

Manufacturer name:	Integra LifeSciences																																																																																									
About the Recall:	Integra LifeSciences has issued a voluntary recall of the MediHoney Wound & Burn products. Reason for Device Correction Packaging failures were identified related to the MediHoney Wound & Burn products, which could lead to a breach in the sterile barriers. Some of the identified failures are as follows: 1. Tube foil induction seal is not completely sealed to the tube 2. Inadequate sealing of sterile barrier packaging 3. Shipping boxed did not adequately protect device during transportation 4. Tube twist-off cap failure.																																																																																									
Products(s) numbers/models that are affected:	<table><tr><th>Manufacturer Product # (Catalog #)</th><th>Issue #</th><th>Product Name (Description)</th><th>UDI Number</th><th>Lot # Expiration Date</th><th>Distribution Dates (MM/DD/YYYY)</th></tr><tr><td>31515</td><td>1,2,3</td><td>MEDIHONEY TUBE - 1.5 FL OZ (44 ML) – W/APPLICATOR- STERILE</td><td>10381780486824</td><td>All unexpired lots</td><td>09/20/2021 to 03/28/2025</td></tr><tr><td>31535</td><td>1,2,3</td><td>MEDIHONEY TUBE - 3.5 FL OZ W/APPLICATOR - STERILE</td><td>10381780486831</td><td>All unexpired lots</td><td>07/14/2021 to 02/12/2025</td></tr><tr><td>31505</td><td>2, 3, 4</td><td>MEDIHONEY IN TUBE .5 FL OZ, TWISTOFF - STERILE</td><td>10381780486930</td><td>All unexpired lots</td><td>02/22/2022 to 03/26/2025</td></tr><tr><td>31612</td><td>2</td><td>MEDIHONEY HCS 8"X12" BURN DRESSING STERILE 1'S, 2/BOX X 5...PK:10/CS</td><td>10381780486947</td><td>All unexpired lots</td><td>03/18/2024 to 03/19/2025</td></tr><tr><td>31620</td><td>2</td><td>MEDIHONEY HYDROGEL 2.4" X 2.4" STERILE 1'S, 10/BOX X 5...PK:50/CS</td><td>10381780471370</td><td>All unexpired lots</td><td>03/26/2024 to 03/25/2025</td></tr><tr><td>31622</td><td>2</td><td>MEDIHONEY HYDROGEL 2.4" X 2.4" SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS</td><td>10381780471356</td><td>All unexpired lots</td><td>07/31/2023 to 07/30/2024</td></tr><tr><td>31640</td><td>2</td><td>MEDIHONEY HYDROGEL 4.3" X 4.3" STERILE 1'S, 10/BOX X 5...PK:50/CS</td><td>10381780471400</td><td>All unexpired lots</td><td>08/31/2023 to 03/24/2025</td></tr><tr><td>31644</td><td>2</td><td>MEDIHONEY HYDROGEL 4.3" X 4.3" SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS</td><td>10381780471363</td><td>All unexpired lots</td><td>07/31/2023 to 07/01/2024</td></tr><tr><td>31720</td><td>2</td><td>MEDIHONEY HYDROGEL 2.8" X 2.8" ADHESIVE STERILE 1'S, 10/BOX X 5...PK:50/CS</td><td>10381780471417</td><td>All unexpired lots</td><td>04/03/2023 to 03/24/2025</td></tr><tr><td>31722</td><td>2</td><td>MEDIHONEY HYDROGEL 2.8" X 2.8" ADHESIVE SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS</td><td>10381780471387</td><td>All unexpired lots</td><td>01/10/2024 to 01/27/2025</td></tr><tr><td>31738</td><td>2</td><td>MEDIHONEY HCS 3" X 8" STERILE 1'S, 10/BOX X 5...PK:50/CS</td><td>10381780486961</td><td>All unexpired lots</td><td>02/06/2025 to 03/13/2025</td></tr><tr><td>31740</td><td>2</td><td>MEDIHONEY HYDROGEL 4.5" X 4.5" ADHESIVE STERILE 1'S, 10/BOX X 5...PK:50/CS</td><td>10381780471424</td><td>All unexpired lots</td><td>07/05/2024 to 03/21/2025</td></tr><tr><td>31744</td><td>2</td><td>MEDIHONEY HYDROGEL 4.5" X4.5" ADHESIVE SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS</td><td>10381780471394</td><td>All unexpired lots</td><td>12/15/2023 to 11/28/2024</td></tr></table>						Manufacturer Product # (Catalog #)	Issue #	Product Name (Description)	UDI Number	Lot # Expiration Date	Distribution Dates (MM/DD/YYYY)	31515	1,2,3	MEDIHONEY TUBE - 1.5 FL OZ (44 ML) – W/APPLICATOR- STERILE	10381780486824	All unexpired lots	09/20/2021 to 03/28/2025	31535	1,2,3	MEDIHONEY TUBE - 3.5 FL OZ W/APPLICATOR - STERILE	10381780486831	All unexpired lots	07/14/2021 to 02/12/2025	31505	2, 3, 4	MEDIHONEY IN TUBE .5 FL OZ, TWISTOFF - STERILE	10381780486930	All unexpired lots	02/22/2022 to 03/26/2025	31612	2	MEDIHONEY HCS 8"X12" BURN DRESSING STERILE 1'S, 2/BOX X 5...PK:10/CS	10381780486947	All unexpired lots	03/18/2024 to 03/19/2025	31620	2	MEDIHONEY HYDROGEL 2.4" X 2.4" STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471370	All unexpired lots	03/26/2024 to 03/25/2025	31622	2	MEDIHONEY HYDROGEL 2.4" X 2.4" SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471356	All unexpired lots	07/31/2023 to 07/30/2024	31640	2	MEDIHONEY HYDROGEL 4.3" X 4.3" STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471400	All unexpired lots	08/31/2023 to 03/24/2025	31644	2	MEDIHONEY HYDROGEL 4.3" X 4.3" SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471363	All unexpired lots	07/31/2023 to 07/01/2024	31720	2	MEDIHONEY HYDROGEL 2.8" X 2.8" ADHESIVE STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471417	All unexpired lots	04/03/2023 to 03/24/2025	31722	2	MEDIHONEY HYDROGEL 2.8" X 2.8" ADHESIVE SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471387	All unexpired lots	01/10/2024 to 01/27/2025	31738	2	MEDIHONEY HCS 3" X 8" STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780486961	All unexpired lots	02/06/2025 to 03/13/2025	31740	2	MEDIHONEY HYDROGEL 4.5" X 4.5" ADHESIVE STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471424	All unexpired lots	07/05/2024 to 03/21/2025	31744	2	MEDIHONEY HYDROGEL 4.5" X4.5" ADHESIVE SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471394	All unexpired lots	12/15/2023 to 11/28/2024
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URL Link(s) to Manufacturer Notice/Web Site:	www.integralife.com																																																																																									

**Actions to be
taken by
customer/Patient:**

Please check your supplies and reference the product listing provided above, should you have product please contact Integra LifeSciences for replacement of product.

Integra LifeSciences may be contacted Monday – Friday 8:00 AM – 8:00 PM EST at 1-800-654-2873, or via email custsvcny@integralife.com