Arcing or Bad Seals”. Although a seal made when you experience arcing may look acceptable, it may be inadequate. Take precautions as if this is an inadequate seal.

2.4 Seal Spacing

NOTE: The Sealer is designed to allow repetitive seals to be made on a length of tubing filled with biopharmaceutical products. However, several factors control how closely the seals may be spaced.

General Guidelines

Seals which progress along an open-ended length of tubing may be spaced as desired, but ½ inch (1 cm) is the recommended minimum.

Seals which progress along a close-ended length of tubing, as in a segmenting process, must be spaced approximately one inch (2.5 cm) to avoid rupture of the tubing due to pressure build-up.

WARNING: Never attempt to make segmentation seals closer than recommended without validating for seal integrity.

WARNING: Multiple seals spaced less than the recommended distance may cause a rupture of a sealed tubing segment.

3. Cleaning the Sealing Head

WARNING: To obtain satisfactory seals at all times, be sure the sealing region and all adjacent areas are always kept clean and dry.

CAUTION: Do NOT, under any circumstances, submerge the Sealing Head in any kind of liquid. This will damage the RF jaw/tube assembly and void the warranty.

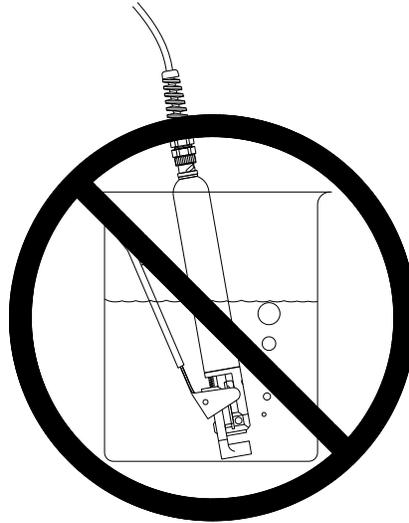


Figure 3.1 Incorrect Cleaning Technique

NOTE: Other than periodic cleaning or when moisture or other contaminants are visible, the Sealing Head is designed to be maintenance free and to withstand substantial wear and tear. However, damage may occur as a result of dropping any of the major components, *i.e.*, the Sealing Head or the power source. If any component is dropped, examine for obvious damage and confirm functionality before using. Verify the movement of the ground jaw while squeezing the lever. The RF jaw and ground jaw should just touch with approximately 1/8 inch gap between the lever magnet and the Sealing Head body (see Figure 3.2). Contact Vante® if the Sealing Head fails to operate properly.

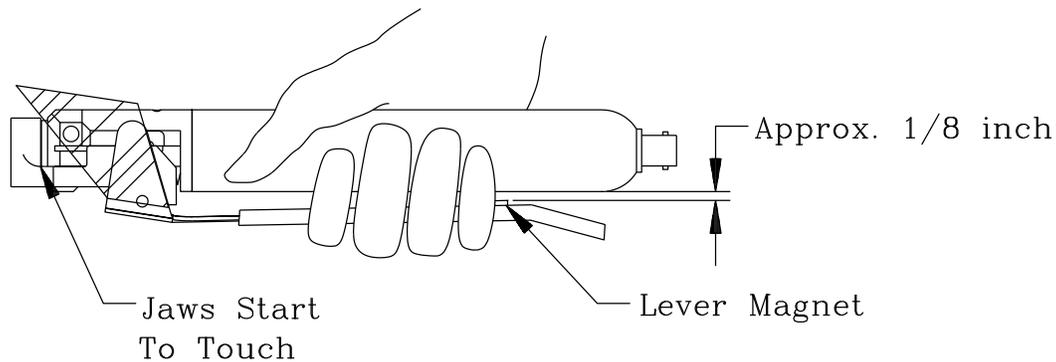


Figure 3.2 Correct Lever/Sealing Body Gap

3.1 Topical Cleaning of the Sealing Region

NOTE: Units returned to Vante® for repair are subject to biohazard charges if any Sealing Head component is contaminated with biopharmaceutical products. See the beginning of this chapter for the recommended cleaning.

WARNING: Topical cleaning of the Sealing Head is performed in this section using denatured or isopropyl alcohol. The user should follow the alcohol manufacturer's recommendations for usage and be sure that the product material safety data sheet is carefully understood and observed.

NOTE: The illustrations in this section show the splash guard removed for clarity. However, to perform a topical cleaning, it is not necessary to remove the splash guard.

Disconnect the Sealing Head from the power source by removing the RF power cable at the Sealing Head.

WARNING: Failure to separate the Sealing Head from the generator prior to cleaning may result in an RF burn to the operator during the cleaning process.

Hold the Sealing Head with the sealing region upward thereby exposing the space between the ground and RF jaws.

Clean the open sealing region with alcohol (denatured or isopropyl) applied to one end of a cotton swab, as shown in Figure 3.3. *Be sure the RF power cable is disconnected from the Sealing Head!*

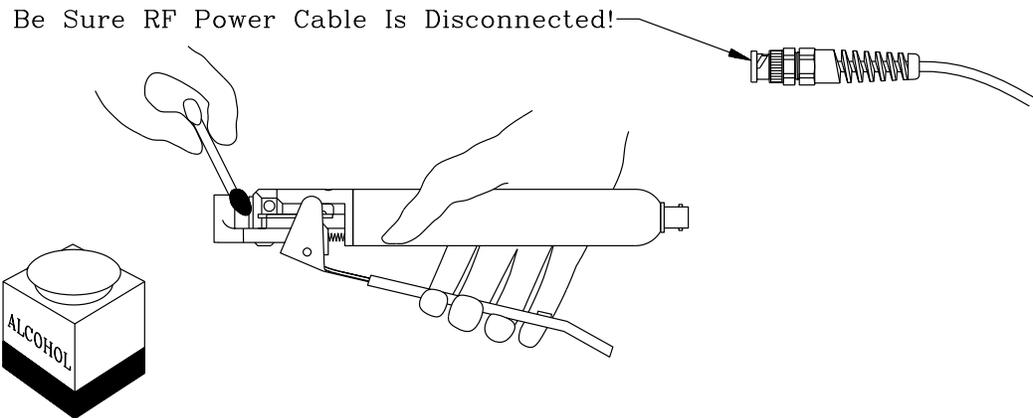


Figure 3.3 Cleaning the Sealing Region

After cleaning the contaminated areas of the sealing region, immediately dry with the dry end of the cotton swab (Figure 3.4).

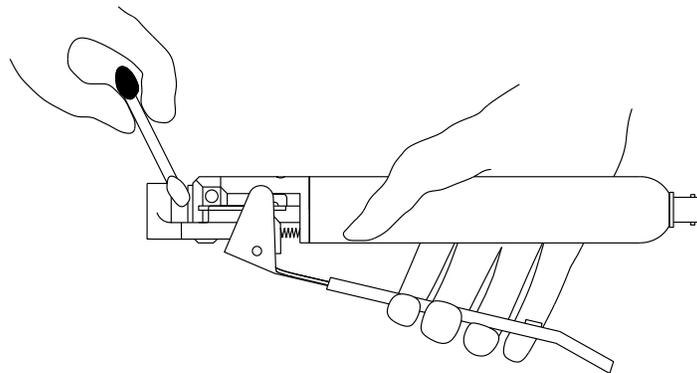


Figure 3.4 Drying the Sealing Region

Clean all areas adjacent to the sealing region using an alcohol-moistened cotton swab, giving special attention to grooves and other recesses where fluids or other contaminants may become trapped. Be sure to dry immediately with the dry end of the cotton swab. Cleaning can be facilitated by squeezing the lever to expose contaminated areas along the sides of the ground jaw and RF jaw (see Figure 3.7 and Figure 3.8). *Be sure the RF power cable is disconnected from the Sealing Head!*

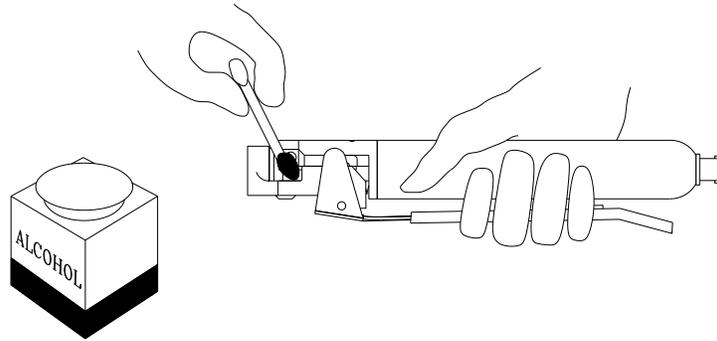


Figure 3.5 Cleaning Ground and RF Jaw Surfaces

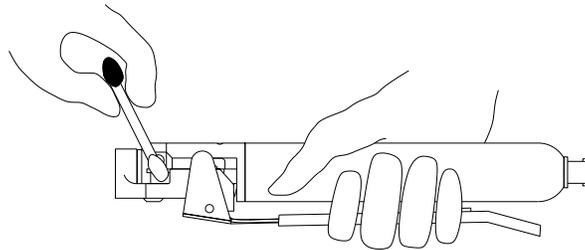


Figure 3.6 Drying Ground and RF Jaw Surfaces

Verify the movement of the ground jaw while squeezing the lever before returning the Sealing Head to service. The sealing region should close evenly *before* the lever comes in contact with the tube body (see Figure 3.2).

If the above procedure does not result in satisfactory performance, see Sections 3.2, 3.3 and 3.4, “Disassembly of the Sealing Head,” “General Cleaning of the Sealing Head” and “Reassembly of the Sealing Head,” respectively.

Properly dispose of all used cleaning materials.

3.2 Disassembly of the Sealing Head

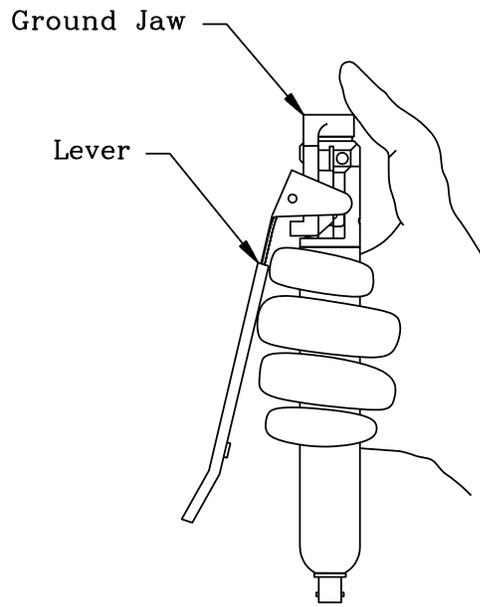
NOTE: The Sealing Head is designed for quick disassembly for cleaning ease. Vante® recommends inspecting the Sealing Head daily when in high use applications. If biopharmaceutical products are present, follow this procedure to clean the Sealing Head.

Disconnect the Sealing Head from the power source by removing the RF power cable at the Sealing Head.

WARNING: Failure to separate the Sealing Head from the power source prior to cleaning may result in an RF burn during the disassembly process.

Remove the splash guard from the lever. Properly dispose of the used splash guard, if necessary.

Holding the Sealing Head in a vertical position, use thumb to completely close the ground jaw, thereby releasing the ground jaw spring tension and the resulting force on the lever as shown in Figure 3.2. If required, additional leverage may be obtained by placing the connector end of Sealing Head tube on a padded surface. *Be sure the RF power cable is disconnected from the Sealing Head!*



Be Sure RF Power Cable Is Disconnected!

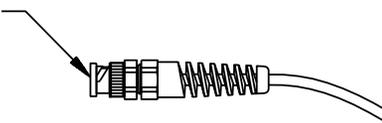


Figure 3.7 Releasing Spring Tension in Sealing Head

Slightly release the ground jaw. Remove the lever by rotating it away, and pulling it down from the RF jaw as shown in Figure 3.8. Remove ground jaw by pulling jaw up and away as shown in Figure 3.8. *Be sure the RF power cable is disconnected from the Sealing Head!*

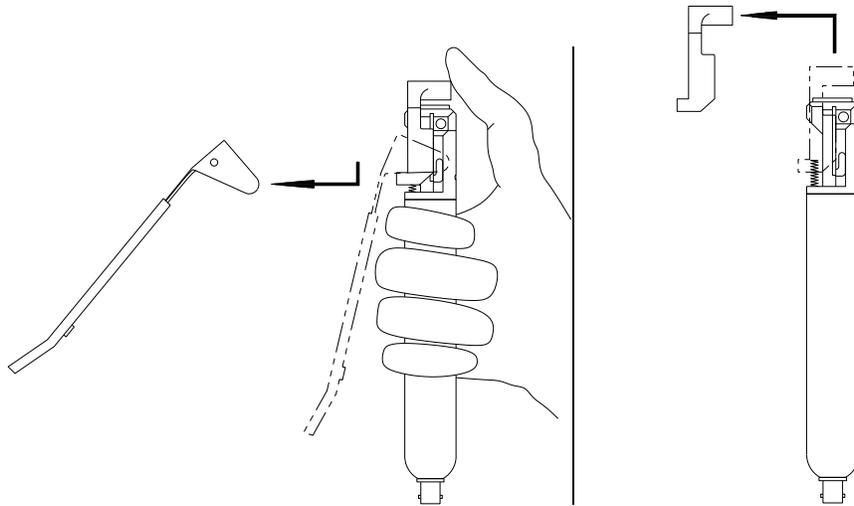


Figure 3.8 Removing the Lever and Ground Jaw

Note that three separate components, the lever, the ground jaw and the RF jaw/tube assembly are now easily accessible for individual cleaning.

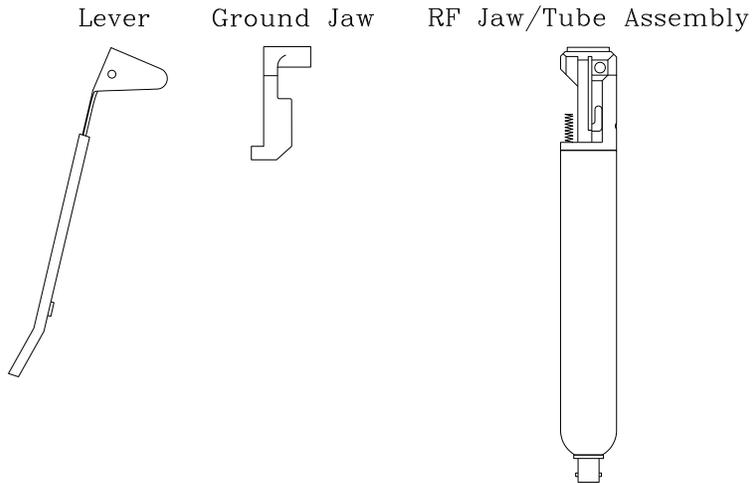


Figure 3.9 Sealing Head Components

3.3 General Cleaning of the Sealing Head

Once the Sealing Head is disassembled (see Section 3.2 for step-by-step instructions), use Amphyl® or equivalent to disinfect (follow manufacturer's instructions). Use alcohol applied to a cotton swab to clean the ground jaw and RF jaw, paying particular attention to the small grooves and slots on the plastic portion of the head (see Figure 3.10). Be sure to clean all areas which may have been subjected to contamination.

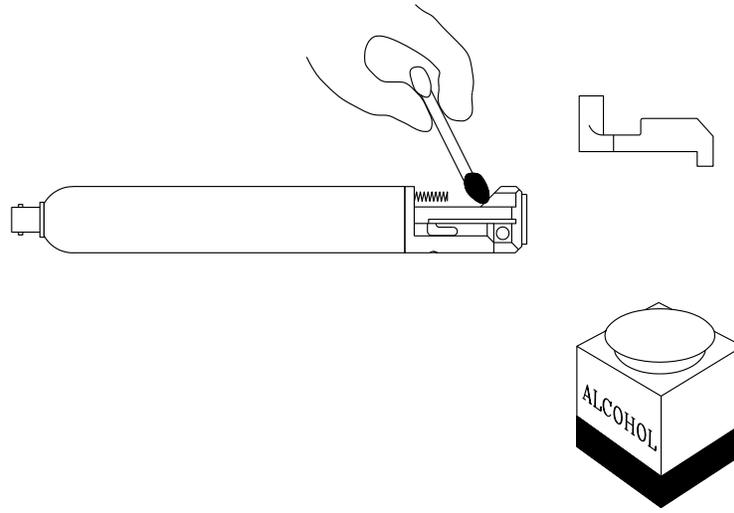


Figure 3.10 Cleaning Individual Sealing Head Components

Dry the separate Sealing Head components thoroughly with a dry paper towel or cheesecloth before reassembling. *Do not reinstall a splash guard on the lever until the Sealing Head has been reassembled.*

Clean splash guard with alcohol or bleach solution.

3.4 Reassembly of the Sealing Head

To reassemble the Sealing Head, slide the ground jaw onto the RF jaw/tube assembly. Note mating tabs on each of the internal sides of the ground jaw and mating grooves on both sides of the RF jaw (see Figure 3.11). *Be sure the RF power cable is disconnected from the Sealing Head.*

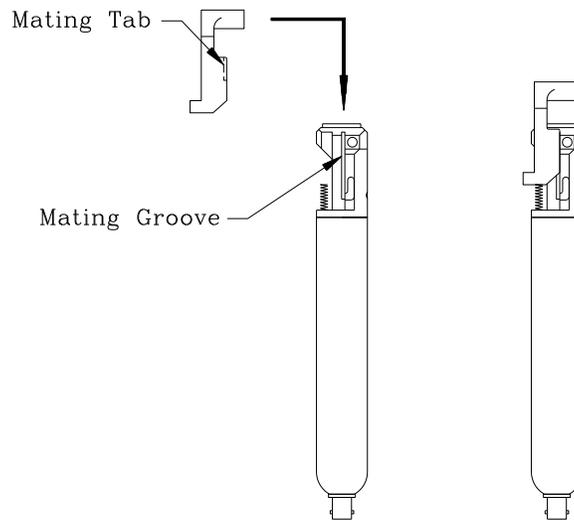


Figure 3.11 Installation of Ground Jaw onto RF Jaw/Tube Assembly

With thumb, slide ground jaw down the grooves in the RF jaw, maintaining constant pressure to depress the ground jaw spring. Replace lever so that its internal pivot pins slide in beneath the bottom edge of the ground jaw and are positioned to enter into the pivot pin slots (see Figure 3.12 and Figure 3.13). A small adjustment of the position of the ground jaw may be required to engage the lever. *Be sure the RF power cable is disconnected from the Sealing Head!*

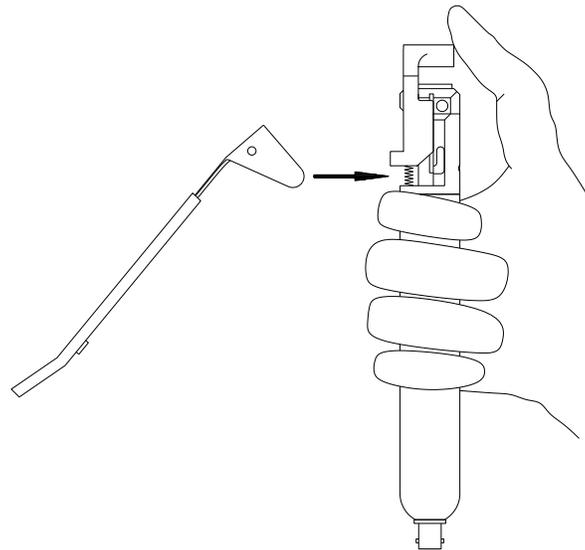


Figure 3.12 Installation of Lever on to Sealing Head

Continue to hold the ground jaw in its retracted position and tip the lever up so the lever roller clears the ground jaw stop. Small adjustments in thumb pressure may be required to accomplish this action. Firmly push the lever to engage its internal pivot pins into their respective slots while slowly releasing ground jaw. See detail in Figure 3.13.

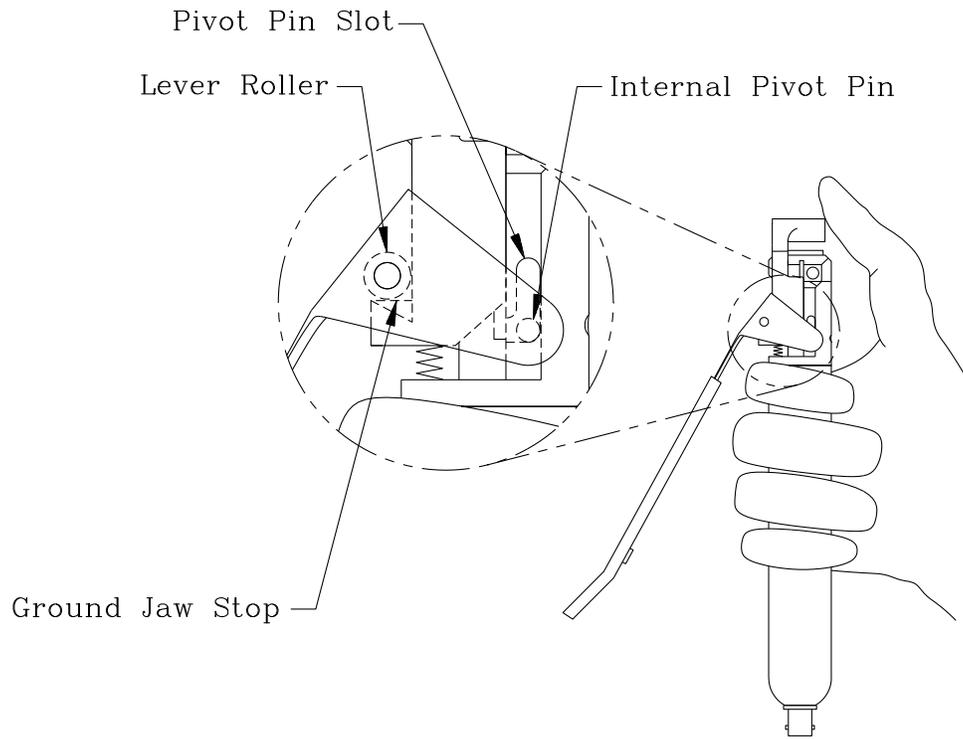


Figure 3.13 Installation of Lever into Pivot Slots

When the thumb is released, the lever should fully engage and secure the ground jaw on the RF jaw/tube assembly, as depicted in Figure 3.14.

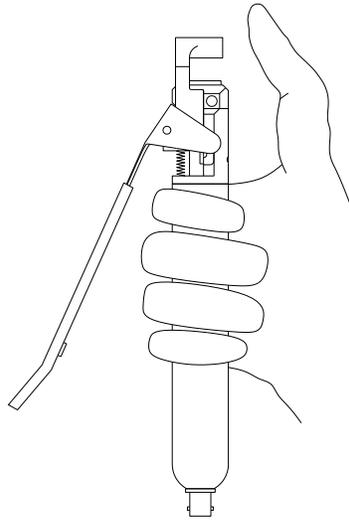


Figure 3.14 Final Assembly of Sealing Head

Verify the Sealing Head's mechanical functions by squeezing the lever. The sealing region should close evenly *before* the lever comes in contact with the tube body (see Figure 3.2).

Attach the splash guard (Section 2.2).

This page intentionally left blank.

4. Repair

4.1 Troubleshooting

Problem	Cause	Action
Sealing Head “Arcs” (“Arcing” is indicated by a flash of blue light at the time of sealing.)	Gap in jaw area when lever is completely closed.	Spring too long. See “Spring Replacement,” Section 4.2.
	Lever assembly out of alignment.	See Figure 3.2 for proper alignment.
	Ground jaw bent out of position.	Call Vante®.
	Tubing or sealing region is moist or contaminated.	Ensure the outside of the tubing, the sealing region and adjacent areas are free of moisture and any other contaminants.
	Sealing Head held improperly.	Ensure the Sealing Head is being held properly (see Figure 2.4), with the sealing region opening upright.
	Sealing Head lever released prematurely.	Ensure the sealing indicator light is completely out before releasing the Sealing Head lever.
	Tubing not properly clamped in sealing region.	Ensure the sealing region closes evenly <i>before</i> the lever comes in contact with the tube body (see Figure 3.2).
Bad seals or intermittent seals occur.	Sealing Head/power source combination may not give optimum performance.	Check to see if another Sealing Head connected to the power source gives better results.
	Improper tubing material is being sealed.	Ensure tubing falls within specifications.
	Tubing not properly clamped in sealing region.	Ensure the sealing region closes evenly before the lever comes in contact with the tube body (see Figure 3.2).
	Short in RF cable.	Try new RF cable (Model 1103).
	Broken reed switch due to impact/age.	Call an authorized Vante® repair center.

4.2 Spring Replacement

4.2.1 Turn off the power supply and disconnect the Sealing Head from the RF cable.

WARNING: Failure to disconnect Sealing Head from the power supply prior to replacing the spring may result in an RF burn.

4.2.2 Disassemble and clean the Sealing Head according to the procedure outlined in Section 3.

4.2.3 Remove all of the old spring and adhesive. Using either the de-soldering tool or a large paper clip, remove the old pieces of spring from the Sealing Head spring hole. Then, using either the soldering tool or the paper clip, scrape the bottom of the hole and remove as much of the old silicone adhesive as possible.

4.2.4 Insert a cotton swab and rapidly rotate it with your fingers to remove, by friction, any adhesive that may still remain. Repeat this process as often as necessary to ensure that ALL old adhesive has been removed from the hole.

CAUTION: Adding a new spring without completely removing the old spring and adhesive will result in poor seals and possible ruptured tubing.

NOTE: Due to manufacturing tolerances, a spring may sometimes be too long.

4.2.5 Assure the proper spring length by first assembling the Sealing Head without using adhesive. Position the spring in the Sealing Head spring hole.

4.2.6 Reassemble the Sealing Head according to procedure outlined in Section 3.4.

4.2.7 After assembly, squeeze the lever. The sealing jaws should come completely together *before* the lever comes in contact with the tube body. If the jaws do touch, go to Step 4.2.9.

WARNING: Wear safety glasses while using the diagonal cutters. The spring pieces may be sharp and fly a considerable distance at high velocity.

4.2.8 If the jaws do not come completely together, disassemble and, using the 4 inch diagonal cutters (wire cutters), cut one coil off of the spring and return to Step 4.2.5. Repeat Steps 4.2.5-4.2.7 as often as required to obtain the desired spring length (i.e., until the jaws touch with no gap).

4.2.9 When the correct jaw closure is obtained, disassemble the Sealing Head and apply a small amount of silicone adhesive to the bottom cut coil of the spring.

NOTE: The silicone adhesive will hold the spring in the hole when the Sealing Head is taken apart for cleaning and maintenance.

4.2.10 Place the spring back in the hole, silicone end first.

4.2.11 Reassemble the Sealing Head according to procedure outlined in Section 3.4.

4.2.12 Allow the Sealing Head to sit for at least one hour before attempting to seal.

4.3 Returning a Unit for Repair

The Sealing Head is designed to be maintenance free, except for cleaning and occasional spring replacement. Do not attempt any other field repair. Questions regarding repairs should be directed to an authorized Vante® repair center.

To return the Sealing Head to Vante® for repair, call the Customer Service Department for an RMA (Return Material Authorization) number. Clean the Sealing Head of any biopharmaceutical products. Use the original shipping containers and packing material if possible. Otherwise, wrap the components separately in plastic bubble wrap or other suitable packing material that will provide sufficient shock protection. Place them in a shipping carton large enough to contain the individually wrapped components or place each one in its own shipping carton of suitable size.

<p>WARNING: Failure to properly package the components for shipping may increase any repair costs.</p>

NOTE: Units returned to Vante® for repair are subject to biohazard charges if any Sealer component is contaminated with media or other potentially biohazardous materials.

This page intentionally left blank.

5. Radio Frequency System Safety Considerations

5.1 General Information

Vante® manufactures a variety of instruments which incorporate the use of radio frequency (RF) for sealing, welding, or forming thermoplastics. Typical uses include biopharmaceutical tube sealing, thermoplastic welding and thermoplastic forming processes. When in operation, these RF instruments emit radio frequency energy to people, other instruments, and equipment located in close proximity. Current Vante® RF instruments operate at a frequency authorized by the Federal Communications Commission (FCC) and the International Telecommunications Union (ITU) for industrial, scientific, and medical (ISM) use. The following is an advisory regarding RF instrument use and associated safety considerations.

5.2 RF Effects On Human Tissue

Misuse or direct contact between tissue and RF electrode(s) can result in severe RF burns.

5.3 RF Effects On Pacemakers

There is no evidence that Vante® RF instruments interfere with the function of modern cardiac pacemakers.

5.4 Electrical Safety

Vante® RF devices meet or exceed appropriate electrical safety standards and pose no electrical shock hazard when used with properly fused and grounded outlets.

5.5 RF Effects On Electronic Equipment

Vante® instruments produce RF power and, during operation, emit some RF energy from the electrodes. While most modern electronic equipment and instruments provide shielding from RF energy, improperly shielded electronic devices operating in close proximity to an RF instrument may be affected. If interference is suspected, appropriate electronic shielding, moving equipment further away from the RF instrument or operating from a different electrical circuit may be necessary.

5.6 RF Effects In Potentially Explosive Atmospheres

Do not operate Vante® RF instruments in any area with a potentially explosive atmosphere. It is possible for the RF electrodes to arc, initiating an explosion or fire.

NOTE: Vante® recommends strict adherence to the procedures specified in the instrument Instruction Manual. Misuse or modification of an instrument may result in unsafe or hazardous situations.