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Alcon

URGENT: FIELD SAFETY NOTICE	
Description	**Field Safety Notice for Specific Lots of Alcon Custom Pak® containing 3M™ Steri-Drape™ Surgical Drapes**
Product Affected	**Alcon Custom Pak®**
Market Action Identifier	**2022.017**

October XX, 2022

«Account_Name»
«Account_Address»
«City», «State» «Zip_Code»

Dear Healthcare Professional,

This letter serves to advise you that Alcon has initiated a Voluntary Medical Device Field Correction for specific lots of Alcon Custom Pak® containing 3M™ Steri-Drape™ Surgical Drapes. Alcon received notice of a product recall from our vendor, 3M, regarding their Steri-Drape™ Surgical Drapes, which are included in specific lots of Alcon Custom Pak®.

3M has requested that customers not use and dispose of the recalled drape. Alcon is asking all affected customers to remove the surgical drape when opening your affected Custom Pak®, and replace with sterile, stand-alone drape, either from your own inventory or those provided by Alcon.

Reason for the Voluntary Medical Device Field Correction:

Based on the notification received from 3M, the 3M™ Steri-Drape™ Surgical Drape recall is due to difficulty removing the liner on the adhesive component of the affected drapes without damaging the product and may render the product unusable. Additionally, 3M has observed an increase in reported adhesive related skin injuries for these affected lots. To date, Alcon has received no reports of patient or user harm related to this issue.

Since the adhesive liner of the 3M™ Steri-Drape™ Surgical Drape does not interface with any other components within the Alcon Custom Pak®, and the drape can be easily removed from the paks upon opening, the remaining components of the Alcon Custom Pak® can be used for their intended surgical procedure.

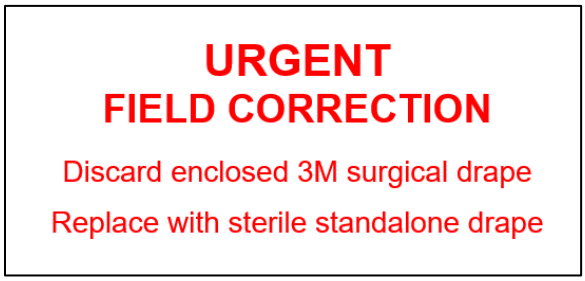
Alcon

Actions to be taken by the Customer / User:

Our records indicate that you have received or may receive an Alcon Custom Pak® with an affected lot number. Please see '*Table 1: Affected Lots of Alcon Custom Pak®*'. We are asking that, upon opening your Custom Pak® for surgical use, you remove and dispose of the surgical drape contained within your specific lot(s) of Alcon Custom Pak® in accordance with the instructions below. **NOTE: Alcon Custom Pak® units and standalone drapes are sterile and should not be opened prior to surgery. The remaining components of the Alcon Custom Pak® are unaffected by this Voluntary Medical Device Field Correction and can be used as intended.**

To assist in this Voluntary Medical Device Field Correction, please take the following steps:

1. Forward this notification to all departments or organizations using your Custom Pak®.
2. See *Table 1* for list of affected Alcon Custom Pak® lots that were distributed to your facility. You may receive Custom Pak® lots assembled prior to this Field Correction notification, and as a result, you may be receiving affected inventory in future shipments. If you receive any affected Alcon Custom Pak® lots in the future, they will be identified by a sticker.



3. Review your inventory of Alcon Custom Pak® lots against the attached table. For affected lots of Custom Pak® in your inventory, affix the provided stickers directly to the outside of your identified affected Custom Pak® units in a location most easily seen for your facility. ***NOTE: Alcon Custom Pak® units and standalone drapes are sterile and should not be opened prior to surgery.***
4. For your current on-hand affected inventory, upon opening of your identified Alcon Custom Pak® for surgical use, remove and dispose of the enclosed 3M™ Steri-Drape™ Surgical Drape. Please call Alcon Customer Service (<<insert local contact info>>) if you need help obtaining replacement sterile standalone drapes.
5. Use a separate sterile standalone surgical drape, either from your own inventory or those supplied by Alcon. For impacted Custom Pak® inventory that will ship in the future, Alcon is planning to ship sterile stand-alone substitutions.
6. Please complete the attached *"Response Form"* indicating your understanding of the included instructions.
7. **Please return the attached "*Response Form*" via fax or email to Alcon.**
8. Keep *Table 1* for your records should you receive any affected Alcon Custom Pak® lots in the near future.

Alcon

In the notification, 3M states that it will not be supplying replacement inventory. If you need to request replacement drapes for any of those impacted Custom Pak® lots, please call Alcon Customer Service (<<insert local contact info>>). Alcon is working diligently to fulfill these orders, but please note that sterile stand-alone drape inventory is very limited at this time. For impacted Custom Pak® inventory that will ship in the future, Alcon is planning to ship sterile stand-alone substitutions.

In the event you have experienced adverse events or product quality issues related to this communication, please contact Alcon via email (<<insert local contact info>>) or by phone (<<insert local contact info>>).

Adverse reactions or quality problems experienced with the use of this product may be reported to the (<<insert local Health Authority name here>>) Adverse Event Reporting program either online, by regular mail or by fax at (<<insert local Health Authority Adverse Event reporting contact info>>).

Should you have any questions or concerns about this matter, or if you would like to receive a copy of the 3M recall notification, please feel free to call our Customer Service or contact your Alcon Sales Representative.

Sincerely,

(<<insert local QA contact info>>)

Alcon

Table 1: Affected Lots of Alcon Custom Pak®

Custom Pak® #	Custom Pak® Description	Lot Number(s)
«Custom Pak #»	«Custom Pak Description»	«Custom Pak lot #»

If you have any questions about the lots you have in inventory, please feel free to call our Customer Service at <<insert local contact info>> *or contact your Alcon Sales Representative.*

Insert local letterhead

Alcon

RESPONSE FORM

MA 2022.017 **Field Safety Notice for Specific Lots of Alcon Custom Pak® containing 3M™ Steri-Drape™ Surgical Drapes**	«Account_Name» «Account_Address» «City», «State» «Zip_Code» «Telephone_Number» Account «Account #»

Please follow these important steps:

1. Forward this notification to all departments or organizations using your Alcon Custom Pak®.
2. See *Table 1* for list of affected Alcon Custom Pak® lots that were distributed to your facility. You may receive Custom Pak® lots assembled prior to this Field Correction notification, and as a result, you may be receiving inventory in future shipments. If you receive any affected Alcon Custom Pak® lots in the future, they will be identified by a sticker on the pack.
3. Review your inventory of Alcon Custom Pak® lots against the attached table. For Custom Pak® in your inventory, affix the provided stickers directly to the outside of your identified affected Custom Pak® units in a location most easily seen for your facility.
   NOTE: Alcon Custom Pak® units and standalone drapes are sterile and should not be opened prior to surgery.
4. Upon opening of your identified Alcon Custom Pak® for surgical use, remove and dispose of the enclosed surgical drape.
5. Use a separate sterile standalone surgical drape, either from your own inventory or those supplied by Alcon.
6. Please complete and return this *"Response Form"* indicating your understanding of the included instructions.
7. Keep *Table 1* for your records should you receive any affected Alcon Custom Pak® lots in the near future.

Fax: <<insert local contact info>> **Email**: <<insert local contact info>>

Your signature below attests that you have read and understood Alcon's request and instructions.

Signature of Facility Representative:
Printed Name and Title:
Date:

Include local Letterhead

COMMUNICATION OF FIELD SAFETY NOTICE FROM 3M IMPACTING ALCON CUSTOM-PAK™	
Description	**3M™ Steri-Drape™ Surgical Drapes Field Safety Notice affecting Specific Lots of Alcon Custom Pak®**
Product Affected	**3M™ Steri-Drape™ Surgical Drapes**
Market Action Identifier	**2022-10 FSCA Steri-Drape**

October XX, 2022

«Account_Name»
«Account_Address»
«City», «State» «Zip_Code»

Dear Healthcare Professional,

This letter serves to advise you of a Voluntary Medical Device Field Correction initiated by 3M that impacts specific lots of Alcon Custom Pak® that contain 3M™ Steri-Drape™ Surgical Drapes.

Alcon received notice of a product recall from 3M, manufacturer of Steri-Drape™ Surgical Drapes, which are included in specific lots of Alcon Custom Pak®. 3M has requested that customers not use and dispose of the recalled drape. Alcon is asking all affected customers to remove the surgical drape when opening your affected Custom Pak®, and replace with sterile, stand-alone drape, either from your own inventory or those provided by Alcon.

Reason for the 3M Voluntary Medical Device Field Correction:

Based on the notification received from 3M, the 3M™ Steri-Drape™ Surgical Drape recall is due to difficulty removing the liner on the adhesive component of the affected drapes without damaging the product and may render the product unusable. Additionally, 3M has observed an increase in reported adhesive related skin injuries for these affected lots. To date, Alcon has received no reports of patient or user harm related to this issue.

Since the adhesive liner of the 3M™ Steri-Drape™ Surgical Drape does not interface with any other components within the Alcon Custom Pak®, and the drape can be easily removed from the paks upon opening, the remaining components of the Alcon Custom Pak® can be used for their intended surgical procedure.

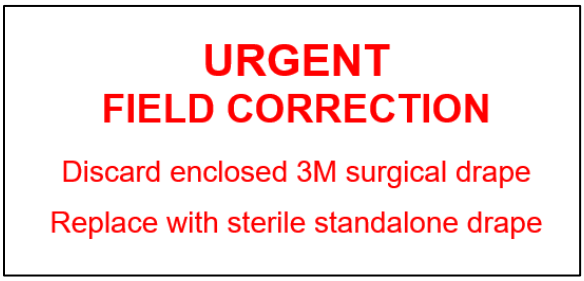
Alcon

Actions to be taken by the Customer / User:

Our records indicate that you have received or may receive an Alcon Custom Pak® with an affected lot number. Please see '*Table 1: Affected Lots of Alcon Custom Pak®*'. We are asking that, upon opening your Custom Pak® for surgical use, you remove and dispose of the 3M surgical drape contained within your specific lot(s) of Alcon Custom Pak® in accordance with the instructions below. **NOTE: Alcon Custom Pak® units and standalone drapes are sterile and should not be opened prior to surgery. The remaining components of the Alcon Custom Pak® are unaffected by this issue and can be used as intended.**

Please take the following steps:

1. Forward this notification to all departments or organizations using your Custom Pak®.
2. See *Table 1* for list of affected Alcon Custom Pak® lots that were distributed to your facility. You may receive Custom Pak® lots assembled prior to this Field Correction notification, and as a result, you may be receiving affected inventory in future shipments. If you receive any affected Alcon Custom Pak® lots in the future, they will be identified by a sticker.



3. Review your inventory of Alcon Custom Pak® lots against the attached table. For affected lots of Custom Pak® in your inventory, affix the provided stickers directly to the outside of your identified affected Custom Pak® units in a location most easily seen for your facility. ***NOTE: Alcon Custom Pak® units and standalone drapes are sterile and should not be opened prior to surgery.***
4. For your current on-hand affected inventory, upon opening of your identified Alcon Custom Pak® for surgical use, remove and dispose of the enclosed 3M™ Steri-Drape™ Surgical Drape. Please call Alcon Customer Service (<<insert local contact info>>) if you need help obtaining replacement sterile standalone drapes.
5. Use a separate sterile standalone surgical drape, either from your own inventory or those supplied by Alcon. For impacted Custom Pak® inventory that will ship in the future, Alcon is planning to ship sterile stand-alone substitutions.
6. Please complete the attached *"Response Form"* indicating your understanding of the included instructions.
7. **Please return the attached "*Response Form*" via fax or email to Alcon.**
8. Keep *Table 1* for your records should you receive any affected Alcon Custom Pak® lots in the near future.

Alcon

In the notification, 3M states that it will not be supplying replacement inventory. If you need to request replacement drapes for any of those impacted Custom Pak® lots, please call Alcon Customer Service (<<insert local contact info>>). Alcon is working diligently to fulfill these orders, but please note that sterile stand-alone drape inventory is very limited at this time. For impacted Custom Pak® inventory that will ship in the future, Alcon is planning to ship sterile stand-alone substitutions.

In the event you have experienced adverse events or product quality issues related to this communication, please contact Alcon via email (<<insert local contact info>>) or by phone (<<insert local contact info>>).

Adverse reactions or quality problems experienced with the use of this product may be reported to the (<<insert local Health Authority name here>>) Adverse Event Reporting program either online, by regular mail or by fax at (<<insert local Health Authority Adverse Event reporting contact info>>).

Should you have any questions or concerns about this matter, or if you would like to receive a copy of the 3M recall notification, please feel free to call our Customer Service or contact your Alcon Sales Representative.

Sincerely,

(<<insert local QA contact info>>)

Alcon

Table 1: Affected Lots of Alcon Custom Pak®

Custom Pak® #	Custom Pak® Description	Lot Number(s)
«Custom Pak #»	«Custom Pak Description»	«Custom Pak lot #»

If you have any questions about the lots you have in inventory, please feel free to call our Customer Service at <<insert local contact info>> *or contact your Alcon Sales Representative.*

Alcon

RESPONSE FORM

MA 2022.017 **Field Safety Notice for 3M™ Steri-Drape™ Surgical Drapes included in Specific Lots of Alcon Custom Pak®**	«Account_Name» «Account_Address» «City», «State» «Zip_Code» «Telephone_Number» Account «Account #»

Please follow these important steps:

1. Forward this notification to all departments or organizations using your Alcon Custom Pak®.
2. See *Table 1* for list of affected Alcon Custom Pak® lots that were distributed to your facility. You may receive Custom Pak® lots assembled prior to this Field Correction notification, and as a result, you may be receiving inventory in future shipments. If you receive any affected Alcon Custom Pak® lots in the future, they will be identified by a sticker on the pack.
3. Review your inventory of Alcon Custom Pak® lots against the attached table. For Custom Pak® in your inventory, affix the provided stickers directly to the outside of your identified affected Custom Pak® units in a location most easily seen for your facility.
   NOTE: Alcon Custom Pak® units and standalone drapes are sterile and should not be opened prior to surgery.
4. Upon opening of your identified Alcon Custom Pak® for surgical use, remove and dispose of the enclosed surgical drape.
5. Use a separate sterile standalone surgical drape, either from your own inventory or those supplied by Alcon.
6. Please complete and return this *"Response Form"* indicating your understanding of the included instructions.
7. Keep *Table 1* for your records should you receive any affected Alcon Custom Pak® lots in the near future.

Fax: <<insert local contact info>> **Email**: <<insert local contact info>>

Your signature below attests that you have read and understood Alcon's request and instructions.

Signature of Facility Representative:
Printed Name and Title:
Date: