Needle-free injectors: going from strength to strength

A third generation intradermal needle-free injection device (IDAL 3G) for pigs has been launched worldwide by MSD Animal Health. According to those who have tried it in the field, it is even better than its predecessor. But why go needle-free in the first place?

by The Technical Team, MSD Animal Health. www.msd-animal-health.com

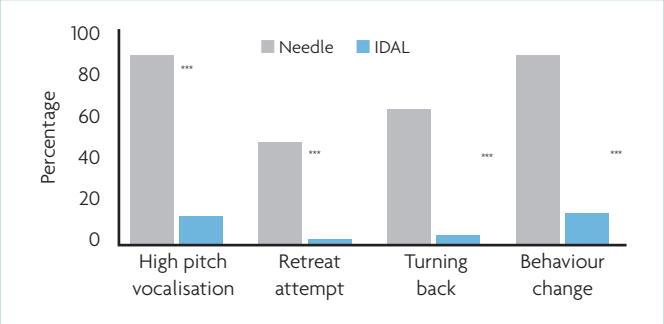

Fig. 1. IDAL injection reduces fear and pain reactions in sows compared to needle injections (42 sows in each treatment group; *** P<0.005).

"Needle-free and intradermal vaccinations are a perfect match," confirms Rika Jolie, Head of Global Swine at MSD Animal Health, during the online launch of IDAL 3G.

"The needle-free approach has great benefits for both pigs and people: it eliminates the risk of the transfer of pathogens, it removes the risk of broken needles in pigs and their meat and avoids needle-stick injuries in operators, and above all, it improves animal welfare."

Studies have confirmed that pigs were less stressed during vaccination campaigns, and are less fearful of farm operators after needle-free vaccine administration compared to those using needles.

Satisfying consumer demand

In practice, during vaccination campaigns, "the same needles are often used for multiple animals, which blunts the needles, meaning the injection becomes increasingly painful for the next animal," confirms Olivia Azlor, Global Marketing Director at MSD Animal Health.

"Animal welfare, healthy meat with minimal antibiotic use are among the top priorities of today's consumers.

Although IDAL is obviously not the answer to all questions, it does help to improve welfare and meat safety, while good vaccination protocols will reduce the need for antibiotics."

But there is another reason why this is a perfect match: IDAL allows the vaccine to be delivered intradermal rather than deeper in the subcutaneous muscle.

"Compared to muscle tissue, the skin is much better adapted to vaccination as it is a truly immunological organ and contains many resident immune cells," confirms Ruud Segers, Head of Global Swine R&D at MSD Animal Health. "In the muscle, there are not only less immune cells, but they are just passing and are not resident to pick up and deal with pathogens and antigens."

The fixed volume of intradermal vaccination (0.2ml) is perfect for the purpose. "It is enough to spread horizontally in the skin and to induce an immune response.

A larger volume would just make the vaccine go elsewhere."

The skin: an immunological organ

This was confirmed by Dr Cathy Hogan at the Massachusetts Institute of Technology, who studied the behaviour of fluid in tissue following injection with the IDAL device. Various tests, including gel penetration, histology and sophisticated radiographs all confirmed that the IDAL-administered liquids mainly stay in the intradermal and immediate subcutaneous tissue.

MSD is not new to the IDAL game. "We started developing needle-free vaccination some 25 years ago, in the Netherlands in the early 1990s," explains Dr Segers.

"Our prime objective at the time was the eradication of Aujeszky's disease (pseudorabies), and the speed of vaccination and prevention of disease transmission was crucial."

This is also the reason why the first dedicated intradermal (ID) vaccines were live vaccines – against Aujeszky's disease and against the porcine respiratory and reproductive syndrome (PRRS) – and best suited to intradermal administration.

"The live vaccine virus will be transported by dendritic cells in the skin to the regional lymph nodes. Here, so-called B-lymphocytes are activated, to produce specific antibodies against the vaccine's disease antigen. Dendritic cells in the skin and adjoining tissues can also efficiently stimulate the so-called memory response."

A growing vaccine portfolio

But dedicated inactivated ID vaccines have also been developed, including against Mycoplasma hyopneumoniae and against the porcine circovirus. "We had to overcome a number of additional challenges," admits Dr Segers. Because of the small volume, these vaccines not only require a tenfold higher antigen concentration, but they can only contain a tenth of the volume of adjuvant. And the vaccine emulsion should remain stable for at least 24 months."

Having two M. hyo vaccines – one for intradermal and one for IM administration – allowed the company to compare their performance in the field. A double-blind study was undertaken on 1,000 piglets on a commercial farm.

"We found that both the ID and IM vaccine worked well and provided full protection." However, the ID was found to significantly outperform the intramuscular vaccine in terms of

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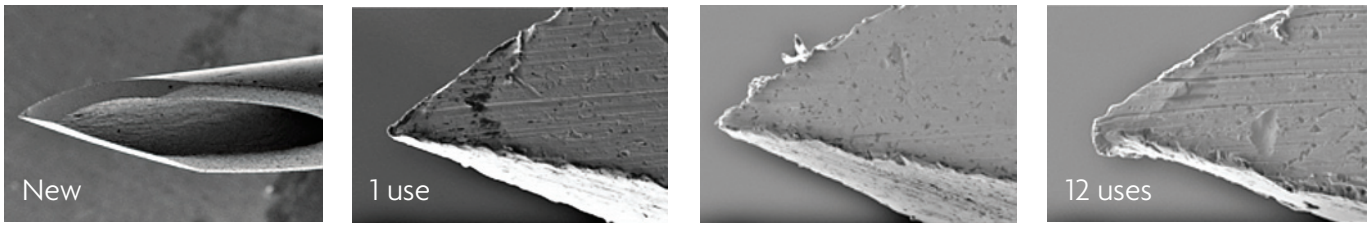
The life span of a needle is short. They become blunt and lose sharpness following less than 12 uses (images courtesy of University of Veterinary Medicine Giessen, Germany in Cooperation with MSD Animal Health, Germany).



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lung lesions and mortality. "The superior results suggest that the ID of administration induces better immune response, possibly due to the more effective presentation of the antigen by the dendritic cells."

As a result, the company decided to focus on the intradermal vaccine and discontinue R&D of its intramuscular equivalent – and not only because of its superior performance. It is easier on the operator, too.

"Intradermal vaccination is animal-friendly. It is a pleasure to vaccinate sows in a calm, stress-free environment, without screaming pigs or chasing after them."

Improving the IDAL

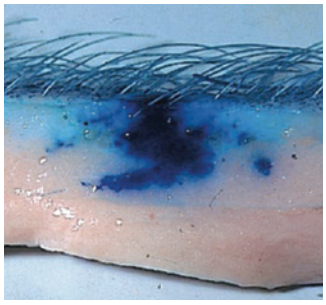
The manufacturing of a sophisticated device such as IDAL requires a high level of technical accuracy and consistency. It is currently manufactured by Henke Sass Wolf (HSW) in Tüttlingen, a medium-sized market town on the Danube in South-western Germany, and home to over 450 surgical and medical equipment companies.

"Our company is world market leader in human rigid endoscopes and syringes, with an expertise in the concept and development of veterinary syringes and application systems," explains Jonas Riess, the IDAL product manager at HSW.

The first needle-free devices were developed in the Netherlands in the 1990s (by Frencken Mechatronics in collaboration with Intervet), and the first IDAL officially appeared on the market in 2001.

HSW took over technical development in 2012. Improved models IDAL 1G and 2G arrived on the market in 2013 and 2014, respectively. "Improvements included a stronger, more robust housing and a more reliable battery. IDAL 2G was equipped with a redesigned case to protect all components and allow thorough cleaning and disinfection for optimal biosecurity. We also worked on longer maintenance intervals, blue-tooth connectivity, an improved battery charger, a position sensor ensuring correct vaccination, and a new display screen allowing good indoor and outdoor visibility."

The shaded blue area shows the depth to which the vaccine penetrates the skin.



The benefits of IDAL vaccination

Advantages of needle-free vaccination for pigs
- Fast, effective immune response.
- Reduced risk of disease transmission.
- Low injection volume required (0.2ml instead of 2ml).
- Faster warm-up of vaccines preventing pain.
- Improved welfare (less pain, less stress, faster recovery).
- No risk of needle breakage/abscesses.
- Fewer systemic adverse events.

Advantages for operators, farmers and consumers
- No risk of accidental needle injury.
- Fast, safe injections, less labour.
- Animals are less stressed.
- The right dose every time, no errors.
- No need to change or dispose of needles.
- Improved carcase quality (no risk of broken needles or abscesses).
- Improved monitoring and traceability (counters for the number of doses, vials etc).

Fast and reliable servicing

Use of IDAL also requires well-equipped and well-trained local service centres. "A fast and reliable service for IDAL devices is essential," stresses Jonas Riess. Whenever a new local service centre is set up, HSW provides calibrated technical equipment and a dedicated HSW team to train the local service team. An audit is done after six months before the centre is certified. After this, an audit is carried out once a year, ensuring that high-quality IDAL service is provided everywhere.

Today, some 6,000 IDAL devices are in use worldwide, with service centres in Germany, Denmark, France, Spain, Russia, Thailand, the Philippines, Brazil, Chile and Mexico. For regulatory reasons, the IDAL is not yet present in North America, "but may be introduced in the future," confirms Rika Jolie.

Frequently asked questions

- **After vaccination with IDAL, I often see some vaccine fluid left on the skin. Does this impact vaccine efficacy?**

After vaccination, you will see some backflow as the skin is breached under high pressure. This is normal with any jet injector. For intradermal vaccine development, the same IDAL devices are used as in the field. So it is all taken into account and does not interfere with vaccine efficacy.

- **Can I use a conventional vaccine in an IDAL at a lower volume?**

No. Due to the lower volume (0.2ml), the antigen must be present at a higher concentration. Only specifically designed intradermal vaccines can be used with an IDAL.

- **What about the vaccine reactions? Are they worse than with intramuscular injections?**

As the intradermal vaccine ends up in the skin rather than deep in the muscle, any post-vaccination reaction (swelling, redness) at the ID injection site is clearly visible at the surface. In IM vaccination, such reactions are hidden from sight. For inactivated vaccines we look carefully at adjuvants to find the right balance between safety and efficacy.

- **What is the risk to biosecurity when sending the IDAL for service or repair?**

Good biosecurity is essential. New IDAL devices are sent from Germany by HSW in a dedicated, cleanable transport case. HSW has set up an elaborate biosecurity process, certified by an SPF company from Denmark. Having longer service intervals and being able to do the nozzle replacements on the farm (as for the IDAL 3G) further reduces the risk of accidental contamination. The IDAL should of course be thoroughly cleaned after every use.

- **Can IDAL be used in other livestock? Other species?**

The IDAL was specifically developed for pigs. However, in view of its success, it would seem there could be opportunities for other livestock species. Due to its feathers, poultry is less suited for these devices.

IDAL 3G: so what's new?

So what is different about IDAL 3G? "First off, its look has changed quite a bit," announces Rika Jolie. 'We heard you – and we have taken your feedback seriously." Number one is ergonomics. The 3G is a lot more balanced, lighter and no longer top-heavy. The handle is ergonomically shaped and the trigger is easy to hold down. The two-component surface provides for an easier, safer grip.

The menu on the display screen has become more intuitive, with two control buttons. The bottle cage is open, allowing for easier fitting and removal of vials. A belt clip to rest the device between injections can be fitted on either side of the device to suit both left and right-handed operators.

IDAL 3G furthermore has a lithium-ion, longer-lasting battery allowing for at least 1,200 injections. It takes about two hours to charge.

The service interval has also improved. "After a training session, farmers can now carry out the 'small service' – nozzle replacement – themselves on-farm every 20,000 injections. And a full service by HSW will only be needed every 100,000 injections – instead of the current 12,000."

The 'Ferrari 'of injectors

What is the feedback from the field? Stephan von Berg, Regional Global Technical Director Swine Europe at MSD Animal Health, reports.

"We tested the 3G prototype on a number of commercial pig farms in Europe that were already familiar with the IDAL 2G. We asked the farmers to vaccinate 'as usual', without any specific instructions on handling or care. Even though these were only prototypes, so not as nice as the final product, all farmers who tested it preferred to keep the prototype!"

One farmer commented "You're going to take the Ferrari back with you and leave us the old Skoda!" ■

References are available from the authors on request

Currently available intradermal vaccines

Live vaccines
- Porcilis Begonia (Aujeszky's disease).
- Porcilis PRRS (type 1).
- PrimePac PRRS (type 2).

Inactivated vaccines
- Porcilis M Hyo ID Once.
- Porcilis PCV ID.