Field Safety Notice

Artisan and Artiflex phakic intraocular lenses

Date: 15-09-2021

FSN identifier: C21-009

Attention: To whom it may concern

Dear valued customer,

In order to continue ensuring long term patient safety and high quality visual results OPHTEC BV hereby notifies you of a revision in the Instructions for Use (IFU) for the Artisan and Artiflex phakic intraocular lenses (PIOLs).

OPHTEC is implementing the following exclusion criteria in the IFU:

- **Preoperative anterior chamber depth measurement of below 3.0 mm from corneal endothelium to the anterior pole of the crystalline lens.**

Long term follow-up has shown that the primary indications for PIOL explantation are age-related cataract and endothelial cell loss (ECL). ECL is a reduction of the number of cells of the corneal endothelium and is a well-known risk factor for PIOL implantation. Information to mitigate the risk for ECL is currently included in the IFU's for the Artisan and Artiflex PIOLs. Strict inclusion criteria are applicable and post-operative follow-up is mandatory. This allows monitoring of the endothelial cell count over time and safe explantation of the PIOL when required.

Analysis of long-term follow-up data has shown that ECL negatively correlates with the anterior chamber depth (ACD) of the eye. Currently the minimal ACD requirement for the Artisan models is 3.00 mm from the corneal epithelium and for the Artiflex models 3.20 mm from the corneal epithelium. In many markets ophthalmologists have implemented more strict inclusion criteria. OPHTEC BV has decided to modify the exclusion criteria regarding minimal ACD requirements for all Artisan an Artiflex lens models. By increasing the minimal ACD requirement, the frequency of long term complications associated with ECL is expected to be reduced or the onset may be delayed. For patients who currently have Artisan or Artiflex PIOLs implanted, the current recommendations for annual follow-up will help to reduce the likelihood of complications associated with ECL.

Sincerely,

Erwin Bouwman
Manager Clinical Research

Contact reference person
In case you have any questions or want to obtain more information, please contact fsn@ophtec.com

Details on applicable medical devices:

Model #	Name	Basic UDI-DI
130**1W	ARTISAN Toric Sxx*Cxx*0˚	8717819ArtisanToric/KY
140**1W	ARTISAN Toric Sxx*Cxx*90˚	
203001W	ARTISAN Hyperopia 5/8.5	8717819Artisan203/3Z
204001W	ARTISAN Myopia 6/8.5	8717819Artisan204/44
206001W	ARTISAN Myopia 5/8.5	8717819Artisan206/4A
40114SW	ARTIFLEX Myopia	8717819Artiflex401/TV
4A0**SW	Artiflex Toric S**.*C-*.*X 0˚	8717819ArtiflexToric/U7
4C0**SW	Artiflex Toric S**.*C-*.*X 90˚	

Device types and intended use:
The Artisan and Artiflex are used for implantation into the phakic adult human eye for the correction of myopia or hyperopia and/or regular astigmatism.

Type of action:
Update to product IFU.

Action to be taken by the user:
Take note of the IFU amendment.

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organization. Please transfer this notice to other organizations on which this action has an impact. If you or your organization distribute these products to other personnel or facilities, please promptly forward the recipients a copy of this Field Safety Notice.

Product IFU's:

EN_IFU L23-HV0209.pdf

EN_IFU L23-HV8106.pdf

EN_IFU L23-HV5310.pdf