

Mitigating Risk with Autoclave Air Removal Tests

AIR REMOVAL VERIFICATION TESTING SHOULD BE PERFORMED DAILY TO MINIMIZE RISK OF FAILURE FOR PREVACUUM STEAM STERILIZERS.

WHY THIS IS IMPORTANT

The presence of air in an autoclave sterilization cycle can adversely affect steam penetration and steam contact with the materials being sterilized. Saturated steam condensing on a surface is essential in killing microorganisms that may be present on the material surface. Daily use of the STERIS Steraffirm® Bowie-Dick Test Pack confirms sufficient air removal and steam penetration in the autoclave and ensures compliance with international regulations and current good manufacturing practices (cGMPs).

REGULATORY GUIDANCE AGREES

Draft EU Annex 1 Revision, Section 8.59

“There should be adequate assurance of air removal prior to and during sterilization when the sterilization process includes air purging...For autoclaves, this should include an air removal test cycle (normally performed on a daily basis)...”

ANSI/AAMI ST79, Section 13.7.6.1

“ A Bowie-Dick (Type 2 CI) test should be performed each day the sterilizer is used, before the first processed load...A Bowie-Dick test is conducted every day the sterilizer is used, before the first processed load or at the same time each day, and during sterilizer qualification testing because it is a sensitive and rapid means of detecting air leaks, inadequate air removal, inadequate steam penetration, and noncondensable gases. Insufficient air removal in a dynamic-air-removal sterilizer, particularly a prevacuum cycle, can defeat sterilization and result in nonsterile supplies if undetected.”

EN 285, Section 17.1

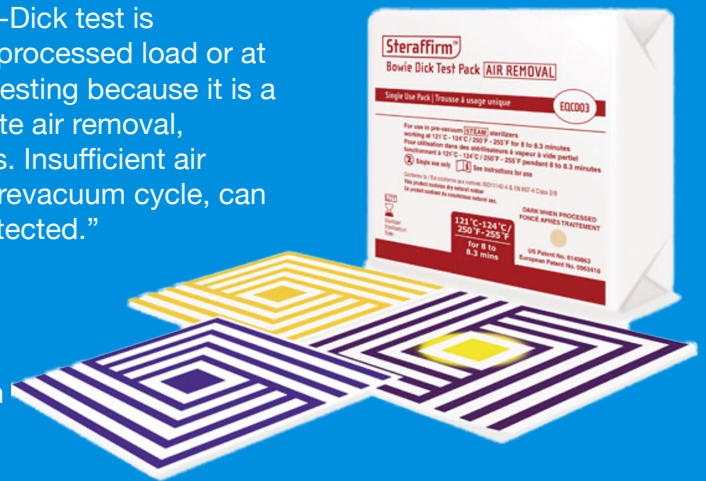
“The Bowie and Dick test was conceived as a test for successful air removal for vacuum porous load sterilizers. A successful Bowie and Dick test indicates rapid and even penetration of steam into the standard test pack or reduced test pack.”

ISO 17665-1, Section 12.1.6

“If the sterilization process relies on the removal of air from the sterilizer chamber in order to achieve rapid and even amounts of steam into the sterilizer load, a steam penetration test shall be carried out each day before the sterilizer is used. The steam penetration test is carried out using a device having a defined challenge to air removal and steam penetration for the process.”

ISO 17665-2, Section B.4.2

“The efficacy of the air removal system of a dynamic-air-removal sterilizer is tested using a steam penetration test similar to the Bowie-Dick test.”

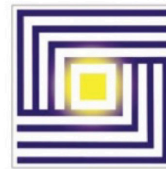
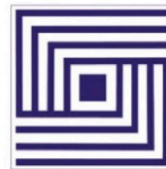
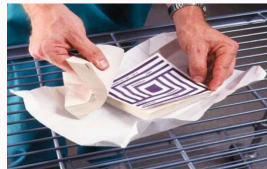


CHOOSING THE BEST AIR REMOVAL TEST

- The Steraffirm Bowie-Dick Test Pack is manufactured, tested and conforms to ISO 11140-4 and EN867-4 as a Type 2 Chemical Indicator. These regulations mandate testing required for a chemical indicator to be used for air removal and steam penetration detection.
- The Steraffirm Bowie-Dick Test Pack is validated for use at temperatures between 121-124°C (250-255°F), which is typical for pharmaceutical and biotech autoclave processes. A passing test demonstrates conformance of steam sterilizers to EN285 and as a routine test of performance in ISO17665-1.
- The Steraffirm Bowie-Dick Test Pack verifies that the prevacuum steam sterilizer effectively removes air. Test data demonstrate that, in a steam sterilizer in the presence of saturated steam at 121-124°C for 8 to 8.3 minutes, the sensitivity of the pack is sufficient to detect a 2°C (3.6°F) temperature depression at the start of exposure.
- The Steraffirm Bowie-Dick Test Pack detects problems with steam quality and may serve as a diagnostic tool in the event of a failure.

EASY TO USE

After a warm-up cycle at the beginning of each day the Bowie Dick Test cycle is run with Steraffirm Bowie-Dick Test Pack placed into the autoclave chamber over the drain. After the test cycle is complete, the test pack is removed from the sterilizer. The test pack is opened and the chemical indicator card is evaluated. Typically, this process takes less than 20 minutes to complete.



MITIGATING RISK

- Frequency of performing the air removal test is determined by evaluating the quality, business and regulatory risk. The impact of not detecting sufficient air removal during the autoclave prevacuum cycle must be taken into consideration, as the sterility of all materials processed since the last passing test would be called into question.
- Inadequate air removal from an autoclave has direct impact on product quality; therefore, failure to comply leads to a lengthy Quality Assurance investigation. Depending on investigation results, the worst-case scenario is non-sterile product and possible product recall. Equipment remediation requires downtime and lost production, which impacts overall business. Non-compliance with regulatory expectations and cGMPs may result in citations and other negative repercussions.
- In routine production, the probability of not adequately removing air from the autoclave chamber may be low. However, the impact of not detecting inadequate air removal is quite severe, as this has direct impact on sterility assurance of the materials. Daily air removal verification using the STERIS Steraffirm Bowie-Dick Test Pack is the simplest and most robust form of detection.

To learn more, refer to STERIS Technical Tip: 5518 "Importance of Air Removal in an Autoclave Steam Sterilization Process"