WHITE PAPER

Well defined procedures can reduce the risk of integrity failures

Optimized Handling of DPTE-BetaBag® Tyvek® in steam sterilization

Following specified load and autoclave cycle parameters will result in the best performance for DPTE-BetaBag® Tyvek®. These easy steps will improve outcomes and reduce the risk of non-compliance.

Sometimes less is more

Original DPTE® aseptic transfer

There is a human tendency to push the limits of any system. But more is not necessarily better. By following the specified load and autoclave parameters, you can reduce the risk of DPTE-BetaBag® degradation and save money that could be wasted by rejecting them.

by Anne-Claude Gilbert and Cyril Mounier

What is a DPTE-BetaBag® Tyvek® ?

The DPTE-BetaBag® Tyvek® is a combination of a DPTE® Beta part and a bag designed with two films welded together; one side is Tyvek® material, and the other is high-density polyethylene (HDPE).

Image 1: DPTE-BetaBag® Tyvek® Ø190 10L double bag

What is DPTE®?

The double door for leaktight transfer system (or DPTE® system) involves interlocking "alpha" and "beta" units, with the alpha part mounted on the containment wall, and the beta part attached to a container or bag.

The flexible DPTE-BetaBag® has long been considered the optimal solution for safe, fast, and contamination-free transfer of components. The Tyvek® range is specifically designed for steam sterilization.

What is a DPTE-BetaBag® Tyvek® used for?

These bags are used for loading components into an aseptic filling line. First the components (caps, stoppers or plungers) are inserted into the bag which is then sterilized in an autoclave. The bag is brought to the line where the sterilized components are unloaded directly into the aseptic zone.

Image 2: DPTE-BetaBag® Tyvek® Ø190 docked to a DPTE® Alpha port

Why is autoclaving important?

Autoclaving is critical to contamination prevention. A proper technique is required for success.

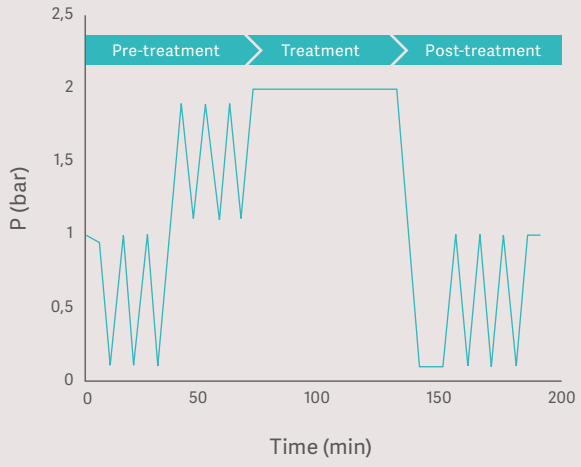
Steam vapor sterilization is a very stressful treatment for plastic raw materials, which must be treated with care. To obtain the best result in terms of seal resistance and bag integrity, a DPTE-BetaBag® Tyvek® should be filled to a pre-determined loading level and undergo a specified autoclave cycle protocol.

What happens during an autoclave cycle?

An autoclave is a pressure chamber used to sterilize equipment by pressurized saturated steam at 121°C. An autoclave sterilization cycle can be divided into three main parts:

- Pre-treatment = conditioning phase / air removal
- Treatment = sterilizing phase
- Post-treatment = drying phase

This study focused on the treatment (sterilizing) and post-treatment (drying) steps, as these are the highest-impact conditions of an autoclave cycle for the DPTE-BetaBag® Tyvek®.



During each autoclave cycle

The bag inflates and deflates several times according to the pressure modifications inside the sterilizer. Indeed the pressure equilibrium between the autoclave and the DPTE-BetaBag® is not immediate during the pressure variation in the chamber, pressure differential is created between the autoclave and the bag. Each pressure decrease inflates the bag; each pressure increase deflates it (images 11 and 12).

Image 3: DPTE-BetaBag® ready for sterilization in a Getinge GE6913 sterilizer

Study parameters

In comprehensive test programs[I,II] conducted by Getinge on a Getinge GE6913 sterilizer in Vendôme (France) we analyzed several important parameters in the autoclaving process.

General process parameters:

- Bag capacity
- Bag position

Within the treatment (sterilization) step:

- Sterilization time
- Sterilization temperature

Within the post-treatment (drying) step:

- Vacuum ramp
- Post-treatment pulses

The study used dimensional analysis to evaluate the degradation of the bag. If the bag dimension has increased after a steam sterilization treatment, we can deduce that the bag has supported a stress higher than the elastic limit of the film material.
The study showed the extent that the bag was affected by changes in parameters. After each cycle, the dimensions of the bag were measured and the bag was tested for integrity using Methylene Blue Test[III]. Increased bag deformation correlated with an increased failure risk.

Research concluded that sterilization time and number of post-treatment pulses did not have a critical impact on bag deformation and bag integrity.

By controlling the four remaining factors of capacity, position, temperature, and vacuum ramp, optimal results can be achieved.

Best practices for achieving DPTE-BetaBag® Tyvek® Ø190 autoclaving success

Avoid overloading

The more components are present in the bag, the more likely the bag is to deform. Users should avoid overloading components to ensure structural integrity.

Recommended bag limits are as follows:

- 8L load for the 10L DPTE-BetaBag® Tyvek® double bag
- 13L load for the 23L DPTE-BetaBag® Tyvek® single bag
- 18L load for the 25L DPTE-BetaBag® Tyvek® double bag

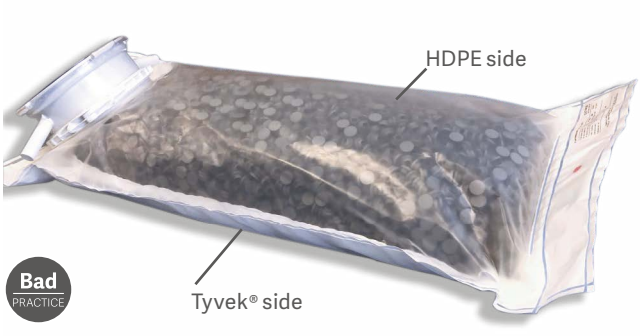


Image 4: 25L DPTE-BetaBag® Tyvek® overloaded

Image 5: 23L DPTE-BetaBag® Tyvek® overloaded

Image 6: 25L DPTE-BetaBag® Tyvek® loaded to maximum recommended level

Image 7: 23L DPTE-BetaBag® Tyvek® loaded to maximum recommended level

Position the bags properly

Place the bags on the shelves in a flat position on the Tyvek® side.

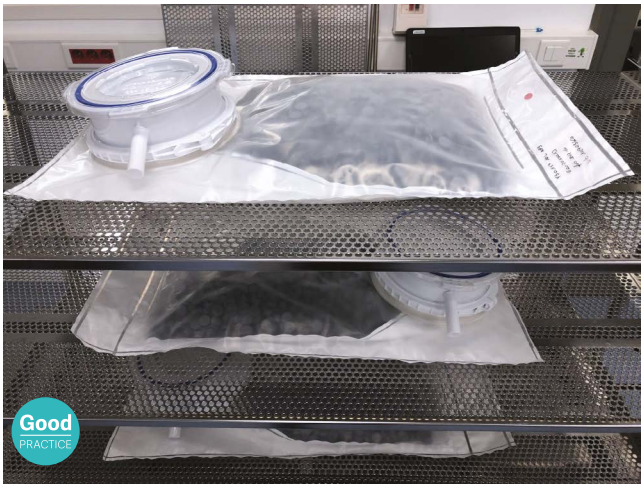


Image 8: Correct placement of a DPTE-BetaBag® Tyvek®

The distance between shelves can be reduced to 15 cm to maximize throughput. The constraint provided by the upper shelf does not adversely affect bag integrity.

Image 9: Constraints on the HDPE film

When the bag is placed on the HDPE side, the mechanical constraints on the film are increased by the weight of the components, which is unfavorable to maintaining the bag integrity (see image 9).

Control temperature

Dimensional analysis of the bag revealed that the bags sterilized at 121°C, 123°C and 124°C, presented the same dimensions after sterilization. However, higher temperatures affect the structural integrity and functionality of the bag (image 14).

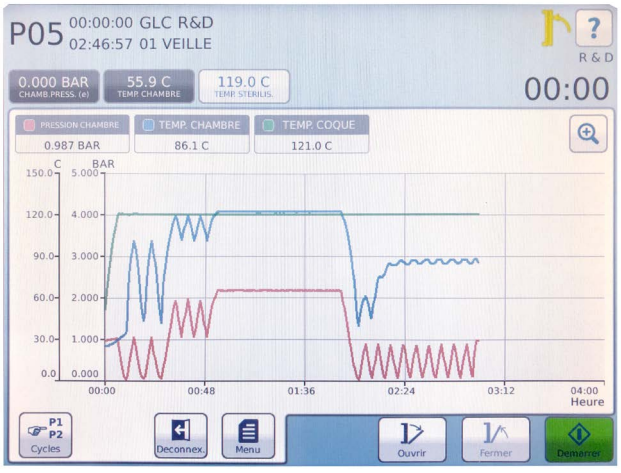


Image 10: View of the Pressure and Temperature evolution in the autoclave chamber

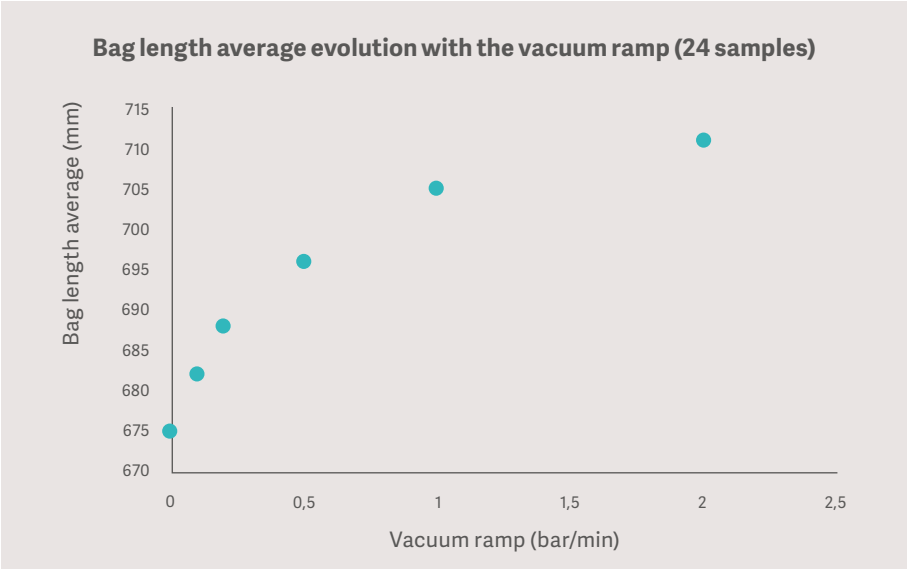
Minimize vacuum ramp

During an autoclave cycle, the bag will inflate and deflate several times according to the pressure modifications inside the autoclave. Each pressure decrease will inflate the bag; each pressure increase will deflate the bag.

The photos below show the DPTE-BetaBag® Tyvek® in a GE6913 sterilizer with integrated visualization window. The autoclave is used for testing in Getinge's R&D laboratory, Vendôme France.

Image 11: Inflation during pressure decrease. Image shows the contact between the DPTE® Beta part and shelf above

Image 12: Deflated bag during pressure increase



The dimensional analysis of the bag revealed that the higher the vacuum ramp, the greater the elongation of the bag.

The greater the elongation, the higher the risk of failure from film breakage.

Figure 1 : Average evolution of the bag length with the vacuum ramp

Conclusions

There are four important steps to take to ensure DPTE-BetaBag® autoclaving success. By following these steps, it is possible to minimize the risk of on-compliance. This can reduce risks of contamination and costs associated with the waste of bags and components.

Do not overload the bag

Excess capacity can increase the risk of integrity loss.

Maintain temperatures between 121°C and 123°C

Higher temperatures damage the bag.

Place bag flat, on the Tyvek™ side

The Tyvek™ side provides a flat surface, undisturbed by the DPTE® Beta port.

Set the minimum acceptable value for the vacuum ramp

The risk of structural failure increases beyond 0.5 bar/mln.

Four types of non-compliance

Image 13: Bag welding has peeled due to bag overloading

Image 14: Outer and inner bags of the DPTE-BetaBag® double bag, stuck together due to partial film melting (excessive temperature)

Image 15: Critical film elongation due to bag overloading and/or excessive vacuum ramp

Image 16: Critical film elongation at the connector edge due to HDPE side positioning and/or excessive vacuum ramp

Areas to be observed

- All the sealing lines, i.e. around the rigid connector;
- Tyvek® to HDPE assembly (longitudinal, top of bag and bag-to-bag seal at the bottom of the bag).

References

[I] Gilbert AC, Mounier C. Study on the DPTE-BetaBag® Tyvek® Behavior Inside an Autoclave — Part A: Autoclave Cycle Parameters. Study conducted by Getinge La Calhène. July 2019

[II] Gilbert AC, Mounier C. Study on the DPTE-BetaBag® Tyvek® Behavior Inside an Autoclave — Part B: DPTE-BetaBag® Material and Filling Load. Study conducted by Getinge La Calhène. July 2019

[III] ASTM F 1929 "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration"

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Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and for life science companies and institutions. Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving the everyday life for people - today and tomorrow.

Ekebergsvägen 26 · Box 69 · SE-305 05 Getinge · Sweden

www.getinge.com

LS3143-DPTE-BetaBag®-sterilization-white-paper-20191113