5900 Optical Court
San Jose, CA, 95138 USA
t: 408-754-2000

URGENT MEDICAL DEVICE RECALL

SERFAS 90^{O} ENERGY PROBE (279-350-101)

June 5, 2015

Attn: Materials Manager
Customer Name
Customer Address
Customer Number:

Description: SERFAS 90^{o} Energy Probe, Part number 279-350-101
Lot Number: All non-expired product
(Lot numbers13128AE2 through 14337AE2)

The purpose of this letter is to advise you that Stryker Endoscopy is voluntarily recalling the SERFAS 90^{o} Energy Probe (also known as the 90R probe), part number 279-350-101, all non-expired product (lot numbers 13128AE2 through 14337AE2). Note that this recall is only for this specific probe.

Reason for the Recall: There have been a total of 23 reports of fragments of the probe breaking off into the patient since December 2013.

Risk to Health: There is a potential risk that fragments may be released into the joint space as a result of the probe breaking requiring immediate surgical intervention to remove the fragments. In addition, there is a potential risk the fragments may remain within the joint space, resulting in function impairment.

Actions to be taken: Recipients of this letter are confirmed to have received shipments of at least one SERFAS 90^{o} Energy Probe. Please:

1. Inform individuals within your organization who need to be aware of this device removal.
2. Review inventory of lots of part number 279-350-101 and determine if you have the affected product (all non-expired devices) in stock. **Response is required.**
3. If no product is found, notify your local Stryker office.
4. If you do have product, segregate the product and call your local Stryker office to arrange for product return and issuance of credit.

We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

Sincerely,

[redacted]

Stryker Endoscopy
endorecall@stryker.com

Health care professionals and consumers may report adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone. Online: www.fda.gov/MedWatch/report.htm Mail: Use postage paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers La ne, Rockville, MD 20852-9787 Phone: 1-800-FDA-1088 Fax: 1-800-FDA-0178