Barkey®
human warmth

CASE STUDY – plasmatherm

Driving Innovation for Patient-Safety and Laboratory Efficiency

Lizette Caballero – University of California San Francisco Blood and Marrow Transplant (BMT) Laboratory Senior Supervisor

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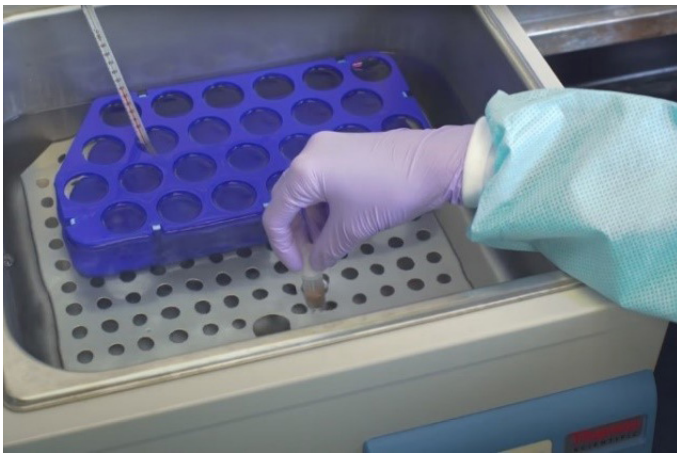
In the United States, a 37°C water bath is the most used device to thaw cellular therapy products. This method requires manually submerging product directly into a temperature-controlled water and massaging the bags, or swirling the vial, to ensure a complete thaw. Most importantly, with water baths, there's a widely held, prevalent concern for microbial contamination by exogenous germs that can further sicken or even kill an already fragile patient.

„Water baths are a headache for already busy laboratory staff because of the monitoring and maintenance associated with changing the water after every use."

Always with an attention to quality and innovation, Lizette Caballero, who was the Senior Supervisor at the University of California San Francisco (UCSF) Blood and Marrow Transplant Laboratory for almost 10 years, and who is now the Janssen Pharmaceutical Companies of Johnson & Johnson Chimeric Antigen Receptor T cells (CAR-T) Specialist, sought a safer, more hygienic, and efficient way to thaw cryopreserved apheresis hematopoietic stem/progenitor cells while at UCSF.

When blood components are processed, mechanical forces may cause small cracks (a higher concern with frozen bags) that may allow the invasion of pathogens into the blood components. This prevailing clinician concern of contamination by water-bourne pathogens is so significant that almost all of Germany has eliminated the use of water baths.
Additionally, water baths are a headache for already busy laboratory staff because of the monitoring and maintenance associated with changing the water after every use.



Ms. Caballero was pleased to discover the Barkey Plasmatherm, which is a dry heating device that gently thaws products between two water-filled cushions with a undulating paddle where the water in the cushions is only changed once a year.

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The Barkey plasmatherm means the following:

1. *Increased patient-safety by virtually eliminating risk of water-bourne pathogen contamination.*

2. *Standardization of this very manual, less predictable hand swirling of vials or massaging of bags.*

3. *Saving already busy laboratory staff 45 minutes a day of not changing water and cleaning an extra machine, which translates into 196 hours saved, or about $10,000 saved, every year. If the laboratory is changing equipment every 10 years, that's $100,000 saved.*

Always the fact and data-driven scientist, Ms. Caballero performed her own comparison and validation studies. On June 1, 2020, Ms. Caballero presented her study, "Thawing Cryopreserved Apheresis Products: Comparison of Barkey Plasmatherm Dry Heating Device and 37°C Water Bath," which was originally performed at the UCSF Blood and Marrow Transplant Laboratory, at the International Society for Cell and Gene Therapy held virtually in Paris, France (Caballero, McMillan, & Leavitt, 2020).

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First, Ms. Caballero looked at standardized surrogate markers of success, which are stem cell CD 34+ cell dose recovery, viability, and sterility.

Stem Cell CD34+ Cell Dose Recovery, Viability, and Sterility using the Barkey Plasmatherm versus the Fisher Scientific Isotemp water bath at 37°C were equivocal. All products met release criteria.

	 Cryopreserved Stem Cells Independent Collection #1		 Cryopreserved Stem Cells Independent Collection #2		 Cryopreserved Stem Cells Independent Collection #3	
	 *Barkey plasmatherm*	 *Fisher Scientific Isotemp Waterbath*	 *Barkey plasmatherm*	 *Fisher Scientific Isotemp Waterbath*	 *Barkey plasmatherm*	 *Fisher Scientific Isotemp Waterbath*
CD34 Cell Dose Recovery (%) **Must be greater than 60%*	109	90	108	105	116	68
CD34+ Cell Viability (%) **Must be greater than 50%*	94	97	94	81	87	71
Product Sterility	no growth	no growth	no growth	no growth	no growth	no growth
Colony Forming Units	growth	growth	growth	growth	growth	growth

** Stem cells used were discarded, cryopreserved apheresis hematopoietic stem/progenitor cells*

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The true scientist that she is, Ms. Caballero then looked at the stem cell success in living patients. She did this be looking at the engraftment outcomes for the first 15 patients who received products thawed with the Plasmatherm, and compared them to the preceding 165 consecutive transplant recipients who received products thawed in a 37°C water bath.

Neutrophil (white blood cells) and platelet engraftment kinetics in patients who received products thawed with the Barkey Plasmatherm versus the Fisher Scientific Isotemp water bath at 37°C were equivocal.

Barkey plasmatherm

Fisher Scientific Isotemp Waterbath

	First 15 patients to receive stem cells thawed with the Plasmatherm	**Preceding 165 consecutive transplant recipients receiving stem cells thawed with the water bath**
Median CD34 Cell Dose Infused X10^6/kg (Range)	5.07 (4.96–29.5)	4.51 (2.18–43.3)
Absolute Neutrophil Count (White Blood Cells) # Days (Median)	11	11
Absolute Neutrophil Count (White Blood Cells) # Days (Range)	10–15	8–16
Platelet # Days (Median)	20	21
Platelet # Days (Range)	17–28	10–49

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Each thawed product was tested for CD34+ cell dose recovery and 7AAD viability using Beckman FC500 Flow Cytometer with CXP software and Beckman Coulter stem-kit reagents, sterility by bacterial culture, and colony forming unit (CFU) growth (Stem Cell Technologies).

Ms. Caballero says, “In healthcare, we should always be focused on patient-safety and delivering the best care possible. I’m excited to leverage innovation to advance the field of stem cell transfusion. The Barkey Plasmatherm makes the handling of stem cells safer while also adding standardization and scalability to laboratory medicine. And my employees love me even more when I can save them 45 minutes a day of tedious water changing and machine cleaning. I look forward to continuously improving healthcare and sharing my expertise.”

References

Caballero, L., McMillan, M., & Leavitt, A. (May 2020). Thawing Cryopreserved Apheresis Products: Comparison of Barkey Plasmatherm Dry Heating Device and 37C Water Bath. International Society of Cell & Gene Therapy. Paris Virtual.

Platton, S., Elegbe, O., Bower, L., Cardigan, R., Lancut, J., McCullagh, J., & Green, L. (November 2019). Thawing times and hemostatic assessment of fresh frozen plasma thawed at 37°C and 45°C using water-bath methods. Transfusion, 3478-3484.

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