



Urgent Field Safety Notice

Type of measure: Recall

Concerning: cerabone® plus, Ref. – 1811, Lot. - 20J50080

Date: 30.07.2021

Sender:

botiss biomaterials GmbH
Hauptstraße 28
15806 Zossen

Addressee:

User *[Name and address of the doctors that received the product]*

Dear Sir or Madame,

we are writing to inform you that the batch of cerabone® plus that you received does not comply with the product end specifications.

Description of problem and possible hazards

cerabone® plus is a particular bovine bone substitute material containing hyaluronic acid as an excipient. The medical device is provided in sterile condition due to irradiation with gamma radiation.

It came to our attention that 10 products of a batch presenting deviation within the microbial testing before sterilization were distributed in the Romanian market. botiss cannot guarantee the sterility of products of respective batch (20JA50080).

Non-sterile product might possibly cause health hazards to the patient, i.e. infection. So far botiss is not aware of any adverse events or complaints in connection with the affected product batch.

botiss biomaterials GmbH has decided to initiate a Field Corrective Action to address this and retract affected products from the market.

Identification of the affected product(s)

According to our records you have received

| Product Code (Ref.) | Brand name | Content | Batch number (lot.) | Quantity | Date of shipping |
|---------------------|----------------|---------|---------------------|----------|------------------|
| 1811 | cerabone® plus | 1 ml | 20J50080 | XXXXXXXX | XXXXXXXXXX |

The Lot number can be found on the outer packaging besides the symbol for lot number or on the inner packaging as circled in the examples:



Actions to be taken:

1. If the article listed in the table above is still in your inventory, then stop use of the product immediately and quarantine/ segregate it physically.
2. If the article listed in the table above is still in your inventory, return it to the attention of your local distributor MegaGen Dental Implant (please find contact details below).
3. If you have already used the cerabone[®] plus with the above given article and lot number, please document receipt of the Field Safety Notice in the applicable patient files. Complete and return the enclosed Customer Confirmation Form via mail or email to the address given on the form **within 7 days**. If products were already implanted, please also report the outcome of the surgical treatment with this product on the enclosed Form.
4. In all cases, complete and return the enclosed Customer Confirmation Form via email to *[mail address of local distributor]* or via mail to *[address of local distributor]*

Transmission of the Medical Device Recall

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where affected devices have been transferred.

This action is being conducted after consultation with the competent authorities in Germany and Romania.

Please keep this information at least until this measure has been completed.

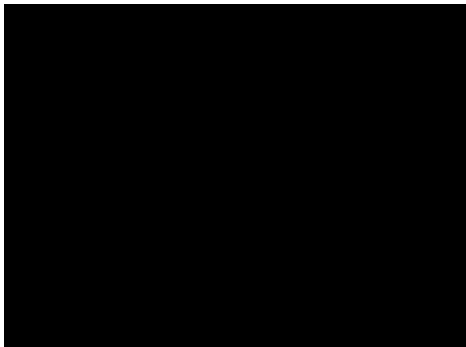


Contact Information

| | |
|--|--|
| <p>Legal Manufacturer</p> <p>botiss biomaterials GmbH Hauptstraße 28 15806 Zossen</p> <p>Contact person: Dr. Christiane Marinc Phone: +49 30 607398 eMail: siba@botiss.com</p> | <p>Local distributor</p> <p>MegaGen Dental Implant Delea Noua nr 38, sector 3 030925 Bucuresti, Romania</p> <p>contact person: <i>[name, phone, email of contact person]</i></p> |
|--|--|

We apologize for any inconvenience that this may cause.

Kind regards,





botiss biomaterials GmbH
Hauptstr. 28
15806 Zossen
Germany

Tel.: +49 33769 / 88 41 985
Fax: +49 33769 / 88 41 986
contact@botiss.com
www.botiss.com

Amtsgericht Potsdam
HRB 27418 P, UID: DE263026844
Managing Partner: Oliver
Bielenstein, Dr. Drazen Tadic

Berliner Volksbank
IBAN: DE38100900002157239000
BIC: BEVODEBBXXX
Visa, MasterCard, PayPal



CUSTOMER CONFIRMATION FORM

Please return this form within 7 days after receipt!

| Instructions: Complete form and mail to: MegaGen Dental Implant <i>[c/o contact person]</i> Delea Noua nr 38, sector 3 030925 Bucuresti, Romania <i>[email address]</i> | Contact Category: <input type="checkbox"/> Initial Contact <input type="checkbox"/> 2 nd Contact <input type="checkbox"/> 3 rd Contact | | | | | | | | |
|---|---|--------------|-------------------|-------------|------------------|------|-----------|------------|-------------------|
| Field Action Identification Number: <i>[FSCA Number if available]</i> | Date: | | | | | | | | |
| Our records indicate you have x pieces of the following affected product: | | | | | | | | | |
| <table border="1"><thead><tr><th>Product code</th><th>Batch number</th><th>Expiry date</th><th>Date of shipping</th></tr></thead><tbody><tr><td>1811</td><td>20JA50080</td><td>30.09.2021</td><td><i>xx.xx.xxxx</i></td></tr></tbody></table> | | Product code | Batch number | Expiry date | Date of shipping | 1811 | 20JA50080 | 30.09.2021 | <i>xx.xx.xxxx</i> |
| Product code | Batch number | Expiry date | Date of shipping | | | | | | |
| 1811 | 20JA50080 | 30.09.2021 | <i>xx.xx.xxxx</i> | | | | | | |
| Customer: <i>[details of customer]</i> | | | | | | | | | |

Section to be completed by Customer:

| |
|--|
| Status of Affected Product(s): I have received the notice concerning the Filed Corrective Action and (please check all that apply): <input type="checkbox"/> A total of _____ unused packages of cerabone® plus are being returned to MegaGen <input type="checkbox"/> A total of _____ pieces of cerabone® plus have been used and will not be returned. <input type="checkbox"/> I confirm that not of this FSCA has been added to the patient's medical history file. |
|--|

Print Name: _____

(Name and title)

Signature/ Date: _____

Phone / Fax/ E-mail: _____

For Internal Use Only (to be completed by local distributor):

| | |
|--------------------------|--------------------|
| Quantity received: _____ | Received by: _____ |
| Date received: _____ | (Print Name) |
| | Signature: _____ |

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IBAN: DE3810090002157239000
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Visa, MasterCard, PayPal



CUSTOMER TREATMENT OUTCOME FORM (to be completed only in case products were implanted)

Please return this form within 7 days after receipt!

| Instructions: Complete form and mail to: MegaGen Dental Implant <i>[c/o contact person]</i> Delea Noua nr 38, sector 3 030925 Bucuresti, Romania <i>[email address]</i> | Contact Category: <input type="checkbox"/> Initial Contact <input type="checkbox"/> 2 nd Contact <input type="checkbox"/> 3 rd Contact | | | | | | | | |
|---|---|--------------|-------------------|------------------|------|-----------|------------|-------------------|--|
| Filed Action Identification Number: <i>[FSCA Number if available]</i> | Date: | | | | | | | | |
| Our records indicate you have <i>x</i> pieces of the following affected product: | | | | | | | | | |
| <table border="1"><thead><tr><th>Product code</th><th>Batch number</th><th>Expiry date</th><th>Date of shipping</th></tr></thead><tbody><tr><td>1811</td><td>20JA50080</td><td>30.09.2021</td><td><i>xx.xx.xxxx</i></td></tr></tbody></table> | Product code | Batch number | Expiry date | Date of shipping | 1811 | 20JA50080 | 30.09.2021 | <i>xx.xx.xxxx</i> | |
| Product code | Batch number | Expiry date | Date of shipping | | | | | | |
| 1811 | 20JA50080 | 30.09.2021 | <i>xx.xx.xxxx</i> | | | | | | |
| Customer: <i>[details of customer]</i> | | | | | | | | | |

Section to be completed by Customer:

Date of surgery (mm/dd/yy) _____

Tooth position(s) _____

Indication where used (please describe) _____

Outcome of Surgery:

As expected

Not as expected, please explain _____



Print Name: _____
(Name and title)

Signature/ Date: _____

Phone / Fax/ E-mail: _____

For Internal Use Only (to be completed by local distributor):

| | |
|-----------------------|--------------------------------------|
| Date received: _____ | Received by: _____ (Print Name) |
| Follow-up call: _____ | Follow-up with _____ (Print Name) |
| Date of Call: _____ | |
| Comments: _____ | |