Sterilization Test Report

Optimum Fluid Dispensing Components

An Optimum syringe barrel, piston, and general purpose dispensing tip.

Introduction

This test report provides an evaluation of the impact of various sterilization methods on the viability of Nordson EFD's Optimum® dispensing components. Standard Optimum syringe barrels, pistons, and end and tip caps, as well as general purpose and tapered dispensing tips underwent industry standard gamma irradiation, ethylene oxide (ETO), and autoclave sterilizations. Components were evaluated for post sterilization damage and loss of functional properties.

Please note that this document does not serve as sterilization instructions but rather as a study of the impacts of the most common sterilization methods on Nordson EFD's Optimum components.

Results Summary

All tested sterilization methods were observed to be compatible with the Optimum high-density polyethylene (HDPE) pistons, standard tapered tips, and general purpose tips. Autoclave caused discoloration in the Optimum syringe barrels and heat damage to low-density polyethylene (LDPE) pistons, end caps, and tip caps. And gamma irradiation was found to be incompatible with our polypropylene (PP) syringe barrels.

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Test Methods

Ethylene Oxide (ETO) Sterilization

EFD standard anti-static bags were filled with a standard number of individual products, vented, and placed inside cardboard boxes, which were loaded into the ETO chamber. The chamber was flooded with 2.0 in HgA/minute of ETO gas at 43° C (110° F) for 4 hours after conditioning for humidity and then cleaned with a nitrogen post wash. Parts were placed in the same packaging for further analysis.

Gamma Irradiation Sterilization

EFD standard anti-static bags were filled with a standard number of individual products and then fitted with a 20 kGy radiation indicator and placed inside a cardboard box. Boxes were hand loaded into a radiation chamber at a specified distance from the radiation source to ensure that a total dosage of 20-35 kGy could be achieved over 3 hours. Parts were placed back in the same packaging for further analysis.

Autoclave Sterilization

Nordson EFD products were re-bagged into Tyvek vented header bags and sterilized for 30 minutes at 121° C (249° F). Post-autoclave bags were re-packaged into cardboard boxes for further analysis.

Post Sterilization Test

Barrels were inspected for three primary attributes that would be impacted by sterilization:

1. Visual inspection (yellowing / clarity)
2. Impact strength
3. Hydrostatic burst strength

General purpose dispensing tips were tested with a cannula pull strength test using a Chatillon motorized tester and inspected for needle damage, glue failure, hub slip, or hub failure.

Pistons and tapered dispensing tips were tested on the Instron® 5960 Series Dual Column Table Frames tensile and compression tester with Bluehill V3.1 material testing software.

Test Results

The summary of the test results from the product sterilization compatibility of the inspected attributes are displayed in the tables below.

Compatibility with Sterilization Methods

Optimum Standard Components			
	Autoclave	Ethylene Oxide Gas	High-Energy Gamma Radiation
Syringe barrels (PP)	OK*	OK	X
Pistons (LDPE)	X	OK	OK
Pistons (HDPE)	OK	OK	OK
Tip caps (LDPE)	X	OK	OK
End caps (LDPE)	X	OK	OK
Standard tapered tips	OK	OK	OK
General purpose tips	OK	OK	OK

* Discoloration (yellowing) may occur but does not affect the impact or burst strength of the product.

Conclusions

Nordson EFD's Optimum dispensing components were introduced to three standard methods of sterilization. Visual and functional tests were performed to evaluate the results. This document is released for informational / referential purposes only. The individual user should verify results using their own methodology.

Compatibility of the current Optimum product line with sterilization methods is driven primarily by the base material used. Nordson EFD's components can be broken into four groups: syringe barrels (PP), pistons (LDPE, HDPE for standard only), end and tip caps (LDPE), and dispensing tips.

The LDPE resin used in end and tip caps and pistons is suitable for both ETO and gamma sterilization but suffers in autoclave due to its limited temperature use. The HDPE pistons provide a higher use temperature that minimizes this weakness. The polypropylene (PP) syringe barrels perform well with autoclave and ETO sterilization methods but not gamma radiation. Autoclave caused some discoloration.

In addition, all standard tips including Nordson EFD tapered tips and general purpose tips were observed to be compatible with all three sterilization methods for strength, damage, and cannula dislodging via tip pull test. There was no substantial impact on impact strength or burst strength on Optimum barrels because of the sterilization. All components passed pull strength tests regardless of sterilization method.

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