Moist heat sterilization for skin drug delivery device VAX-ID, a pandemic readiness strategy

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1. INTRODUCTION

Moist heat or steam sterilization is a well-established method across the globe. Compared to other routes like radiation or Ethylene Oxide, it's an attractive method for sterilization of medical devices especially when sudden high demands arise, like in pandemic scenarios.

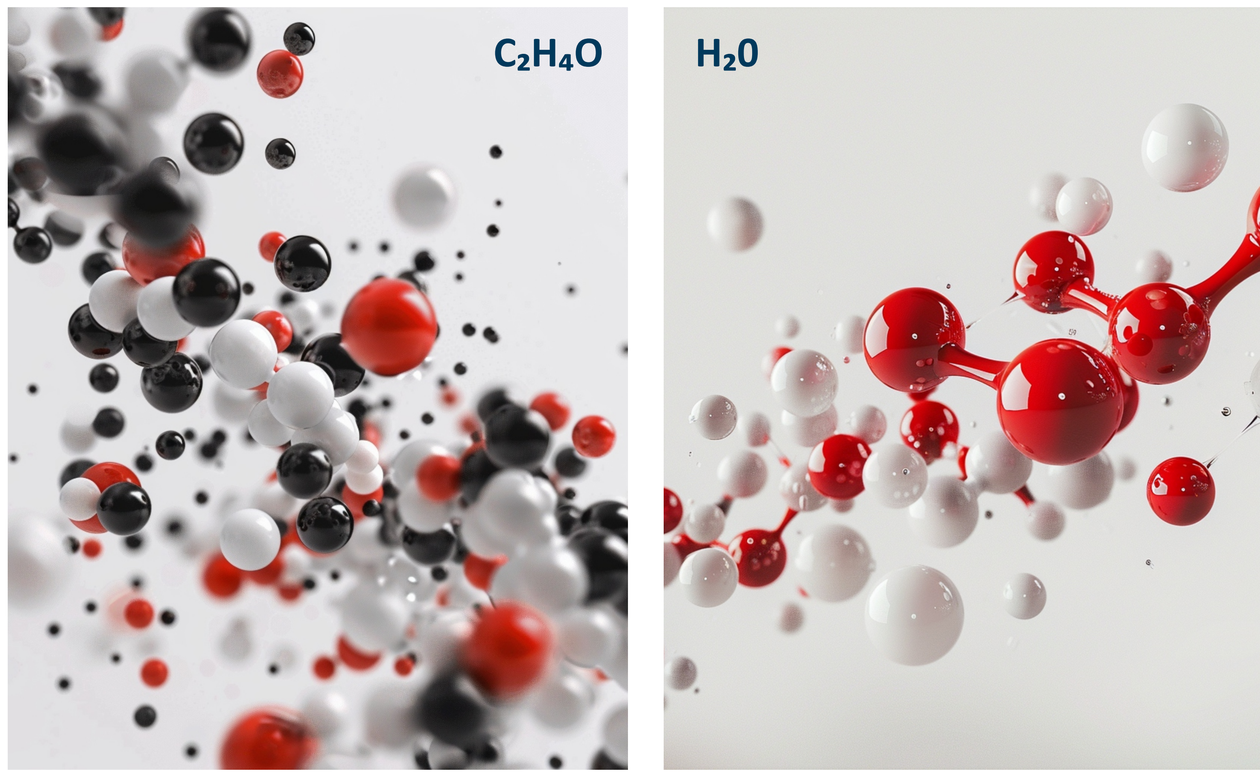
VAX-ID®2200 is a medical device by Idevax that allows for reliable and easy intradermal injections. It's well suited for mass vaccination campaigns as it offers a dose-sparing effect that can save up to 10x in vaccine dose. The aim of the study was to assess compatibility of VAX-ID with steam sterilization offering a quick roll-out and increase in vaccination capacity in a short timeframe.

Picture: an autoclave for moist heat sterilization of medical equipment and devices.

2. METHOD

A total of 4960 VAX-ID® devices were exposed to steam, minimum temperature of 122,0°C, set point temperature of 123,5°C, maximum temperature of 125,0°C, stabilization duration of 6 minutes, and sterilization duration of 20 minutes at Mithra (BE).

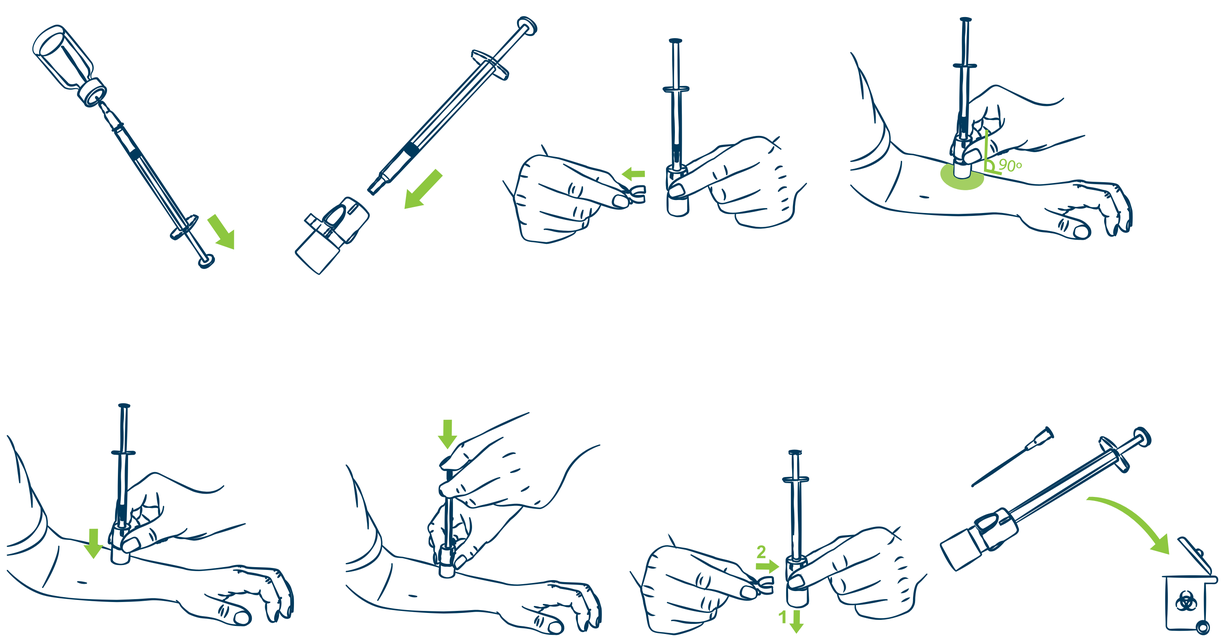
Next, 246 devices were inspected and tested externally and at Idevax to determine the impact of the moist heat on the product's mechanical, physical and functional features. Tests were performed on devices and their packaging that had gone through transport simulation (ASTM D4169 DC13) and accelerated aging simulations (ASTM F1980) of 2 and 5 years.
Tests included: (i) visual inspection, (ii) physical appearance and moisture tests, (iii) safety pin tests, (iv) friction tests, (v) visual purging tests, (vi) physical purging tests, (vii) technical tests (ISO 11608), and (viii) integrity tests.



Ethylene Oxide *Molecules for EO sterilization VERSUS* ***Steam*** *Molecules for Moist Heat sterilization*

3. RESULTS

All devices passed the different tests and inspections. There were no findings of functionality breaches such as leakages, polymer deterioration, blockages, nor impartment on removing the safety pin.
No moisture retention was observed. Only the white product label showed a slight change in physical appearance, but text and symbols were easily readable and intact like prior to sterilization.



VAX-ID® 2200 instructions for use

4. CONCLUSION

Steam sterilization had no significant impact on the mechanical properties, functionality and appearance of the VAX-ID® devices and therefore performance nor safety.

These results indicate that steam sterilization is a suitable sterilization method for VAX-ID® as a drug delivery device. Thus, it's compatibility with steam sterilization can offer a quick roll-out of stock-piled devices and increase in vaccination capacity in a short timeframe for emerging pandemics as steam sterilization is a commonly available infrastructure.

Picture of VAX-ID® 2200

VAX-ID®

Elsevier Vaccine | September 8-11 2024 | Lisbon, Portugal | Poster 2.54
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