

How Modular Passive Pharma Packaging Systems Enable Strategically Refined COVID-19 Vaccine Shipping Regimes

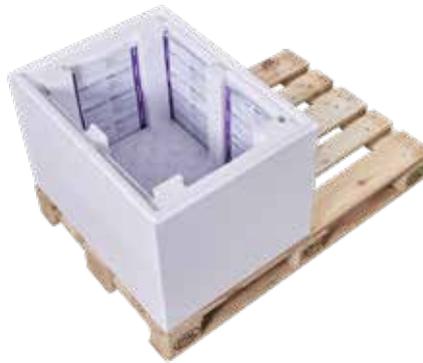
This task is more immense, complex and time-critical than ever before. The world is waiting for the safe, reliable and rapid distribution of the approved vaccines designed to combat the COVID-19 pandemic. In our discussion with Sven Rölle, Head of Sales at the German high-tech company eutecma, we will find out what contribution this company can make towards this logistical tour de force.

What policies and processes should be adopted for the optimal cold chain management of vaccines?

As is always the case: Product integrity and patient safety must never be compromised, under any circumstances, and this applies even more now than in “normal times”. The vaccines will only protect patients if they remain intact. This is the only way they can suppress this pandemic and reach the high level of acceptance we need to achieve herd immunity for the entire human race. The packaging industry has a unique chance to step into the limelight with this vaccine supply chain. A much wider public is suddenly very interested in what our products can do. Because, let’s be honest here: Who else usually cares about packaging solutions for pharmaceuticals other than the specialists?

What factors do you have to take into account when developing a cooling system on the scale required by a global pandemic?

All vaccines are different. Where one vaccine requires extremely low transport and storage temperatures of down to -70°C in order to reach its destination in a stable form, another might only require refrigerator temperatures between +2°C to +8°C or -20°C to remain stable. Other temperature ranges may also be necessary. If we assume that, in a public vaccination centre for instance, vaccines from *different manufacturers* will be administered, it would be helpful to have a high-performance packaging solution that works for *all* temperature ranges and *packaging volumes* during *different pandemic phases*, whilst still ensuring that they are *handled in the same way* to avoid



The PROTECT ½ Euro Pallet Shipper, with a volume of 49, 95 or 141 litres, is also modular in design. photo: eutecma

any process errors. “One box fits all” – that’s how we would describe this model. Luckily, our eutecma portfolio fulfils precisely these complex requirements.

How exactly does this universality function?

Irrespective of whether it holds 4 or 1600 litres – our PROTECT system packaging is configured so that every high-tech box uses the same cool brick format, regardless of the box size. The design is based on a versatile lock and key principle. The ICECATCH® passive energy storage units can be smoothly inserted into predefined slots in the side walls of the PROTECT boxes. They are securely anchored in the slots during transport and provide uniform cooling energy in a precisely defined temperature range. Additionally, these ICECATCH® elements are designed for all pharmaceutical temperature ranges: Frozen (<-20°C), cool (+2°C to +8°C) and ambient (+15°C to +25°C). We use dry ice for our deep frozen range, which has recently been

qualified in one of our four in-house climate chambers. This means that the temperature can be kept constant for over 120 hours. The temperature-stable eutecma system, based on *highly efficient high-tech boxes* and *compatible passive energy storage units*, is therefore easily scalable with regard to both *temperature* and *payload*. All PROTECT boxes are modular and can transport various freight volumes, depending on how many stacking frames are added. In short, these temperature-controlled eutecma transport boxes can be expanded or shrunk according to requirements. We are not aware of any other box manufacturer that can offer such modularity.

How can this modularity be of use for vaccine transport logistics?

We have a box for every eventuality. I can explain this using our largest cool box, the XL PROTECT pallet box, as an example. If smaller volumes of vaccine need delivering to numerous vaccination centres during the initial delivery phase, the box can be shrunk just by adding three or even two frames, instead of the standard four frames for airfreight shipments. The result: Instead of shipping a half-filled box by truck or air, you only use the exact payload required. There is no wasted space, which enables significant weight and cost-savings, particularly with regard to air freight. When production ramps up and larger quantities of vaccines need shipping, then the maximum payload of 1275 litres can be exploited by using all four frames to reach the maximum air freight height. The shipper can select the precise number of frames needed during intermediate phases where transport is required to distant destinations with smaller



The PROTECT pallet packaging system is always the same, whether it holds 1275, 495, 333 or 172 litres. photo: eutecma/Axel Heiter Fotodesign

populations or where local fine distribution only has a need for smaller quantities. If you combine this modularity with the matching cooling/heating elements – ICECATCH® Solid Insulated (+2°C to +8°C), ICECATCH® Solid Frozen (<-20°C) or ICECATCH® Solid Ambient (+15°C to +25°C) – then you have a highly innovative system. This modular packaging system therefore enables a clever, strategic approach that takes the various logistics phases required for global distribution into account.

With the knowledge that this vaccine will be distributed all around the world, with products travelling thousands of miles, exposed to widely varying ambient environments, is there a need to create different packaging depending on the country of destination or means of transport?

I can answer that with a definite ‘no’ when it comes to eutecma. Our PROTECT system packaging covers all pharma-relevant temperature ranges. You only need the appropriate ICECATCH® passive energy storage units for the temperature range, plus dry ice for -70°C or -20°C transport. This is how it works in practice: Our customers provide their temperature profile specifying the maximum temperature stress the cool box will be subjected to, and must withstand, on its journey to the final destination – including ramp times, ground handling, intermediate stops, etc. We test these extremes in our in-house climate chambers, so that the box is fully qualified



Products for customers are qualified in the four eutecma climate chambers. The PROTECT pharmaceutical packaging is subjected here to extreme stress tests.

photo: eutecma/Axel Heiter Fotodesign

for shipping. We work with empirical data from the German Weather Service entered in a transport calendar, which is used to compute the ambient temperature situations for hundreds of transport connections. We always assume and test the worst-case scenario in the climate chamber so as to provide an extra security buffer. Irrespective of whether your PROTECT box is shipped to the desert or to permafrost regions – your specific temperature range or cold chain will not be lost during transport.

The box never changes, just the quantity and type of passive energy storage units used differ, i.e., ICECATCH® elements or dry ice. This depends on the duration and prevailing temperatures during transport until arrival. In our opinion, the entire process chain should be given greater consideration in all distribution concepts. Is it possible/necessary to re-ice the boxes or are they delivered immediately? Can the packaging solutions be stored pre-assembled and rapidly shipped out when deliveries are required? Or are the boxes only assembled following an order? These are all questions that can positively or negatively affect supply chain efficiency and which we can optimally respond to with our PROTECT packaging solutions.

TEST SCENARIO

PROTECT Frozen 8.7l · 25 plastic vials (à 20ml) · 18 kg dry ice (nuggets) below -70°C



The PROTECT packaging system, when filled with dry ice, maintains a temperature of -70 °C for 120 hours. The ISTA 7D cold/hot profile was tested here. photo: eutecma

Taking into consideration that the vaccines will not all be distributed at the same time, it may be necessary to conduct staggered delivery regimes. How could this be done in practice?

Staggered delivery processes are very likely as the vaccines being delivered will be correlated with warehouse availability and the number of people who can be vaccinated per day at each location X. The eutecma system is particularly suitable for such fluctuating freight volumes due to its modularity. The available interior volume varies according to how many modules are used. And our system has another advantage: When national and international vaccinations start and very large quantities of COVID-19 vaccines need transportation,



“One size fits all”. These universal ICECATCH® passive energy storage units are available for all pharmaceutical temperature ranges: Frozen (<-20 °C), Cool (+2 °C to +8 °C) and Ambient (+15 °C to +25 °C). photo: eutecma/Axel Heiter Fotodesign

any number of PROTECT boxes can be pre-packed and stored in ambient, cool or frozen warehouse areas. Once the dispatch order comes in, the warehouse worker only needs to insert the appropriate number of ICECATCH® cool bricks in the wall slots, close the box and send it off on its journey. So, a lot can be prepared before final dispatch, which greatly accelerates the shipping process.

In your opinion, what will be the biggest challenge in delivering COVID-19 vaccines?

The availability of transport resources on the road, but above all in the air. Due to this corona pandemic, many planes are grounded which means there is a lack of air freight capacity around the world. Lower capacities mean higher freight prices. This also applies to normal temperature-controlled air transport of pharmaceuticals. Shipping of vaccines will worsen this bottleneck. Manufacturer and shippers must therefore be careful about pack-out, about filling the boxes as efficiently as possible so as not to waste any interior space. Our modular eutecma packaging system is designed for precisely this purpose. Additionally, the temperature-controlled eutecma cool boxes are made from EPS/Styropor. This material is both robust and resistant to ageing, but very light compared to other packaging solutions, which is a huge benefit given the strained air freight resources at present. Because every freight kilo or litre saved here is essential. And there is yet another point where eutecma can provide an efficient response to reduced air freight

capacities in the deep frozen sector (-70°C): In parallel with using just dry ice, we have developed concepts where this ultra-cold medium can be combined with ICECATCH® cold energy storage units. This reduces the use of dry ice by up to 30 per cent! As the amount of dry ice that can be transported in a plane is limited for safety reasons, this combination offers a very great advantage.

Some governments are indicating that they may have to defer their vaccination programmes pending the arrival of vaccine types that are easier to store and transport. What storage and handling training should locations that store vaccines implement?

The lack of trained personnel in the cold chain sector, capable of safeguarding the processes for storing temperature-stable vaccines in distribution centres, for instance, is in principle the second greatest challenge in this pandemic. If temperature-controlled transport containers are sent to interim storage or a distribution centre, they must be correctly stored and even re-cooled in some circumstances. This is particularly critical for deep frozen transportation. The logistic personnel on site must be able to handle the dry ice cooling media competently as it poses various risks and hazards. Cool bricks may also need to be replaced for products stored between +2°C and +8°C. Personnel who don't work in this field on a daily basis therefore need to be trained. The following maxim applies in all cases: The simpler the packaging and cooling medium set-up is, the less room there is for errors.

This was precisely our guiding principle while developing the eutecma system. The PROTECT boxes are designed to be as simple and easy to use as possible and to be easily fitted with the ICECATCH® passive energy storage elements. Our ingenious trick is that PROTECT cool boxes do not need to be fully unloaded to insert new elements. The “exhausted” ICECATCH® elements can simply be removed from the insertion slots and replaced with new elements. The “exhausted” elements can then be treated in a second process so that they can be re-used. This applies to all temperature ranges. So, we can certainly say that universal packaging systems, such as those made by eutecma, can minimise errors. The simple handling of our PROTECT system packaging had already been explained in two training videos, well before the COVID-19 pandemic, using the XL PROTECT pallet box and the PROTECT Euro pallet box. Both videos can be found at www.eutecma.com/movies. You can also take a look at the “Reusability Guidelines” video, which explains how our packaging solutions and ICECATCH® bricks can be used more than once. It shows the user precisely what needs to be monitored and when parts need exchanging.

Good catchword, since at IPI we take an interest in supporting eco-friendly and sustainable businesses. Can you tell us more about what eutecma does to help the environment?

Sustainability is playing an increasingly important role at eutecma. The main motto this year was to make existing products more sustainable, but at the same time save our customers the cost of renewed qualifications. We managed this extremely well in various areas. Example number 1: Starting from January 2021, we will successively start producing ICECATCH® elements with a composite film that consists of at least 50% sugar cane waste instead of 100% crude oil. They will bear the “I'm green” quality seal developed by Braskem, the Brazilian producer of sugar-cane-based polyethylene, and a QR code leading to more detailed information. This approach is very smart, because this “green polyethylene” does not supplant any foodstuffs, instead it cleverly recycles otherwise worthless waste. At the end of the product cycle, this organic plastic can be easily recycled. Example number 2: We will also start significantly increasing the percentage of recycled Styropor in our packaging boxes in the first quarter of 2021. We are working on this project together with BASF, the world's largest chemicals



As of January 2021, eutecma will be cooperating with their partner BASF to offer high quality PROTECT packaging systems made of EPS/Styropor® Cycled. photo: BASF

producer. In addition to conventional EPS/Styropor, a virgin material, we will use Styropor Cycled in a variety of PROTECT packaging boxes. This secondary material consists of pyrolysis oil recycled from plastic wastes. During chemical recycling, this material is converted into feedstock for the chemical industry and allocated to products within the BASF production network via a mass balance method. Even though Styropor Cycled has exactly the same properties as Styropor gained from fossil fuels, it has a significantly better CO₂ footprint. Both innovations are just as efficient as their predecessors and do not affect the quality of our products in any way, but improve our environmental footprint and that of our customers. Re-qualification for "I'm green" or Styropor Cycled products is not necessary. Our message to all pharma companies who place value in sustainability along their supply chain and who also want to communicate this during their dialogue with their stakeholders: eutecma is the partner to have at your side.

In contrast to the Biontech-Pfizer vaccine, which needs ultra-low temperatures, most of the potential vaccines will require a temperature of +2°C to +8°C, with some needing a slightly colder -15°C to -25°C. Does eutecma intend to participate in the global distribution of the vaccines?

We belong to the lucky companies who have not suffered so far from the corona

pandemic. On the contrary: Many of our customers have increased their pharmaceutical cooling packaging stocks for safety reasons. We recognised and invested in this development early on, which meant our production was increased accordingly over the course of this year. Our warehouses are well stocked with ICECATCH® passive energy storage units and PROTECT system packaging. We can ramp up our production even further for vaccination transport. With our recent qualification for deep frozen transports, and the millionfold-proven reliability of our products in all other pharma-relevant temperature ranges, we are well prepared to contribute towards this historical logistics challenge. We are already doing so in one area. Antigen tests have already provided good service during this pandemic by detecting whether a person is infectious or not in approximately 30 minutes. A study released in November 2020 by the Berlin Charité hospital, under the top virologist Dr. Christian Drosten, investigated seven antigen tests, coming to the conclusion that, although some performed better than others, they all functioned well. The specificity of the investigated tests lay between 88.24% and 100%. Five of the seven tests investigated originate from manufacturers that use eutecma products. We are proud that we can already support our customers in safely transporting these antigen tests from A to B.



Sven Rölle

Since it was founded in 2008, eutecma has been researching, developing and producing passive cooling systems that are always used where the cold chain must be maintained for temperature-sensitive products. This innovative mid-sized company has shown strong growth over the years, particularly in the pharma and diagnostics sector. Sven Rölle, after holding positions in several packaging companies, including SCA, is an eutecma employee of the first hour and has contributed to many milestones in eutecma's history. With a degree in business administration, the Head of Sales has his finger on the pulse of numerous global players in the pharmaceutical industry, many of which are eutecma customers. With a finely-developed sense for intelligent solutions driven by "outside-the-box" thinking, he and his team push the development of new, ground-breaking cooling systems and accompanying services.