

A Letter Regarding SILSOFT® (elastofilcon A) Contact Lenses

June 28, 2021

Dear Eye Care Professional,

We are writing to inform you of a supply situation with our SILSOFT® (elastofilcon A) contact lenses. Since the introduction of SILSOFT® lenses more than 30 years ago, we have continued to invest in our manufacturing technology to provide these lenses to you and your patients. Unfortunately, due to a combination of supplier changes, component obsolescence and regulatory requirements, there is a possibility that we may have to discontinue the production of these lenses in the United States.

Our team has been working diligently with representatives from both inside and outside the company to identify all possible alternatives so we can keep this product on the market for you and your patients. We have investigated new materials to replace the product's original essential components and explored new container/closure systems used by other contact lens products in an effort to find a suitable replacement product.

We believe that one of the container systems we have identified can meet the manufacturing and regulatory requirements for the product, as well as provide equivalent functionality.

We are in the process of working with the U.S. Food and Drug Administration (FDA) on requirements to obtain approval. While we have identified a route to potentially keep this product on the market, it is not a guarantee, and we want to provide you with sufficient time to consider alternatives.

We are also working with leading clinicians who have surgical experience with pediatric cataract patients, as well as experience fitting all types of corrective lenses on the eye. Together with this group, we will be sharing educational information to assist you. This information will include guidance and insights on treatment options, such as certain RGP lenses, which are indicated for, and have been found to be effective in, treating aphakia in children with non-diseased eyes according to a report by the American Academy of Ophthalmology.¹

At this time, we expect to provide an update on this new container system by September 2021. In the meantime, our SILSOFT® lenses will be available for purchase until our existing supply has been depleted, which we expect could occur by September 2021.

If we are able to receive FDA approval of this new container system, we anticipate that we will be unable to supply these lenses for up to nine months, and possibly longer, following the depletion of our current supply. This is the current estimated timeframe that we believe we'll need to build up our supply of the new container system.

We are deeply committed to providing you with the highest quality products and level of service support possible. If you have any questions on this situation, we encourage you to contact your Bausch + Lomb sales representative or our Customer Service team at 1-800-828-9030.

It is our greatest privilege and honor to serve you and your patients with our eye health portfolio, and we thank you for your support and understanding as we continue to work through this evolving situation.

Sincerely,



John Ferris
Vice President and General Manager
U.S. Vision Care
Bausch + Lomb



Chuck Hess
Vice President and General Manager
U.S. Surgical
Bausch + Lomb

References

1. Lambert, Scott R et al. Contact Lens Correction of Aphakia in Children: A report by the American Academy of Ophthalmology. 2018.125;9 1452-1458, <https://doi.org/10.1016/j.ophtha.2018.03.014>.

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