



CODE	UN169	ISSUE	02
DATE	05 SEPT 2016		
REVIEW PERIOD	2 YEARS	REVIEW DATE	SEPT 2018

FIELD SAFETY NOTICE – ISSUED ON 25 MAY 2017

Dear Customer

PRODUCT DESCRIPTION: Yellow Handled Sharp/Blunt Supasnip Scissors

REFERENCE CODE: F811004

LOT NUMBERS: ALL LOT NUMBERS

We have issued this Field Safety Notice in compliance with our Vigilance Procedure due to an issue that has been brought to the attention of Unisurge International Limited. It has been identified that a few of the scissors detailed above have brown marks on the yellow plastic handles. This has been investigated and the brown marks have been identified to be oily marks from the manufacturing process used by our supplier, which has discoloured during the sterilisation process. The oil is a lubricant used on the stainless steel blades during the manufacturing process. This is a cosmetic issue and does not affect the functionality of the product. The product is considered safe for use. As a result of the issues raised this Field Safety Notice has been issued to advise the end users of the situation.

We apologise for any inconvenience that this issue may cause. We are working with the MHRA to resolve the situation.

Please can you complete the attached documents and return by either of the following methods:

Fax – 08455 213210

Email – ks@unisurge.com

Please can you ensure these forms are returned **as soon as possible** but by **midday on Friday 9TH MAY 2017**.

Any queries or concerns regarding this notice should be addressed to:

KATHRYN SPARK – Quality Assurance & Regulatory Affairs Manager

Unisurge International Limited

E: ks@unisurge.com

T: 08455 213111 EXT 318



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ACTION TO BE TAKEN BY THE USER

1. Please **CHECK YOUR STOCK** of F811004 supplied by Unisurge International.
2. If you have stock of the **AFFECTED REFERENCE CODE, F811004**, and you are unhappy to use the product, please advise Unisurge using the attached form.
3. Ensure all relevant personnel are **AWARE OF THIS FIELD SAFETY NOTICE**.
4. **CONTACT UNISURGE** using the reply form on page 3 and provide us with all the relevant details if product requires uplifting.
5. We will arrange collection of the faulty stock once the details have been received.
6. Replacement stock of F811004 is currently unavailable but will be arranged once further stock is available and the information has been provided.
7. This notice should be passed on to all those who need to be aware of it within your organisation.

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

This notice has been notified to the appropriate Regulatory Agency and Competent Authority.

Signed:*K Spark*..... 25/05/17

Mrs Kathryn Spark
Regulatory Affairs & Quality Assurance Manager



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REPLY FORM

HOSPITAL / ORGANISATION	
NAME (please print)	
POSITION	
TELEPHONE NUMBER	
EMAIL ADDRESS	
DATE	

PRODUCT CODE	F811004
DESCRIPTION	Yellow Handled Supasnip Scissors
LOT NUMBER	All
QTY TO BE UPLIFTED	

NO OF CASES TO COLLECT	
COLLECTION ADDRESS	
COLLECTION CONTACT	
COLLECTION TEL NO	

PLEASE COMPLETE AND:

FAX TO 08455 213210 OR EMAIL TO ks@unisurge.com

BY MIDDAY ON FRIDAY 9TH MAY 2017