The Solid Dose Alternative:
VACCINE DELIVERY USING THE GLIDE SDI®

- Vaccine supply chain management would be simplified, with a reduced need for cold storage, if more stable vaccine formulations could be made.
- The Glide SDI® (Solid Dose Injector) has been designed for safety, easy and convenient delivery of both vaccines and therapeutics.
- The dosage is formulated as a tiny implant of material with a pointed end. The dosage is pushed into the skin with the Glide SDI® without the need of a needle.
- The dosage is pre-filled during manufacture into a single use disposable cassette and the spring powered actuator can be reused.

- Glide has conducted a number of vaccination studies to evaluate immune and protective responses generated by SDI® implants formulated with existing and new vaccine antigens.
- These include influenza A (representative of seasonal flu); diphtheria and Haemophilus influenzae type B. Novel peptide vaccines targeting cancer and a 'Universal' flu approach were also studied and readouts of cell-mediated immunity were carried out.
- Some evidence to support reduced dosing was obtained.

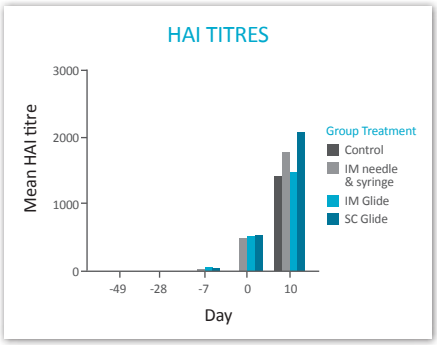
VACCINES ("TRADITIONAL")	PROTECTIVE ANTIBODY GENERATED	SUCCESSFUL CHALLENGE STUDY
Seasonal flu*	✔	✔
Diphtheria*	✔	✔
Hib	✔	✔

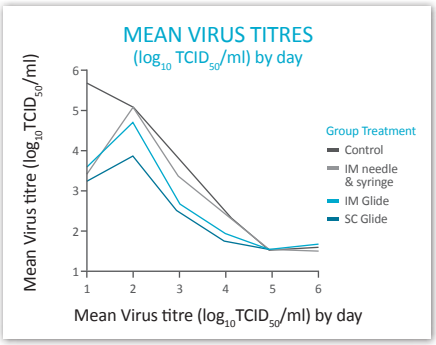
**Evidence of dose-sparing effect*

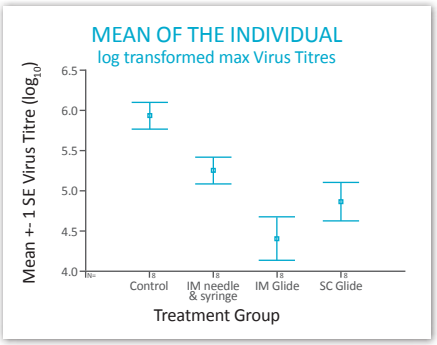
VACCINES (NOVEL)	CELL MEDIATED IMMUNITY ACHIEVED
"Universal flu"	✔
Peptide cancer vaccine	✔

SEASONAL FLU EXAMPLE:

Glide SDI® implants containing influenza A material, (whole inactivated A/Wisconsin/67/2005(H3N2)) containing 15µg haemagglutinin per dose were used to immunize ferrets previously primed intranasally with an H1N1 virus. The study compared the protection obtained using Glide SDI® implants delivered by either sub cutaneous or intra muscular routes, with that seen using reconstituted implants delivered intra muscularly by conventional syringe and needle. Priming took place on day -49. Vaccinations were carried out on days -28 and -7. On day 0 all ferrets were challenged with H3N2 live virus. Serum HAI titres were determined at days -49, -28, -7, 0 and +10. Virus excretion post challenge was recovered by nasal washes.







A protective HAI response (1/40 or above) was obtained in the Glide SDI® implant sub-cut group after a single dose. There were no significant differences in HAI titre between the groups after the second vaccinations. Following challenge the negative control group exhibited high viral titres and symptomology.

All three vaccine formulations delayed peak virus shedding by a day and by approximately 2 $logs_{10}$. The delay in virus shedding in the vaccine groups was accompanied by a delay in the onset of symptoms. The greatest reduction in symptom score was seen (cumulative scores) in the Glide SDI® implant sub-cut group.

CONCLUSION: **The Glide SDI® was equal or better than a conventional delivery system in abrogating influenza infection. Protective antibody responses were seen after a single dose of antigen delivered sub cut by the Glide SDI®**

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