

July 5, 2018

Subject: Approved Expanded Uses for EVO Visian ICL™ and Changes to DFU

Dear Customers:

We are pleased to advise you that STAAR Surgical Company announced that our European Regulatory Notified Body recently concluded that STAAR may expand use of the EVO Visian ICL family of ICLs in the following two ways:

1. the age range for the EVO Visian ICL family of ICLs indicated for the correction/reduction of myopia increased from adults age 21 to 45, to the new age range of adults age 21 to 60; and
2. the required minimum ACD for the EVO Visian ICL family of ICLs indicated for the correction/reduction of myopia was revised from requiring an ACD equal to or greater than 3.0 mm to the new minimum parameter of an ACD equal to or greater than 2.8 mm.

The newly approved indications are as follows:

“EVO Visian® Implantable Collamer Lenses are indicated for use in phakic eye treatment for:

1. The correction/reduction of myopia in adults ranging from -0.5 D to -20.0 D at the spectacle plane in adults 21 – 60 years of age with an anterior chamber depth (ACD) equal to or greater than 2.8 mm, as measured from the corneal endothelium to the anterior lens capsule.
2. The correction/reduction of myopia in adults with myopia ranging from -0.5 D to -20.0 D with less than or equal to 6.0 D of astigmatism at the spectacle plane in adults 21 – 60 years of age with an anterior chamber depth (ACD) equal to or greater than 2.8 mm, as measured from the corneal endothelium to the anterior lens capsule.”

This change only applies to myopic EVO Visian ICLs, and in countries covered by the jurisdiction of the EU Notified Bodies where the CE Mark is recognized (i.e., the EU, EEA, and EFTA).

The EVO Visian ICL products currently in inventory will have the updated Directions For Use (DFU) with this new wording beginning in July 2018. The current DFUs for spherical EVO Visian ICL, spherical EVO+ Visian ICL, toric EVO Visian ICL, and toric EVO+ Visian ICL will be replaced by two DFUs that will combine the product information from spherical EVO/EVO+ Visian ICL and toric EVO/EVO+ Visian ICL. (See below for cover design and additional explanation.)

STAAR appreciates your support and wanted to inform you about this important change in our product information. For further details, please contact our Medical Affairs Department at medicalaffairs.ag@staar.com.

Sincerely,
STAAR Surgical

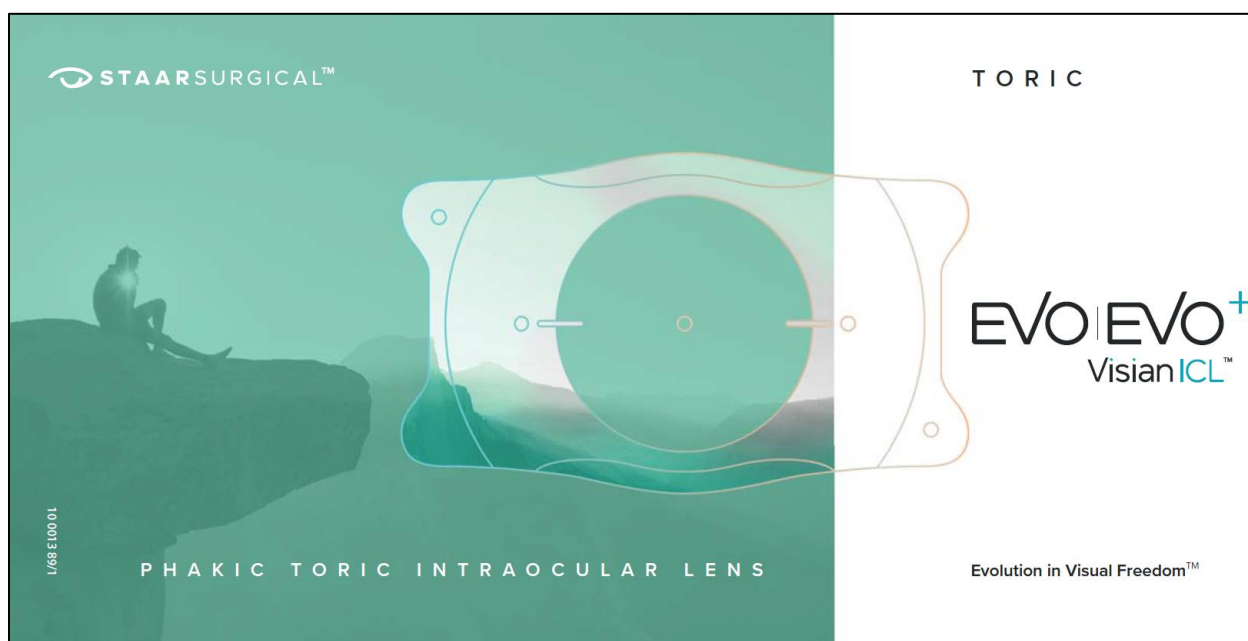
New EVO/EVO⁺ Visian ICL Directions For Use (DFU)--Spherical and Toric

Image A: **Spherical** EVO/EVO⁺ Visian ICL DFU Cover



The new DFU for **spherical** EVO/EVO⁺ Visian ICL combines the product information from both the spherical EVO Visian ICL DFU and spherical EVO⁺ Visian ICL DFU into one DFU.

Image B: **Toric** EVO/EVO⁺ Visian ICL DFU Cover



The new DFU for **toric** EVO/EVO⁺ Visian ICL combines the product information from both the toric EVO Visian ICL DFU and toric EVO⁺ Visian ICL DFU into one DFU.