



SEBRA®

operation manual

VT-108724-US

Model 1105
Hand-Held
Sealing Head

VANTE INC
IGNITING INNOVATION



CONSUMER INFORMATION

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Disclaimer

This manual is intended as a guide to provide the operator with necessary instructions on the proper use and maintenance of certain Vante products. This manual should be used in conjunction with instruction and training supplied by qualified Vante personnel.

Any failure to following the instructions as described could result in impaired product function, injury to the operator or others, or void applicable product warranties. Vante accepts no responsibility for liability resulting from improper use or maintenance of its products.

Utilization of Vante products may require the operator to handle and dispose of blood-contaminated material. An operator must fully understand and implement all regulations governing the safe handling of blood products and waste, including the policies and procedures of their facility.

Handling and use of any blood products collected using Vante equipment are subject to the decisions of the attending physician or other qualified medical personnel. Vante makes no warranty with respect to such blood products.

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PRELIMINARY INFORMATION

Document scope This manual is a guide for the operation, care, and maintenance of the Vante® SEBRA® Model 1105 Hand-Held Sealing Head.

Intended audience This manual is intended for use by nursing, supervisory and/or administrative personnel having technical skills and a thorough knowledge of the procedures for collecting blood and who understand that this product is to be used at their own discretion and risk.

SYMBOLS

Symbols found in this document The terms *Note*, *Caution* and *Warning* are used in this manual with the following symbols to notify the operator of important and/or critical information.



Note: provides useful information regarding a procedure or operating technique when using Vante material.



Caution: *advises the operator against initiating an action or creating a situation that could result in damage to equipment, or impair the quality of the blood products; personal injury is unlikely.*



Warning: **advises the operator against initiating an action or creating a situation that could result in serious personal injury to the donor, the operator, or the blood product recipient.**

Symbols found on the device

The following symbols may be found on the device or device packaging.



Caution, risk of electric shock



Clean with alcohol



Power off



Power on



Protective Earth (PE)



Fuse

PRODUCT OVERVIEW

The Vante® SEBRA® Model 1105 Hand-Held Sealing Head ("the Sealing Head") is part of a system that employs radio frequency (RF) to make uniform, quality seals on a variety of tubing sizes. A Vante® SEBRA® Power Source (Model *1100, *1090, *2100, 2380, *2390, *2490, or 2600) provides RF power to the Sealing Head and controls RF power and sealing time.



**Note: Not all of the Models listed above are currently sold or supported by Vante.*

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 splashguard for operator protection from inadvertent contact with blood and/or blood products in the unlikely event of tubing rupture.

Application

The Model 1105 Hand-Held Sealing Head is part of a system and cannot be used independently. When used in conjunction with a Vante® SEBRA® radio frequency (RF) generator, it is the instrument used to make seals on tubing or bags made of RF reactive thermoplastic materials typically used in blood banks, blood processing facilities and transfusion centers. Tubing or bags utilized in the collection and handling of blood and blood 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.

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.

COMPONENT IDENTIFICATION

The following figure indicates the function of each Model 1105 component.

1. Serial Number
2. Sealing Indicator Light
3. Splash Guard
4. RF Jaw
5. Ground Jaw
6. Lever Assembly

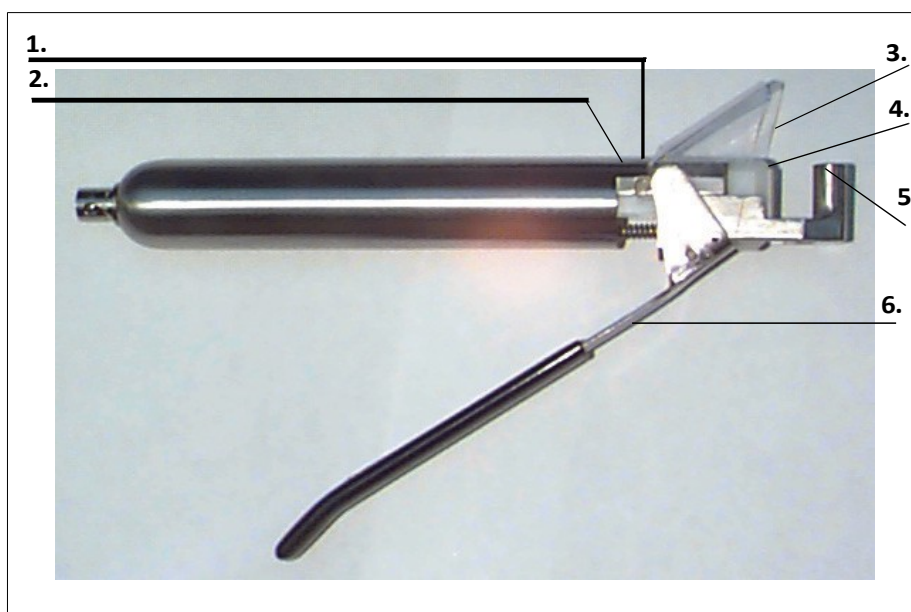


Figure 2-1, Model 1105 Hand-Held Sealing Head

Table 2-1 indicates the function of each component included with the Sealing Head.

Table 2-1, Sealing Head Component Functions

| 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 | Grinds RF as it is applied and molds tubing. |
| Splash Guard | Attached to the lever of the Model 1105. Protects the operator from accidental exposure to blood or blood 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 one second after the indicator light turns completely off. |
| Serial Number | Indicates the serial number. Please make note of this number when calling the Customer Care Center. |

SPECIFICATIONS

The Sealing Head will perform effectively when used in a typical blood bank, blood processing facility or transfusion center 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 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.

Table 2-2, Specifications

| PARAMETERS | SPECIFICATION |
|--------------------------------|------------------------------------------------------------------|
| Mechanical data | |
| 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 |

SETUP

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



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

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 in cartons of 25 (order part number 11054000).

1. Ensure that 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.

2. Fold tab and sides A and B at perforations of the new splash guard. Remove plastic cutout opposite of tab and discard. See Figure 3-1, Tab and Sides A and B of Splash Guard.

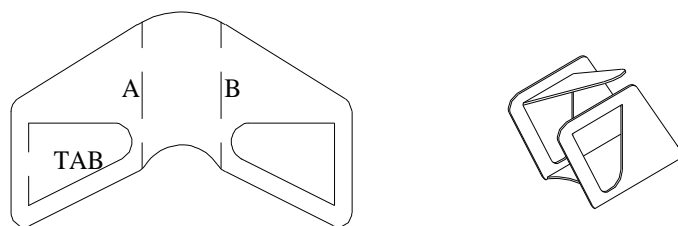


Figure 3-1, Tab and Sides A and B of Splash Guard

3. Close lever and place around sealer head. Insert tab into the splash guard opening on opposite side. See Figure 3-2, Splash Guard Tab.

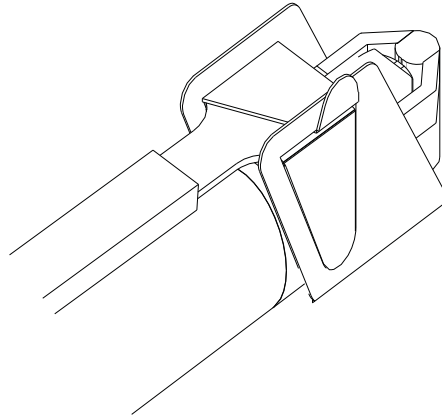


Figure 3-2, *Splash Guard Tab*

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

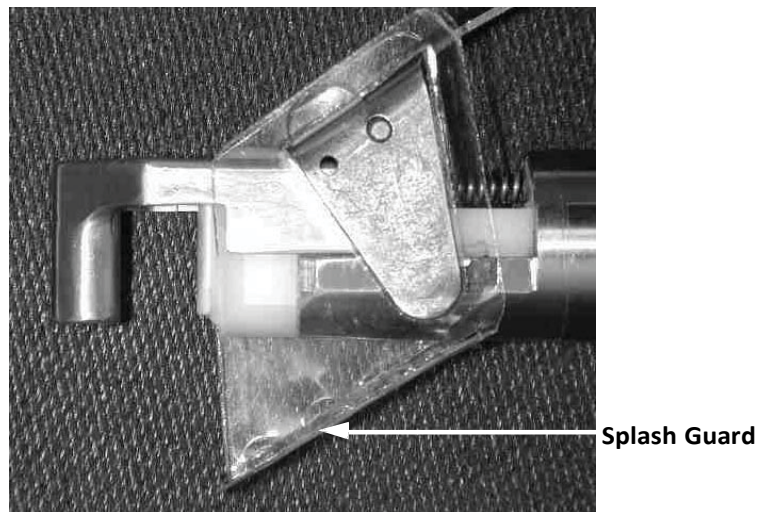


Figure 3-3, *Final Attachment of Splash Guard*

SEALING PROCEDURE

1. 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. 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 blood or plasma 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.

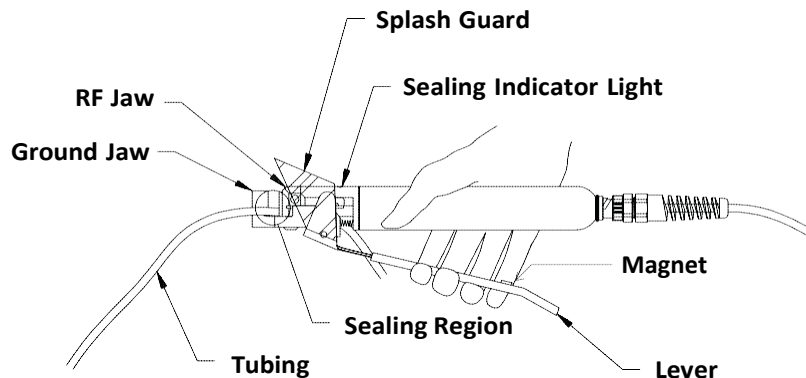


Figure 3-4, Correct Technique for Holding the Sealing Head



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.

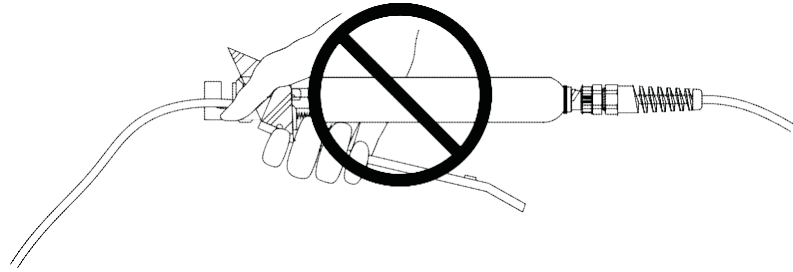


Figure 3-5, Incorrect Technique for Holding the Sealing Head

2. To make a seal, squeeze the lever until the magnet on the lever touches the Sealing Head body, and hold it there. See Figure 3-6, Maintaining Compression During the Entire Sealing Process. 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 until one second after the sealing indicator light goes completely out.*



NOTE: Increase hold down for larger tubing or rapid sealing.



Warning: Dimming of the indicator light will occur, but do not release the lever until one second 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.

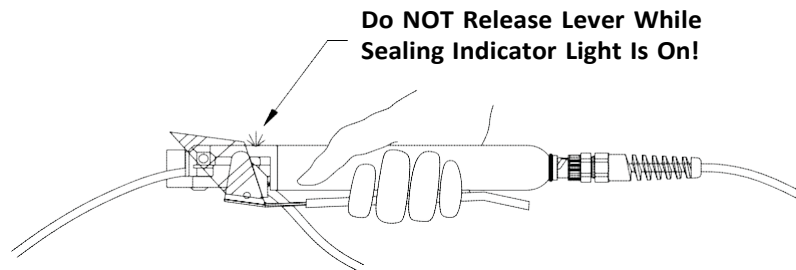


Figure 3-6, Maintaining Compression During the Entire Sealing Process



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.

3. The seal is completed in approximately one second, as indicated when the light on the Sealing Head goes out one second after the lever may be released. *Another seal cannot be made until the moveable lever has been fully opened.* See Figure 3-7, Releasing the Sealing Head Lever at Seal Completion. At this time the tubing segments can be easily separated by manually turning and pulling with a slight snap.

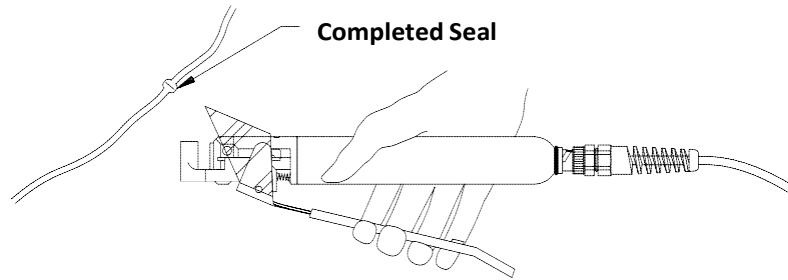


Figure 3-7, Releasing the Sealing Head Lever at Seal Completion



Note: Seals on large cell wash tubing may require an additional lever hold down time of approximately 1½ seconds after the indicator light goes out to ensure formation of the best seal. Typically, this may result in a total seal time (including additional hold down) of 2 seconds.



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 blood or plasma 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 for centrifugation. Take precautions as if this is an inadequate seal.

SEAL SPACING



Note: The Sealer is designed to allow repetitive seals to be made on a length of tubing filled with blood or blood products. However, several factors control how closely the seals may be spaced. For standard blood bag tubing, follow the instructions provided by the bag manufacturer.

General Guidelines

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

Seals that 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.

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.

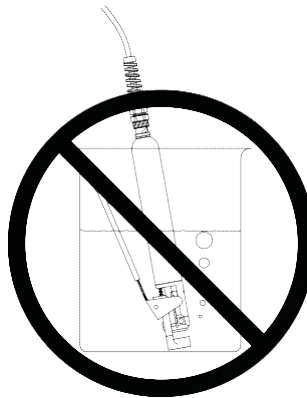


Figure 4-1, Incorrect Cleaning Technique



Note: Other than periodic cleaning, or when moisture, blood or other contaminants are visible, the Sealing Head is designed to be maintenance free; 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. Contact Vante if the Sealing Head fails to operate properly.

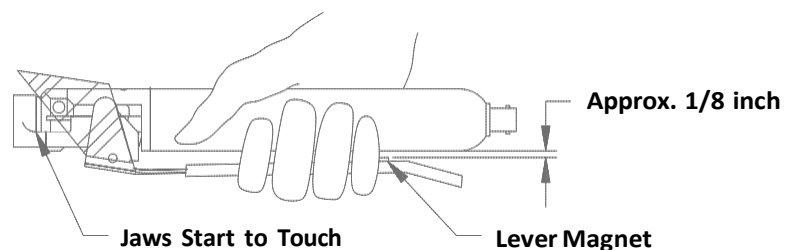


Figure 4-2, Correct Lever/Sealing Body Gap

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 blood or blood 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.

1. Turn off power to sealer, 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.

2. Hold the Sealing Head with the sealing region upward thereby exposing the space between the ground and RF jaws.
3. Clean the open sealing region with alcohol (denatured or isopropyl) applied to one end of a cotton swab. See Figure 4-3, Cleaning the Sealing Region. *Be sure the RF power cable is disconnected from the Sealing Head!*

Be Sure RF Power Cable Is Disconnected!

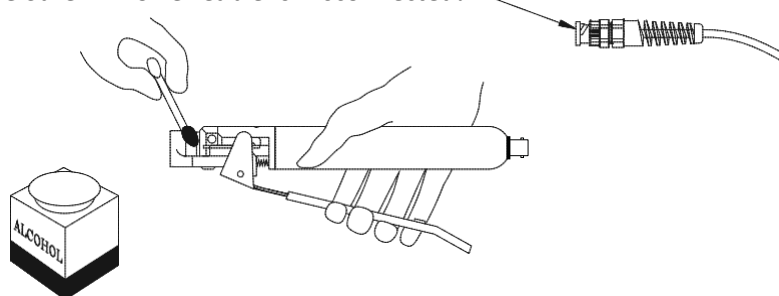


Figure 4-3, Cleaning the Sealing Region

4. After cleaning the contaminated areas of the sealing region, immediately dry with the dry end of the cotton swab. See Figure 4-4, Drying the Sealing Region.

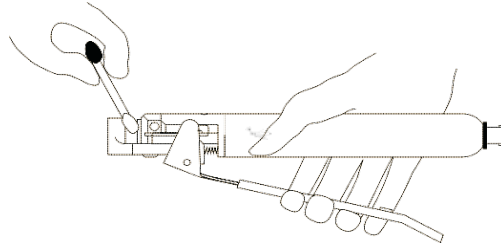


Figure 4-4, Drying the Sealing Region

5. 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 4-5, Cleaning Ground and RF Jaw Surfaces and Figure 4-6, Drying Ground and RF Jaw Surfaces. *Be sure the RF power cable is disconnected from the Sealing Head!*

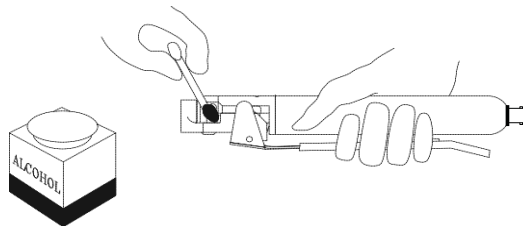


Figure 4-5, Cleaning Ground and RF Jaw Surfaces

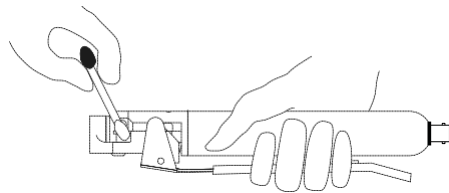


Figure 4-6, Drying Ground and RF Jaw Surfaces

6. 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.
7. If the above procedure does not result in satisfactory performance, see Disassembly of the Sealing Head on page 4-6, General Cleaning of the Sealing Head on page 4-8, Reassembly of the Sealing Head on page 4-9.
8. Properly dispose of all used cleaning materials.

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 (continuous and maximum mode sealing) applications. If blood products are present, follow this procedure to clean the Sealing Head.

1. Turn off power to Sealer, 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.

2. Remove the splash guard from the lever. Properly dispose of the used splash guard, if necessary.
3. 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. See Figure 4-7, Releasing Spring Tension in Sealing Head. 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!*

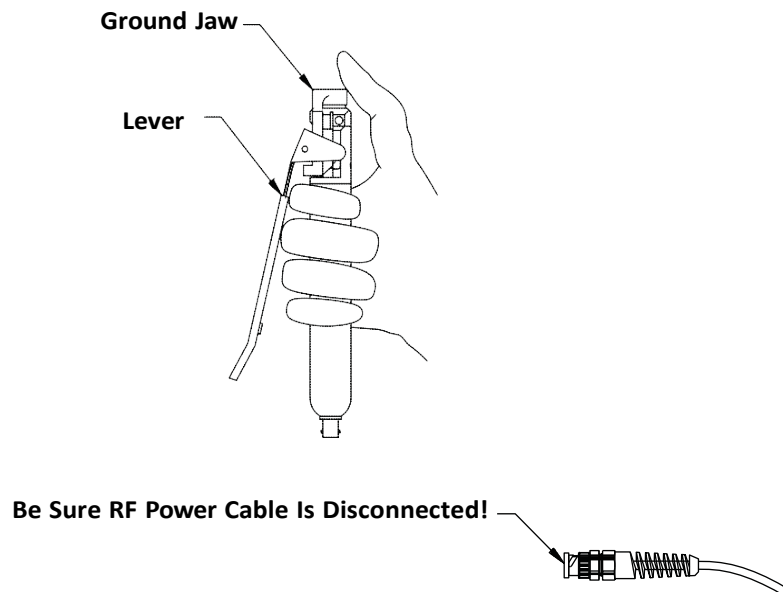


Figure 4-7, Releasing Spring Tension in Sealing Head

4. *Slightly* release the ground jaw. Remove the lever by rotating it away, and pulling it down from the RF jaw. Remove ground jaw by pulling jaw up and away. See Figure 4-8, Removing the Lever and Ground Jaw. *Be sure the RF power cable is disconnected from the Sealing Head!*

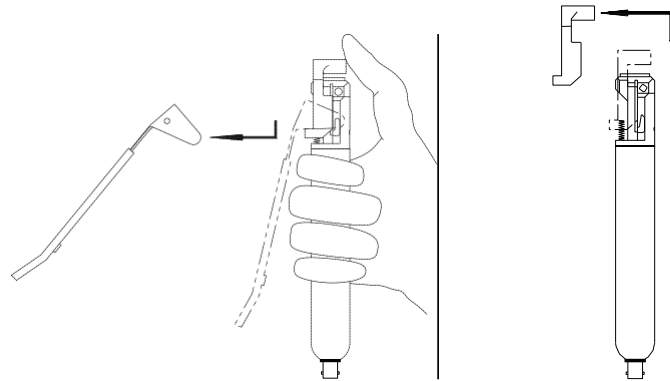


Figure 4-8, Removing the Lever and Ground Jaw

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

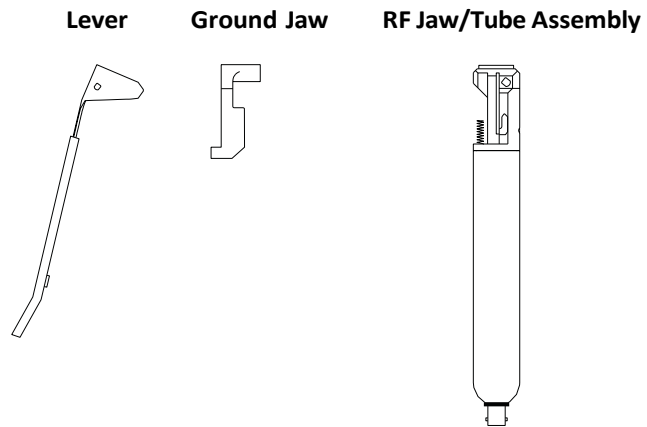


Figure 4-9, Sealing Head Components

GENERAL CLEANING OF THE SEALING HEAD

1. Once the Sealing Head is disassembled (see Disassembly of the Sealing Head on page 4-6 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 4-10, Cleaning Individual Sealing Head Components. Be sure to clean all areas that may have been subjected to contamination.

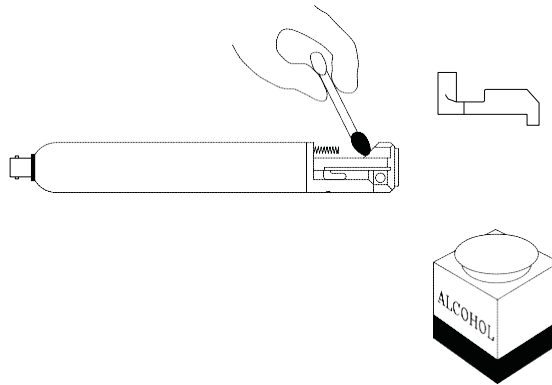


Figure 4-10, Cleaning Individual Sealing Head Components

2. 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.
3. Clean splash guard with alcohol or bleach solution.

REASSEMBLY OF THE SEALING HEAD

1. 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 4-11, Installation of Ground Jaw onto RF Jaw/Tube Assembly. *Be sure the RF power cable is disconnected from the Sealing Head.*

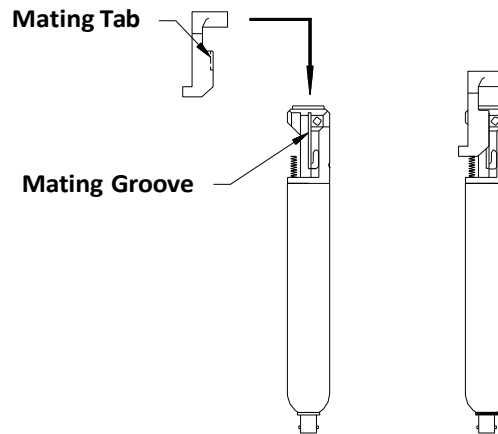


Figure 4-11, Installation of Ground Jaw onto RF Jaw/Tube Assembly

2. 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 4-12, Installation of Lever on to Sealing Head and Figure 4-13, Installation of Lever into Pivot Slots. 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!*

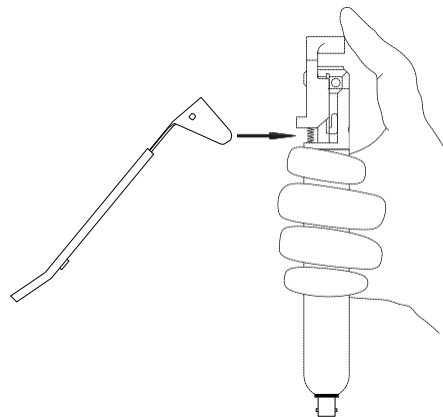


Figure 4-12, Installation of Lever on to Sealing Head

3. 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 4-13, Installation of Lever into Pivot Slots.

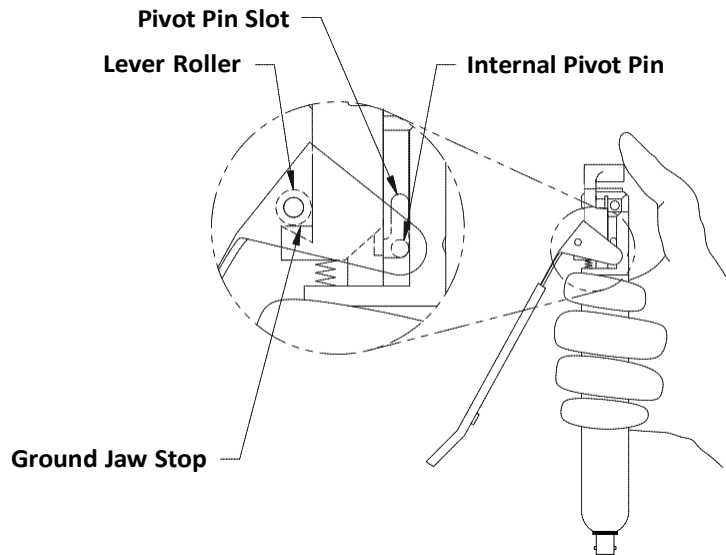


Figure 4-13, Installation of Lever into Pivot Slots

4. When the thumb is released, the lever should fully engage and secure the ground jaw on the RF jaw/tube assembly. See Figure 4-14, Final Assembly of Sealing Head.

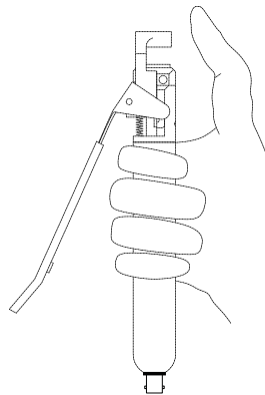


Figure 4-14, Final Assembly of Sealing Head

5. 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 4-2, Correct Lever/Sealing Body Gap.
6. Attach the splash guard. See Chapter 3, Splash Guard Installation on page

TROUBLESHOOTING

Table 5-1, 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" on page 5-3. |
| | Lever assembly out of alignment. | See Figure 4-2, Correct Lever/Sealing Body Gap, for proper alignment. |
| | Ground jaw bent out of position. | Call Vante. |
| | Tubing or sealing region is moist or contaminated. | Ensure that the outside of the tubing, the sealing region and adjacent areas are free of moisture and any other contaminants. |
| | Sealing Head held improperly. | Ensure that the Sealing Head is being held properly (see Chapter 3, Figure 3-6, Maintaining Compression During the Entire Sealing Process) with the sealing region opening upright. |
| | Sealing Head lever released prematurely. | Ensure that the sealing indicator light is completely out before releasing the Sealing Head lever. |
| | Tubing not properly clamped in sealing region. | Ensure that the sealing region closes evenly before the lever comes in contact with the tube body (see Chapter 4, Figure 4-2, Correct Lever/Sealing Body Gap). |
| 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 that tubing for blood and blood products (usually PVC) is being used. |
| | Tubing not properly clamped in sealing region. | Ensure that the sealing region closes evenly before the lever comes in contact with the tube body (See Chapter 4, Figure 4-2, Correct Lever/Sealing Body Gap). |
| | Short in RF cable. | Try new RF cable (Model 1103). |
| | Broken reed switch due to impact/age. | Call Vante® |

SPRING REPLACEMENT

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.

2. Disassemble and clean the Sealing Head according to the procedure outlined in Chapter 4.
3. Remove *all* of the old spring and adhesive. Using either the desoldering 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. 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.

5. Assure the proper spring length by first assembling the Sealing Head without using adhesive. Position the spring in the Sealing Head spring hole.
6. Re-assemble the Sealing Head according to procedure outlined in Chapter 4, Reassembly of the Sealing Head on page 4-9.
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 9 in this section below.



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

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 5 above. Repeat Steps 5-7 above as often as required to obtain the desired spring length (i.e., until the jaws touch with no gap).
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.

10. Place the spring back in the hole, silicone end first.
11. Reassemble the Sealing Head according to the procedure outlined in Chapter 4, Reassembly of the Sealing Head on page 4-9.
12. Allow the Sealing Head to sit for at least one hour before attempting to seal.

CUSTOMER SERVICE

Services

Clinical training

The local Vante representative will provide staff training upon delivery of the equipment and should be contacted to organize further instruction if needed.

Repair service

Vante maintains a worldwide network of company-trained service representatives responsible for responding to technical needs concerning equipment. If service beyond the routine maintenance and cleaning described in this manual is required, Vante® should be contacted to provide specific instruction.

In the continental U.S., the Vante be reached by calling (877) 565-5557

Product return guidelines

If, for any reason, merchandise must be returned to the company, the customer should contact the local Vante representative to arrange for repairs or returns using procedures to ensure proper handling and subsequent analysis. No returns will be accepted without advanced authorization.



Warning: Vante products must be properly cleaned and packaged prior to their return. It remains an important responsibility of the customer to reduce potential health hazards by being aware of the risks involved in the shipping, handling and testing of this material. Units returned to Vante for repair are subject to biohazard charges if any component is contaminated with blood or blood products.

Radio Frequency System Safety Considerations

GENERAL INFORMATION

Vante manufactures a variety of instruments that incorporate the use of radio frequency (RF) for sealing, welding, or forming thermoplastics. Typical uses include the sealing of blood bag and apheresis tubing, and plastic welding or forming manufacturing 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.

RF Effects On Human Tissue

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

RF Effects On Pacemakers

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

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.

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.

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.



Warning: Vante recommends strict adherence to the procedures specified in the instrument Operation Manual. Misuse or modification of an instrument may result in unsafe or hazardous situation.

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