

Recalling Firm	Status	Recall Number	Classification	Product Description	Reason for Recall	Recall Initiation Date
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-2412-2012	Class II	Bard Ventralight ST Mesh. - Ellipse 8" x 10" (20.3 cm x 25.4 cm) Product Code 5954810. The Bard Ventralight ST Mesh is a dual-component (absorbable and nonabsorbable) sterile prosthesis. The device classification name is "Mesh, Surgical, Polymeric." It is in tented for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.	Mislabeled: The 8" x 10" package contains 7" x 9" VENTRALIGHT ST Mesh product and the 7" x 9" package contains 8" x 10" VENTRALIGHT ST Mesh product	9/4/2012
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-2413-2012	Class II	Bard Ventralight ST Mesh. - Ellipse 7" x 9" (17.8 cm x 22.9 cm) Product Code 5954790. The Bard Ventralight ST Mesh is a dual-component (absorbable and nonabsorbable) sterile prosthesis. The device classification name is "Mesh, Surgical, Polymeric." It is in tented for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.	Mislabeled: The 8" x 10" package contains 7" x 9" VENTRALIGHT ST Mesh product and the 7" x 9" package contains 8" x 10" VENTRALIGHT ST Mesh	9/4/2012
Medtronic Neuromodulation	Terminated	Z-0124-2014	Class II	Medtronic RestoreUltra, model 37712, and RestoreSensor, model 37714, Multi-program Rechargeable Neurostimulator for Spinal Cord Stimulation. Medtronic implantable neurostimulation system is indicated for spinal cord stimulation (SCS) systems as an aid in the management of chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain associated with the following conditions: - Failed Back Syndrome (FBS) or low back syndrome or failed back - Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk - Postlaminectomy pain - Multiple back operations - Unsuccessful disk surgery - Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and surgical interventions - Peripheral causalgia - Epidural fibrosis - Arachnoiditis or lumbar adhesive arachnoiditis - Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia	Medtronic notified customers regarding over stimulation or stimulation in the wrong area related to select Medtronic neurostimulators. Upon a specific set of conditions, typically related to device recovery from an over discharge, there is a potential for over stimulation or stimulation directed to a lead electrode other than what was intended.	9/30/2013
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-0819-2014	Class II	Composix L/P with Echo PS 10" X 13" Product Code 0144113 The Composix L/P Mesh with Echo PS Positioning System is a non-absorbable sterile lightweight mesh prosthesis, with a preattached removable positioning system. This system is indicated and designed for the reconstruction of soft tissue deficiencies during laproscopic ventral hernia repair.	Product labeling does not match product configuration.	1/3/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-0820-2014	Class II	Composix L/P with Echo PS 6" X 8" Product Code 0144680 The Composix L/P Mesh with Echo PS Positioning System is a non-absorbable sterile lightweight mesh prosthesis, with a preattached removable positioning system. This system is indicated and designed for the reconstruction of soft tissue deficiencies during laproscopic ventral hernia repair.	Product labeling does not match product configuration.	1/3/2014
Ethicon, Inc.	Ongoing	Z-1329-2014	Class II	Proceed Surgical Mesh, Product Codes PCDB1, PCDT1, and PCDJ1. Ethicon Inc., Johnson & Johnson Medical GmbH, used for the repair of hernias and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.	The possibility exists that an incomplete seal on the packaging compromised the sterility of the device and introduced the potential for delamination.	2/19/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1682-2014	Class II	Composix" LP with Echo PS" 10x13 HUXH0294 HUXL0314 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1683-2014	Class II	Composix" LP with Echo PS" 6x10 Reorder Number: 0144610 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1684-2014	Class II	Composix" LP with Echo PS" 6 x8 Reorder Number: 0144680 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1685-2014	Class II	Bard Δ Composix" LIP Mesh with Echo PS" 7"x9" Reorder Number: 0144790 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1686-2014	Class II	Bard Δ Composix" LIP Mesh with Echo PS" 8"x10" Reorder Number: 0144810 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1687-2014	Class II	Bard Δ Ventralight" ST Mesh with Echo PS" 10"x13" Reorder Number: 5955113 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1688-2014	Class II	Bard Δ Ventralight" ST Mesh with Echo PS" 12"x14" Reorder Number: 5955124 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1689-2014	Class II	Bard Δ Ventralight" ST Mesh with Echo PS" 4.5" Circle Reorder Number: 5955450 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1690-2014	Class II	Bard Δ Ventralight" ST Mesh with Echo PS" 4"x6" Reorder Number: 5955460 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014

Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1691-2014	Class II	BardÅž Ventralight" ST Mesh with Echo PS" 6" Circle Reorder Number: 5955600 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1692-2014	Class II	BardÅž Ventralight" ST Mesh with Echo PS" 6"x10" Reorder Number: 5955610 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1693-2014	Class II	BardÅž Ventralight" ST Mesh with Echo PS" 6"x8" Reorder Number: 5955680 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1694-2014	Class II	BardÅž Ventralight" ST Mesh with Echo PS TM 7"x9" Reorder Number: 5955790 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1695-2014	Class II	BardÅž Ventralight" ST Mesh with Echo PS" 8" Circle Number: 5955800 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-1696-2014	Class II	BardÅž Ventralight" ST Mesh with Echo PS" 8"x10" Reorder Number: 5955810 Indicated for use in the reconstruction of soft tissue deficiencies, such as the repair of hernias.	Pouch holding sterile inflation assembly and inflation adapter may be open or have a weak seal.	4/24/2014
Davol, Inc., Subs. C. R. Bard, Inc.	Terminated	Z-0191-2015	Class II	BardÅž PerFix Light Plug The BardÅž PerFix Light Plug is indicated for reinforcement if soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.	The patient record peel-off label product code and size did not match the other labeling and actual product in the packaging for the Bard Small PerFix Light Plug.	10/8/2014
Windstone Medical Packaging, Inc.	Completed	Z-0208-2017	Class II	Hernia Pack, Kit number AMS1519 convenience custom kits used for general surgery in hospital operating room	The Medtronic COVER LIGHT HANDLE DISPOSABLE GLOVES, Part # 13140, of the custom AMS kit were recalled because gloves may contain splits or holes compromising sterility.	4/22/2015
Windstone Medical Packaging, Inc.	Ongoing	Z-1315-2017	Class II	Hernia Pack, part number AMS3859	The Medtronic COVER LIGHT HANDLE DISPOSABLE GLOVES of the custom Aligned Medical Solutions (AMS) kits were recalled because gloves may contain splits or holes compromising sterility.	1/11/2017