SBMF
South Bend Medical Foundation

CLIENT NOTICE

Notification Date: **25 JAN 2023**
Effective Date: **25 JAN 2023**

Important Information for SBMF Clients

Please see the attached article from our partners at Cerus regarding platelet product handling.

Follow the link below for an important update from the FDA regarding bacterial contamination of platelets for transfusion:

Important Information for Blood Establishments and Transfusion Services Regarding Bacterial Contamination of Platelets for Transfusion

Questions: Please contact **CLIENT SUPPORT** at **574-236-7263**

SOUTH BEND MEDICAL FOUNDATION
3355 Douglas Road • South Bend, Indiana 46635
(574) 234-4176 • (800) 544-0925 • www.sbmf.org
Nita Gerig, MD • Chief Medical Officer

cerus

INTERCEPT® Blood System for Platelets: Handling Recommendations for Hospitals

INTRODUCTION

Cerus is committed to providing customers with quality products and services as well as guidance on best practices for their use. All platelet containers are designed to have high gas (O_2 and CO_2) permeability. Cerus carefully chose a commercially supplied polyolefin elastomer blend sheeting for the final storage containers. As with platelet storage containers from other manufacturers, these materials are susceptible to damage caused by friction, pinching, excessive pressure, heat exposure or other mechanical stresses. Therefore, the containers must be handled with care and the environment should be kept clean to minimize the risk of damage and contamination.

These recommendations provide best practices Cerus has identified in the care and handling of the final storage container and contents in the hospital environment, for distribution within the hospital and transporting between hospital campuses.

USE ENVIRONMENT

☑ Decontamination of Surfaces / Workspaces / Storage Areas:

- Conduct daily cleaning and disinfection on reusable equipment and work surfaces that may be contaminated with blood. For example: counters and transport carts.[1]
- Disinfect surfaces or equipment in the event of a leak or spill.

☑ Inspection of Surfaces / Workspaces / Storage Areas:

- Areas should be free of objects that could result in punctures or abrasions.
- Routinely check agitator drawers for any damage to the surfaces or the interfaces for opening and closing the drawers.

CONSIDERATIONS FOR HOSPITAL PROCESSES

☑ General Product Handling:

- Handle final storage containers with care.
- Ensure manipulation does not cause pinching, friction or excessive pressure.
- Avoid stacking multiple units on top of each other, which can lead to risk of one or more units falling or create pressure points with rigid objects (e.g., clamps, tie tags).

General Product Handling (cont'd):

- Inspect the containers for any scrapes or leaks throughout the handling. If a leak is detected:
  - » Take a picture of the damaged area and retain the set for Cerus investigation.
  - » Contact Customer Services at **Customerservices.americas@cerus.com** or notify your Cerus representative at **hospitalsupport@cerus.com.**

Temporary storage of multiple bags. The image on the right shows folded flaps and too many units on top of each other.

Final Storage Container Agitation:

- Place containers in portrait position and ports flat against the agitator drawer with the label up and the container away from agitator drawer/slide interface.
  - » Portrait position minimizes container movement.
  - » Label up minimizes container handling.
  - » Keeping containers away from the interface between the drawer and slide interface minimizes potential damage.
- Position containers on agitator drawer so that they are not overlapping with the shelf or other containers.
- Position containers so that they are fully within the drawer, no overhang on the front lip of the drawer.

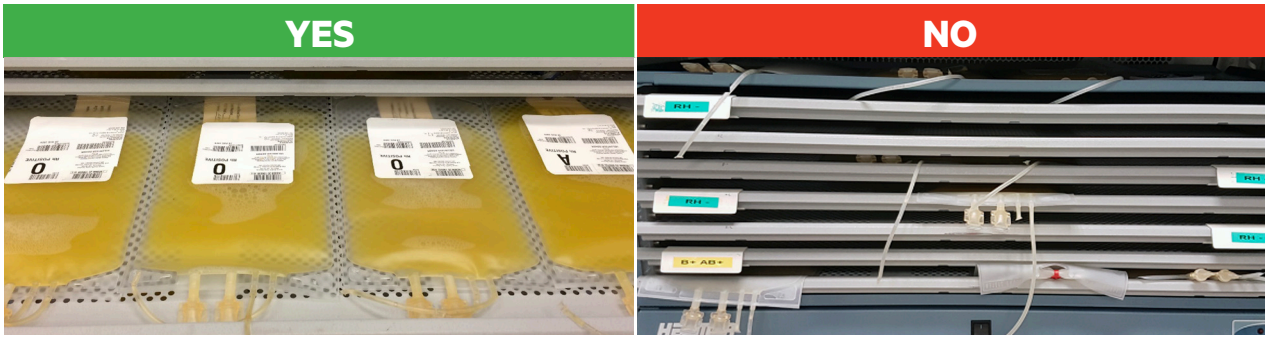

Image on the right shows containers and tubing hanging out of the shelves and too close to the sides.

Centrifugation:

- Do not centrifuge the INTERCEPT platelet storage container.
- Transfer platelet contents to a container designed for centrifugation.

Pneumatic Tube System Transport:

- Validate use of the pneumatic tube system.
- Ensure the carrier is well padded and airtight.
- Place platelet inside sealed transport bag or pouch before placing in the carrier.
- Ensure there are no pressure points on the container when placed in the tube.
- Ensure ports of the platelet bag are pointing away from the direction of travel.
- Minimize the number of times the platelet is transported via pneumatic tube.
- If the container must be folded to fit within the tube, fold at the bottom where the INTERCEPT BLOOD SYSTEM embossing is, and not at the ports.

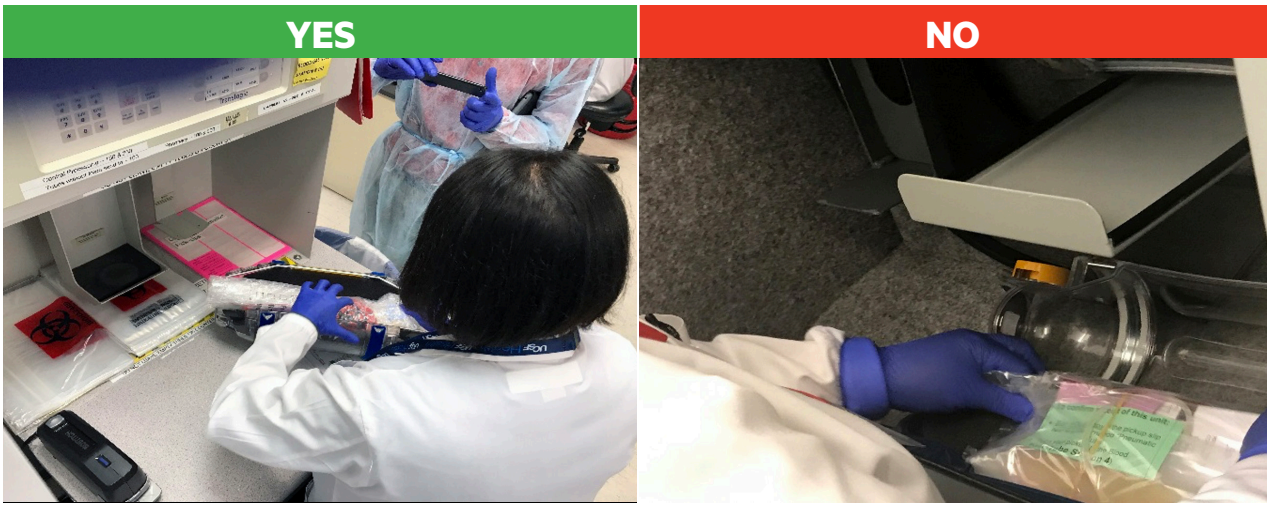

Image on the right does not have padding to inside the carrier.

Packing for Transport from Hospital to Hospital or Hospital to Blood Center:

- Inspect the storage containers for any scrapes or leaks. If a leak is detected follow the instructions in General Product Handling.
- Routinely disinfect shipping container per institutional procedure and schedule.
- Remove any clamps from containers prior to packing.
- If using an overwrap, ensure the size is adequate for the amount of containers shipped. Overwraps should be single use only.
- Follow your blood center's training procedures and requirements (if applicable) for packing platelets for transport to another hospital or blood center.

Packing for Transport from Hospital to Hospital or Hospital to Blood Center (cont'd):

- Pack containers to avoid friction or pressure points.
  - » Place tie tags flat against the container and near the end flap.
  - » Flat placement within the shipping container is preferred with ports alternating with the stack.
  - » If the container must be folded to fit within the shipping container, fold at the bottom not at the ports.
- Avoid excessive compression on contents when packing the shipping container.
- Consider acquiring shipping containers that best fit the size of the INTERCEPT storage container if they are unable to be placed flat.

Please consult the INTERCEPT Blood System for Platelets package insert for detailed instructions, contraindications, warnings and precautions.[2]

cerus

GLOBAL HEADQUARTERS | 1220 Concord Ave | Concord, CA US 94520 | 855.835.3523
www.cerus.com | www.intercept-usa.com

Rx only. There is no pathogen inactivation process that has been shown to eliminate all pathogens. Certain non-enveloped viruses (e.g., HAV, HEV, B19 and poliovirus) and *Bacillus cereus* spores have demonstrated resistance to the INTERCEPT process. See package insert for full prescribing information.

1. AABB Technical Manual, 20th Edition (Chapter 2, Facilities, Work Environment, and Safety).
2. Current versions of the package inserts can be found on https://www.INTERCEPT-USA.com/resources/package-inserts.