
PATIENT INFORMATION IEAFLETS - SIMEDICE FAMILY OF IOLS

1.Description

The **Simedice Family of Lenses(preloaded and non-preloaded)** are artificial lenses implanted in the eye of adult patients following cataract surgery. The **Simedice IOLs** are designed to allow for clear distance vision. However, you will likely still need glasses for reading and for distance vision particularly if you already have astigmatism. The **Simedice Toric IOLs** are also designed to correct pre-existing corneal astigmatism, which is the inability of the eye to focus clearly at any distance because of difference curvatures on the cornea, and provide distance vision.

2.Warnings / Precautions

You may experience and need to contact your eye doctor immediately if you have any of the following symptoms after cataract surgery: itching, redness, watering of your eye. The safety and effectiveness of these IOLs have not been established in patients with eye conditions, such as an increase in eye pressure (glaucoma) or complications of diabetes in the eye (diabetic retinopathy). As with any surgical procedure, there are risks involved. These risks may include but are not limited to infection, damage to cornea, retinal detachment, inflammation or swelling inside or outside the eye, damage to the iris, or an increase in eye pressure. There is a possibility that the IOL may be placed incorrectly or could move within the eye. This may result in less improvement or a reduction in vision, or it may cause visual symptoms. The **Simedice Toric IOLs** correct astigmatism only when placed in the correct position in the eye. There is a possibility that these Toric IOLs could be placed incorrectly or could move within the eye. This may result in less improvement or a reduction in vision because your astigmatism has not been fully corrected, or it may cause visual symptoms.

3.Expected lifetime of the device

Based upon material characterization of the Simedice Family of intraocular lens, the IOL is expected to be stable indefinitely over the lifetime of the patient. The IOL will remain in your eye after implantation and will not be removed unless your doctor recommends it.

4.Magnetic Resonance(MR) Safe

The Simedice Family of Lenses is MR-Safe as the IOL consists of acrylate/methacrylate copolymer material, which is a non-conducting, non-metallic, non-magnetic material that poses no known hazards in all magnetic resonance imaging environments.

5.Materials and substances to which patients can be exposed

After intraocular lens implantation, the materials and substances to which the patient can be exposed is Hydrophobic Acrylate / Methacrylate Copolymer with Ultraviolet Filtering. The total quantity of leachable substance including PEA, PEMA, BDDA and UV-13 is less than 100 µg/g, which is far less than the human tolerable intake.

6. Attention to ensure safe use of the device by the patient

As with any surgical procedure, there are risks involved. Prior to surgery, discuss any questions about possible risks and benefits associated with your eye doctor. Additional information about your IOL can be found in a document called "Summary of safety and clinical performance" or SSCP on the website of EUDAMED (<https://webgate.ec.europa.eu/eudamed>).

7. Device Model and Manufacture

The patient information included in this document relates to the following Simedice models:

Model	Performance characteristics
SM60AS, SM60AS1, SM60AS2, SM60AS3	Aspheric, monofocal
AS-P22, AS1-P22, AS2-P22, AS3-P22	
ST1, STS2, ST3, ST4, ST5, ST6, ST7, ST8, ST9, ST10	Aspheric, monofocal toric



Henan Simedice Biotechnologies Co., Ltd
No. 28, Floor 7, Unit A, Building 1, No. 8
Guohuai Ave., Hi-tech Industries Development Zone,
Zhengzhou, Henan 450001, P.R.China



MedNet EC-REP C IIb GmbH,
Borkstrasse 10, 48163 Münster, German



Last revised: 2025-11-03