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**Class 2 Device Recall PDS" Plus Antibacterial Suture**



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**Class 2 Device Recall PDS" Plus Antibacterial Suture**



<b>Date Initiated by Firm</b>	June 08, 2018
<b>Create Date</b>	July 24, 2018
<b>Recall Status</b> <sup>1</sup>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-2532-2018
<b>Recall Event ID</b>	<a href="#">80401</a> <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K061037</a> <sup>24</sup>
<b>Product Classification</b>	<a href="#">Suture, surgical, absorbable, polydioxanone</a> <sup>25</sup> - <b>Product Code</b> <a href="#">NEW</a> <sup>26</sup>
<b>Product</b>	PDS Plus Antibacterial (Polydioxanone) Suture-PDS PLUS Undyed Suture 45cm (18") 4-0 Single Armed PS-4 Prime Needle Product Code: PDP507G (GTIN 10705031203983)
<b>Code Information</b>	Lot Number: MBK743
<b>Recalling Firm/Manufacturer</b>	Ethicon, Inc. Us Highway 22 West Somerville NJ 08876
<b>For Additional Information Contact</b>	SAME 908-218-0707
<b>Manufacturer Reason for Recall</b>	Products do not meet a tensile strength specification
<b>FDA Determined Cause</b> <sup>2</sup>	Under Investigation by firm
<b>Action</b>	Johnson & Johnson Affiliate Japan notified consignees on 6/08/18 by customer letter through post or email or sales representative visits. Accounts requested to Examine inventory, remove and quarantine such product(s) and complete the Business Reply Form (BRF). Product to requested to be returned.
<b>Quantity in Commerce</b>	4992
<b>Distribution</b>	Japan
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>

<sup>1</sup> A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. [Learn more about medical device recalls](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

<sup>3</sup> The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

**510(K) Database**      [510\(K\)s with Product Code = NEW and Original Applicant = ETHICON, INC.](#)<sup>29</sup>