



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Stradis Healthcare Unable to Confirm that Women’s Health Devices were Produced According to Design and Manufacture Standards

Recall Date	Product Description	Recalling Firm	Recall Reason
10/27/2021	Tenaculum, Plastic 2483 kits Part Number: 356T	Stradis Medical, LLC dba Stradis Healthcare, Peachtree Corners, Georgia	Firm unable to confirm that the tenaculum devices were produced in accordance with required design and manufacturing standards.
10/27/2021	IUD Insertion Pack 20 kits Part Number: 618-034	Stradis Medical, LLC dba Stradis Healthcare, Peachtree Corners, Georgia	Devices may not meet required standards.
10/27/2021	IUD Insertion Kit 14,959 kits Part Number: 935K	Stradis Medical, LLC dba Stradis Healthcare, Peachtree Corners, Georgia	Devices may not meet required standards.
10/27/2021	Endometrial Biopsy Kit 1,639 kits Part Number: 936K	Stradis Medical, LLC dba Stradis Healthcare, Peachtree Corners, Georgia	Devices may not meet required standards.
10/27/2021	Foundation Kit 790 kits Part Number: A10	Stradis Medical, LLC dba Stradis Healthcare, Peachtree Corners, Georgia	Devices may not meet required standards.

10/27/2021	Standard IUD Insertion Kit 280 kits Part Number: M20	Stradis Medical, LLC dba Stradis Healthcare, Peachtree Corners, Georgia	Devices may not meet required standards.
------------	---	--	--

Recall Class	Product Identification	Distribution	Affected Dates
Voluntary	Tenaculum, Plastic Part Number: 356T	Nationwide, including California	August 2021 and prior
Voluntary	IUD Insertion Pack Part Number: 618-034	Nationwide, including California	August 2021 and prior
Voluntary	IUD Insertion Kit Part Number: 935K	Nationwide, including California	August 2021 and prior
Voluntary	Endometrial Biopsy Kit Part Number: 936K	Nationwide, including California	August 2021 and prior
Voluntary	Foundation Kit Part Number: A10	Nationwide, including California	August 2021 and prior
Voluntary	Standard IUD Insertion Kit Part Number: M20	Nationwide, including California	August 2021 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

