



## URGENT FIELD SAFETY NOTICE

GE Healthcare  
Thomas Medical Products  
65 Great Valley Parkway  
Malvern, PA 19355  
USA

<Date>

GEHC Ref # 35011

To: <Purchasing Agent / Buyer, Quality Director, Risk Manager, Materials Manager>

Re: MEDICAL DEVICE RECALL of the SafeSheath® CSG® Coronary Sinus Guide Braided Core Hemostatic Introducer, SafeSheath® Worley Telescopic Braided Series & Situs LDS 2 Lead Delivery System

Thomas Medical Products, a GE Healthcare Company, has recently become aware of an issue with the radiopaque segment of the above listed products that may impact patient safety. **Please ensure that all potential users are made aware of this safety notification and the recommended actions.**

### Safety Issue

The radiopaque segment may detach during in vivo use resulting in device fragments that will remain in the patient's vasculature.

### Safety Instructions

1. Immediately segregate all affected product in a manner that ensures it will not be used.
2. Return any product with reference to the return authorization (RA) number on the product reconciliation form, or contact your customer service representative at the phone number listed below to facilitate return of the affected product.
3. If any affected product has been forwarded to another facility, contact that facility to arrange return.
4. By returning product, you attest that you have returned all unused product in your inventory.

Attached is a product reconciliation form. Please complete the form and fax back as indicated. This is required for us to confirm communication with all of our customers.

### Affected Product Details

<u>Catalog No.</u>	<u>Lot Number</u>	<u>Catalog No.</u>	<u>Lot Number</u>	<u>Catalog No.</u>	<u>Lot Number</u>
FCL-069-02	S30852X1	FCL-070-01	S31962	FCL-083-03	S30333X1
FCL-069-02	S30919X1	FCL-070-01	S32178X1	FCL-083-03	S30622X1
FCL-069-02	S31098	FCL-070-01	S32263	FCL-083-03	S31076
FCL-069-02	S31212X1	FCL-070-01	S32506X1	FCL-083-03	S31316
FCL-069-02	S31306	FCL-070-01	S32565X1	FCL-083-03	S31340
FCL-069-02	S31331X1	FCL-070-01	S32675	FCL-083-03	S31507
FCL-069-02	S31534X1	FCL-070-01	S32715	FCL-083-03	S31563
FCL-069-02	S32139	FCL-070-01	S32831	FCL-083-03	S31650
FCL-069-02	S32282	FCL-070-01	S33067	FCL-083-03	S31674
FCL-069-02	S32308	FCL-070-01	S33398	FCL-083-03	S31917X1
FCL-069-02	S32543X1	FCL-070-01	S33758	FCL-083-03	S32327
FCL-069-02	S32602	FCL-070-01	S33939	FCL-083-03	S32605X1
FCL-069-02	S32684	FCL-083-02	S30262X1	FCL-083-03	S32610
FCL-069-02	S32882	FCL-083-02	S30332X1	FCL-083-03	S32796
FCL-069-02	S33149X1	FCL-083-02	S30739	FCL-083-03	S33322
FCL-069-02	S33236	FCL-083-02	S31005X1	FCL-083-03	S33543
FCL-069-02	S33399	FCL-083-02	S31097	FCL-090-00	S30956X1
FCL-069-02	S33614	FCL-083-02	S31245	FCL-090-00	S30970

**Affected Product Details (Cont.)**

<u>Catalog No.</u>	<u>Lot Number</u>	<u>Catalog No.</u>	<u>Lot Number</u>	<u>Catalog No.</u>	<u>Lot Number</u>
FCL-069-03	S30889X1	FCL-083-02	S31709	FCL-090-00	S30986X1
FCL-069-03	S31327X1	FCL-083-02	S31771X1	FCL-090-00	S30987X1
FCL-069-03	S31535X1	FCL-083-02	S32102	FCL-090-00	S31080X1
FCL-069-03	S32222	FCL-083-02	S32566X1	FCL-090-00	S31334
FCL-069-03	S32568X1	FCL-083-02	S32699X1	FCL-090-00	S31341
FCL-069-03	S32737	FCL-083-02	S32714	FCL-090-00	S31779X1
FCL-069-03	S33403	FCL-083-02	S32716	FCL-090-00	S32717
FCL-070-01	S30630	FCL-083-02	S32957	FCL-090-00	S33324
FCL-070-01	S30901X1	FCL-083-02	S33129	FCL-090-00	S33544
FCL-070-01	S30913	FCL-083-02	S33161X1	FCL-090-00	S34485
FCL-070-01	S31142X1	FCL-083-02	S33687	XD-1986-32	S32156
FCL-070-01	S31215X1	FCL-083-03	S30060X1	XD-1986-32	S33076
FCL-070-01	S31533X1	FCL-137-00	S33026	XD-2879-00	S32219
FCL-129-00	S24359	FCL-137-00	S33238	XD-2879-01	S27288
FCL-129-00	S24683	FCL-137-00	S33478	XD-2879-01	S27477
FCL-129-00	S24838	FCL-137-00	S33889	XD-2879-01	S27947
FCL-129-00	S24932	FCL-137-00	S33921	XD-2879-01	S28401
FCL-129-00	S25489	FCL-137-00	S34026	XD-2879-01	S28791
FCL-129-00	S26861	FCL-137-00	S34096	XD-2879-01	S31439
FCL-129-01	S24618	FCL-137-00	S34342	XD-2879-01	S32167
FCL-129-01	S25222	FCL-137-00	S34375	XD-2879-01	S33065
FCL-129-01	S25540	FCL-137-00	S34689	XD-2879-01	S33301
FCL-129-01	S26881	FCL-137-00	S36110X1	XD-2879-01	S33412
FCL-129-02	S25772	FCL-137-01	S36118X1	XD-2879-01	S34082
FCL-129-02	S25945	FCL-137-01	S26539	XD-2879-02	S26759
FCL-129-03	S24064	FCL-137-01	S34690	XD-2879-02	S26987
FCL-129-03	S24120	FCL-137-02	S26560	XD-2879-02	S27222
FCL-129-03	S25544	FCL-137-03	S26460	XD-2879-02	S27971
FCL-129-03	S25937	FCL-137-03	S26540	XD-2879-02	S28339
FCL-137-00	S26333	FCL-137-04	S28632X1	XD-2879-02	S32238
FCL-137-00	S26420	XD-2054-19	S24129	XD-2879-02	S32765
FCL-137-00	S29083	XD-2054-20	S27275	XD-2879-02	S33084
FCL-137-00	S29878	XD-2054-20	S27370	XD-2879-02	S33649
FCL-137-00	S31045	XD-2879-00	S27221	XD-2879-03	S27478
FCL-137-00	S31081	XD-2879-00	S27985	XD-2879-03	S28023
FCL-137-00	S32994	XD-2879-00	S28172	XD-2879-03	S28306

**Product Correction**

Replacement product will be provided free of charge.

**Contact Information**

Please contact your local distributor if you have any questions or concerns about product return.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Thank you,



Senior Executive QARA  
GE Healthcare Systems



Chief Medical Officer  
GE Healthcare



**URGENT FIELD SAFETY NOTICE CONFIRMATION**  
**SafeSheath® CSG® Coronary Sinus Guide Braided Core Hemostatic Introducer,**  
**SafeSheath® Worley Telescopic Braided Series**  
**Situs LDS 2 Lead Delivery System**

Return Authorization # (RA#) **2369**  
 Customer  
 Address  
 City, State Zip  
 Attention: Contact

Our records indicate your facility received products subject to the above recall described in the Thomas Medical Products Inc. (TMP) Medical Device Recall Letter. The listing of the affected lots and catalog numbers is listed at the end of this form.

**Part 1: Letter Acknowledgement (Hospital or Distributor)**

We are aware of the notification of the above recall, and have set aside any remaining units to preclude continued use of the product. Product may be returned directly to the address below.

\_\_\_\_\_  
 Signature /Printed Name/Position                      Contact Phone Number      Date

**Part 2: Product Acknowledgement (Hospital or Distributor)**

Please enter requested information below and fax this form to the TMP QA fax number **(610) 651-5003**  
 Alternate transmission: scan and email to [tmpinfo@ge.com](mailto:tmpinfo@ge.com)

- a) Quantity of affected units remaining in inventory at time of recall (Return all these units): \_\_\_\_\_ (Qty)
- b) Scope (Check only one): The count of the affected product is for ( ALL /  NOT ALL) usage and storage locations at this Ship-To Acct#. If "ALL" is checked, proceed to "Signature" below.
- c) If NOT for entire facility, quantity listed above is ONLY FOR following location(s) in facility:

\_\_\_\_\_

- d) List Area(s) of facility where additional product may be located (Please copy those areas):

\_\_\_\_\_

\_\_\_\_\_  
 Signature /Printed Name/Position                      Contact Phone Number      Date  
 (For assistance returning the product or any questions relating to the scope of this recall contact Customer Service at 1-866-446-3003)

<See reverse for product return instructions and affected lot and catalog numbers>

Please return all Product (and copy of completed Acknowledgement Form and a packing list) to:

**Innerspace**  
**3201 Fox Street**  
**Philadelphia, PA 19129**  
**Attention: Thomas Medical Products RA#2278**

Return product via UPS ground service. Bill of lading should indicate 3<sup>rd</sup> Party Billing to Thomas Medical Products. Account #7327X2 (small package services) or Account #43790412 (LTL Freight services). Please list Return Authorization (RA) Number 2369 from top of this form on outside of shipper.

**Part 3: Listing of affected lots and catalog numbers**

**Lot Numbers & Catalog Number Affected**

<u>Catalog No.</u>	<u>Lot Number</u>	<u>Catalog No.</u>	<u>Lot Number</u>	<u>Catalog No.</u>	<u>Lot Number</u>
FCL-069-02	S30852X1	FCL-070-01	S31962	FCL-083-03	S30333X1
FCL-069-02	S30919X1	FCL-070-01	S32178X1	FCL-083-03	S30622X1
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FCL-069-02	S31212X1	FCL-070-01	S32506X1	FCL-083-03	S31316
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FCL-069-02	S33614	FCL-083-02	S31245	FCL-090-00	S30970
FCL-069-03	S30889X1	FCL-083-02	S31709	FCL-090-00	S30986X1
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FCL-069-03	S32568X1	FCL-083-02	S32699X1	FCL-090-00	S31341
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FCL-070-01	S30630	FCL-083-02	S32957	FCL-090-00	S33324
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FCL-070-01	S31215X1	FCL-083-03	S30060X1	XD-1986-32	S33076
FCL-070-01	S31533X1				

<Affected Product Details Continued on Next Page>

**Part 3: Listing of affected lots and catalog numbers (continued from previous page)**

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FCL-129-00	S24683	FCL-137-00	S33478	XD-2879-01	S27477
FCL-129-00	S24838	FCL-137-00	S33889	XD-2879-01	S27947
FCL-129-00	S24932	FCL-137-00	S33921	XD-2879-01	S28401
FCL-129-00	S25489	FCL-137-00	S34026	XD-2879-01	S28791
FCL-129-00	S26861	FCL-137-00	S34096	XD-2879-01	S31439
FCL-129-01	S24618	FCL-137-00	S34342	XD-2879-01	S32167
FCL-129-01	S25222	FCL-137-00	S34375	XD-2879-01	S33065
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FCL-129-02	S25945	FCL-137-01	S26539	XD-2879-02	S26759
FCL-129-03	S24064	FCL-137-01	S34690	XD-2879-02	S26987
FCL-129-03	S24120	FCL-137-02	S26560	XD-2879-02	S27222
FCL-129-03	S25544	FCL-137-03	S26460	XD-2879-02	S27971
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FCL-137-00	S26420	XD-2054-19	S24129	XD-2879-02	S32765
FCL-137-00	S29083	XD-2054-20	S27275	XD-2879-02	S33084
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FCL-137-00	S31045	XD-2879-00	S27221	XD-2879-03	S27478
FCL-137-00	S31081	XD-2879-00	S27985	XD-2879-03	S28023
FCL-137-00	S32994	XD-2879-00	S28172	XD-2879-03	S28306
FCL-137-00	S33026	XD-2879-00	S32219		