



April 26, 2024

URGENT: VOLUNTARY RECALL:
RCM6 COLLAGEN MEMBRANE 30MM x40MM Part 5098000 Lot FG24020071

Dear Customer:

Please be advised that ACE Surgical Supply Co. has become aware that one lot of RCM6 Collagen Membrane 30MM X 40MM was packaged with a 20MM X 30MM size membrane. ACE Surgical Supply Co. is voluntarily recalling lot FG24020071 of RCM6 Collagen Membrane.

Reason for the RECALL:

The reason for the recall is that wrong size collagen membrane (20mm x 30mm) was mistakenly packaged in the RCM6 COLLAGEN MEMBRANE 30MM x40MM box, part number 5098000 lot FG24020071.

Type of Action by the Company:

ACE Surgical is contacting all customers who our shipping records confirmed your receipt of lot FG24020071 and request they return the product in question to ACE Surgical for a credit. If the product in question has been distributed to an end user, please reach out to them and instruct them to not use the product and have the product returned.

Risk to Health:

The collagen membrane 20mm x 30mm is the same material as the 30MM X 40MM but a smaller size. There is a risk that the doctor will not have enough material for desired outcome in performing a specific procedure.

The Collagen Membrane 20MM X 30MM, as a stand-alone product, poses no risk of harm to the patient.

Customer Actions to Be Taken:

Please refer to the lot number on the outer box label. The lot in question is FG24020071.

If you confirm this lot number on ACE Surgical Supply product, DO NOT USE THE PRODUCT and segregate it to prevent future use.

Please be advised that the recalled lot identified was from a specific batch produced in January 2024. If you have received this notification, our shipping records confirm that you received this specific batch that was affected.

All products subject to this RECALL will need to be returned to ACE Surgical.

Please complete the RESPONSE form and follow the instructions for submission.

Sincerely,

Jim Weatherby
Senior Quality Manager



RESPONSE FORM

Product and Distribution Information:

Product Name	Catalog Number	Lot Number	Expiration Date
RCM6 COLLAGEN MEMBRANE 30MM x40MM	5098000	FG24020071	2026-05-31

Please complete the response section below:

Please complete this section whether you have product to return or not and email or mail this form within 30 days of receipt to:

ACE Surgical
1034 Pearl Street
Brockton, MA 02301

Re: RCM6 Recall

Do you have any product as listed above in your facility inventory? **YES** NO

If you have product to return, please indicate quantity: 70 un.

Please have all product returned within 30 days.

Name of Practice Guillaume Rossi Account No. 708241

Email address fr.qualite@henryschein.fr

If you do have product to be returned, please return the response form to jenniferpage@acesurgical.com

If you do have inventory to return, once the response form is received and confirmed, an ARS Label will be issued.

If you have any further questions, please contact Jennifer Page 508-588-3100, Extension 718 or jenniferpage@acesurgical.com