

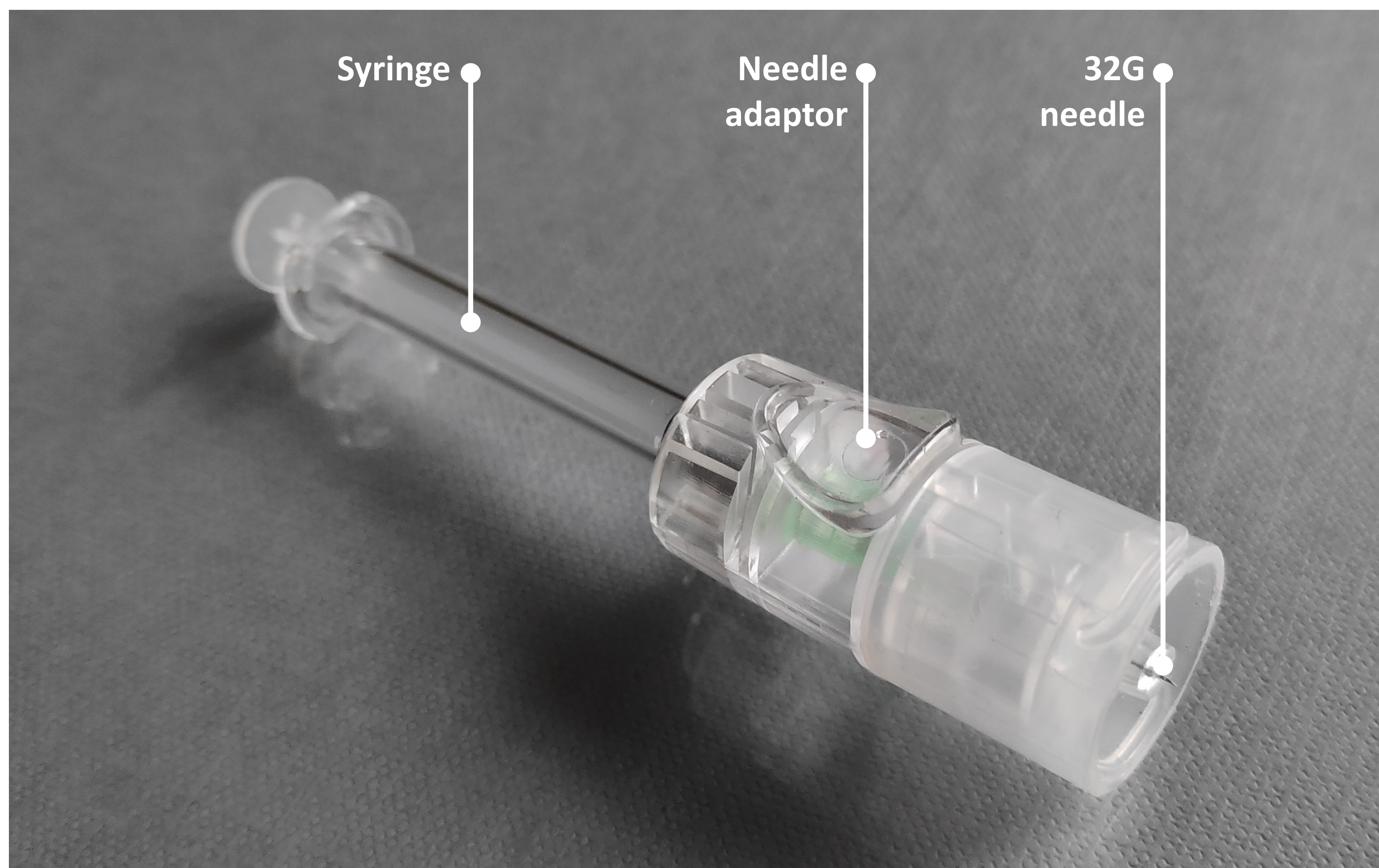
In vivo assessment of the injectability and suitability of intradermal injections using VAX-ID®

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INTRODUCTION

VAX-ID® 2200 is the most recent variant of an innovative medical device developed by IDEVAX for accurate, dose-sparing, and user-independent intradermal drug delivery. VAX-ID® answers to a medical need since the current standard of care method for intradermal injections is not always reliable, requires extensive training, and is perceived as painful. Multiple therapeutic substances and vaccines can be delivered by the device. VAX-ID® allows for injection of liquid vaccines at a penetration depth of 0.85mm up to 1.20mm depending on needle gauge used (32G vs 27G respectively). Therefore, VAX-ID® can be a game-changing device in making vaccines more accessible.



VAX-ID® is a newly developed intradermal injection device, allowing reliable, accurate and standardized injection in the dermis with high ease of use.

GOAL

The goal of this study was to evaluate injectability, safety and performance of the VAX-ID® 2200 device in vivo.

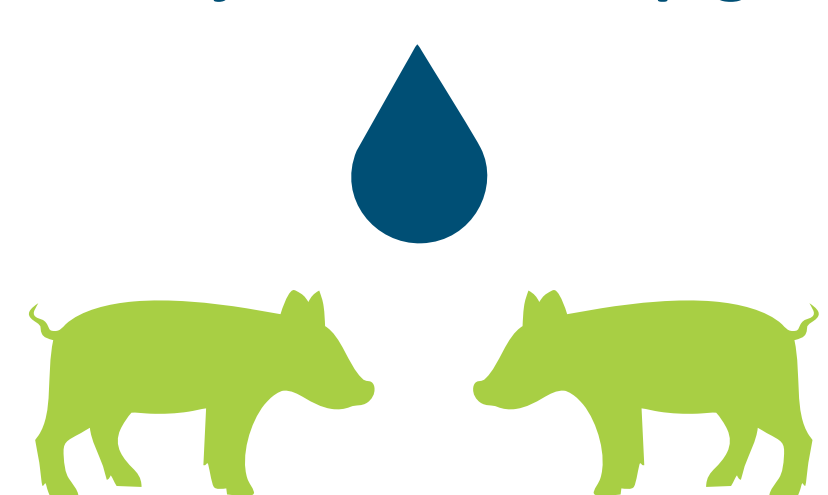
MATERIALS & METHODS

A total of 19 injections with VAX-ID® 2200 devices with 32G needles, plus 6 additional injections with VAX-ID® devices with 27G needles were performed in two living piglets of 12 kg at the facilities of Medanex Clinic. The injection fluid used is a mixture of NaCl 0,9% and Chinese ink 1:0.15 ratio. This mixture is easy to visualize and is maintained after histological preparations.

The piglets received the injections using a 32G needle in triplicate in the following injection sites (regions): neck, back, and abdomen. One additional injection using the 27G needle in the same sites was performed as a comparator.

Visual inspection was performed for the evaluation of bleb formation, leakage, and adverse effects. Biopsy sampling was performed collecting skin samples reaching a small portion of the muscle underlining, these tissues were stained with standard hematoxylin and eosin (H&E) and further evaluated using light microscope.

n=25 injections in 2x piglets



visual inspection and tissue collection (n=19)



histology



RESULTS & DISCUSSION

Visual inspection

The visual inspection showed bleb formation in 95.24% of the samples, the average bleb diameter was 0.61 cm. Bleb formation is a visual sign of successful ID injection, VAX-ID® Gen 2 adaptor will cause a donut-like print on the skin, so the bleb formed will not be pronounced centrally where the needle has been inserted as the case of Mantoux injection, but rather the bleb will be formed on the area of the skin that is not depressed by the device adaptor.

Transient erythema was observed in the injection site, micro bleeding was only noticed in two samples, and macro bleeding was not observed in any of the samples. No serious adverse effects were observed.

Histological evaluation

VAX-ID® 2200 is serving the function to deliver an injected substance to the dermal layer of the skin. The samples (Figures 1 & 2) confirmed that the dermis is the main site for dye deposition. The dye reached both reticular and papillary dermis and was well distributed along the dermis instead of moving or dispersing into the epidermis.

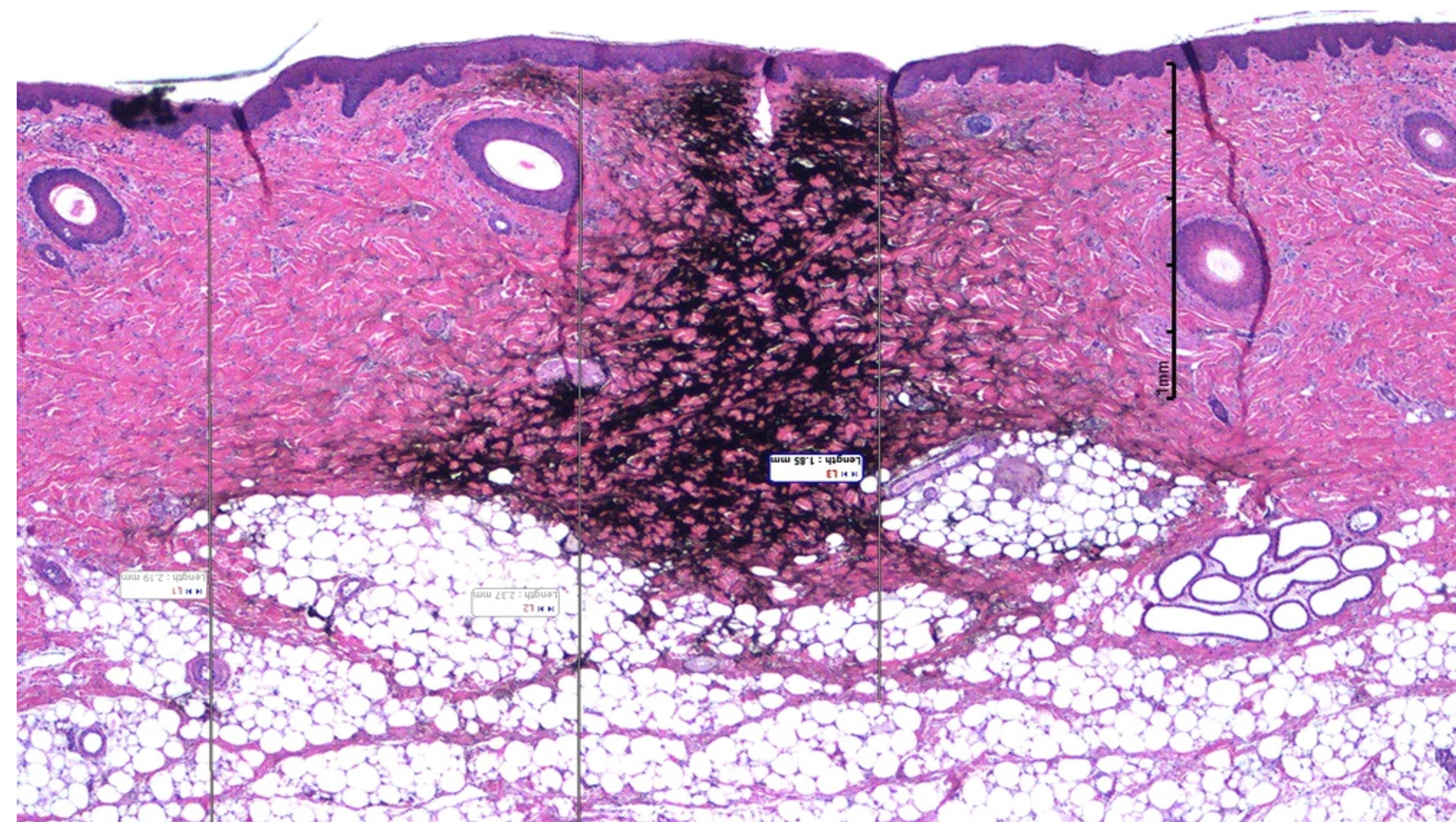


Figure 1: Piglet skin dye deposition post injection with VAX-ID® 32G. H&E stain 20x

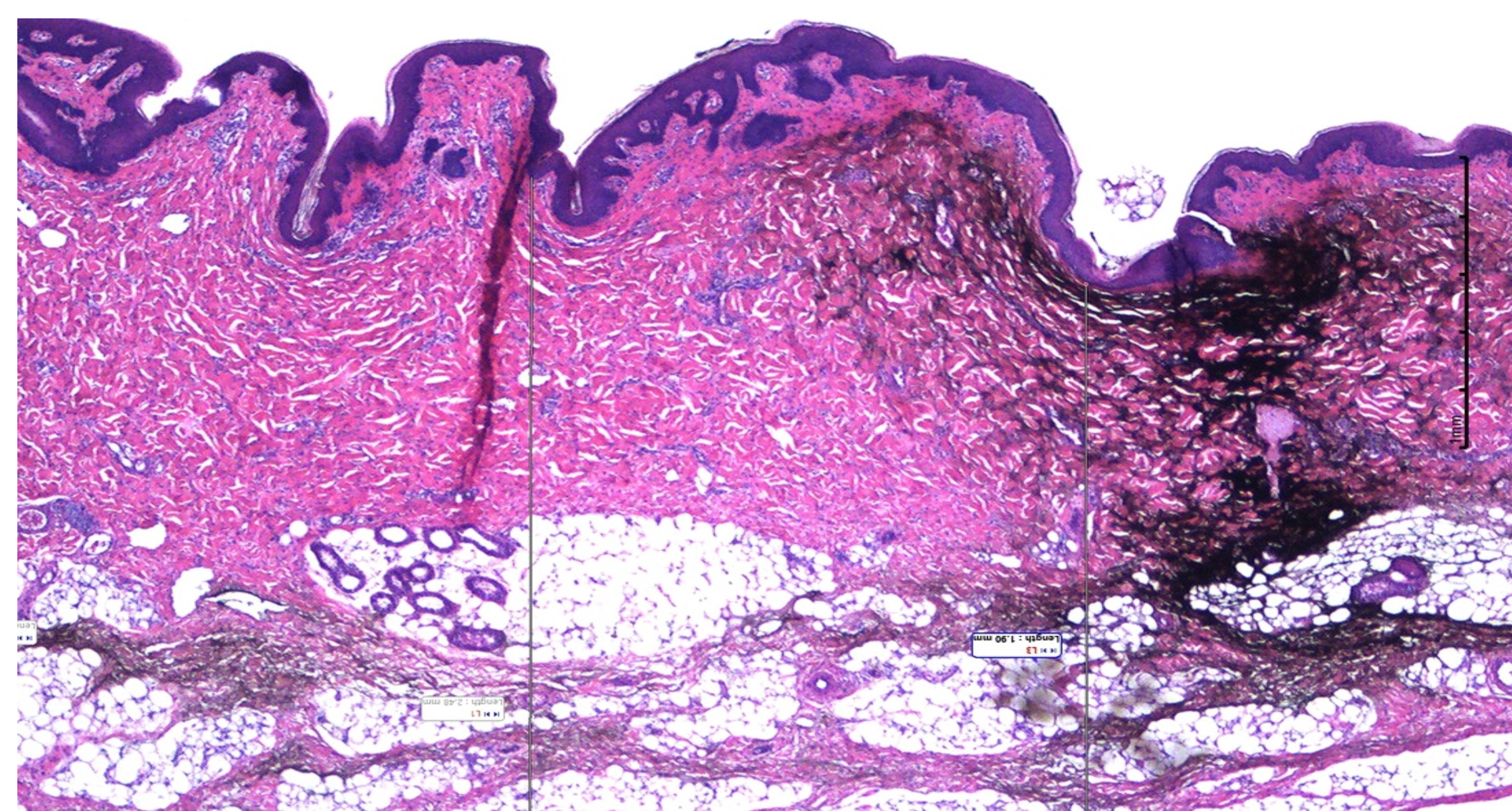


Figure 2: Piglet skin dye deposition post injection with VAX-ID® 27G. H&E stain 20x

CONCLUSION

The VAX-ID® 2200 device was able to inject the dye in the dermal layer of the skin in piglets of 12 kg reaching the papillary dermis, shown by the histological evaluation on dye deposition. The injections with the devices induced bleb formation, which suggests successful intradermal injection. No serious adverse events were observed with the use of VAX-ID® 2200.