

B. Braun Melsungen AG
Division Hospital Care und OPM
34209 Melsungen

Your reference:
Our reference: FSCA-2019-07-02 SK/AS

Contact:
Fon: 05661 71-1339
Fax: 05661 71-1339
Email: stephan.krause@bbraun.com
Internet: <http://www.bbraun.de>

Date: July 02, 2019

TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY NOTICE – PERIFIX FILTER 0,2µM ISO NRFit

To whom it may concern,

We, the B. Braun Melsungen AG have decided to recall the following product in the context of a FIELD SAFETY CORRECTIVE ACTION from the market:

Article Number	Article Name	Batch
4515501N-01	PERIFIX FILTER 0,2µM ISO NRFit	ALL

All batches manufactured until June-2019 inclusively are affected. The manufacturing date can be read out from the batch number. The first two digits represent the year and the capital letter the month. Example: 19Fxxxxxx stands for manufactured in June 2019. Any product manufactured in June 2019 or earlier is affected. Newly produced articles with manufacturing dates from July 2019 onwards (19Gxxxxxx), you will receive in future, are not affected.

The concerned article is also used as a component of finished sets listed in Annex 1. Thus, all Perifix NRFit Sets up to batch 19Fxxxxxx are affected. However, to ensure continued clinical use of regional anaesthesia with Perifix NRFit sets we do not recall the sets listed in Annex 1, but we provide Perifix NRFit filters to be exchanged in the hospital. These exchange Perifix NRFit filters have undergone 100% inspection and are confirmed to be in specification. Exchange Perifix NRFit filters are readily available and will be provided to affected hospitals within the next days.

REASON FOR THE RECALL/FSCA

During the production it was identified that the membrane in the Perifix filter may not fulfil the specified requirements. The results indicate that in isolated filters the full filter capacity of 0,2µM is not achieved due to damages in the filter membrane. The effect cannot be limited to specific batches.

A damage of the filter can increase the risk for a microbial infection or infusion of particles into the patient.

Up to now we received no market feedback on any adverse patient outcome which could be associated to the above described observation. However, due to an increased risk of microbial contamination to patients we decided to proactively inform our customers.

Chairman of the Supervisory Board:
Executive Board:

Corporate Office: Melsungen
Register Court: Local Court Fritzlar
HRB 11 000
WEEE-Reg.-No. DE 42690900

Address:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

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Page 2 to the letter of July 02, 2019 TO WHOM IT MAY CONCERN

ACTIONS TO BE TAKEN:

Our records have shown that your hospital has received single packed sterile PERIFIX FILTER 0,2µM ISO NRFit as mentioned above or one of the products containing a PERIFIX FILTER 0,2µM ISO NRFit as specified in Annex 1.

We kindly ask you to initiate the following activities immediately and with priority:

1. Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned products in your organization and other concerned persons are informed about this Field Safety Corrective Action.
If you are a distributor, please forward this correction notification to your customers.
2. Please identify, quarantine and return single packed sterile filters.
3. Perifix NRFit filters currently in use at the patient do not need to be exchanged. The risk associated to system modifications is believed to be higher than the risk of a decreased filter capacity.
4. You will receive unaffected single packed sterile filters within the next days. Please make sure that all affected single packed sterile filters are quarantined before you receive and start using new Exchange Perifix NRFit filters.
5. Clinical use of Perifix Sets with NRFit connectors as listed in Annex 1 shall be interrupted until exchange Perifix NRFit filters are available in the hospital.
6. To use affected Perifix Sets with NRFit connectors, the old Perifix NRFit filter included in the set shall be exchanged with the newly delivered single sterile Perifix NRFit filter.
7. Please confirm the receipt of this information.

If more information is needed, please contact

Local contact 1
Name
Title
Email
telephone

Local contact 2

Kindly accept our apologies for any inconveniences.

Yours sincerely,

Annex 1

Article Number	Article Name	Batch
8429103UP	PERIFIX FILTER 0,2µM ISO NL	ALL
8429103	PERIFIX FILTER 0,2µM ISO NL	ALL
4510097N-01	PERIFIX SOFT TIP 701 NRFIT-EU	ALL
4510305N-01	PERIFIX 901 COMPLETE SET NRFIT-EU	ALL
45120061N-01	PERIFIX ONE PAED SET 18 NRFIT-EU	ALL
45120141N-01	PERIFIX ONE PAED SET 20 NRFIT-EU	ALL
4514009N-01	PERIFIX 400 NRFIT-EU	ALL
45140171N-01	PERIFIX ONE 401 FILTER SET NRFIT-EU	ALL
4514017N-01	PERIFIX 401 FILTER SET G18 NRFIT-EU	ALL
45140251N-01	PERIFIX ONE 402 FILTER SET NRFIT-EU	ALL
4514025N-01	PERIFIX 402 FILTER SET G16 NRFIT-EU	ALL
45142111N-01	PERIFIX ONE 421 COMPLETE SET NRFIT-EU	ALL
4514211N-01	PERIFIX 421 COMPLETE SET NRFIT-EU	ALL
4515501N-01	PERIFIX FILTER 0,2µM NRFIT-EU	ALL
4517309N-01	PERIFIX SOFTTIP 730 FILTER SET-NRFIT-EU	ALL
4898115NR	CONT. C SET SH,15°,25GX190MM NRFIT	ALL
4898130NR	CONT. C SET SH,30°,25GX190MM NRFIT	ALL
4898305NR	CONTIPLEX D SET SH 18GX55MM 15° NRFIT	ALL
4898311NR	CONTIPLEX D SET SH 18GX110MM 15° NRFIT	ALL
4898323NR	CONTIPLEX D SET SH 20GX33MM 15° NRFIT	ALL
4898405NR	CONT. S SET SH, 20°, 18GX50MM NRFIT	ALL
4898410NR	CONT. S SET SH, 20°,18GX100MM NRFIT	ALL
4898415NR	CONT. S SET SH, 20°,18GX150MM NRFIT	ALL
4898504NR	CONT. TUOHY SET SH, 18GX40MM NRFIT	ALL
4898505NR	CONT. TUOHY SET SH, 18GX50MM NRFIT	ALL
4898510NR	CONT. TUOHY SET SH, 18GX100MM NRFIT	ALL
4898515NR	CONT. TUOHY SET SH, 18GX150MM NRFIT	ALL
4898610NR-27	CONT S ULT360,18GX100MM NR-CIS/AP/EU/SA	ALL
4898615NR-27	CONT S ULT360,18GX150MM NRF-CIS/AP/EU/SA	ALL
4898650NR-27	CONT S ULT360,18GX50MM NRF-CIS/AP/EU/SA	ALL
4898704NR-01	CONT. TUOHY ULTRA 360,18GX40MM NRFIT-EU	ALL
4898705NR-01	CONT. TUOHY ULTRA 360,18GX50MM NRFIT-EU	ALL
4898710NR-01	CONT. TUOHY ULTRA 360,18GX100MM NRFIT-EU	ALL
4898715NR-01	CONT. TUOHY ULTRA 360,18GX150MM NRFIT-EU	ALL
4451113	PROSET PERIFIX SOFT TIP NRFIT	ALL
4451114	PROSET PERIFIX SOFT TIP NRFIT	ALL
4451115	PROSET PERIFIX SOFT TIP NRFIT	ALL
4451116	PROSET PERIFIX SOFT TIP NRFIT	ALL
4476655	PROSET PERIFIX NRFIT	ALL
4476656	PROSET PERIFIX NRFIT	ALL
4476657	PROSET PERIFIX NRFIT	ALL
4476658	PROSET PERIFIX NRFIT	ALL
4477831	PROSET PERIFIX ONE NRFIT	ALL
4477832	PROSET PERIFIX ONE NRFIT	ALL
4477833	PROSET PERIFIX ONE NRFIT	ALL
4477834	PROSET PERIFIX ONE NRFIT	ALL
4450272N	PROSET PERIFIX NRFIT	ALL
4450370N	PROSET PERIFIX ONE NRFIT	ALL
4452409N	PROSET PERIFIX NRFIT	ALL
4458039N	PROSET CONTIPLEX S ULTRA 360 100MM NRFIT	ALL
4458040N	PROSET CONTIPLEX D 55MM 18G NRFIT	ALL
4476735N	PROSET PERIFIX ONE NRFIT	ALL
4476859N	PROSET PERIFIX NRFIT	ALL
4476948N	PROSET PERIFIX ONE NRFIT	ALL

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Page 2 to the letter of July 02, 2019 TO WHOM IT MAY CONCERN

Article Number	Article Name	Batch
4890020N	PROSET PERIFIX ONE NRFIT	ALL
8850548	EPIDURAL SET NRFIT	ALL
8850560	EPIDURAL SET NRFIT	ALL
8850561	EPIDURAL SET PAED 18G NRFIT	ALL
8850579	EPIDURAAL SET NRFIT	ALL
8850582	EPIDURAAL SET SOFTTIP NRFIT	ALL
8850583	EPIDURAL SET NRFIT	ALL
8850587	EPIDURAL SET NRFIT	ALL
8850588	EPIDURAL SET NRFIT PAED	ALL
8864001	NRFIT PERICAN G16 STANDARD CATH. PACK #1	ALL
8864002	NRFIT PERICAN G18 STANDARD CATH. PACK #2	ALL
8864003	NRFIT PERICAN G18 SOFT-TIP CATH. PACK #2	ALL
8864004	NRFIT PERICAN G16 ONE CATHETER PACK #1	ALL
8864005	NRFIT PERICAN G18 ONE CATHETER PACK #2	ALL
8864007	NRFIT PERICAN G16 SOFT TIP CATH. PACK #1	ALL
339114	ES1725KFXN ESPOCAN SPINAL/EPID TRY NRFIT	ALL
339115	ES1827KN SPINAL/EPIDURAL TRAY NRFIT	ALL
339160	FEF100N FLAT EPIDURAL FILTER NRFIT	ALL
339183	CE17TKN CONT EPIDURALTUOHY NRFIT	ALL
339184	CE17TKFN PERIFIX CONT EPID TRAY NRFIT	ALL
339185	CE17TKFSN EPIDURAL TRAY NRFIT	ALL
339186	CE17TKFCN EPID TRAY W/ 17GA TUOHY NRFIT	ALL
339187	CE17TKFCSN CON EPI TRAY W/17G TUHY NRFIT	ALL
339188	CE18TKN ACCU-BLOC PERIFIX KIT NRFIT	ALL
339189	CE18HKN ACCU-BLOC PERIFIX KIT NRFIT	ALL
339190	CE18TKON PERIFIX ONE EPID FULL TRY NRFIT	ALL
339191	CE18TKSTN CONT EPID W/SOFT TIP NRFIT	ALL