

## For Medical Products

C.R. 1010112398 A Limited Liability Co.  
Capital S.R. (34,500,000) Fully Paid

SMMP

رقم العضوية ٥٥٣٥٨

## السعودية للمنتجات الطبية

س.ت. ١٠١٠١١٢٣٩٨ شركة ذات مسؤولية محدودة  
رأس المال المدفوع (٣٤.٥٠٠.٠٠٠) ريال مدفوع بالكامل

**URGENT- FIELD SAFETY NOTICE**

Doc. # F-7-2-3-2

Date: 23-04-2018

Commercial Name of affected Product	Sterile Single Use Spinal needle with Introducer
Type of action	Recall
SMMP Reference	720-2490
Product Lot Nos	3j818F & K811

Dear Customers,

Saudi Mais Medical Products is issuing a recall for the above mentioned product.

**Description of the problem**

SMMP is recalling the product referenced above because the needle may not enter the introducer. This was identified that few introducers are packed with small hole size in which case function of spinal needle is expected to be compromised.

No patient injuries have been reported related to this product.

**FIELD SAFETY CORRECTIVE ACTIONS****ADVICE ON ACTION TO BE TAKEN BY MEDICAL AND INVENTORY STAFF**

We request you check your inventory for the product within the scope of this field action. Stop the distribution of stock of these both Lots and Quarantine immediately.

If these both lots are being in use by medical staff, it is advised to check carefully that the spinal needle is entered in introducer as in normal use.

In other case we recommend you to cease use of these lots and quarantine as our customer services will collect the affected products.

We will be replacing the remaining effected quantities with the good one.

Your assistance is appreciated and we apologize for any inconvenience in this situation

Factory : 3rd Industrial Area, Al-Kharj Road, Street No.: 256  
P.O. Box : 3900 - Riyadh 14335 - 7599 - Saudi Arabia  
Tel.: +966 11 2650184 - Fax : 2650139  
Riyadh Branch (011) 2650184  
Jeddah Branch (012) 6897262  
Dammam Branch (013) 8435088  
Madina Branch (Tel/Fax) (014) 8486894  
Qassem Branch (Tel/Fax) (016) 3262781



E-mail : medical@mais.com.sa  
Website : www.mais.com.sa

المصنع : المملكة العربية السعودية - الرياض - المنطقة الصناعية الثالثة  
طريق الخرج شارع رقم: ٢٥٦ ص.ب. ٣٩٠٠ - الرياض ١٤٣٣٥-٧٥٩٩  
هاتف : ٢٦٥٠١٨٤ ١١ ٩٦٦ - فاكس : ٢٦٥٠١٣٩  
فرع الرياض هاتف ٢٦٥٠١٨٤ (٠١١)  
فرع جدة هاتف ٦٨٩٧٢٦٢ (٠١٢)  
فرع الدمام هاتف ٨٤٣٥٠٨٨ (٠١٣)  
فرع المدينة (تليفاكس) ٨٤٨٦٨٩٤ (٠١٤)  
فرع القصيم (تليفاكس) ٣٢٦٢٧٨١ (٠١٦)

## For Medical Products

SMMP

## السعودية للمنتجات الطبية

C.R. 1010112398 A Limited Liability Co.

Capital S.R. (34,500,000) Fully Paid

رقم العضوية ٥٥٣٥٨

س.ت ١٠١٠١١٢٣٩٨ شركة ذات مسؤولية محدودة  
رأس المال المدفوع (٣٤,٥٠٠,٠٠٠) ريال مدفوع بالكامل

## Transmission of this Field Safety Notice:

This Notice should be passed on to all persons who need to be aware within your organization and in any other organization where the potentially affected products have been transferred. Supply chain / distribution centers, practitioners will be considered in circulating this Notice.

## Confirmation of National Competent Authority:

kindly note that this recall is made with the cooperation of Saudi food and drug authority because there are some remarks on the product.

## Contact Person Reference:

Mr. Badea Manar (Sales In-Charge)

Tel: 966-11-2650184

Email: [medical@mais.com.sa](mailto:medical@mais.com.sa)

Saudi Mais Medical Products is committed to providing High quality, safe and effective products and always looking for a high-level customer satisfaction. We sincerely apologies for any inconvenience.

Factory : 3rd Industrial Area, Al-Kharj Road, Street No.: 256  
P.O. Box : 3900 - Riyadh 14335 - 7599 - Saudi Arabia  
Tel.: +966 11 2650184 - Fax : 2650139  
Riyadh Branch (011) 2650184  
Jeddah Branch (012) 6897262  
Dammam Branch (013) 8435088  
Madina Branch (Tele/Fax) (014) 8486894  
Qassem Branch (Tel/Fax) (016) 3262781



E-mail : [medical@mais.com.sa](mailto:medical@mais.com.sa)  
Website : [www.mais.com.sa](http://www.mais.com.sa)

المصنع : المملكة العربية السعودية - الرياض - المنطقة الصناعية الثالثة  
طريق الخرج شارع رقم: ٢٥٦ ص.ب ٣٩٠٠ - الرياض ١٤٣٣٥-٧٥٩٩  
هاتف : ٢٦٥٠١٨٤ ١١ ٩٦٦ - فاكس : ٢٦٥٠١٣٩  
فرع الرياض هاتف ٢٦٥٠١٨٤ (٠١١)  
فرع جدة هاتف ٦٨٩٧٢٦٢ (٠١٢)  
فرع الدمام هاتف ٨٤٣٥٠٨٨ (٠١٣)  
فرع المدينة (تليفاكس) ٨٤٨٦٨٩٤ (٠١٤)  
فرع القصيم (تليفاكس) ٣٢٦٢٧٨١ (٠١٦)