

Dose accuracy assessment of a skin drug delivery device for intradermal vaccination in an artificial arm

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1. INTRODUCTION

Intradermal vaccination with a lower dose, into the rich network of antigen presenting cells of the skin, has been shown to elicit a non-inferior immune response compared to intramuscular vaccination with a full dose. As a result, intradermal vaccination could offer a promising solution to increase vaccine availability in the fight against cervical cancer.

The aim of the current study was to assess the performance of VAX-ID®, a novel intradermal drug delivery device, in a preclinical setting.

2. METHOD

The injection fluid was a mixture of NaCl 0,9 % and Chinese ink in a 1:0.15 ratio. Injections were performed using VAX-ID® preconfigured with a 32G needle or a 27G needle with a predefined penetration depth of 0.85mm or 1.80mm, respectively, in an artificial 3D printed average adult forearm ('ARMID') equipped with multiple isolated layers of viscose cellulose and polypropylene fiber patches. The patches were disassembled after injection to evaluate liquid deposit and distribution, and injection depth.

3. RESULTS

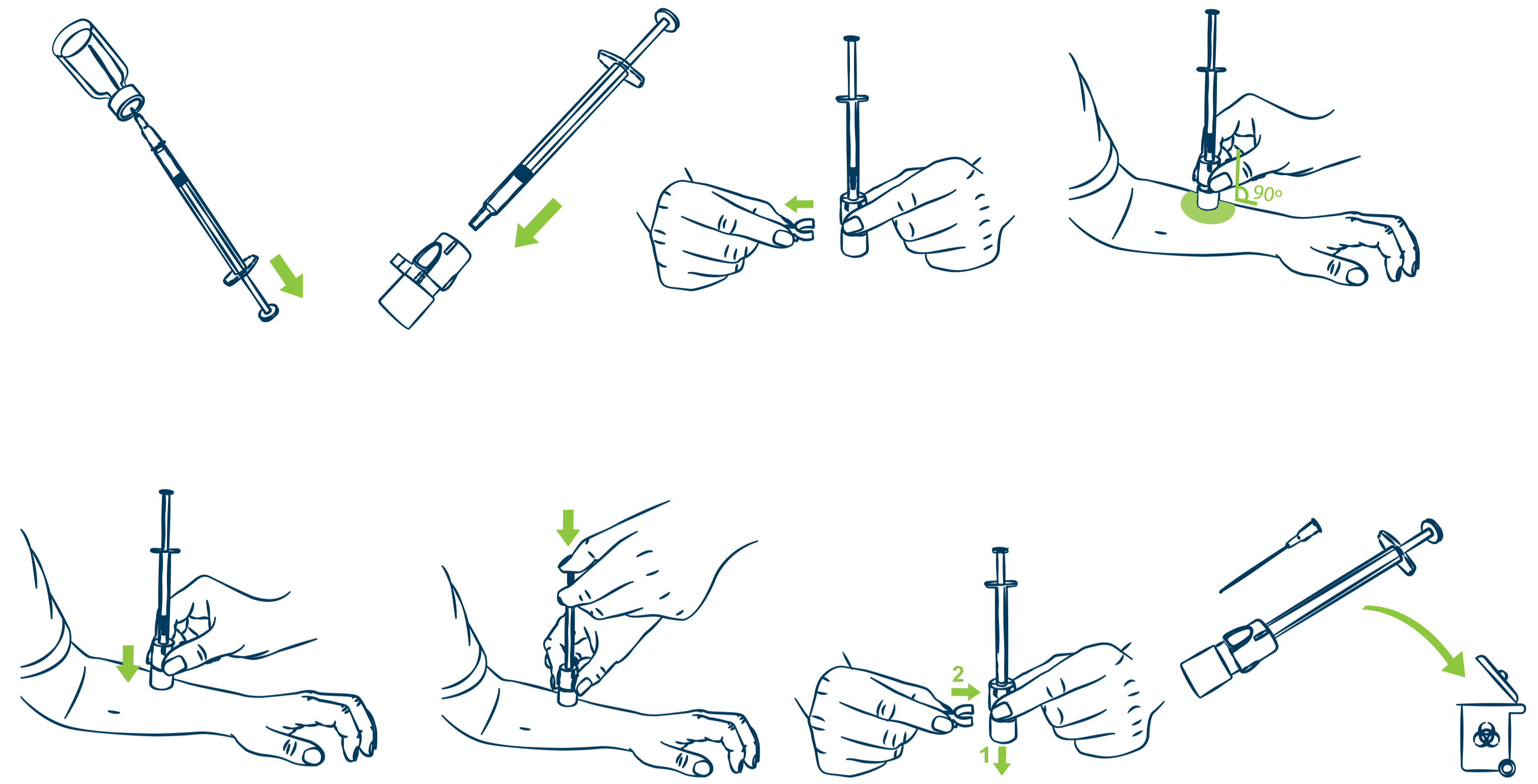
Inspection of the patches of the 32G needle showed 43% of the liquid distributed at a depth of 0-0.6mm and 44% at a depth of 0.6-1.2mm, with 12% below 1.2mm. Total distribution in patch volume was 56mm³.

Inspection of the patches of the 27G needle showed 4% of the liquid distributed at a depth of 0-0.6mm, 19% at a depth of 0.6-1.2mm, and 42% at a depth of 1.2-1.8mm, with 35% below 1.8mm. Total distribution in patch volume was 55mm³.

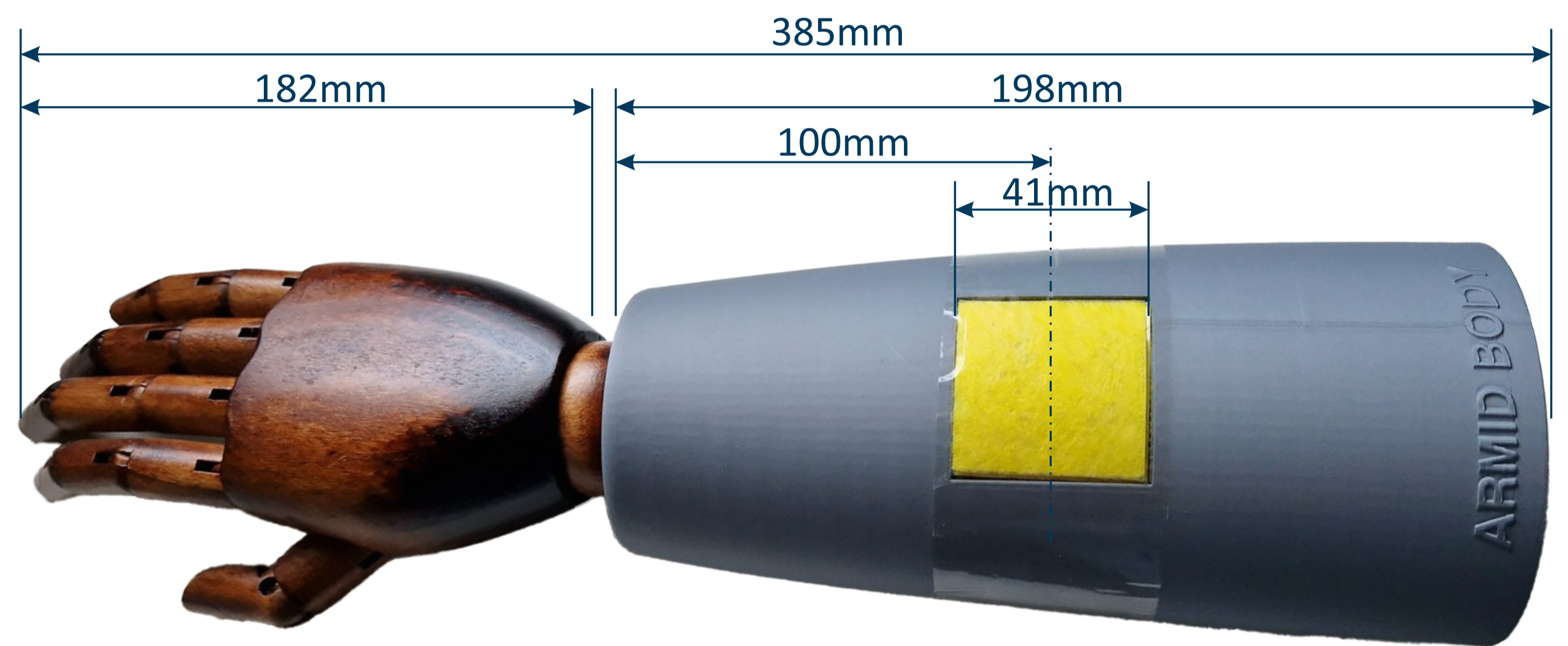
4. CONCLUSION

The artificial arm showed to offer an accurate preclinical model to assess the performance of skin drug delivery. VAX-ID® allowed for a reliable deposit of substances at the device's predefined needle depth, with a low dead volume, high dose accuracy and a high ease of use.

Studies in humans will allow confirming these findings and assess effectiveness of HPV vaccines.



VAX-ID® 2200 instructions for use

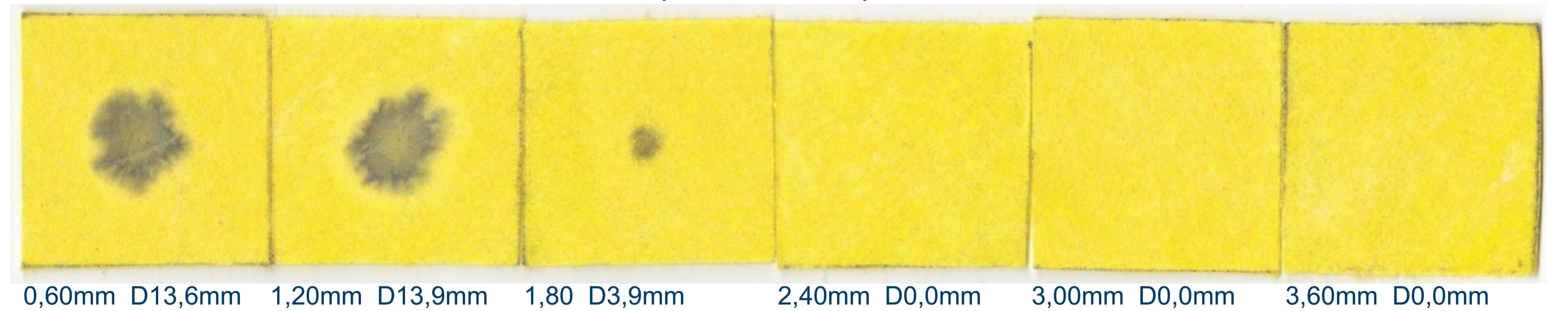


Picture: ARMID arm and dimension, with yellow cellulose and polypropylene fiber patches.

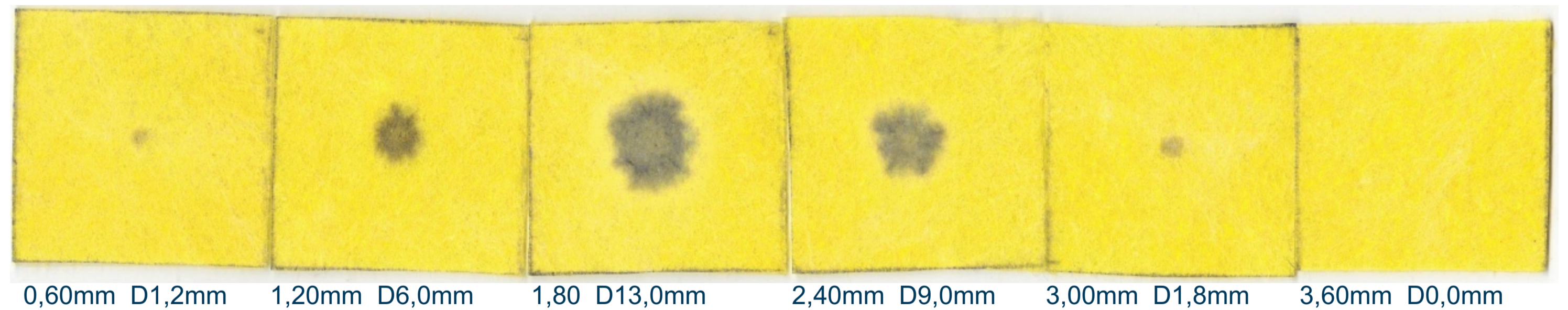


Pictures: injections with VAX-ID in ARMID arm

32G, REF D00046, LOT 23E293 - 0,85mm penetration depth



27G, REF D00047, LOT 23E291 - 1,80mm penetration depth



Pictures: dismantled patches after injection with VAX-ID 32G (top), and VAX-ID 27G (bottom).

32G, D00046, LOT23E293

Dye deposition in different layers

	Layer 1 0.00 - 0.60 mm deep - Surface area: 42.73 mm² - average thickness of the layer: 535 µm RESULTED VOLUME: 24.14 µL	24.14 µL 43% of 55.73µL
	Layer 2 0.60 - 1.20 mm deep - Surface area: 43.67 mm² - average thickness of the layer: 535 µm RESULTED VOLUME: 24.67 µL	24.67 µL 44% of 55.73µL
	Layer 3 1.20 - 1.80 mm deep - Surface area: 12.25 mm² - average thickness of the layer: 535 µm RESULTED VOLUME: 6.92 µL	6.92 µL 12% of 55.73µL

Graph: analyses of dye deposition per layer, with VAX-ID 32G



Picture of VAX-ID® 2200