Baxter

IMPORTANTE INFORMAZIONE DI PRODOTTO

Onorevole Ministero della Salute
Direzione Generale dei Farmaci e Dispositivi Medici
Ufficio Dispositivi Medici (Ufficio V)
Via Giorgio Ribotta, 5
00144 ROMA

Roma, 30 aprile 2019

Oggetto: Avviso di sicurezza – Set Prismaflex e Kit MARS – Kinking nella linea di accesso sangue
Nomi dei Prodotti: Set Prismaflex, OXIRIS S, Prismaflex MARS, Set Septex
Codici Prodotti: 106697, 107140, 107142, 109990, 107640, 107144, 107636, 955503, 112017,800540
Numeri di lotto: Vedere Tabella allegata

Alcuni centri hanno segnalato di aver rilevato una piegatura sulla linea di accesso (kinking della linea) durante il trattamento con i Set Prismaflex. Se il kinking della linea impedisce il flusso ematico, si attiva un allarme sui sistemi Prismaflex o Prismax. La problematica è isolata ad un sottogruppo di lotti, sulla base delle date di produzione.

Baxter ha implementato azioni correttive volte a ridurre il verificarsi di tale piegatura sulle linee di accesso dei set Prismaflex di recente produzione.

Il kinking della linea di accesso può potenzialmente causare riduzione della dose terapeutica, coaguli nel circuito ematico dovuti al ridotto flusso sangue o a emolisi. Non sono stati riportati gravi danni associati a questa problematica e ci si aspetta che siano improbabili. Baxter sta inviando una Importante Informazione di Prodotto per informare gli operatori sanitari che se si osserva il kinking della Linea prima del trattamento, il set Prismaflex deve essere sostituito come indicato nelle Istruzioni per l'Uso. Se si identifica il kinking della linea durante il trattamento, la terapia deve essere interrotta, il sangue presente nel circuito deve essere restituito al paziente secondo la normale procedura ed il set deve essere sostituito per continuare la terapia.

Baxter invierà la comunicazione allegata ai propri clienti.

In caso di domande Vi chiediamo di contattare la Dott.ssa Alessandra Di Leva al n. 06/32491221

Con osservanza

BAXTER S.p.A.
Dott.ssa C. Capo
Regulatory Affairs

Sede Legale e Amministrativa
Baxter S.p.A.
Piazzale dell'Industria 20, 00144 Roma
Tel (+39) 06 324911 – Fax (+39) 06 3221643
Sito Internet: www.baxteritalia.it
Capitale Sociale € 7.000.000,00 i.v. – Iscritta al Registro delle Imprese di ROMA – C.F. 00492340583 - P. IVA: 00907371009 – Nr. REA 323287
Indirizzo PEC: baxterspa@pec.baxter.com
Privacy: Baxterprivacy@pec.baxter.com
Central Workshop Italia
Viale Trentino 18/20, 35043 Monselice PD
Tel (+39) 0429 768540 – Fax (+39) 0429 768592
Field Technical Service
Via Camurana 71, 41036 Medolla MO
Tel (+39) 0535 50411 – Fax (+39) 053525960

TNT

Busta domestica

Con No
MY0754 1882

Piece: 01 of 01
Weight: 0,500

Service

Option

Customer Reference
840061222

Origin: RM5
Date: 30/04/2019

Microzona / Fermo

B

RM21

Dest Depot **RM3**

7500003922999243723560 46

MY0754 1882 5

myTNT.it

Sender
BAXTER SPA
P.LE DELL'INDUSTRIA 20
ROMA
00144 RM
IT
Contac FABRIZIO TROIANI
Tel: 0632491575

Delivery Address
MINISTERO DELLA SALUTE
VIALE GIORGIO RIBOTTA 5

00100 ROMA
IT

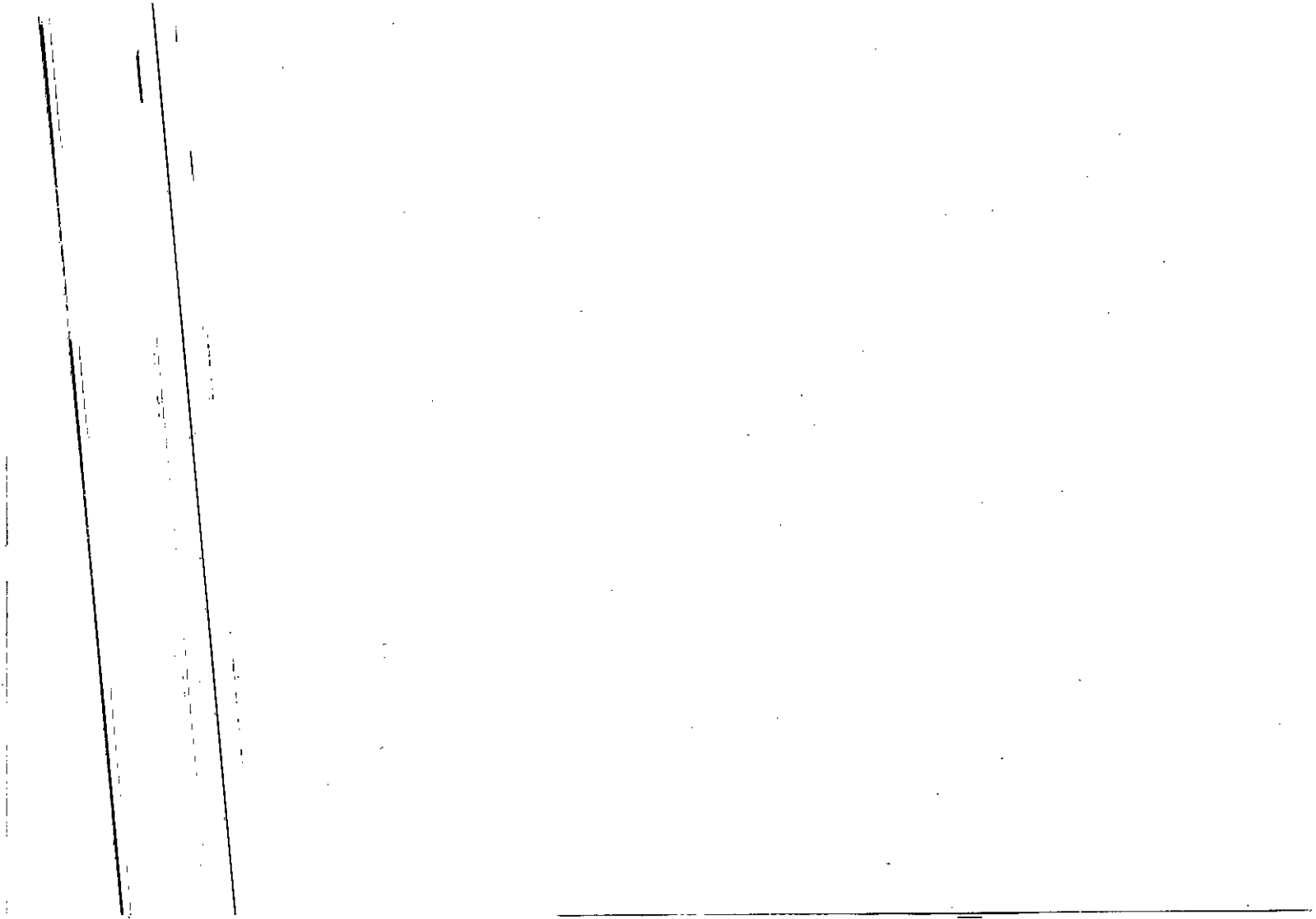
Contact:
UFF.DISP.MED.(UFF.V
Tel:

Description of
DOCS (C.CAPO)

Consignment Volume: 0,001 m³

BUSTA

Special Delivery Instructions
OGGETTO : AVVISO DI SICUREZZA - SET PRISMAFLEX E KIT MARS



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IMPORTANTE INFORMAZIONE DI PRODOTTO

.... Aprile 2019

Gentile cliente,

Descrizione del problema

alcuni centri hanno segnalato di aver rilevato una piegatura sulla linea di accesso (kinking della linea) durante il trattamento con i Set Prismaflex Se il kinking della linea impedisce il flusso ematico, si attiva un allarme sui sistemi Prismaflex o Prismax. La problematica è isolata ad un sottogruppo di lotti, sulla base delle date di produzione. I prodotti impattati sono elencati nella sottostante tabella.

Baxter ha implementato azioni correttive volte a ridurre il verificarsi di tale piegatura sulle linee di accesso dei set Prismaflex di recente produzione.

Prodotti impattati

Codice Prodotto	Descrizione Prodotto	Numeri di lotto
106697	Set Prismaflex M100	Tutti i lotti con date di scadenza tra 1/3/2020 e 1/3/2021
107140	Set Prismaflex HF100	Tutti i lotti con date di scadenza tra 1/3/2020 e 1/2/2021
107142	Set Prismaflex HF1400	Tutti i lotti con date di scadenza tra 1/3/2020 e 1/1/2021
109990	Set Prismaflex M150	Tutti i lotti con date di scadenza tra 1/3/2020 e 1/3/2021
107640	Set Prismaflex ST150	Tutti i lotti con date di scadenza tra 1/3/2020 e 1/2/2021
107144	Set Prismaflex TPE2000	Tutti i lotti con date di scadenza tra 1/3/2020 e 1/2/2022
107636	Set Prismaflex ST100	Tutti i lotti con date di scadenza tra 1/3/2020 e 1/2/2021
955503	OXIRIS S	Tutti i lotti con date di scadenza tra 1/3/2020 e 1/3/2021
112017	Set Septex	Tutti i lotti con date di scadenza tra 1/7/2021 e 1/1/2022
800540	Kit trattamento MARS tipo 1116/1 X-MARS	Tutti i lotti con date di scadenza tra 30/11/2020 e 31/10/2021

Rischio implicato

Il kinking della linea di accesso può potenzialmente causare riduzione della dose terapeutica, coaguli nel circuito ematico dovuti al ridotto flusso sangue o a emolisi. Non sono stati riportati gravi danni associati a questa problematica e ci si aspetta che siano improbabili

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Azioni da intraprendere da parte dei clienti

1. I clienti possono continuare ad usare in modo sicuro i set Prismaflex sopraelencati impattati da questa problematica. Se si osserva il kinking della Linea prima del trattamento, il set Prismaflex deve essere sostituito come indicato nelle Istruzioni per l'Uso. Se si identifica il kinking della linea durante il trattamento, la terapia deve essere interrotta, il sangue presente nel circuito deve essere restituito al paziente secondo la normale procedura ed il set deve essere sostituito per continuare la terapia.
2. **Se il prodotto è stato acquistato direttamente da Baxter, Le chiediamo gentilmente di compilare il "modulo di risposta cliente" allegato e di rispedirlo a Baxter** via fax o tramite e-mail **anche se non si dispone di inventario**. L'invio tempestivo del "modulo di risposta cliente" confermerà la ricezione della presente notifica e Le eviterà di ricevere ripetuti solleciti.
3. Se il prodotto è stato acquistato da un distributore, La preghiamo di notare che il "modulo di risposta cliente" non è applicabile. Se il suo distributore o grossista Le invia un modulo glielo restituisca secondo le istruzioni fornite.
4. Se il prodotto viene distribuito ad altre strutture o reparti all'interno della Sua Azienda Ospedaliera, Le chiediamo di diffondere questa comunicazione.
5. Se Lei è un distributore, grossista, rivenditore o un produttore di apparecchiature che ha distribuito il prodotto in questione ad altre sedi/dipartimenti, La preghiamo di diffondere questa informativa ai suoi clienti.

Ci scusiamo per qualsiasi inconveniente questa comunicazione possa causare a Lei ed al Suo staff.

In fede

Baxter S.p.A.

Allegato: Tabella dei lotti impattati

Affected Product Table

Product Code	Product description	Lot
106697	Prismaflex M100 set	18C0802
106697	Prismaflex M100 set	18D0302
106697	Prismaflex M100 set	18D0701
106697	Prismaflex M100 set	18D1002
106697	Prismaflex M100 set	18D1605
106697	Prismaflex M100 set	18D1802
106697	Prismaflex M100 set	18D1803
106697	Prismaflex M100 set	18E1804
106697	Prismaflex M100 set	18E2505
106697	Prismaflex M100 set	18G1706
106697	Prismaflex M100 set	18I2006
106697	Prismaflex M100 set	18I2008
106697	Prismaflex M100 set	18I2807
106697	Prismaflex M100 set	18J0405
106697	Prismaflex M100 set	18J1202
106697	Prismaflex M100 set	18J3005
106697	Prismaflex M100 set	18J3008
106697	Prismaflex M100 set	18K1401
106697	Prismaflex M100 set	18K1505
106697	Prismaflex M100 set	18K2301
106697	Prismaflex M100 set	18K2803
106697	Prismaflex M100 set	18L2002
107140	Prismaflex HF1000 set	18D1202
107140	Prismaflex HF1000 set	18D2402
107140	Prismaflex HF1000 set	18I2503
107140	Prismaflex HF1000 set	18J0103
107140	Prismaflex HF1000 set	18J1201
107140	Prismaflex HF1000 set	18J3103
107140	Prismaflex HF1000 set	18K0803
107140	Prismaflex HF1000 set	18K2205
107140	Prismaflex HF1000 set	18K2709
107140	Prismaflex HF1000 set	18L0701
107140	Prismaflex HF1000 set	19A0901
107140	Prismaflex HF1000 set	19A1701
107142	Prismaflex HF1400 set	18C0204
107142	Prismaflex HF1400 set	18C0804
107142	Prismaflex HF1400 set	18C2706
107142	Prismaflex HF1400 set	18D0904

107142	Prismaflex HF1400 set	18D2604
107142	Prismaflex HF1400 set	18E1406
107142	Prismaflex HF1400 set	18E2402
107142	Prismaflex HF1400 set	18E2901
107142	Prismaflex HF1400 set	18G1804
107142	Prismaflex HF1400 set	18H3003
107142	Prismaflex HF1400 set	18I1703
107142	Prismaflex HF1400 set	18I2405
107142	Prismaflex HF1400 set	18J0404
107142	Prismaflex HF1400 set	18J2305
107142	Prismaflex HF1400 set	18J2506
107142	Prismaflex HF1400 set	18K0701
107142	Prismaflex HF1400 set	18K1508
107142	Prismaflex HF1400 set	18K3002
107142	Prismaflex HF1400 set	19A1601
107144	Prismaflex TPE 2000 set	18C1904
107144	Prismaflex TPE 2000 set	18E2306
107144	Prismaflex TPE 2000 set	18F1104
107144	Prismaflex TPE 2000 set	18G2305
107144	Prismaflex TPE 2000 set	18H2803
107144	Prismaflex TPE 2000 set	18I0304
107144	Prismaflex TPE 2000 set	18I1303
107144	Prismaflex TPE 2000 set	18I1804
107144	Prismaflex TPE 2000 set	18J1901
107144	Prismaflex TPE 2000 set	18K0208
107144	Prismaflex TPE 2000 set	19A0803
107144	Prismaflex TPE 2000 set	19A1504A
107144	Prismaflex TPE 2000 set	19A2107
107636	prismaflex ST100 set	18C1501
107636	prismaflex ST100 set	18F1105
107636	prismaflex ST100 set	18F1902
107636	prismaflex ST100 set	18F2704
107636	prismaflex ST100 set	18G1104
107636	prismaflex ST100 set	18I1407
107636	prismaflex ST100 set	18K1303
107636	prismaflex ST100 set	18L0802
107640	Prismaflex ST150 set	18C0102Z
107640	Prismaflex ST150 set	18C0201Z
107640	Prismaflex ST150 set	18C0603
107640	Prismaflex ST150 set	18C0903
107640	Prismaflex ST150 set	18C1205

107640	Prismaflex ST150 set	18C1903
107640	Prismaflex ST150 set	18C2002
107640	Prismaflex ST150 set	18D0503
107640	Prismaflex ST150 set	18D0602
107640	Prismaflex ST150 set	18D1102
107640	Prismaflex ST150 set	18D1201
107640	Prismaflex ST150 set	18D1804
107640	Prismaflex ST150 set	18D2504
107640	Prismaflex ST150 set	18E0405
107640	Prismaflex ST150 set	18E1504
107640	Prismaflex ST150 set	18E1705
107640	Prismaflex ST150 set	18E1802
107640	Prismaflex ST150 set	18E2504
107640	Prismaflex ST150 set	18E2902
107640	Prismaflex ST150 set	18E2903
107640	Prismaflex ST150 set	18E3102
107640	Prismaflex ST150 set	18F0705
107640	Prismaflex ST150 set	18F2804
107640	Prismaflex ST150 set	18H2703Z
107640	Prismaflex ST150 set	18H3001
107640	Prismaflex ST150 set	18H3002
107640	Prismaflex ST150 set	18I1003
107640	Prismaflex ST150 set	18I1501
107640	Prismaflex ST150 set	18I2404
107640	Prismaflex ST150 set	18I2703
107640	Prismaflex ST150 set	18I2802
107640	Prismaflex ST150 set	18J0403
107640	Prismaflex ST150 set	18J0501
107640	Prismaflex ST150 set	18J0505
107640	Prismaflex ST150 set	18J1003
107640	Prismaflex ST150 set	18J1804
107640	Prismaflex ST150 set	18J2401
107640	Prismaflex ST150 set	18J3002
107640	Prismaflex ST150 set	18K0202
107640	Prismaflex ST150 set	18K0605
107640	Prismaflex ST150 set	18K1506
107640	Prismaflex ST150 set	18K2003
107640	Prismaflex ST150 set	18K2802
107640	Prismaflex ST150 set	18L0102
107640	Prismaflex ST150 set	18L0406
107640	Prismaflex ST150 set	18L0504

107640	Prismaflex ST150 set	18L0702
107640	Prismaflex ST150 set	18L0704
107640	Prismaflex ST150 set	19A0305
107640	Prismaflex ST150 set	19A0702
107640	Prismaflex ST150 set	19A1602
107640	Prismaflex ST150 set	19A2806
107640	Prismaflex ST150 set	19A2907
107640	Prismaflex ST150 set	19B2006
109990	Prismaflex M150 set	18C2205
109990	Prismaflex M150 set	18C2303
109990	Prismaflex M150 set	18C2905
109990	Prismaflex M150 set	18I0101
109990	Prismaflex M150 set	18I2809
109990	Prismaflex M150 set	18J0506
109990	Prismaflex M150 set	18J3105
109990	Prismaflex M150 set	18K0302
109990	Prismaflex M150 set	18K2302
109990	Prismaflex M150 set	18K2605
109990	Prismaflex M150 set	18L0502
109990	Prismaflex M150 set	18L0503
109990	Prismaflex M150 set	19A1902
112017	Septex set	18G0501
112017	Septex set	18I0306
112017	Septex set	19A0402
114877	Prismaflex HP-X set	18D3002
800540	MARS Treatment Kit type 1116/1 X-MARS	0000023691
800540	MARS Treatment Kit type 1116/1 X-MARS	0000023745
955503	oXiris S	18C2206
955503	oXiris S	18D0502A
955503	oXiris S	18D2706A
955503	oXiris S	18E2203
955503	oXiris S	18F0604
955503	oXiris S	18F2506
955503	oXiris S	18G1702
955503	oXiris S	18G2304
955503	oXiris S	18J0102
955503	oXiris S	18J2204
955503	oXiris S	18K0504A
955503	oXiris S	18K2603A
955503	oXiris S	18K2704

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Conferma di ricezione della comunicazione
(Importante Informazione di Prodotto del .../5/2019)
Nomi dei Prodotti: Set Prismaflex, OXIRIS S, Prismaflex MARS, Set Septex
Codici Prodotti: 106697, 107140, 107142, 109990, 107640, 107144, 107636, 955503, 112017,800540
Numeri di lotto: Vedere Tabella allegata

Per confermare il ricevimento della presente notifica, la preghiamo di completare il presente modulo e di trasmetterlo via fax o via e-mail ai seguenti recapiti:

Fax : 06-32491329

E-mail: Italy_SHS_QA_RA_FCA_Management@baxter.com

(Non è necessario anteporre alcuna pagina iniziale di trasmissione)

Denominazione ed indirizzo della struttura:	
Modulo di risposta Compilato da: (Si prega di scrivere in stampatello)	
Titolo:	
Numero di telefono: (incluso prefisso)	

Confermiamo di aver ricevuto la comunicazione in oggetto, e di aver diffuso l'informazione fornita ad altri servizi e sedi

Firma/Data: _____
CAMPO OBBLIGATORIO

La Sua firma indica che Lei ha compreso il contenuto della lettera allegata, effettuato le azioni richieste e diffuso le informazioni se applicabile

10.4 ANNEX 4 - REPORT FORM FOR FIELD SAFETY CORRECTIVE ACTION

Report Form

Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)

v.01.13

1. Administrative information	
To which NCA(s) is this report being sent? Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom The following countries may also report to their Competent Authority: Albania, Andorra, Bahrain, Egypt, Iran, Jordan, Kazakhstan, Kenya, Kosovo, Kuwait, Lebanon, Libyan Arab, Macedonia, Montenegro, Pakistan, Qatar, Russia, Saudi Arabia, Serbia, South Africa, Sudan, Syria, Tunisia, Ukraine, United Arab Emirates	
Type of report ☒ Initial report ☐ Follow up report ☐ Final report	
Date of this report 30/04/2019	
Reference number assigned by the manufacturer FA-2019-019	
FSCA reference number assigned by NCA N/A	
Incidence reference number assigned by NCA	
Name of the co-ordinating national competent authority (if applicable) N/A	
2. Information on submitter of the report	
Status of Submitters ☒ Manufacturer ☐ Authorised representative within EEA, Switzerland and Turkey ☐ Other (identify the role)	
3. Manufacturer information	
Name GAMBRO INDUSTRIES	
Contact name Els de Turck	
Address 7, AVENUE LIONEL TERRAY	
Postcode 69883	City MEYZIEU
Phone +33 4 72 45 25 83	Fax N/A
E-mail md_vigilance@baxter.com	Country FRANCE
4. Authorized representative information	
Name N/A	

Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country

5. National contact point information

National contact point name Baxter S.p.A	
Name of the contact person Susi Soatti	
Address Via Modenese 66	
Postcode 41036	City Medolla
Phone +39 053550118	Fax +39 053550833
E-mail Susi_Soatti@baxter.com	Country Italy

6. Medical device information

Class ☐ AIMD Active implants ☒ MDD Class III – Catalogue: 112016 955503 ☒ MDD Class IIb ☐ MDD Class IIa ☐ MDD Class I	 ☐ IVD Annex II List A ☐ IVD Annex II List B ☐ IVD Devices for self-testing ☐ IVD General
Nomenclature system (preferable GMDN) GMDN	Nomenclature code Group A, B: 44601
Nomenclature text: Group A, B: Haemofilter	
Commercial name/brand name/make Group A: 1) Prismaflex M100 set 2) Prismaflex HF1000 set 3) Prismaflex HF1400 set 4) Prismaflex ST100 set 5) Prismaflex ST150 set 6) Prismaflex M150 set 7) Septex set Group B: 1) Oxiris S	
Model number NA	Catalogue number Group A: 1) 106697 2) 107140 3) 107142 4) 107636 5) 107640 6) 109990 7) 112017

	Group C: 1) 955503
Serial number(s) NA	Lot/batch number(s) Please see attached Affected Product Table
Device Manufacturing date Between 01 Mar 2018 to 01 Mar 2019	Expiry date Between 01 Mar 2020 to 01 Mar 2021
Software version number (if applicable) N/A	
Accessories/associated device (if applicable) N/A	
Notified body (NB) ID- number (BSI) 0086	

7. Description of FSCA

Background information and reason for the FSCA
Baxter has received customer reports of kinked access lines observed during treatment using Prismaflex sets. If the kink prevents blood flow, it causes the Prismaflex or Prismax Control Unit to alarm.

Description and justification of the action (corrective/preventive)
The issue has been isolated to a subset of lots, based on production dates. Baxter has implemented corrective actions to mitigate the occurrence of kinks in the access lines of newly manufactured Prismaflex sets.

A kinked access line has the potential to cause delay in therapy, blood circuit clotting as a result of reduced blood flow, or hemolysis. There have been no reports of serious injury associated with this issue and any are expected to be unlikely.

Advice on actions to be taken by the distributor and the user
Progress of FSCA, together with reconciliation data (Mandatory for a Final FSCA)

Users are asked to:

- Continue to safely use the affected Prismaflex sets. If a kink is observed before treatment, the Prismaflex set must be replaced as instructed by the Instructions for Use. If a kink is identified during treatment, therapy must be interrupted, extracorporeal blood in the circuit returned to the patient per normal procedure, and the set must be replaced to continue therapy.
- Acknowledge receipt of the Device correction (Using the Customer Reply Form)
- Forward a copy of this letter to other facilities or departments within their institutions to ensure that those locations are aware of this Important Product Information (where the user is a Hospital/Clinic/Healthcare facility)
- Distributors are asked to notify their customers of this communication in accordance with their procedures

Attached please ☐ Field Safety Notice (FSN) in English ☒ FSN in national language ☐ Others (please specify):	FSN Status ☐ Draft ☒ Final

Time schedule for the implementation of the different actions

Implementation date : **07/05/2019**
Regional targeted closure date : **To be communicated once available**
Local targeted closure date : **To be communicated once available**

These countries within the EEA and Switzerland and Turkey are affected by this FSCA
Within EEA, Switzerland and Turkey:

☒ AT	☒ BE	☒ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK	☒ EE	☒ ES
☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE	☒ IS	☒ IT	☐ LI	☒ LT
☒ LU	☒ LV	☒ MT	☒ NL	☒ NO	☒ PL	☒ PT	☒ RO	☒ SE	☒ SI

☒ SK ☒ TR

Candidate Countries:
☒ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:
Albania, Andorra, Bahrain, Egypt, Iran, Jordan, Kazakhstan, Kenya, Kosovo, Kuwait, Lebanon, Libyan Arab, Macedonia, Montenegro, Pakistan, Qatar, Russia, Saudi Arabia, Serbia, South Africa, Sudan, Syria, Tunisia, Ukraine, United Arab Emirates

18. Comments

I affirm that the information given above is correct to the best of my knowledge.

.....
Signature

Name	City	Date
Susi Soatti	Medolla (Mo)	30/04/2019

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person

10.4 ANNEX 4 - REPORT FORM FOR FIELD SAFETY CORRECTIVE ACTION

Report Form

Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)

v.01.13

1. Administrative information	
To which NCA(s) is this report being sent? Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom The following countries may also report to their Competent Authority: Albania, Andorra, Bahrain, Egypt, Iran, Jordan, Kazakhstan, Kenya, Kosovo, Kuwait, Lebanon, Libyan Arab, Macedonia, Montenegro, Pakistan, Qatar, Russia, Saudi Arabia, Serbia, South Africa, Sudan, Syria, Tunisia, Ukraine, United Arab Emirates	
Type of report ☒ Initial report ☐ Follow up report ☐ Final report	
Date of this report *30/04/2019*	
Reference number assigned by the manufacturer FA-2019-019	
FSCA reference number assigned by NCA N/A	
Incidence reference number assigned by NCA	
Name of the co-ordinating national competent authority (if applicable) N/A	
2. Information on submitter of the report	
Status of Submitters ☒ Manufacturer ☐ Authorised representative within EEA, Switzerland and Turkey ☐ Other (identify the role)	
3. Manufacturer information	
Name GAMBRO INDUSTRIES	
Contact name Els de Turck	
Address 7, AVENUE LIONEL TERRAY	
Postcode 69883	City MEYZIEU
Phone +33 4 72 45 25 83	Fax N/A
E-mail md_vigilance@baxter.com	Country FRANCE
4. Authorized representative information	
Name N/A	

Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country

5. National contact point information

National contact point name Baxter S.p.A	
Name of the contact person Susi Soatti	
Address Via Modenese 66	
Postcode 41036	City Medolla
Phone +39 053550118	Fax +39 053550833
E-mail Susi_soatti@baxter.com	Country Italy

6. Medical device information

Class ☐ AIMD Active implants ☐ MDD Class III ☒ MDD Class IIb ☒ MDD Class IIa ☐ MDD Class I	☐ IVD Annex II List A ☐ IVD Annex II List B ☐ IVD Devices for self-testing ☐ IVD General
Nomenclature system (preferable GMDN) GMDN	Nomenclature code 36194
Nomenclature text: Apheresis filter	
Commercial name/brand name/make Prismaflex TPE 2000 set, Prismaflex HP-X set	
Model number NA	Catalogue number 107144, 114877
Serial number(s) NA	Lot/batch number(s) Please see attached Affected Product Table
Device Manufacturing date Between 01 Mar 2018 to 01 Mar 2019	Expiry date Between 01 Mar 2020 to 01 Mar 2021
Software version number (if applicable) N/A	
Accessories/associated device (if applicable) N/A	
Notified body (NB) ID- number (BSI) 0086	

7. Description of FSCA

Background information and reason for the FSCA
Baxter has received customer reports of kinked access lines observed during treatment using Prismaflex sets. If the kink prevents blood flow, it causes the Prismaflex or Prismax Control Unit to alarm.

Description and justification of the action (corrective/preventive)
The issue has been isolated to a subset of lots, based on production dates. Baxter has implemented corrective actions to mitigate the occurrence of kinks in the access lines of newly manufactured Prismaflex sets.

A kinked access line has the potential to cause delay in therapy, blood circuit clotting as a result of reduced blood flow, or hemolysis. There have been no reports of serious injury associated with this issue and any are expected to be unlikely.

Advice on actions to be taken by the distributor and the user
Progress of FSCA, together with reconciliation data (Mandatory for a Final FSCA)

Users are asked to:

- Continue to safely use the affected Prismaflex sets. If a kink is observed before treatment, the Prismaflex set must be replaced as instructed by the Instructions for Use. If a kink is identified during treatment, therapy must be interrupted, extracorporeal blood in the circuit returned to the patient per normal procedure, and the set must be replaced to continue therapy.
- Acknowledge receipt of the Device correction (Using the Customer Reply Form)
- Forward a copy of this letter to other facilities or departments within their institutions to ensure that those locations are aware of this Important Product Information (where the user is a Hospital/Clinic/Healthcare facility)
- Distributors are asked to notify their customers of this communication in accordance with their procedures

Attached please find	FSN Status
☐ Field Safety Notice (FSN) in English	☐ Draft
☒ FSN in national language	☒ Final
☐ Others (please specify):	

Time schedule for the implementation of the different actions

Implementation date : **07/05/2019**
Regional targeted closure date : **To be communicated once available**
Local targeted closure date : **To be communicated once available**

These countries within the EEA and Switzerland and Turkey are affected by this FSCA
Within EEA, Switzerland and Turkey:

☒ AT	☒ BE	☒ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK	☒ EE	☒ ES
☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE	☒ IS	☒ IT	☐ LI	☒ LT
☒ LU	☒ LV	☒ MT	☒ NL	☒ NO	☒ PL	☒ PT	☒ RO	☒ SE	☒ SI
☒ SK	☒ TR								

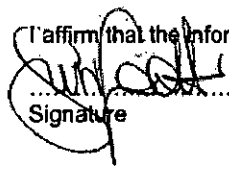
Candidate Countries:
☒ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:
Albania, Andorra, Bahrain, Egypt, Iran, Jordan, Kazakhstan, Kenya, Kosovo, Kuwait, Lebanon, Libyan Arab, Macedonia, Montenegro, Pakistan, Qatar, Russia, Saudi Arabia, Serbia, South Africa, Sudan, Syria, Tunisia, Ukraine, United Arab Emirates

8. Comments

I affirm that the information given above is correct to the best of my knowledge.



.....
Signature

Name	City	Date
Susi Soatti	Medolla	30/04/2019

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person

10.4 ANNEX 4 - REPORT FORM FOR FIELD SAFETY CORRECTIVE ACTION

Report Form

Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)

v.01.13

1. Administrative information

To which NCA(s) is this report being sent?
Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom

The following countries may also report to their Competent Authority:

Albania, Andorra, Bahrain, Egypt, Iran, Jordan, Kazakhstan, Kenya, Kosovo, Kuwait, Lebanon, Libyan Arab, Macedonia, Montenegro, Pakistan, Qatar, Russia, Saudi Arabia, Serbia, South Africa, Sudan, Syria, Tunisia, Ukraine, United Arab Emirates

Type of report

☒ Initial report

☐ Follow up report

☐ Final report

Date of this report
30/04/2019

Reference number assigned by the manufacturer
FA-2019-019

FSCA reference number assigned by NCA
N/A

Incidence reference number assigned by NCA

Name of the co-ordinating national competent authority (if applicable)
N/A

2. Information on submitter of the report

Status of Submitters

☒ Manufacturer

☐ Authorised representative within EEA, Switzerland and Turkey

☐ Other (identify the role)

3. Manufacturer information

Name GAMBRO LUNDIA AB (manufacturing facility GAMBRO ROSTOCK GMBH in Germany)	
Contact name Heike Mohrholz	
Address MAGISTRATSVÄGEN 16	
Postcode 69883	City LUND
Phone +49 381 25266 100	Fax N/A
E-mail complaints_europe@baxter.com	Country SWEDEN

4. Authorized representative information

Name N/A

Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country

5. National contact point information

National contact point name Baxter S.p.A	
Name of the contact person Susi Soatti	
Address Via Modenese 66	
Postcode 41036	City Medolla
Phone +39 053550118	Fax +39 053550833
E-mail Susi_soatti@baxter.com	Country Italy

6. Medical device information

Class ☐ AIMD Active implants ☐ MDD Class III ☒ MDD Class IIb ☐ MDD Class IIa ☐ MDD Class I	☐ IVD Annex II List A ☐ IVD Annex II List B ☐ IVD Devices for self-testing ☐ IVD General
Nomenclature system (preferable GMDN) GMDN	Nomenclature code 46212
Nomenclature text: Bound solute dialysis system component set	
Commercial name/brand name/make MARS Treatment Kit type 1116/1 X-MARS	
Model number NA	Catalogue number 800540
Serial number(s) NA	Lot/batch number(s) Please see attached Affected Product Table
Device Manufacturing date Between 04 Jun 2018 to 04 Apr 2019	Expiry date Between 30 Nov 2020 to 31 Oct 2021
Software version number (if applicable) N/A	
Accessories/associated device (if applicable) N/A	
Notified body (NB) ID- number (BSI) 0086	

7. Description of FSCA

Background information and reason for the FSCA Baxter has received customer reports of kinked access lines observed during treatment using Prismaflex sets. If the kink prevents blood flow, it causes the Prismaflex or Prismax Control Unit to alarm.
Description and justification of the action (corrective/preventive)

The issue has been isolated to a subset of lots, based on production dates. Baxter has implemented corrective actions to mitigate the occurrence of kinks in the access lines of newly manufactured Prismaflex sets.

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Advice on actions to be taken by the distributor and the user
Progress of FSCA, together with reconciliation data (Mandatory for a Final FSCA)

Users are asked to:

- Continue to safely use the affected Prismaflex sets. If a kink is observed before treatment, the Prismaflex set must be replaced as instructed by the Instructions for Use. If a kink is identified during treatment, therapy must be interrupted, extracorporeal blood in the circuit returned to the patient per normal procedure, and the set must be replaced to continue therapy.
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- Forward a copy of this letter to other facilities or departments within their institutions to ensure that those locations are aware of this Important Product Information (where the user is a Hospital/Clinic/Healthcare facility)
- Distributors are asked to notify their customers of this communication in accordance with their procedures

Attached please find	FSN Status
☐ Field Safety Notice (FSN) in English	☐ Draft
☒ FSN in national language	☒ Final
☐ Others (please specify):	

Time schedule for the implementation of the different actions

Implementation date :**30/04/2019**
Regional targeted closure date : To be communicated once available
Local targeted closure date : To be communicated once available

These countries within the EEA and Switzerland and Turkey are affected by this FSCA
Within EEA, Switzerland and Turkey:

☒ AT	☒ BE	☒ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK	☒ EE	☒ ES
☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE	☒ IS	☒ IT	☐ LI	☒ LT
☒ LU	☒ LV	☒ MT	☒ NL	☒ NO	☒ PL	☒ PT	☒ RO	☒ SE	☒ SI
☒ SK	☒ TR								

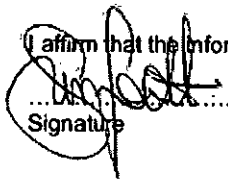
Candidate Countries:
☒ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:
Albania, Andorra, Bahrain, Egypt, Iran, Jordan, Kazakhstan, Kenya, Kosovo, Kuwait, Lebanon, Libyan Arab, Macedonia, Montenegro, Pakistan, Qatar, Russia, Saudi Arabia, Serbia, South Africa, Sudan, Syria, Tunisia, Ukraine, United Arab Emirates

8. Comments

I affirm that the information given above is correct to the best of my knowledge.



.....
Signature

Name	City	Date
Susi Soatti	Medolla (Mo)	30/04/2019

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person