

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Cardinal Health has recently been informed that **Sol Millennium** is initiating a recall due to these products requiring 510(k) clearance. Please see **Sol Millennium** Urgent Product Recall.

Sol-Millennium is initiating a voluntary recall for low dead space (“LDS”) syringes, luer slip tip syringes, and “combined” syringes with needle and syringe components packaged together. These products were found by the FDA to be substantially different from our current cleared 510(k)s with a major change or modification to the device’s intended use without a 510(k) clearance that remain outside our control beyond the distributor level. The affected company SKUs are listed below.

This recall action has been identified due to the U.S. Food and Drug Administration’s (“FDA”) determination that these devices require 510(k) clearance, as the absence of FDA review to appropriately verify and validate the changes could lead to adverse health consequences.

Cardinal Health Catalog # Sol Millennium Sku # Lot Number

P180010ST

P80010STS
SP180010ST

P180010ST

04302012, 04303050

181025

S181025

181025

04302039

1811815B

1811815B

04203043

1831815B

S1831815B SS1831815B 1831815B 04304001

1832015 1832015 04105118

1832115 1832115 04306035, 04202035, 04106053

1851815B
S1851815B 1851815B 04203042, 04212009, 04308044

32210SN 32210SN 04301035, 04312117, 04007046

32558SN 32558SN 04104018, 04007048

P180001PP SP180001PP P180001PP 08106028, 08106029, 08106030,
08106031, 04106032, 04106082,
04106086, 08103004, 08104004,
08105047, 08105053, 08106033

P180003ST P180003ST 04105121

P180005ST	P180005ST	04104054
P180010ET	P180010ET	04209010
P180020ST SP180020ST	P180020ST	04110055, 04303048, 04110014
P180030ST	P180030ST	04302041
P180060ST	P180060ST	04302042
SSTCB01 STCB01	STCB01	04201063, 04209005, 04307016, 04308061
STCB02	STCB02	04201064
1812010 S1812010	1812010	04202007, 04401068
1812110	1812110	04202008, 04308068, 04401025

1832110	1832110	04105119, 019041740
		019041741, 04103028, 04106048,
1832310	1832310	04106049, 04106052, 04110007,
		04110053, 019021823, 019041741
		04010033, 04103016, 04103017,
1832558	1832558	04110012, 04007045
		01004002, 01004039, 01006001,
		01012017, 01102039, 01103012,
11812558	11812558	01104002, 01107027, 01108027,
		01108031, 01108046
		01008024, 01012018, 01103013,
		01104003, 01104016, 01107028,
11812705	11812705	01108028, 01108032, 01108051,
		01910016

11813005	11813005	01012024
11832010	11832010	01107029, 01108047
11832015	11832015	01010016, 01012011, 01012019, 01110067, 01112021, 01112056 01108033, 01108048, 01110066, 01111052, 01112020, 01112055,
11832110	11832110	01910017
11832115	11832115	01107030, 01108029, 01108034, 01108049
11832210	11832210	01010017, 01012012, 01012020, 01110068, 01112022, 01201008, 01910018, 01203020 01010018, 01012013, 01012021, 01102036, 01107031, 04102053, 04106153, 04202003, 04306034,
11832215	11832215	04307015, 04307043, 04308047, 04309030, 04310033 01006002, 01010007, 01010009,

11832310	11832310	01010019, 01011007, 01011008, 01011009, 01011010, 01011011, 01012014, 01012022, 01102037, 01103011, 01104001, 01104017, 01104018, 01104019, 01104020, 01104021, 01108034, 01910019 01008025, 01010010, 01010020, 01012015, 01012023, 01102038, 01104022, 01105001
11832315	11832315	01012025, 01102041, 01103015, 01104005, 01105004, 01107032, 01108036, 01108052
11832558	11832558	04001001, 04003019, 04110083, 04110084, 04202004, 04308046, 04308088, 04312097, 019052010
1852215	1852215	01010008, 01010021, 01012016, 01102040, 01103014, 01104004, 01105002, 01105003, 01108030, 01108050, 01910020
11832510	11832510	