

CONSUMABLES WEEKLY OPEN RECALL REPORT 5/1/2023 to 5/7/2023

Inventory Disposition
 Located (L), Segregated (S),
 Disposed (D), Not Applicable
 (N/A)

Recall Date	Recall Number	OEM	Model Name	Model Number	Item, Catalog, Article, Material, Product or Reference Number	Lot Code, Lot Number and Expiration Date. Batch Number.	UDI	Recall QTY	US Distribution	Reported Issue	(L)	(S)	(D)	(N/A)
5/2/2023	Z-1497-2023	Beaver Visitec International, Inc.	CryoTreQ		Ref: CT00.D01	All Affected Lots: 20214450, 20214366, 20214367, 20214518, 20214522, 20214615, 20214744, 20214745, 20214961, 20214962, 20215203, 20215204, 20215479, 20216263, 20216264, 20216010, 20227952, 20227950, 20227951, 20228408, 20228657, 20228897, 20228898, 20229034, 20229138, 20229334, 20229460, 20229630, 20229748, 20230261, 20221083, 20221140, 20221364, 20221746, 20221894, 20222365	8719214223458	501	Nationwide	Device suddenly and forcefully disassembled after cryotherapy				
5/2/2023	Z-1499-2023	ASO LLC	WALGREENS BANDAGES, 110 CT VALUE PACK, 24 BOXES/MASTER (shipping container), Walgreens Family Pack ASSORTED BANDAGES, 110 ASSORTED SIZES (retail package)		Item number 196568	Lot Numbers: 00176259, 00176260, 00176582.	311917124506	919 cases of 24 units	IL, FL, CA, CT, OH, TX, IL, SC, and WI	The adhesive bandage contains 0.1% benzalkonium chloride impregnated in the pad and is not disclosed on the labeling.				
5/3/2023	Z-1505-2023	Siemens	ADVIA Centaur Cortisol 50T		Material Number 10994924	Kit Lot Numbers: 49741344, 07241346, 88318346, 29109348 and higher;	630414602943	18,961 kits	Nationwide	There is a negative bias with urine patient samples and urine cortisol Quality Control (QC) results intermittently out of range low.				
5/3/2023	Z-1505-2023	Siemens	ADVIA Centaur Cortisol 250T		Material Number 10994926	Kit Lot Numbers: 49742344, 88319346, 29108348 and higher;	630414602950	18,961 kits	Nationwide	There is a negative bias with urine patient samples and urine cortisol Quality Control (QC) results intermittently out of range low.				
5/3/2023	Z-1505-2023	Siemens	ADVIA Centaur Cortisol REF 250T		Material Number 10994927	Kit Lot Numbers: 75474344, 11352346 and higher	630414598659	18,961 kits	Nationwide	There is a negative bias with urine patient samples and urine cortisol Quality Control (QC) results intermittently out of range low.				
5/3/2023	Z-1504-2023	Siemens	Atellica IM Cortisol 50T		Material Number 10995538	Kit Lot Numbers: 50732343, 50733343, 88975345, 29106347, 29107347 and higher;	630414598659	34,746 kits	Nationwide	There is a negative bias with urine patient samples and urine cortisol Quality Control (QC) results intermittently out of range low.				
5/3/2023	Z-1504-2023	Siemens	Atellica IM Cortisol 250T		Material Number 10995537	Kit Lot Numbers: 50734343, 88974345, 29105347 and higher;	630414598642	34,746 kits	Nationwide	There is a negative bias with urine patient samples and urine cortisol Quality Control (QC) results intermittently out of range low.				
5/3/2023	Z-1504-2023	Siemens	Atellica IM Cortisol (REF) 250T		Material Number 11206248	Kit Lot Numbers: 53842343, 58039343, 94430345 and higher	630414293608	34,746 kits	Nationwide	There is a negative bias with urine patient samples and urine cortisol Quality Control (QC) results intermittently out of range low.				
5/4/2023	Z-1519-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 7MM X 55MM		Item Number: 15-2028/09	All lot numbers	4026575044016	12 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1520-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 9MM X 55MM		Item Number: 15-2028/10	All lot numbers within the labeled expiration date	4026575044023	13 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1548-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 13 MM X 50 MM		Item Number: 15-2230/08	All lot numbers within the labeled expiration date	4026575429189	5 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				

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5/4/2023	Z-1554-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 8 MM X 55 MM		Item Number: 15-2230/15	All lot numbers within the labeled expiration date	4026575436750	5 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1509-2023	Linkbio Corp.	LINK SLED Knee System: ENDO SLED KNEE FEM COMP, MEDIUM		Item Number: 15-2020/52	All lot numbers within the labeled expiration date	4026575043903	17 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1513-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 11MM X 45MM		Item Number: 15-2028/03	All lot numbers within the labeled expiration date	4026575043958	13 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1524-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 9MM X 58MM		Item Number: 15-2028/14	All lot numbers within the labeled expiration date	4026575359462	15 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1531-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 11 MM X 50 MM		Item Number: 15-2030/07	All lot numbers within the labeled expiration date	4026575044115	14 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1543-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 9 MM X 45 MM		Item Number: 15-2230/02	All lot numbers within the labeled expiration date	4026575429127	5 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1549-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 9 MM X 55 MM		Item Number: 15-2230/10	All lot numbers within the labeled expiration date	4026575429202	3 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1553-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 8 MM X 50 MM		Item Number: 15-2230/14	All lot numbers within the labeled expiration date	4026575436743	8 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1510-2023	Linkbio Corp.	LINK SLED Knee System: ENDO SLED KNEE FEM COMP, LARGE		Item Number: 15-2020/60	All lot numbers within the labeled expiration date	4026575043910	12 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1522-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 13MM X 55MM		Item Number: 15-2028/12	All lot numbers within the labeled expiration date	4026575044047	14 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1526-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 13MM X 58MM		Item Number: 15-2028/16	All lot numbers within the labeled expiration date	4026575359486	18 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				

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5/4/2023	Z-1527-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 9 MM X 45 MM		Item Number: 15-2030/02	All lot numbers within the labeled expiration date	4026575044061	17 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1536-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 8 MM X 45 MM		Item Number: 15-2030/13	All lot numbers within the labeled expiration date	4026575436705	13 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1539-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO SLED KNEE FEM COMP, SMALL		Item Number: 15-2220/40	All lot numbers within the labeled expiration date	4026575429073	5 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1541-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO SLED KNEE FEM COMP, MEDIUM		Item Number: 15-2220/52	All lot numbers within the labeled expiration date	4026575429097	7 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1508-2023	Linkbio Corp.	LINK SLED Knee System: ENDO SLED KNEE FEM COMP, MEDIUM SMALL		Item Number: 15-2020/46	All lot numbers within the labeled expiration date	4026575209491	18 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1515-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 7MM X 50MM		Item Number: 15-2028/05	All lot numbers within the labeled expiration date	4026575043972	19 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1517-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 11MM X 50MM		Item Number: 15-2028/07	All lot numbers within the labeled expiration date	4026575043996	19 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1518-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 13MM X 50MM		Item Number: 15-2028/08	All lot numbers within the labeled expiration date	4026575044009	24 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1521-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 11MM X 55MM		Item Number: 15-2028/11	All lot numbers within the labeled expiration date	4026575044030	15 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1532-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 13 MM X 50 MM		Item Number: 15-2030/08	All lot numbers within the labeled expiration date	4026575044122	20 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1535-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 13 MM X 55 MM		Item Number: 15-2030/12	All lot numbers within the labeled expiration date	4026575044160	15 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				

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5/4/2023	Z-1542-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO SLED KNEE FEM COMP, LARGE		Item Number: 15-2220/60	All lot numbers within the labeled expiration date	4026575429103	5 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1545-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 13 MM X 45 MM		Item Number: 15-2230/04	All lot numbers within the labeled expiration date	4026575429141	5 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1551-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 13 MM X 55 MM		Item Number: 15-2230/12	All lot numbers within the labeled expiration date	4026575429226	5 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1511-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 7MM X 45MM		Item Number: 15-2028/01	All lot numbers within the labeled expiration date	4026575043934	14 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1512-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 9MM X 45MM		Item Number: 15-2028/02	All lot numbers within the labeled expiration date	4026575043941	13 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1523-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 7MM X 58MM		Item Number: 15-2028/13	All lot numbers within the labeled expiration date	4026575359455	18 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1525-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 11MM X 58MM		Item Number: 15-2028/15	All lot numbers within the labeled expiration date	4026575359479	15 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1544-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 11 MM X 45 MM		Item Number: 15-2230/03	All lot numbers within the labeled expiration date	4026575429134	5 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1550-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 11 MM X 55 MM		Item Number: 15-2230/11	All lot numbers within the labeled expiration date	4026575429219	3 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1529-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 13 MM X 45 MM		Item Number: 15-2030/04	All lot numbers	4026575044085	16 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1533-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 9 MM X 55 MM		Item Number: 15-2030/10	All lot numbers within the labeled expiration date	4026575044146	12 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				

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5/4/2023	Z-1537-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 8 MM X 50 MM		Item Number: 15-2030/14	All lot numbers within the labeled expiration date	4026575436712	14 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1547-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 11 MM X 50 MM		Item Number: 15-2230/07	All lot numbers within the labeled expiration date	4026575429172	3 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1528-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 11 MM X 45 MM		Item Number: 15-2030/03	All lot numbers within the labeled expiration date	4026575044078	15 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1530-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 9 MM X 50 MM		Item Number: 15-2030/06	All lot numbers within the labeled expiration date	4026575044108	14 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1534-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 11 MM X 55 MM		Item Number: 15-2030/11	All lot numbers within the labeled expiration date	4026575044153	20 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1546-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 9 MM X 50 MM		Item Number: 15-2230/06	All lot numbers within the labeled expiration date	4026575429165	5 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1552-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO MODEL SLED TIBIAL COMP 8 MM X 45 MM		Item Number: 15-2230/13	All lot numbers within the labeled expiration date	4026575436736	5 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1507-2023	Linkbio Corp.	LINK SLED Knee System: ENDO SLED KNEE FEM COMP, SMALL		Item Number: 15-2020/40	All lot numbers within the labeled expiration date	4026575043897	14 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1514-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 13MM X 45MM		Item Number: 15-2028/04	All lot numbers within the labeled expiration date	4026575043965	14 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1516-2023	Linkbio Corp.	LINK SLED Knee System: ALL POLY TIBIAL COMPONENT 9MM X 50MM		Item Number: 15-2028/06	All lot numbers within the labeled expiration date	4026575043989	15 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/4/2023	Z-1538-2023	Linkbio Corp.	LINK SLED Knee System: ENDO MODEL SLED TIBIAL COMP 8 MM X 55 MM		Item Number: 15-2030/15	All lot numbers within the labeled expiration date	4026575436729	16 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				

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5/4/2023	Z-1540-2023	Linkbio Corp.	LINK SLED Knee System: POREX ENDO SLED KNEE FEM COMP, MEDIUM SMALL		Item Number: 15-2220/46	All lot numbers within the labeled expiration date	4026575429080	4 units	NY, NV	Additional Label Warnings: Amendment / reinforcement of the Surgical Technique and future product training on the updated technique				
5/5/2023	Z-1564-2023	Bard Peripheral Vascular Inc	Bard Mission Disposable Core Biopsy Instrument Kit, 20G x 10CM		REF: 2010MSK	Lot number: 0001445946. Exp Date: 11/28/2024	801741097089	4,120	PR, AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY .	Coaxial cannula internal diameter and length of biopsy instruments exceed the external diameter and length of the biopsy needle				
5/5/2023	Z-1564-2023	Bard Peripheral Vascular Inc	Bard Mission Disposable Core Biopsy Instrument Kit, 20G x 16CM		REF: 2016MSK	Lot number: 1458844. Exp Date: 02/28/2025	801741097096	4,120	PR, AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY .	Coaxial cannula internal diameter and length of biopsy instruments exceed the external diameter and length of the biopsy needle				
5/5/2023	Z-1569-2023	Aesculap	CAIMAN MARYLAND ARTICULATING D5/360MM		Product Code: PL771SU	Lot Number: 52785146	4046964837340	6 pieces	OH	Potential for the spring to become loose and fall out of the device				