

March 27, 2026

Important Drug Warning Letter

Subject: Injection molding defect at the tip of the needle sheath with the potential to manifest as a hole in Carpuject® Syringe System and potential non-sterility of the needle assembly impacting multiple U.S. lots across multiple products.

Dear Customer,

To prevent and mitigate drug shortages, Hospira Inc. a Pfizer company, (herein Pfizer) is issuing this Important Drug Warning Letter in coordination with the U.S. Food and Drug Administration to inform Health Care Providers of an injection molding defect at the tip of the needle sheath with the potential to manifest as a hole in multiple Carpuject products (**See Figure 1**) to ensure appropriate awareness, inspection and action prior to use.

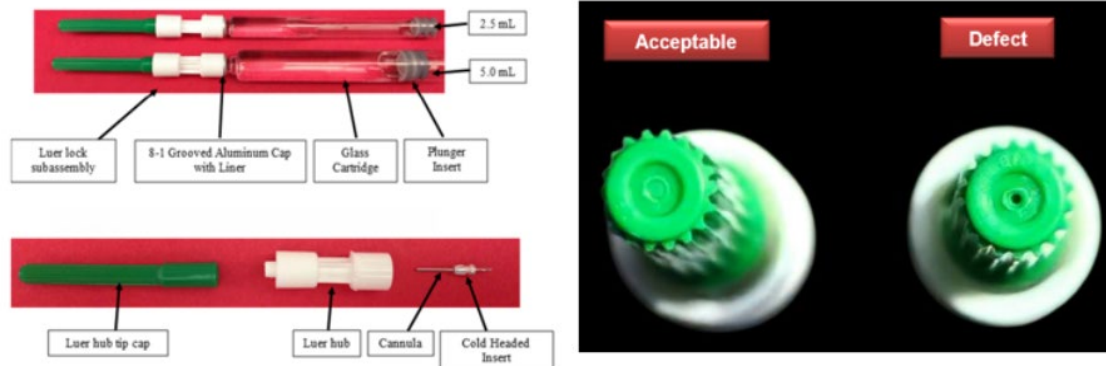
Issue Summary and Impact:

This injection molding defect was observed during routine inspection of incoming retain samples. There is a potential for non-sterility of the needle assembly. The overall patient risk is low and no safety signals or product quality complaints have been identified. The root cause of the injection molding defect has been identified, and corrective and preventative actions are in place.

The Carpuject Syringe System is used in the products listed in the table below; refer to the **Appendix** for a listing of lots:

Product
Buprenorphine Hydrochloride Injection, USP, CIII
Diazepam Injection, USP, CIV
Demerol® (meperidine hydrochloride injection, USP, CII)
Heparin Sodium Injection, USP
Hydromorphone Hydrochloride Injection, USP, CII
Labetalol Hydrochloride Injection, USP
Lorazepam Injection, USP, CIV
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)
Naloxone Hydrochloride Injection, USP

Figure 1: Photos of Carpuject Cartridges



Directions for Health Care Provider:

Health Care Providers should continue standard practice of visually examining Carpuject® units prior to administration and **should discard any unit showing a hole at the tip of the needle sheath** as per Figure 1 above, prior to administration.

Please contact Pfizer Customer Service at 844-646-4398 (Mon.-Fri. 8 am-6 pm ET) or your Pfizer representative for any questions you may have regarding this Important Drug Warning letter.

If you have any questions regarding this notification, please call the appropriate contact center below.

Contact Center	Contact Information	Area of Support
Pfizer Medical Information	800-438-1985, option 3 (Mon.-Fri. 9 am-5 pm ET) www.pfizermedical.com	For medical questions regarding this product
Pfizer Drug Safety	800-438-1985, option 1 (24 hours a day, 7 days per week)	Report adverse events or product complaints

Reporting Adverse Events:

Adverse events, medication errors or quality problems experienced with the use of these products may be reported to the U.S. Food and Drug Administration's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Complete and submit a report online: www.fda.gov/medwatch/report.htm.
- Regular mail or fax: download a reporting form from www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form. Complete the form and return it to the specified address on the form or submit the form by fax to 800-FDA-0178 (800-332-0178).

We appreciate your immediate attention and cooperation and regret any inconvenience this issue may cause you.

Sincerely,



Meera Bhavsar
U.S. Commercial Lead, Global Hospital & Biosimilars

APPENDIX: Affected Product Lots & Expiration Dates

Buprenorphine Hydrochloride injection, USP, CIII

Unit NDC	Carton NDC	Strength/Packaging	Lot Number	Expiration Date
0409-2012-03	0409-2012-32	0.3mg/mL Carpuject® Luer Lock Glass Syringe (no needle)	NE0823	30NOV2026
			MF4525	31MAR2026

Demerol® (meperidine hydrochloride injection, USP, CII)

Unit NDC	Carton NDC	Strength/Packaging	Lot Number	Expiration Date
0409-1178-03	0409-1178-30	50 mg/mL Carpuject® Luer Lock Glass Syringe (no needle)	NC0328	31JUL2027

Diazepam Injection, USP, CIV

Unit NDC	Carton NDC	Strength/Packaging	Lot Number	Expiration Date
0409-1273-03	0409-1273-32	10 mg/2 mL (5 mg/mL) Carpuject® Luer Lock Glass Syringe (no needle)	MX0249	31DEC2026
			MX0257	
			MX0261	

Heparin Sodium Injection, USP

Unit NDC	Carton NDC	Strength/Packaging	Lot Number	Expiration Date
0409-1316-11	0409-1316-32	5,000 USP Units/mL Carpuject® Luer Lock Glass Syringe (no needle)	NF0917	31JAN2027
			NF0916	
			NF0915	
			NC6697	
			NC6696	
			NF0909	
			ND4766	
			NN2537	30APR2027
			MA5879	31MAY2026
			MA5882	
			MA5883	
			NC7243	31JAN2027
			NC7253	
			NC7254	

APPENDIX: Affected Product Lots & Expiration Dates (Continued)

Hydromorphone Hydrochloride Injection, USP, CII

Unit NDC	Carton NDC	Strength/Packaging	Lot Number	Expiration Date
0409-1283-03	0409-1283-31	1 mg/mL Carpuject® Luer Lock Glass Syringe (no needle)	MT1362	31MAY2027
			NC0198	30JUN2027
			NJ9714	30SEP2027
			MM4164	30APR2027
			NK7983	30SEP2027
			NH9363	31AUG2027
			LR6293	31AUG2026
			LT9979	
			LT3987	
			LR6302	30SEP2026
			LW7148	
			LY1456	31OCT2026
			LY8270	
			LT9988	30NOV2026
			LY6537	
			LY4397	
			LY5708	
			ME9980	31DEC2026
			ME9982	
			ME0158	
			MF3776	
			MF3956	31JAN2027
			MG5031	
			MJ6437	
			MF3950	
			MJ6439	28FEB2027
			ML4551	
			MJ5328	
			MK6766	
			MM4175	30APR2027
			MP4517	
			MX0250	31MAY2027
			NA5400	
0409-1312-03	0409-1312-30	2 mg/mL Carpuject® Luer Lock Glass Syringe (no needle)	LR4095	30SEP2026
			LY1457	31OCT2026
			MF3957	31DEC2026
			NJ9718	31AUG2027
			NA5401	31JUL2027
0409-1304-03	0409-1304-31	4 mg/mL Carpuject® Luer Lock Glass Syringe (no needle)	LR6288	31AUG2026

APPENDIX: Affected Product Lots & Expiration Dates (Continued)

Labetalol Hydrochloride Injection, USP

Unit NDC	Carton NDC	Strength/Packaging	Lot Number	Expiration Date
0409-2339-24	0409-2339-34	20 mg/4 mL (5 mg/mL) Carpuject® Luer Lock Glass Syringe (no needle)	NG2684	31AUG2027
			NE4388	30JUN2027
			NC0213	30JUN2027
			NA5396	31AUG2027
			NG2685	30SEP2027
			NG1110	30SEP2027
			NN7662	30NOV2027
			NN7668	30NOV2027
			NN7670	30NOV2027
			NN7672	30NOV2027
			MP2739	31MAY2027
			MP2744	
			MP2746	
			MR2100	
			MR2101	
			MR2102	
			MT5481	
			MW3190	
			NC0203	30JUN2027
			NE4390	31JUL2027

Lorazepam Injection, USP, CIV

Unit NDC	Carton NDC	Strength/Packaging	Lot Number	Expiration Date
0409-1985-03	0409-1985-30	2 mg/mL Carpuject® Luer Lock Glass Syringe (no needle)	NA5399	30JUN2027

APPENDIX: Affected Product Lots & Expiration Dates (Continued)

Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)

Unit NDC	Carton NDC	Strength/Packaging	Lot Number	Expiration Date
0409-1890-03	0409-1890-01	2 mg/mL Carpuject® Luer Lock Glass Syringe (no needle))	NJ9719	30SEP2027
			MX6019	30JUN2027
			NG1111	31JUL2027
			NF9418	31JUL2027
			MR5178	31MAY2027
			MR0315	31MAY2027
			NM4772	30NOV2027
			NM4773	30NOV2027
			NM2066	31OCT2027
			LY6217	30NOV2026
			MD2895	
			MA6373	
			MF3952	31JAN2027
			ML5308	28FEB2027
0409-1891-03	0409-1891-01	4 mg/mL Carpuject® Luer Lock Glass Syringe (no needle)	NF0912	30JUN2027
			NM5936	30JUN2027
			NM4784	31OCT2027
			MD1692	31DEC2026
			MG5037	31JAN2027

Naloxone Hydrochloride Injection, USP

Unit NDC	Carton NDC	Strength/Packaging	Lot Number	Expiration Date
0409-1782-03	0409-1782-69	0.4 mg/mL Carpuject® Luer Lock Glass Syringe (no needle)	NH9362	31JUL2027