Tilganga | INSTITUTE OF OPHTHALMOLOGY

The Fred Hollows Intraocular Lens Laboratory

The Fred Hollows IOL Lab, Nepal

Welcomes

Our Distinguished Guests

Date:02-01-2025

Dr. Sanduk Ruit and Dr. Fred Hollows

About Us

- The Fred Hollows Intraocular Lens Laboratory (FH IOL Lab) is an integral part of Nepal Eye Program, Tilganga Institute of Ophthalmology.
- The establishment of FH IOL Lab is a result of common vision ‘‘Preventing Needless Blindness’’ shared by Dr. Fred Hollows and Dr. Sanduk Ruit.
- Their vision was supported by Government of Australia, The Fred Hollows Foundation, technical experts from Australia and New Zealand along with many other supports from local and international levels.
- FH IOL Lab was established in 1994 & started commercial production of Rigid Intraocular Lenses (PMMA) from 1995. Received accreditation following successful audit for regulatory compliance with CE mark, EN46002 and ISO9002:1994 from SGS, UK in Feb 1998.

About Us

- FH IOL Lab is currently manufacturing PMMA, Hydrophilic & Hydrophobic IOLs.
- FH IOL Lab has produced over 7 million IOLs till the date. 50% of which have been consumed locally and remaining exported to over 70 countries across the globe.
- Current FHIOL Lab infrastructure has outgrown its capacity and started relocation project at Hetauda, 80km south of Kathmandu.
- From the new facility at Hetauda, FHIOL Lab aims to diversify its product portfolio and increase its global presence.

Our Mission Statement

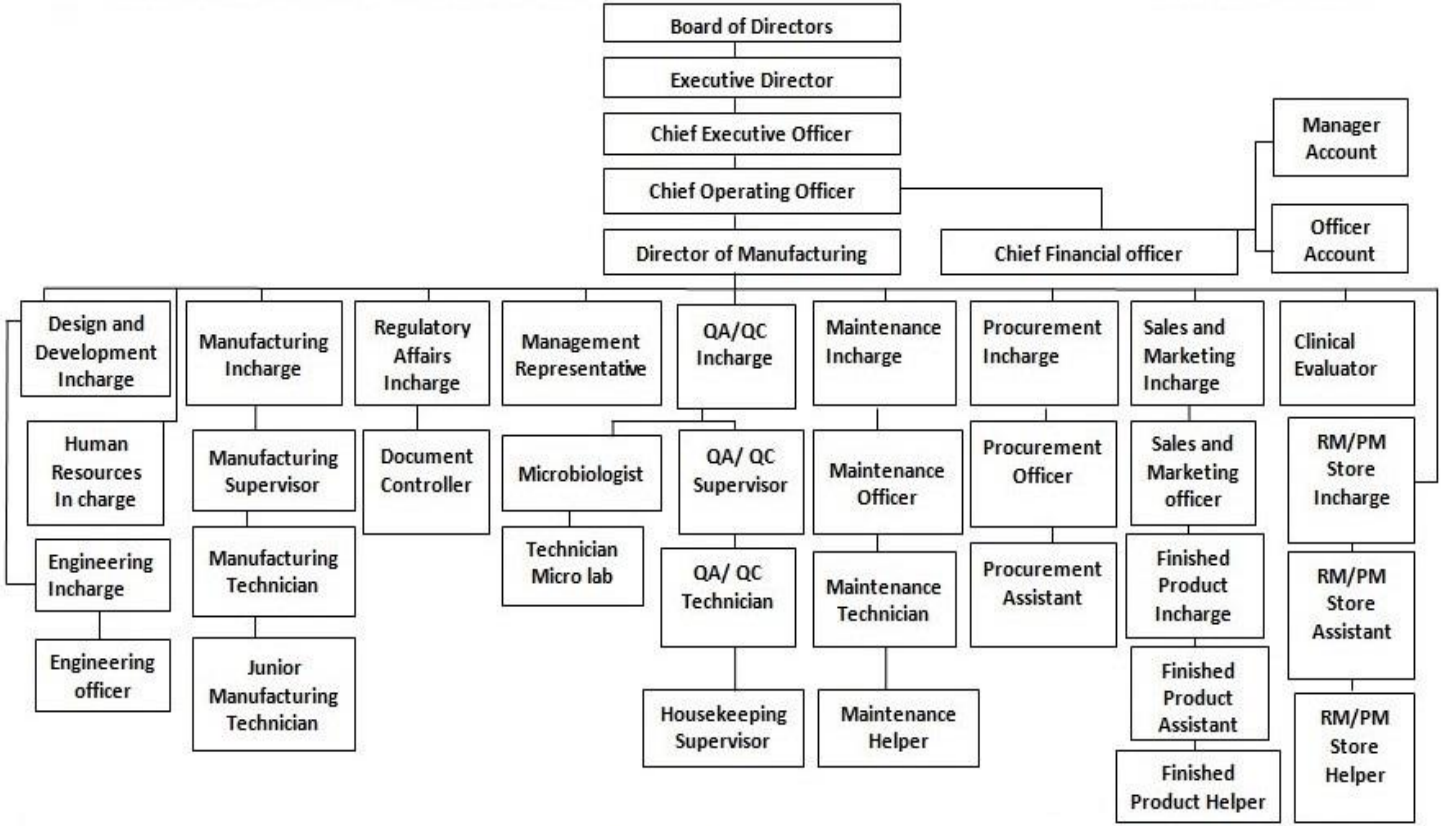
- To integrate international and Nepali work culture to maintain a high technology ophthalmic medical device manufacturing laboratory capable of manufacturing world class quality products at low cost which will facilitate eradication of needless blindness.

Our Quality Policy

Commitment to comply with requirements and meet the customer needs in providing “Intraocular Lens & Ophthalmic Surgical Products” through continual improvement in the entire process, approach by assessing and controlling risk throughout manufacturing and supply.

- Compiled and maintained by the effectiveness of Medical Device Quality Management System (MDQMS):
  - Competent Personnel
  - Lean Manufacturing
  - Stringent Quality Assurance
  - On-time Delivery
  - Periodic Review of Regulatory Requirements in compliance with MDQMS & MDD/MDR
  - Periodic Assessment of Interested Parties
  - Periodic Assessment of Quality Objectives
  - Periodic Process Audits

Organization Structure



FH IOL Lab Team

Name	Designation
Dr. Sanduk Ruit	Founder & Executive Director
Dr. Reeta Gurung	Chief Executive Officer
Mr. Pitambar Adhikari	Chief Operating Officer
Mr. Ram Chandra Khanal	Chief Financial Officer
Dr. Eli Pradhan	Clinical Evaluator
Er.Upendra Narayan Chaudhary	Acting Head FH IOL Lab & Head of Design & Development
Er. Abhay Shrestha	Head of Manufacturing
Mr. Binaya Raj Koirala	Head of Regulatory Affairs& QA-QC
Mr. Dilip Koirala	Head of Sales & Marketing

Human Resources

Department	Nos.
Manufacturing	35
QA/QC	17
Engineering, Design & Development	6
RQ and Clinical Evaluation	5
RM/PM Store	3
Procurement	2
Sales and Marketing	8
Total	**76**

QA/QC Activities

- Incoming Material Inspection
- In-process Quality Control Inspection
- Finished Product Test and Product Release to FP Store
- Finished Product Release for Sales (Dispatch)
- Other Activities
- Handling NC/CAPA
- Handling Customer complaint
- Calibration of equipment and Validation of process

Foldable_QC Flow Chart

PMMA_QC Flow Chart

Strength of The FH IOL Lab

S.N.	Product	Model Details			Remarks
		ISO 13485	CE	ISO 13485 to be taken on Jan 2025	
1.0	Hydrophobic	HQ56C			Monofocal Hydrophobic
		HQ56D			Monofocal Hydrophobic
				ED024	Hydrophobic EDOF
				ED024Y	Hydrophobic EDOF Yellow
2.0	Hydrophilic	FLEX	FLEX		
		TETRA	TETRA		
		FLEX Q			Aspheric Square Edge
		FLEX QY			Aspheric Square Edge
				SLICK	Foldable Dual Haptic Yellow
				OCTA	Foldable EDOF TETRA Haptics
				ULTRA	Foldable EDOF Dual Haptic Yellow

Strength of The FH IOL Lab

S. N.	Product	Model Details			Remarks
		ISO 13485	CE	ISO 13485 to be taken in Jan 2025	
3.0	PMMA	FH105	FH105		
		FH106	FH106		
		FA60B	FA60B		
		FCTR11	FCTR11		
		FCTR12	FCTR12		
		FCTR13	FCTR13		
				SQ106Y	Square Edge Yellow
				SQ105	Square Edge Clear
				SQ106	Square Edge Clear
				KL106	Kennel (Dog) Lens
				ED106	EDOF PMMA Clear
				ED106Y	EDOF PMMA Yellow

Sterile Hydrophobic Foldable Intraocular Lens: Model HQ56D (Commercially Launched Product)

Optic Design	Aspheric Biconvex Monofocal	
Optic powers	+10.0D to +30.0D with power increment of +0.5D	
Body Diameter	6.0mm	
Overall Diameter	+13.00mm	
Angulation	0^0	
Features	Enhanced Quality Vision, Significantly Less PCO	
A Constant	Optical (SRK/T)	Ultrasound(SRK/T)
	119.50	119.10
	Optical (SRK/II)	Ultrasound(SRK/II)
	119.90	119.50

Visual Outcome of Sterile Hydrophobic Foldable Intraocular Lens: Model HQ56D

Visual Acuity	Uncorrected Visual Acuity	Best Corrected Visual Acuity
6/6	12	20
6/9	2	4
6/12	5	1
6/18	4	-
6/24	2	-
6/36	-	-
6/60	-	-
Total	25	25

Multifocal EDOF Hydrophobic IOL: Model ED024 (Under Clinical Study)

Optic Design	Aspheric Multifocal EDOF	
Optic powers	+8.0D to +32.0D with power increment of +0.5D	
Body Diameter	6.0mm	
Overall Diameter	+13.00mm	
Angulation	0^0	
Power Addition	Intermediate:+1.75D and Near+3.75D	
A Constant	Optical (SRK/T)	Ultrasound(SRK/T)
	119.10	118.7
	Optical (SRK/II)	Ultrasound(SRK/II)
	119.50	119.10

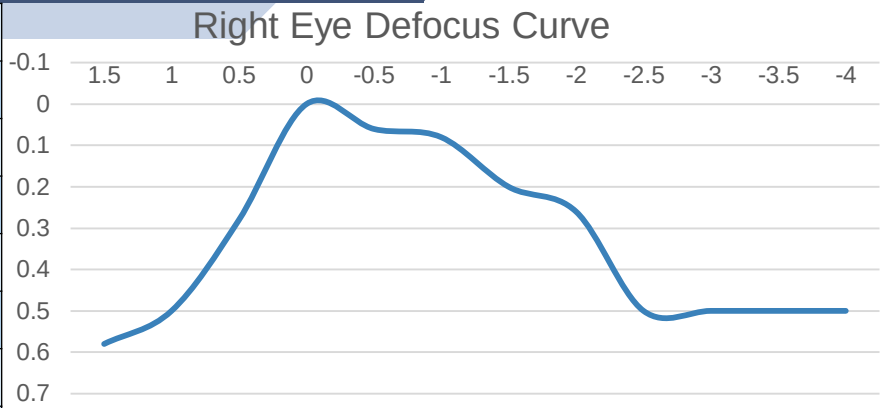
Features of Sterile Hydrophobic Foldable Intraocular Lens : Model HQ56D

- Material: Hydrophobic Acrylic Biocompatible UV blocker Clear material supplied by renowned raw material Supplier. Material is accepted in global market
- Delivery: Good in Delivery of IOL from Injector
- Unfolding: Within few seconds for Unfolding
- Stability: No tilt, Good Centration,
- Visual Outcome: Excellent visual Outcome
- PCO: Significantly less PCO
- Glistening: No glistening
- Competitive Price
- Spherical aberration Neutral
- Cut off wavelength at 10% of Spectral transmittance=378nm
- Refractive index=1.56 at 22^{0}C

Multifocal EDOF Hydrophobic IOL: Model ED024
Visual Acuity for Day 7

S.N.	UDVA	UIVA	UNVA
1	6/12P	0.2	N8
2	6/6P	0.2	N8
3	6/6	0.2	N6
4	6/9P	0.24	N10
5	6/6P	0.2	N6
6	6/6	0.2	N6
7	6/9P		N6
8	6/9P		N6

Lumbini Camp		
SN	DVA	NVA
1.	6/6	N10
2.	6/6	N10



Note: According to the American Academy Task Force's definition [1], EDOF IOLs, monocular depth of focus needs to be at least 0.5 D greater than that of monofocal IOLs at logMAR 0.2 in the defocus curve, distance-corrected intermediate visual acuity has to be superior to monofocals, and 50% of the eyes have to achieve at least logMAR 0.2 in the intermediate distance (66cm)

AATFC

Vivity IQ

x
Features of FH Hybrid MF EDOF-TECSHARP “VIVITEC”

- Delivery: Good in Delivery of IOL from Injector
- Unfolding: Within few seconds for Unfolding
- Stability: No tilt, Good Centration, consistency in positioning
- Visual Outcome: Excellent Visual Outcome in all range of vision.
- PCO: Significantly less PCO
- Glistening: No glistening
- Competitive Price
- Biocompatible material
- Renowned raw material Supplier: Material is accepted in global market
- Hybrid MF EDOF, the hydrophobic material provides a continuous range of uncorrected vision at different distances.

Features of FH Hybrid MF EDOF-TECSHARP “VIVITEC”

- Delivers superb visual acuity, consistent performance, and outstanding patient outcomes without glistening.
- Less Posterior capsule opacification (PCO).
- Hybrid of EDOF and multifocal optics.
- Provides a continuous and extended range of clear vision from near to intermediate to
- far distances.
- Smooth transition from near to intermediate to far distance and vice versa without the need for adjustments.
- Targeting for Extended range with spectacles Independence(glasses-free vision)
- Compatible for all age groups with optimum vision quality.
- Promising feature of EDOF and Trifocal lens

Tilganga INSTITUTE OF OPHTHALMOLOGY

The Fred Hollows Intraocular Lens Laboratory

	Posterior	Chaber	A/C	CTR
PMMA PC also available in square edge				
	FH105	FH106+	FA60B	Capsular Tension Ring

	Aspheric			Spheric	
Foldable					
	Flex QY (Yellow)	Flex Q	Slick (Yellow) Dual Haptic	Flex	Tetra

Hydrophobic

- UV/Blue Light Filter
- Excellent Bio - Adhesion
- Glistening Free
- Aspheric optic & Yellow Aspheric
- Bio-compatible material

Quality Assurance of our product

- Our journey starting from 1994 to the present in 2024, we have maintained a flawless record with no product recalls in both national and international markets. The process and product certifications is being maintained since the beginning.
- Till date, 7.0 million people are seeing the world with our IOLs.
- No major complaint received till date.
- A Randomized, Single-Center Study of Equivalence of 2 Intraocular Lenses Used in Cataract Surgery:AcrySof SA60AT lens (Alcon, Inc, Fort Worth, TX) or the low-cost Tecsoft Flex lens (Fred Hollows Foundation, Tilganga, Nepal).

(Approved by the Human Research Ethics Committee of the Royal Victorian Eye and Ear Hospital, Melbourne, Australia.)

Clinical study.pdf

Product Certifications

- Registered with Department of Drug Administration, Nepal under Ministry of Health and Population
- Certified with
- ISO 13485:2016 (MDQMS)
- ISO 9001:2015 (QMS)
- CE (MDD 93/42EEC)
- First organization to receive ISO in Nepal.
- First and only organization to receive CE mark in Nepal and first in South Asian Countries

List of Registered Countries

Registration Status (Completed)

- Registered in National Medical Products Administration (NMDA China)
- Registered in The Directorate General of Drug Administration (DGDA Bangladesh)
- Registered in Thai Drug and Food Registration (Thailand) Registered in National Medicine
- Regulatory Authority (NMRA) Srilanka
- Registered in Taiwan Food and Drug Administration Taiwan
- Turkey

Registration Status (Ongoing)

- Kazakhstan

Global Distribution Channel

- China
- Pakistan
- Thailand
- South Africa
- Sri Lanka
- Vietnam
- Singapore
- Philippines
- Trinidad & Tobago
- Ghana
- Bangladesh
- Turkey
- Tanzania
- Taiwan
- Armenia
- Bhutan
- Myanmar
- Fizi
- Mongolia
- Nepal (Direct sales from TIO)

Target Countries

- Indonesia
- Ethiopia
- Ghana
- Mexico
- Malaysia
- Brazil
- India
- Afghanistan
- Kyrgyzstan
- Tanzania
- Fiji
- Cambodia

Published Article

- ✓ Constantinou et al. Study of Equivalnce of 2 IOLs. Ophthalmology 2013; 120:482-488
- ✓ Pradhan et al. Stability and effectiveness of Tecsoft™ Acrylic Hydrophilic Intraocular Lens with its Outcome in Nepalese Population: A 2-Year Review". EC Ophthalmology 11.1 (2020): 01-10
- ✓ Adhikari et al. Pediatric cataract surgery with hydrophilic acrylic IOL in Nepalese children. Clin Ophthalmology 2018:12 7-11
- ✓ Bajimayas et al Outcomes of phacoemulsification surgery. Nepal J Ophthalmol 2012; 4(8):248-255
- ✓ Gurung RL et al: Outcome of Pediatric cataract surgery in TIO, Nepal. BJHS 2018;3(1)5 : 331-337.
- ✓ Memon, M. S. et al .A comparative analysis of postoperative visual outcomes following cataract surgery with different brands of Monofocal Intraocular Lenses. Pakistan Journal of Medical Sciences, 40(1). https://doi.org/10.12669/pjms.40.1.8157

On Going Research

- Safety and clinical performance of Sterile Foldable Acrylic Intraocular Lens (FLEX and TETRA) / Aspheric Foldable Intraocular Lens (FLEX Q) and Yellow Aspheric Foldable Acrylic Intraocular Lens (FLEX QY) in patients undergoing cataract surgery in a tertiary eye hospital, Nepal''
- Pilot study of Sterile Hydrophobic Foldable Intraocular lens implantation and its outcome at Tilganga Institute of Ophthalmology

What doctors say

Since entering into commercial operation in 1995, The Fred Hollows IOL Laboratory, Kathmandu has exported its products through-out the world. The IOLs have been used extensively and have been tested by leading international authorities in ophthalmology. Here's what some of them who have visited the manufacturing facility in Kathmandu have to say about the Laboratory and its products.

"YOU HAVE CHOSEN A DESIGN (FH106) WHICH WE THINK IS AN ABSOLUTE STATE OF ART, IN TERMS OF SURFACE FINISH AND GENERAL SEM APPEARANCE I'VE NEVER SEEN A BETTER LENS MANUFACTURE".

Prof David J. Apple, MD, USA
Director of the David J. Apple Center for Ocular Biodevices
Dr. Apple is recognized around the world for his contributions to ocular pathology, and in particular, for his work on intraocular lens explants. A noted international lecturer, Dr. Apple is the former chair of ophthalmology at The Medical University of South Carolina's Storm Eye Institute.

"I HAD A VERY NICE TOUR OF THE MANUFACTURING FACILITY. IT'S AMAZING & IMPRESSIVE THAT THE STANDARDS ARE SO HIGH. I FEEL CONFIDENT NOW IMPLANTING THEM IN THE HUMAN EYE."

-Prof. M. Edward Wilson, MD
Director, Storm Eye Institute, South Carolina, USA
Prof. Wilson is also the executive editor of the American Journal of Ophthalmology. He also serves as a consultant to the National FDA Ophthalmic Device panel of USA.

"THE INTRAOCULAR LENS MANUFACTURING FACILITY IS AT PAR WITH THE BEST MANUFACTURING FACILITY OF THE WEST - BEAUTIFUL CLEAN-ROOM FACILITY AND EXCELLENT QUALITY CONTROL. SO THIS IS A REAL SERVICE NOT JUST TO THE PEOPLE OF NEPAL BUT TO OTHER COUNTRIES AS WELL."

-Prof. David Chang, MD
David Chang, M.D., clinical professor at the University of California, San Francisco is a leader in cataract surgery technology, techniques, and teaching. He is a terrific source of information and inspiration to practicing physicians and has recently been named to the Cataract Clinical Committee of the American Society of Cataract and Refractive Surgery.

"YOU HAVE VERY IMPRESSIVE MANUFACTURING FACILITY UNDER UNBELIEVABLE CLEAN ROOM ENVIRONMENTS. I BELIEVE YOUR PRODUCTS ARE OF TOP NOTCH WHICH SHOULD BE USED ANYWHERE IN THE WORLD."

-Prof. Alan S. Crandall, MD
Professor and Senior Vice Chair of Ophthalmology & Visual Sciences.
Director of Glaucoma and Cataract
The University of Utah
Salt lake city, Utah. USA

Furthermore on Our Discussion:

THANKS!