

**URGENT : MEDICAL DEVICE RECALL**  
**DR WOUND NANO SILVER SPRAY**  
**MDA NO. : GC3497719-26935**

(See enclosed Product Label)

**Attention To : All Distributors and Customers.**

Dear Device Distributor and Customer,

06<sup>th</sup> June 2024

The purpose of this letter to advise you that Farmasia Sdn. Bhd. Is voluntarily recalling the Product Dr Wound Nano Silver Spray. Product detail as follows:

**Product Name** : Dr Wound Nano Silver Spray  
**MDA No.** : GC3497719-26935  
**Intended Use** : Dr Wound Nano Silver Spray is intended as wound rinsing and cleansing spray solution for cleaning all types of wounds. Its is also non-irritant and suitable for all types of wounds.

This recall falls under *Class II – Medium Risk* and is initiated voluntarily due to a **Contamination Problem - Code A18**. The issue may pertain to the stability issue of the raw material nano colloidal silver stock used, resulting in the agglomeration of silver particles, subsequently diminishing the concentration of silver and causing microbial levels to surpass the specified limit of <10 CFU/mL. This could potentially affect the device's performance or intended use. On June 5th, 2024, we received a retested Microbial Limit Test (MLT) report for batch 24JL0042, indicating microbial growth was detected on the device. However, the issue remains under investigation.

The effect of the microbial contamination in Dr Wound Nano Silver Spray, batch 24JL0042 however has not yet been studied and could possibly cause temporary or reversible health consequences. Nevertheless, to current date, Dr Wound Nano Silver Spray, batch 24JL0042 have not received any complaints and has no reported adverse event associated to this issue.

Consequently, we would like to immediately execute product recall for mentioned device manufactured and distributed as following details:

**Product Name** : Dr Wound Nano Silver Spray 50mL  
**Product Identifier** : FFP005.050  
**Batch No** : 24JL0042  
**Manufacturing Date** : 05/2024  
**Expiry Date** : 05/2027  
**Quantity** : 2748

A total of 888 from 2748 units have been packaged as promotional packs (Dr Wound Mini Twin Pack, Batch P24J011) alongside another device named Dr Wound BioHeal Gel, bearing the MDA No GC7343919-29139, which are unaffected by this recall.

As a responsible manufacturer, we are committed ensuring the safety and quality of our products is of paramount importance to us, and upon discovering this issue, we have taken immediate action to address it. We urge you to discontinue distributing of Dr Wound Nano Silver Spray of the said batch and to return any remaining units to Farmasia Sdn Bhd. Additionally, we urge you to notify any customers or end-users who may have purchased this batch of the product to cease its use and return it to you for further action.

This recall should be carried out to the retail level and recalled product shall be returned to Farmasia Sdn Bhd. For end-user level, kindly discontinue use or discard the product.

Kindly complete and return the enclosed return response form as soon as possible (*See attachment*). Your cooperation is highly appreciated and necessary to prevent any further consequences from the authority. Should you have any questions, kindly contact us through contact details below:

Name : Nurul Asikin Mohamad Rapi  
Contact No : 03 – 8925 1888  
Email : asikin@farmasia.com.my  
Address : Farmasia Sdn Bhd  
B2-2, Block Ribosom, UKM-MTDC Technology  
Centre, 43650 Dengkil Selangor

*Note : This recall is being made with the knowledge of the Medical Device Authority (MDA).*

Authorised by:



Name : Wan Rizzal Bin Wan Zaki  
Title : General Manager  
Contact No. : 03 – 8925 1888  
Email : rizzal@farmasia.com.my

**MEDICAL DEVICE RECALL RETURN RESPONSE**  
**Acknowledgement and Receipt Form**  
Response is required

**Customer Information :**

Customer Name :  
Address :

Product Name : Dr Wound Nano Silver Spray  
Lot/Serial numbers : 24JL0042  
MDA No. : GC3497719-26935

1) I have read and understand the recall instructions provided in the 06<sup>th</sup> June 2024 letter.

Yes  
 No

2) Any adverse incidents associated with recalled product?

Yes  
 No

If yes, please explain:

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Affected product information:

Affected Product Information Table			
Product Name	Manufacturer's Product number	Lot No/Batch No	Quantity
Dr Wound Nano Silver Spray	FFP005.050	24JL0042	2748

**Return Response Box :**

**PLEASE RETURN COMPLETED RESPONSE FORM TO :**

Name : Nurul Asikin Mohammad Rapi  
Contact No. : 03-89251888  
Email : [asikin@farmasia.com.my](mailto:asikin@farmasia.com.my)

**OR MAIL TO :**

Address : Farmasia Sdn. Bhd.  
B2-2, Blok Ribosom, UKM-MTDC Technology Centre, 43650, Bandar Baru Bangi,  
Selangor Darul Ehsan.





06<sup>th</sup> June 2024

**URGENT - Field Safety Notice**

To all distributors and customers of the Dr Wound Nano Silver Spray

**Re: Dr Wound Nano Silver Spray with Contamination Problem**

Dear distributor and customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using Dr Wound Nano Silver Spray with the following details:

Product Number	Lot Number	Manufacturing Date	Expiration Date	Quantity
FFP005.050	24JL0042	05/2024	05/2027	2748

Please note that a total of 888 from 2748 units has been packaged as promotional packs (Dr Wound Mini Twin Pack, Batch P24J011) alongside another device named Dr Wound BioHeal Gel, bearing the MDA No GC7343919-29139, which are unaffected by this recall.

**When does this malfunction occur and what are the potential risks?**

The issue may pertain to the stability issue of the raw material nano colloidal silver stock used, resulting in the agglomeration of silver particles, subsequently diminishing the concentration of silver and causing microbial levels to surpass the specified limit of <10 CFU/mL. This could potentially affect the device's performance or intended use. On June 5th, 2024, we received a retested Microbial Limit Test (MLT) report for batch 24JL0042, indicating microbial growth was detected on the device. However, the issue remains under investigation.

The effects of the microbial contamination in Dr Wound Nano Silver Spray however have not yet been studied and could possibly cause temporary or reversible health consequences; or there is remote probability that the device will cause serious consequences. Nevertheless, to current date, Dr Wound Nano Silver Spray has not received any complaints and has no reported adverse event associated to this issue.

**What steps can the user take to avoid the potential risk of this issue?**

- Immediate stop and discontinuance of the Dr Wound Nano Silver Spray usage.
- Return the remaining stock of Dr Wound Nano Silver Spray to the Manufacturer.
- Seek medical attention if any adverse reaction is observed.

**How will the issue finally be resolved?**

Farmasia Sdn Bhd continues to investigate the underlying cause of the contamination matter. Presently, we urge customers to cease usage and dispose of the affected batch.

If you have sold/distributed this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority (MDA)** will be informed of this notice.

Sincerely Yours,  
For and on behalf of FARMASIA SDN. BHD.



**WAN RIZZAL BIN WAN ZAKI**  
GENERAL MANAGER

Contact person of this notification:  
Nurul Asikin Mohammad Rapi  
Telephone : 03- 89251888  
E-mail: [asikin@farmasia.com.my](mailto:asikin@farmasia.com.my)