



## URGENT Field Safety Notice (FSN) Collagen Products FSN-02-21-2023-001-FSCA

**Date issued:** 16<sup>th</sup> March 2023

**Dear valued customer**

RESORBA Medical GmbH ("RESORBA") has initiated a recall for the devices below ("Product"). This affects all Product in the field within shelf life, affected lots are detailed in the table below:

Device Name	REF	Lot Number	Expiration Date	Basic UDI-DI	Intended Use
GENTA-COLL®	GC525	R00086283	21/11/2025	50599812090201UT	Hemostat
	GC525	R00087428	28/11/2025	50599812090201UT	
	GC525	R00087448	05/12/2025	50599812090201UT	
	GC110	R00087762	08/12/2025	50599812090201UT	
GENTA-FOIL® resorb	GF25	R00088294	27/12/2025	50599812090401V5	Hemostat
	GF1010	R00088461	05/01/2026	50599812090401V5	
	GF1010	R00088539	10/01/2026	50599812090401V5	
KOLLAGEN resorb™	RK9011	R00088277	03/01/2028	50599812090501VA	Adhesion barrier
PARASORB® RESODONT	RD3503	R00087760	13/12/2027	50599812090401V5	Barrier Membrane (Dental)
		R00087948	13/12/2027	50599812090401V5	
PARASORB® RESODONT Forte	RDF1502	R00084416	09/09/2027	50599812090401V5	Barrier Membrane (Dental)
		R00085782	28/10/2027	50599812090401V5	
		R00085872	08/11/2027	50599812090401V5	
	RDF2502	R00087871	13/12/2027	50599812090401V5	
		R00087897	16/12/2027	50599812090401V5	
		R00088266	20/12/2027	50599812090401V5	
	RDF3503	R00086281	15/11/2027	50599812090401V5	
		R00086282	18/11/2027	50599812090401V5	
	RDF0703	R00087453	06/12/2027	50599812090401V5	
		R00087484	09/12/2027	50599812090401V5	

**Product Issue**

RESORBA has detected blue particulate matter in the Product during internal inspection. This is an isolated incident. The particles have been confirmed to originate from the manufacturing process and are known to be Chloroprene coated with blue natural rubber. The particles are small, there can be multiple particles on a Product and not easily detectable by the eye.

**Potential Risk**

Assessment concluded a low likelihood to cause serious harm if particles enter the body. However, as the particles contain rubber material it has the potential to induce an allergic response upon implantation. To date there has been no complaints or adverse events reported associated with this defect.

**Required actions regarding the use of the Product**

Our records indicate that you have received stock of the Product and you are therefore affected by this action.

We kindly request that you read this Field Safety Notice ("FSN") carefully and complete the following actions within 14 days of receipt of this Notice:

**DISTRIBUTOR / LOGISTIC CENTRES**

**(Any organisation that buys Product from RESORBA and then provides them to end users or to sub-distributors)**

1. Immediately check your internal inventory and quarantine all Product pending safe destruction.
2. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached '**APPENDIX 1 - DISTRIBUTOR / LOGISTIC CENTRES FORM**' and return it to RESORBA either by post or by email to the addresses stated on the form.
3. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached '**APPENDIX 3 - CERTIFICATE OF DESTRUCTION FORM**' and return it to RESORBA either by post or by email to the addresses stated on the form.
4. Please immediately distribute this FSN to all affected end user customers/Healthcare facilities alongside the attached '**APPENDIX 2 - CUSTOMER REPLY FORM**' and '**APPENDIX 3 - CERTIFICATE OF DESTRUCTION**'. Please advise them to execute the actions and collect the forms from your customers.
5. The FSN does not need to be communicated to patients. There is no action to take with patients.
6. Product will be replaced free of charge automatically. If this is not preferred, please contact RESORBA customer services.
7. Customer Services Name and Contact Number: Volha Dahms +49 9128 9115 31  
Email: Volha.dahms@resorba.com



RESORBA Medical GmbH

Fon +49 (0) 9128/9115 0  
Fax +49 (0) 9128/9115 91

RESORBA . Am Flachmoor 16 . 90475 Nürnberg

www.resorba.com

### ALL OTHER CUSTOMERS

(Any organisation that buys Product from RESORBA for end use)

1. Immediately check your internal inventory and quarantine all Product pending safe destruction.
2. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached '**APPENDIX 2 - CUSTOMER REPLY FORM**' and return it to RESORBA either by post or by email to the addresses stated on the form.
3. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached '**APPENDIX 3 - CERTIFICATE OF DESTRUCTIONFORM**' and return it to RESORBA either by post or by email to the addresses stated on the form.
4. The FSN does not need to be communicated to patients. There is no action to take with patients.
5. Product will be replaced free of charge automatically. If this is not preferred, please contact RESORBA customer services.
6. Customer Services Name and Contact Number: Andreas Gaßner +49 9129 9115 28  
Email: andreas.gassner@resorba.com

### Contacts

We sincerely apologise for any inconvenience caused by this FSN, patient safety and compliance is very important to us.

In the meantime, if you have any other questions related to this FSN please contact regulatory.affairs@resorba.com

The undersigned confirms this FSN will be notified to the appropriate Competent Authorities.


### Enclosed forms

Appendix 1. Field Safety Notice: **DISTRIBUTOR / LOGISTIC CENTRES FORM**

Appendix 2. Field Safety Notice: **CUSTOMER REPLY FORM**

Appendix 3. **CERTIFICATE OF DESTRUCTION**

Yours faithfully,

DocuSigned by:  
  
3CA20BA01E41427...

**Dr Karl Beck**  
**PRRC (Person Responsible for Regulatory Compliance)**  
**For and on behalf of RESORBA Medical GmbH**



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## **Appendix 1. Field Safety Notice: DISTRIBUTOR / LOGISTIC CENTRES FORM**

<b>1. Field Safety Notice (FSN) information</b>	
FSN Reference number	02-21-2023-001-FSCA
FSN Date	16 <sup>th</sup> March 2023
Details of affected Products	GENTA-COLL® GENTA-FOIL resorb® KOLLAGEN resorb™ PARASORB® RESODONT PARASORB® RESODONT Forte
Refer to Field Safety Notice for further Product details	

<b>2. Return Acknowledgement to sender</b>	
Email	volha.dahms@resorba.com
Customer Service	+49 9128 9115 31
Postal Address	RESORBA Medical GmbH Am Flachmoor 16 90475, Nuremberg
Deadline for returning the Distributor reply form	This form is to be returned no later than 14 days after receipt of this FSN.

<b>3. Distributor/Importer Details</b>	
Company Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email	



<b>4. Distributors/Importers (Tick all that apply)</b>		
<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the FSN	
<input type="checkbox"/>	I have checked my Product stock and quarantined inventory	Date Quarantined:
<input type="checkbox"/>	I have identified customers that received or may have received this Product	
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	I have destroyed affected Product – enter number destroyed and date complete	Please provide a Certificate of Destruction as attached:
<input type="checkbox"/>	Neither I nor any of my customers has any affected Product in inventory	
Print Name (Distributor name):		
Signature (Distributor signature):		
Date :		

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.



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## Appendix 2. Field Safety Notice: CUSTOMER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	02-21-2023-001-FSCA
FSN Date	16 <sup>th</sup> March 2023
Device name	GENTA-COLL® GENTA-FOIL resorb® KOLLAGEN resorb™ PARASORB® RESODONT PARASORB® RESODONT Forte
Refer to Field Safety Notice for further product details	

2. Customer Details	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation (Tick all that apply)		
<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the FSN	
<input type="checkbox"/>	I have checked my Product stock and quarantined inventory	
<input type="checkbox"/>	I have destroyed affected Product–enter number destroyed and date complete	Please provide a Certificate of Destruction as attached:
<input type="checkbox"/>	I confirm any Product not destroyed has already been used	
Print Name:		
Signature:		



Date :	
<b>4. Return acknowledgement to Sender</b> <b>If you are not a direct customer of RESORBA , please return this form to your distributor.</b>	
Email	
Customer Helpline	
Postal Address	
Deadline for returning the Customer reply form	This form is to be returned no later than 14 days after receipt of this FSN.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.



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**Appendix 3 - CERTIFICATE OF DESTRUCTION**

In respect of the Products subject to 02-21-2023-001-FSCA, and in regard to the provided FSN; I hereby confirm that I have destroyed the following items and quantities as instructed:

Device Name	REF	LOT Number	Qty (carton/boxes)

Name: \_\_\_\_\_

Institution/Company Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

This form is to be returned **no later than 14 days after receipt of this FSN.**





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