RESORBA . Am Flachmoor 16 . 90475 Nürnberg

RESORBA Medical GmbH

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

www.resorba.com

URGENT Second Field Safety Notice (FSN)
Collagen Products FSN V2 02-21-2023-001-FSCA

Date issued: 23rd March 2023

Dear valued customer

With reference to the FSN V1 dated 16th March 2023

Following further assessment with a competent authority this second FSN is issued to provide you with additional guidance and instructions.

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® *resorb*	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	Adhesion barrier
	GF1010	R00088461	05/01/2026	50599812090401V5	
	GF1010	R00088539	10/01/2026	50599812090401V5	
KOLLAGEN *resorb*®	RK9011	R00088277	03/01/2028	50599812090501VA	Hemostat
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	

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Device Name	REF	Lot Number	Expiration Date	Basic UDI-DI	Intended Use
	RDF0703	R00087453	06/12/2027	50599812090401V5	
		R00087484	09/12/2027	50599812090401V5	

Components of Blue Particles

Rubber belt	Polychloroprene	Synonyms are Neoprene
Coating	Natural rubber (NRL)	Contains: Natural rubber, filler, anti-aging agent and accelerator Ammonia is not used
Dye	Renol-PV/GUM Blue 60 E	2,6-Di-Tert-Butyl-p-Cresol, CAS 128-37-0, <0.1% w/w Vinyl acetate, CAS 108-05-4, 0.25 – 0.5% Poly-ethylene vinyl acetate (EVA), CAS 24937-78-8, 99.4 – 99.8% w/w
Dye	RENOL RED PV3305D14B-BN/GUM 40%	Silicon dioxide, CAS 14808-60-7, <0.1% w/w Rosin (Colophony), CAS 8050-09-7, 3 – 5% w/w Poly-ethylene vinyl acetate (EVA), CAS 24937-78-8, 95 – 97% w/w

Potential Risk

Following feedback from a competent authority we have obtained further expert opinion. Assessment concluded that the most likely cause of harm to a patient with low probability would be an adverse local tissue reaction or allergic response upon implantation. Other potential risks with remote or unlikely probability are development of latex sensitivity, healing complications from non-absorbable material and carcinogenic or mutagenic effects. To date there has been no complaints or adverse events reported associated with this defect.

Required actions regarding the use of the Product

Where Product has already been implanted in patients under a three-month time period, patients should be monitored for symptoms during routine clinical follow up. If you are aware of any patient experiencing symptoms related to this FSN it should be reported to RESORBA straight away.

All Distributors and Customers must ensure that the FSN, as amended, is sent to treating clinicians at facilities within 24 hours of receipt of this second Notice.

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Contacts

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

If you have any 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. Second Field Safety Notice: **DISTRIBUTOR / LOGISTIC CENTRES FORM**
Appendix 2. Second Field Safety Notice: **CUSTOMER REPLY FORM**

Yours faithfully,

[redacted]

[redacted]

[redacted]

For and on behalf of RESORBA Medical GmbH

RESORBA . Am Flachmoor 16 . 90475 Nürnberg

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

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN V2 02-21-2023-001-FSCA
FSN Date	23rd 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	

2. Return Acknowledgement to sender	
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.

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

RESORBA . Am Flachmoor 16 . 90475 Nürnberg

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4. Distributors/Importers (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the FSN	
☐	I have informed the identified customers of this FSN	
☐	I have received confirmation of reply from all identified customers	
	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. Second Field Safety Notice: CUSTOMER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN V2 02-21-2023-001-FSCA
FSN Date	23rd 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)		
☐	I confirm the receipt, the reading and understanding of the FSN	
	Print Name:	
	Signature:	
	Date :	

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4. Return acknowledgement to Sender If you are not a direct customer of RESORBA , please return this form to your distributor.	
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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URGENT Field Safety Notice (FSN)
Collagen Products FSN-02-21-2023-001-FSCA

Date issued: 16th 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	

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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 facilites 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

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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,

[redacted]

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

1. Field Safety Notice (FSN) information	
FSN Reference number	02-21-2023-001-FSCA
FSN Date	16th 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	

2. Return Acknowledgement to sender	
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.

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

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4. Distributors/Importers (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the FSN	
☐	I have checked my Product stock and quarantined inventory	Date Quarantined:
☐	I have identified customers that received or may have received this Product	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have destroyed affected Product – enter number destroyed and date complete	Please provide a Certificate of Destruction as attached:
☐	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	16th 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)		
☐	I confirm the receipt, the reading and understanding of the FSN	
☐	I have checked my Product stock and quarantined inventory	
☐	I have destroyed affected Product– enter number destroyed and date complete	Please provide a Certificate of Destruction as attached:
☐	I confirm any Product not destroyed has already been used	
	Print Name:	
	Signature:	

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Date :	

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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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