

BIOTRONIK Vertriebs GmbH & Co. KG
 Joachim Staub

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 Berlin, October 25, 2011
 OEM/OEM-5

RE: GEHC- Ref# 35011
Urgent Medical Device Correction from Thomas Medical Products/GE

Dear Mr. Staub,

herewith we would like to inform you that *Thomas Medical Products*, a subsidiary of *GE Medical* has issued an urgent medical device correction of its *SafeSheath® CSG® Coronary Sinus Guide Hemostatic Introducer System* and *LVI Lateral Vein Introducers*. The primary distributor of these products is Pressure Products, Inc.

The following products with corresponding LOT numbers are affected by the recall and were sent to BIOTRONIK:

BIO Part#	LOT	Name	PP Part#
375227	S31142X1	CSG Worley Bcor-2-09	FCL-070-01
375227	S31533X1	CSG Worley Bcor-2-09	FCL-070-01
375227	S32715	CSG Worley Bcor-2-09	FCL-070-01
375228	S30852X1	CSG Worley Bcor-1-09	FCL-069-02
375228	S30919X1	CSG Worley Bcor-1-09	FCL-069-02
375228	S31098	CSG Worley Bcor-1-09	FCL-069-02
375228	S31212X1	CSG Worley Bcor-1-09	FCL-069-02
375228	S31306	CSG Worley Bcor-1-09	FCL-069-02
375228	S31331X1	CSG Worley Bcor-1-09	FCL-069-02
375228	S32139	CSG Worley Bcor-1-09	FCL-069-02
375228	S32882	CSG Worley Bcor-1-09	FCL-069-02
375228	S33399	CSG Worley Bcor-1-09	FCL-069-02
361207	S25544	LVI/TELE/B-60-07-HO	FCL-129-03
361207	S25937	LVI/TELE/B-60-07-HO	FCL-129-03
361686	S25945	LVI/TELE/B-60-07-HS	FCL-129-02
368981	S26560	LVI/75-5-62-07-HS	FCL-137-02
382989	S26560	LVI/75-5-62-07-HS	FCL-137-02
N/A	S26861	LVI/TELE/B-60-07-RE	FCL-129-00

Please see the attached letter of *Thomas Medical Products* for a full description of the issue.

According to our documents, you have received one or more of the affected products.

Safety Instructions:

- Inform your sales force, dealers, representatives or agents about the manufacturer's UMDC using the original letter of Thomas Medical Products.
- Identify and remove all products concerned from your warehouse, any trunk, consignment stock.
- Identify all hospitals and consignment stocks that have received the affected products and send an appropriate list to birgit.nowak@biotronik.com.
- Inform all identified customers who have affected products in their stock using the original letter of Thomas Medical Products and collect the affected products for return.
- **Return all affected devices under the following RA Numbers:**
 - Egypt **11/572** - Iraq **11/578**
 - Kuwait **11/573** - Palestine **11/579**
 - Saudi Arabia **11/574** - UAE **11/580**

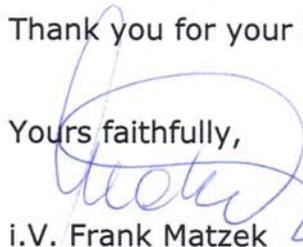
to BIOTRONIK Berlin. Please follow the respective guidelines for returning products to BIOB.

- Return the attached acknowledgement form signed by your field representative confirming that no affected device is in hospital stock to birgit.nowak@biotronik.com.
- Please document your activities appropriately.
- Please notify us, upon completion of these instructions which should not occur later than November 30, 2011.

The manufacturer has informed us, that replacement products are available and we will keep you informed about their availability.

Thank you for your immediate attention to this matter.

Yours faithfully,


i.V. Frank Matzek
OEM Business Development


i.A. Birgit Nowak
OEM Supply Quality

Attachement:

Urgent Medical Device Correction GEHC Ref# 35011
Acknowledgment Form



URGENT MEDICAL DEVICE CORRECTION

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

7-October-2011

GEHC Ref # 35011

To: Pressure Products, Inc.

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

<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

**Details
(Cont.)**

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**

You may contact the Customer Service number at 1-866-446-3003 Monday through Friday from 8:30AM to 5:00PM EDT, if you have any questions about product return.

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,



James Dennison
Senior Executive QARA
GE Healthcare Systems



William Denman, M.D., FRCA
Chief Medical Officer
GE Healthcare

Acknowledgment Form UMDC GEHC REF# 35011

Please use 1 Acknowledgement Form for each customer only.

*Sender: _____

*(please use capital letters)

(NAME IN CAPITAL LETTERS)

Customer Information:

*Hospital: _____ *City: _____

*Contact: _____ *Date: _____

The following products have been removed from the hospital today:

BIO Part#	LOT	Name	Quantity
375227	S31142X1	CSG Worley Bcor-2-09	
375227	S31533X1	CSG Worley Bcor-2-09	
375227	S32715	CSG Worley Bcor-2-09	
375228	S30852X1	CSG Worley Bcor-1-09	
375228	S30919X1	CSG Worley Bcor-1-09	
375228	S31098	CSG Worley Bcor-1-09	
375228	S31212X1	CSG Worley Bcor-1-09	
375228	S31306	CSG Worley Bcor-1-09	
375228	S31331X1	CSG Worley Bcor-1-09	
375228	S32139	CSG Worley Bcor-1-09	
375228	S32882	CSG Worley Bcor-1-09	
375228	S33399	CSG Worley Bcor-1-09	
361207	S25544	LVI/TELE/B-60-07-HO	
361207	S25937	LVI/TELE/B-60-07-HO	
361686	S25945	LVI/TELE/B-60-07-HS	
368981	S26560	LVI/75-5-62-07-HS	
382989	S26560	LVI/75-5-62-07-HS	
N/A	S26861	LVI/TELE/B-60-07-RE	

Herewith I confirm that I presented the above mentioned customer with the Urgent Medical Device Correction GEHC REF#35011 from Thomas Medical Products / GE Healthcare and that I collected all affected products from the customer for return to BIOTRONIK Berlin. Hence the customer does not have any affected product in his stock.

Signature / Date

Please return to BIOB OEM SQM by

FAX +49 30 6890 596-2922