

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



رقم العضوية ٥٥٣٥٨



س.ت ١٠١٠١٢٣٩٨ شركة ذات مسؤوليـــة مـحــــدودة رأس المال المدفوع (٣٤.٥٠٠.٠٠٠) ريــال مــدفوع 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
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 3262781

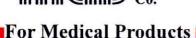


E-mail: medical@mais.com.sa Website: www.mais.com.sa المصنع: المملكة العربية السعودية - الرياض - المنطقة الصناعية الثالثة طريق الخسرج شارع رقم: ٢٥٦ ص.ب ٣٩٠٠ - السرياض ٧٩٩٩-١٤٣٣٥ هـ اتفاق ٢٩٠٠ - السرياض ٢٥٠١٣٩ المرادة ١٤٣٥-٢٦٥٠ هـ اتفاق المرادة ١٤٣٥-٢٦٥٠ المرادة المر

__رع الري___اض هاتف ٢٦٥٠١٨٤ (٠١١)

رع المدينة (تبياكس) ١٩٨٢٨٩٨ (١١٤)

_رع القصيم اللبناكس ٢٢٦٢٧٨١ (١٦٠)







السعودية للمنتجات الطبية

س بن ۱۰۱۰۱۲۳۹۸ شرکة ذات مسؤوليــــة محـــــدودة رأس المال المدفوع (۲۲٬۰۰۰٬۰۰۰) ريــال مــدفوع بالكامل

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رقم العضوية ٥٥٣٥٨

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

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.

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المصنع: المملكة العربية السعودية - الرياض - المنطقة الصناعية الثالثة طريق الخسرج شارع رقم: ٢٥٠ ص.ب ٢٩٠٠ - السرياض ٥٩٥٧-١٤٣٣٥ هـ الشرياض ٥٩٥٧-٢٦٠١٣٩ هـ الشرياض ١٤٠٠١٣٩ في المرياض ١٤٠٠١٣٩ في المرياض ١٤٠٠١٣٩ في المريان المري

رع الريـــاض هاتف ٢٦٥٠١٨٤ (٠١١)

نے رع جے دہ هاتف ۲۲۷۹۸۲ (۱۲۰) نے رع الدم ام هاتف ۸۵۳۵۸۸ (۱۳۰)

رع المدينة (تليناكس) ٨٤٨٢٨٩٤ (١١٤)

رع القصيم اللبناعي ٢٨٢٧٧١ (١١٠)