

**To the attention of Medical Device Vigilance
Manager / Central Pharmacy**

Saint Priest, 20/02/2020

Subject: **URGENT - FIELD SAFETY NOTICE** – NEURAGEN 7MM NERVE GUIDE- Recall

Legal manufacturer:

Integra NeuroSciences PO Box 167 Carr. 402, KM 1.2 Añasco, P. R. 00610

EC Representative:

INTEGRA LIFESCIENCES (France) SAS – Immeuble Séquoia 2 – 97 Allée Alexandre Borodine – 69800 SAINT PRIEST.

Medical devices:

NeuraGen® nerve guide is an absorbable implant for the repair of peripheral nerve discontinuities. NeuraGen® nerve guide, provides a protective environment for peripheral nerve repair, after injury, and is designed to be an interface between the nerve and surrounding tissue and to create a conduit for axonal growth across a nerve gap. When hydrated, NeuraGen® nerve guide is an easy to handle, soft, pliable, nonfriable, porous collagen tube. NeuraGen® nerve guide is supplied sterile, nonpyrogenic, for single use in double peel packages in a variety of sizes.

Primary clinical purpose of device(s):

NeuraGen® nerve guide is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

Concerned reference:

Lot # 3388360

Dear Valued Customer,

The purpose of this letter is to inform you that Integra LifeSciences is voluntarily issuing a Field Safety Recall Notice for 7mm NeuraGen® Nerve Guide (Part # PNG720; Lot # 3388360).

Integra LifeSciences released one lot (lot # 3388360) of the NeuraGen® Nerve Guide, part number PNG720, that was out of specification for a finished goods release test used as a surrogate to predict product resorption once implanted. Because the product did not meet its release criteria, Integra LifeSciences has decided to voluntarily recall the impacted product.



Figure 1: The lot number is located on the white label on the front of the box

No serious injuries and/or deaths have occurred due to the failure mode associated with this recall. There have been no reported complaints.

The severity of harm has been assessed to be negligible. Medical and science personnel have evaluated the failure and concluded that there would be no immediate or long-term health impact to patients due to thermo-mechanical test results being slightly above threshold specification, and that this would pose no detectable risk to the repaired nerve. Additionally, time-based shelf-life predictive analysis indicates the product was likely within the required range at the time of release and subsequent use. All other finished good testing met the product acceptance criteria including the cytotoxicity testing for which results were found to be in the normal range.

The risks mentioned above have been assessed based on standard ISO 14971 and other applicable regulations listed in our internal procedures.

Because the time-based shelf-life predictive analysis indicates the product was likely within the required range at the time of release, there is no product failure anticipated to occur, and therefore no performance issues anticipated to be noticed during the progressive recovery of the nerve being treated with the NeuraGen® Nerve Guide. Integra does not recommend explantation for this issue. Explantation is always at the discretion of the health care professional.

Still, out of an abundance of caution, Integra LifeSciences has chosen to voluntarily recall the one lot of impacted product. The voluntary recall is limited to the part number with specific lot codes and expiration dates specified in this communication. No other products were impacted and should be used with confidence.

We are notifying you of the Field Safety Corrective Action as our records indicate that you have been supplied with:

Description of Concerned product	Reference	Concerned Lot Number	Manufacturing/ Distribution Dates	Expiration Date (MM/DD/YYYY)
NEURAGEN 7MM NERVE GUIDE	PNG720	3388360	01/18/19	01/31/2021

To mitigate the risk, we kindly ask you to:

- Identify Device
- Quarantine Device
- Return Device

Integra Customer Service or your sales representative will contact you upon receipt of this notice to organize the return of the concerned products (Return Merchandise Authorization number assignment).

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially concerned devices have been transferred. (As appropriate)

Please transfer this notice to other organizations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

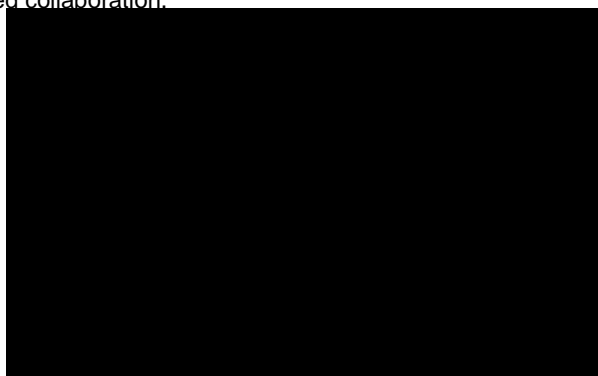
Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Customer reply is required. A form is attached to this Field Safety Notice. The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information. **We expect a response within 3 weeks.**

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

Please feel free to contact me at angelique.aubert@integralife.com for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,



Enclosed: Field Safety Notice Customer Reply Form (2 pages)

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-HHE-165-16122019
FSN Date*	20th of February 2020
Product/ Device name*	NEURAGEN 7MM NERVE GUIDE
Product Code(s)	PNG720
Batch/Serial Number (s)	3388360

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A	
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A	
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty: Qty: N/A	Lot/Serial Number: Lot/Serial Number: Comments:
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
<input type="checkbox"/>	Other Action (Define) :		
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A	
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	

Print Name*	Customer print name here
Signature*	Customer sign here
Date*	

4. Return acknowledgement to sender	
Email	emea-fsca-recon@integralife.com
Customer Helpline	+33 (0) 4 37 47 59 16
Postal Address	Regulatory Affairs Integra Immeuble Séquoia 2, 97 allées Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	www.integralife.eu
Fax	+33 (0)4 37 47 59 30
Deadline for returning the customer reply form*	16th of March 2020

Mandatory fields are marked with *

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

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