XENIA®

CORNEAL IMPLANT

FOR **KERATOCONUS**

MY
VISION.
MY
LIFE.

RESTORING VISION

PREVENTING CORNEAL TRANSPLANTATION

XENIA for KERATOCONUS

XENIA implants are used to avoid corneal transplantation in patients with keratoconus or ectasia or, at the very least, to defer corneal transplantation as long as possible.

The XENIA implant for keratoconus and ectasia is crosslinked and therefore **significantly stronger** as compared to the patient's own stroma and thus stabilizes the patient cornea.

At the same time the XENIA implant regularizes the patient corneal topography. It flattens the cornea, as well as reduces Higher Order Aberrations (like for example Coma), and therefore **improves the patient's visual acuity.**

STABILIZATION AND VISION IMPROVEMENT

SMART

THE SMART ALTERNATIVE TO DALK

For patients suffering from advanced keratoconus, DALK surgery (Deep Anterior Lamellar Keratoplasty) has been the surgical solution of choice in order to prevent corneal blindness. However, DALK surgery is very complex, involves general anaesthesia, requires corneal sutures and with any transplant surgery, there is always the risk of graft rejection.

The XENIA corneal implant for keratoconus is a substantially **less complex**, and minimally invasive alternative to a DALK transplant. Implanting XENIA is a **standardized**, straightforward and **fast** procedure. Simply insert the implant into a corneal pocket created by a Femto-Laser, **no sutures** required.

Requiring only topical anaesthesia, the surgery can be performed as an **out-patient procedure**.

XENIA is a sutureless procedure. Therefore, you eliminate all suture-related complications resulting in **better vision, faster visual recovery** and far **fewer follow-up visits** for patients.

The XENIA procedure reinforces and supports patient corneal tissue without a transplant which, therefore, thickens the cornea while avoiding all graft-related problems, like for example rejection, or downgrade from DALK to full Penetrating Keratoplasty (PK) due to (bubble-related) complications.

Using XENIA not only **reduces all kinds of risks,** it also offers flexibility because XENIA is **reversible** and a DALK could still be performed in a worst-case situation.

Finally, XENIA can be used **in combination with Corneal Cross-Linking (CXL)**, because XENIA is increasing the corneal thickness, hence enabling CXL in patients with thinner corneas.

QUICK OUT-PATIENT SURGERY
NO SUTURES
RAPID RECOVERY
LOW RISK PROCEDURE

CUSTOM-MADE

THE REAL THING...

What is XENIA?

XENIA is a **corneal implant** made of natural corneal collagen of animal (porcine) origin.

The XENIA material, natural corneal collagen, has been successfully validated by Mother Nature – with **a follow-up of more than 450 million years** with excellent results.[1]

The XENIA material undergoes a special process to remove foreign cells including antigens. This special process is called **decellularization**.

It has been routinely used for more than 30 years in cardiology (artificial heart valves/bioprosthesis) and has helped countless patients with heart problems who needed heart valve replacement.

XENIA is like "the real thing": it is made from **natural corneal collagen**, just like traditional corneal transplants used in millions of successful corneal procedures for more than 100 years.

XENIA is in fact "even better than the real thing": a human transplant still contains corneal cells from the donor (e.g. keratocytes), while the XENIA material is completely devoid of foreign cells and, hence much more **tolerable**.

XENIA is a **custom-made** product that is available only on a physician's prescription and is exclusively manufactured for the individual patient.

XENIA's Technical Documentation is in full compliance with the latest EU Medical Device Regulation (MDR) 2017/745.

[1] Parker, A. R. (2009). "On the origin of optics". Optics & Laser Technology. 43 (2): 323–329.

...EVEN BETTER THAN THE REAL THING

ADDITIVE

XENIA® IS UNIQUE IN MANY WAYS

XENIA is additive
Unlike many other corneal procedures that are subtractive (taking away material from the cornea), XENIA provides the patient with extra collagen material to re-shape, thicken and strengthen the cornea.

XENIA is reversible
It can always be removed from the patient cornea, essentially restoring the situation from before the implantation.

XENIA is exchangeable
In some cases the patient's vision or corneal situation changes over time. In such a case the XENIA implant can be exchanged with another XENIA implant that is better aligned with the new corneal or visual situation of the patient.

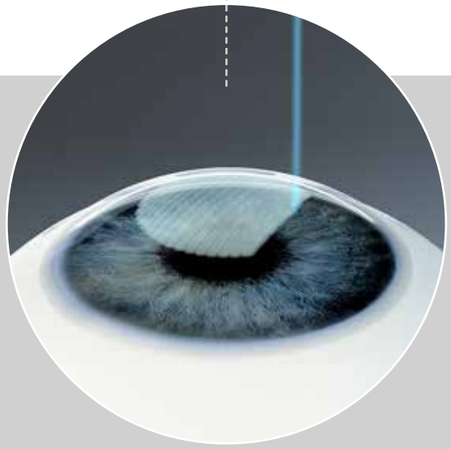
XENIA is custom
Unlike the vast majority of ophthalmic implants (e.g. intra-ocular lenses – IOLs) that are mass-manufactured to pre-defined standards the XENIA implant is custom-made for each and every patient. It can be tailored individually to be perfectly aligned for the individual need of the individual patient.

ADDITIVE
REVERSIBLE
EXCHANGEABLE
CUSTOM

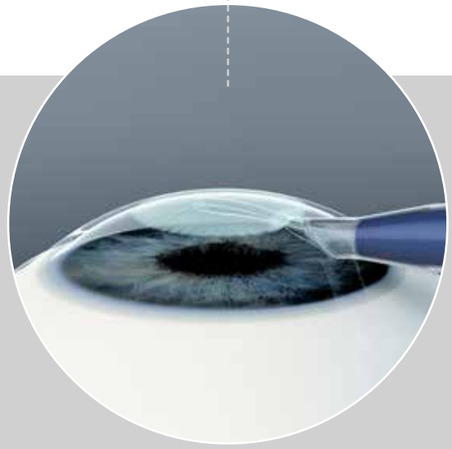
THE SURGICAL PROCEDURE

SMALL-INCISION **LIKE**®
LENTICULAR **I**NTRASTROMAL **KE**RATOPLASTY

1 For keratoconus patients a **corneal stromal pocket** with a small opening is created.



2 The XENIA implant is **inserted** by means of an injector or forceps.



3 After insertion, the XENIA implant is **unfolded** in the pocket.

MINIMALLY INVASIVE

TECHNOLOGY

CUTTING EDGE CORNEAL TISSUE ENGINEERING

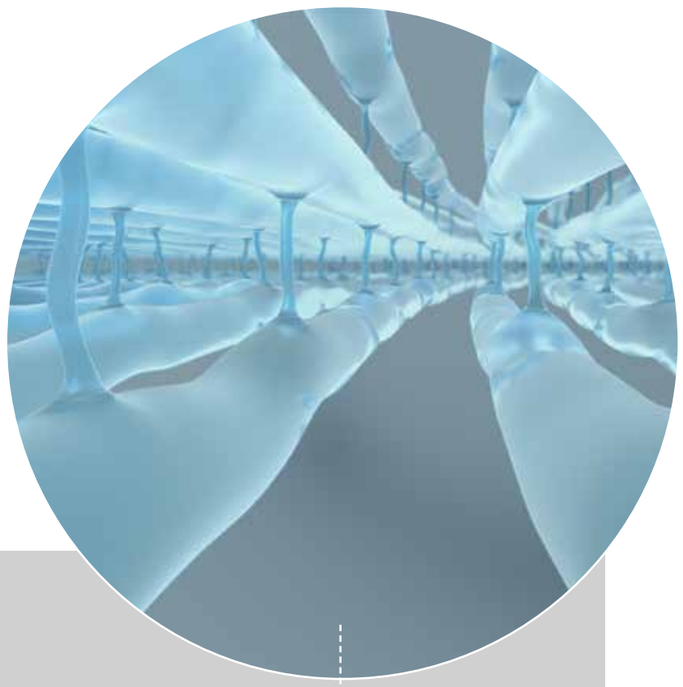
In order to create highly **compatible** and purified corneal collagen, a **sophisticated biochemical decellularization process** is applied. This process removes all foreign cells as well as all unwanted epitopes and antigens from the XENIA material.

In addition to this, the XENIA material undergoes a **proprietary crosslinking process** which stabilizes the material, providing the XENIA implant with **significant strength.**

1 Porcine corneal collagen with **keratocytes,** carrying epitopes and antigens.

2 Decellularization process: **Removal** of all foreign cells with all unwanted epitopes and antigens.

3 **Purified** corneal extracellular matrix.



4 The XENIA material after crosslinking process: **Natural corneal collagen, purified and stabilized.**

Xenia – Greek: **ξενία**
Romanized: **xenía**

Xenia – meaning "guest-friendship" – is the ancient Greek concept of hospitality.

According to the concept of Xenia, a host shall be hospitable to the guest, and a guest shall offer presents, be gentle, and not be a threat or a burden to the host.

We, from Gebauer, have gone to great lengths to develop the XENIA implant to be fully compatible with our patients' cornea, and at the same time provide the highest degree of performance.

In the spirit of Xenia, our implant is designed to provide patients with a gift of improved vision and a better quality of life.

XENIA – My Vision. My Life.

THE GIFT OF VISION

MY VISION.
MY LIFE.

OVER 40 YEARS OF INNOVATION AND EXPERTISE IN OPHTHALMOLOGY

Gebauer's 40 years history of extensive and groundbreaking developments brings ophthalmology exciting new products for innovative surgical procedures.

We offer peak performance medical products for corneal surgery that have never been available before.

Through our time-honored and respected knowledge, we thrive on innovative developments by continuously cooperating with top class ophthalmologists worldwide and observing market requirements.

We apply this valuable input to implement new technological advancements into all our ophthalmic medical products, which we manufacture in our German facility based near Stuttgart.

Here at Gebauer our experienced, highly motivated, and specialized employees ensure the highest level of superior quality products and services in accordance with our quality management system certified to ISO 13485, and in full compliance with the EU Medical Device Regulation 2017/745 (MDR).

Gebauer

SURGEON EXPERIENCES WITH XENIA

"The XENIA Lenticule is a ground-breaking treatment which can help Keratoconus and Post Lasik Ectasia patients. Early results have been very promising with very happy patients."

Mr B Ilango *MBBS DO FRCS FRCOphth Cert LRS*
Group Medical Director: Optimax/Ultralase Clinics UK
Royal College Certified Laser & Multifocal Lens
Implant Specialist, Wolverhampton Eye Infirmary

"For me, the XENIA procedure has vast advantages over DALK. Implanting XENIA is so much easier because it is a quick, sutureless out-patient procedure with no general anaesthesia. It provides my patients with superior corneal regularity, rapid visual rehabilitation and fewer follow-ups. Therefore, XENIA is an excellent alternative to performing DALK surgery in patients with advanced keratoconus."

Ahmed Elmassry *MD, PhD*
Head of Ophthalmology Department
Professor of Ophthalmology
Alexandria University
Egypt

CONTACT OUR XENIA APPLICATION SPECIALISTS

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Ahmed Elmassry, *MD, PhD*
Head of Ophthalmology Department
Professor of Ophthalmology
Alexandria University, Egypt

"The XENIA Implant presents a fresh and novel approach towards keratoconus and post-ectasia treatment. The quick and effortless implantation procedure has allowed my keratoconus patients to live a life they couldn't have possibly imagined before this intervention. In my opinion, the XENIA implant can serve as a platform for addressing wider vision issues beyond Keratoconus."

Mr Marwan Ghabra, *MD DO MRCOphth FRCS*
Senior Consultant Ophthalmic Surgeon
Barts Health NHS Trust
Whipps Cross University Hospital
Leytonstone, London, UK

"XENIA Implant:
The beginning of a new treatment approach for corneal disease."

Jorge L. Alió, *MD, PhD, FEBOphth*
Professor and Chairman of Ophthalmology
Founder Vissum Miranza
Alicante, Spain

Gebauer

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