Attention: Health Care Distributor, Health Care Professional

IMPORTANT FIELD SAFETY NOTICE

Related to Field Safety Corrective Actions

Bonalive Biomaterials Ltd No., item reference number NC43/18

Affected Product	Catalogue Numbers	Lot Numbers
Bonalive® putty MIS, System pack (1 x 5 cc prefilled cartridge with dispenser)	18100	BM-03/18/9, BM-04/18/9
Bonalive® putty MIS, Single pack (1 x 5 cc prefilled cartridge)	18131	BM-03/18/9, BM-04/18/9

Dear Customer,
This action has been issued to ensure that users are aware of important Information concerning the devices listed above. You are required to read this Field Safety Notice and then sign and return the Customer Response Form (Page 3) confirming that you have completed the actions requested by the manufacturer.

Issue:

Batches BM-03/18/9 and BM-04/18/9 of the product Bonalive putty MIS have exceeded the upper specification limit for viscosity (during re-testing). The deficiency cannot be observed by eye. Increased viscosity can cause problems when extruding, for example, the cartridge may break by snapping or by cleavage. The likelihood of breakage rises significantly if the device is not used according to the guidance given in the IFU, which is to "gently press the dispenser trigger".

There are no performance issues with the implantable putty mass (*actual device*). Safety and efficacy of the actual device within the indications for use is not compromised (filling bony voids and gaps). Also, the bioactivity of the actual device is not compromised due to elevated viscosity. Therefore, it is not necessary to return the products. Also, the use of the product can continue, if the following precaution is taken:

- Gently press the dispenser outside of patient in order to see that putty mass starts to extrude from the cartridge (user instructions and illustration therein)

Bonalive Biomaterials Ltd has decided to temporarily discontinue shipping Bonalive putty MIS product, with the exception of deliveries to clinical studies, until corrections are made to the device. It is estimated that the implementation of improvement will take approximately 3-6 months to complete.

To date, Bonalive Biomaterials Ltd has received no reports of injuries or harm to patients or users of the device directly due to this issue.

The appropriate National Competent Authorities have been notified of this Field Safety Corrective Action.

Required actions:

1. Examine your inventory to determine whether you have any affected products.
2. Complete the attached Customer Reply Form confirming your receipt of this letter and examination of your stock. Send the Customer Reply Form to Bonalive at the e-mail address provided on the form. Even if you do not have any of the affected lots in your inventory, please complete the Customer Reply Form and return as indicated above.
3. Share this notice with all your customers / users of the product within your facility / distribution area to ensure awareness. Forward a copy of this Field Safety Notice to all relevant personnel within your organization or to any other organizations/persons to which/whom these devices might have been transferred.
4. There is no need to return the products unless this is requested by the local distributor or if it is the preference of the user to return the products. If products are not returned to Bonalive from the distributor / end user, the further deliveries from the distributor / use can continue only when end user has received the information of this Field Safety Notice and is aware of the increased risk of breakage.
5. Please inform Bonalive of any possible adverse events or breakages concerning the use of the subject devices.

   We request that you respond to this notice within 7 calendar days from the date of receipt.

Contact information:

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact her directly.

Company: Bonalive Biomaterials Ltd
Name: Lola Keskikallio
Position: Customer Service Coordinator
Telephone: +358 (0)401 77 4400
Email: lola.keskikallio@bonalive.com

On behalf of Bonalive Biomaterials Ltd we thank you sincerely for your help and support in completing this action by the target date and regret any inconvenience that may be caused. We would like to reassure you that Bonalive is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours Sincerely,

Karri Airola

Director Quality

bonalive

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Related to Field Safety Corrective Actions

Bonalive Biomaterials Ltd, item reference number NC43/18

CUSTOMER REPLY FORM

Please assist Bonalive Biomaterials by promptly returning this form

Cat. number	Lot	Product	Amount
18100	BM-03/18/9	Bonalive® putty MIS, System pack (1 x 5 cc prefilled cartridge with dispenser)	
18131	BM-03/18/9	Bonalive® putty MIS, Single pack (1 x 5 cc prefilled cartridge)	
18100	BM-04/18/9	Bonalive® putty MIS, System pack (1 x 5 cc prefilled cartridge with dispenser)	
18131	BM-04/18/9	Bonalive® putty MIS, Single pack (1 x 5 cc prefilled cartridge)	

Please complete and return this form to the e-mail below as confirmation that You have received this notification.
lola.keskikallio@bonalive.com

Facility Name	
Address	
Street	
City State / Country Zip	
Contact Name	
Title	
Phone Number	
Fax Number	
E-mail	

☐ We will return the abovementioned products to Bonalive.

☐ We will not return the abovementioned products to Bonalive. If we continue distribution / use of the product, the information provided in this FSN will be supplied to the end-user.

☐ We have no remaining inventory of the affected units.

Date: Signature:
Name in print:

E-mail to Bonalive Biomaterials Ltd at **lola.keskikallio@bonalive.com**