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Product description

Product	**Single-Use High Speed Vitreous Cutters Uno Colorline, sterile**
Article	G-42001, G-42002, G-42004, G-42301, G-42302, G-42304, G-42501, G-42502, G-42504, G-46001, G-46002, G-46004, G-46301, G-46302, G-46304, G-46501, G-46502, G-46504
Remarks	Accessory: G-42009, G-46009

GMDN-Code	47424: Vitrectomy system handpiece tip
UMDNS-Code	14-386: Vitrectomy units
PN-Code CA	86 QOH: Cutter, vitreous infusion suction

Product description

The sterile, SINGLE-USE HIGH SPEED VITREOUS CUTTER UNO COLORLINE" is a device for an ophthalmological surgery, particularly to remove some or all of the vitreous body from the eye. The vitreo-retinal procedures are surgical techniques, which are commonly performed deep inside the eye's interior, in the posterior segment of the eye.

For this reason usually three tiny incisions in the eye will be made, to create openings for the various instruments that will be inserted to complete the vitrectomy. The Geuder Trocar System is therefore compatible and has the same size in Gauge as the vitrectors. These incisions are placed in the area of pars plana of the eye, located just behind the iris but in the front of the retina.

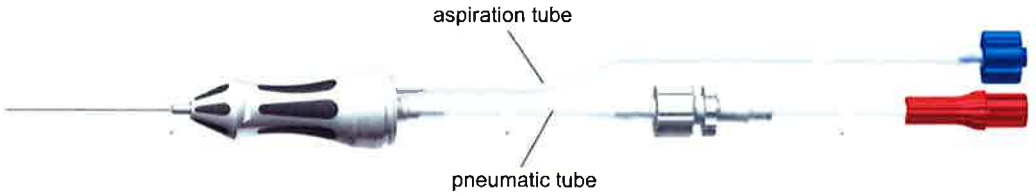
The SINGLE-USE HIGH SPEED VITREOUS CUTTER UNO COLORLINE, sterile consists of a plastic handpiece with a metal outer tube. The vitreous cutter is an accessory to the GEUDER ophthalmic surgical devices of the Megatron series and is connected via a pneumatic- and an aspiration tube. The vitreous body is aspirated in cutting edge aperture, chopped mechanically and aspirated from the eye.

The single-use vitreous cutter Uno Colorline is Class IIa device (MDD 93/42/EEC), intended for transient use (continuous use less than 60 minutes) and is designed for single-use

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only ⊗.

The Infusion Tube is an accessory for the SINGLE-USE HIGH SPEED VITREOUS CUTTER, 20 Gauge, and is used only in cases of emergency anterior vitrectomy.



All products are available in ***20G; 23G and 25G*** and in the following modification: ***single-blade; double-blade (MACH 2)*** and ***quadruple-blade (MACH 4) vitrector***. All of them have completely the same function: to remove some or all of the vitreous body from the eye; in details, through suction and crush of the vitreous body.

The only differences between three modifications are:

- Different cutting edge geometry and hence
- An increase of the effectiveness and functionality of the vitrectors from single-blade through to the quadruple-blade vitrector. Thus, the quadruple-blade vitrector converts 4 cuts pro impulse/cut actuation and is the most effective one.

Product variants

Article No.	Description
G-42001	Single-use high speed vitreous cutter 20 G Uno Colorline Red, 20 gauge/0.9 mm, pneumatic, 1 pc. per box, sterile
G-42002	Single-use high speed vitreous cutter 20 G Uno Colorline Red, MACH2, 20 gauge/0.9 mm, pneumatic, 1 pc. per box, sterile
G-42004	Single-use high speed vitreous cutter 20 G Uno Colorline Red, MACH4, 20 gauge/0.9 mm, pneumatic, 1 pc. per box, sterile
G-42301	Single-use high speed vitreous cutter 23 G Uno Colorline Green, 23 gauge/0.6 mm, pneumatic, 1 pcs. per box, sterile
G-42302	Single-use high speed vitreous cutter 23 G Uno Colorline Green, MACH2, 23 gauge/0.6 mm, pneumatic, 1 pcs. per box, sterile
G-42304	Single-use high speed vitreous cutter 25 G Uno Colorline Blue, MACH4, 25 gauge/0.5 mm, pneumatic, 1 pcs. per box, sterile

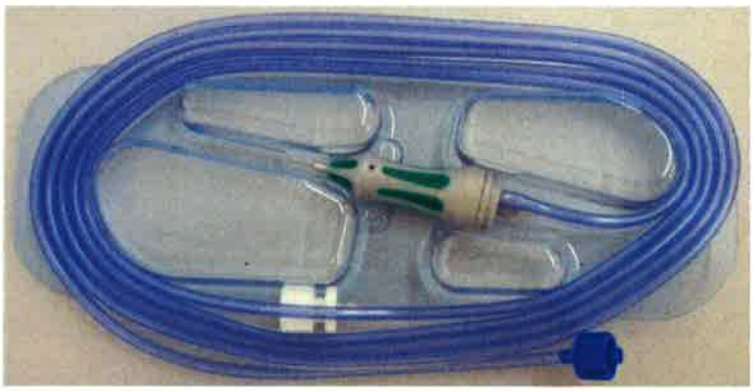
G-42501	Single-use high speed vitreous cutter 25 G Uno Colorline Blue, 25 gauge/0.5 mm, pneumatic, 1 pcs. per box, sterile
G-42502	Single-use high speed vitreous cutter 25 G Uno Colorline Blue, MACH2, 25 gauge/0.5 mm, pneumatic, 1 pcs. per box, sterile
G-42504	Single-use high speed vitreous cutter 25 G Uno Colorline Blue, MACH4, 25 gauge/0.5 mm, pneumatic, 1 pcs. per box, sterile
G-46001	Single-use high speed vitreous cutter 20 G Uno Colorline Red, 20 gauge/0.9 mm, pneumatic, 6 pc. per box, sterile
G-46002	Single-use high speed vitreous cutter 20 G Uno Colorline Red, MACH2, 20 gauge/0.9 mm, pneumatic, 6 pc. per box, sterile
G-46004	Single-use high speed vitreous cutter 20 G Uno Colorline Red, 20 gauge/0.9 mm, pneumatic, 6 pc. per box, sterile
G-46301	Single-use high speed vitreous cutter 23 G Uno Colorline Green, MACH4, 23 gauge/0.6 mm, pneumatic, 6 pcs. per box, sterile
G-46302	Single-use high speed vitreous cutter 23G Uno Colorline Green, MACH2, 23 gauge/0.6 mm, pneumatic, 6 pcs. per box, sterile
G-46304	Single-use high speed vitreous cutter 23G Uno Colorline Green, MACH4, 23 gauge/0.6 mm, pneumatic, 6 pcs. per box, sterile
G-46501	Single-use high speed vitreous cutter 25G Uno Colorline Blue, 25 gauge/0.5 mm, pneumatic, 6 pcs. per box, sterile
G-46502	Single-use high speed vitreous cutter 25G Uno Colorline Blue, MACH2, 25 gauge/0.5 mm, pneumatic, 6 pcs. per box, sterile
G-46504	Single-use high speed vitreous cutter 25G Uno Colorline Blue, MACH4, 25 gauge/0.5 mm, pneumatic, 6 pcs. per box, sterile

Accessories

Article No. G-	**Description**
42009	Single-use infusion tube 20 G Uno Colorline Red, 20 gauge/0.9 mm for 20 gauge vitreous cutters G-42001 and G-46001, 1 pcs. per box, sterile
46009	Single-use infusion tube 20 G Uno Colorline Red, 20 gauge/0.9 mm for 20 gauge vitreous cutters G-42001 and G-46001, 6 pcs. per box, sterile

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Pictures





G-42001 bis G-46504

G-42009 /G-46009	

Material in contact with the patient

Component	**Material**
Cutting Tube (inner and outer) G-42001 to G-46504	Stainless steel 1.4301
Accessory: Infusion Tube G-42009 and G-46009	Stainless steel 1.4401

Production plants and Marketing authorisation holder (MAH)		
Article No.	**Production plant**	**MAH**
G-42001, G-42002, G-42004, G-42301, G-42302, G-42304, G-42501, G-42502, G-42504, G-46001, G-46002, G-46004, G-46301, G-46302, G-46304, G-46501, G-46502, G-46504 G-42009, G-46009	SteriMed Tec AG Hafnerwisenstr. 2, CH-9442 Berneck Switzerland Geuder AG Hertzstr. 4 69126 Heidelberg Germany	Geuder AG Hertzstr. 4 69126 Heidelberg Germany

Sterilization	
Sterilization method	Gamma Irradiation
Sterilization plant G-42001, G-42002, G-42004, G-42301, G-42302, G-42304, G-42501, G-42502, G-42504, G-46001, G-46002, G-46004, G-46301, G-46302, G-46304, G-46501, G-46502, G-46504 G-42009, G-46009	Synergy Health Däniken Hogenweidstrasse 6 Däniken, CH-4658
Shelf-Life	3 years

Document changes		
Version	**Date**	**Description**
V1.0	August 12, 2011	First release
V2.0	August 25, 2014	New Template
V3.0	February 20th 2015	update
V4.0	June 30th, 2016	new family member

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Drafted by	Reviewed by	Released by
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