

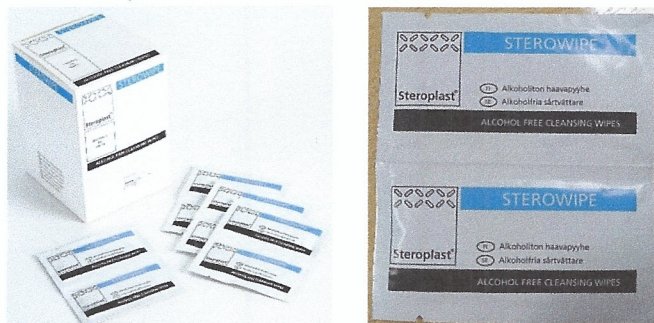
August 2025

Urgent Field Safety Notice **SH2025-01**

Device Information	
Name:	Sterowipe Alcohol Free Cleansing Wipe (Non-Sterile)
Product Code(s)	8021 & 8021B
Lot Number (s)	All lots currently on the market
Manufacturer Name	Steroplast Healthcare Ltd

For the Attention of: Quality Personnel
FSN Ref: SH2025-01

Product Description: The Sterowipe Alcohol Free Cleansing Wipes are individually wrapped cleansing wipes, with a formulation consisting of water, 0.2% Cetrimide, and 0.02% Chlorhexidine Gluconate. They may be provided in a box of 100, or loose in other amounts (bulk box of 2000, etc.).



Product Issue: The UKHSA has found a potential link between an outbreak of *Burkholderia Stabilis*, and non-sterile, Alcohol Free Cleansing Wipes of varying brands.

Potential Risks: *Burkholderia Stabilis* is a bacteria that can cause infection when introduced into the bloodstream. In some individuals, it can lead to more severe complications. At time of writing, there have been 51 confirmed cases of infection in the UK, dated between June 2018 and April 2025. The risk increases if the non-sterile wipes are used as not intended e.g. if used to cleanse wounds or are used to clean intravascular devices.



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Steroplast's Actions:

Steroplast has investigated the potential contamination issue and, though there has been no confirmed link between any outbreak cases and our wipes, we have decided to issue this Field Safety Notice.

As these wipes are not sterile, we cannot guarantee that the wipes will be free of this bacteria. Steroplast has made the decision to discontinue the non-sterile Alcohol Free wipes and replace them with a **STERILE alcohol free wipe (Product code: 9021)**.

Steroplast has stopped sale of the Sterowipe non-sterile Alcohol Free Wipes, and are notifying all customers who have purchased these wipes of the potential issue.

We require all customers to take the following actions.

Customer Actions Needed:

1. Reply to the email address that sent you this notification, and acknowledge receipt of this Field Safety Notice. Please send confirmation of receipt within 3 days.
2. Inspect your inventory and immediately remove from sale all Sterowipe non-sterile Alcohol Free Wipes.
3. Complete Appendix A below and return to the below email address. Steroplast will advise when you can expect replacement sterile wipe stock to be sent to you.
4. Forward this Field Safety Notice to others in your organisation who need to be made aware of its contents.
5. Forward the details in this Field Safety Notice to any non-end-user customers that you have provided with Sterowipe non-sterile Alcohol Free Wipes. The information from your customers (amounts of wipes, lot numbers) should be gathered and sent to Steroplast.
6. End users should be advised to dispose of the stock.

Please respond even if you do not have any Sterowipe non-sterile Alcohol Free Wipes in stock, so that we can keep our records up to date, and reduce the need to send reminder notices.

The Contact information for Steroplast is listed below. If you have any queries regarding this matter, please do not hesitate to contact us.

Email Address: wipesFSN@steroplast.co.uk

We confirm that this FSN has been notified appropriately to the competent authority in your country.

Steroplast Healthcare Ltd are committed to ensuring the high quality of our devices. We thank you for your help and support in completing these actions, and apologise for any inconvenience caused.

Sincerely,

Afzal Ramzan
Operations Director

Steroplast Healthcare Limited, Alpha Point, Bradnor Road, Manchester M22 4TE England
Tel: 0161 902 3030 Email: enquiries@steroplast.co.uk Web: www.steroplast.co.uk

Directors: AC Brown (MD), A Ramzan, J Williams Registered No: 504340



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Attachment: Appendix A – Reply Form

Appendix A
Reply Form SH2025-01

Device Information	
Name:	Sterowipe Alcohol Free Cleansing Wipe (non-sterile)
Product Code(s)	8021 & 8021B
Lot Number (s)	All lots currently on the market
Manufacturer Name	Steroplast Healthcare Ltd

Response is required. Please complete and sign this form, and return it by email to the address listed in the Field Safety Notice.

- ☐ We confirm that we have checked our inventory and removed all Sterowipe non-sterile Alcohol Free Wipes from sale (please fill out table 1 below).
- ☐ We have no Sterowipe non-sterile Alcohol Free Wipes in our inventory.
- ☐ We have passed the attached Field Safety Notice details to all our non-end user customers that have purchased Sterowipe non-sterile Alcohol Free Wipes. We will gather the information from our customers, and provide this to Steroplast so that they can send us the replacement wipes to distribute.

Table 1

Product Type	Number in Stock	Batch & Expiry details
8021 (Box of 100)		
8021B (Bulk carton of 2000)		
Single Wipes		
Other (please specify):		

I confirm that I have read and understood the instructions provided. I have carried out steps 1-6 of the Field Safety Notice SH2025-01, and removed all of the potentially affected wipes from sale. This letter has been circulated internally to all staff that need to be aware of its contents, and externally to customers as advised. I agree to communicate any information received from these customers to Steroplast Healthcare as required, and to perform at least 2 attempts to contact non-responsive customers.

Form completed by:

Company Name: _____
 Contact Name: _____
 Title: _____
 Email: _____
 Date: _____
 Signature: _____

Steroplast Healthcare Limited, Alpha Point, Bradnor Road, Manchester M22 4TE England

Tel: 0161 902 3030 Email: enquiries@steroplast.co.uk Web: www.steroplast.co.uk

Directors: AC Brown (MD), A Ramzan, J Williams Registered No: 504340



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