

Date of issue: 03/06/2018

URGENT FIELD SAFETY NOTICE

Urgent– Please bring this letter to the immediate attention of the person(s) responsible for usage of the below product:

Dear Valued Customer,

The purpose of this letter is to inform you that Biometrix is conducting a voluntary recall of the **Temperature Sensor Catheters** distributed to your facility.

The details of the lots to be re-called are detailed in the table below:

Catalog Number	Product Description	Batch Number	Quantity
BY-5073	CPT - CV Astana	SN170086	50
BY-5073	CPT - CV Astana	SN170396	47
BY-5073	CPT - CV Astana	SN170504	50
BY-5073	CPT - CV Astana	SN170506	40
BY-5073	CPT - CV Astana	SN180008	87
BY-5074	CPT - CV Almaty Karaganda Adults	SN170138	50
BY-5074	CPT - CV Almaty Karaganda Adults	SN170397	50
BY-5074	CPT - CV Almaty Karaganda Adults	SN170398	100
BY-5074	CPT - CV Almaty Karaganda Adults	SN170593	50
BY-5074	CPT - CV Almaty Karaganda Adults	SN180123	30
BY-5074	CPT - CV Almaty Karaganda Adults	SN180222	60
BY-5074	CPT - CV Almaty Karaganda Adults	SN180245	20
BY-5074	CPT - CV Almaty Karaganda Adults	SN180246	25
BY-5075	CPT - CV Pack for Aktobe	SN170225	110
BY-5075	CPT - CV Pack for Aktobe	SN170226	30
BY-5075	CPT - CV Pack for Aktobe	SN170399	50
BY-5075	CPT - CV Pack for Aktobe	SN170441	40
BY-5075	CPT - CV Pack for Aktobe	SN170641	50
BY-5082	CPT - CV Astana adults	SN170192	30
BY-5082	CPT - CV Astana adults	SN180119	20
BY-5082	CPT - CV Astana adults	SN180224	35
BY-5085	CPT - CV Almaty Syzganova Adults	SN170230	40
BY-5085	CPT - CV Almaty Syzganova Adults	SN170558	60
BY-5085	CPT - CV Almaty Syzganova Adults	SN180088	35
BY-5085	CPT - CV Almaty Syzganova Adults	SN180090	22
BY-5085	CPT - CV Almaty Syzganova Adults	SN180346	26
BY-5087	Heart Surgery Pack	SN170141	50
BY-5087	Heart Surgery Pack	SN170142	44
BY-5087	Heart Surgery Pack	SN170422	20
BY-5087	Heart Surgery Pack	SN170445	30
BY-5087	Heart Surgery Pack	SN170455	6
BY-5087	Heart Surgery Pack	SN170473	30

Catalog Number	Product Description	Batch Number	Quantity
BY-5087	Heart Surgery Pack	SN170549	51
BY-5087	Heart Surgery Pack	SN170550	46
BY-5087	Heart Surgery Pack	SN180085	50
BY-5087	Heart Surgery Pack	SN180238	100
BY-5087	Heart Surgery Pack	SN180239	20
BY-5093	Heart Surgery Pack	SN180074	40
BY-5093	Heart Surgery Pack	SN180075	50
BY-5093	Heart Surgery Pack	SN180213	30
BY-5093	Heart Surgery Pack	SN180373	40
BY-5093	Heart Surgery Pack	SN180393	40
BY-5094	Heart Surgery Kit - Pedatric	SN180203	15
BY-5095	Cardio Kit	SN170233	100
BY-5095	Cardio Kit	SN170407	100
BY-5095	Cardio Kit	SN170408	100
BY-5095	Cardio Kit	SN170446	50
BY-5095	Cardio Kit	SN170601	48
BY-5095	Cardio Kit	SN180070	120
BY-5095	Cardio Kit	SN180237	70
BY-5095	Cardio Kit	SN180315	140
BY-5096	CPT - CV Almaty Adults	SN170409	54
BY-5096	CPT - CV Almaty Adults	SN170410	50
BY-5096	CPT - CV Almaty Adults	SN170411	50
BY-5096	CPT - CV Almaty Adults	SN170481	25
BY-5096	CPT - CV Almaty Adults	SN180067	20
BY-5096	CPT - CV Almaty Adults	SN180207	35
BY-5096	CPT - CV Almaty Adults	SN180241	5
BY-6073	Mitral Valve Replacement Kit	SL173897	100
BY-6074	Kit for CABG – 2 grafts	SL173203	50
BY-6074	Kit for CABG – 2 grafts	SL173204	50
BY-6074	Kit for CABG – 2 grafts	SL173205	50
BY-6074	Kit for CABG – 2 grafts	SL173209	50
BY-6074	Kit for CABG – 2 grafts	SL173210	100
BY-6074	Kit for CABG – 2 grafts	SL173359	10
BY-6074	Kit for CABG – 2 grafts	SL173949	50
BY-6074	Kit for CABG – 2 grafts	SL173950	50
MN-0108	8Fr Foley Catheter With Temperature Sensor	BN170021	150
MN-0108	8Fr Foley Catheter With Temperature Sensor	LE180226	50
MN-0108	Foley Catheter 8Fr with temperature sensor	LE170720	286
MN-0110	10fr Foley Catheter With Temperature Sensor	LE180002	200
MN-0112	12fr Foley Catheter With Temperature Sensor	LE170864	447
MN-0112	12Fr Foley Catheter With Temperature Sensor	LE180227	50
MN-0114	14fr Foley Catheter With Temperature Sensor	BN170027	42
MN-0114	14fr Foley Catheter With Temperature Sensor	LE170718	1,044
MN-0114	14fr Foley Catheter With Temperature Sensor	LE171123	3,566

Catalog Number	Product Description	Batch Number	Quantity
MN-0114	14fr Foley Catheter With Temperature Sensor	LE171328	1,140
MN-0114	14fr Foley Catheter With Temperature Sensor	LE171477	500
MN-0116	16fr Foley Catheter With Temperature Sensor	LE170443	1,082
MN-0116	16fr Foley Catheter With Temperature Sensor	LE170444	160
MN-0116	16fr Foley Catheter With Temperature Sensor	LE170858	1,480
MN-0116	16fr Foley Catheter With Temperature Sensor	LE171197	2,187
MN-0116	16fr Foley Catheter With Temperature Sensor	LE171329	2,220
MN-0116	16fr Foley Catheter With Temperature Sensor	LE171330	2,180
MN-0116	16fr Foley Catheter With Temperature Sensor	LE171416	3,000
MN-0116	16fr Foley Catheter With Temperature Sensor	LE171501	1,120
MN-0118	Foley Catheter 18Fr with temperature sensor	LE171622	480
MN-0118	Foley Catheter 18Fr with temperature sensor	LE180306	120

Description of Issue:

The above lots suspected to contain catheters with defective temperature sensor; such parts will show lower body temperature measurement than actual temperature of a patient (~-2°C). Failure to correctly measure lead to insufficient treatment.

Please immediately follow the Required Customer Actions set forth below.

- 1) Please forward this information to the immediate attention of the persons responsible for usage of the affected parts. Sub-recall must be initiated by your company to collect any distributed product from the suspected list.
- 2) Please fill in the attached Recall Response form and indicate the quantity of the affected product in your possession.
- 3) Promptly return the completed Recall Response form to Biometrix by e-mail to: eti@biometrixmedical.com

The affected product should be returned to Biometrix facility in Israel or Slovakia:

Contact Details:

Eti El-Yaakov, Export Logistics Coordinator

Office: +972-2-5861241/121

Mobile: +972-52-3826777

Fax: +972-2-5861322

e-mail: eti@biometrixmedical.com

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure patient and customer satisfaction.

Sincerely,

Andrew Holman, Managing Director

