

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.

CE 59279

Issued To:

**Volk Optical Inc
7893 Enterprise Drive
Mentor
Ohio
44060
USA**

In respect of:

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of single use ophthalmic lenses for diagnostic examinations and for use in the therapy of intraocular abnormalities.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2001-06-29**

Date: **2021-03-15**

Expiry Date: **2024-05-26**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 59279

Issued To:

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Number	Device Name	Intended purpose per IFU
Class Is		
MD 0105	Sterile Single Use Ophthalmic Lenses for diagnostic examinations and therapy	---

First Issued: **2001-06-29**Date: **2021-03-15**Expiry Date: **2024-05-26**

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 59279**
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Subcontractor:

Service(s) supplied

Rudolf Riester Gmbh
 Bruckstraße 31
 72417 Jungingen
 Germany

EU Representative

STERIS Isomedix Services
 380 90th Avenue NW
 Minneapolis
 Minnesota
 55433
 USA

ETO Sterilization

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Certificate History

Certificate No: **CE 59279**
 Date: **2021-03-15**
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Date	Reference Number	Action
29 June 2001		First issue.
08 April 2005	4670846	Extension of scope to include sterile, single use vitrectomy ophthalmic lenses. Addition of First Engineering Optics PTE LTD as lenses manufacturing subcontractor and Centurion Sterilization Services as ETO Sterilization, Packaging and Testing subcontractor.
31 May 2006	4828172	Certificate renewal.
19 March 2008	7183955	Change of name of significant subcontractor 'First Engineering Optics Pte Ltd, First Engineering Techno Centre' to 'First Engineering Plastics Pte Ltd.'
26 May 2011	7650551	Addition of Keeler Limited as EU representative. Removal of Retinal Scales from scope. Removal of First Engineering Plastics (Malaysia) SDN BHD as significant subcontractor. Certificate renewal.
21 March 2013	7970102	Removal of Centurion Sterilization Services and addition of Phakos as significant subcontractor.
26 January 2015	8283147	Addition of 'Steris Isomedix Services' as significant subcontractor.

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Date	Reference Number	Action
30 November 2015	8437736	Extension to scope to cover ophthalmic lenses for diagnostic examinations and for use in the therapy of intraocular abnormalities.
29 April 2016	8499729	Certificate renewal. Removal of Phakos as significant subcontractor.
14 th February 2019	7781217	Traceable to NB 0086.
02 December 2020	3254266	Change in Eu representative from Keeler Ltd (UK) to Rudolf Riester GmbH (Germany). Addition of a device table.
Current	3389714	Certificate Renewal.

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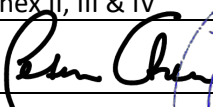
Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

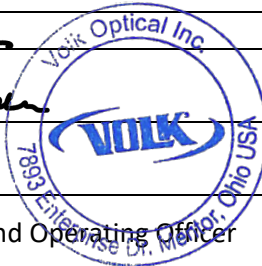
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Declaration of Conformity

Manufacturer		European Union Authorized Representative
Volk Optical Inc. 7893 Enterprise Drive Mentor, Ohio 44060 USA Tel: +1 (800) 345-8655 Fax: +1 (440) 942-2257 volk@volk.com www.volk.com SRN: US-MF-000017843		Rudolf Riester GmbH Bruckstraße 31 72417 Jungingen Germany Tel: (+49) 7477-9270-0 Fax: (+49) 7477-9270-70 info@riester.de www.riester.de SRN: DE-AR-000015844
Product	Lenses, iNview & VistaView, Merlin & ROLS Surgical Systems, and accessories (see Appendix A)	
Risk Classification	Class I devices, Rules 1, 10 & 13 according to Annex VIII of the MDR	
We hereby declare that this declaration of conformity is issued under the sole responsibility of Volk Optical Inc. and that the above-mentioned devices are in conformity with the EU Medical Devices Regulation (MDR), Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.		
Conformity Assessment	Annex II, III & IV	
Signature		
Name	Peter Chen	
Position	Chief Financial and Operating Officer	
Date	March 7, 2022	
Place of Issue of Declaration	Mentor, OH	





Appendix A:

BINOCULAR INDIRECT OPHTHALMOSCOPE (BIO) LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
V14LC	14D Large Clear	1	81160801BIOSE	The Volk Optical BIO Lenses are intended for visualization during diagnosis and laser therapy of the human retina (fundus) using a binocular indirect ophthalmoscope.
V15LC	15D Large Clear	1		
V20LC	20D Large Clear	1		
V20LC-BE	20D – Blue Ring	1		
V20LC-GD	20D – Gold Ring	1		
V20LC-GN	20D – Green Ring	1		
V20LC-PE	20D – Purple Ring	1		
V20LC-RD	20D – Red Ring	1		
V20LC-SR	20D – Silver Ring	1		
V20LC-CC	20D – Custom Color Ring	1		
K20LC	20LC (Distributor Version)	1		
L20LC	20LC (Distributor Version)	1		
VP20LC-PK	20LC (Distributor Version)	1		
V25LC	25D Large Clear	1		
V28LC	28D Large Clear	1		
V28LC-BE	28D – Blue Ring	1		
V28LC-GD	28D – Gold Ring	1		
V28LC-GN	28D – Green Ring	1		
V28LC-PE	28D – Purple Ring	1		
V28LC-RD	28D – Red Ring	1		
V28LC-SR	28D – Silver Ring	1		
L28LC	28LC (Distributor Version)	1		
V30LC	30D Large Clear	1		
V30SC	30D Small Clear	1		
V40LC	40D Large Clear	1		
VPRC	Pan Retinal 2.2 Clear	1		
VPRC-BE	Pan Retinal 2.2 – Blue Ring	1		
VPRC-GD	Pan Retinal 2.2 – Gold Ring	1		
VPRC-GN	Pan Retinal 2.2 – Green Ring	1		
VPRC-PE	Pan Retinal 2.2 – Purple Ring	1		
VPRC-RD	Pan Retinal 2.2 – Red Ring	1		
VPRC-SR	Pan Retinal 2.2 – Silver Ring	1		
LPRC	Pan Retinal 2.2 (Distributor Version)	1		
VMP5.5	Macula Plus 5.5	1		
VDGTLCF	Digital ClearField	1		
VDGTLCF-BK	Digital ClearField – Black Ring	1		
VDGTLCF-GD	Digital ClearField – Gold Ring	1		
VDGTLCF-GN	Digital ClearField – Green Ring	1		
VDGTLCF-PE	Digital ClearField – Purple Ring	1		
VDGTLCF-RD	Digital ClearField – Red Ring	1		
VDGTLCF-SR	Digital ClearField – Silver Ring	1		
VDGTLCM	Digital ClearMag	1		
VSLV20	Silver 20D	1		
VSLV28	Silver 28D	1		
C20	20D Cielo	1		
C28	28D Cielo	1		
V20LCACSPV	20D Clear ACS® PermaView	1		
V28LCACSPV	28D Clear ACS® PermaView	1		



NON-CONTACT SLIT LAMP LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
V60C	60D Clear	1	81160801SLITNG	The Volk Optical Non-Contact Slit Lamp Lenses are intended for visualization during diagnosis and laser therapy of the human retina (fundus) using a slit lamp.
V78C	78D Clear	1		
V78C-BE	78D Clear – Blue Ring	1		
V78C-GD	78D Clear – Gold Ring	1		
V78C-GN	78D Clear – Green Ring	1		
V78C-PE	78D Clear – Purple Ring	1		
V78C-RD	78D Clear – Red Ring	1		
V78C-SR	78D Clear – Silver Ring	1		
V78C-CC	78D Clear – Custom Color Ring	1		
L78C	78D Clear (Distributor Version)	1		
K78C-BE	78D Clear (Distributor Version)	1		
VP78C-PK	78D Clear (Distributor Version)	1		
V90C	90D Clear	1		
V90C-BE	90D Clear – Blue Ring	1		
V90C-GD	90D Clear – Gold Ring	1		
V90C-GN	90D Clear – Green Ring	1		
V90C-PE	90D Clear – Purple Ring	1		
V90C-RD	90D Clear – Red Ring	1		
V90C-SR	90D Clear – Silver Ring	1		
V90C-CC	90D Clear – Custom Color Ring	1		
L90C	90D Clear (Distributor Version)	1		
K90C-BE	90D Clear (Distributor Version)	1		
VP90C-PK	90D Clear (Distributor Version)	1		
VSLV78	Silver 78D	1		
VSLV90	Silver 90D	1		
C78	78D Cielo	1		
C90	90D Cielo	1		
VS66	Super 66° Stereo Fundus	1		
VS66-BE	Super 66° – Blue Ring	1		
VS66-GD	Super 66° – Gold Ring	1		
VS66-GN	Super 66° – Green Ring	1		
VS66-PE	Super 66° – Purple Ring	1		
VS66-RD	Super 66° – Red Ring	1		
VS66-SR	Super 66° – Silver Ring	1		
VSFNC	SuperField® NC	1		
VSFNC-BE	SuperField® NC – Blue Ring	1		
VSFNC-GD	SuperField® NC – Gold Ring	1		
VSFNC-GN	SuperField® NC – Green Ring	1		
VSFNC-PE	SuperField® NC – Purple Ring	1		
VSFNC-RD	SuperField® NC – Red Ring	1		
VSFNC-SR	SuperField® NC – Silver Ring	1		
VSFNC-CC	SuperField® NC, Custom Color	1		
KSFNC-BE	SuperField® NC (Distributor Version)	1		
VPSFNC-PK	SuperField® NC (Distributor Version)	1		
VSPXL	SuperPupil® XL	1		
VSVF	Super VitreoFundus®	1		
VDGTL1	Digital 1.0X Imaging	1		
VDGTLWF	Digital Wide Field®	1		
VDGTLWF-BK	Digital Wide Field® – Black Ring	1		
VDGTLWF-GD	Digital Wide Field® – Gold Ring	1		
VDGTLWF-GN	Digital Wide Field® – Green Ring	1		
VDGTLWF-PE	Digital Wide Field® – Purple Ring	1		
VDGTLWF-RD	Digital Wide Field® – Red Ring	1		
VDGTLWF-SR	Digital Wide Field® – Silver Ring	1		



VDGTLWF-CC	Digital Wide Field® – Custom Color	1		
KDGLWF	Digital Wide Field® (Distributor Version)	1		
VPDGLWF-PK	Digital Wide Field® (Distributor Version)	1		
VDGTLHM	Digital High Mag®	1		
VDGTLHM-BK	Digital High Mag® – Black Ring	1		
VDGTLHM-GD	Digital High Mag® – Gold Ring	1		
VDGTLHM-GN	Digital High Mag® – Green Ring	1		
VDGTLHM-PE	Digital High Mag® – Purple Ring	1		
VDGTLHM-RD	Digital High Mag® – Red Ring	1		
VDGTLHM-SR	Digital High Mag® – Silver Ring	1		
GONIOSCOPY LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
V3MIR	3-Mirror Gonio Fundus NF	1	81160801GONIO GU	Volk Optical’s Gonioscopy Lenses are indicated for use as diagnostic contact lenses for eye examinations (including the anterior chamber, trabecular meshwork, central retina, and peripheral retina) and use in the therapy of intraocular abnormalities.
V3MIRANF+	3-Mirror Gonio Fundus ANF+	1		
VU3MIR	3-Mirror Gonio Fundus (Uncoated) NF	1		
VU3MIRANF+	3-Mirror Gonio Fundus (Uncoated) ANF+	1		
VE3MIR	3 Mirror Lens (Distributor Version)	1		
VG1	G-1 Glass Trabeculum Glass Flange	1		
VG1NF	G-1 Glass Trabeculum No Flange No Fluid	1		
VG2	G-2 Glass Trabeculum Glass Flange	1		
VG2NF	G-2 Glass Trabeculum No Flange No Fluid	1		
VG3	G-3 Glass Gonio Fundus Glass Flange	1		
VG3NF	G-3 Glass Gonio Fundus No Flange No Fluid	1		
VG3MININF	G-3 Glass Gonio Fundus Mini No Flange No Fluid	1		
VEG3	G-3 Goniofundus (Distributor Version)	1		
VG4	G-4 Glass Gonio Glass Flange Fluid	1		
VG4LNF	G-4 Glass Hand Held Gonio (Large Ring) No Flange No Fluid	1		
VG4SNF	G-4 Glass Hand Held Gonio (Small Ring) No Flange No Fluid	1		
VG4HAN2	G-4 Glass 2 in 1 Handle Gonio No Flange No Fluid 3.5"	1		
VEG4	G-4 Goniolaser (Distributor Version)	1		
VG4HM	G-4 Glass High Mag Gonio Flange (Large Ring)	1		
VG4HMLNF	G-4 Glass High Mag Gonio No Flange (Large Ring) No Fluid	1		
VG4HMSNF	G-4 Glass High Mag Gonio No Flange (Small Ring) No Fluid	1		
VG4HMHAN2	G-4 Glass High Mag 2 in 1 Handle Gonio No Flange No Fluid	1		
VEG4HM	G-4 HighMag (Distributor Version)	1		
VG6LNF	G-6 Glass Hand Held Gonio – Large	1		
VG6HAN2	G-6 Glass NF 2 in 1 Handle	1		
V4MANF+	Mini 4 Mirror ANF+	1		
VSLT	Selective Laser Trabeculoplasty (SLT)	1		
VESLT	SLT Lens (Distributor Version)	1		
VMSLT	Rapid SLT	1		
VSGACS	Surgical Gonio	1		
VESGACS	Surgical Gonio (Distributor Version)	1		
VTSTVG	Alcon Vold TVG Surgical Gonio	1		
VTSVVG	Volk Vold Surgical Gonio	1		



CONTACT LASER & DIAGNOSTIC LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VAC	Area Centralis	1	81160801CONTA CTJR	Indicated for use as diagnostic contact lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.
VACNF	Area Centralis NF	1		
VACANF+	Area Centralis ANF+	1		
VEAC	Area Centralis® (Distributor Version)	1		
VEPNF	Equator Plus® NF	1		
VEPANF+	Equator Plus® ANF+	1		
VHRC	HR Centralis	1		
VEHRC	HR Centralis (Distributor Version)	1		
VHRWF	High Resolution Wide Field	1		
VEHRWF	High Resolution Wide Field (Distributor Version)	1		
VPDT	PDT Lens	1		
VQPED	Quad Pediatric	1		
VQFL	QuadrAspheric®	1		
VQFLNF	QuadrAspheric® NF	1		
VQFLANF+	QuadrAspheric® ANF+	1		
VEQFL	QuadrAspheric® (Distributor Version)	1		
VSMAC2.2	Super Macula® 2.2	1		
VSQUAD160	Super Quad® 160	1		
VSQUAD160NF	Super Quad® 160 NF	1		
VESQUAD160	Super Quad® 160 (Distributor Version)	1		
VTE	TransEquator®	1		
VTENF	TransEquator® NF	1		
VTEANF+	TransEquator® ANF+	1		
VETE	TransEquator® (Distributor Version)	1		
VCAPS	Capsulotomy	1		
VECAPS	Capsulotomy Lens (Distributor Version)	1		
VCD	Centralis Direct®	1		
VCDANF+	Centralis Direct® ANF+	1		
VFUNDUS	Fundus	1		
VFUNDUS20	Fundus 20MM	1		
VIRID	Iridectomy	1		
VEIRID	Iridectomy (Distributor Version)	1		
VMPIRID	MagPlus Iridectomy	1		
VEMPIRID	MagPlus Iridectomy (Distributor Version)	1		
VBIRID	Blumenthal Iridotomy	1		
VEBIRID	Blumenthal Iridotomy (Distributor Version)	1		
VBSL	Blumenthal Suturelysis	1		
VIMV	Volk Idrees Mid-Vitreous	1		
VEIMV	Idrees MidVitreous (Distributor Version)	1		
VSMV	Volk Singh Mid-Vitreous	1		
VESMV	Singh MidVitreous (Distributor Version)	1		
VITRECTOMY LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VCRLVIT	Central Retinal	1	81160801VITVU	Volk Vitrectomy Contact Lenses are indicated for use as diagnostic contact lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.
VCRLVITSSV	Central Retinal SSV®	1		
VDVVIT	DynaView 156	1		
VHRXVIT	HRX Vit	1		
VHRXVITSSV	HRX SSV® Vit	1		
VMQVIT	Mini Quad®	1		
VMQVITSSV	Mini Quad® SSV®	1		
VMQXLVIT	Mini Quad® XL	1		
VMQXLVITSSV	Mini Quad® XL SSV®	1		



VSMACVIT	Super Macula®	1		
VMQVITACS	Mini Quad® ACS®	1		
VMQVITSSVACS	Mini Quad® SSV® ACS®	1		
VCRLVITACS	Central Retinal ACS®	1		
VCRLVITSSVACS	Central Retinal SSV ACS®	1		
VHRXVITACS	HRX Vit ACS®	1		
VHRXVITSSVACS	HRX Vit SSV® ACS®	1		
VHRD1XACS	HR Direct 1x Vit	1		
VHRD1XNSRACS	HR Direct 1x NSR Vit	1		
VHRDBCACS	HR Direct Bi-concave	1		
VHRDHMACS	HR Direct HM Vit	1		
VHRDHMNSRACS	HR Direct HM NSR Vit	1		
VHRD20PACS	HR Direct 20° Prism Vit	1		
VPRISMSSVACS	15° Prism SSV® ACS®	1		
V30PRISMSSVACS	30° Prism SSV® ACS®	1		
V45PRISMSSVACS	45° Prism SSV® ACS®	1		
VAFXSSVACS	Air Fluid Exchange SSV® ACS®	1		
VFLATSSVACS	Flat SSV® ACS®	1		
VFHMSSVACS	Direct Image High Mag ACS®	1		
VMFSSVACS	Mid Field SSV® ACS®	1		
INVIEW RETINAL CAMERA				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VINVIEW-5S	Volk iNview for iPhone 5s	1	81160801INVUE	The Volk iNview ophthalmic camera is intended to take photographs of the retina of the eye for the purposes of general visualization and patient education.
VINVIEW-6	Volk iNview for iPhone 6	1		
VINVIEW-TCH	Volk iNview for iPod Touch	1		
VINVIEWC-TCH	Volk iNview Touch Camera	1		
VISTAVIEW RETINAL CAMERA				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VVISTAVIEW	VistaView	10	81160801VVB3	The Volk VistaView is a mydriatic fundus camera that is intended to capture and store images of the fundus of the dilated eye.
VVISTAVIEW2	VistaView	10		
LENS ACCESSORIES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VVITHAN-LG	VitreoLens Handle Long	1	81160801VITHNX	The Volk VitreoLens® Handle is an ophthalmic forceps device and is intended to aid in manual ophthalmic surgical procedures.
VVITHAN-MQXL	VitreoLens Handle for MQXL	1		
VINFHAN	Volk Infusion Handle	1	81160801VINFHKY	The Volk Infusion Handle is an ocular surgery irrigation device intended to be suspended over the ocular area during ophthalmic surgery to deliver continuous, controlled irrigation to the surgical field.
VSR2	Suture Ring	1	81160801SR2NA	The Volk Suture Ring is an ophthalmic ring device and is intended to aid in manual ophthalmic surgical procedures.



VCLEARPOD90D	Volk ClearPod, 90D	1	81160801CLPODE Z	The Volk ClearPod is intended to reduce lens fogging while performing eye examinations on patients wearing facemasks.
VCLEARPOD78D	Volk ClearPod, 78D	1		
VCLEARPODSFNC	Volk ClearPod, SFNC	1		
VCLEARPODDGTLWF	Volk ClearPod, DGTLWF	1		
MERLIN® ROTATIONAL ASSEMBLY (RA)				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11179	Rotational Assembly	1	81160801MRAU4	Provides attachment assembly for Lens Positioning Unit with 360° rotation about optical axis.
MERLIN® CONDENSER LENS ASSEMBLY (CLA) Auto				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11375	Assy, CLA, Auto, 175mm	13	81160801MCLAA UTONM	Provides attachment assembly for Lens Positioning Unit with 360° rotation about optical axis.
11376	Assy, CLA, Auto, 200mm	13		
11181	Auto CLA (No Condensing Lens)	13		
MERLIN® CONDENSER LENS ASSEMBLY (CLA) Manual				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11377	Assy, CLA, Manual, 175mm	1	81160801MCLAM ANFN	Provides attachment assembly for Lens Positioning Unit with 360° rotation about optical axis.
11378	Assy, CLA, Manual, 200mm	1		
11270	Manual CLA (No Condensing Lens)	1		
MERLIN® LENS POSITIONING UNIT (LPU)				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11171	Assy, LPU, For RA, 175mm	1	81160801MLPU MV	Holds the lens over the patient with full-scale adjustment.
11172	Assy, LPU, For RA, 200mm	1		
11173	Assy, LPU, For CLA, 175mm	1		
11174	Assy, LPU, For CLA, 200mm	1		
MERLIN® LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11182	Assy, Mid-Field NC Lens	1	81160801MLENS HK	The Merlin non-contact lens is the optical viewing element which attaches to the LPU for viewing the eye anatomy.
11183	Assy, Wide Angle NC Lens	1		
11184	Assy, Small Orbit Wide Angle NC Lens	1		
ROLS® ∞ Manual				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11313	ROLS Infinity, Zeiss – Manual	1	81160801ROLSIN FM5G	Provides high resolution reinverted images during vitreoretinal surgery
11315	ROLS Infinity, Leica – Manual	1		
ROLS® ∞ Auto				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11363	ROLS Infinity, Zeiss - Auto	13	81160801ROLSIN FA4Q	Provides high resolution reinverted images during vitreoretinal surgery
11364	ROLS Infinity, Leica - Auto	13		
MERLIN® MICROSCOPE MOUNTING ADAPTER KITS				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11411	Merlin RA Mount, Leica 690	1	81160801MMOU NTL2	Serve as mounting hardware to attach Merlin devices to a microscope.
11552	Merlin RA Mount, Zeiss MD	1		
11481	Merlin CLA Mount, Leica 690	1		
11553	Merlin CLA Mount, Zeiss MD	1		
11409	Merlin Mount, Leica	1		
11408	Merlin Mount, Zeiss	1		
11410	Merlin Mount, Moleller Weidel	1		
11412	Merlin Mount, Takagi	1		



11413	Merlin Mount, Topcon	1		
11654	Merlin Mount, Inami	1		
11732	Merlin Mount, Alcon	1		
11947	Merlin Mount, Topcon OMS90	1		
12171	Merlin Mount, Leica M822	1		
12159	Merlin Mount, Leica M690	1		
12160	Merlin Mount, L 820/840/841/844	1		
12161	Merlin Mount, MW HS HiR	1		
12163	Merlin Mount, Zeiss Visu	1		
11425	Merlin Mount, Spacer Kit	1		
MERLIN® POWER SYNC CABLES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11627	Merlin Power Sync Cable - 18"	1	81160801MSYNC M8	Passes power between the Merlin CLA & ROLS Infinity.
11669	Merlin Power Sync Cable - 24"	1		
ROLS® REINVERTER				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VROLS-Z	ROLS Reinverter - Zeiss	1	81160801VROLSP C	The ROLS is an advanced panoramic viewing system that provides reinverted viewing during vitreoretinal surgery, delivering high resolution, correctly-oriented retinal images.
VROLS-Z+	ROLS Reinverter - Zeiss +	1		
VROLS-L	ROLS Reinverter - Leica	1		
VROLS-L+	ROLS Reinverter - Leica+	1		
VROLS-LX	ROLS Reinverter - Leica, Open Flange	1		
VROLS-LX+	ROLS Reinverter - Leica+, Open Flange	1		

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Volk Optical Inc.
7893 Enterprise Drive
Mentor
Ohio
44060
USA

Holds Certificate Number:

FM 71461

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture, and distribution of ophthalmic diagnostic, therapeutic and surgical lenses, sterile single-use lenses, ophthalmic surgical viewing systems, and other associated ophthalmic accessories which comprise the following categories of products: non-contact binocular indirect lenses, non-contact and contact laser & diagnostic lenses, contact gonioscopy lenses, contact vitrectomy lenses, and non-contact surgical microscope accessories. The design, manufacture and distribution of products and accessories for diagnostic electronic imaging.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2001-06-05

Latest Revision Date: 2022-10-04

Effective Date: 2022-07-16

Expiry Date: 2025-07-15

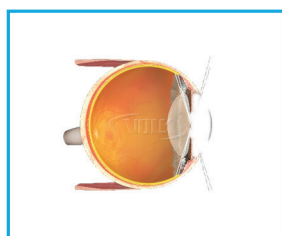
Page: 1 of 1



...making excellence a habit.™



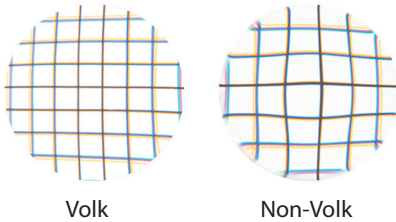
The Finest Ophthalmic Imaging



catalog
FEB 2019

See the Difference

All lenses are not the same; different lenses will not deliver the same image quality. Ensure you get the highest quality lenses to deliver the highest resolution, distortion-free imaging. The image below represents an actual side by side comparison of a Volk 20D lens and a non-Volk lens over a 2 mm grid. The photo is not retouched.



Volk

Non-Volk



Our Promise

Volk is known worldwide as the premier designer and manufacturer of the highest quality ophthalmic lenses. The first aspheric indirect ophthalmoscopy lens was developed by Dr. David Volk 60 years ago. This led to the patented double aspheric designs of the 20D, 78D, and 90D lenses – the leading standards in the ophthalmic industry.

Continual improvement led to the evolution and development of our 2nd generation, the Super Series Lenses, and to the unsurpassed image quality you can achieve today with our 3rd generation, the Digital Series Lenses.

Volk's unmatched image quality can be appreciated across our comprehensive range of imaging products, including gonio lenses, direct and indirect laser lenses, and a full range of surgical and diagnostic imaging products.

Lens Care

For lens care, cleaning, disinfection, and sterilization instructions refer to <https://volk.com/cleaning-and-care>

Contact Volk



online

volk.com
volk@volk.com



phone

+1 (440) 942-6161
+1 (800) 345-8655
(toll-free in USA)



mail

Volk Optical Inc.
7893 Enterprise Drive
Mentor, Ohio 44060, USA

volk.com

Visit the Volk website to get the information you need to review, compare, and order your lenses online.

An SSL secure certificate guarantees secure transactions over the internet, protecting your privacy for online purchases. The site's distributor locator helps you quickly find your closest authorized Volk dealer.

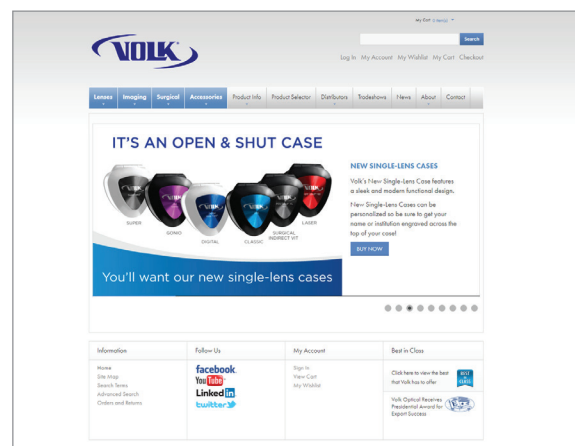


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Classic BIO Lenses

Aspheric ophthalmic lenses were developed by Dr. David Volk in 1956, correcting aberrations induced by the then-common spherical lenses.

Several developments occurred with the aspheric lens designs through the years, delivering far superior imaging for BIO examinations. In 1982, all Volk lenses for indirect ophthalmoscopy were redesigned with both surfaces aspheric, providing a substantial improvement in image quality.

The 20D and other Volk BIO lenses have been known as the industry standard for decades, and are still widely used in every corner of the world today.

Classic Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
Macula Plus® 5.5	36° / 43°	5.50x	0.18x	80 mm	Ultra-high resolution viewing of posterior pole
14D	36° / 47°	4.30x	0.23x	75 mm	High magnification viewing of posterior pole
15D	36° / 47°	4.11x	0.24x	72 mm	
20D	46° / 60°	3.13x	0.32x	50 mm	General diagnosis and treatment
Pan Retinal® 2.2	56° / 73°	2.68x	0.37x	40 mm	
25D	52° / 68°	2.54x	0.39x	38 mm	Mid-peripheral diagnosis and treatment
28D	53° / 69°	2.27x	0.44x	33 mm	Small pupil diagnosis and treatment
30D Small	46° / 60°	2.10x	0.48x	30 mm	Small profile lens for ease of use within the orbit
30D	58° / 75°	2.15x	0.47x	30 mm	Small pupil diagnosis and treatment
40D	69° / 90°	1.67x	0.60x	20 mm	Retinal examination and diagnosis at the far periphery
Digital Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
Digital Clear Field	55° / 72°	2.79x	0.36x	37 mm	For mid and far-peripheral retinal examination
Digital Clear Mag	38° / 49°	3.89x	0.26x	60 mm	For detailed optic disc and posterior pole examination

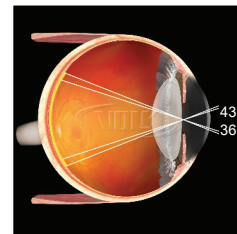


Macula Plus® 5.5

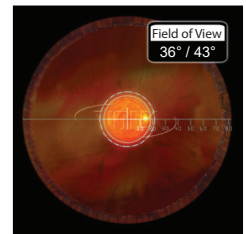
Primary Application – Ultra-High Magnification View of the Central Retina

- Excellent stereo imaging for diagnosis of macular abnormalities
- High magnification facilitates examination of geriatric patients
- Lens adapter provides stability with extended working distance

Product code:
VMP5.5



2D View



Field of View

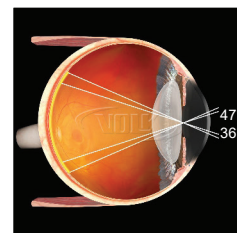


14D

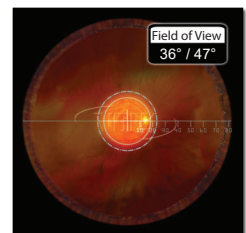
Primary Application – High Magnification Viewing of the Posterior Pole

- High magnification provides excellent imaging of the macula and optic disc
- Detailed view of the optic disc facilitates glaucoma screening examination

Product code:
V14LC



2D View



Field of View

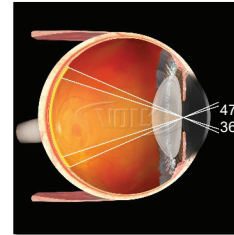


15D

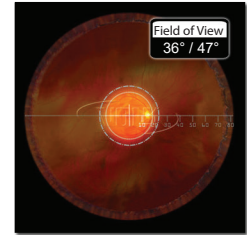
Primary Application – High Magnification Viewing of the Posterior Pole

- High magnification allows thorough examination of the macula and optic disc
- Detailed view of the optic disc facilitates glaucoma screening

Product code:
V15LC



2D View



Field of View



20D

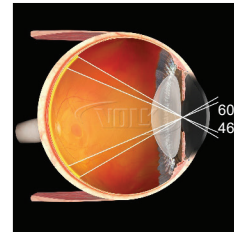
Primary Application – Industry Standard General Diagnostic Lens

- Perfect balance of magnification and field of view makes this lens well suited for general diagnostic exams
- Also available in autoclave sterilizable (ACS®) design (see page 32) or single-use design (see page 36)

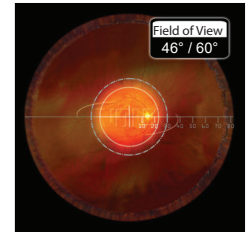
Available in 7 different colors
(shades may vary)



Product code:
V20LC



2D View



Field of View



Pan Retinal® 2.2

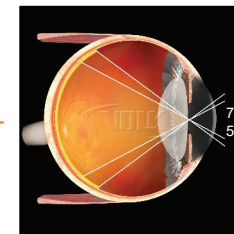
Primary Application – Excellent for General Diagnosis and Treatment

- Balance of magnification and field of view for general diagnosis
- Examine through small pupils

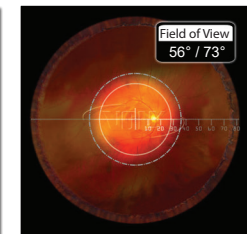
Available in 7 different colors
(shades may vary)



Product code:
VPRC



2D View



Field of View

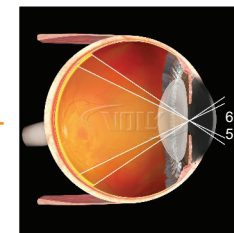


25D

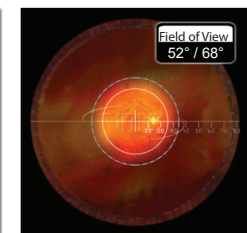
Primary Application – Mid-Peripheral Diagnosis and Treatment

- Field of view extends from the central to the mid-peripheral retina
- Smaller diameter facilitates manipulation within the orbit

Product code:
V25LC



2D View



Field of View



Available in 7 different colors
(shades may vary)

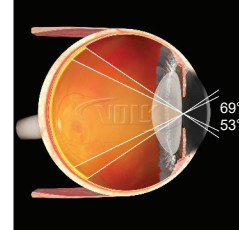


28D

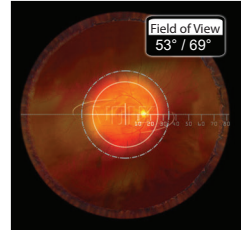
Primary Application – Ideal for Fundus Scanning

- Excellent for small pupil diagnosis and treatment
- Available in autoclave sterilizable (ACS®) design (see page 32) or single-use design (see page 36)

Product code:
V28LC



2D View



Field of View

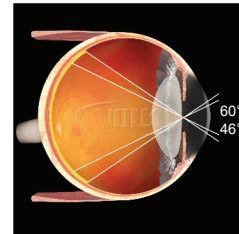


30D Small

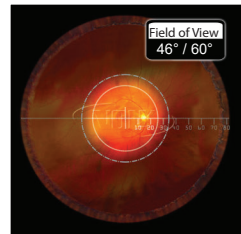
Primary Application – Small Pupil and Pediatric Examination

- Optical design delivers high resolution views through a small pupil
- Small profile lens for ease of use within the orbit during examination

Product code:
V30SC



2D View



Field of View

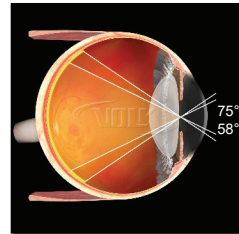


30D

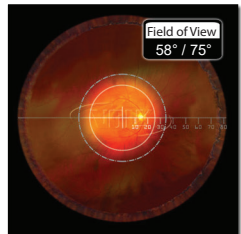
Primary Application – Small Pupil and Pediatric Examination

- Optical design delivers high resolution views through a small pupil
- Dynamic BIO exam yields a field of view slightly wider than the mid-peripheral retina

Product code:
V30LC



2D View



Field of View

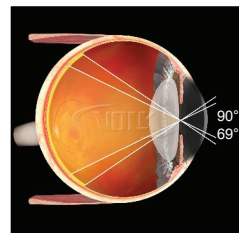


40D

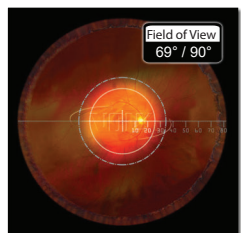
Primary Application – Low Mag Scanning out to the Far-Peripheral Retina

- Widest field of view available in a BIO lens
- Great for small pupil and pediatric exams

Product code:
V40LC



2D View



Field of View

Digital Series BIO Lenses

The digital series BIO lenses are a result of Volk's spirit of innovation and undying commitment to optical excellence. The double aspheric design was further improved using advanced modeling techniques coupled with low-dispersion glass thereby reducing chromatic aberrations to provide superior high definition images. Advanced A/R coating reduces reflections and glare up to 50% more than traditional A/R coatings.

Classic Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
Macula Plus® 5.5	36° / 43°	5.50x	0.18x	80 mm	Ultra-high resolution viewing of posterior pole
14D	36° / 47°	4.30x	0.23x	75 mm	High magnification viewing of posterior pole
15D	36° / 47°	4.11x	0.24x	72 mm	
20D	46° / 60°	3.13x	0.32x	50 mm	
Pan Retinal® 2.2	56° / 73°	2.68x	0.37x	40 mm	General diagnosis and treatment
25D	52° / 68°	2.54x	0.39x	38 mm	Mid-peripheral diagnosis and treatment
28D	53° / 69°	2.27x	0.44x	33 mm	Small pupil diagnosis and treatment
30D Small	46° / 60°	2.10x	0.48x	30 mm	Small profile lens for ease of use within the orbit
30D	58° / 75°	2.15x	0.47x	30 mm	Small pupil diagnosis and treatment
40D	69° / 90°	1.67x	0.60x	20 mm	Retinal examination and diagnosis at the far periphery
Digital Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
Digital Clear Field	55° / 72°	2.79x	0.36x	37 mm	For mid and far-peripheral retinal examination
Digital Clear Mag	38° / 49°	3.89x	0.26x	60 mm	For detailed optic disc and posterior pole examination



Available in 7 different colors
(shades may vary)

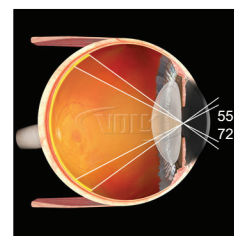


Digital Clear Field | Next Gen 20D

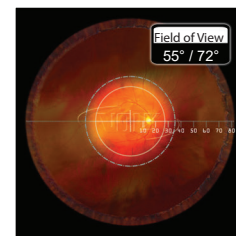
Primary Application – High Resolution Retinal Exam

- 20% wider field of view than the Classic 20D lens
- High resolution view from the central to the mid-peripheral retina, even through small pupils

Product code:
VDGTLCF



2D View



Field of View

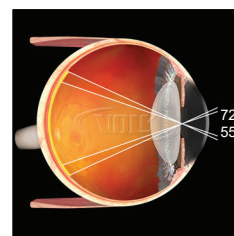


Digital Clear Mag | Next Gen 14D/15D

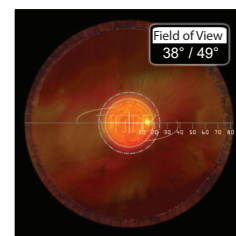
Primary Application – High Resolution Exam of the Posterior Pole

- With a similar field of view, upgrading to the Digital Clear Mag is an easy transition from the Classic 14D or Classic 15D
- High resolution view from the central to the mid-peripheral retina

Product code:
VDGTLCM



2D View



Field of View

Classic Series Slit Lamp Lenses

From starting the revolution of slit lamp fundus examination in the 1950s to establishing the standard of retinal examination, Volk has been committed to providing you with the right tools to diagnose and treat ocular pathologies.

A series of indirect ophthalmoscopy lenses were developed, resulting in the choice of the 90 Diopter lens as the most practical for indirect ophthalmoscopy with the slit lamp. The Volk 60D and 90D lenses were commercialized providing a variety of characteristics: magnification, field of view, and undilated pupil examination.

Classic Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
60D	68° / 81°	1.15x	0.87x	13 mm	High magnification view of the posterior pole
78D	81° / 97°	0.93x	1.08x	8 mm	General diagnosis and treatment
90D	74° / 89°	0.76x	1.32x	7 mm	General diagnosis/small pupil examinations
Super Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
Super 66®	80° / 96°	1.0x	1.0x	11 mm	High magnification view of the central retina
SuperField®	95° / 116°	0.76x	1.30x	7 mm	General retinal scanning situations
Super VitreoFundus®	103° / 124°	0.57x	1.75x	4-5 mm	Wide field retinal scanning and small pupil exams (3-4 mm)
SuperPupil® XL	103° / 124°	0.45x	2.20x	4 mm	Examination through small pupils (2-3 mm)
Digital Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
Digital Wide Field®	103° / 124°	0.72x	1.39x	4-5 mm	High resolution, wide field retinal scanning and reduced glare and reflections
Digital High Mag®	57° / 70°	1.30x	0.77x	13 mm	Highest resolution and magnification for imaging of the posterior pole with reduced glare and reflections
Digital 1.0x Imaging Lens	60° / 72°	1.0x	1.0x	12 mm	High resolution 1.0x imaging with reduced glare, ideal for optic disc measurements and slit lamp photography

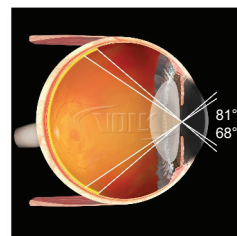


60D

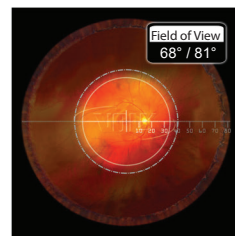
Primary Application – High Magnification View of the Posterior Pole

- High magnification lens for detailed optic disc and macula imaging
- Ideal diameter for use in the orbital area

Product code:
V60C



2D View



Field of View

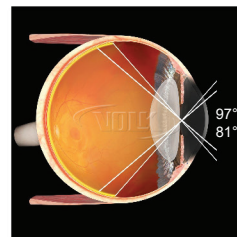


78D

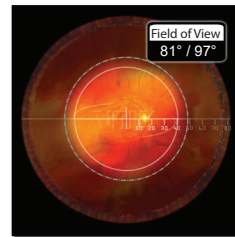
Primary Application – General Diagnosis and Laser Treatment

- Ideal balance of magnification and field of view
- Optimally designed for use within range of motion of all slit lamps

Product code:
V78C



2D View



Field of View

Available in 7 different colors
(shades may vary)

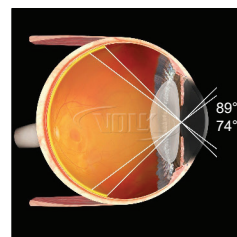


90D

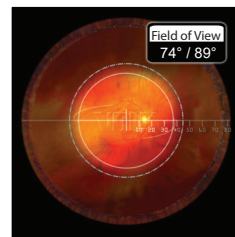
Primary Application – General Diagnosis and Small Pupil Examinations

- Original 90D lens that started the slit lamp fundus examination revolution
- Small diameter ring is ideal for dynamic funduscopy
- Outstanding general diagnostic lens, even through small pupils

Product code:
V90C



2D View



Field of View

Available in 7 different colors
(shades may vary)



Super Series Slit Lamp Lenses

Our drive to improve indirect imaging at the slit lamp led us to develop our 2nd Generation slit lamp lenses: The Super Series. Working with high grade glass types, we reviewed and improved the double aspheric designs which were so successful in the classic 90D, 78D and 60D lenses, to bring you the Super Series. A group of four lenses was developed to deliver wide field, high magnification, and specialty features such as unsurpassed small pupil capabilities – the full diagnostic spectrum!

Classic Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
60D	68° / 81°	1.15x	0.87x	13 mm	High magnification view of the posterior pole
78D	81° / 97°	0.93x	1.08x	8 mm	General diagnosis and treatment
90D	74° / 89°	0.76x	1.32x	7 mm	General diagnosis/small pupil examinations
Super Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
Super 66®	80° / 96°	1.0x	1.0x	11 mm	High magnification view of the central retina
SuperField®	95° / 116°	0.76x	1.30x	7 mm	General retinal scanning situations
Super VitreoFundus®	103° / 124°	0.57x	1.75x	4-5 mm	Wide field retinal scanning and small pupil exams (3-4 mm)
SuperPupil® XL	103° / 124°	0.45x	2.20x	4 mm	Examination through small pupils (2-3 mm)
Digital Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
Digital Wide Field®	103° / 124°	0.72x	1.39x	4-5 mm	High resolution, wide field retinal scanning and reduced glare and reflections
Digital High Mag®	57° / 70°	1.30x	0.77x	13 mm	Highest resolution and magnification for imaging of the posterior pole with reduced glare and reflections
Digital 1.0x Imaging Lens	60° / 72°	1.0x	1.0x	12 mm	High resolution 1.0x imaging with reduced glare, ideal for optic disc measurements and slit lamp photography



Available in 7 different colors
(shades may vary)

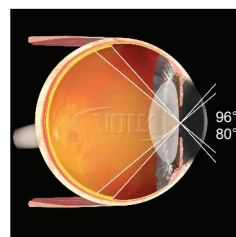


Super 66®

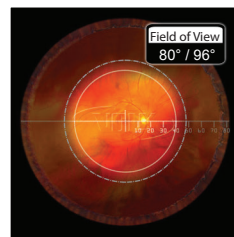
Primary Application – High Magnification Viewing of the Central Retina

- Enables 3D discernment of subtle macular and optic disc details
- 1.0x magnification simplifies optic disc measurement

Product code:
VS66



2D View



Field of View



Available in 7 different colors
(shades may vary)

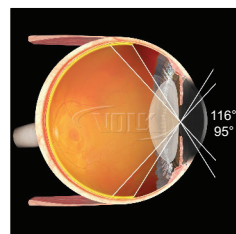


SuperField®

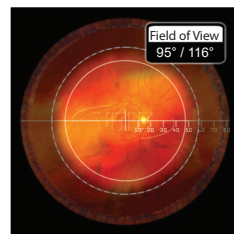
Primary Application – Wide Field Pan Retinal Examination

- The 'Super 90D' – same magnification with a wider field of view
- Combines a wide field of view with a comfortable working distance

Product code:
VSFNC



2D View



Field of View

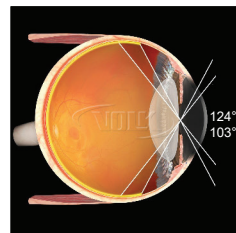


Super VitreoFundus®

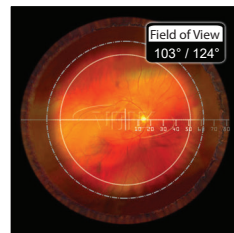
Primary Application – Wide Field Pan Retinal Examination

- Widest field of view in a non contact lens with views past the vortex
- Excellent small pupil capability through a 3–4 mm pupil

Product code:
VSVF



2D View



Field of View

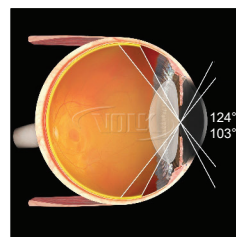


SuperPupil® XL

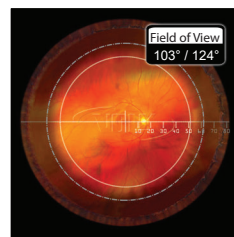
Primary Application – Small Pupil Pan Retinal Examination

- Optimal small pupil capability through a pupil as small as 2–3 mm
- Excellent for funduscopy through a miotic pupil

Product code:
VSPXL



2D View



Field of View

Digital Series Slit Lamp Lenses

Volk has taken double aspheric lenses to the next level with our 3rd Generation slit lamp lenses: The Digital Series. Similar to the Digital BIO lenses, we combined advanced engineering techniques with higher grades of glass to produce detailed views of the retina that were previously unattainable at the slit lamp. Our Digital Series slit lamp lenses are equipped with an advanced A/R coating that reduces reflections and glare by up to 50%, as compared to a traditional coating.

Whether you're looking for a wider field of view or higher magnification, Volk's Digital Series slit lamp lenses have you covered. The Digital Wide Field®, Digital High Mag®, and Digital 1.0x Imaging Lens offer the highest image resolution available.

Classic Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
60D	68° / 81°	1.15x	0.87x	13 mm	High magnification view of the posterior pole
78D	81° / 97°	0.93x	1.08x	8 mm	General diagnosis and treatment
90D	74° / 89°	0.76x	1.32x	7 mm	General diagnosis/small pupil examinations
Super Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
Super 66®	80° / 96°	1.0x	1.0x	11 mm	High magnification view of the central retina
SuperField®	95° / 116°	0.76x	1.30x	7 mm	General retinal scanning situations
Super VitreoFundus®	103° / 124°	0.57x	1.75x	4-5 mm	Wide field retinal scanning and small pupil exams (3-4 mm)
SuperPupil® XL	103° / 124°	0.45x	2.20x	4 mm	Examination through small pupils (2-3 mm)
Digital Series	Field of View	Image Mag.	Laser Spot Mag.	Working Distance	Primary Application
Digital Wide Field®	103° / 124°	0.72x	1.39x	4-5 mm	High resolution, wide field retinal scanning and reduced glare and reflections
Digital High Mag®	57° / 70°	1.30x	0.77x	13 mm	Highest resolution and magnification for imaging of the posterior pole with reduced glare and reflections
Digital 1.0x Imaging Lens	60° / 72°	1.0x	1.0x	12 mm	High resolution 1.0x imaging with reduced glare, ideal for optic disc measurements and slit lamp photography



Available in 7 different colors
(shades may vary)

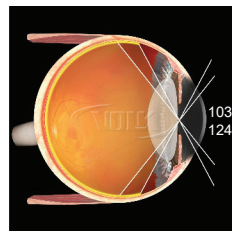


Digital Wide Field® | 3rd Generation 90D

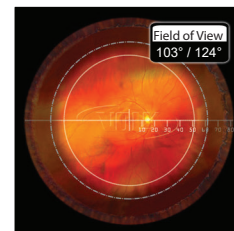
Primary Application – High Resolution Pan Retinal Exam

- 40% more field of view than Classic 90D, the widest field of view available in a non-contact lens
- Enhanced double aspheric design paired with high index glass ensures highest resolution stereo image, even through small pupils

Product code:
VDGTLWF



2D View



Field of View



Available in 7 different colors
(shades may vary)

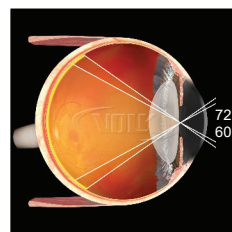


Digital High Mag® | 3rd Generation 60D

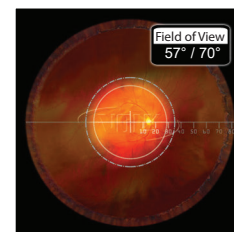
Primary Application – High Resolution, High Magnification Retinal Exam

- High magnification, along with outstanding stereopsis, provide detailed views of the optic disc, the optic nerve, and the retinal nerve fiber layer making this lens ideal for glaucoma screening
- Image magnification of 1.30x is the highest magnification available in a non-contact slit lamp lens

Product code:
VDGTLHM



2D View



Field of View

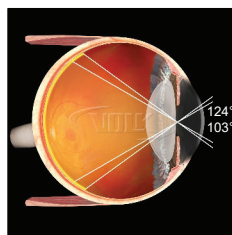


Digital 1.0x Imaging Lens

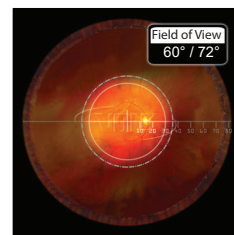
Primary Application – Digital Slit Lamp Photography

- Unique glass surface curves and coating minimize photographic distortion and reflections
- 1.0x magnification simplifies optic disc measurements
- High index, high resolution glass allows improved stereopsis and image clarity

Product code:
VDGTL1



2D View



Field of View

Indirect Contact Laser Lenses

Volk's range of indirect contact laser lenses are designed to provide retinal images and are ergonomically designed keeping both practitioner and patient comfort in mind.

Our exclusive advanced no fluid (ANF+) flange is designed to provide optimal stability during examination without the need for contact fluid. However, it may be beneficial to utilize a lubricating fluid for patient comfort. A coupling fluid should be used during laser procedures.

We recommend using flanged versions when using a laser. Flanged versions provide optimal stability on the cornea. A coupling fluid should be used with our flanged laser lenses.

No flange (NF) versions of our lenses have a smaller corneal contact area than our flanged versions. A coupling fluid should be used with our no flange (NF) lenses during laser procedures.

Lens	Field of View	Image Mag.	Laser Spot Mag.	Primary Application
Super Quad® 160	160° / 165°	0.50x	2.0x	Wide field of view for pan retinal examination and laser treatments
H-R Wide Field	160° / 165°	0.50x	2.0x	
QuadrAspheric®	120° / 144°	0.51x	1.97x	
Area Centralis®	70° / 84°	1.06x	0.94x	High magnification examination and treatment of the posterior pole
H-R Centralis	74° / 88°	1.08x	0.93x	
Super Macula® 2.2	60° / 78°	1.49x	0.67x	
TransEquator®	110° / 132°	0.70x	1.44x	Mid-peripheral diagnosis and grid laser therapy
Equator Plus®	114° / 137°	0.44x	2.27x	Small pupil diagnosis and treatment
Quad Pediatric	100° / 120°	0.55x	1.82x	ROP and other pediatric conditions
PDT Laser	115° / 137°	0.67x	1.50x	Photodynamic therapy

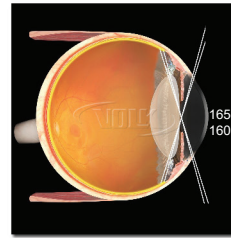


Super Quad® 160

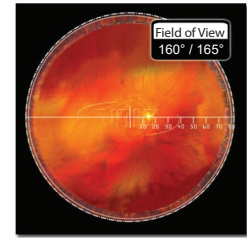
Primary Application – Wide Field of View for Pan Retinal Examination and Laser Treatments

- Wide field views for complete retinal imaging out to the ora serrata
- Excellent for PRP and other laser treatments out to the far-peripheral retina

Product code:
With Flange: VSQUAD160
No Flange: VSQUAD160NF



2D View



Field of View

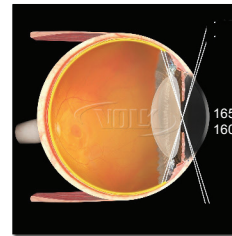


H-R Wide Field

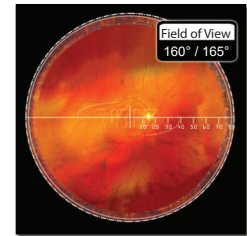
Primary Application – Wide Field of View for Pan Retinal Examination and Laser Treatments

- Same field of view and image magnification as the Super Quad® 160 but at half the size and half the weight
- Low-dispersion glass reduces chromatic aberrations and ensures excellent imaging to the ora serrata

Product code:
With Flange: VHRWF



2D View



Field of View

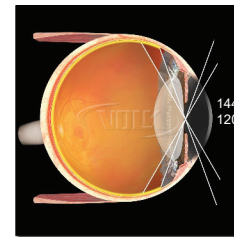


QuadrAspheric®

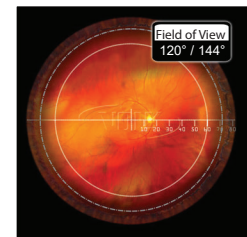
Primary Application – Wide Field of View for Pan Retinal Examination and Laser Treatments

- High resolution imaging of the peripheral retina with small pupil capability
- Excellent general diagnostic and laser treatment lens

Product code:
With Flange: VQFL
No Flange: VQFLNF
ANF+ Flange: VQFLANF+



2D View



Field of View

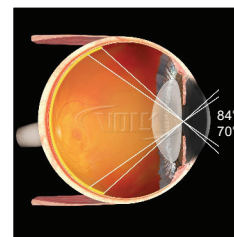


Area Centralis®

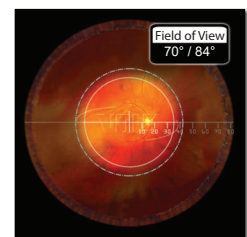
Primary Application – High Magnification Examination and Treatment of the Posterior Pole

- Ideal for focal/grid laser treatment
- High magnification image of the posterior pole with expanded field of view

Product code:
With Flange: VAC
No Flange: VACNF
ANF+ Flange: VACANF+



2D View



Field of View

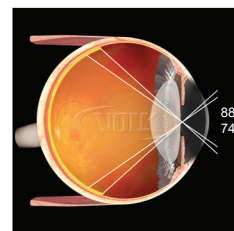


H-R Centralis

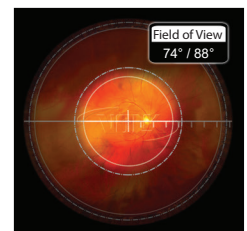
Primary Application – High Magnification Examination and Treatment of the Posterior Pole

- Low-dispersion glass and advanced double aspheric design produces a high resolution view out to the peripheral retina
- Excellent capability with pupils as small as 4 mm

Product code:
With Flange: VHRC



2D View



Field of View

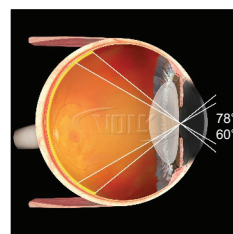


Super Macula® 2.2

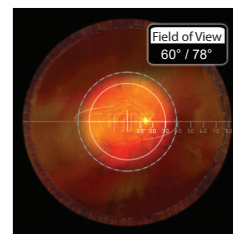
Primary Application – High Magnification Examination and Treatment of the Posterior Pole

- Highest magnification imaging of the posterior pole of any indirect contact lens
- Excellent for critical evaluation of the optic nerve head and macula

Product code:
With Flange: VSMAC2.2



2D View



Field of View
60° / 78°

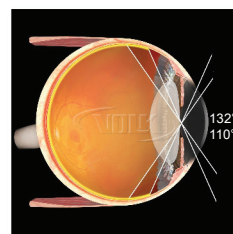


TransEquator®

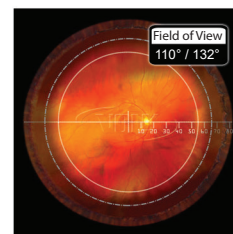
Primary Application – Mid-Peripheral Retinal Diagnosis and Focal/Grid Laser Therapy

- Wide field of view past the equator for pan retinal imaging and treatment
- Excellent substitute for Rodenstock pan fundus lens
- Available in numerous contact options including our exclusive advanced no fluid (ANF+)

Product code:
With Flange: VTE
No Flange: VTENF
ANF+ Flange: VTEANF+



2D View



Field of View
110° / 132°

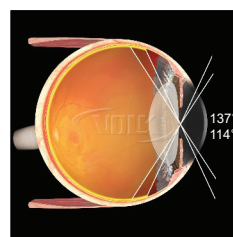


Equator Plus®

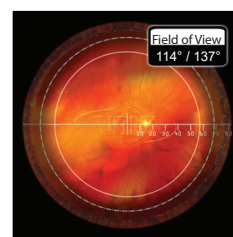
Primary Application – Small Pupil Diagnosis and Treatment

- Optimally sized to maximize maneuverability in the orbit
- High resolution wide field imaging with small pupil capability
- Available in numerous contact options including our exclusive advanced no fluid (ANF+)

Product code:
ANF+ Flange: VEPANF+
No Flange: VEPNF



2D View



Field of View
114° / 137°

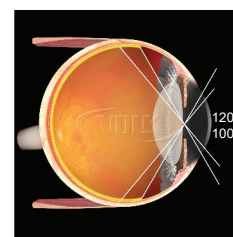


Quad Pediatric

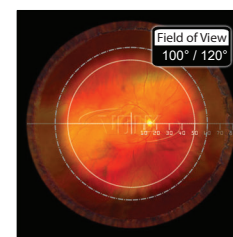
Primary Application – Retinopathy of Prematurity and Pediatric Diagnosis and Treatment

- Patented double aspheric glass optics provide enhanced imaging
- Miniaturized contact diameter ideal for diagnosis and treatment of ROP and other infant conditions
- Excellent for treatment of patients with narrow palpebral fissures

Product code:
With Flange: VQPED



2D View



Field of View
100° / 120°

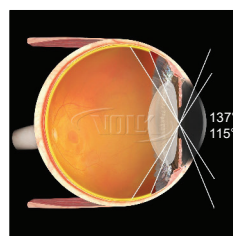


PDT Laser

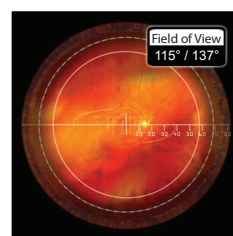
Primary Application – Photodynamic Therapy

- Delivers maximum laser spot size for treatment of the choroidal neovascular membranes
- Ideal combination of magnification and field of view to facilitate PDT procedures
- Optimized A/R coating for 689 nm wavelength used for PDT procedures

Product code:
With Flange: VPDT



2D View



Field of View
115° / 137°

Direct Contact Laser Lenses

Volk's fundus laser lenses provide high resolution views of the fundus for treatment of the posterior pole.

Flanged versions provide optimal stability on the cornea.

Our exclusive advanced no fluid (ANF+) flange is designed to provide optimal stability during examination without the need for contact fluid. However, it may be beneficial to utilize a lubricating fluid for patient comfort. A coupling fluid should be used during laser procedures.

Lens	Field of View	Image Mag.	Laser Spot Mag.
Centralis Direct®	22° / 26°	0.90x	1.11x
Fundus Laser	35° / 40°	1.25x	0.80x
Fundus 20 mm Laser	25° / 30°	1.44x	0.70x

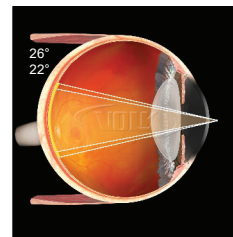


Centralis Direct®

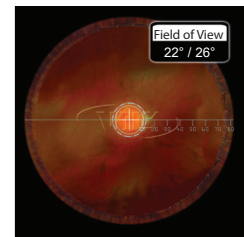
Primary Application – Direct Image Viewing and Treatment of the Posterior Pole

- High profile design eliminates filament reflection
- Optimized aspheric corneal contact design for improved fit and maneuverability
- Available in both flanged and advanced no fluid (ANF+) flanged designs

Product code:
VCD
VCDANF+



2D View



Field of View

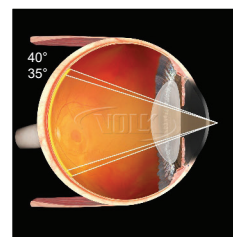


Fundus Laser

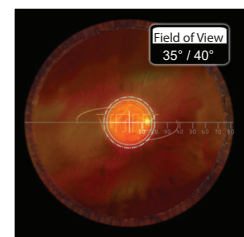
Primary Application – Direct Image Viewing and Treatment of the Posterior Pole

- Patented double aspheric glass optics provide enhanced imaging
- Superior high magnification viewing and treatment of the posterior pole and macula
- Laser Window protects imaging element from contamination ensuring precise laser spot placement

Product code:
VFUNDUS



2D View



Field of View

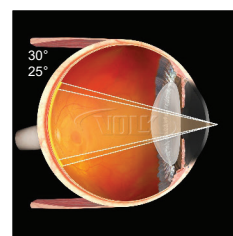


Fundus Laser 20 mm

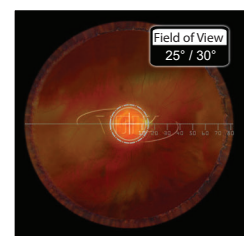
Primary Application – Direct Image Viewing and Treatment of the Posterior Pole

- Superior highest magnification viewing and treatment of the posterior pole and macula
- Laser Window protects imaging element from contamination ensuring precise laser spot placement
- Large contact element provides superior stability

Product code:
VFUNDUS20



2D View



Field of View

Specialty Treatment Lenses

Volk's range of specialty treatment lenses are specially crafted for laser treatment of the anterior segment ocular pathologies. Experience precision and clarity like never before with our capsulotomy and iridotomy lenses.

Lens	Image Mag.	Laser Spot Mag.
Singh Mid-Vitreous	1.16x	0.86x
Idrees Mid-Vitreous	1.11x	0.90x
Rapid SLT	1.0x	1.0x
Selective Laser Trabeculoplasty (SLT)	1.0x	1.0x
Capsulotomy	1.57x	0.63x
Blumenthal Iridotomy	1.54x	0.65x
Mag Plus Iridectomy Lens	1.60x	0.63x
Iridectomy	1.70x	0.58x
Blumenthal Suturelysis	2x-3x	0.50x-0.33x

Note :

Capsulotomy, Iridectomy and Iridotomy lenses are suitable for argon, diode and YAG laser treatments.

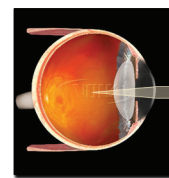


Singh Mid-Vitreous

Primary Application – Laser Treatment of Vitreous Floaters

- Enables clear visualization of vitreous floaters from the posterior capsule to the retina
- Unique flanged contact element provides stability during laser procedures and is ideal for patients with small palpebral fissures

Product code:
VSMV



2D View

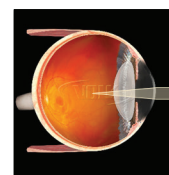


Idrees Mid-Vitreous

Primary Application – Laser Treatment of Vitreous Floaters

- Tall lens body makes this the preferred lens for treating patients with deep set eyes
- Flanged contact element provides stability during laser procedures

Product code:
VIMV



2D View

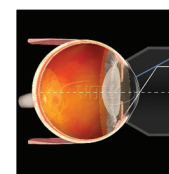


Rapid SLT

Primary Application – SLT Procedures

- Four-mirror design reduces the time taken for the SLT procedure by half
- Simultaneously visualize of all quadrants of the trabecular meshwork

Product code:
VMSLT



2D View

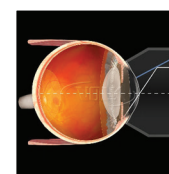


Selective Laser Trabeculoplasty (SLT)

Primary Application – SLT Procedures

- 1.0x magnification maintains laser spot size and power density at the treatment site
- Large internally reflective facet provides excellent view of the angle

Product code:
VSLT



2D View

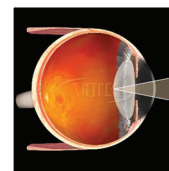


Capsulotomy

Primary Application – Laser Capsulotomy Procedures

- Enables precise focusing of the laser beam at the posterior lens capsule
- Laser Window provides a protective barrier for internal imaging components

Product code:
VCAPS



2D View

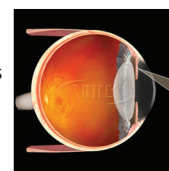


Blumenthal Iridotomy

Primary Application – Far Peripheral Laser Iridotomy Procedures

- Unique contact design allows indentation to open the angle and flatten the peripheral iris
- Improved lens performance uses lower energy for less iris tissue damage and post laser inflammation
- Larger lens housing aids manipulation and allows more oblique viewing
- Aspheric lens element provides superior optical quality for sharply focused laser spots

Product code:
VBIRID



2D View

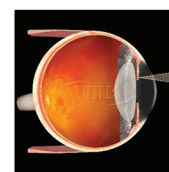


Mag Plus Iridectomy

Primary Application – Laser Iridotomy Procedures

- Larger offset viewing area delivers superior clarity and resolution with larger laser spot size
- Shallow Laser Window curves reduce astigmatic distortion
- Laser Window protects imaging element from contamination ensuring precise laser spot placement

Product code:
VMPIRID



2D View

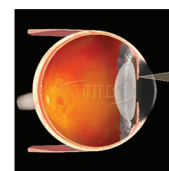


Iridectomy

Primary Application – Laser Iridotomy Procedures

- High magnification of the iris ensures precise placement of the laser beam
- Laser Window provides a protective barrier for internal imaging components

Product code:
VIRID



2D View



Blumenthal Suturelysis

Primary Application – Suturelysis Procedures

- Unique pointed tip reduces compressive force needed to visualize sutures, reducing patient discomfort
- High magnification enables treatment of deep seated sutures
- Unique design facilitates visualization through thick Tenon's layer or a subconjunctival hemorrhage

Product code:
VBSL



2D View

Gonio Lenses

Volk's Gonio Lenses are the industry standard for performing static, dynamic, and indentation gonioscopy. Our no flange G-Series lenses (G-1, G-2, G-3, G-4, and G-6) have a small contact area which maximizes patient comfort and minimizes corneal wrinkling during dynamic exams.

Volk's flanged G-Series and coated 3-Mirror gonio lenses can be used to perform laser trabeculoplasty for patients with primary open angle glaucoma. The standard flange on our G-Series gonio lenses and the advanced no fluid (ANF+) flange of our coated 3-Mirror lens provide optimal stability on the cornea during laser procedures. It is important to note that while the ANF+ flange does not require coupling fluid for routine examination, Volk does recommend using a coupling fluid for laser procedures.

Every glaucoma specialist should have at least one of Volk's gonio lenses in their portfolio.

Lens	Mirror Angles	Image Magnification	Laser Spot Size	Contact Diameter
G-1 Gonio	62°	1.50x	0.67x	15 mm
G-1 Gonio, No Flange	62°	1.50x	0.67x	8.4 mm
G-2 Gonio	60° / 64°	1.50x	0.67x	15 mm
G-2 Gonio, No Flange	60° / 64°	1.50x	0.67x	8.4 mm
3 Mirror, No Flange	60° / 66° / 76°	1.06x	0.94x	15.3 mm
3 Mirror, ANF+	60° / 66° / 76°	1.06x	0.94x	18 mm
G-3 Gonio	60° / 66° / 76°	1.06x	0.94x	15 mm
G-3 Gonio, No Flange	60° / 66° / 76°	1.03x	0.97x	11.4 mm
G-3 Gonio Mini, No Flange	60° / 66° / 76°	1.0x	1.0x	9.6 mm
G-4 Gonio	4x64°	1.0x	1.0x	15 mm
G-4 Gonio, No Flange	4x64°	1.0x	1.0x	8.4 mm
G-4 High Mag Gonio	4x64°	1.50x	0.67x	15 mm
G-4 High Mag Gonio, No Flange	4x64°	1.50x	0.67x	8.4 mm
Mini 4-Mirror	4x62°	1.0x	1.0x	15 mm
G-6 Gonio, No Flange	6x63°	1.0x	1.0x	8.4 mm

Note :

A coupling fluid should always be used with the flanged version of our G-Series gonio lenses.

No flange (NF) versions have a small corneal contact area and are excellent for diagnostic work. It may not be necessary to use a contact fluid with these versions (G-Series gonio lenses only).

A coupling fluid should be used with our 3-Mirror, no flange gonio lens.



G-1 Gonio

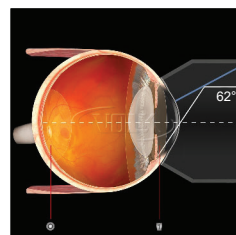
1-Mirror, All-Glass Design

- High magnification (1.50x) enables detailed viewing of the trabecular meshwork
- All-glass design provides superior clarity and durability
- Available in two formats: flanged (recommended for laser trabeculoplasty) and no flanged (recommended for routine gonioscopy)

Product code:

Flange: VG1 (as shown)

No Flange: VG1NF



2D View



G-2 Gonio

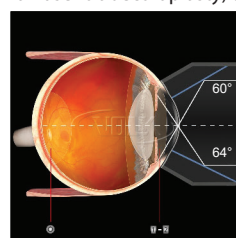
2-Mirror, All-Glass Design

- High magnification (1.50x) combined with dual mirror angles (60°/64°) allows for both a detailed and a broad view of the anterior chamber
- All-glass design provides superior clarity and durability
- Available in two formats: flanged (recommended for laser trabeculoplasty) and no flanged (recommended for routine gonioscopy)

Product code:

Flange: VG2 (as shown)

No Flange: VG2NF



2D View



Available in mini version for pediatric and patients with small orbits

G-3 Gonio

3-Mirror, All-Glass Design

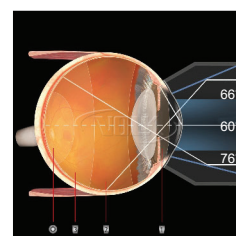
- 60° mirror provides a view of the iridocorneal angle
- 66° mirror provides a retinal image from the equator to the ora serrata
- 76° mirror provides a view of the mid-peripheral/peripheral retina
- Available in two formats: flanged (recommended for laser trabeculoplasty) and no flanged (recommended for routine gonioscopy)

Product code:

Flange: VG3

No Flange: VG3NF (as shown)

Gonio Mini, No Flange: VG3MININF (as shown)



2D View



3-Mirror

Primary Application – 3-Mirror, Acrylic Design

- 3-mirror design provides the same views as our G-3 Gonio lenses but in a light weight acrylic design
- Uncoated lenses are ideal for diagnostic exams while coated lenses are perfect for laser treatments
- Advanced no fluid (ANF+) flange only requires a coupling fluid during laser procedures

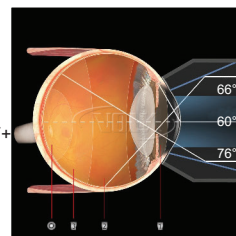
Product code:

No Flange: V3MIR (as shown)

ANF+ Flange: V3MIRANF+

No Flange, No Coating (Diagnostic): VU3MIR

ANF+ Flange, No Coating (Diagnostic): VU3MIRANF+



2D View



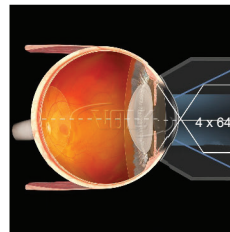
G-4 Gonio

4-Mirror, All-Glass Design

- 4-mirror design allows for comprehensive examination and treatment of the trabecular meshwork with minimal lens rotation
- Available with a large ring (28.5 mm), a small ring (25.5 mm), or a 2-position handle (right/left handed)
- No flange version is ideal for dynamic and indentation gonioscopy while flanged version provides stability for laser trabeculoplasty

Product code:

With Flange: VG4 (as shown)
 No Flange, Small Ring (25.5 mm): VG4SNF
 No Flange, Large Ring (28.5 mm): VG4LNF
 No Flange, Extended Handle: VG4HAN2



2D View



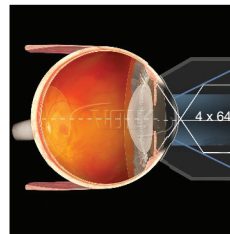
G-4 High Mag Gonio

4-Mirror, All-Glass Design

- 50% more image magnification than our classic G-4 Gonio enables more detailed viewing of the trabecular meshwork
- Available with a large ring (28.5 mm), a small ring (25.5 mm), or a 2-position handle (right/left handed)
- No flange version is ideal for dynamic and indentation gonioscopy while flanged version provides stability for laser trabeculoplasty

Product code:

With Flange: VG4HM (as shown)
 No Flange, Small Ring (25.5 mm): VG4HMSNF
 No Flange, Large Ring (28.5 mm): VG4HMLNF
 No Flange, Extended Handle: VG4HMHAN2



2D View



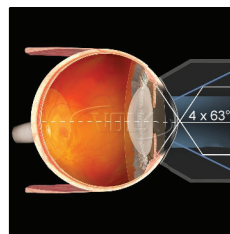
Mini 4-Mirror

4-Mirror, Acrylic Design

- Smaller, lighter-weight design facilitates easy manipulations within the orbit
- Advanced no fluid (ANF+) flange does not require coupling fluid during routine gonioscopy

Product code:

V4MANF+



2D View



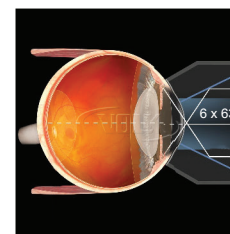
G-6 Gonio

6-Mirror, All-Glass Design

- 6 closely-aligned mirrors create a panoramic view of the anterior chamber and minimize the need for dynamic gonioscopy
- Available with a large ring (28.5 mm) or a 2-position handle (right/left handle)

Product code:

No Flange, Large Ring (28.5 mm): VG6LNF
 No Flange, Extended Handle: VG6HAN2



2D View

Surgical Gonio Lenses

Lens	Image Mag.	Contact Diameter	Ring Diameter	Handle Length
VVG Lens	1.20x	9 mm	14 mm	84 mm
Surgical Gonio Lens	1.20x	9 mm	10 mm	75 mm

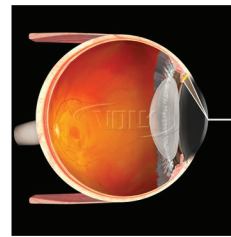


VVG Lens

Primary Application – Direct Views for Micro-Invasive Glaucoma Surgery (MIGS) and all Intraoperative Gonio Procedures

- Stabilization ring provides control of the globe
- Minimizes corneal pressure to prevent anterior chamber distortion
- Visualizes angle in primary phaco position with minimal microscope and head adjustments
- Fully steam sterilizable

Product code:
VTSVVG



2D View

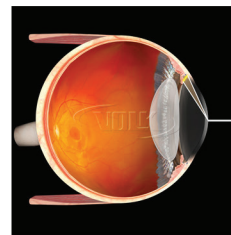


Surgical Gonio Lens

Primary Application – Direct Views for Intraoperative Gonio Procedures

- Lens position can be adjusted relative to the handle: for left hand and right hand or center position
- Applicable for MIGS procedures
- Sterilizable by either steam autoclave or ethylene oxide (ETO)

Product code:
VSGACS



2D View

Experience unmatched image quality and focusing capability with Volk's single-use laser and gonio lenses. Single-use lenses are perfect for routine examination, laser treatments, and surgical procedures.

Volk's single-use lenses are pre-sterilized and individually-packaged in a Tyvek® pouch. Single-use lenses are sold in boxes of 10.

Lens	Mirror Angles	Image Mag.	Laser Spot Mag.
Volk®1 Single-Use Capsulotomy	N/A	1.57x	0.63x
Volk®1 Single-Use Iridotomy	N/A	1.70x	0.59x
Volk®1 Single-Use SLT	63°	1.0x	1.0x
Volk®1 Single-Use 3-Mirror Gonio	60° / 66° / 76°	1.0x	1.0x
Volk®1 Single-Use 4-Mirror Gonio	4x64°	1.0x	1.0x

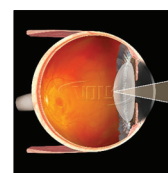


Volk®1 Single-Use Capsulotomy

Primary Application – Laser Capsulotomy Procedures

- Facilitates accurate laser beam focus on the posterior lens capsule

Product code:
VCAPSD10



2D View

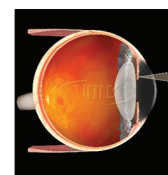


Volk®1 Single-Use Iridotomy

Primary Application – Laser Iridotomy Procedures

- Magnified view of the peripheral iris enables precise laser placement for iridotomy procedures

Product code:
VIRIDD10



2D View

Note : Capsulotomy and Iridotomy lenses are suitable for argon, diode and YAG laser treatments.

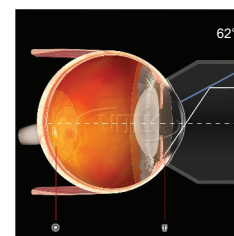


Volk®1 Single-Use SLT

Primary Application – SLT Procedures, Static and Dynamic Gonioscopy

- Single-mirror lens angled at 63° ensures proper laser placement during Selective Laser Trabeculoplasty
- Single-use SLT lens can also be used for ALT procedures

Product code:
VSLTD10



2D View

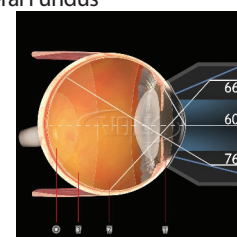


Volk®1 Single-Use 3-Mirror Gonio

Primary Application – Gonioscopy and Examination of the Central and Peripheral Fundus

- 60° mirror provides a view of the iridocorneal angle
- 66° mirror provides a retinal image from the equator to the ora serrata
- 76° mirror provides a view of the mid-peripheral/peripheral retina

Product code:
V3MIRD10



2D View

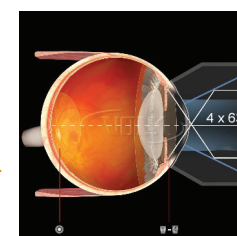


Volk®1 Single-Use 4-Mirror Gonio

Primary Application – Static and Dynamic Gonioscopy

- Four-mirror design allows for comprehensive examination and treatment of the trabecular meshwork with minimal lens rotation

Product code:
V4MIRD10



2D View



Diagnostic Imaging Devices

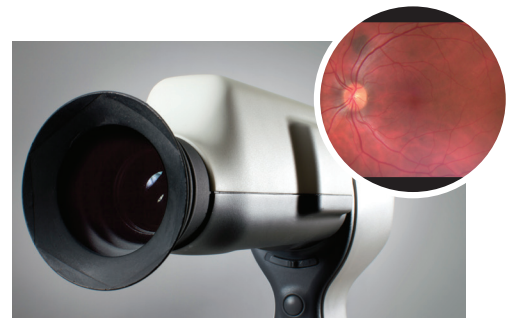




The Pictor Plus portable ophthalmic camera can take your practice places. From the exam room to on-location screenings, nursing home calls and everywhere in between.

Two easily interchangeable modules provide high resolution retinal (non-mydriatic) or external eye imaging.

- **Retinal Module** - Pictor Plus retinal imaging enables non-mydriatic fundus examination with a 40° field of view. With digital still and video images, the appearance of optic disc, macula and retinal vasculature can be screened and documented for ocular lesions and anomalies.
- **Anterior Module** - Pictor Plus anterior imaging provides high-resolution images of the surface of the eye and areas directly surrounding the eye. The cobalt blue LED light allows fluorescent imaging to detect a dry eye or any trauma on the ocular surface.





Digitize your fundus exam with iNview. Leverage the power and convenience of the Apple iPhone with the trusted quality of Volk optics.

Quickly & effortlessly capture fundus images for visualization & patient education. Helps facilitate patient discussions related to disease progression and treatment plan.

- Free mobile application available in the Apple App Store (search Volk iNview)
- Offers 1 Megapixel resolution with a static 50° field of view
- View the peripheral retina dynamically out to 80°
- Available auto-capture & manual capture imaging modes
- Mydriatic; requires minimum 5mm pupil
- HIPAA-compliant storage and export from iPhone to PC or Mac
- Compatible in Apple iPhone 6s/6/5s and iPod Touch (Gen 6) modules

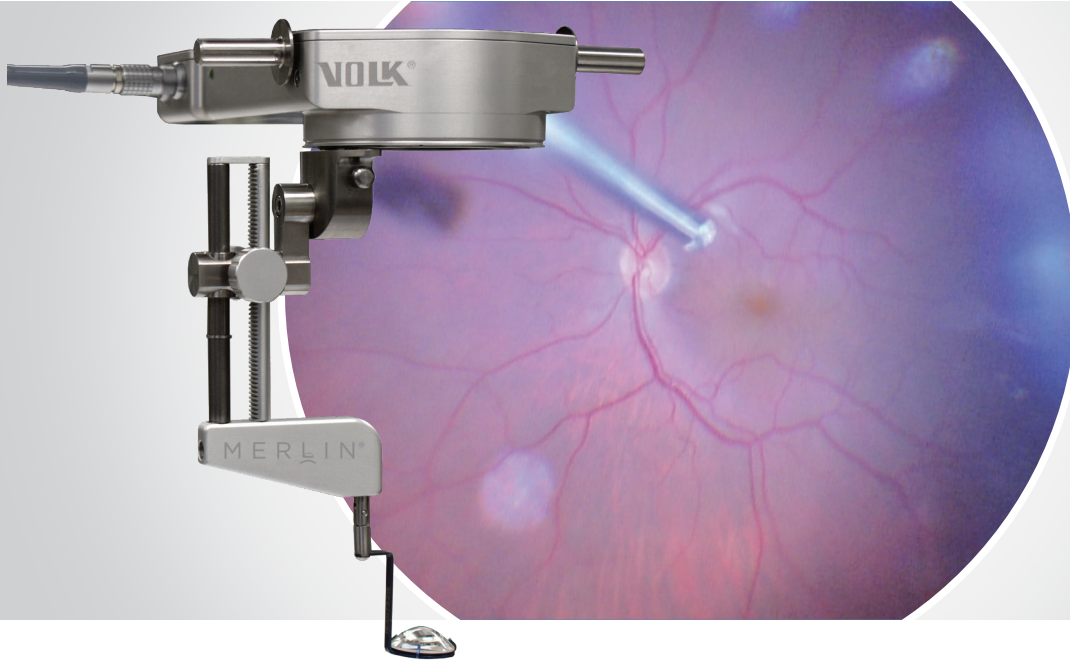




Surgical Viewing Systems & Surgical Lenses



MERLIN® Surgical System



The MERLIN® Surgical System is the finest system for noncontact vitreoretinal visualization. Using Volk's proprietary double aspheric lens technology, MERLIN® delivers unmatched image resolution and depth-of-field, superior to any other non-contact system.

The MERLIN® system features an exclusive Condensing Lens Assembly (CLA) that slides a condenser lens into the optical train when the system is engaged. The condenser lens minimizes the need for refocusing of the microscope. It also features an anti-reflection coating that significantly improves light transmission, reducing the risk of phototoxicity.

The unique design of the Lens Positioning Unit (LPU) is precisely aligned to the optical axis of the microscope and offers a simple pivoting mechanism that folds away when not in use. An intuitive fine focus wheel provides smooth, graduated adjustment to optimally position the lens.

3 Options to Suit Your Lens Needs

All MERLIN® lenses are designed using Volk's proprietary double aspheric lens technology. Built with PermaView™ glass, lenses withstand repeat steam sterilization without degradation. Each lens is equipped with a hinge mechanism to ensure patient safety in case of accidental contact.

WIDE ANGLE ACS® Lens

102°/120°
FIELD OF VIEW

0.43x
IMAGE MAG

19 mm
LENS DIAMETER

- Widest field of view, allowing visualization of the retina approaching the ora serrata
- Superior clarity and depth of field from the macula to the peripheral retina

MID-FIELD ACS® Lens

80°/95°
FIELD OF VIEW

0.74x
IMAGE MAG

19 mm
LENS DIAMETER

- Higher magnification lens for clearest views of the macula
- Intermediate field of view allows visualization to the equator

SMALL WIDE ANGLE ACS® Lens

95°/112°
FIELD OF VIEW

0.42x
IMAGE MAG

13 mm
LENS DIAMETER

- Smallest diameter lens, ideal for patients with small pupils or deep seated eyes, and pediatric cases
- Provides a very wide field of view, while maintaining superior clarity and depth of field

Reinverting Operating Lens System® (ROLS®)

The ROLS® is an advanced panoramic viewing system that provides reinverted viewing during vitreoretinal surgery, delivering high resolution, direct retinal images. ROLS® is compatible with all surgical microscopes for viewing the retina with indirect contact surgical lenses and the MERLIN non-contact surgical viewing system.

Easily installed on all standard surgical microscopes

The ROLS+ reinverter delivers the added benefit of a decreased working distance when switching between a plano/concave lens to a wide field indirect lens, providing a more comfortable working position.



Removable magnetic latching handles facilitate cleaning and sterilization

ROLS® ∞ (Infinity)

The ROLS∞ is our newest reinverter and provides superior image quality with minimal image shift. It is available in manual and powered versions. The powered version works with the Merlin surgical system, engaging automatically when the LPU is pivoted into place. The powered version can also be operated by an available footswitch.

Easily installed on all standard microscopes



LED indicator informs image alignment (direct/indirect)

Removable handles facilitate cleaning and sterilization

Surgical Vitrectomy Lenses

Volk offers a variety of vitrectomy lenses over a range of optical profiles and efficiently built to cater to various vitrectomy procedures.

Lens	Field of View	Image Mag.
HRX Vit Lens	130° / 150°	0.43x
Mini Quad® XL	112° / 134°	0.39x
Mini Quad®	106° / 127°	0.39x
DynaView	95° / 127°	0.39x
Central Retinal	73° / 88°	0.71x
Super Macula®	64° / 77°	1.03x



HRX Vit Lens

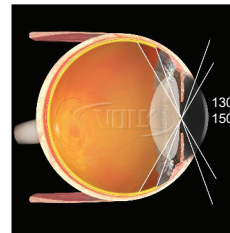
Primary Application – Far-Peripheral Indirect Vitreoretinal Procedures

- High index glass delivers widest field, distortion free retinal views of any surgical lens
- Small profile ring facilitates instrument manipulation and surgical procedures
- Available in standard and patented self stabilizing contact (SSV®) options
- Ideal for retinal detachments and giant retinal tears

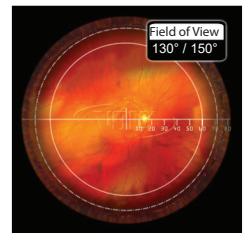
Product code:

VHRXVIT

Self Stabilizing: VHRXVITSSV (as shown)



2D View



Field of View



Mini Quad® XL

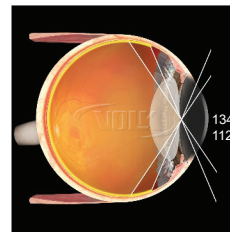
Primary Application – Indirect Viewing and Treatment of Peripheral Retinal Disorders

- Wide field of view of the entire retina including the ora serrata
- Ideal for retinal detachments and giant retinal tears
- Available in standard and self stabilizing contact (SSV®) options

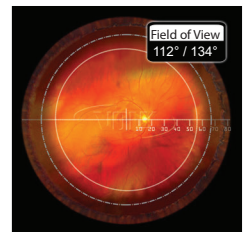
Product code:

VMQXLVIT (as shown)

Self Stabilizing: VMQXLVITSSV



2D View



Field of View

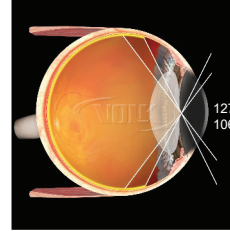


Mini Quad®

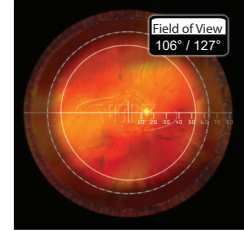
Primary Application – Indirect Viewing and Treatment of Peripheral Retinal Disorders

- Wide field of view of the entire retina including the ora serrata
- Smaller ring facilitates manipulation within the orbit
- Ideal for retinal detachments and giant retinal tears
- Available in standard and self stabilizing contact (SSV®) options
- Available in autoclave sterilizable design (see page 33)

Product code:
VMQVIT (as shown)
Self Stabilizing: VMQVITSSV



2D View



Field of View

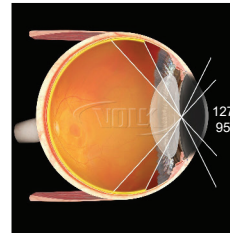


DynaView

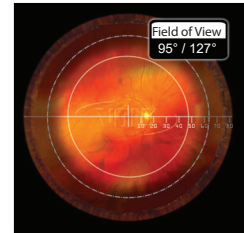
Primary Application – Treatment of Retinopathy of Prematurity

- Enhanced design provides wide field imaging out to the ora serrata
- Minified housing facilitates extension of instruments
- Reduced contact size ideal for pediatric examination

Product code:
VDVVIT



2D View



Field of View

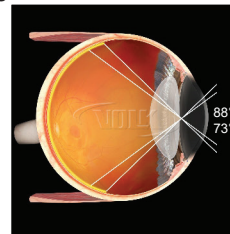


Central Retinal

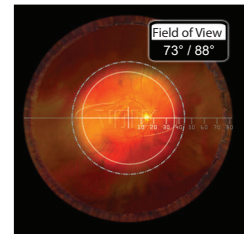
Primary Application – High Magnification Indirect Viewing and Treatment of the Central Retinal

- High resolution, high magnification imaging to the equator
- Ideal for membrane peeling, retinal tears and other small detail procedures
- Available in standard and self stabilizing contact (SSV®) options
- Available in autoclave sterilizable design (see page 33)

Product code:
VCRLVIT (as shown)
Self Stabilizing: VCRLVITSSV



2D View



Field of View

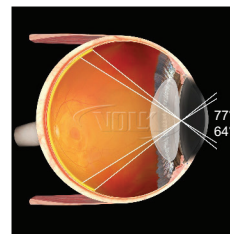


Super Macula®

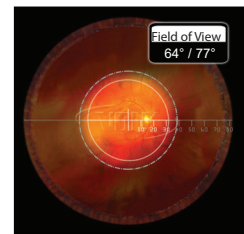
Primary Application – Highest Magnification Indirect Viewing and Treatment of the Central Retinal

- High resolution, highest magnification imaging of the central retina
- Ideal for macular holes, epiretinal membranes, and submacula surgery
- 2x field of view compared to plano/concave direct image lenses

Product code:
VSMACVIT



2D View



Field of View

High Resolution (HR) Direct Image Surgical Vitrectomy Lenses

Volk's high resolution direct image lenses utilize a high index glass to deliver superior image quality. This robust glass type is highly resistant to the rigors of continued steam sterilization and will not deteriorate or discolor.

Volk's No Stabilizing Ring (NSR) range of lenses allow suitable stability without the need for suturing or stabilizing rings. Two of the lenses in the group are also available in a no suture ring design. The profiles of these two lenses allows them to stabilize suitably without the need for an additional stabilizing ring.

Lens	Field of View	Image Mag.
HR Direct Image 1x	30°	1.0x
HR Direct Bi-Concave	45° (Mid Field) 30° (AFX)	0.50x (Mid Field) 1.0x (AFX)
HR Direct High Mag	20°	1.40x
HR Direct 20° Prism	40° (Offset 20°)	0.50x



1X



1X (NSR)

HR Direct 1x

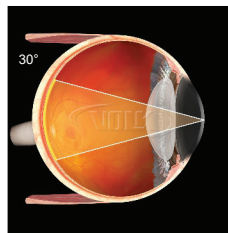
Primary Application – Direct Image Vitreoretinal Surgery of the Central Retina

- High index glass delivers highest resolution direct image of the central retina
- Highly suited for repeated steam sterilization with no material degradation
- Standard design fits all major suture rings
- Unique optional no stabilizing ring (NSR) design available

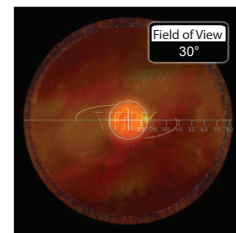
Product code:

Stabilizing Ring: VHRD1XACS

No Stabilizing Ring: VHRD1XNSRACS



2D View



Field of View



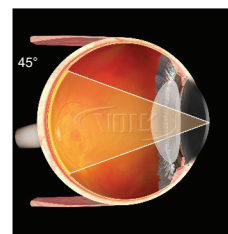
HR Direct Bi-Concave

Primary Application – Wide Field and AFX (Air Fluid Exchange) Direct Image Vitreoretinal Surgery

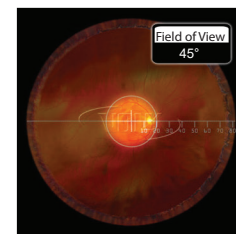
- High index glass in a bi-concave design delivers highest resolution imaging for wide field and AFX procedures
- Highly suited for repeated steam sterilization with no material degradation
- Standard design fits all major suture rings

Product code:

VHRDBCACS



2D View



Field of View



High Mag



High Mag (NSR)

HR Direct High Mag

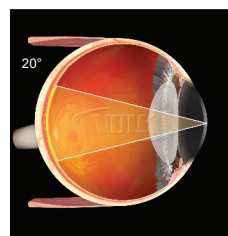
Primary Application – High Magnification Direct Image Vitreoretinal Surgery of the Central Retina

- High index glass delivers highest resolution, high magnification of the central retina
- Highly suited for repeated steam sterilization with no material degradation
- Standard design fits all major suture rings
- Unique optional no stabilizing ring (NSR) design available

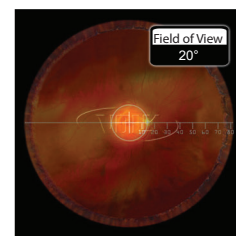
Product code:

Stabilizing Ring: VHRDHMACS

No Stabilizing Ring: VHRDHMNSRACS



2D View



Field of View



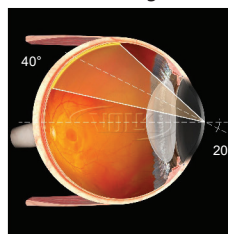
HR Direct 20° Prism

Primary Application – Off Axis Wide Field Direct Image Vitreoretinal Surgery

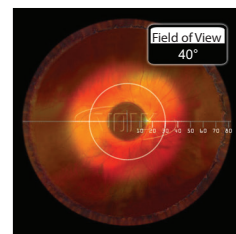
- High index glass delivers highest resolution off axis (20°) direct image retinal views
- Improved design delivers wider field (40°) off axis views
- Highly suited for repeated steam sterilization with no material degradation

Product code:

VHRD20PACS



2D View



Field of View

Autoclavable Surgical BIO Lenses

Combine the optical excellence of Volk lenses with the comfort of reduced processing time in a surgical environment with the autoclavable lens line.

Lens	Field of View	Image Mag.	Laser Spot Mag.	Working Distance
20D ACS®	46° / 60°	3.13x	0.32x	50 mm
28D ACS®	53° / 69°	2.27x	0.44x	33 mm

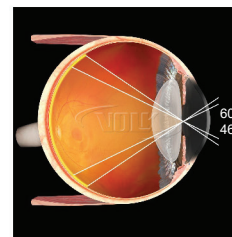


20D ACS®

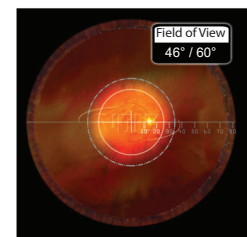
Primary Application – Industry Standard Diagnostic Lens in an Autoclavable Format

- Steam sterilizable for use in a surgical environment
- High quality PermaView™ glass withstands the rigors of repeated sterilization
- Perfectly corrected for field curvature, astigmatism, aberrations and coma

Product code:
V20LCACSPV



2D View



Field of View

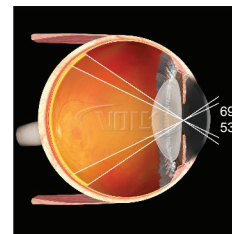


28D ACS®

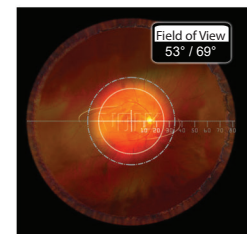
Primary Application – Fundus Scanning Lens in an Autoclavable Format

- Steam sterilizable for use in a surgical environment
- High quality PermaView™ glass withstands the rigors of repeated sterilization
- Excellent for small pupil diagnosis and treatment

Product code:
V28LCACSPV



2D View



Field of View

Autoclavable Surgical Vitrectomy Lenses

Lens	Field of View	Image Mag.
HRX ACS®	130° / 150°	0.43x
Mini Quad® ACS®	106° / 127°	0.48x
Central Retinal ACS®	73° / 88°	0.71x

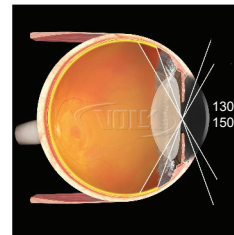


HRX ACS®

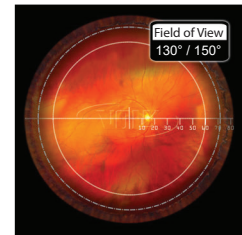
Primary Application – Widest Field Views for Vitreoretinal Procedures

- Superior high index glass design ensures widest field views of any vitrectomy lens
- Advanced aspheric design provides unmatched high resolution imaging
- Steam sterilizable for reduced processing time

Product code:
VHRXVITACS (as shown)
VHRXVITSSVACS



2D View



Field of View

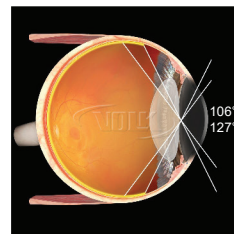


Mini Quad® ACS®

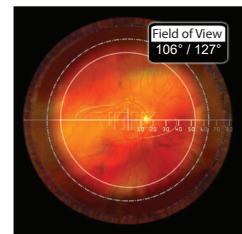
Primary Application – Peripheral Indirect Vitreoretinal Procedures

- Steam sterilizable for reduced processing time
- Smaller ring facilitates manipulation within the orbit
- Ideal for retinal detachments and giant retinal tears

Product code:
VMQVITACS
Self Stabilizing: VMQVITSSVACS (as shown)



2D View



Field of View

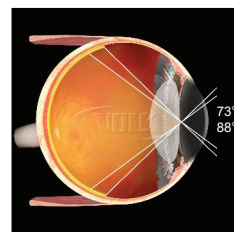


Central Retinal ACS®

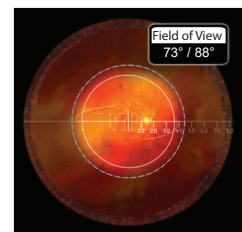
Primary Application – High Magnification Indirect Vitreoretinal Procedures

- High resolution, high magnification imaging to the equator
- Steam sterilizable for reduced processing time
- Ideal for membrane peeling, retinal tears and other small detail procedures

Product code:
VCRLVITACS (as shown)
Self Stabilizing: VCRLVITSSVACS



2D View



Field of View

Direct Surgical Vitrectomy Lenses (Self Stabilizing)

Volk's surgical vitrectomy lens designs were developed with K.V.Chalam, MD. The self stabilizing vitrectomy (SSV®) ACS® contact design eliminates the need for suture rings.

Lens	Field of View	Image Mag.
Direct Image Flat SSV® (ACS®)	30°	0.92x
Direct Image High Mag SSV® (ACS®)	15°	1.50x
Direct Image Mid Field SSV® (ACS®)	40°	0.50x
Direct Image 15° Prism SSV® (ACS®)	30° (15° Offset)	0.90x
Direct Image 30° Prism SSV® (ACS®)	30° (30° Offset)	0.90x
Direct Image 45° Prism SSV® (ACS®)	30° (45° Offset)	0.90x
Direct Image AFX SSV® (ACS®) (Air Fluid Exchange - Air Filled Eye)	30°	0.82x

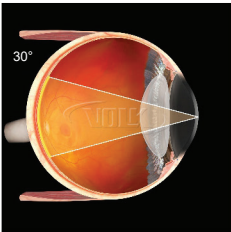
Direct Image Flat SSV® (ACS®)

Primary Application – Routine Direct Image Vitreoretinal Surgery of the Central Retina

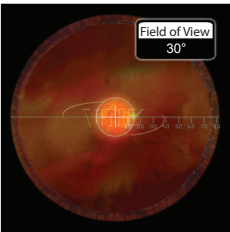
- Delivers high resolution direct image of the central retina
- Steam sterilizable for reduced processing time



Product code:
VFLATSSVACS



2D View



Field of View

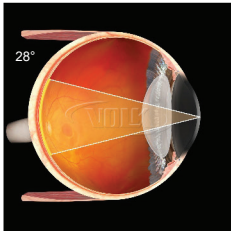
Direct Image High Mag SSV® (ACS®)

Primary Application – High Magnification Direct Image Vitreoretinal Surgery of the Central Retina

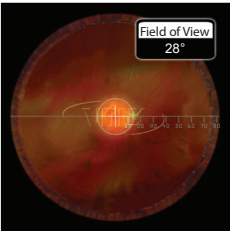
- Delivers high resolution, high magnification direct image of the central retina
- Steam sterilizable for reduced processing time



Product code:
VFHMSSVACS



2D View



Field of View

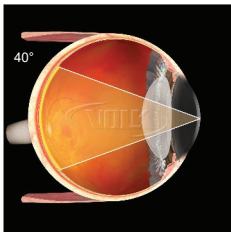
Direct Image Mid Field SSV® (ACS®)

Primary Application – Wide Field Direct Image Vitreoretinal Surgery

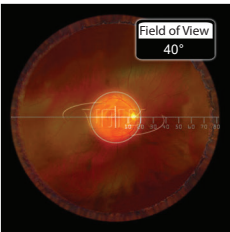
- Bi-concave design provides widest field available in a direct image lens
- Can be used for air/gas exchange procedures
- Steam sterilizable for reduced processing time



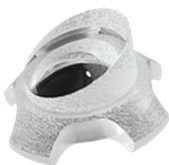
Product code:
VMFSSVACS



2D View



Field of View

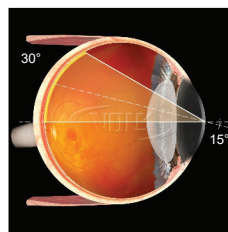


Direct Image 15° Prism SSV® (ACS®)

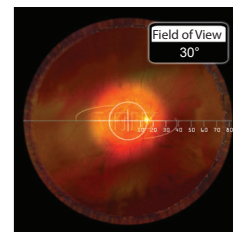
Primary Application – Off Axis Direct Image Vitreoretinal Surgery

- Design delivers 15° off axis retinal views
- Steam sterilizable for reduced processing time

Product code:
VPRISMSSVACS



2D View



Field of View

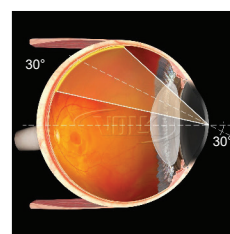


Direct Image 30° Prism SSV® (ACS®)

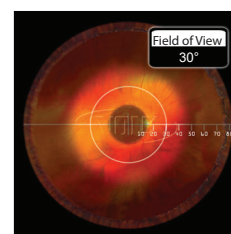
Primary Application – Off Axis Direct Image Vitreoretinal Surgery

- Design delivers 30° off axis retinal views
- Steam sterilizable for reduced processing time

Product code:
V30PRISMSSVACS



2D View



Field of View

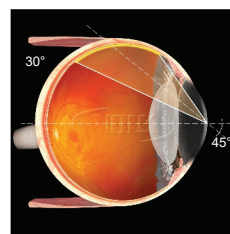


Direct Image 45° Prism SSV® (ACS®)

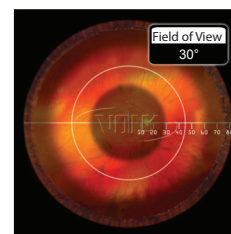
Primary Application – Off Axis Direct Image Vitreoretinal Surgery

- Design delivers 45° off axis retinal views
- Steam sterilizable for reduced processing time

Product code:
V45PRISMSSVACS



2D View



Field of View

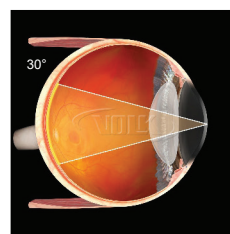


Direct Image AFX SSV® (ACS®)

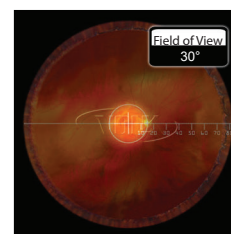
Primary Application – Direct Image Vitreoretinal Surgery During Air Fluid Exchange Procedures

- Delivers high resolution central retinal imaging
- Steam sterilizable for reduced processing time

Product code:
VAFXSSVACS



2D View



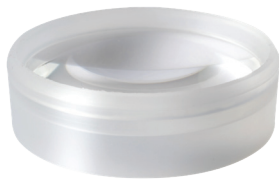
Field of View



Single-Use Surgical BIO Lenses

Volk®1 single-use surgical BIO lenses combine high-quality optics that Volk is known for and the convenience of pre-sterilization into a ready-to-use design. Volk's single-use surgical BIO lenses enable convenient pre- and post-operative examination and laser treatment.

Single-use lenses are pre-sterilized and individually-packaged in a Tyvek® pouch. Single-use lenses are sold in boxes of 10.

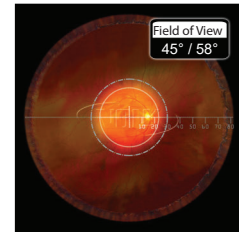
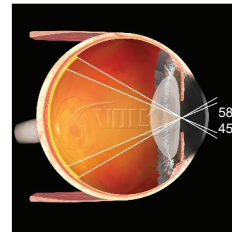


Volk®1 Single-Use 20D

Primary Application – Industry Standard Diagnostic Lens in a Single-Use Format

- Perfectly balanced magnification and field of view make this lens ideal for general diagnostic examination

Product code:
V20LCD10

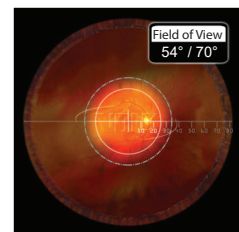
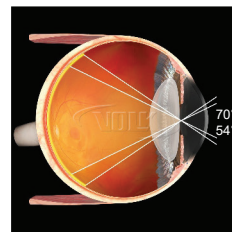


Volk®1 Single-Use 28D

Primary Application – Fundus Scanning Lens in a Single-Use Format

- Excellent for examination and treatment through a small pupil

Product code:
V28LCD10





Single-Use Surgical Direct Image Vitrectomy Lenses

Available in six popular styles, these lenses deliver high resolution direct-image retinal views for all vitrectomy procedures. The SSV® (self stabilizing) contact design eliminates the need for sutures or rings, designed in collaboration with K.V. Chalam, MD. They are packaged individually in an easy to open peel pack and are boxed in quantities of 10 lenses.

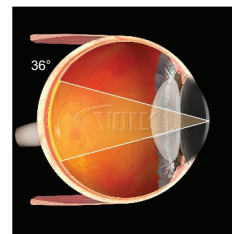
Lens	Field of View	Image Mag.
Volk®1 Single-Use Flat Standard	36°	1.0x
Volk®1 Single-Use Flat SSV®	30°	0.92x
Volk®1 Single-Use Magnifying	30°	1.50x
Volk®1 Single-Use Wide Field	48°	0.50x
Volk®1 Single-Use Bi-Concave	25°	0.80x
Volk®1 Single-Use 30° Prism	33° (Offset 30°)	1.0x



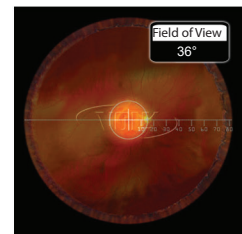
Volk®1 Single-Use Flat Standard

Primary Application – Routine Direct Image Vitreoretinal Surgery of the Central Retina

Product code:
VFD10



2D View



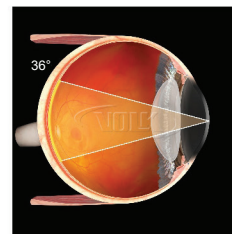
Field of View



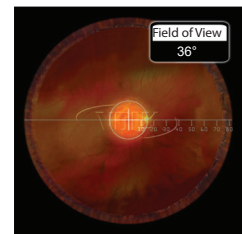
Volk®1 Single-Use Flat Self Stabilizing SSV®

Primary Application – Routine Direct Image Vitreoretinal Surgery of the Central Retina

Product code:
VFLATSSVD10



2D View



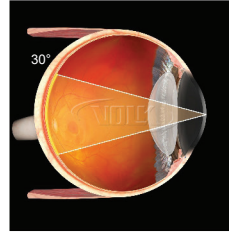
Field of View



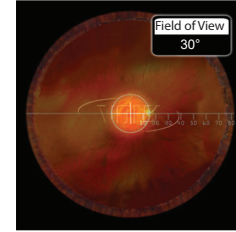
Volk® 1 Single-Use Magnifying

Primary Application – High Magnification Direct Image Vitreoretinal Surgery of the Central Retina

Product code:
VMD10



2D View



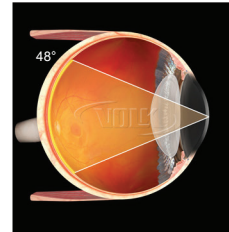
Field of View



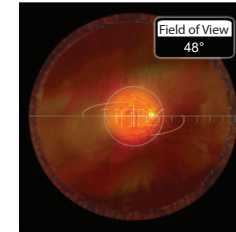
Volk® 1 Single-Use Wide Field

Primary Application – Wide Field Direct Image Vitreoretinal Surgery

Product code:
VWFD10



2D View



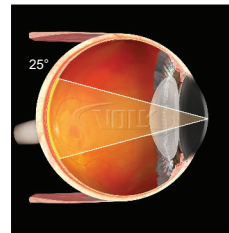
Field of View



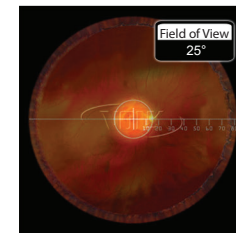
Volk® 1 Single-Use Bi-Concave

Primary Application – Direct Image Vitreoretinal Surgery During Air Fluid Exchange

Product code:
VBCD10



2D View



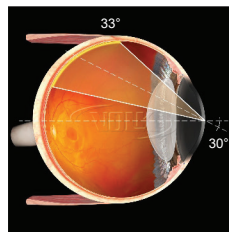
Field of View



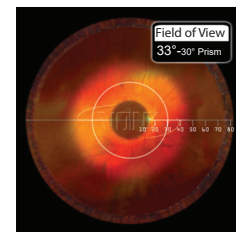
Volk® 1 Single-Use 30° Prism

Primary Application – Off Axis Direct Image Vitreoretinal Surgery

Product code:
V30PD10



2D View



Field of View

Research Lenses

Lens	Part Number	Image Mag.	Contact Diameter	Lens Height	Handle Length
2 mm Fundus	V2MFUNDUS	1.0x	2 mm	5 mm	76 mm
2 mm Gonio	V2MGONIO	1.0x	2 mm	11 mm	84 mm



Fundus Lens

Provides high resolution views of the posterior pole. Its upper surface has an A/R coating to minimize reflections and glare and maximize laser throughput. The contact surface is conically shaped to facilitate placement and does not require viscous coupling fluid. Its handle is fixed at 45°.



Glass Gonio Lens

Provides high resolution views of the anterior chamber angle structures with four equally angled mirrors. Views of the optic nerve and posterior retina can be obtained through the center of the lens. The small contact surface does not require viscous coupling fluid. Its handle may be fixed in two positions: straight or at a 45° angle.

Volk Accessories



Volk Lens Pen®

Primary Application – Dry Cleaning of Coated Ophthalmic Lens Surfaces

- Carbon based cleaning pad wipes away smudges and reduces static build up
- Cost effective device good for 400–500 uses
- Conveniently stows away like a pen with a pocket clip

Product code:
VLENSPEN

Not for use on surfaces that contact the eye.



Precision Optical Lens Cleaner

Primary Application – Cleaning of Ophthalmic Lenses

- Absorbent, moistened lint-free towelette cleans lenses instantly, free from smudges, haze and water spots
- Ideal for use on Volk lenses, microscope eyepieces, cameras and other precision optical surfaces
- Packaged in boxes of 24. Bulk case purchase contains 108 boxes

Product code:
Box: VPOLC1
Case: VPOLCCASE

Not for use on surfaces that contact the eye.



Steady Mount

Primary Application – Precisely Holds and Positions Volk Lenses at the Slit Lamp

- Holds lenses steady at the slit lamp to facilitate photography and routine examinations
- Lens can be positioned, tilted and angled in all planes providing versatility
- Adapts to all slit lamps and holds all Volk lenses ensuring ease of use

Product code:
VSM



Suture Ring

Primary Application – Provides a Stable Lens Platform During Vitreoretinal Surgery

- Premium surgical implant grade titanium for optimal durability and ease of sterilization
- Larger radius provides enhanced functionality and safety during use
- Compatible with all Volk direct and indirect contact vitrectomy lenses (except SSV® styles)

Product code:
VSR2



Infusion Handle

Primary Application – Infusion of Saline Solution Beneath the Lens During Vitreoretinal Surgery

- Flushes blood and debris providing a clear view during surgery
- Autoclave sterilizable for reduced processing time
- Ideal for diabetic surgery

Product code:
VINFHAN



Vitreolens Handle

Primary Application – Holding and Stabilization of Lenses During Vitreoretinal Surgery

- Holds vitrectomy lenses stably to assist vitreoretinal surgery
- Malleability allows user to bend the handle to suit their preference
- Autoclave sterilizable for reduced processing time

Product code:
Mini Quad and Central Retinal: VVITHAN-LG
HRX, Mini Quad XL and Super Macula: VVITHAN-MQXL



Sterilization Tray

Primary Application – Sterilization of Ophthalmic Lenses

- Autoclave safe and approved for use with ETO
- Small tray (2.7" x 1.5" x 1.25") houses Volk surgical and smaller indirect and slit lamp lenses
- Large tray (6" x 2.5" x 1.25") houses the largest Volk lenses and accessories including vitrectomy handles

Product code:
Small Tray: VSCA
Large Tray: VSCB

Cases and Personalization



Volk's new single-lens case features a sleek and modern functional design. We've incorporated a robust hinge designed to withstand over 50,000 openings and a magnetic closure that keeps your lens securely stored within the case.

Engraving

Add a personal touch to your lenses and single-lens cases by engraving custom text on them to create a personal possession that will last a lifetime.

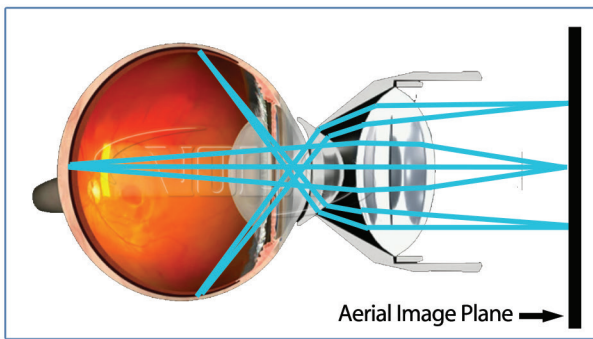


Want to keep your lenses together?

Keep all our lenses in one convenient location with our multi-lens cases. Our multi-lens cases are available in two sizes: 3"x4" for up to 3 lenses or 4"x6" for up to 6 lenses. Almost any combination can be accommodated. Even if a standard case cannot meet your need, we can provide a customized solution for you.



Design Options



Patented Double Aspheric Lens Design

All Volk lenses are optically engineered using proprietary computer ray tracing and design criteria. The laser contact lens ray tracing at left shows light rays originating at the illuminated fundus and proceeding through the pupil and cornea to the first contact element. The diverging light bundles are converged and redirected towards the double aspheric imaging lens which further refracts and focuses the rays as a conjugate fundus image in the aerial image plane. From the beginning on the drawing board to final production and sale, each Volk lens is designed and produced to the quality standards that your practice demands.

Contact Options (Gonio Lenses)

Flanged versions provide optimal stability on the cornea and are suggested for laser treatment use.

No flange (NF) versions have a small corneal contact area and are excellent for diagnostic work. It may not be necessary to use a contact fluid with these versions (gonio lenses only)

Our exclusive **ANF+** flanged version is designed to provide optimal stability without the need for a contact fluid. It is beneficial to utilize a lubricating fluid for patient comfort.

Contact Options (Contact Laser Lenses)

Flanged versions provide optimal stability on the cornea.

No flange (NF) versions have a smaller corneal contact area than flanged versions. It is still necessary to use a contact fluid with these versions.

Our exclusive **ANF+** flanged version is designed to provide optimal stability without the need for a contact fluid. During diagnosis, it may be beneficial to utilize a lubricating fluid for patient comfort. However, during laser procedures, an appropriate coupling must be used.

Volk Laser/Anti-Reflective Coatings and Filters

Most Volk lenses come standard with high efficiency laser/anti-reflective (A/R) coatings to optimize laser throughput and to assist in diagnosis by reducing glare in the visible spectrum.

Please contact Volk for additional information on laser coatings.

Warranty Information

Warranty Service

If the product fails to function due to defects in either materials or workmanship, Volk will, at its option, either repair or replace the product without charge, subject to the Warranty Limitations.

Non-Contact Slit Lamp & BIO Lenses

Volk Optical warrants its Non-contact Slit Lamp & BIO Lenses against defects in materials or workmanship for a period of 10 years from receipt by end user.

Laser & Diagnostic Lenses

Volk Optical warrants its Volk Contact Laser & Diagnostic Lenses against defects in materials or workmanship for a period of 5 years from receipt by end user.

G-Series Gonio Lenses

Volk Optical warrants its All GLASS G-Series Gonio Lenses against defects in materials or workmanship for a period of 4 years from receipt by end user.

Standard 3 & 4 Mirror Lenses

Volk Optical warrants its standard 3 & 4 Mirror Lenses against defects in materials or workmanship for a period of 1 year from receipt by end user.

2 mm Research Lenses

Volk Optical warrants its 2 mm research lenses (fundus and gonio) against defects in materials or workmanship for a period of 1 year from receipt by end user.

Pictor, Pictor Plus, & Volk Eye Check

Volk Optical warrants its Pictor, Pictor Plus, and Volk Eye Check ophthalmic imaging devices against defects in materials or workmanship for a period of 1 year from receipt by end user.

MERLIN® & ROLS® Reinverter

Volk Optical warrants its MERLIN® and ROLS® Reinverter against defects in materials or workmanship for a period of 1 year from receipt by end user.

Surgical Vitrectomy Lenses

Volk Optical warrants its Surgical Vitrectomy Lenses against defects in materials or workmanship for a period of 1 year from receipt by end user.

Autoclave Sterilizable Vitrectomy & Surgical Gonio Lenses

Volk Optical warrants its Autoclave Sterilizable (ACS) Vitrectomy and Surgical Gonio Lenses against defects in materials or workmanship for the lesser of 6 months from receipt by end user or 100 sterilization cycles.

Volk Power, Contact, Yellow Filter, Retinal Scale and Lid Lens Adapters; VitreoLens Handle®, Infusion Handle & Steady Mount

Volk Optical warrants its Volk Power, Contact, Yellow Filter, Retinal Scale and Lid Lens Adapters; VitreoLens Handle®, Infusion Handle & Steady Mount against defects in materials or workmanship for a period of 6 years from receipt by end user.

Volk® 1 Single-Use Lenses

Volk Optical warrants its Volk® 1 Single-Use Lenses against defects in material and workmanship for the period ending with the product's sterility expiration.

Product Returns

All product returns must be disinfected and/or sterilized prior to return and be accompanied by a Return Authorization Number.

Please contact Volk Optical for a Return Authorization Number. Customers are responsible for returning products to Volk Optical; 7893 Enterprise Drive; Mentor, OH 44060; U.S.A. We recommend that all returns be insured and be sent by a traceable shipment method. Volk cannot be held responsible for lost shipments.

Warranty Limitations

Warranty service may not be provided without proof the product was purchased from Volk Optical Inc. or an authorized Volk Distributor.

This warranty becomes null and void if the customer fails to return the product in packaging consistent with the original protective packaging and it results in shipping damage.

This warranty becomes null and void if the customer fails to follow the recommended cleaning, disinfection and sterilization instructions and/or cautions contained in the product instruction manual.

This warranty does not cover service required because of disassembly, unauthorized modifications or service, misuse and abuse.

Warranty repairs will include labor, adjustments and replacements parts. Replacement parts may be remanufactured or contain remanufactured materials.

Limit of Liability

Seller makes no other warranty, express or implied, of the product supplied hereunder, including, without limitation, implied warranties of merchantability and fitness for a particular purpose, and all such warranties are hereby expressly excluded. Seller shall have no liability for loss of profits, or special, incidental, or consequential damages under any circumstances or legal theory, whether based on negligence, breach of warranty, strict liability, tort, contract, or otherwise. Seller shall in no event be liable in respect of this order and/or product delivered on account of this order for any amount greater than that paid to seller on account of this order. The purchaser acknowledges that it is purchasing the goods solely on the basis of the commitments of the seller expressly set forth herein.

Ordering Information

4 easy ways to order!



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Phone: +1 (440) 942-6161



FM 71461



ML-1001

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Rev. Feb. 2019

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 11.07.2023

Solicitantul FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6, tel./fax: 022-273712, e-mail: contact@datacontrol.md solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- 1) Volk Loupes, Ref.: V78C, V90C, VG3

Se anexează următoarele acte:

- 1) Declarație de Conformitate, din 07.03.2022;
- 2) Certificat ISO 13485, No. FM 71461 din 16.07.2022 ;
- 3) Certificat CE NR. CE 59279 din 15.03.2021.

Data 11.07.2023

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu
17/6

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- 1) Declarație de Conformitate, din 07.03.2022;
- 2) Certificat ISO 13485, No. FM 71461 din 16.07.2022 ;
- 3) Certificarte CE NR. CE 59279 din 15.03.2021.

Sunt autentice și corespund realității.

Numele, prenumele și funcția

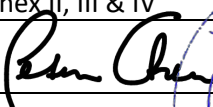
Semnătura _____

Grabazei Alexandru, director general.

Data 11.07.2023



Declaration of Conformity

Manufacturer		European Union Authorized Representative			
Volk Optical Inc. 7893 Enterprise Drive Mentor, Ohio 44060 USA Tel: +1 (800) 345-8655 Fax: +1 (440) 942-2257 volk@volk.com www.volk.com SRN: US-MF-000017843		Rudolf Riester GmbH Bruckstraße 31 72417 Jungingen Germany Tel: (+49) 7477-9270-0 Fax: (+49) 7477-9270-70 info@riester.de www.riester.de SRN: DE-AR-000015844			
Product	Lenses, iNview & VistaView, Merlin & ROLS Surgical Systems, and accessories (see Appendix A)				
Risk Classification	Class I devices, Rules 1, 10 & 13 according to Annex VIII of the MDR				
We hereby declare that this declaration of conformity is issued under the sole responsibility of Volk Optical Inc. and that the above-mentioned devices are in conformity with the EU Medical Devices Regulation (MDR), Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.					
Conformity Assessment	Annex II, III & IV				
Signature					
Name	Peter Chen				
Position	Chief Financial and Operating Officer				
Date	March 7, 2022				
Place of Issue of Declaration	Mentor, OH				



Appendix A:

BINOCULAR INDIRECT OPHTHALMOSCOPE (BIO) LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
V14LC	14D Large Clear	1	81160801BIOSE	The Volk Optical BIO Lenses are intended for visualization during diagnosis and laser therapy of the human retina (fundus) using a binocular indirect ophthalmoscope.
V15LC	15D Large Clear	1		
V20LC	20D Large Clear	1		
V20LC-BE	20D – Blue Ring	1		
V20LC-GD	20D – Gold Ring	1		
V20LC-GN	20D – Green Ring	1		
V20LC-PE	20D – Purple Ring	1		
V20LC-RD	20D – Red Ring	1		
V20LC-SR	20D – Silver Ring	1		
V20LC-CC	20D – Custom Color Ring	1		
K20LC	20LC (Distributor Version)	1		
L20LC	20LC (Distributor Version)	1		
VP20LC-PK	20LC (Distributor Version)	1		
V25LC	25D Large Clear	1		
V28LC	28D Large Clear	1		
V28LC-BE	28D – Blue Ring	1		
V28LC-GD	28D – Gold Ring	1		
V28LC-GN	28D – Green Ring	1		
V28LC-PE	28D – Purple Ring	1		
V28LC-RD	28D – Red Ring	1		
V28LC-SR	28D – Silver Ring	1		
L28LC	28LC (Distributor Version)	1		
V30LC	30D Large Clear	1		
V30SC	30D Small Clear	1		
V40LC	40D Large Clear	1		
VPRC	Pan Retinal 2.2 Clear	1		
VPRC-BE	Pan Retinal 2.2 – Blue Ring	1		
VPRC-GD	Pan Retinal 2.2 – Gold Ring	1		
VPRC-GN	Pan Retinal 2.2 – Green Ring	1		
VPRC-PE	Pan Retinal 2.2 – Purple Ring	1		
VPRC-RD	Pan Retinal 2.2 – Red Ring	1		
VPRC-SR	Pan Retinal 2.2 – Silver Ring	1		
LPRC	Pan Retinal 2.2 (Distributor Version)	1		
VMP5.5	Macula Plus 5.5	1		
VDGTLCF	Digital ClearField	1		
VDGTLCF-BK	Digital ClearField – Black Ring	1		
VDGTLCF-GD	Digital ClearField – Gold Ring	1		
VDGTLCF-GN	Digital ClearField – Green Ring	1		
VDGTLCF-PE	Digital ClearField – Purple Ring	1		
VDGTLCF-RD	Digital ClearField – Red Ring	1		
VDGTLCF-SR	Digital ClearField – Silver Ring	1		
VDGTLCM	Digital ClearMag	1		
VSLV20	Silver 20D	1		
VSLV28	Silver 28D	1		
C20	20D Cielo	1		
C28	28D Cielo	1		
V20LCACSPV	20D Clear ACS® PermaView	1		
V28LCACSPV	28D Clear ACS® PermaView	1		



NON-CONTACT SLIT LAMP LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
V60C	60D Clear	1	81160801SLITNG	The Volk Optical Non-Contact Slit Lamp Lenses are intended for visualization during diagnosis and laser therapy of the human retina (fundus) using a slit lamp.
V78C	78D Clear	1		
V78C-BE	78D Clear – Blue Ring	1		
V78C-GD	78D Clear – Gold Ring	1		
V78C-GN	78D Clear – Green Ring	1		
V78C-PE	78D Clear – Purple Ring	1		
V78C-RD	78D Clear – Red Ring	1		
V78C-SR	78D Clear – Silver Ring	1		
V78C-CC	78D Clear – Custom Color Ring	1		
L78C	78D Clear (Distributor Version)	1		
K78C-BE	78D Clear (Distributor Version)	1		
VP78C-PK	78D Clear (Distributor Version)	1		
V90C	90D Clear	1		
V90C-BE	90D Clear – Blue Ring	1		
V90C-GD	90D Clear – Gold Ring	1		
V90C-GN	90D Clear – Green Ring	1		
V90C-PE	90D Clear – Purple Ring	1		
V90C-RD	90D Clear – Red Ring	1		
V90C-SR	90D Clear – Silver Ring	1		
V90C-CC	90D Clear – Custom Color Ring	1		
L90C	90D Clear (Distributor Version)	1		
K90C-BE	90D Clear (Distributor Version)	1		
VP90C-PK	90D Clear (Distributor Version)	1		
VSLV78	Silver 78D	1		
VSLV90	Silver 90D	1		
C78	78D Cielo	1		
C90	90D Cielo	1		
VS66	Super 66° Stereo Fundus	1		
VS66-BE	Super 66° – Blue Ring	1		
VS66-GD	Super 66° – Gold Ring	1		
VS66-GN	Super 66° – Green Ring	1		
VS66-PE	Super 66° – Purple Ring	1		
VS66-RD	Super 66° – Red Ring	1		
VS66-SR	Super 66° – Silver Ring	1		
VSFNC	SuperField® NC	1		
VSFNC-BE	SuperField® NC – Blue Ring	1		
VSFNC-GD	SuperField® NC – Gold Ring	1		
VSFNC-GN	SuperField® NC – Green Ring	1		
VSFNC-PE	SuperField® NC – Purple Ring	1		
VSFNC-RD	SuperField® NC – Red Ring	1		
VSFNC-SR	SuperField® NC – Silver Ring	1		
VSFNC-CC	SuperField® NC, Custom Color	1		
KSFNC-BE	SuperField® NC (Distributor Version)	1		
VPSFNC-PK	SuperField® NC (Distributor Version)	1		
VSPXL	SuperPupil® XL	1		
VSVF	Super VitreoFundus®	1		
VDGTL1	Digital 1.0X Imaging	1		
VDGTLWF	Digital Wide Field®	1		
VDGTLWF-BK	Digital Wide Field® – Black Ring	1		
VDGTLWF-GD	Digital Wide Field® – Gold Ring	1		
VDGTLWF-GN	Digital Wide Field® – Green Ring	1		
VDGTLWF-PE	Digital Wide Field® – Purple Ring	1		
VDGTLWF-RD	Digital Wide Field® – Red Ring	1		
VDGTLWF-SR	Digital Wide Field® – Silver Ring	1		



VDGTLWF-CC	Digital Wide Field® – Custom Color	1		
KDGLWLF	Digital Wide Field® (Distributor Version)	1		
VPDGLWLF-PK	Digital Wide Field® (Distributor Version)	1		
VDGTLHM	Digital High Mag®	1		
VDGTLHM-BK	Digital High Mag® – Black Ring	1		
VDGTLHM-GD	Digital High Mag® – Gold Ring	1		
VDGTLHM-GN	Digital High Mag® – Green Ring	1		
VDGTLHM-PE	Digital High Mag® – Purple Ring	1		
VDGTLHM-RD	Digital High Mag® – Red Ring	1		
VDGTLHM-SR	Digital High Mag® – Silver Ring	1		
GONIOSCOPY LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
V3MIR	3-Mirror Gonio Fundus NF	1	81160801GONIO GU	Volk Optical’s Gonioscopy Lenses are indicated for use as diagnostic contact lenses for eye examinations (including the anterior chamber, trabecular meshwork, central retina, and peripheral retina) and use in the therapy of intraocular abnormalities.
V3MIRANF+	3-Mirror Gonio Fundus ANF+	1		
VU3MIR	3-Mirror Gonio Fundus (Uncoated) NF	1		
VU3MIRANF+	3-Mirror Gonio Fundus (Uncoated) ANF+	1		
VE3MIR	3 Mirror Lens (Distributor Version)	1		
VG1	G-1 Glass Trabeculum Glass Flange	1		
VG1NF	G-1 Glass Trabeculum No Flange No Fluid	1		
VG2	G-2 Glass Trabeculum Glass Flange	1		
VG2NF	G-2 Glass Trabeculum No Flange No Fluid	1		
VG3	G-3 Glass Gonio Fundus Glass Flange	1		
VG3NF	G-3 Glass Gonio Fundus No Flange No Fluid	1		
VG3MININF	G-3 Glass Gonio Fundus Mini No Flange No Fluid	1		
VEG3	G-3 Goniofundus (Distributor Version)	1		
VG4	G-4 Glass Gonio Glass Flange Fluid	1		
VG4LNF	G-4 Glass Hand Held Gonio (Large Ring) No Flange No Fluid	1		
VG4SNF	G-4 Glass Hand Held Gonio (Small Ring) No Flange No Fluid	1		
VG4HAN2	G-4 Glass 2 in 1 Handle Gonio No Flange No Fluid 3.5"	1		
VEG4	G-4 Goniolaser (Distributor Version)	1		
VG4HM	G-4 Glass High Mag Gonio Flange (Large Ring)	1		
VG4HMLNF	G-4 Glass High Mag Gonio No Flange (Large Ring) No Fluid	1		
VG4HMSNF	G-4 Glass High Mag Gonio No Flange (Small Ring) No Fluid	1		
VG4HMHAN2	G-4 Glass High Mag 2 in 1 Handle Gonio No Flange No Fluid	1		
VEG4HM	G-4 HighMag (Distributor Version)	1		
VG6LNF	G-6 Glass Hand Held Gonio – Large	1		
VG6HAN2	G-6 Glass NF 2 in 1 Handle	1		
V4MANF+	Mini 4 Mirror ANF+	1		
VSLT	Selective Laser Trabeculoplasty (SLT)	1		
VESLT	SLT Lens (Distributor Version)	1		
VMSLT	Rapid SLT	1		
VSGACS	Surgical Gonio	1		
VESGACS	Surgical Gonio (Distributor Version)	1		
VTSTVG	Alcon Vold TVG Surgical Gonio	1		
VTSVVG	Volk Vold Surgical Gonio	1		



CONTACT LASER & DIAGNOSTIC LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VAC	Area Centralis	1	81160801CONTA CTJR	Indicated for use as diagnostic contact lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.
VACNF	Area Centralis NF	1		
VACANF+	Area Centralis ANF+	1		
VEAC	Area Centralis® (Distributor Version)	1		
VEPNF	Equator Plus® NF	1		
VEPANF+	Equator Plus® ANF+	1		
VHRC	HR Centralis	1		
VEHRC	HR Centralis (Distributor Version)	1		
VHRWF	High Resolution Wide Field	1		
VEHRWF	High Resolution Wide Field (Distributor Version)	1		
VPDT	PDT Lens	1		
VQPED	Quad Pediatric	1		
VQFL	QuadrAspheric®	1		
VQFLNF	QuadrAspheric® NF	1		
VQFLANF+	QuadrAspheric® ANF+	1		
VEQFL	QuadrAspheric® (Distributor Version)	1		
VSMAC2.2	Super Macula® 2.2	1		
VSQUAD160	Super Quad® 160	1		
VSQUAD160NF	Super Quad® 160 NF	1		
VESQUAD160	Super Quad® 160 (Distributor Version)	1		
VTE	TransEquator®	1		
VTENF	TransEquator® NF	1		
VTEANF+	TransEquator® ANF+	1		
VETE	TransEquator® (Distributor Version)	1		
VCAPS	Capsulotomy	1		
VECAPS	Capsulotomy Lens (Distributor Version)	1		
VCD	Centralis Direct®	1		
VCDANF+	Centralis Direct® ANF+	1		
VFUNDUS	Fundus	1		
VFUNDUS20	Fundus 20MM	1		
VIRID	Iridectomy	1		
VEIRID	Iridectomy (Distributor Version)	1		
VMPIRID	MagPlus Iridectomy	1		
VEMPIRID	MagPlus Iridectomy (Distributor Version)	1		
VBIRID	Blumenthal Iridotomy	1		
VEBIRID	Blumenthal Iridotomy (Distributor Version)	1		
VBSL	Blumenthal Suturelysis	1		
VIMV	Volk Idrees Mid-Vitreous	1		
VEIMV	Idrees MidVitreous (Distributor Version)	1		
VSMV	Volk Singh Mid-Vitreous	1		
VESMV	Singh MidVitreous (Distributor Version)	1		
VITRECTOMY LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VCRLVIT	Central Retinal	1	81160801VITVU	Volk Vitrectomy Contact Lenses are indicated for use as diagnostic contact lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.
VCRLVITSSV	Central Retinal SSV®	1		
VDVVIT	DynaView 156	1		
VHRXVIT	HRX Vit	1		
VHRXVITSSV	HRX SSV® Vit	1		
VMQVIT	Mini Quad®	1		
VMQVITSSV	Mini Quad® SSV®	1		
VMQXLVIT	Mini Quad® XL	1		
VMQXLVITSSV	Mini Quad® XL SSV®	1		



VSMACVIT	Super Macula®	1		
VMQVITACS	Mini Quad® ACS®	1		
VMQVITSSVACS	Mini Quad® SSV® ACS®	1		
VCRLVITACS	Central Retinal ACS®	1		
VCRLVITSSVACS	Central Retinal SSV ACS®	1		
VHRXVITACS	HRX Vit ACS®	1		
VHRXVITSSVACS	HRX Vit SSV® ACS®	1		
VHRD1XACS	HR Direct 1x Vit	1		
VHRD1XNSRACS	HR Direct 1x NSR Vit	1		
VHRDBCACS	HR Direct Bi-concave	1		
VHRDHMACS	HR Direct HM Vit	1		
VHRDHMNSRACS	HR Direct HM NSR Vit	1		
VHRD20PACS	HR Direct 20° Prism Vit	1		
VPRISMSSVACS	15° Prism SSV® ACS®	1		
V30PRISMSSVACS	30° Prism SSV® ACS®	1		
V45PRISMSSVACS	45° Prism SSV® ACS®	1		
VAFXSSVACS	Air Fluid Exchange SSV® ACS®	1		
VFLATSSVACS	Flat SSV® ACS®	1		
VFHMSSVACS	Direct Image High Mag ACS®	1		
VMFSSVACS	Mid Field SSV® ACS®	1		
INVIEW RETINAL CAMERA				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VINVIEW-5S	Volk iNview for iPhone 5s	1	81160801INVUE	The Volk iNview ophthalmic camera is intended to take photographs of the retina of the eye for the purposes of general visualization and patient education.
VINVIEW-6	Volk iNview for iPhone 6	1		
VINVIEW-TCH	Volk iNview for iPod Touch	1		
VINVIEWC-TCH	Volk iNview Touch Camera	1		
VISTAVIEW RETINAL CAMERA				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VVISTAVIEW	VistaView	10	81160801VVB3	The Volk VistaView is a mydriatic fundus camera that is intended to capture and store images of the fundus of the dilated eye.
VVISTAVIEW2	VistaView	10		
LENS ACCESSORIES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VVITHAN-LG	VitreoLens Handle Long	1	81160801VITHNX	The Volk VitreoLens® Handle is an ophthalmic forceps device and is intended to aid in manual ophthalmic surgical procedures.
VVITHAN-MQXL	VitreoLens Handle for MQXL	1		
VINFHAN	Volk Infusion Handle	1	81160801VINFHKY	The Volk Infusion Handle is an ocular surgery irrigation device intended to be suspended over the ocular area during ophthalmic surgery to deliver continuous, controlled irrigation to the surgical field.
VSR2	Suture Ring	1	81160801SR2NA	The Volk Suture Ring is an ophthalmic ring device and is intended to aid in manual ophthalmic surgical procedures.



VCLEARPOD90D	Volk ClearPod, 90D	1	81160801CLPODE Z	The Volk ClearPod is intended to reduce lens fogging while performing eye examinations on patients wearing facemasks.
VCLEARPOD78D	Volk ClearPod, 78D	1		
VCLEARPODSFNC	Volk ClearPod, SFNC	1		
VCLEARPODDGTLWF	Volk ClearPod, DGTLWF	1		
MERLIN® ROTATIONAL ASSEMBLY (RA)				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11179	Rotational Assembly	1	81160801MRAU4	Provides attachment assembly for Lens Positioning Unit with 360° rotation about optical axis.
MERLIN® CONDENSER LENS ASSEMBLY (CLA) Auto				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11375	Assy, CLA, Auto, 175mm	13	81160801MCLAA UTONM	Provides attachment assembly for Lens Positioning Unit with 360° rotation about optical axis.
11376	Assy, CLA, Auto, 200mm	13		
11181	Auto CLA (No Condensing Lens)	13		
MERLIN® CONDENSER LENS ASSEMBLY (CLA) Manual				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11377	Assy, CLA, Manual, 175mm	1	81160801MCLAM ANFN	Provides attachment assembly for Lens Positioning Unit with 360° rotation about optical axis.
11378	Assy, CLA, Manual, 200mm	1		
11270	Manual CLA (No Condensing Lens)	1		
MERLIN® LENS POSITIONING UNIT (LPU)				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11171	Assy, LPU, For RA, 175mm	1	81160801MLPU MV	Holds the lens over the patient with full-scale adjustment.
11172	Assy, LPU, For RA, 200mm	1		
11173	Assy, LPU, For CLA, 175mm	1		
11174	Assy, LPU, For CLA, 200mm	1		
MERLIN® LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11182	Assy, Mid-Field NC Lens	1	81160801MLENS HK	The Merlin non-contact lens is the optical viewing element which attaches to the LPU for viewing the eye anatomy.
11183	Assy, Wide Angle NC Lens	1		
11184	Assy, Small Orbit Wide Angle NC Lens	1		
ROLS® ∞ Manual				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11313	ROLS Infinity, Zeiss – Manual	1	81160801ROLSIN FM5G	Provides high resolution reinverted images during vitreoretinal surgery
11315	ROLS Infinity, Leica – Manual	1		
ROLS® ∞ Auto				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11363	ROLS Infinity, Zeiss - Auto	13	81160801ROLSIN FA4Q	Provides high resolution reinverted images during vitreoretinal surgery
11364	ROLS Infinity, Leica - Auto	13		
MERLIN® MICROSCOPE MOUNTING ADAPTER KITS				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11411	Merlin RA Mount, Leica 690	1	81160801MMOU NTL2	Serve as mounting hardware to attach Merlin devices to a microscope.
11552	Merlin RA Mount, Zeiss MD	1		
11481	Merlin CLA Mount, Leica 690	1		
11553	Merlin CLA Mount, Zeiss MD	1		
11409	Merlin Mount, Leica	1		
11408	Merlin Mount, Zeiss	1		
11410	Merlin Mount, Moleller Weidel	1		
11412	Merlin Mount, Takagi	1		



11413	Merlin Mount, Topcon	1		
11654	Merlin Mount, Inami	1		
11732	Merlin Mount, Alcon	1		
11947	Merlin Mount, Topcon OMS90	1		
12171	Merlin Mount, Leica M822	1		
12159	Merlin Mount, Leica M690	1		
12160	Merlin Mount, L 820/840/841/844	1		
12161	Merlin Mount, MW HS HiR	1		
12163	Merlin Mount, Zeiss Visu	1		
11425	Merlin Mount, Spacer Kit	1		
MERLIN® POWER SYNC CABLES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11627	Merlin Power Sync Cable - 18"	1	81160801MSYNC M8	Passes power between the Merlin CLA & ROLS Infinity.
11669	Merlin Power Sync Cable - 24"	1		
ROLS® REINVERTER				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VROLS-Z	ROLS Reinverter - Zeiss	1	81160801VROLSP C	The ROLS is an advanced panoramic viewing system that provides reinverted viewing during vitreoretinal surgery, delivering high resolution, correctly-oriented retinal images.
VROLS-Z+	ROLS Reinverter - Zeiss +	1		
VROLS-L	ROLS Reinverter - Leica	1		
VROLS-L+	ROLS Reinverter - Leica+	1		
VROLS-LX	ROLS Reinverter - Leica, Open Flange	1		
VROLS-LX+	ROLS Reinverter - Leica+, Open Flange	1		

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Volk Optical Inc.
7893 Enterprise Drive
Mentor
Ohio
44060
USA

Holds Certificate Number:

FM 71461

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture, and distribution of ophthalmic diagnostic, therapeutic and surgical lenses, sterile single-use lenses, ophthalmic surgical viewing systems, and other associated ophthalmic accessories which comprise the following categories of products: non-contact binocular indirect lenses, non-contact and contact laser & diagnostic lenses, contact gonioscopy lenses, contact vitrectomy lenses, and non-contact surgical microscope accessories. The design, manufacture and distribution of products and accessories for diagnostic electronic imaging.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2001-06-05

Latest Revision Date: 2022-10-04

Effective Date: 2022-07-16

Expiry Date: 2025-07-15

Page: 1 of 1



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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 59279****Issued To:**

**Volk Optical Inc
7893 Enterprise Drive
Mentor
Ohio
44060
USA**

In respect of:

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of single use ophthalmic lenses for diagnostic examinations and for use in the therapy of intraocular abnormalities.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2001-06-29**

Date: **2021-03-15**

Expiry Date: **2024-05-26**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

Supplementary Information to CE 59279

Issued To:

Volk Optical Inc
7893 Enterprise Drive
Mentor
Ohio
44060
USA

Number	Device Name	Intended purpose per IFU
Class Is		
MD 0105	Sterile Single Use Ophthalmic Lenses for diagnostic examinations and therapy	---

First Issued: **2001-06-29**Date: **2021-03-15**Expiry Date: **2024-05-26**

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 59279**
 Date: **2021-03-15**
 Issued To: **Volk Optical Inc**
7893 Enterprise Drive
Mentor
Ohio
44060
USA

Subcontractor:

Service(s) supplied

Rudolf Riester Gmbh
 Bruckstraße 31
 72417 Jungingen
 Germany

EU Representative

STERIS Isomedix Services
 380 90th Avenue NW
 Minneapolis
 Minnesota
 55433
 USA

ETO Sterilization

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EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 59279**
 Date: **2021-03-15**
 Issued To: **Volk Optical Inc**
7893 Enterprise Drive
Mentor
Ohio
44060
USA

Date	Reference Number	Action
29 June 2001		First issue.
08 April 2005	4670846	Extension of scope to include sterile, single use vitrectomy ophthalmic lenses. Addition of First Engineering Optics PTE LTD as lenses manufacturing subcontractor and Centurion Sterilization Services as ETO Sterilization, Packaging and Testing subcontractor.
31 May 2006	4828172	Certificate renewal.
19 March 2008	7183955	Change of name of significant subcontractor 'First Engineering Optics Pte Ltd, First Engineering Techno Centre' to 'First Engineering Plastics Pte Ltd.'
26 May 2011	7650551	Addition of Keeler Limited as EU representative. Removal of Retinal Scales from scope. Removal of First Engineering Plastics (Malaysia) SDN BHD as significant subcontractor. Certificate renewal.
21 March 2013	7970102	Removal of Centurion Sterilization Services and addition of Phakos as significant subcontractor.
26 January 2015	8283147	Addition of 'Steris Isomedix Services' as significant subcontractor.

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Page 1 of 2

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Date	Reference Number	Action
30 November 2015	8437736	Extension to scope to cover ophthalmic lenses for diagnostic examinations and for use in the therapy of intraocular abnormalities.
29 April 2016	8499729	Certificate renewal. Removal of Phakos as significant subcontractor.
14 th February 2019	7781217	Traceable to NB 0086.
02 December 2020	3254266	Change in Eu representative from Keeler Ltd (UK) to Rudolf Riester GmbH (Germany). Addition of a device table.
Current	3389714	Certificate Renewal.

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Page 2 of 2

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