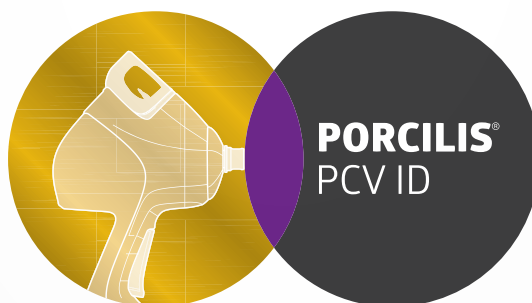


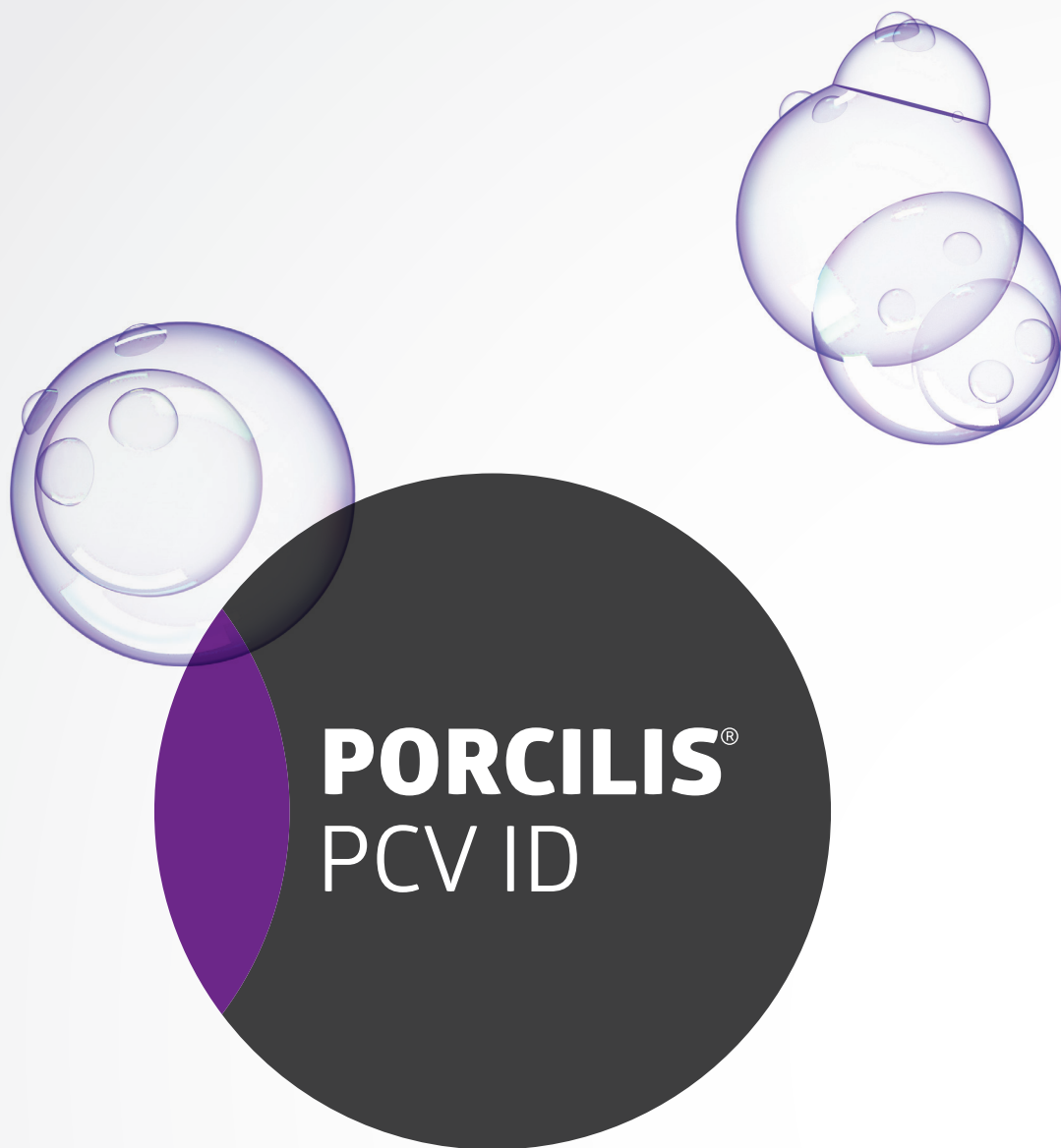
Porcilis[®] PCV ID

**The only intradermal
PCV vaccine**



THE IDAL[®]WAY

• Needle-free • Efficacy • Innovation •



The only PCV vaccine for
intradermal administration
with a needle-free device.





23 WEEKS IMMUNITY

Porcilis® PCV ID protects for 23 weeks post-vaccination.



REDUCED VIRAL LOAD

Porcilis® PCV ID is indicated to reduce:

- Viraemia caused by PCV2 infection
- Virus load in lungs and lymphoid tissues caused by PCV2 infection
- Virus shedding caused by PCV2 infection



IMPROVED PRODUCTIVITY

Porcilis® PCV ID can reduce loss of daily weight gain and mortality associated with PCV2 infection.



CONCURRENT USE

Porcilis® PCV ID and Porcilis® M Hyo ID ONCE can be given simultaneously with the IDAL® 3G Twin device.



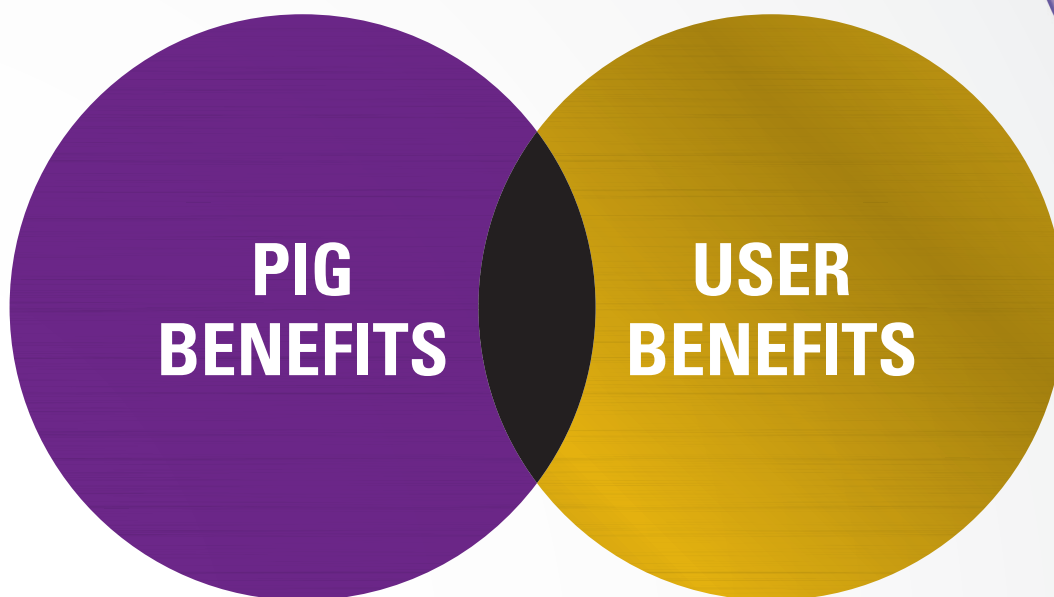
A good choice for you and the pigs

Vaccinating 'The IDAL® Way' is a good choice. Needle-free and intradermal application of vaccines is the most advanced method for vaccinating pigs today.

The ergonomically designed, reliable and easy-to-use IDAL® device makes vaccination safe and less stressful for people and pigs, while ensuring efficacy at the same time.

Together with the broadest range of specifically formulated intradermal vaccines – Porcilis® PCV ID, Porcilis® M Hyo ID ONCE, Porcilis® PRRS, Prime Pac® PRRS and Porcilis® Begonia IDAL – The IDAL® Way is an important step forward in controlling major diseases affecting pig operations worldwide.





WELFARE

No needles and a vaccination volume of only 0.2 ml means less pain and stress for the pigs. Fear and pain indicators at time of injection are reduced.⁴

Following vaccination, pigs recover more quickly, as indicated by less lying and more suckling.¹¹

HYGIENE

Reduces risk of transmitting diseases between pigs caused by reusing needles.

SAFETY

Fewer adverse systemic events.^{1,2}

QUALITY

No risk of finding broken needles in the tissue that can cause damage.

EFFICACY

Delivers a quick and effective immune response.^{5,6} Antigen presenting cells in the dermis induce an effective immune response against a broad range of diseases. Pre-existing immunity may be overcome since (maternal) antibodies are not located in the skin.

EASE OF USE

The one-piece IDAL[®] device is easy to handle.

ACCURACY

The IDAL[®] device delivers a fixed vaccine volume under a constant pressure. Therefore, large numbers of pigs are vaccinated with the proper dose every time.

FLEXIBILITY

Pending on the vaccine, pigs can be vaccinated with IDAL[®] in various locations.

SAFETY

Needle-free vaccination reduces the risk of self-injection.

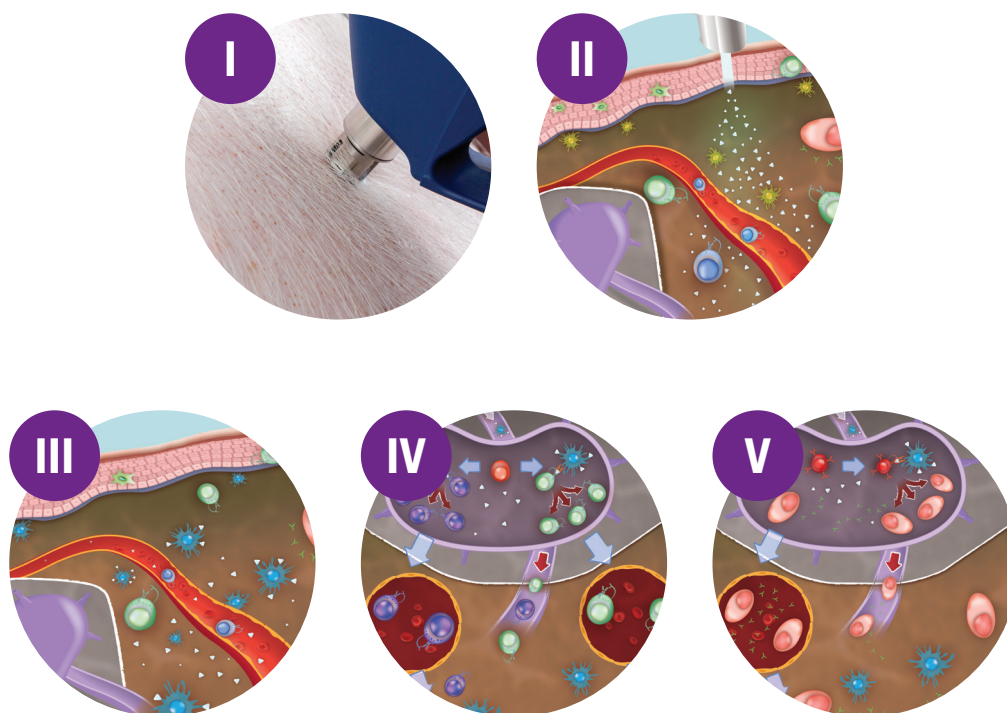
MEAT CONSISTENCY

Potential damage to muscle tissue is reduced and there is no risk of needle pieces remaining in the meat due to broken needles.

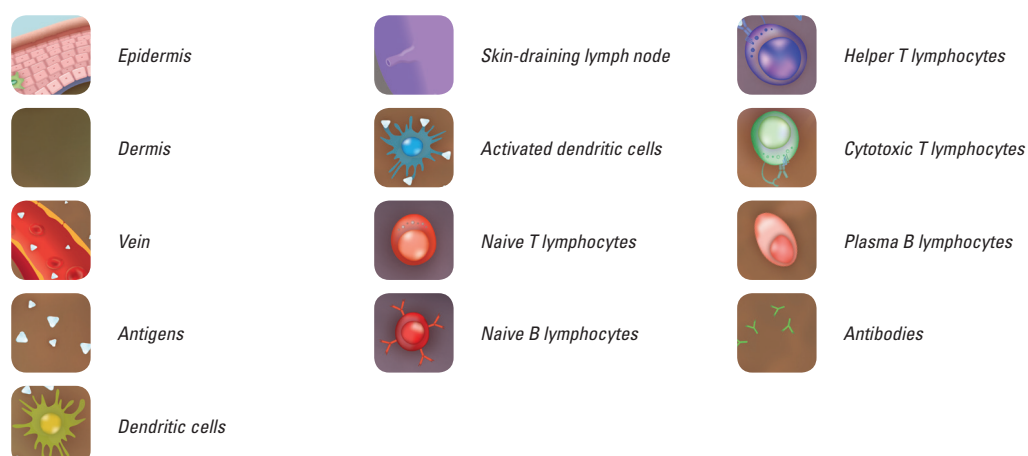
Why intradermal vaccination stimulates an effective immune response

Compared to intramuscular (IM) administration, vaccination into the dermis is advantageous because high concentrations of powerful, specialized cells located in the skin respond very quickly and efficiently to vaccine antigens.

Studies show that intradermal (ID) vaccine administration can stimulate an immune response as efficiently as or better than IM administration.^{1,2}



- I II Vaccine antigens are administered intradermal using the IDAL[®] device.
- III Dendritic cells are activated in order to capture and process the antigens, carrying important information to the nearest skin-draining lymph node.^{5, 6}
- IV V Once in the lymph node, dendritic cells present antigen materials to naive T lymphocytes and B lymphocytes found within the lymph node. Now activated, these cells stimulate a direct and strong immune response to the antigen so the pig can start building immunity against future infections. Cytotoxic T lymphocytes destroy virus-infected cells and provide cell-mediated immunity. Helper T lymphocytes help transform B lymphocytes into Plasma B lymphocytes, which produce specific antibodies and also provide humoral immunity.



Limited number of local reactions with Porcilis® PCV ID

Results from two trials in Hungary in suckling piglets demonstrate that vaccination with Porcilis® PCV ID doesn't cause any significant local reactions. There were no reactions in Study A, while the observed reactions in Study B ranged from 2% to 11% pending on the group.⁷



3,120 SUCKLING PIGLETS

Study A: 1,810 piglets

Study B: 1,322 piglets

Herds with confirmed PCV2 and Mhyo infections.



STUDY A REACTIONS:

- No local reactions.

STUDY B REACTIONS:

- Maximum incidence of Porcilis® PCV ID local reactions were observed 14 days post-vaccination in 2% of piglets in the PCV group and 8% in the PM group.
- Maximum incidence of Porcilis® M Hyo ID ONCE local reactions were observed 21 days post-vaccination in 11% of piglets in the PM group and 8% in the M group.
- Maximum size of the local reactions:
 - PCV group: 3 cm
 - PM group: 4 cm Porcilis® PCV ID side and 6 cm Porcilis® M Hyo ID ONCE side
 - M group – 4 cm



VACCINATION PROTOCOL

Group PCV – Vaccinated intradermal with Porcilis® PCV ID.

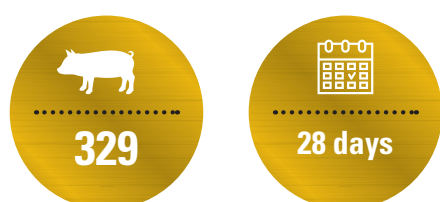
Group PM – Vaccinated intradermal with Porcilis® PCV ID and Porcilis® M Hyo ID ONCE concurrently.

Group M – Vaccinated intradermal with Porcilis® M Hyo ID ONCE single 0.2 ml dose. Group M was in Study B only.

Group C – Untreated control group.

Strong immune response with Porcilis® PCV ID

Both intramuscular and intradermal vaccination induced a clear and detectable humoral and cellular immune response based on IgG and IFN- γ secreting cells (SC), indicating that both vaccination routes induce a solid immune response.³



329 WEANED PIGLETS
History of PCV2 disease.



VACCINATION PROTOCOL

ID: Vaccinated with Porcilis® PCV ID intradermal and needle-free with IDAL®.

IM: Vaccinated with Porcilis® PCV intramuscular.

C: Control, not vaccinated.

HUMORAL AND CELLULAR IMMUNE RESPONSE 21 DAYS POST-VACCINATION

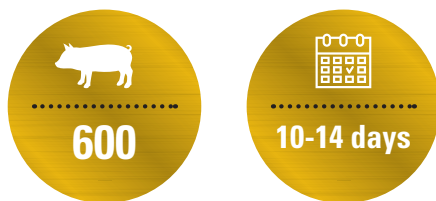
	ID	IM	C
IgG (mean \pm sd log2)	2.9 \pm 0.4 ^b	3.3 \pm 0.17 ^a	neg
% Ig G Seroconversion	96% (23/24)	100% (25/25)	0% (0/26)
IFN- γ (SC/10 ⁶ PBMC)	17.9 ^a	26.4 ^a	2.0 ^b

Serology test – Ingezim Circo IgG, Ingenasa.

^{a, b} Values with different superscripts within a row are statistically significantly different ($p < 0.001$).

Strong immune response with Porcilis® PCV ID

Porcilis® PCV ID vaccination induced a more robust and prompt increase of both humoral and cell mediated immunity compared to the traditional intramuscular vaccination with a competitor vaccine. Interestingly, in the ID animals, 4 weeks post-vaccination the level of ELISA antibodies were significantly higher as compared to the IM vaccinated.⁸



600 SUCKLING PIGLETS
History of PCV2 disease.



VACCINATION PROTOCOL

ID: One-dose ID vaccine. IM: One-dose IM vaccine.
C: Control.

At weaning (21 days), pigs were vaccinated
according to their group.

FIGURE 1: PCV2-ELISA antibodies.

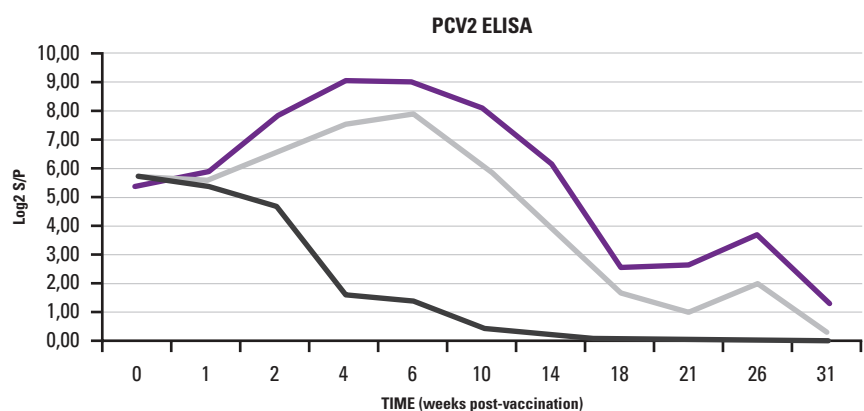
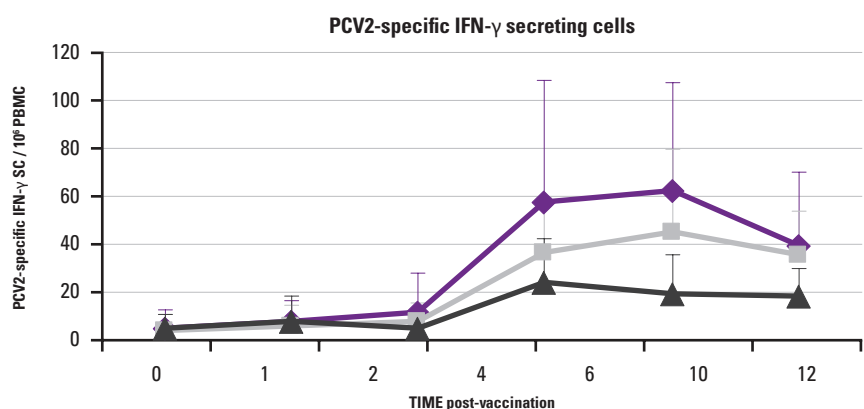


FIGURE 2: IFN-γ secreting cells.



Comparative field efficacy trial between Porcilis® PCV ID and an intramuscular PCV vaccine

Under the conditions of this study, ID vaccination resulted in significantly higher antibody titres at the end of nursery, grower and finishing stage. In contrast, only one of the Group A pigs had detectable levels of antibodies against PCV2 during the finishing phase. This may be explained by the long duration of immunity of Porcilis® PCV ID, which resulted in a 1.24 kg higher average slaughter weight than Group B pigs (Not-significant). Both vaccines also controlled PCV2 viremia. In summary, Porcilis® PCV ID performed equally well or better than an intramuscularly administered PCV2 vaccine.⁹



280

280 WEANED PIGLETS

History of PCV2 circulation.



28 days



Group A



Group B

VACCINATION PROTOCOL

Group A (N = 141 pigs) – vaccinated with Porcilis® PCV ID (0.2 ml).

Group B (N = 139 pigs) – vaccinated intramuscularly with a licensed PCV2 vaccine (1 ml).

FIGURE 1: Average live weight for group A and B at weaning, nursery, grower and finishing stage.

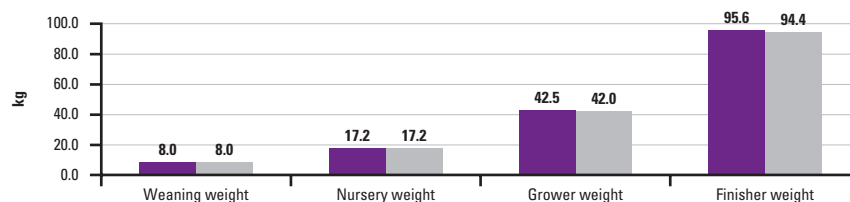


FIGURE 2: Average daily live weight for group A and B from wean to nursery, nursery to the grower stage, grower to finishing stage and weaning to slaughter.

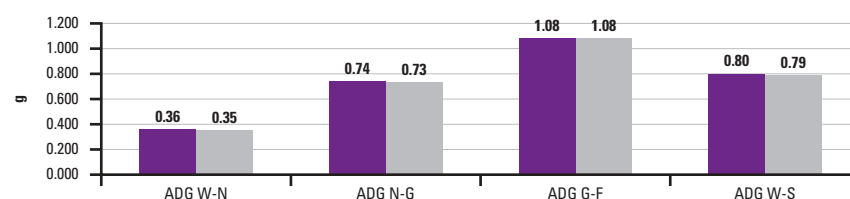


FIGURE 3: Pigs removed from the study due to mortality or poor health (%).

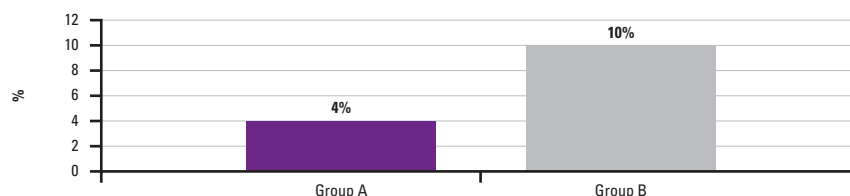
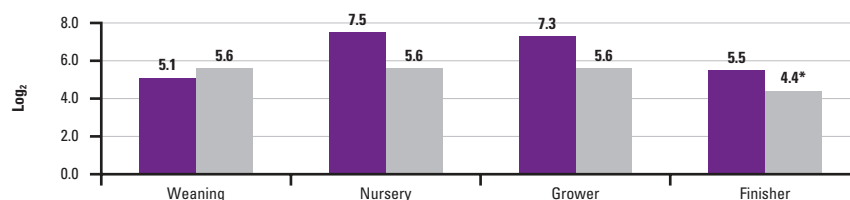


FIGURE 4: Average PCV antibody titres (AlphaLISA-PCV2) at weaning, nursery, grower and finishing stage for group A and B. (*only one Group B sample positive.)



Improved productivity following concurrent vaccination with Porcilis® PCV ID and Porcilis® M Hyo ID ONCE

Under the conditions of this study, ID pigs had a significantly higher ADG than IM pigs, resulting in a higher average live weight at slaughter. The extra 3.3 kg of live body weight represented a significant increase in profitability of £1.90 per pig at slaughter (including feed cost).¹⁰



119

119 WEANED PIGLETS

History of PCV2 circulation and *Mycoplasma hyopneumoniae*-like lung lesions.



28 days



Group ID



Group IM

VACCINATION PROTOCOL

Group ID (N = 61) – vaccinated with Porcilis® PCV ID (0.2 ml) and Porcilis® M Hyo ID ONCE (0.2 ml).

Group IM (N = 58) – vaccinated concurrently with a 2 ml PCV2 intramuscularly and a Mhyo vaccine (0.2 ml intradermal).

FIGURE 1: Live weight (kg) at the end of the finishing period for the ID and IM group. Different superscripts (a, b) indicate significant difference ($p < 0.05$).

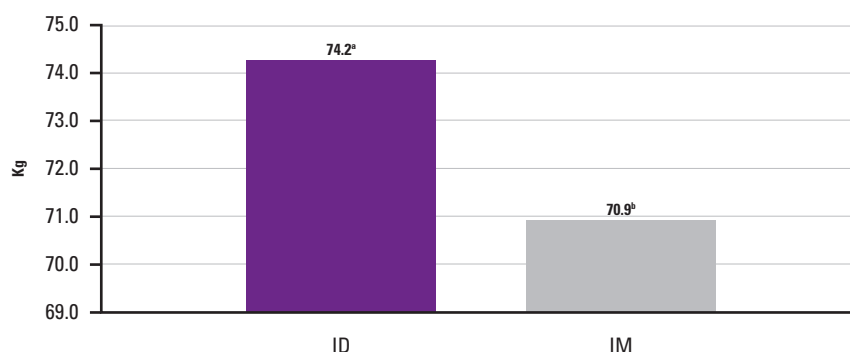
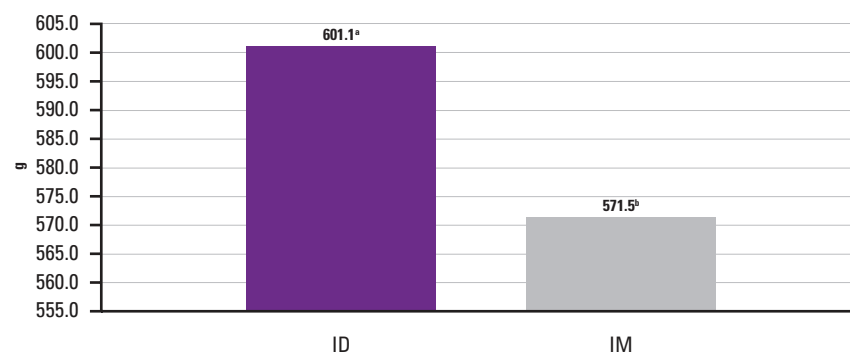
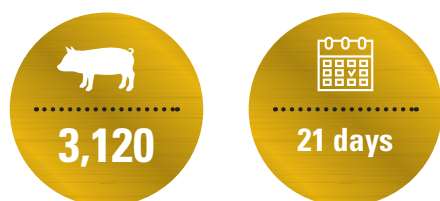


FIGURE 2: Average daily live weight gain from weaning to slaughter (period of 113 days) for ID and IM group. Different superscripts (a, b) indicate significant difference ($p < 0.05$).



Better growth with Porcilis® PCV ID and Porcilis® M Hyo ID ONCE concurrent use

In two Hungarian field trials, vaccination of 3 week old piglets with both Porcilis® PCV ID and/or Porcilis® M Hyo ID ONCE significantly improved average daily weight gain in the finishing phase (between 44 and 59 g/day).⁷



3,120 SUCKLING PIGLETS

Study A: 1,810 piglets

Study B: 1,322 piglets

Herds with confirmed PCV2 and Mhyo infections.



VACCINATION PROTOCOL

Group PCV – Vaccinated intradermal with Porcilis® PCV ID.

Group PM – Vaccinated intradermal with Porcilis® PCV ID and Porcilis® M Hyo ID ONCE concurrently.

Group M – Vaccinated intradermal with Porcilis® M Hyo ID ONCE single 0.2 ml dose. Group M was in Study B only.

Group C – Untreated control group.

FIGURE 1: Uninhibited growth during the nursery phase.

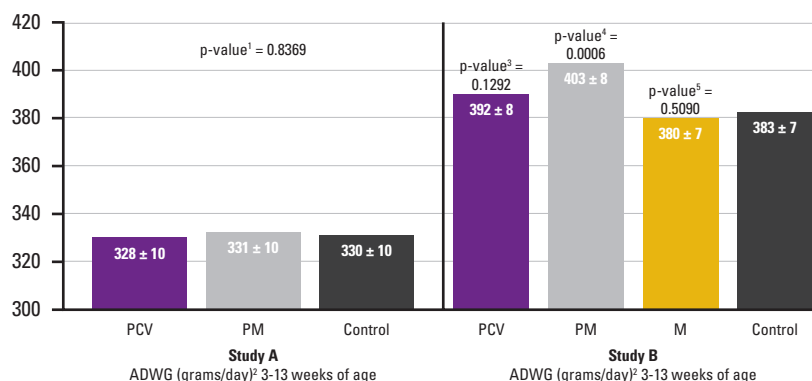
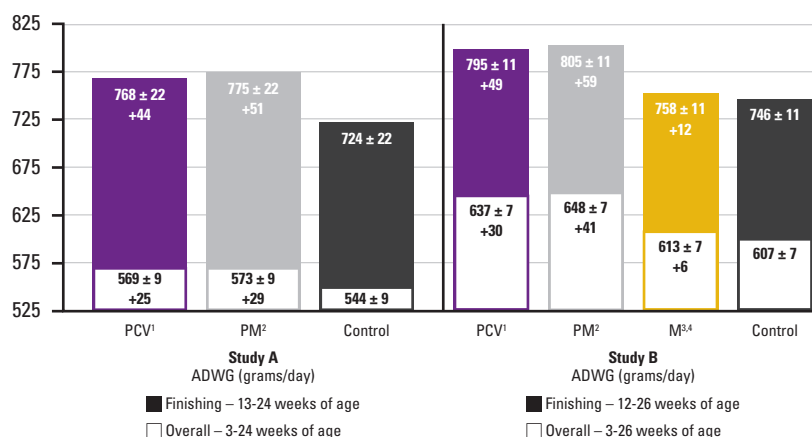


Figure 2: Increased ADWG throughout the entire study period.



Vaccination with Porcilis® PCV ID or Porcilis® PCV ID + Porcilis® M Hyo ID ONCE reduced viremia

In two Hungarian field trials with both PCV2 and *M. hyopneumoniae*, vaccination of 3 week old piglets with Porcilis® PCV ID and/or Porcilis® M Hyo ID ONCE significantly reduced PCV2 viraemia.⁷



3,120 SUCKLING PIGLETS

Study A: 1,810 piglets

Study B: 1,322 piglets

Herds with confirmed PCV2 and Mhyo infections.



21 days



Group PCV



Group PM



Group M



Group C

VACCINATION PROTOCOL

Group PCV – Vaccinated intradermal with Porcilis® PCV ID.

Group PM – Vaccinated intradermal with Porcilis® PCV ID and Porcilis® M Hyo ID ONCE concurrently.

Group M – Vaccinated intradermal with Porcilis® M Hyo ID ONCE single 0.2 ml dose. Group M was in Study B only.

Group C – Untreated control group.

FIGURE 1: Reduced PCV2 viraemia. Study A – Viral load in serum.

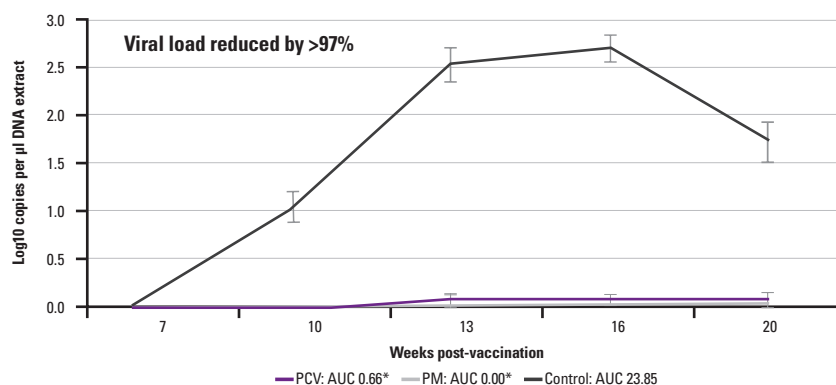
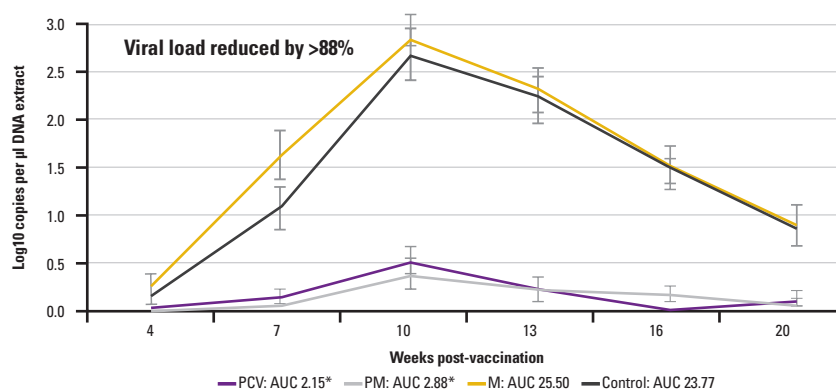


FIGURE 2: Reduced PCV2 viraemia. Study B – Viral load in serum.

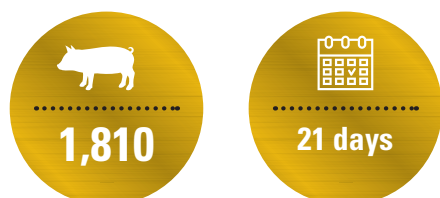


* = significantly different from control (p<0.05). AUC = area under the curve

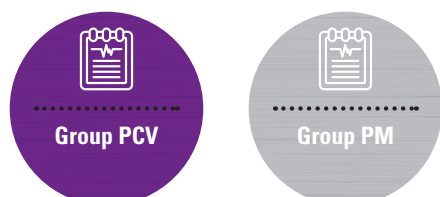
MORTALITY REDUCTION TRIAL — HUNGARY

Vaccination with Porcilis® PCV ID or Porcilis® PCV ID + Porcilis® M Hyo ID ONCE reduced mortality

In a Hungarian field trial with both PCV2 and *M. hyopneumoniae*, vaccination of 21 days old piglets with Porcilis® PCV ID and/or Porcilis® M Hyo ID ONCE significantly reduced mortality by 35%.⁷



1,810 SUCKLING PIGLETS
Herds with confirmed PCV2
and Mhyo infections.



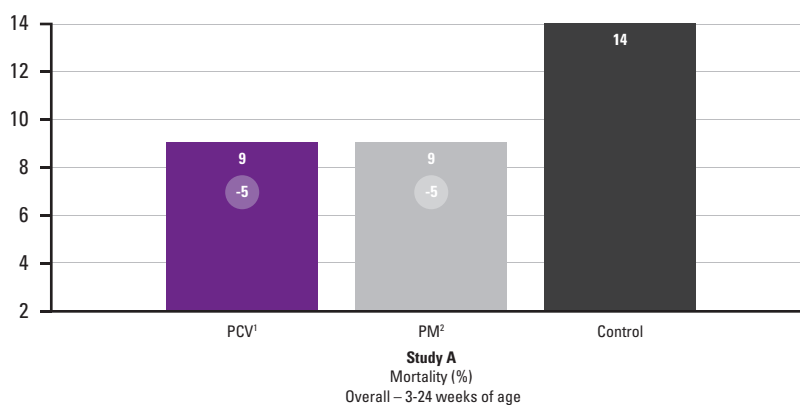
VACCINATION PROTOCOL

Group PCV – Vaccinated intradermal
with Porcilis® PCV ID.

Group PM – Vaccinated intradermal with
Porcilis® PCV ID and Porcilis® M Hyo ID ONCE
concurrently.

Group C – Untreated control group.

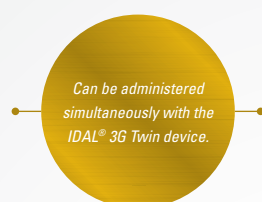
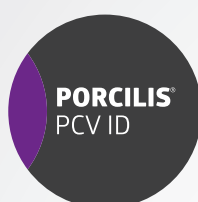
FIGURE 1: Reduced mortality throughout the entire study period



1. Porcilis® PCV ID group vs. Control group – *p*-value < 0.0004

2. Porcilis® PCV ID + Porcilis® M Hyo ID ONCE group vs. Control group – *p*-value < 0.0020

Porcilis® intradermal vaccine portfolio for needle-free administration



The first intradermal PCV vaccine for active immunization of pigs as early as 3 weeks of age. Vaccination reduces PCV2 viremia, viral load in lung and lymphoid tissue, and virus shedding. In addition, loss of daily weight gain and mortality associated with a PCV2 infection are also reduced. Duration of immunity is 23 weeks following vaccination.

One-dose vaccine for immunization of piglets as early as 3 weeks of age to reduce lung lesions and decrease in daily weight gain during the finishing period following a *Mycoplasma hyopneumoniae* infection.

Modified live vaccine for the immunization of pigs against PRRSv throughout the production system from as early as 2 weeks of age.



Modified live vaccine for immunization of pigs as early as 2 weeks of age against PRRSv-2.

Live, attenuated vaccine for the immunization of pigs against Aujeszky's disease virus (Pseudorabies) infections.



References

- 1 Chase C.C.L., Daniels C.S., Garcia R., Milward F. and Nation T. Needle-free injection technology in swine: Progress toward vaccine efficacy and pork quality. J Swine Health Prod. 2008;16(5):254-261.
- 2 Summerfield A. The dermis as a prime site of vaccine delivery. International Pig Topics. October 2014.
- 3 Temple D. et al. Comparative study to determine PCV vaccination immune response following different administration routes (IM VS ID). ESPHM 2017.
- 4 Temple D., Mainau E., Amat M. and Manteca X. Animal welfare benefits of the intradermal vaccination in pregnant sows. Porcine Health Management (2017) 3:9.
- 5 Romani N., Flacher V., Tripp C., Sparber F., Ebner S. and Stoitzner P. Targeting Skin Dendritic Cells to Improve Intradermal Vaccination. Current Topics in Microbiology and Immunology, 2012. 351: 113-138.
- 6 Teunissen M., Haniffa M. and Collin M. Insight into the immunobiology of human skin and functional specialization of skin dendritic cell subsets to innovate intradermal vaccination design. Current Topics in Microbiology and Immunology, 2012. 351: 25-76.
- 7 Sno M. et al. Efficacy and safety of a new intradermal PCV2 vaccine in pigs. Trials in Vaccinology 5 (2016) 24–31.
- 8 Canelli E. Comparison between the immune responses induced by a new intradermal PCV2 vaccination and a classical intramuscular one in three weeks old piglets. ESPHM 2017.
- 9 Sola X. et al. Comparative field efficacy of an intradermal PCV2 vaccine and a licensed intramuscular PCV2 vaccine. ESPHM 2017.
- 10 Waddilove J. et al. Assessment of PCV2 and Mycoplasma hyopneumoniae intradermal vaccination on swine production parameters. ESPHM 2017.
- 11 Goller M., Fels M., Gerdt W., Knoppel H., Fiebig K. and Kemper N. Evaluation of welfare aspects in suckling piglets after vaccine application with the IDAL injector. ESPHM 2015.