# FREEZE BOOSTER® Controlled Nucleation



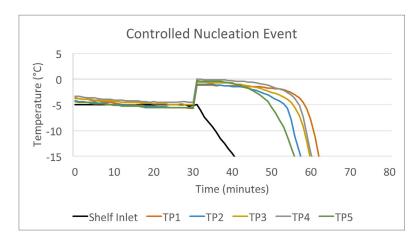
### Take ultimate control over your freezing process.

#### Why Use Controlled Nucleation?

Saves money, time and increases product quality. Controlling nucleation during the freezing step in a product to be lyophilized has been shown to shorten drying times, decrease reconstitution time and improve the quality traits of the product.

#### The Controlled Nucleation Advantage

Controlled nucleation of the product eliminates the variation in the degree of super-cooling and consequent freezing rate thereby creating ice crystal growth of optimal pore size to support the fastest sublimation rate possible. Controlled nucleation is designed to create ice matrix uniformity by controlling the freezing of the product in the same way throughout the batch and from cycle to cycle.



#### Freezing—What Happens if You Don't Have Controlled Nucleation?

The importance of the freezing step is well documented and continues to be studied in the attempt to enhance the characteristics of the frozen matrix prior to lyophilization. Historically the product is "ramped" down in temperature dynamically to a temperature below its critical melting point. Because of a number of factors this simple ramping down in temperature of the product usually creates a great variation in the ice matrix. Most notably the degree of super-cooling is often inconsistent and the size of the resulting ice crystals, in turn, is inconsistent. The ice matrix created during the freezing step essentially creates the resulting pore structure and size, and hence ability of water vapor to leave the product during primary drying. An inconsistent structure will result in inconsistent sublimation rates and cycles must be built conservatively with the worse ice matrix in mind.

# How Do I Get Controlled Nucleation on My Existing Laboratory Freeze Dryer? Just change the door and attach the NS20.

The Millrock FreezeBooster is a stand-alone module that can be attached to almost any laboratory freeze dryer. It does not require that the dryer have ASME rated chambers for high pressure and works within the parameters that the normal laboratory lyophilizer is designed for.



FreezeBooster NS20 (portable) attached to a REVO® Pro Lab



# EASILY RETROFIT FREEZEBOOSTER ON YOUR EXISTING LAB FREEZE DRYER

Will work on lab systems up to 20 sq ft.
Installation is as simple as a door
swap out



### FREEZEBOOSTER CAN BE USED ON MULTIPLE LYOPHILIZERS AND CAN BE SERVICED BY ONE

FreezeBooster is portable equipment that can be moved from one machine to another



# AVOID HASSLES, COMPLEX AND COSTLY FACTORY OR FIELD SERVICE INSTALLATION

No control system upgrades required

No additional isolation valves required

No external condenser required

No ASME rated vessels required

# FREEZE BOOSTER® Controlled Nucleation

Millrock's FreezeBooster Controlled Nucleation Station injects ice crystals under the optimum condition into the product chamber to initiate nucleation throughout the entire batch.

# Features & Benefits

#### ON DEMAND NUCLEATION

Nucleates all vials across the batch at the same time and temperature, resulting in a uniform starting point for crystal growth.

#### **EASY INSTALL ON ANY FREEZE DRYER**

One nucleation station can be used on all your lyophilizers with a simple door change. The nucleation station can be used on any freeze dryer brand, and is designed to be moved easily by one operator from lyophilizer to lyophilizer.

#### UTILIZE ON A VARIETY OF PRODUCT CONTAINERS

The FreezeBooster process has been demonstrated to work on all types of containers, including tubes, microtiter plates, and much more.

#### **ENHANCE QUALITY & REPEATABILITY**

Creates freezing uniformity across the shelf and allows control from batch to batch.

#### REDUCE OPERATING COSTS

Lower product cake resistance for shorter primary drying times.

#### STERII IZARI E

Can be sterilized via H2O2, for GMP applications.

#### PC/PLC CONTROLLED SYSTEM

System is programmed via a PLC and has the ability for remote access for troubleshooting.

#### **COST EFFECTIVE**

No need to buy a new freeze dryer. No need for major retrofits or system upgrades. Stands alone—one nucleation station will nucleate multiple lyophilizers.

# **Models**



For use on laboratory style freeze dryers up to 20 sq ft. Interfaces with the product chamber door. Mounted on an adjustable height table, the NS20 version is easily moved between freeze dryers. Option for H2O2 sterilization capability.



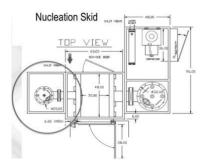
## **NS100**

For use with production style lyophilizers rom 30 sq ft to 100 sq ft. Interfaces with the product chamber door. Console style cabinet that is easily moved between freeze dryers. Option for H2O2 sterilization capability.



## **NSS100**

For use with ASME rated production style freeze dryers from 30 sq ft to 100 sq ft. Interfaces with the product chamber via an 8" port. Skid style format for connection in the service alley. Steam sterilizable.



We also make custom designed units for your larger freeze dryers.

Specifications subject to change without noticifation. All specifications based on 20C ambient and 60 Hz Trademarks registered to Millrock Technology, Inc. FB61016

Patent # 8839528, 8875413

FreezeBooster® Controlled Nucleation: page 2 of 2