



<Customer address>

Field Safety Notice

Name of the affected product: 3M™ Lingual Retainer Wire,
Reference Number 260-032

FSCA-identifier: FSCA 2021-09 Lingual Wire

Type of action: Disposal of affected products

Date: September 23rd, 2021

Attention: 3M Health Care Business Customers

Dear Customer,

3M is notifying all users of the above-mentioned **3M™ Lingual Retainer Wire** of a field safety corrective action.

Details on affected devices:

The following lots of 3M™ Lingual Retainer Wire, Reference Number 260-032, are affected by this field action:

Affected Lots of Reference Number 260-032
KM7YQ
KN3RH
KP6QW
KV4DI
KV8GO

Description of the problem and potential hazard and risk for the patient/user:

During a recent quality investigation, 3M discovered that these lots of Lingual Retainer Wires underwent an incorrect manufacturing process step and as a result these wires are soft and do not keep their shape as intended. This issue should be recognized by the orthodontist already during application of the product. Because customers may be receiving a product that does not meet the specification, 3M is notifying all customers and asking them to dispose of the affected products in their inventory.

Please note that only the lot numbers detailed above are subject to this Field Safety Corrective Action Notification.

Action to be taken by the user:

All users of the **3M™ Lingual Retainer Wire** are being asked to take the following actions:

- Ensure all your internal and external customers are informed about this corrective action.
- Please identify the affected product listed above, remove from your inventory and do not use.
- Please discard all remaining affected product listed above per facility procedures.
- Complete and return by e-mail to meddev.utk@mmm.com the enclosed Acknowledgement Form, indicating that the corrective action was understood and executed. Please also indicate the number of devices you have disposed of.

Transmission of this Field Safety Notice:

Please pass on this notice immediately to all departments who might use the concerned products. In addition, ensure that the information is provided to any organisation where the concerned products potentially have been distributed.

Thank you for your immediate attention and cooperation. We apologise for any inconvenience this matter may cause.

Contact reference person:

If you have questions, please contact your local 3M representative.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Karin Watzek
Safety Officer
3M Deutschland GmbH, Health Care Business
Carl-Schurz-Strasse 1, 41453 Neuss, Germany
Mail: meddev.utk@mmm.com

Acknowledgement Form – FSCA 2021-09 Lingual Wire

Email completed form to: meddev.utk@mmm.com

Please examine your inventory to determine if you have any stock of the affected product lots indicated below. Note, this notification only applies to the indicated lots of 3M™ Lingual Retainer Wire, Reference Number 260-032.

☐ We have examined our inventory, identified the following quantity of units on hand and have disposed of them per facility protocol.

Affected Lot	Quantity of Units
KM7YQ	
KN3RH	
KP6QW	
KV4DI	
KV8GO	

☐ We have examined our inventory and do not have any above listed lot of 3M™ Lingual Retainer Wire, Reference Number 260-032, on stock.

☐ I acknowledge that I have read and understood this letter and will complete the actions requested.

Email completed form to: meddev.utk@mmm.com

Person completing this form:

Name		Company Name	
Signature		City, State, Country	
Date		Phone	
		E-mail	