



SEBRA®

operation manual

VT-108732-US

Model 2605
Segmenting 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 Corporation 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.

Table of Contents

Chapter 1, Introduction

PRELIMINARY INFORMATION.....	1-1
Document scope.....	1-1
Intended audience.....	1-1
SYMBOLS.....	1-1
Symbols found in this document.....	1-1
Symbols found on the device.....	1-1

Chapter 2, Sealing Head Description

PRODUCT OVERVIEW.....	2-1
Application.....	2-1
THEORY OF OPERATION.....	2-1
COMPONENT IDENTIFICATION.....	2-2
SPECIFICATIONS.....	2-3
Environment.....	2-3
Mechanical and Weight.....	2-3

Chapter 3, Sealing Head Operation

SETUP.....	3-1
RECOMMENDED TUBING.....	3-1
SEALING PROCEDURE.....	3-2
SEAL SPACING.....	3-5

Chapter 4, Cleaning the Sealing Head

CLEANING THE SEALING HEAD.....	4-1
TOPICAL CLEANING OF THE SEALING REGION.....	4-2
SPLASH GUARD REPLACEMENT.....	4-4
CLEANING SEALING HEAD CASE.....	4-6

Chapter 5, Repair

TROUBLESHOOTING.....	5-1
CUSTOMER SERVICE.....	5-2
Services.....	5-2

Chapter 6, Handling Blood and Blood Products

CLEANING AND DISPOSAL PROCEDURES.....	6-1
Be prepared.....	6-1
Maintain awareness.....	6-1
Protect others.....	6-1

Confine and absorb the spill 6-1
 Disinfect..... 6-2
 Decontaminate equipment 6-2
 Safely dispose of waste 6-2

Chapter 7, Radio Frequency System Safety Considerations

GENERAL INFORMATION 7-1
 RF Effects On Human Tissue..... 7-1
 RF Effects On Pacemakers 7-1
 Electrical Safety 7-1
 RF Effects On Electronic Equipment 7-1
 RF Effects In Potentially Explosive Atmospheres 7-1

List of Figures

Figure 2-1, Model 2605 Segmenting Head 2-2
 Figure 3-1, Correct Technique for Holding the Tubing..... 3-2
 Figure 3-2, Incorrect Technique for Holding the Tubing..... 3-3
 Figure 3-3, Repeating the Seal Process..... 3-4
 Figure 3-4, Multiple Seal Spacing..... 3-5
 Figure 4-1, Incorrect Cleaning Technique 4-1
 Figure 4-2, Cleaning the Sealing Region..... 4-2
 Figure 4-3, Drying the Sealing Region..... 4-3
 Figure 4-4, Removing Splash Guard from Sealing Head 4-4
 Figure 4-5, Removing Adhesive Residue..... 4-5

Chapter 1

PRELIMINARY INFORMATION

Document scope This manual is a guide for the operation, care and maintenance of the Vante® SEBRA® Model 2605 Segmenting Head.

Intended audience This manual is intended for use by personnel having technical skills and a thorough understanding of the products, procedures, and safety requirements for the collecting, processing and handling of biological products.

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



Caution (refer to accompanying documents)



Protective Earth (PE)



Power on



Power off



Fuse



Serial number



Catalog number

Chapter 2

PRODUCT OVERVIEW

The Vante® SEBRA® Model 2605 Segmenting Head ("the Sealing Head") is part of a system that employs radio frequency (RF) to make uniform, quality seals on blood bags, transfer sets and IV tubing. A Vante SEBRA Model 2600 RF Power Source 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 blood and/or blood products in the unlikely event of tubing rupture.

Application

The Model 2605 Segmenting Head is part of a system and cannot be used independently. When used in conjunction with the Model 2600 RF Power Source, 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 is 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 Power Source 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

Figure 2-1, Model 2605 Segmenting Head, illustrates the Sealing Head. Table 2-1 indicates the function of each component included with the Sealing Head.

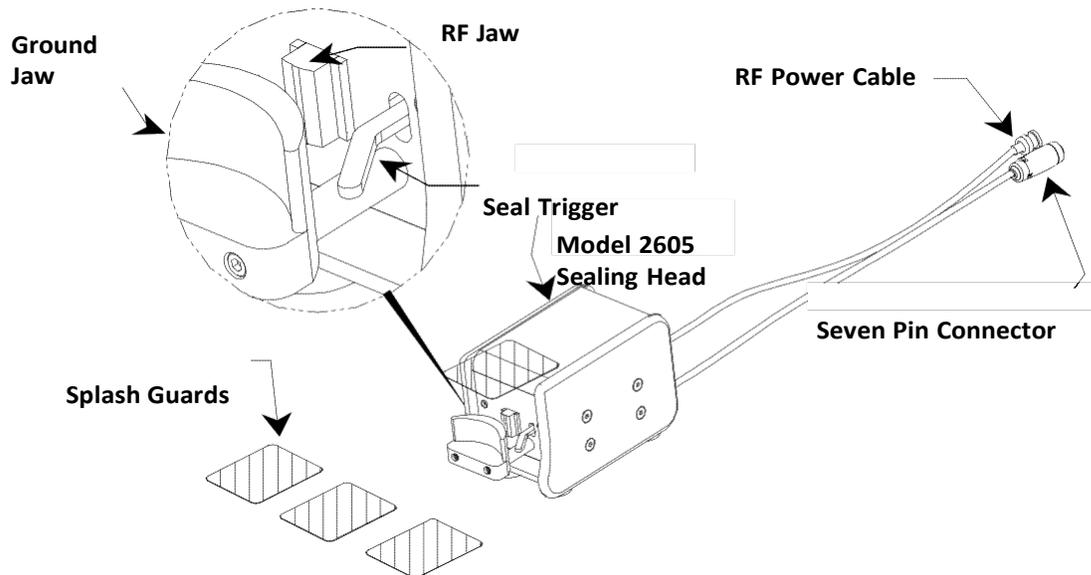


Figure 2-1, Model 2605 Segmenting Head

Table 2-1, Sealing Head Component Functions

Component	Function
Ground Jaw	Compresses tubing while RF is applied to form seal.
RF Jaw	Delivers RF energy to tubing to form seal.
Splash Guard	Protects the operator from accidental exposure to blood or blood products in the unlikely event of a tubing rupture.
Seal Trigger	A microswitch that activates the sealing head jaws.
RF Power Cable	Provides RF power connection to the Model 2600 Power Source.
Seven Pin Connector	Provides control voltage connection to the Model 2600.

SPECIFICATIONS

Environment

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 RF ground 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.

Mechanical and Weight

Table 2-2, Mechanical and Weight Specifications

PARAMETERS	SPECIFICATION
Dimensions:	7 in. L x 4 in. W x 4.2 H (17.8 cm L x 10.2 cm W 10.7 cm H)
Operating weight:	5.3 lb (2.4 kg)
Shipping weight:	8 lb (3.6 kg)

Sealing Head Operation

SETUP

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



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

See the Operation Manual for the Model 2600 Power Source for proper setup and RF power settings.

RECOMMENDED TUBING

Shown in Table 3-1 are typical size categories and corresponding dimension ranges of PVC tubing. The Sealer is designed to seal blood bag, transfer sets and intravenous tubing (small or medium size) with typical outside diameter of 0.148-1.18 inch (3.8-4.6 mm) and wall thickness of 0.020-0.037 inch (0.5-.94 mm).

Table 3-1, Recommended Tubing

Tubing Size Category	Outside Diameter Range	Wall Thickness Range	Examples
Small	0.080-0.147 inch 2.0-3.7 mm	0.020-0.030 inch 0.5-0.8 mm	Anti-coagulant and saline drip lines
Medium	0.148-0.18 inch 3.8-4.6 mm	0.020-0.037 inch 0.5-.94 mm	Blood bag tubing, some apheresis ^a

a. Although the 2605 may make good seals on apheresis tubing that falls outside this range, duty cycle and heat buildup may be affected. Call Vante® for more information.

SEALING PROCEDURE



Warning: Wear disposable protective gloves while working with blood and blood products. See Chapter 6.

1. For sealing and segmenting tubing, place the Sealing Head in a convenient location, allowing clear access to the jaws and routing the cable so that it does not interfere with other activities.
2. Lay the tubing through the slot of the sealing region, allowing the weight of the tubing to press against the seal trigger (a slight additional manual force may be required), as shown in Figure 3-1, Correct Technique for Holding the Tubing. When the trigger is activated, the RF sealing jaw will compress the tubing against the ground jaw and RF power will be applied for approximately one second. After the seal is formed, the sealing jaw will retract to its original position.



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.



Note: For clarity, the splash guard is not shown in some of the figures in this manual; however, it should always be in place during the sealing process.

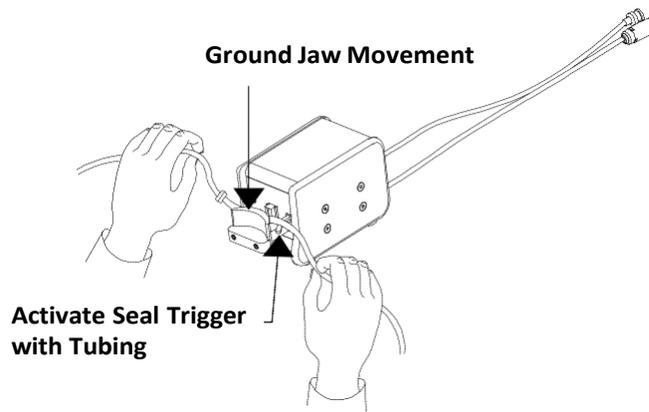


Figure 3-1, Correct Technique for Holding the Tubing



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 contact, resulting in poor or ruptured seals.



Figure 3-2, Incorrect Technique for Holding the Tubing



Note: When the Sealing Head is operated, a minor arc discharge may occur between the sealing jaws.



Note: The Power Source is equipped with a thermal protection switch to prevent the equipment from becoming damaged. If thermal cutout is reached, the power source will not work for several minutes until the temperature of equipment lowers.



Warning: The Power Source is designed for rapid sealing applications; however, extreme heavy duty use may result in thermal build up in the jaw area which can cause hemolysis, poor seal quality or tubing ruptures. If you should experience these problems, reduce the rate of sealing, as necessary, or allow for periods of rest for the Sealing Head.



Caution: Never trigger the jaws 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 jaws and poor Sealing Head operation may result.

3. The seal is completed in approximately one second, as indicated when the sealing jaw retracts. Another seal cannot be made until the sealing jaw fully retracts and the seal trigger has been completely released. To make another seal, lift the tubing up to release the trigger and push the tubing to the next seal position (see Figure 3-3, Repeating the Seal Process).
4. Activate the seal trigger to either the right or left, but for best results, move the completed seals to the left (while facing the jaws) to avoid their interfering with the seal trigger.

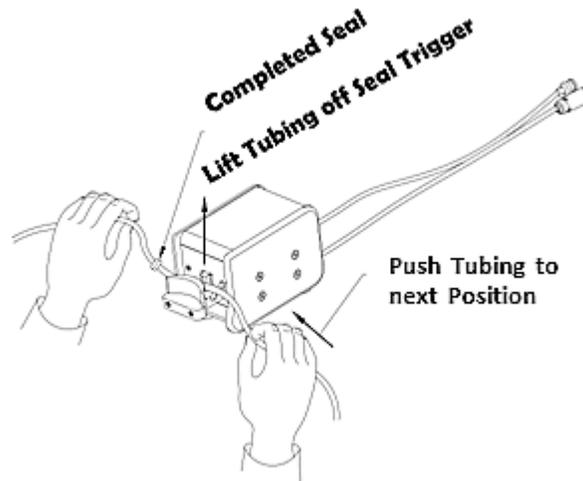


Figure 3-3, Repeating the Seal Process



Warning: Be sure to *push* the tubing through the sealing region to the next position. Under *no* circumstances should the tubing or bag be separated by pulling it while the sealing jaws are clamped. 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 Chapter 5, Table 5-1, "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

Seals that progress along a **close-ended** length of tubing, as in a segmenting process, must be spaced *no less* than the blood bag manufacturers recommendation, to avoid rupture of the tubing due to pressure build-up.

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

Multiple seals in close proximity are not required, nor are they recommended when using the Power Source. If multiple seals must be used, they should be spaced at least one inch (2.5 cm) apart, as shown in Figure 3-4, Multiple Seal Spacing.

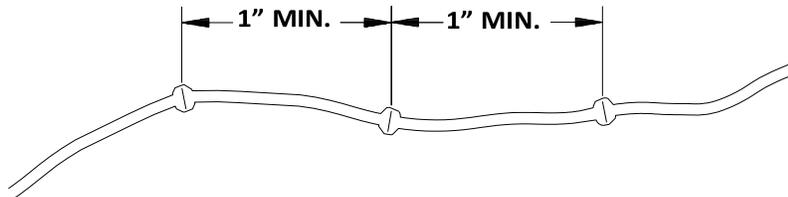


Figure 3-4, Multiple Seal Spacing



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

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.

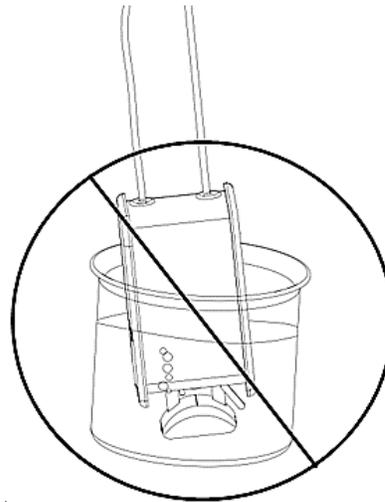


Figure 4-1, Incorrect Cleaning Technique



Note: Other than periodic cleaning, 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. Contact Vante if the Sealing Head fails to operate properly.

TOPICAL CLEANING OF THE SEALING REGION



Warning: Always wear disposable protective gloves while working with blood and blood products. See Chapter 6.



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 below 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. Disconnect the Sealing Head from the power source by removing the RF power cable and five-pin connector from the power source.



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

2. Clean the open sealing region, including the RF jaw, with alcohol (denatured or isopropyl) applied to one end of a cotton swab, as shown in Figure 4-2, Cleaning the Sealing Region. *Be sure the RF power cable is disconnected from the RF power source!*

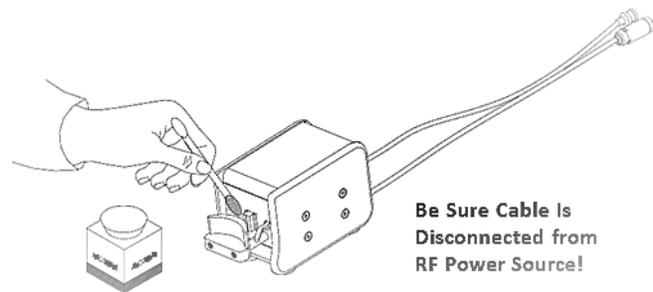


Figure 4-2, Cleaning the Sealing Region



Caution: Clean the RF jaw, ground jaw and adjacent areas with alcohol only!

3. After cleaning the contaminated areas of the sealing region, immediately dry with the dry end of the cotton swab (Figure 4-3, Drying the Sealing Region).

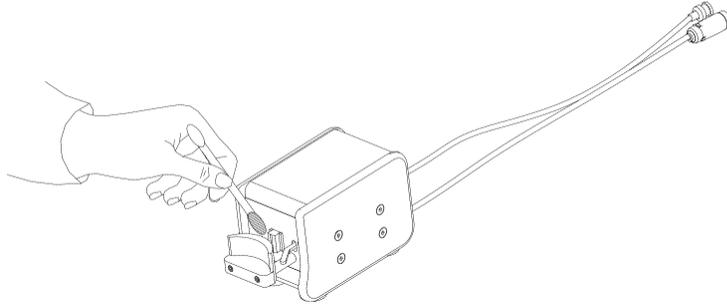


Figure 4-3, Drying the Sealing Region

If the splash guard was removed for topical cleaning, be sure to follow the cleaning procedure in Splash Guard Replacement on page 4-5 before reinstalling a new splash guard.

If the above procedure does not result in satisfactory performance, contact Vante.

4. Properly dispose of all used cleaning materials.



Warning: Always dispose of any materials that have come in contact with blood or blood products in accordance with procedures provided in Chapter 6.

SPLASH GUARD REPLACEMENT



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. It is made with a self-adhesive coating for easy attachment to the lever. Extra splash guards are provided with each shipment and are available for purchase from Vante (order part number 10800061).



Warning: To avoid coming in contact with any blood or blood products, wear disposable protective gloves while handling and cleaning the Sealing Head components. See Chapter 6.

1. Disconnect the Sealing Head from the Power Source by removing the RF power cable and seven pin connector from the Power Source.



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. Remove the existing splash guard from the Sealing Head and properly dispose of it.



Warning: Always dispose of any materials that have come in contact with blood or blood products in accordance with procedures provided in Chapter 6.

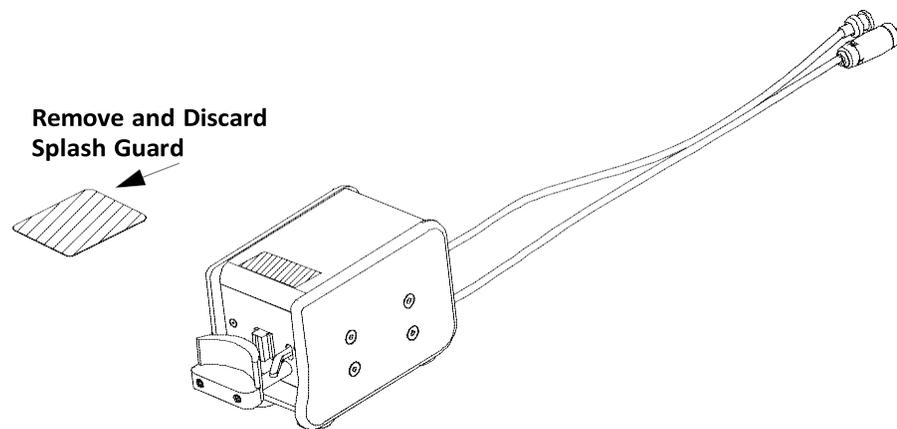


Figure 4-4, Removing Splash Guard from Sealing Head

3. Remove the adhesive residue from the surface with a commercially available solvent cleaner such as De-Solv-It[®], Goo Gone[®] or WD-40[®], applied to a cotton swab (see Figure 4-5, Removing Adhesive Residue).

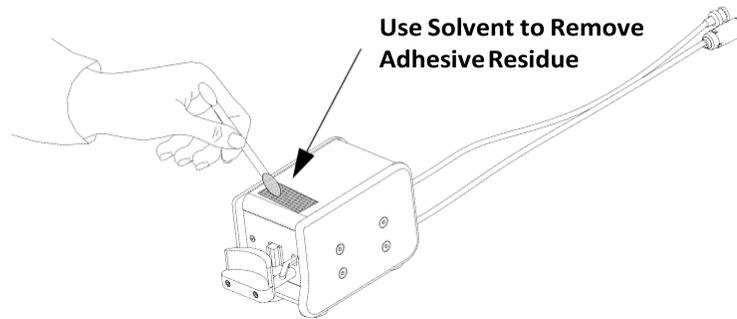


Figure 4-5, Removing Adhesive Residue

4. Dry the Sealing Head completely.
5. Remove the paper backing from adhesive on the new splash guard.
6. Align and attach the new splash guard. See Figure 4-6, Attachment of New Splash Guard.

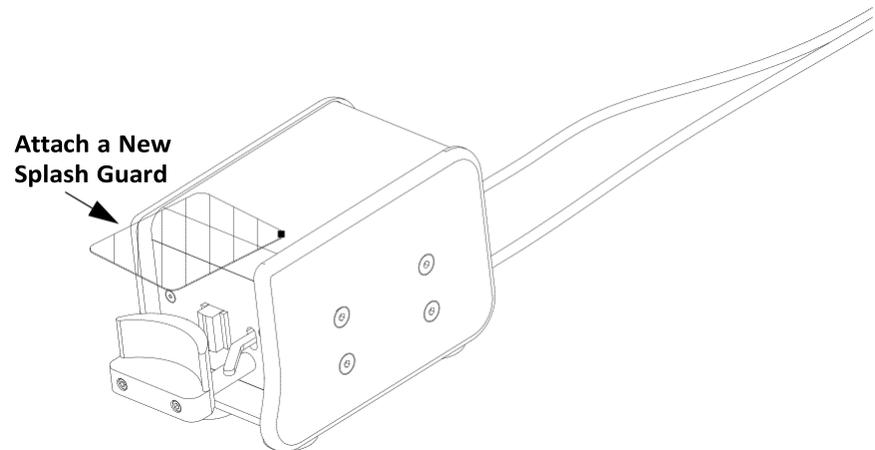


Figure 4-6, Attachment of New Splash Guard

CLEANING SEALING HEAD CASE

1. Disconnect the Sealing Head from the power source.
2. Apply a cleaning solution made from a mild detergent or household cleaner such as Formula 409® (NO BLEACH) and water to a soft wiping tissue. Wipe the power source and/or Segmenting Head case with the *damp* tissue until clean. Make sure the surfaces are completely dry before putting back into service.



Caution: *Do not apply fluids directly to the Sealing Head case and do not over saturate the cleaning solution applicator. The fluids may run into the electronic components and cause contamination of the electronics and subsequent unit malfunction. Never immerse the power source or Segmenting Head in any liquid. Use only alcohol to clean the sealing region and adjacent areas.*

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.)	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.
	Jaws bent out of position or not properly aligned.	Call Vante.
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 proper size and material tubing (usually PVC) is being used.
RF jaw fails to move or chatters when triggered.	Sealing Head cables not properly connected to Power Source.	See Operation Manual for Power Source.
	Sealing region is contaminated.	Ensure the sealing region and adjacent areas are free of any contaminants.

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., Vante may 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.

Chapter 6

Handling Blood and Blood Products

CLEANING AND DISPOSAL PROCEDURES

When using the Sealing Head or related blood handling equipment, always be aware of the potential for coming in physical contact with blood and blood products while performing cleaning and maintenance, or in the event of a blood or blood product spill. The following recommendations should be employed to properly clean and safely decontaminate any affected areas and/or to properly dispose of any clean up materials and equipment.

Be prepared

Design blood handling areas to facilitate the cleanup process. Place necessary supplies, equipment and instructions in a specific, well-marked location near any areas where the potential for blood spills exists. Be sure all personnel involved with blood handling are thoroughly trained in spill management procedures. Develop and implement a regular cleaning schedule of the working area and equipment.

Maintain awareness

Assign individuals responsibility for the maintenance of clean-up supplies and equipment, spill handling leadership and training, and record keeping. Significant blood spill occurrences should be reviewed and analyzed as a means of reducing such incidents by enhancing personnel understanding of possible causes of spills and how to avoid them.

Protect others

Keep nonessential personnel away from the spill area and warn them of the potential danger.

Protect yourself

Wear disposable protective gloves while using blood and blood product equipment and during any spill clean-up. If sharp objects are present in a spill area, gloves must be puncture resistant, or use appropriate instruments (e.g., a broom and dustpan) for clean-up to avoid contact with objects that could puncture gloves. Protective eye wear and outerwear (gown or lab coat) are also recommended.

Confine and absorb the spill

Using paper towels, or other absorbent material, absorb the spill, working from the outside perimeter of the spill area toward the center. Totally absorb the spill and be sure to remove any broken glass and other contaminated debris with a broom and dustpan.

Disinfect

Once the spill area is free of debris and fluid, clean it with detergent. Wipe away any excess detergent and flood the area with a 10% bleach solution (1 part household bleach to 9 parts water), or other suitable disinfectant, and let it stand for at least 20 minutes. Wipe the area with clean, dry paper towels or gauze pads.

Decontaminate equipment

Any non-disposable clean-up items that cannot be laundered (e.g., protective eye wear, brooms and dustpans, etc.), that have, or may have, come in direct contact with blood must be decontaminated with an appropriate disinfectant such as a 10% bleach solution, or by autoclaving, if applicable. A contaminated Sealing Head RF jaw/tube assembly head should be cleaned with alcohol in accordance with the procedures in this document, while wearing disposable protective gloves. Contaminated protective outerwear and other items that can be laundered must be handled as little as possible and placed in bags or containers (marked with biohazard labels) which prevent leakage and/or soak-through to the exterior. The bags or containers must be transported to a facility equipped to properly launder blood contaminated items.

Safely dispose of waste

All contaminated waste materials must be placed in biohazard bags or containers and transported to a facility equipped to dispose of blood contaminated items by means of incineration or autoclaving. Maintain records to show proof of destruction of all contaminated materials.

Chapter 7

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 situations.

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