

November 24, 2025

**To:** International Distributors, Sales Representatives, and Distributor Operation Managers

**Subject:** **URGENT MEDICAL DEVICE RECALL**

**Affected Product: Zimmer Air Dermatome and Zimmer Dermatome AN**

Item Number	Item Description	GTIN Number	Serial Numbers
00-8801-001-00	Zimmer® Air Dermatome	00889024375901	See <b>Attachment 2 – Affected Product List</b> for the International Serial Numbers
88710100	Zimmer® Dermatome AN	00889024484834	



Zimmer Biomet is conducting a serial specific medical device recall for the Zimmer Air Dermatome and Zimmer Dermatome AN listed in **Attachment 2 – Affected Product List**. Multiple complaints have been received related to Air Dermatome devices that were cutting beyond the proper depth. Inspections of the returned complaint devices confirmed that affected devices may have a misaligned thickness control bar. If the device has a misaligned thickness control bar from manufacture, it would be expected to manifest such that any potential negative outcomes would be present upon the first few uses.

All devices manufactured between March 2023 and April 2025, that have not been returned for repair or preventive maintenance, are within scope of the recall. Your devices in scope will need to be returned for repair. Once the repair is completed, the devices will be provided back to you.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Tissue Damage, minor	Tissue damage, moderate
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Potential scarring due to gouging	Potential scarring due to gouging and/or second graft harvest

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between April 2023 and July 2025.



## Your Responsibilities

1. Review this notification and ensure that affected team members are aware of the contents.
2. Immediately locate and return all affected product from your region to the Dover repair center or to the certified repair center within your region.
  - a. Prior to returning your devices, obtain a Work Order number by emailing **Attachment 1 – Recall Response Form** to [dover.repairs@zimmerbiomet.com](mailto:dover.repairs@zimmerbiomet.com).
  - b. Submit completed **Attachment 1 – Recall Response Form** for each return to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com) and [dover.repairs@zimmerbiomet.com](mailto:dover.repairs@zimmerbiomet.com).
    - i. This form must be returned even if you do not have affected products available to return in your territory.
  - c. Request an IRA by emailing [zimmerbiometintlirarequests@zimmerbiomet.com](mailto:zimmerbiometintlirarequests@zimmerbiomet.com)
  - d. Include a hardcopy of **Attachment 1** in each carton of your return shipment for immediate processing.
  - e. Mark “RECALL” on the outside of the returned cartons.
3. Retain a copy of **Attachment 1** and product return forms for your records in the event of a compliance audit of your facility.
4. If you have further questions or concerns after reviewing this notice, please call customer service at 1-800-613-6131 between 8:00 a.m. and 5:00 p.m. EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com).

## Other Information

This recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Call: 1-800-332-1088 to request a reporting form
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing [product.experience@zimmerbiomet.com](mailto:product.experience@zimmerbiomet.com).

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. Your urgent cooperation is needed. The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

A handwritten signature in black ink that reads 'Stephanie Leppo'.

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Stephanie Leppo  
Quality Associate Director



**ATTACHMENT 1 - Recall Response Form**

**IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED**

**Affected Product:** Zimmer Air Dermatome and Zimmer Dermatome AN      **ZFA Number:** 2025-00141

Please fill out the below information in its entirety and send to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com) **and** [dover.repairs@zimmerbiomet.com](mailto:dover.repairs@zimmerbiomet.com):

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

**Printed Name:** \_\_\_\_\_ **Signature:** \_\_\_\_\_

**Title:** \_\_\_\_\_ **Telephone:** (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Email:** \_\_\_\_\_

**Territory Name:** \_\_\_\_\_ **Territory Number:** \_\_\_\_\_

**Return Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **ZIP:** \_\_\_\_\_

**Please return the affected product to the appropriate address below with a spreadsheet containing item number and serial number**

**Zimmer Biomet  
ZFA 2025-00141 Recall  
ATTN: Servicing Department  
200 West Ohio Avenue  
Dover, OH 44622**

Part Number	Serial Number

Part Number	Serial Number

Complete this table for all affected items returned. If additional space is needed, please provide a spreadsheet and return it to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com) and [dover.repairs@zimmerbiomet.com](mailto:dover.repairs@zimmerbiomet.com) with this form.

**Repaired devices will be returned to the address above once the repair is completed.**

**Note:** This form will be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com) and [dover.repairs@zimmerbiomet.com](mailto:dover.repairs@zimmerbiomet.com) or fax to 574-373-3589 or 574-372-4011.

**Please do not return affected product with other returns.**

**ATTACHMENT 2 - Affected Product List (International Serial Numbers)**

Item Number	00-8801-001-00	Item Description:	Zimmer® Air Dermatome		
Lot Number	Serial Number	Lot Number	Serial Number	Lot Number	Serial Number
65944745	115827	66185344	116068	66588831	116306
	115835		116070		116311
	115836		116078		116319
65944748	115854	66185345	116091	66588832	116324
	115856		116095		116327
	115858		116097		116337
65944750	115859	66252794	116101	66609568	116350
	115860	66360518	116103		116355
	115864	66252795	116130		116356
	115865		116131		116357
	115869		116132		116358
	115877		116133		116360
			116134		116361
65944752	115883		116135	66609569	116364
	115886		116136		116365
	115887		116137		116366
66053364	115893		116138	66609569	116367
	115909		116139		116368
66053365	115917		116140	66609569	116370
	115922		116141		116372
	115927		116142		116373
	115929	66360519	116143		116375
	115931		116163		116376
	115934		116168		116390
66121180	115938		116169	66609570	116404
	115952		116170		116407
	115957		116171		116408
66121181	115962	66427989	116172	66620922	116409
	115963		116173		116410
	115965		116175		116411
	115966		116178		116426
	115968		116198	66620923	116437
	115971	66428246	116202		116491
	115972		116215	66694115	116495
	115973	66472343	116225		116496
	115974		116226		116498
	66121182	115975	66488262	116231	66694116
115976		116232		116516	
115978		116244		116521	
115988		116246		116521	
66121183	115991	66531522	116248	66799188	116544
	116007		116271		116545
66121184	116011	66531523	116284	66799188	116546
	116023		116289		116547
66185343	116031	66531525	116291	66847657	116555
	116039		116292		116557
	116046		116293		116561
	116049		116296		116564
	116051		116299		116575
66185344	116052		116305		116577
	116066	66588831	116305		116581

Item Number	00-8801-001-00	Item Description:	Zimmer® Air Dermatome		
Lot Number	Serial Number	Lot Number	Serial Number	Lot Number	Serial Number
66847657	116582	67044538	116737	67198241	116893
66886861	116600		116738		116894
66847658	116615		116739		116896
	116620		116740		116897
	116622		116741		116901
66995359	116648	67044539	116742	67198239	116908
	116650		116751		116915
	116651		116752		116917
	116660		116760		116918
66995360	116665	67044540	116764	67198240	116920
66995361	116701		116778		116931
67044537	116703	67139329	116781	67199552	116944
	116705		116863		116945
	116708		116875		116946
	116710		116877		116948
			116882		116949
67044538	116725	67198241	116883		116950
	116726		116886		116951
	116729		116887		116954
	116730		116889		116955
	116734		116890		116959
	116735		116891		

Item Number	88710100	Item Description:	Zimmer® Dermatome AN		
Lot Number	Serial Number	Lot Number	Serial Number	Lot Number	Serial Number
65900465	701343	65944825	701379	66121190	701418
	701345		701380		701426
	701346		701381		701427
	701350		701386		701428
	701352		701387		701429
	701353		701388		701430
	701354		701390		701431
	701355		701391		701432
65944825	701359	66016265	701393	66121191	701433
	701361		701395		701434
	701362		701396		701435
	701363		701397		701436
	701364		701398		701437
	701365		701399		701440
	701366	701400	66252848	701441	
	701367	701402		701442	
	701368	701403		701443	
	701369	701404		701444	
	701370	701405		701445	
	701371	701406		701447	
	701372	701410	66252849	701451	
	701374	701411		701452	
	701375	701413		701453	
	701376	701415		701454	
	701377	701416		701455	
	701378	701417		701456	

Item Number	88710100	Item Description: Zimmer® Dermatome AN						
Lot Number	Serial Number	Lot Number	Serial Number	Lot Number	Serial Number			
66252849	701458	66531527	701545	66620983	701641			
	701459		701546		701642			
	701460		701548		701647			
	701461		701549		701648			
	701462		701550		701652			
	701463		701552		701655			
	66252850	701464	66531529	701553	66751092	701656		
		701465		701561		701657		
		701466		701562		701658		
		701467		701563		701659		
		701468		701564		701660		
		701469		701565		701664		
		701470		701566		701665		
701471		701567		701666				
701486		701568		701668				
701488		701569		701669				
701490		701570		701670				
66342488		701502		66531528		701571	66751093	701671
		701503				701574		701672
	701504	701575	701673					
	701505	701576	701675					
	701506	701578	701676					
	701507	701580	701677					
	701509	701582	701678					
	701510	701583	701679					
66531526	701511	66609571	701584	66849858	701680			
	701512		701585		701681			
	701513		701589		701683			
	701514		701590		701684			
	701515		701591		701685			
	701516		701592		701686			
	701517		701593		701687			
	701518		701600		701689			
	701520		701602		701690			
	701521		701604		701693			
	701523		701607		701697			
	701524		701609		701698			
	66531527		701525		66620981	701612	66849859	701699
701526		701613	701703					
701527		701615	701706					
701528		701618	701710					
701532		701619	701712					
701535		701620	701714					
701538		701621	701715					
701539		701624	701717					
701540		701625	701719					
701541		701626	701720					
701542		701627	701722					
701543		701628	701726					
701544		701629	701727					



Item Number		88710100		Item Description: Zimmer® Dermatome AN	
Lot Number	Serial Number	Lot Number	Serial Number	Lot Number	Serial Number
66849859	701728	67080990	701779	67198242	701845
	701729		701780		701847
	701730		701784		701851
66995362	701731	67044648	701786	67277943	701853
	701732		701791		701855
	701733		701792		701857
	701734		701794		701858
	701735		701795		701860
	701736		701796		701861
	701737		701797		701862
	701738		701798		701863
	701739		701802		701866
	701740		701803		701870
	701741		701804		701871
	701742		701805		701873
	701743		701806		701874
	701744		701808		701875
	701745		701809		701876
	701746		701810		701877
	67025608		701747		67214429
701749		701812	701879		
701750		701813	701880		
701752		701814	701881		
701753		701815	701885		
701754		701816	701890		
701755		701820	701892		
701756		701822	701893		
701758		701823	701894		
701759		701824	701895		
701760		701826	701898		
67080990	701761	67198242	701831	67198249	701901
	701762		701832		701904
	701763		701835		701905
	701764		701836		701906
	701765		701839		701907
	701767		701840		701908
	701768		701842		701909
	701771		701843		701910
	701774		701844		