California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Belmont Instrument LLC 3.0 Recalls Liter Disposable Set, Straight Inflow/Outflow Patient Line Kit, Straight Inflow/Bifurcated Outflow Line Kit, and Hyperthermia Pump Procedure Kit

Recall Date	Product Description	Recalling Firm	Recall Reason
04/25/2025	3.0 Liter Disposable Set (4 sets/case). Model Number: 903-00032. The P/N 903-00032 consists of 4 Large Volume Reservoirs (P/N 903-00018) and 4 Heat Exchanger/Patient Line set (P/N 403-00382). The two components are packaged separately in individual pouches and placed in the same case for shipment. The female quick connector that may be cracked is located on the Heat Exchanger/Patient Line set.	Belmont Instrument LLC	Potential crack in the female connector located on the Heat Exchanger/patient line set, which will lead to a fluid leak through the crack during priming of the Rapid Infuser.
04/25/2025	Straight Inflow/Outflow Patient Line Kit. Model Number: 902-00037. Sterile, single-use, disposable set used with the Hyperthermia Pump. The Straight Inflow/Outflow Patient Line Kit (P/N 902-00037) consists of 4.4 Liter Reservoir (P/N 902-00034P), Heat Exchanger set (P/N 902-00006P) and Straight Inflow/Outflow Patient Line (P/N 902-00039P). The three components are packaged separately in individual pouches and boxes and placed in the same case for shipment. All three components are connected prior to use. The female quick connector	Belmont Instrument LLC	Potential crack in the female connector located on the Heat Exchanger in the set, which will lead to a fluid leak through the crack during priming of the rapid infuser.

	that may be cracked is located on the Heat Exchanger set (P/N 902-00006P).		
04/25/2025	Straight Inflow/Bifurcated Outflow Line Kit. Model Number: 902-00038. Sterile, single-use, disposable set used with the Hyperthermia Pump. The Straight Inflow/Outflow Patient Line Kit (P/N 902-00038) consists of 4.4 Liter Reservoir (P/N 902-00034P), Heat Exchanger set (P/N 902-00006P) and Straight Inflow/Bifurcated Outflow Patient Line (P/N 902-00040P). The three components are packaged separately in individual pouches and boxes and placed in the same case for shipment. All three components are connected prior to use. The female quick connector that may be cracked is located on the Heat Exchanger set (P/N 902-00006P).	Belmont Instrument LLC	Potential crack in the female connector located on the Heat Exchanger in the set, which will lead to a fluid leak through the crack during priming of the rapid infuser.
04/25/2025	Hyperthermia Pump Procedure Kit. Model Number: 902-00045. Sterile, single-use, disposable set used with the Hyperthermia Pump. The Hyperthermia Procedure kit (P/N 902-00045) consists of 4.4 Liter Reservoir (P/N 902-00034P), Heat Exchanger set (P/N 902-00006P) and HP Procedure Pack (P/N 902-00048P). The three components are packaged separately in individual pouches and boxes and placed in the same case for shipment. All three components are connected prior to use. The female quick connector that may be cracked is located on the Heat Exchanger set (P/N 902-00006P).	Belmont Instrument LLC	Potential crack in the female connector located on the Heat Exchanger in the set, which will lead to a fluid leak through the crack during priming of the rapid infuser.

Recall Class	Product Identification	Distribution	Affected Dates
II	Model Number: 903-00032. UDI-DI: 00896128002534. Lot Numbers: 20240911, 20241004, 20241011, 20241105	19 customers/86 cases (QTY: 4 per case) in California	March 2025 and Prior
II	Model Number: 902-00037. UDI-DI: 00896128002213. Lot Numbers: 20241012, 20241107	1 customer/4 cases (QTY: 1 per case) in California	March 2025 and Prior
II	Model Number: 902-00038. UDI-DI: 00896128002220. Lot Number: 20241013	0 customers- not distributed in California	March 2025 and Prior
II	Model Number: 902-00045. UDI-DI: 00896128002589. Lot Numbers: 20241005, 20241108	3 customers/12 cases (QTY: 1 per case) in California	March 2025 and Prior

For additional information, please visit this FDA Website 3.0 Liter Disposable Set, this FDA Website Straight Inflow/Outflow Patient Line Kit, this FDA Website Straight Inflow/Bifurcated Outflow Line Kit, and this FDA Website Hyperthermia Pump Procedure Kit.

Confidential - Low