

Urgent- FIELD SAFETY NOTICE

Field correction Notice: FSN/ SM/001-2018

Date:	Monday 16 th July 2018.
Products Affected:	SEERS Medical Bariatric Drop End Couches – Single & Dual Foot Sections
Model Numbers:	SM3484, SM3684, SM3483 & SM3683
Affected serial number:	see page 3 for the SMA number affected

Dear Customer,

Our records indicate that you purchased one or more Bariatric Drop End/Split legs couch from SEERS Medical, between March 2013 and June 2018.

This letter is to inform of a change to the User Manual to minimise the couch from tipping forwards if a load is unevenly spread and the wheels not facing forwards.

As part of our post market surveillance, SEERS Medical received a customer complaint, where the couch tipped forwards, when a patient leant forwards with the leg sections raised. There were no serious injuries related to this incident.

However, SEERS Medical LTD sees it as a potential hazard, for the patient and the clinician.

SEERS Medical investigated the issue and concluded that if the wheels on the couch were not facing forward and the load was concentrated on the leg rests when horizontal, the couch could become unstable and tip, resulting in a potential risk to the patient and the clinician.

Next steps:

- 1 - Ensure that all the Users of the Bariatric Drop End Couches are made aware of this Field Safety Notice (FSN).
- 2 - Complete and sign the enclosed Acknowledgement Form and return this form to SEERS Medical Ltd.
- 3 - Please note that as per the User Manual, the wheels need to face forwards (outwards from the base frame) and the load needs to be evenly spread across the couch surface.
- 4 – The leg rest(s) should be lowered prior to the patient mounting or dismounting the couch.

Distribution:

This Field Safety Notice needs to be distributed to Users who need to be aware within your organisation or to any organisation where the potentially affected couches are being used.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We deeply regret this inconvenience but appreciate your understanding as we take preventative action to ensure patient and clinician remain safe whilst using this type of couch.

If you have any further question or require assistance, then please contact Seers Medical

Kind Regards / Cordialement

Julie Shaftoe

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Product Code	Product Description	SMA	s/n
SM3483-230T-3WH	Bariatric Drop End Electric B/rest & Footrest - IBC	22564	35379
SM3484-230T-3WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	21972	34222
SM3484-230T-3WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	22852	35862
SM3484-230T-3WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	23736	37233
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	23689	37509
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	25520	40406
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	27313	43727
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	27927	45559
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	29378	47397
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	29964	48521
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	30558	49764
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	31200	52307
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	31335	52145
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	32873	54743
SM3683-230T-3WF	Bariatric Drop End Couch Electric Backrest & Footrest	23784	37500
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	13572	20015
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	20284	31739
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	20714	32212
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	22569	35685
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	23150	36219
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	23647	37499
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	25055	40132
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	25940	41984
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	26820	42837
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	27312	43725
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	30335	5211/52107/52106
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	30526	52112
SM3683W-230T-3WH	Deluxe Bariatric Drop End-Elec Height,B/rest&Foot-LMWD	14376	21856
SM3683W-230T-3WH	Deluxe Bariatric Drop End-Elec Height,B/rest&Foot-LMWD-105cm	19176	30561
SM3684-230T-3WH	Bariatric Dual Foot - Elec Height,B/rest & F/Sect LMWD	14975	22520
SM3684-230T-3WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect LMWD	16634	25938
SM3684-230T-3WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect LMWD	16777	25942
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	31200	52307
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	31335	52145
SM3684-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect LMWD	33001	55235/55234
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	17236	13842
SM3683-230T-3WH	Deluxe Bariatric Drop End Couch - Elec - LMWD	28558	45427
SM3684-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect LMWD	28781	47449
SM3484-230T-4WH	Bariatric Dual Foot - Elec Heigh,B/rest & F/Sect IBC	32873	54743

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Acknowledgment Form - Field Safety Notice - FSN/ SM/001-2018

This response form is to confirm receipt of the enclosed answer.

I acknowledge receipt of the SEERS Medical Filed Safety Notice dated the 14/07/18 for the Bariatric Couch Drop End Couches and actioned as required in the Instruction of the letter

Name:

Signed :

Date:

Name of the person completing the questionnaire in Block capitals	
Title:	
Institution:	Couch Serial Number and SMA
Address:	Postcode:
Phone	Email:
Country:	

It is important that your organisation takes the actions detailed in the FSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this FSN. Your organisations reply is evidence which, Seers Medical and subsequently the MHRA, needs to monitor the progress of the FSN. Without your reply SEERS Medical cannot verify the completeness of the FSN and the MHRA may need to issue a Medical Device Alert.