# Customizable Automated Thawing Device Series for Cryogenic Vials



## Summary

The vial thawing protocol in cell therapy industry is an unstandardized and quite variable process. Biocision identified clinical tools to standardize and automate for pharmaceutical, biotechnology, and other healthcare industries. The first platform to transform and automate the 40+ year conventional water bath thawing process was the ThawSTAR. Such a device is convenient in a GMP setting where due to the potential contamination risk, water baths are generally avoided.

BioCison tasked Gener8's engineers to architect, develop a low-cost instrument to replace existing water bath solutions. Our integrated end-to-end design to manufacturing capabilities enabled the customer to go from proof-of-concept to Beta testing units in only four months and with early low- to mid-manufacturing in six-eight months.


## Methods Employed

In reviewing the customer's requirements, Gener8 focused on the user experience and in eliminating the human error aspect that was resulting in low-yield in thawed cell therapy. The instrument was designed such that it was configurable to work with different standard cryogenic CFT and AT vials (1.0 mL, 1.5 mL, and 6 mL) as well 10 mL and 25 mL for future designs such that minimum design alterations would be required. The instrument was also designed to be compatible with different branded vials with minor dimensional differences. Additionally, the instrument was packaged to be stable, compact, and light weight with the only user input being to turn the device "on & off".

Early concept of the solid-state instrument.

## At A Glance

### Customer

BioCision/Medcision

### Product

ThawSTAR CFT 1.0
ThawSTAR CFT 1.5
ThawSTAR AT 6

### Services/ Market

Biotech, Life Sciences

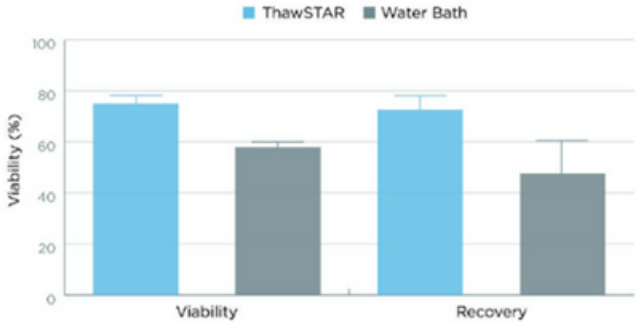
### Challenge

Cell cultures can be lost or have reduced survivability due to inconsistent thawing times. The water bath technique requires a subjective determination of the thawing end-point by the user. The user must look through the vial to estimate the size of the remaining ice. Further complicating the problem, the vials are translucent and may be obscured with labels. Excessive warming time causes the cells to metabolize the toxic cryo-solution which reduces the cell viability and population.

In addition, careless motion of the cryovial through the water bath could result in contamination of the cell culture from water becoming entrained in the cap threads of the cryovial. Inconsistent thawing times can compromise comparative analyses of cell cultures (i.e., corrupting the survivability fraction from one culture to another).

## Solution

.Gener8 met BioCision's requirements in engineering and manufacturing a simple, easy to use, fully solid-state heating instrument that mirrored the heating profile of a water bath. A study performed by UCSF Diabetes Center and Transplant Surgery observed improved viability of cells thawed using the ThawSTAR instrument compared to the conventional water bath method. Additional comparative data has been obtained for K562 erythroleukemia cells, human peripheral blood mononuclear cells (PBMCs), human spenocytes, human CD8 T-cells and mouse hybridoma cells. In all cases the cell recovery and viability was equivalent to that seen in a water bath thaw. The adaptable solid-state heating instrument eliminated contamination concerns and streamlined workflows to reduce cost and time while improving sterile operating conditions.




A total of 6 vials (2 each from 3 donors) containing ex vivo stimulated B cells, were frozen in a -80°C freezer using a CoolCell® cell freezing container and then stored in liquid nitrogen (LN2) for two weeks. One vial from each donor was removed from LN2, placed into a ThawSTAR® CFT2 Transporter and thawed in a ThawSTAR CFT2 Automated Cell Thawing Instrument. The other vial from each donor was removed from LN2 and hand-carried to a water bath. **The vials transported and thawed in the ThawSTAR Transport and Thawing System performed better in terms of cell viability and recovery.**

- Data generated by UCSF Diabetes Center and Transplant Surgery


## Expertise Employed

- Architecture design
- Thermal fluidic analysis
- Design for manufacturing
- Design for ease of assembly
- Electronics design
- Embedded firmware
- Smart algorithm design