

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Smiths Medical ASD, Inc. Recalls Smiths Medical ProPort Plastic Venous Access System

Recall Date	Product Description	Recalling Firm	Recall Reason
02/13/2025	smiths medical ProPort Plastic Venous Access System, Silicone Catheter, 2.87,,O.D. (8.4Fr) s 1.0mm I.D., REF 21-4150-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a manufacturing defect.
02/13/2025	smiths medical ProPort Plastic Venous Access System, Silicone Catheter, 2.8mm (8.4Fr) O.D. x 1.0mm I.D., 9 Fr Introducer, REF 21-4151-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a manufacturing defect.
02/13/2025	smiths medical ProPort Plastic Venous Access System, PolyFlow Polyurethane Catheter, 1.9mm O.D. (5.8 Fr) x 1.0mm I.D., REF 21-4152-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a manufacturing defect.
02/13/2025	smiths medical ProPort Plastic Venous Access System, PolyFlow Polyurethane Catheter, 1.9mm (5.8Fr) O.D. x 1.0mm I.D., 6Fr Introducer, REF 21-4153-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a manufacturing defect.

02/13/2025	smiths medical ProPort Plastic Venous Access System, PolyFlow Polyurethane Catheter, 2.6mm O.D. (7.8Fr) x 1.6mm I.D., REF 21-4155-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a manufacturing defect.
02/13/2025	smiths medical ProPort Plastic Venous Access System, Pre-assembled with PolyFlow Polyurethane Catheter, 2.6mm (7.8Fr) O.D. x 1.6mm I.D., 8.6Fr Introducer, REF 21-4165-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a manufacturing defect.
02/13/2025	smiths medical ProPort Plastic Venous Access System, PolyFlow Catheter, 2.6 (7.8Fr) O.D. x 1.6mm I.D., 8.5Fr Introducer, REF 21-4171-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a manufacturing defect.
02/13/2025	smiths medical ProPort Plastic Venous Access System, Pre-assembled with PolyFlow Polyurethane Catheter, 2.6mm O.D. (7.8Fr) x 1.6mm I.D., REF 21-4172-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a manufacturing defect.
02/13/2025	smiths medical ProPort Plastic Venous Access System, Pre-assembled with PolyFlow Polyurethane Catheter, 2.6mm (7.8Fr) O.D. x 1.6mm I.D., 8.5Fr Introducer, REF 21-4173-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a manufacturing defect.
02/13/2025	smiths medical ProPort Plastic Venous Access System, Implantable Venous Access Systems, 82-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a

			manufacturing defect.
02/13/2025	smiths medical ProPort Low Profile Plastic Venous Access System, PolyFlow Polyurethane Catheter, 1.9mm (5.8Fr) O.D. x 1.0mm., 6Fr Introducer, REF 21-4183-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a manufacturing defect.
02/13/2025	smiths medical ProPort Low Profile Plastic Venous Access System, Silicone Catheter, 2.8mm (8.4Fr) O.D. x 1.0mm I.D., 9Fr Introducer, REF 21-4187-24	Smiths Medical ASD, Inc.	The plastic port housing and port reservoir of the ProPort Plastic Implantable Ports may separate because of a manufacturing defect.

Recall Class	Product Identification	Distribution	Affected Dates
I	UDI/DI 10610586012518, Lot Number 4235595	3 units	March 2025 and Prior
I	UDI/DI 10610586012532, Lot Numbers: 3968088, 4052396, 4063411, 4101698, 4122782, 4219344, 4232319, 4235596, 4242786, 4317072, 4325879, 4397749, 4420759, 4445594, 4449874.	643 units	March 2025 and Prior
I	UDI/DI 10610586012549, Lot Numbers: 3928188, 3953708, 3957301, 3968097, 3977434, 3988450, 4006475, 4022600, 4027912, 4036893, 4073108, 4086999, 4103105, 4114110, 4122783, 4136362, 4139518, 4152689, 4153871, 4173433, 4189866, 4222392, 4227822, 4235597, 4276226, 4307472, 4317085, 4349806, 4378522, 4387732, 4395511, 4460618, 4434228, 4449233, 4449875, 6013082, 6014983, 4468606, 4426417, 6062037, 6071256.	2311 units	March 2025 and Prior
I	UDI/DI 10610586012563, Lot	9506 units	March 2025 and

	Numbers: 3926121, 3928189, 3953709, 3957303, 4006476, 4008521, 4036894, 4046803, 4096337, 4108664, 4114114, 4114115, 4136363, 4146466, 4153872, 4173601, 4232305, 4235508, 4235598, 4271453, 4291483, 4294059, 4317075, 4317092, 4358052, 4366693, 4366694, 4387733, 4434229, 4449244, 4453603, 4453604, 4453605, 6001912, 6026649, 6051324, 6062012, 6071257, 6077416.		Prior
I	UDI/DI 10610586012594, Lot Numbers: 3926119, 3928191, 3944833, 3960347, 3968098, 3988451, 4027913, 4057817, 4087000, 4139520, 4146467, 4173474, 4196758, 4221725, 4235599, 4256939, 4291484, 4295931, 4302979, 4307473, 4307474, 4437254, 4447572, 4449876, 4460619, 6037144, 6006017, 6059285, 6026682, 6062025, 6071258.	3263 units	March 2025 and Prior
I	UDI/DI 10610586012686, Lot Numbers: 3918902, 3984420, 4079312, 4189868, 4221726, 4235543, 4242787, 4294897, 4307477, 4356314, 4364692, 4390226, 4445595, 4468593, 6003890.	1695 units	March 2025 and Prior
I	UDI/DI 10610586012716, Lot Numbers: 3941279, 3969275, 3984421, 4022601, 4136364, 4148590, 4153873, 4196768, 4227788, 4232310, 4235600, 4248718, 4276227, 4302980, 4307478, 4317093, 4325880, 4358053, 4358054, 4395512, 4415445, 4420760, 4437255, 4449234, 4449877, 4460620, 6013083, 6003891, 6053532, 6062026.	1961 units	March 2025 and Prior
I	UDI/DI 10610586012723, Lot Numbers: 4235509	1 unit	March 2025 and Prior

I	UDI/DI 10610586012747, Lot Numbers: 4317077	12 units	March 2025 and Prior
I	UDI/DI 10610586012754, Lot Numbers: 4196769	0 units	March 2025 and Prior
I	UDI/DI 10610586012778, Lot Numbers: 3916028, 3969277, 4006477, 4022602, 4036895, 4057818, 4060894, 4096338, 4108453, 4114117, 4146468, 4153874, 4163556, 4196775, 4221727, 4235565, 4235567, 4235601, 4248694, 4256927, 4256928, 4256964, 4276228, 4294894, 4294895, 4364693, 4366695, 4366696, 4378523, 4382349, 4392370, 4395513, 4405010, 4420761, 4426418, 4434230, 4453606, 4468579, 4468580, 6005957, 6005958, 6026650, 6026651, 6037122, 6037124, 6051325.	8515 units	March 2025 and Prior
I	UDI/DI 10610586012839, Lot Numbers: 3906623, 3922514, 4120026, 4152690, 4157409, 4196736, 4227806, 4264408, 4271442, 4317086, 4337691, 4382350, 4387734, 4405011, 4440712, 4445592, 4460621, 4468591, 6013085, 6026683, 6037136, 6051319, 6071259.	2236 units	March 2025 and Prior

For additional information, please visit this [FDA Website \(REF 21-4150-24\)](#), this [FDA Website \(REF 21-4151-24\)](#), this [FDA Website \(REF 21-4152-24\)](#), this [FDA Website \(REF 21-4153-24\)](#), this [FDA Website \(REF 21-4155-24\)](#), this [FDA Website \(REF 21-4165-24\)](#), this [FDA Website \(REF 21-4171-24\)](#), this [FDA Website \(REF 21-4172-24\)](#), this [FDA Website \(REF 21-4173-24\)](#), this [FDA Website \(REF 82-24\)](#), this [FDA Website \(REF 21-4183-24\)](#), and this [FDA Website \(REF 21-4187-24\)](#).