

DR. RAJENDRA PRASAD CENTRE FOR OPHTHALMIC SCIENCES  
ALL-INDIA INSTITUTE OF MEDICAL SCIENCES  
ANSARI NAGAR, NEW DELHI-29

Ref. No.SO/RPC/SSK/Ologen/2015-16

Dated: 13.05.2015

**Subject: Purchase of Ologen Collagen matrix Implant for Glaucoma Services, Dr. R.P.Centre at AIIMS, New Delhi-29 on proprietary basis- Inviting comments thereon.**

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The request received from respective faculties of Dr. R.P.Centre AIIMS for the purchase of Ologen Collagne Matrix Implant from M/s. Aeon Astron Europe BV, The Netherlands on proprietary basis. In this regard, the proposal and PAC submitted by M/s. Aeon Astron B.V., The Netherlands are attached and uploaded on website.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within 15 days from the date of issue/uploading of the notification giving reference SO/RPC/SSK/Ologen/2015-16

.The comments should be sent to Stores Officer, Room No. 180, Ist Floor, Dr. R.P. Centre, AIIMS, New Delhi – 110 029 on or before **30.05.2015 upto 12.30 P.M.**, failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

**Yours faithfully,**

**STORES OFFICER (RPC)**

**Encl: Related documents enclosed.**

- 1. PAC Certificate enclosed.**
- 2. Specification of equipment.**

## Proprietary Article Certificate

Date: December 16, 2014

To whom it may concern,

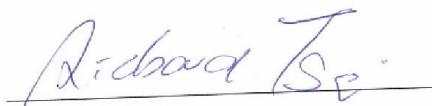
This is to certify that ologen<sup>®</sup> Collagen Matrix is a Proprietary Product of Aeon Astron Europe B.V., a company incorporated under the laws of The Netherlands with principal office at J.H. Oortweg 19, 2333 CH Leiden, The Netherlands, with the following unique specifications and features:

- Composed of Type I atelocollagen and glycosaminoglycan
- A stiffness with 60-80 KPa
- Pore size with 20-300 µm
- *In vitro* simulated degradation window with 3-6 month
- A registered medical device in India with Registration Certificate No.: MD-1232
- A registered medical device in US, Canada, Europe, Korea, Jordan, Iran, Egypt, KSA
- At least 2-year efficacy and safety reports post market launch

It is further certified that Aeon Astron Europe B.V. owns all the right, title, interest, trademark, trade secrets, technology, methodology, composition and know-how to manufacture, sell and market ologen<sup>®</sup> Collagen Matrix. Aeon Astron Europe B.V. have all the EXCLUSIVE right to manufacture and supply ologen<sup>®</sup> Collagen Matrix to all hospitals in India.

Sincerely,

Aeon Astron Europe B.V.



Richard W.C. Tsai  
India Country Manager



\* This Declaration is for M/s Chaturbhuj & Bros' participation of tender process in All India Institute of Medical Sciences only and shall not be used for any other purpose.

## Letter of Certificate

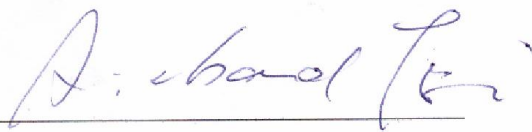
Date: November 26, 2014

To whom it may concern,

This letter is hereby to certify that Aeon Astron Europe B.V., a company incorporated under the laws of The Netherlands with principal office at J.H. Oortweg 19, 2333 CH Leiden, The Netherlands, owns the trademark of ologen<sup>®</sup> and the technology, methodology, composition and knowledge to manufacture ologen<sup>®</sup> Collagen Matrix. We have the exclusive right to manufacture and supply ologen<sup>®</sup> Collagen Matrix to all hospitals in India.

Sincerely,

Aeon Astron Europe B.V.



Richard W.C. Tsai

India Country Manager

- \* This Declaration is for M/s Chaturbhuj & Bros' participation of tender process in All India Institute of Medical Sciences only and shall not be used for any other purpose.
- \* ologen<sup>®</sup> Collagen Matrix is registered medical device in India, Registration Certificate No.: MD-1232

**Letter of Certificate**

Date: Nov-03-2014

To whom it may concern,

We, Aeon Astron Europe B.V., hereby certify that:

**M/s Chaturbhuj & Bros**

Address: G-45, Connaught Place, Opp Madras hotel, New Delhi 110001

Drug License No.: 16 (266)

TIN No.: 07650025965

is our authorized supplier of ologen<sup>®</sup> Collagen Matrix and M/s Chaturbhuj & Bros may negotiate, prepare quotation, participate in bids, supply, raise invoice, collect payment, and provide after sale supports on behalf of Aeon Astron Europe B.V. for All India Institute of Medical Sciences, New Delhi during the period of November 03, 2014 to March 31, 2015.

Sincerely,

Aeon Astron Europe B.V.



Richard W.C. Tsai  
India Country Manager

# ologen<sup>®</sup>

## Collagen Matrix

New Anti-fibrotic Implant  
for ophthalmology / glaucoma surgeries



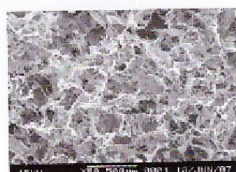
www.ologen.com



### About ologen<sup>®</sup> Collagen Matrix




ologen<sup>®</sup> Collagen Matrix (ologen<sup>®</sup> CM) is a new wound care implant composed of a porous matrix of cross-linked atelocollagen and glycosaminoglycan. ologen<sup>®</sup> collagen Matrix is a new **anti-fibrotic implant** designed to promote wound healing **without the use of MMC** in glaucoma & other ophthalmic surgeries. ologen<sup>®</sup> Collagen Matrix enables formation of a prominent **healthy vascular bleb** as opposed to the MMC induced, thin, a vascular bleb with late complication of bleb leakage, blebitis, and endophthalmitis. The dangers of handling MMC are avoided. The surgery is made more time efficient by eliminating the need for handling, application and disposal of MMC.

### Device Description



- ▶ Type I atelocollagen with porous structure and pore diameter between 10- 300µm
- ▶ comprises > 90% atelocollagen and < 10% Glycosaminoglycan( GAG)
- ▶ Dry form scaffold

### Product Specification

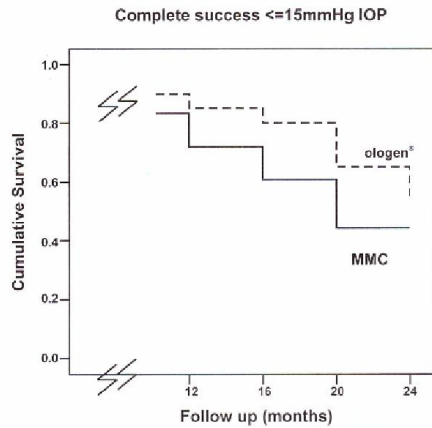
Product shape	Model Number	Size
	830601	6mm(D) x 2 mm(H)
	862051	12 mm(D) x 1 mm(H)
	870051	10 mm(W) x 10 mm (L) x 2mm(H)

For other customized models, please contact Aeon Astron Europe B.V.

ologen<sup>®</sup> is a registered trademark owned by Body Organ Biomedical Corporation



**ologen<sup>®</sup> CM is a safe and effective alternative to MMC**

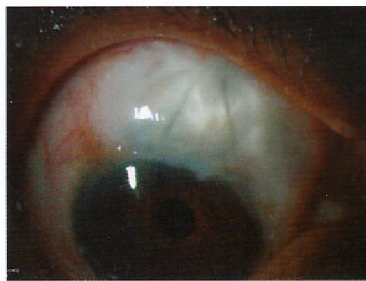


The two-year complete success with ologen<sup>®</sup> Collagen Matrix (defined as IOP < 15 mmHg without medication) was 50% compared to 40% for the MMC group. Log-rank test shows ologen<sup>®</sup> Collagen Matrix to be comparable as MMC in complete success < 15 mmHg IOP ( $p > 0.05$ ).

Ref: S. Cillino et al. Biodegradable collagen matrix implant VS mitomycin C as an adjuvant in trabeculectomy: a 24 month, randomized clinical trial. Eye (2011), 1-9

**Prominent vascular bleb without MMC**

Bleb comparison photos by Dr. S. Sarkisian  
The Dean McGee Eye Institute of the University of Oklahoma



MMC



ologen<sup>®</sup> CM 6 Months

Bleb Photos by Prof. S. Cillino  
University of Palermo, Italy. Department of Experimental Biomedicine and Clinical Neuroscience Ophthalmology Section

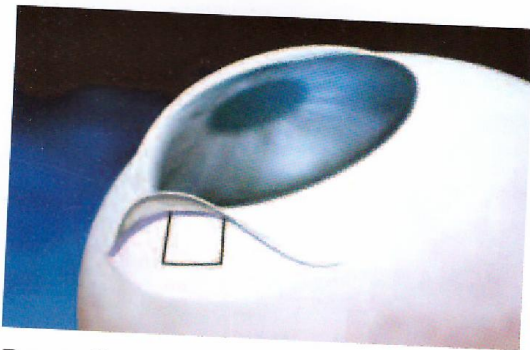


ologen<sup>®</sup> CM 24 Months

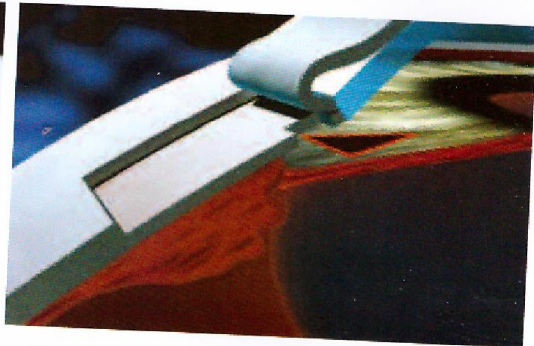


ologen<sup>®</sup> CM 32 Months

Standard procedure with loose suture technique



Preparation of the conjunctiva and scleral flap



Create the fistula beneath the scleral flap



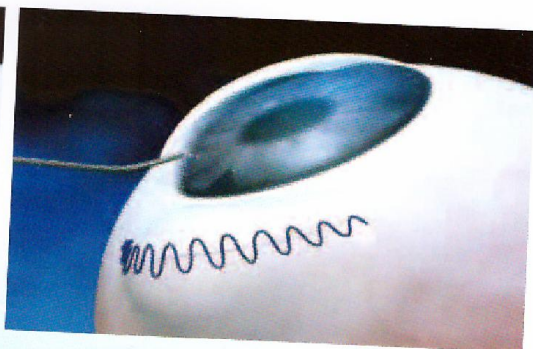
Suture the scleral flap loosely



Implant ologen® CM over the scleral flap



Close the conjunctiva flap

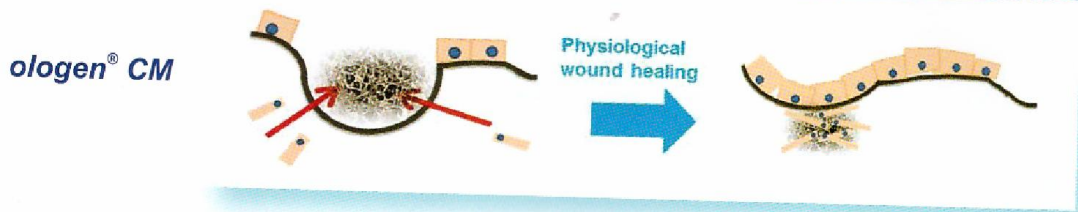


Reform the anterior chamber



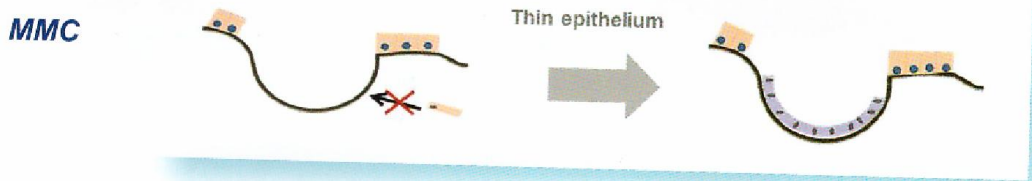
**ologen<sup>®</sup> CM selectively stabilize fibroblasts**

**Live fibroblasts stabilized**



Highly porous scaffold provides spacious biological binding sites for fibroblasts stabilization

**Induced fibroblasts & non-selective cell apoptosis**



Non-selective cell death and apoptosis results in incomplete wound healing with thin avascular epithelium

**Comparison of anti-fibrotics ologen<sup>®</sup> CM vs MMC**

ologen <sup>®</sup> Collagen Matrix	MMC
<ul style="list-style-type: none"> <li>• Non-teratogenic</li> <li>• No significant risk known</li> <li>• Phyalogic,functional bleb</li> <li>• Complarable surgical success rate</li> <li>• No priar preparalion required</li> <li>• Save operation times</li> </ul>	<ul style="list-style-type: none"> <li>• Cytotoxic &amp; teratogenic</li> <li>• Non-selective cell death</li> <li>• Thin bleb wall &amp; avascular bleb</li> <li>• Increased risk to infection</li> <li>• Increased risk to endophthalmitis &amp; blebitis</li> <li>• Requires special handling &amp; disposal</li> <li>• Prolonged surgical time</li> </ul>