



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Karl Storz Endoscopy Sterilization Trays for New Instructions Specific to Each Tray Model

Recall Date	Product Description	Recalling Firm	Recall Reason
6/28/2023	<p>Radel Sterilization Trays Models: 27717A, 27717B, 39301A, 39301C, 39231XA, 39301C1, 39311A, 39317A</p>	<p>Karl Storz Endoscopy El Segundo, California</p>	<p>Plastic sterilization trays used to encase and protect medical devices during sterilization have a new 510(k) with instructions for use that is for the first time specific to the tray models, that also includes information regarding the sterilization modality.</p>
6/28/2023	<p>Metal Sterilization Trays Metal Tray, 178 x 135 x 37 mm, REF: 11580A; Metal Tray, 275 x 178 x 35 mm, REF: 11580B; Metal Tray, 373 x 178 x 35 mm, REF: 11580C; Metal Tray, 275 x 175 x 37 mm, REF: 11580D; Wire Tray f. Cleaning, 290x60x52mm, REF: 39501A1; Wire Tray f. Cleaning, 352 x 125 x 54 mm, REF: 39501A2; Wire Tray f. Cleaning, 487 x 125 x 54 mm, REF: 39501B2; Wire Tray for ENDOCAMELEON, REF: 39501BEC; Tray, with lid, 670x80x52mm, REF: 39501C; Wire Tray for ENDOCAMELEON, long version, REF: 39501CEC; Wire Tray Retromolar Intub. Endoscope, REF: 39501F; Wire basket for c-mac</p>	<p>Karl Storz Endoscopy El Segundo, California</p>	<p>Metal sterilization trays used to encase and protect medical devices during sterilization have a new 510(k) with instructions for use that is for the first time specific to the tray models, that also includes information regarding the sterilization modality.</p>

	videolaryngoscope, REF: 39501LC2; Tray, URS, 644 x 150 x 80 mm, REF: 39501X; Wire Tray, URS, REF: 39501XK; Wire tray PECD, REF: 39501XP; Tray, paranasal sinus shaver system, REF: 39550A		
--	---	--	--

Recall Class	Product Identification	Distribution	Affected Dates
II	Radel Sterilization Trays Model - UDI-DI/GTIN: 27717A - 4048551089262, 27717B - 4048551089286, 39301A - 4048551156957, 39301C - 4048551157046, 39231XA, 39301C1, 39311A, 39317A. All Lots.	1698 Units in California	April 2023 and Prior
II	Metal Sterilization Trays REF/UDI-DI: 11580A/ 04048551051801; 11580B/ 04048551051818; 11580C/ 04048551051825; 11580D/ 04048551051832; 39501A1/ 04048551157619; 39501A2/ 04048551157626; 39501B2/ 04048551157657; 39501BEC/ 04048551241400; 39501C/ 04048551157671; 39501CEC/ 04048551254158; 39501F/ 04048551157695; 39501LC2/ 04048551273432; 39501X/ 04048551157756; 39501XK/ 04048551157763; 39501XP/ 04048551157770; 39550A/ 04048551157879. All lots.	61 Units in California	April 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov

