WORK INSTRUCTION: WIN-000351

Title: Decontamination of Returned Products

Nondisclosure Statement

TABLE OF CONTENTS

1. SCOPE

Bioventus LLC is committed to providing a safe and healthy work environment for all employees. The purpose of this procedure is to give instructions on how to safely decontaminate returned Devices that arrives at Bioventus facilities for evaluation, repair and/or recommissioning.

This procedure applies to Receiving and Product Servicing Department personnel who perform work on returned Devices and any other personnel who may come into contact with the operations associated with returned product.

This work instruction aligns with the Bioventus Exposure Control Plan (Document #: TRN-000389), and ensures that universal precautions are taken, in accordance with 29 CFR 1910.1030 (b).

2. REFERENCES

2.1. External Standards and Regulations

Reference	Description
AAMI: ST35 2003	Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Nonclinical Settings.

2.2. Internal Procedures and Documents

Reference	Description
PCD-000510	Bioventus Global Returns Procedure
00097-BC	Product Complaint Form
TRN-000389	Bloodborne Pathogens: Protecting Yourself & Others - PowerPoint
FRM-000684	Return Material Decontamination Attestation Form
FRM-000690	Form – Manual Cleaning Procedure Console and Footswitch
FRM-000695	Form – Manual Cleaning Procedure Handpiece(s) Probe Covers, Wrenches, Front Housing(s), Silicone Connector, Sterilization Tray
FRM-000696	Form – Automatic Cleaning Procedure Handpiece(s) Probe Covers, Wrenches, Front Housing(s), Silicone Connector, Sterilization Tray

3. DEFINITIONS

Term or Abbreviation	Definition
Bloodborne Pathogens	Infectious microorganisms in human blood that can cause disease in humans.

Term or Abbreviation	Definition
Contaminated	The presence of undesirable substances on an item or surface, including the presence or reasonably anticipated presence of blood or potentially infectious materials.
Decontaminate	The process of using physical or chemical means to remove undesirable substances and inactivate or destroy bloodborne pathogens on a surface or on an item to the point where they are no longer capable of transmitting infectious particles, and they are rendered safe for handling.
Personal Protective Equipment (PPE)	Specialized clothing or equipment worn by an employee for protection against a hazard. This includes gloves, protective eye wear, facial mask, coveralls, etc.
Sterilization	A process that destroys or eliminates all forms of microbial life and is carried out by physical or chemical methods.
Disinfection	To reduce or eliminate pathogenic agents (such as viruses or bacteria) using an antimicrobial agent on objects or surfaces.

4. EQUIPMENT AND MATERIALS

Equipment or Material	Description
Autoclave	A machine used to kill harmful bacteria, viruses, fungi, and spores that may be on items placed inside, by using steam under high temperature and pressure to neutralized potentially infectious agents

5. INSTRUCTIONS

All personnel involved in handling returned Devices shall utilize universal precautions – a common approach to infection control in which all human blood and body fluids are treated as if they are known to be infectious (Document #: TRN-000389). Personnel shall don the required PPE when performing initial visual inspections and decontamination operations and will follow all requirements of the Bioventus Exposure Control Plan (Document #: TRN-000389) in order to ensure proper protocols are followed in the event of an exposure.

All returned Devices received into a Bioventus facility will be moved to a quarantine area where it will undergo visual inspection and verification of customer paperwork.

All Devices will be placed in a quarantine area awaiting receipt and inspection prior to servicing.

Device(s) MUST be decontaminated per this procedure under the following scenarios:

1. No customer attestation of decontamination that accompanies the product return.,
2. There is visible soiling of the Device(s) upon visual inspection. Even if the customer attestation of decontamination is present, any devices with visible soiling will be decontaminated prior to servicing.

Device(s) may be moved directly into service and repair ONLY under the following scenario:

1. The attestation of decontamination accompanies the shipment AND no visible soiling is observed upon inspection.

5.1. Roles and Responsibilities

5.1.1. Receiving Department

The Receiving Department is responsible for placing all returned Devices from customers or distributors into the designated quarantine area for receipt and inspection. If needed execution of the decontamination process.

5.1.2. Product Servicing Department

The product servicing department is responsible for all processes used to decontaminate devices returned from a customer or distributor prior to servicing. This includes documentation, ensuring decontamination of devices is performed according to this work instruction for each device, and maintaining a clean and orderly work environment in the decontamination work area.

Product Service personnel are responsible for following all PPE requirements when coming into contact with returned Devices

5.1.3. Facilities / EHS Department

The Facilities/EHS Department is responsible for maintaining, reviewing and updating this program at least annually, or whenever necessary, to include new or modified processes.

5.1.4. Manufacturing Engineering Department

The Manufacturing Engineering Department is responsible for advising personnel involved in decontamination operations, and the EHS Department, of any product changes or modifications that may affect how decontamination procedures are performed.

5.1.5. Quality/ Regulatory Department

The Quality/ Regulatory Department is responsible for ensuring that the process is followed and that the annual review is completed.

5.2. Storage of Returned Devices

Step	Action
1	All returned devices shall be stored in a separate designated “Quarantine Area” while awaiting inspection, decontamination and further servicing. This area shall be clearly marked, and only authorized personnel shall be permitted in the designated area.
2	The Repair Receiving Area shall be separated from other production, warehousing, or Service and Repair activities by distance or physical barriers. It should be located adjacent to or co-located with the designation “Device Quarantine/ Decontamination” area.
3	Receiving personnel shall keep returned Device(s) in the packaging in which it was transported, so as not to be exposed, while transporting it to the Quarantine Area for visual inspection and verification of customer paperwork.

5.3. Decontamination Instructions

Step	Action
1	The Receiving Department transports the returned package to the designated Quarantine Area for staging prior to inspection and/or decontamination by the Product Servicing Department
2	Personnel will don the appropriate PPE prior to opening and handling contents of the package. Required PPE for inspecting potentially contaminated Devices and performing decontamination activities includes: gloves, lab coat/coverall, and protective eye wear or face shield
3	Personnel will review the RMA (Return Material Decontamination Attestation Form - FRM-000684) that accompanies the returned Device(s) and note any unique circumstances noted by the customer/distributor that may affect decontamination.
4	Personnel will document if the RMA form is complete or incomplete from the customer/distributor and will visually inspect the Devices for any visible soiling. - If the RMA form is complete and there is no visible soiling, the Devices can be moved into repair for servicing. - If the RMA form is not complete or there is any visible soiling found during inspection, the devices will be decontaminated.

5	Decontamination activities will take place according to this procedure and forms FRM-000690 Form – Manual Cleaning Procedure Console and Footswitch FRM-000695 Form – Manual Cleaning Procedure Handpiece(s) Probe Covers, Wrenches, Front Housing(s), Silicone Connector, Sterilization Tray FRM-000696 Form – Automatic Cleaning Procedure Handpiece(s) Probe Covers, Wrenches, Front Housing(s), Silicone Connector, Sterilization Tr
6	• There shall be an autoclave designated exclusively for decontamination operations only. This autoclave should be co-located within the space where decontamination work takes place, in order to limit the number of personnel in the area. • All personnel who will be involved performing device decontamination must be properly trained on the safe operation of the autoclave.
7	If autoclaved, attach the sterilization printout from autoclave to the disinfection record. Contents of the autoclave must be allowed to cool before proceeding with service.
8	Any component that is automatically disposed of (i.e filters in consoles) shall be placed in the designated biohazardous waste container. Maintenance of the biohazardous waste containers, as well as proper disposal when containers become full, is the responsibility of the Facilities/EHS Department.
9	Upon completion of decontamination of equipment, operator shall sign as required on the decontamination record(s) Then the devices shall be moved to the service and repair work staging area for further product servicing activities.
10	All materials used to disinfect components (ex. wipes) will be placed in a biohazardous waste container (i.e., red bag) located in the decontamination work area. Disposal PPE used shall also be placed in the biohazardous waste container.
11	All other PPE shall be placed for laundering or cleaned and stored properly for its next use.
12	Personnel must remove all PPE before leaving the Device Decontamination area

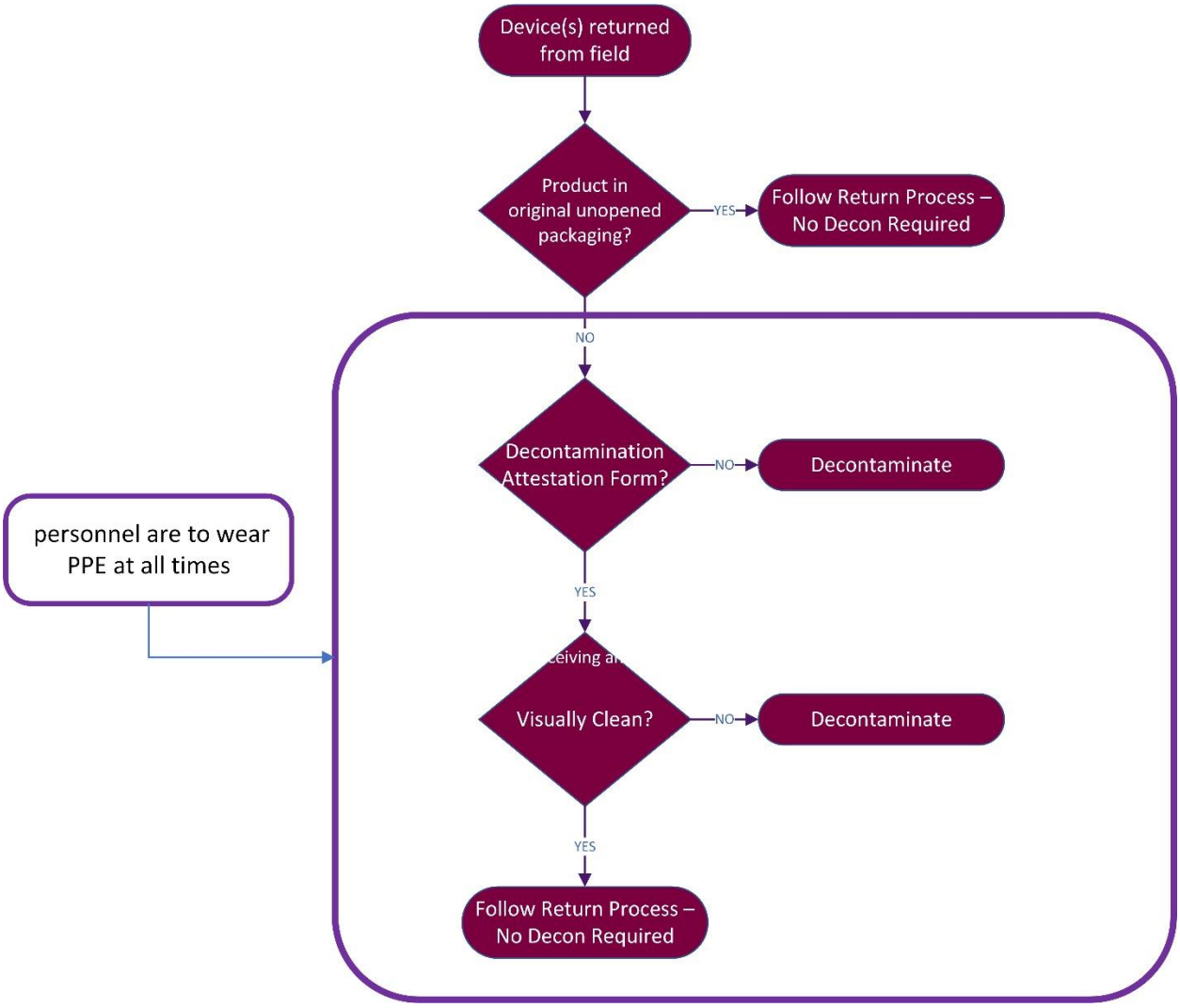
5.4. Additional Safety Precautions

- Even if there is no known exposure, product decontamination personnel are required to wash their hands immediately or as soon as feasible after removal of gloves and PPE, after decontaminating Devices.
- If there is an exposure to blood or other potentially infectious materials (ex. failure of PPE, infectious material that enters an open wound), employees shall wash hands and any other exposed skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible. Reporting of the exposure shall be performed as per the Bioventus Exposure Control Plan.
- **There shall be no eating, drinking or handling of contact lenses in any area where decontamination activities are taking place**.
- Contaminated PPE or other materials that are contaminated with blood or other potentially infectious body fluids will be disposed of in a biohazardous waste receptacle (i.e. red bag) and disposed of through an approved vendor and according to state and local regulatory requirements.
- Product servicing personnel shall notify the Facilities/EHS Department when biohazardous waste containers become full and must be replaced. Waste containers must not be overfilled.

Important:

- Prior to decontamination of product, employees must ensure they have reviewed and are familiar with the operation of this Devices and all safety warnings associated with it by reading the Instructions for Use (IFU)/Devices Manual.
- The IFU all products are available, through www.bioventus.com and may be referred to as necessary.

Decontamination Process Flow



Document Detail

Type: Work Instructions

Document No.: WIN-000351[B]

Title: Decontamination of Returned Products

Owner: BARRY.MITCHELL Barry Mitchell

Status: RELEASED

Review

Level	Owner Role	Actor	Sign-off Date	Sign-off By
0	BV Configuration Analyst BV Configuration Analyst	AMBER.PLOTNER Amber Plotner	04-Jun-2024 3:05 pm	AMBER.PLOTNER
1	BV Doc Owner / Author BV Doc Owner / Author	BARRY.MITCHELL Barry Mitchell	05-Jun-2024 8:54 pm	BARRY.MITCHELL
1	BV Doc Approver BV Doc Approver	MARK.SCHAEFER Mark Schaefer	10-Jun-2024 1:17 pm	MARK.SCHAEFER
1	BV Doc Approver BV Doc Approver	WILLIAM.HEARD William Heard	13-Jun-2024 9:22 pm	WILLIAM.HEARD
1	BV Doc Approver BV Doc Approver	GRACE.SKLBA Grace Sklba	05-Jun-2024 3:41 pm	GRACE.SKLBA
1	BV Doc Approver BV Doc Approver	OMER.PLACO Omer Placo	05-Jun-2024 5:40 pm	OMER.PLACO
2	BV Configuration Analyst BV Configuration Analyst	AMBER.PLOTNER Amber Plotner	14-Jun-2024 3:28 pm	AMBER.PLOTNER