



## CALIFORNIA DEVICE RECALL INFORMATION SHEET

### Megadyne Recalls MEGA Series Patient Return Electrodes for Electrosurgery because of Burns

Recall Date	Product Description	Recalling Firm	Recall Reason
7/5/2023	<b>Mega 2000 Patient Return Electrode</b> Used during electrosurgery	<b>MEGADYNE MEDICAL PRODUCTS, INC.</b> Blue Ash, Ohio	Firm has received reports of patient burns in surgical procedures where device was used.
7/5/2023	<b>Mega Soft Reusable Patient Return Electrode</b> Used during electrosurgery	<b>MEGADYNE MEDICAL PRODUCTS, INC.</b> Blue Ash, Ohio	Firm has received reports of patient burns in surgical procedures where device was used.
7/5/2023	<b>Mega Soft Dual Reusable Patient Return Electrode</b> used during electrosurgery	<b>MEGADYNE MEDICAL PRODUCTS, INC.</b> Blue Ash, Ohio	Firm has received reports of patient burns in surgical procedures where device was used.
7/5/2023	<b>Mega Soft Pediatric Patient Return Electrode</b> Used during electrosurgery	<b>MEGADYNE MEDICAL PRODUCTS, INC.</b> Blue Ash, Ohio	Firm has received reports of patient burns in surgical procedures where device was used.
7/5/2023	<b>Mega Soft Universal &amp; Universal Plus Patient Return Electrodes</b> Used during electrosurgery	<b>MEGADYNE MEDICAL PRODUCTS, INC.</b> Blue Ash, Ohio	Firm has received reports of patient burns in surgical procedures where device was used.
7/5/2023	<b>Mega Soft Universal &amp; Universal Plus Dual Patient Return Electrode</b> Used during electrosurgery	<b>MEGADYNE MEDICAL PRODUCTS, INC.</b> Blue Ash, Ohio	Firm has received reports of patient burns in surgical procedures where device was used.

Recall Class	Product Identification	Distribution	Affected Dates
I	<b>Mega 2000 Patient Return Electrode</b> Model No. 0800; UDI-DI: 10614559100936; All Units	21100 Units Nationwide	June 2023 and prior
I	<b>Mega Soft Reusable Patient Return Electrode</b> Model No. 0830; UDI-DI: 10614559101797; All Units.	21100 Units Nationwide	June 2023 and prior
I	<b>Mega Soft Dual Reusable Patient Return Electrode</b> Model No. 0835; UDI-DI: 10614559101872; All Units.	21100 Units Nationwide	June 2023 and prior
I	<b>Mega Soft Pediatric Patient Return Electrode</b> Model No. 0840; UDI-DI: 10614559103395; All Units.	21100 Units Nationwide	June 2023 and prior
I	<b>Mega Soft Universal &amp; Universal Plus Patient Return Electrodes</b> Model No. 0845 & 0847; UDI-DI: 10614559103906 & 10614559104842; All Units.	21100 Units Nationwide	June 2023 and prior
I	<b>Mega Soft Universal &amp; Universal Plus Dual Patient Return Electrode</b> Model No. 0848 & 0846; UDI-DI: 10614559104859 & 10614559104248; All Units.	21100 Units Nationwide	June 2023 and prior

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