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TSK Laboratory white paper.

TSK LOW DEAD SPACE Needle can help in the fight against COVID-19 (SARS-CoV2).

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1. A dose-saver solution for mass vaccination programmes.

The race is on around the globe to develop a vaccine for COVID-19 (SARS-CoV2), with multiple programmes, in multiple countries, actively developing and testing different solutions.

The unprecedented speed with which research and progress is being made in finding a safe, effective, and functioning vaccine means that hopefully it will not be too long before we will soon see one approved for use. This will have a major impact around the world and finally provide a resolution to a pandemic which continues to decimate populations across all continents.

Governments and not-for-profit medical organisations are keen to invest, and invest heavily, to build up adequate supplies and orders from those pharmaceutical companies and partnerships which are beginning to show the most potential at making it to the finish line with a vaccine which can be delivered en masse, at national and global levels[1]. Of course, when the roll-out occurs, it will be unlike anything we have ever seen before with potentially billions of doses required to be administered, on an annual basis. Medical authorities, policy makers, and vaccine manufacturers need to think carefully about the ways in which mass vaccination of this kind can be delivered expediently, and cost-effectively, to the population and must consider the best tools for the job.

Hypodermic needles and syringes are readily available, and low cost, which makes them immediately attractive for delivering vaccines to a large cohort of patients, but what if there was a new solution available which could further reduce the cost burden of vaccinating so many people? Well, we believe that there is.

TSK Laboratory has designed a patented needle hub called the TSK Low Dead Space Needle which eliminates the wasted space inside the needle hub (see Figure 1).

The LDS hub is designed to reduce, as close to zero as possible, the space left behind in the needle hub, leading to significant cost savings when injecting high cost drugs or precious vaccines. A standard hypodermic syringe with a standard needle has an average dead space of 99µl. This would present a significant loss of vaccine medication per person injected, which cumulatively could result in fewer people vaccinated with the quantity of vaccine produced[2].

Whilst so many vaccines are still in development, now is a perfect time to consider potential mechanisms for making vaccination, and particularly mass vaccination, more efficient by using the best possible needle technology. No matter which vaccine candidate proves to be the most effective and safe, maximising the efficient and reliable delivery method to a global population will be key – waste is not an option.

99

µl average waste due to dead space.

1. "Industry Builds Fill/Finish Capacity for Pandemic Response" PharmaTech.com, July 15, 2020
2. https://slideplayer.com/slide/5964204/ William Zule; Harry Cross RTI International, United States Presented at AIDS 2012 – XIX International AIDS Conference Washington, DC • July 22–27, 2012

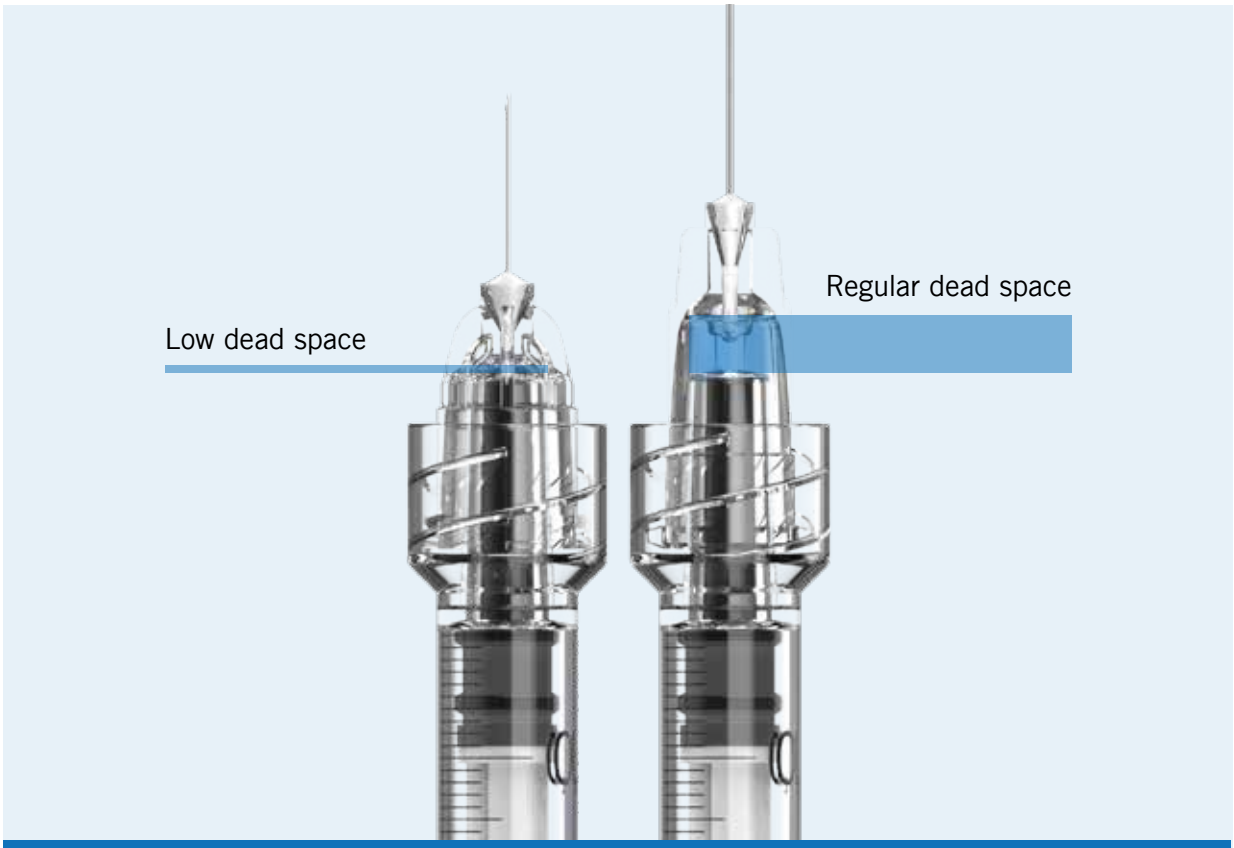

Figure 1: *TSK Low Dead Space hub (left) versus a traditional needle hub (right).*

2. COVID-19 vaccine developments – the story so far.

By the summer of 2020, only a matter of months after the start of the global coronavirus pandemic, the Lancet[3] was reporting that there were ten candidates in clinical trials to find a vaccine for SARS-CoV2, the cause of COVID-19[3]. Named candidates included a variety of different approaches including mRNA vaccines (mRNA-1273 (**Moderna** and **NIAID**) and BNT162 (**BioNTech** and **Pfizer**)), plus DNA vaccines (INO-4800 **(Inovio Pharmaceuticals**)), the use of inactivated virus (Unnamed (**Wuhan Institute of Biological Products** and **Sinopharm**)), protein subunits (NVX-CoV2373 (**Novavax**)) and finally the use of an Adenovirus (AZD1222 (**University of Oxford** and **Astra Zeneca**)). More candidates have been added since, and the Ministry of Health of the Russian Federation is the first to announce two vaccine approvals, although much controversy surrounds the lack of phase III clinical trials for either vaccine. But clearly, this fast-tracked vaccine development could mean that we have a vaccine on the market somewhere between the end of 2020 and the middle of 2021[4].

3. Covid-19 vaccine development pipeline gears up, Vol 395, June 6 2020 pp 1751 to 1752, www.thelancet.com
4. "COVID-19 vaccine tracker", Regulatory Focus, https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker

6%

average success rate for vaccine development

10Y

average time for vaccine development

Given that, as reported by The Lancet, the average development time for a vaccine is 10 years, it will be an incredible feat if the process can be shortened so significantly to deliver a vaccine as early as this year, just one year after the virus was first identified in Wuhan, China and given its COVID-19 moniker.

However, we must not get complacent, the report also highlights that the typical success rate with vaccine development is as low as 6%. A development programme of 18 months would be regarded as very aggressive by infection experts, so is one year enough time to produce a successful vaccine? Only time will tell.

There is also a stark warning relating to manufacture and supply from the authors who note that, "…global appetite for any successful vaccines, if and when they are ready, will bring its own difficulties. Developers are starting to scale up production even now, despite the risk that their favoured candidates will fall short. Distribution, delivery and administration need to be worked out".

3. Vaccine administration delivery platforms.

Commonplace vaccination programmes include the annual influenza or flu immunisation which is offered as an intramuscular injection for adults or via a nasal spray for children. More and more people now participate in national immunisation programmes, and have experience with being vaccinated against flu, so familiarity will be helpful when it comes to mass vaccination for SARS-CoV2.

Intramuscular injection or nasal delivery are the most common methods of vaccine administration, yet a review of the current clinical trials for COVID-19 vaccination, a sample of 17 studies as published on ClinicalTrials.gov, cites a variety of administration techniques being studied including:

- Intramuscular injection (9 studies)
- Intradermal injection (2 studies)
- Sub-cutaneous injection (2 studies)
- IV Infusions (1 study)
- Not cited (2 studies)
- Electroporation via the Cellectra 2000. (1 Study [INO-4800])

Of course, what this does show is that parenteral delivery by injection, using a hypodermic needle, remains the administration method of choice for vaccination. The cost advantages and convenience of hypodermic needles are undeniable, but we believe that a better delivery platform exists with the LDS needle hub to further reduce costs, whether intramuscular or intradermal injection methods are used, and to meet the unprecedented demand for the rapid and optimised delivery of global, mass vaccination against COVID-19.

4. TSK Low Dead Space (LDS) needle hubs.

The range of needle and syringe designs from TSK Laboratory has become the integrated product of choice for many leading pharmaceutical companies for many years. TSK put great emphasis on developing new technologies and product innovations, such as their Low Dead Space (LDS) needle hub, and aim to deliver new solutions that improve clinical outcomes and produce cost savings, whilst simultaneously improving patient safety and comfort.

As well as having exceptional sharpness to the needles, and the highest quality standards and materials employed, the LDS hub is designed to reduce, as close to zero as possible, the space left behind in the needle hub, leading to significant cost savings when injecting high cost drugs or precious vaccine materials that are in short supply and high demand.

The TSK LDS needle hub is manufactured from an extremely hard polymer hub with exterior threading. This allows for an even tighter Luer lock connection, preventing flexing, leakage, and the chance that the hub will “pop-off” when exposed to high pressures.

0.09

ml of savings with low dead space hub needle. Reduce wastage and achieve maximum efficiency in the global use of any available COVID-19 vaccine.

The LDS needles come in a variety of gauges and needle lengths and can be customised to suit the indication. The development of a new, 2mm needle is also underway which will be suitable for integrated use with the LDS hub for a more reliable intradermal delivery, as compared to the traditional tools used for the Mantoux test for tuberculosis screening, were dose-sparing to be required for COVID-19 vaccine delivery by an intradermal technique.

The core attraction of the patented LDS hub design is that it results in as close to zero space left behind in the needle hub, which equates to a saving of up to 0.09ml per needle, compared to a regular hub. Achieving dose-efficiency through reduced wastage (as well as potentially dose-sparing) would achieve maximum efficiencies in the global use of any available vaccine for COVID-19, which will undoubtedly be constrained in its reach and availability by manufacturing capacity.

5. About TSK Laboratory.

The TSK Group was founded in 1948 and currently has three needle manufacturing sites in Japan as well as global offices in Japan, Canada, The Netherlands, China. They are also due to open operations in the USA and Australia.

At their facilities, TSK dedicate themselves to applying the highest quality standards, from product development through to production, to ensure the safety of every patient that is being treated with their products. All facilities and ISO certified cleanrooms pass the highest level of inspection and auditing standards, incorporated by major overseas pharmaceutical companies, medical companies, and authorities.
TSK focuses on quality, innovation, and customer intimacy. They aim to provide safe, high-quality products, enabling doctors and specialists to provide their patients with the best possible treatment. By improving their manufacturing processes and developing new innovations within the market, they continuously improve their products as well as the way in which they are implemented by medical experts within their field.

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