



June 6th 2024

Ísafjörður, Iceland

Dear Medicare Administrative Contractor,

I am writing to address concerns regarding potential skin substitute shortages following the implementation of the draft LCD proposal. As a diversified global medical device company, Kerecis is well-positioned to meet the increased demand for our MariGen and Shield products, which we expect to be covered under the final LCD policy.

With the implementation of the draft LCD proposal, the potential for a number of products currently on the market to immediately become unavailable may lead to increased demand for products that are covered under the final policy to meet patient needs, including Kerecis' MariGen and Shield products. Many commenters have pointed out potential shortages as a reason for postponing implementation of the proposed LCD.

Kerecis is a global medical device company, and our processing of intact fish skin grafts is built to serve multiple geographical markets and sites of service. For the context of this LCD, under 20% of our intact fish skin graft volume is used in the outpatient wound care market in the USA.

Kerecis is well-prepared to manage potential immediate increased demand:

- **Estimated Medicare Skin Substitute Utilization:** Based on the OPPS ratesetting data file and Medicare Physician provider services lookup tool, we estimate that the total SQ CM utilization for Medicare Beneficiaries is in the range of 3-7 million square centimeters of skin substitutes (estimates from 2021 data).
- **Kerecis skin processing output in 2023 was 5 Million SQ CM of intact fish skin.** During that time, we were using 20% of the peak manufacturing capability. At the current manufacturing setup, Kerecis could provide up to 25 Million SQ CM of skin substitute products next year.
- **Additional Production Capacity Plans Already in Motion:** Scale-up plans to further enhance production capacity have already been developed, and a 3rd manufacturing facility in Isafjordur is anticipated to be ready within the next two years, which would increase peak capacity 3x.
- **Existing Inventory Levels:** Kerecis keeps between 6 and 12 months of inventory on hand in the US at its current sales rates of MariGen and Shield SKUs, with additional inventory held at the production factory in Isafjordur, Iceland. Any immediate demand increase can largely be managed by available inventory.
- **Efficient Logistics:** Kerecis products are shelf-stable for 3 years and can ship via overnight delivery with no temperature control requirements, making the logistics and storage of the product efficient for both the company, hospitals, and private offices as further scale is achieved.
- **Secure Logistic Routes:** Iceland and US are well connected logistically with over 20 flights daily that all offer cargo-services. The Kerecis product is very light and is transported on flights from Iceland to our distribution hubs in Arlington VA and

Minneapolis, MN multiple times per week. The US is Iceland's largest trading partner as well being closely politically and defense integrated. The US is responsible for the defense of Iceland according to the The United States and Iceland signed bilateral defense agreement signed in 1951. As the US, Iceland is a founding member of the NATO defense alliance.

- **Robust Quality and Safety:** The Kerecis manufacturing plant is audited by notified bodies across the globe with live on site audits every other year from European Union and Korean FDA in addition to standard FDA audits. To date there have been no recalls or MAUDE reported safety events with Kerecis products.
- **Abundant Source Materials:** The primary material for Kerecis products is intact fish skin and is readily available in large quantities from our existing supply sources to be able to serve the entire US market. Kerecis currently utilizes a very small portion (less than 1/20th of 1%) of the available fish skin material in Iceland. The material from 1 fishing trawler connected to a fish processing factory could provide enough material for ~25% of the entire US skin substitute market over the course of the year.
- **Short Manufacturing Lead Times:** Material sourcing to finished product cycle time is 8-12 weeks, allowing Kerecis to ramp up and adjust to changing market conditions quickly.

We estimate that the demand for Kerecis products could increase by 50-500% following the implementation of the LCD proposal. This potential growth would be well covered within our existing manufacturing. Furthermore, we have already developed scale-up plans, including the construction of a 3rd manufacturing facility in Isafjordur, which is expected to be operational within the next two years. This expansion will increase our production capacity threefold.

In conclusion, Kerecis is committed to meeting the needs of Medicare beneficiaries and ensuring that they have uninterrupted access to high-quality skin substitute products. We are prepared to handle a sudden increase in demand and can quickly scale our production to meet the market's needs. We look forward to working with Medicare to ensure a smooth transition and maintain the highest standard of care for patients.

Best regards,



Mike Cadigan

Chief Financial Officer



Halfdan Halfdansson

Manufacturing Director