



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Karl Storz Endoscopy Recalls Injection Needles For General And Visceral Surgery For Manual Cleaning Process Efficacy Problem

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|-------------|---|--|--|
| 12/27/2023 | Injection Needle 8598A Curved 23 cm, REF: 8598A | KARL STORZ ENDOSCOPY El Segundo, California | The efficacy of the manual cleaning process cannot be assured for the affected injection needles intended for general surgery and visceral surgery, which if used, may expose the patient to a higher risk of infection. |
| 12/27/2023 | Injection Needle 8598D Distal 45-degrees, 23 cm, REF: 8598D | KARL STORZ ENDOSCOPY El Segundo, California | The efficacy of the manual cleaning process cannot be assured for the affected injection needles intended for general surgery and visceral surgery, which if used, may expose the patient to a higher risk of infection. |
| 12/27/2023 | Injection Needle 3 Fr., REF: 27030N; Injection Cannula, 6 Fr., REF: 27182A | KARL STORZ ENDOSCOPY El Segundo, California | The efficacy of the manual cleaning process cannot be assured for the affected injection needles intended for general surgery and visceral surgery, which if used, may expose the patient to a higher risk of infection. |

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| 12/27/2023 | Injection Needle Single cvd. 70 degrees, REF: 738750; Injection Needle, single cvd. 80 degrees, REF: 738752; Injection Needle, bayonet, 13 cm, REF: 738756; Injection Needle, angular, 13 cm, REF: 738758; Needle, bayonet-shaped, REF: 810505; Needle, Septum, angular, REF: 810506 | KARL STORZ ENDOSCOPY El Segundo, California | The efficacy of the manual cleaning process cannot be assured for the affected injection needles intended for general surgery and visceral surgery, which if used, may expose the patient to a higher risk of infection. |
| 12/27/2023 | Injection Needle LUER-lock,0.8mm, REF: 26175PD | KARL STORZ ENDOSCOPY El Segundo, California | The efficacy of the manual cleaning process cannot be assured for the affected injection needles intended for general surgery and visceral surgery, which if used, may expose the patient to a higher risk of infection. |
| 12/27/2023 | Injection Needle REF: 25207 | KARL STORZ ENDOSCOPY El Segundo, California | The efficacy of the manual cleaning process cannot be assured for the affected injection needles intended for general surgery and visceral surgery, which if used, may expose the patient to a higher risk of infection. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|---------------------|--|----------------------------|-----------------------------|
| II | Injection Needle REF/UDI-DI: 8598A/04048551213278 | 73 Units in California | December, 2023 and prior |
| II | Injection Needle REF/UDI-DI: 8598D/04048551213285 | 423 Units in California | December, 2023 and prior |

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| II | Injection Needle REF/UDI-DI: 27030N/4048551257180, 27182A/4048551081457 All lot numbers. | 990 Units Nationwide | December, 2023 and prior |
| II | Injection Needle REF/UDI-DI: 738750/04048551195437, 738752/04048551195444, 738756/04048551195451, 738758/04048551195468, 810505/04048551203842, 810506/04048551001660 All lot numbers. | 4470 Units Nationwide | December, 2023 and prior |
| II | Injection Needle UDI-DI: 04048551099391. All lot numbers. | 1127 Units Nationwide | December, 2023 and prior |
| II | Injection Needle UDI-DI: 04048551085776. All lot numbers | 1 Unit Nationwide | December, 2023 and prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE [8598](#), [3Fr](#), [Single CVD](#), [LUER-Lock](#), [REF](#)

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