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Jaunākās tehnoloģijas medicīniskai aprūpei

02.08.2023.

State Agency of Medicines of the Republic of Estonia  
Nooruse 1,  
Tartu, 50411, Estonia  
[info@ravimiamet.ee](mailto:info@ravimiamet.ee)

Re: **Alcon Phaco Tips**

Dear State Agency of Medicines:

The purpose of this communication is to notify the State Agency of Medicines of the Republic of Estonia that Alcon has initiated a Voluntary Medical Device Correction for specific catalog numbers of phaco tips and related procedure packs. Alcon provides phaco tips pre-assembled with a plastic wrench intended for use in securing the phaco tip to the system handpiece.

Alcon is conducting this Voluntary Medical Device Correction due to the potential for the end user to damage the included plastic wrench by over-tightening the phaco tip to the handpiece, causing particles to be shaved from the wrench.

If the plastic wrench is damaged by overtightening the Phaco Tip and particles shaved from the wrench subsequently enter the patient's eye during surgery, there is a potential risk of intra- and/or post-operative complications, including intraocular tissue damage, bleeding, and/or associated inflammation. Due to the potential risk of damage to the phaco wrench caused by overtightening, Alcon is advising doctors who have received phaco tips of additional handling precautions to mitigate the risk for over-tightening the tip to the handpiece and subsequent shearing of particles from the included plastic wrench.

This event was identified through our customer complaints process. To date, Alcon is aware of (4) complaints globally which resulted in an adverse event.

This Voluntary Medical Device Correction affects customers worldwide. Alcon will contact affected customers by letter and direct phone call to provide handling instructions intended to mitigate the risk of damaging the wrench by over-tightening the phaco tip to the handpiece.

If you have any questions regarding this matter, please contact Janika Lind, +372 53416347, [janika.lind@nmselpa.lv](mailto:janika.lind@nmselpa.lv).

Sincerely,

Ilmars Curkste  
Member of the Board

A handwritten signature in blue ink, consisting of a long horizontal stroke followed by a loop and a tail.