



U.S. Food & Drug Administration

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Class 2 Device Recall DOLPHIN INFLATION DEVICE CALIBER INFLATION DEVICE

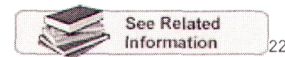


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Class 2 Device Recall DOLPHIN INFLATION DEVICE CALIBER INFLATION DEVICE



Date Initiated by Firm	April 05, 2017
Create Date	April 28, 2017
Recall Status¹	Open ³ , Classified
Recall Number	Z-1891-2017
Recall Event ID	77100 ²³
510(K)Number	K042449 ²⁴
Product Classification	Syringe, balloon inflation ²⁵ - Product Code MAV ²⁶
Product	DOLPHIN INFLATION DEVICE CALIBER INFLATION DEVICE; Catalog Number: CL3030- 018SNA- 018SND 0185NA 0185ND; INTERNAL CODE NUMBER: 0185TR- 0185NA- 018SND 0185NA 0185ND
Code Information	1 5045606 - 15055430 - 15065340 - 15065685 -15065744- 15065858- 15065970- 15075121 - 15075265 - 15075411- 15075821 - 1 5075851 - 15075942 - 15085001 - 15085075 - 15085378- 15085435 -15085515- 15085555 -15105052- 15125214- 16015267- 16025034- 16025640
Recalling Firm/ Manufacturer	PEROUSE MEDICAL ROUTE DU MANOIR Ivry Le Temple France
Manufacturer Reason for Recall	Complaints regarding broken blister.
FDA Determined Cause ²	Packaging change control
Action	Consignees were notified of the recall on April 5, 2017. They were informed of the issue and asked to take the following steps: 1. Inspect your stock to determine if you still have in your ownership devices among which the references and batch codes are listed in front page; 2. Control the potential damage of the blister according to the pictures above and the instructions mentioned on the labeling and the Instruction For Use: any damaged and/or cracked blister must be immediately discarded; 3. Use the compliant products without risk, after control. Indeed, the primary packaging will not deteriorate in time. If, to date, there is no crack in the blister, then the integrity of the product is not compromised; 4- Do not use the non-compliant products; 5. Complete and sign the attached reply form, then return it within 5 working days following the reception of this letter, and keep a copy; 6. Contact customer service for the modalities of return, replacement and associated support at +33 (0) 4.72.39.74.13 or by fax at +33 (0)3.44.08.17.67 or by email at iblayon@vvgon.com (CC mhpourriere@vygon.com); 7. Communicate the safety information to any person concerned in your company and to all end customers to which the product were transferred.
Quantity in Commerce	18,431
Distribution	US: AZ (shipped through Belgium to USA), MN, TN
Total Product Life Cycle	TPLC Device Report ²⁷