

CeramOptec GmbH | Siemensstraße 44 | D-53121 Bonn



CeramOptec GmbH
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www.ceramoptec.de

26th April 2021

Product Recall

URGENT: SAFETY NOTICE No. FSN-2021-04-12

Date: 26/04/2021 For the attention of: Distributor, clinical staff, end user

Dear Customer,
CeramOptec GmbH issues this action notice requesting the immediate return / destruction of the following non-sterile components:

482536 Opened retractor wing shape;
Referenznummer des Herstellers: A.4086.1.

482534 HeLP@ Proctoscope + introducer with Working Channel;
Referenznummer des Herstellers: A.40238

Type of action:

Immediate return to CeramOptec and / or destruction of the products. Details of the components in question, which may be non-sterile:

Description of the problem:

Due to issues with the manufacturer's third-party service provider, it is possible that „Retractor" and „Proctoscope" are not sterile. This FSN applies to the product codes and lots listed in the Appendix.

The products are included in the following kits:

FiLaC@ Fistula Kit,
LHP@ Procedure Kit,
HeLP@ Procedure Kit

Instructions to the user:

1. Immediately destroy the „Retractor" and „Proctoscope" lots listed in the Appendix that are still in your possession. Destroy products with codes and batches not listed in the attachment that you still have in stock.
2. Please tell us the number of products destroyed and confirm it informally. This information is necessary so that we can monitor the progress of the action.
3. Due to the problem described above, Biolitec is currently unable to supply complete LHP kits. The part numbers of these kits are 501100220 or 503100220, depending on the laser used.

 **Geschäftsführer**
Dr. Damian Plange
Dr. Roland Dreschau

 **Register**
HRB 4633

 **Amtsgericht**
Bonn

USt-IdNr.
DE 811 188 951

 **Commerzbank AG**
IBAN DE 92 8204 0000 0258 3078 00
BIC COBADEFFXXX

Kontakt

bestellungen@biolitec.com

CeramOptec GmbH

Dr. Roland Dreschau

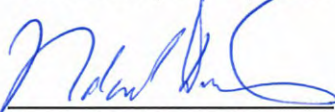
E-Mail: roland.dreschau@ceramoptec.com

Telefon: +49 (0) 173/53 8'18 02

It is important to us that we supply products to patients and users that comply with all applicable regulatory requirements. Therefore, we have taken all possible measures and responded to the situation accordingly. We regret any inconvenience caused in this regard and would like to resolve the issue as quickly and efficiently as possible. For this purpose, we need your cooperation and the cooperation of the field service.

We thank you in advance for your support and apologize once again for any inconvenience caused. We hope that we will soon be able to provide you with the usual offers again.

Date: Bonn, 26th April 2021



Dr. Roland Dreschau
Managing Director
CeramOptec GmbH



Dr. Sönke Asmussen
Head of Quality Management
CeramOptec GmbH

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Product overview list

Dear Sir or Madam,

we have been informed by Sapimed on Friday, April 23, 2021 that after completion of all inspections, the following lots from previous GULL shipments should no longer be used and will be officially recalled:

2018

18A022I shipped to CeramOptec 29/03/2018 / 29/05/2018.

18G011I shipped to CeramOptec 16/11/2018 / 29/01/2019

18J002I shipped to CeramOptec 03/04/2019

2019

19A003I shipped to CeramOptec 24/05/2019

19E024I no delivery

19E008I shipped to CeramOptec 20/09/2019

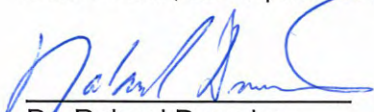
19F027I delivered to CeramOptec 06/01/2020

19I010I delivered to Ceram Optec 21/02/2020 / 03/03/2020

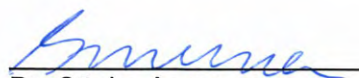
If you have any of the above-mentioned products in stock or if you know that these products have not yet been used, please recall or quarantine these products and inform us which quantity is affected. Sapimed will then decide whether to return these goods to Italy or destroy them.

This list will be passed on to the sales force.

Date: Bonn, 26th April 2021



Dr. Roland Dreschau
Managing Director
CeramOptec GmbH




Dr. Sönke Asmussen
Head of Quality Management
CeramOptec GmbH

 Geschäftsführer
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