

## California Device Recall Information Sheet

### Food and Drug Branch – Device Recalls

Mercury Enterprises, Inc. dba Mercury Medical Neo-Tee T-Piece Resuscitator

| Recall Date | Product Description                                                                                                                                                                             | Recalling Firm                                | Recall Reason                                                                                                                                                                                                                                                                                           |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01/10/2025  | <p>Neo-Tee T-Piece Resuscitator, for pediatric emergency respiratory support</p> <p>Part: 1050805, 1050808, 1050809, 1050810, 1050811, 1050814, 1050832, 1050839, 1050840, 1050841, 1050842</p> | Mercury Enterprises, Inc. dba Mercury Medical | Gas powered emergency resuscitator has a circuit flow controller manufactured with an undersized spring, which may cause resuscitator not reach the high and low ends of the PIP and PEEP pressure ranges, which may cause a loss of positive pressure, impacting effective ventilation of the patient. |

| Recall Class | Product Identification                                                                                                        | Distribution            | Affected Dates     |
|--------------|-------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------|
| I            | <p>Part: 1050805</p> <p>UDI-DI: 10641043508053, 30641043508057</p> <p>Lot: 2421450805, 2423550805, 2423650805, 2426750805</p> | 37,370 units nationwide | December and prior |

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|  | <p>Part: 1050808<br/> UDI-DI: 10641043508084,<br/> 30641043508088<br/> Lot: 2426450808, 2426750808,<br/> 2426850808, 2429050808,<br/> 2429350808</p> <p>Part: 1050809<br/> UDI-DI: 10641043508091,<br/> 30641043508095<br/> Lot: 2426450809, 2426750809,<br/> 2429050809, 2429150809,<br/> 2429350809, 2429750809,<br/> 2429850809, 2430050809,<br/> 2430250809</p> <p>Part: 1050810<br/> UDI-DI: 10641043508107,<br/> 30641043508101<br/> Lot: 2426750810, 2429350810,<br/> 2429750810, 2429850810,<br/> 2430250810</p> <p>Part: 1050811<br/> UDI-DI: 10641043508114,<br/> 30641043508118<br/> Lot: 2426550811, 2426650811,<br/> 2426750811, 2429050811,<br/> 2429150811, 2429250811,<br/> 2429350811, 2429450811,<br/> 2429750811, 2429850811,<br/> 2429950811, 2430250811</p> <p>Part: 1050814<br/> UDI-DI: 10641043508145,<br/> 30641043508149<br/> Lot: 2426450814, 2426750814,<br/> 2429050814, 2429750814,<br/> 2430250814</p> <p>Part: 1050832<br/> UDI-DI: 10641043508329,<br/> 30641043508323<br/> Lot: 2429050832, 242985083</p> |  |  |
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|  | Part: 1050839<br>UDI-DI: 10641043508398,<br>30641043508392<br>Lot: 2430350839<br><br>Part: 050840<br>UDI-DI: 10641043508404,<br>30641043508408<br>Lot: 2429050840, 2429750840<br><br>Part: 1050841<br>UDI-DI: 10641043508411,<br>30641043508415<br>Lot: 2429050841<br><br>Part: 1050842<br>UDI-DI: 10641043508428,<br>30641043508422<br>Lot: 2426750842 |  |  |
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For additional information, please visit the [FDA Website](#).