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**Class 2 Device Recall Stryker EliteCore FullCore Biopsy devices**

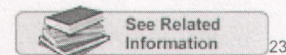


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**Class 2 Recall  
Stryker EliteCore FullCore Biopsy  
devices**



<b>Date Posted</b>	May 26, 2015
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1671-2015
<b>Recall Event ID</b>	<a href="#">71185<sup>24</sup></a>
<b>Premarket Notification 510(K) Number</b>	<a href="#">K112945<sup>25</sup></a>
<b>Product Classification</b>	<a href="#">Instrument, Biopsy<sup>26</sup></a> - <b>Product Code</b> <a href="#">KNW<sup>27</sup></a>
<b>Product</b>	EliteCore 18G, 20cm with and without HiLiter tip, 15 cm with and without HiLiter tip, and 10 cm with and without HiLiter tip.
<b>Code Information</b>	Stryker Product Numbers: 0915-820-000; 0905-820-000; 0915-815-000; 0905-815-000; 0915-810-000; 0905-810-000; RLS Product Numbers: 931018, 931518, 941518. Stryker lot numbers distributed 16-JUN-2014 to 10-FEB-2015 affected: 61406001, 61406002, 61406007 RLS lot numbers distributed 28-MAR-2013 to 16-JUN-2014 affected: 61302001, 61203001, 61108001, 61208002, 61309001
<b>Recalling Firm/Manufacturer</b>	<a href="#">Stryker Instruments Div. of Stryker Corporation</a> 4100 E Milham Ave Portage, Michigan 49002-9704
<b>For Additional Information Contact</b>	Julie Forsyth 269-389-2458
<b>Manufacturer Reason for Recall</b>	Stryker Instruments is initiating a recall of the EliteCore device due to a product failure which occurred during a standard Quality Inspection Process where it was determined that there is the potential for the device cannula to overthrow past the intended length.
<b>FDA Determined Cause<sup>2</sup></b>	OTHER/UNDETERMINED: Under Investigation by the firm
<b>Action</b>	Stryker sent an Urgent Medical Device Recall Notification letter dated May 5, 2015, to all affected customers via Fed Ex overnight. Customers were instructed to quarantine any product found, return the response form even if there is no product on hand, forward the letter if further distribution of recalled product occurred, return recalled product to Stryker. Customers were instructed to 269-389-2458 with any questions.
<b>Quantity in Commerce</b>	1,420 Units
<b>Distribution</b>	Nationwide Distribution including AL, AR, AZ, CA, CO, FL, GA, IL, IN, KS, KY, LA, MI, MN, MO, MS, NJ, NM, NV, NY, OK, OR, PA, TN, TX, UT, VA, and WI.
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report<sup>28</sup></a>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<sup>29</sup>](#)

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

**510(K) Database**      510(K)s with Product Code = KNW and Original Applicant = INRAD INC.<sup>30</sup>