Geuder®
Precision made in Germany

Product description

Product	**Single-use Fiber optic, Uno Colorline**
Article No.	G-42021, G-42022, G-42023, G-42321, G-42322, G-42323, G-42521, G-42522, G-42523, G-46021, G-46022, G-42023, G-46321, G-46322, G-46323, G-46521, G-46522 , G-46523
Remarks	n.a.

GMDN-Code	45193: ophthalmic fiberoptic light instrument, single-use
UMDNS-Code	12-345 Light source fiberoptic
PN-Code CA	86MPA : Endoilluminator

Product description

The fiber optic, Uno Colorline, is a device intended to be used to provide visible illumination of the surgical field, especially in the posterior eye segment.

The device consists of a cannula (stainless steel 1.4301) containing the optical fibers in different diameters. The fibers are made of PMMA (Polymethyl Methacrylat) in the core and cladded by a Fluorinated Polymer. The cannula is guided in a handgrip of Makrolon as hard component with soft component parts in different colours to distinguish the sizes from each other. The fixation is guaranteed by using epoxy glue between cannula and handgrip and between the fibers and the cannula.
From the handgrip to the connector plug the fibers are insulated by black PVC tubing. The connector plug is made out of Aluminium alloy.

The possible access into the eye is provided through a suitable port placed in the area of the pars plana or a transscleral incision.

This instrument is compatible to a device unit e.g. Xenotron III, as external light source, which is embedded with PHOTOTOXGUARD to reach a high level of integrated security.

Product variants

Article No. G-	Description
42021	Single-use fiber optic S 20 G Uno Colorline red, diameter 20 gauge / 0.9 mm, spot, 1 pcs per box, sterile

42022	Single-use fiber optic W 20 G Uno Colorline red, diameter 20 gauge / 0.9 mm, wide angle, 1pcs per box, sterile
42023	Single-use fiber optic WS 20 G Uno Colorline red, diameter 20 gauge / 0.9 mm, wide angle shielded, 1pcs per box, sterile
42321	Single-use fiber optic S 23 G Uno Colorline green, diameter 23 gauge / 0.6 mm, spot, 1pcs per box, sterile
42322	Single-use fiber optic W 23 G Uno Colorline green, diameter 23 gauge / 0.6 mm, wide angle, 1pcs per box, sterile
42323	Single-use fiber optic WS 23 G Uno Colorline green, diameter 23 gauge / 0.6 mm, wide angle shielded, 1pcs per box, sterile
42521	Single-use fiber optic S 25 G Uno Colorline blue, diameter 25 gauge / 0.5 mm, spot, 1pcs per box, sterile
42522	Single-use fiber optic W 25 G Uno Colorline blue, diameter 25 gauge / 0.5 mm, wide angle, 1pcs per box, sterile
42523	Single-use fiber optic WS 25 G Uno Colorline blue, diameter 25 gauge / 0.5 mm, wide angle shielded, 1pcs per box, sterile
46021	Single-use fiber optic S 20 G Uno Colorline red, diameter 20 gauge / 0.9 mm, spot, 6pcs per box, sterile
46022	Single-use fiber optic W 20 G Uno Colorline red, diameter 20 gauge / 0.9 mm, wide angle, 6pcs per box, sterile
46023	Single-use fiber optic WS 20 G Uno Colorline red, diameter 20 gauge / 0.9 mm, wide angle shielded, 6pcs per box, sterile
46321	Single-use fiber optic S 23 G Uno Colorline green, diameter 23 gauge / 0.6 mm, spot, 6pcs per box, sterile
46322	Single-use fiber optic W 23 G Uno Colorline green, diameter 23 gauge / 0.6 mm, wide angle, 6pcs per box, sterile
46323	Single-use fiber optic WS 23 G Uno Colorline green, diameter 23 gauge / 0.6 mm, wide angle shielded, 6pcs per box, sterile
46521	Single-use fiber optic S 25 G Uno Colorline blue, diameter 25 gauge / 0.5 mm, spot, 6pcs per box, sterile
46522	Single-use fiber optic W 25 G Uno Colorline blue, diameter 25 gauge / 0.5 mm, wide angle, 6pcs per box, sterile
46523	Single-use fiber optic WS 25 G Uno Colorline blue, diameter 25 gauge / 0.5 mm, wide angle shielded, 6pcs per box, sterile

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Accessories	
Article No. G-	**Description**
	n.a.
Pictures (examples)	
G-42323 shielded, 23 gauge	
G-42521 Spot, 25 gauge	

Production plants and Marketing authorisation holder (MAH)		
Article No. G-	**Production plant**	**MAH**
42021, 42022, 42023, 42321, 42322, 42323, 42521, 42522, 42523, 46021, 46022, 46023, 46321, 46322, 46323, 46521, 46522, 46523	**Oberon GmbH Fiber Technologies** Freiheitsstrasse 120 15745 Wildau Germany	GEUDER AG Hertzstr.4 D-69126 Heidelberg
Material in contact with the patient*		
Component	**Material**	
Cannula tube*	**Stainless steel 1.4301**	
Handgrip (hard component) Handgrip (soft component)	Makrolon 2458 TEP, red, green, blue (depending on the gauge size)	
Optical Fiber*	**Plastic Optical Fiber (POF)** **PMMA Poly(methyl-methylacrylate Resin (core)** **Fluorinated polymer (Cladding)**	
Insulation tube	PVC no DOP	
Connector plug	AlMg3	
Glue*	**EPO-TEK 301**	

Sterilization	
Sterilization method	**Ethylene oxide**
Sterilization plant G-42021, G-42022, G-42023, G-42321, G-42322, G-42323, G-42521, G-42522, G-42523, G-46021, G-46022, G-42023, G-46321, G-46322, G-46323, G-46521, G-46522, G-46523	Osypka AG Earl-H.-Wood-Str.1 79618 Rheinfelden-Herten Germany
Shelf-Life	**3 years**

Document changes		
Version	**Date**	**Description**
V1.0	August 26, 2014	First release
V2.0	August 08, 2012	Change of products
V3.0	Sept.9th. 2012	New supplier
V4.0	April, 15th 2015	Actualisation, second source
V5.0	October, 15th 2015	Change of contract manufacturer

Drafted by	**Reviewed by**	**Released by**
Name: Stephanie Haas QM/RA	Name: Heike Kheil QM/RA	Name: Matthias Welke, Head of QM/RA
Date/Signature Stephanie Haas 30. OKT. 2015	Date/Signature Heike Kheil 30. OKT. 2015	Date/Signature Matthias Welke 30. OKT. 2015