

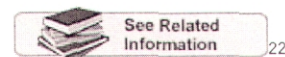
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## Class 2 Device Recall Raindrop Near Vision Inlay


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### Class 2 Device Recall Raindrop Near Vision Inlay



<b>Date Initiated by Firm</b>	February 07, 2017
<b>Create Date</b>	March 21, 2017
<b>Recall Status</b> <sup>1</sup>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1518-2017
<b>Recall Event ID</b>	<a href="#">76422</a> <sup>23</sup>
<b>PMA Number</b>	<a href="#">P150034</a> <sup>24</sup>
<b>Product Classification</b>	<a href="#">Implant, corneal, refractive</a> <sup>25</sup> - <b>Product Code</b> <a href="#">LQE</a> <sup>26</sup>
<b>Product</b>	Raindrop Near Vision Inlay, Model# RD1-1
<b>Code Information</b>	multiple lots since 08/01/2016
<b>Recalling Firm/ Manufacturer</b>	Revision Optics Inc 25651 Atlantic Ocean Dr Ste A1 Lake Forest CA 92630-8835
<b>For Additional Information Contact</b>	949-707-2744
<b>Manufacturer Reason for Recall</b>	ReVision Optics has updated the instructions for use (IFU) for the Raindrop Near Vision Inlay to emphasize that only Balanced Salt Solution (BSS) may be used to irrigate under the flap and that topical medications or lubricants should not be administered until centration of the inlay and proper flap positioning has been confirmed at the slit lamp.
<b>FDA Determined Cause</b> <sup>2</sup>	Use error
<b>Action</b>	A Dear Doctor letter was sent to inform customers that ReVision Optics wanted to share a surgical update regarding the Raindrop Near Vision Inlay procedure. Customers are informed that no ophthalmic medications or lubricants should be used immediately prior to or during placement of the Raindrop Near Vision Inlay. Only Balanced Salt Solution (BSS) should be used to irrigate under the flap during the Raindrop procedure. Customers are informed that ophthalmic medications or lubricants should be administered only after verifying proper inlay centration and flap positioning as observed at the slit lamp. This ensures that no further inlay or flap manipulation is required. ReVision Optics has updated the instructions for use (IFU) for the Raindrop Near Vision Inlay to emphasize that only BSS may be used to irrigate under the flap and that topical medications or lubricants should not be administered until centration of the inlay and proper flap positioning has been confirmed at the slit lamp. Customers with questions are instructed to contact Luis Vargas regarding the surgical procedure update.
<b>Quantity in Commerce</b>	1,279 devices
<b>Distribution</b>	US: AL, AZ, CA, FL, GA, HI, IL, IN, LA, MA, MD, MI, MN, MO, MS, NC, ND, NE, NH, NJ, NY, OH, OK, PA, SD, TN, TX, UT, WA
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>