B BRAUN
SHARING EXPERTISE

B. Braun Surgical, S.A.
Carretera de Terrassa, 121
08191 Rubí
España
www.bbraun.com

Urgent Field Safety Notice
MONOSYN UNDYED 7/0 (0,5)45CM DSMP7; Reference: C0023647; Batch: 116432
Return of the Medical Device to the manufacturer
Att. Aesculap AG. Germany

January 30th, 2017

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling several reference/batches of Monosyn, a synthetic absorbable sterile surgical monofilament suture.

From a routinely test in the control laboratory, the company noticed that the degradation test results in some Monosyn reference-batches were not fulfilling product specifications.

Depending on the indication where the suture is used, it could provoke dehiscence (i.e. skin wound dehiscence, anastomotic leakage) that might lead to permanent impairment or life-threatening injury, as well as, infection, bad cosmetic result or hemorrhage. Potential need of treatment or reparation may not be discarded. Product functionality is not guaranteed for the intended use during shelf life.

We have checked our files and we sent to customers in Germany 4 boxes (144 units) in November 2016 of one of the affected products, see details:

Reference name:	MONOSYN UNDYED 7/0 (0,5)45CM DSMP7
Reference number:	C0023647
Batch:	116432

In enclosure 1 there is the customer distribution list.

Please check with your customers if they still have the listed product in their warehouse. If yes, ask them to send the product back to you immediately.

Once you have all affected units for return contact us for the management of the material.

Please, fill out the attached "Recall Confirmation Form" and send the completed form to us by March 2nd, 2017.

This notice needs to be passed on all those who need to be aware within your organization and to any organization where the potentially affected devices have been transferred.

If you have any questions regarding this voluntary product recall, please contact us at the e-mail: vigilance_CT@bbraun.com.

We inform you that in accordance with the European Guidelines this recall has to be reported to the Competent Authority. Please check your national regulations and proceed accordingly.

We apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,

[redacted]

n Surgical, S.A.
ra de Terrassa, 121
Rubí (Barcelona)
586 62 00

B. Braun Surgical, S.A.

[redacted]

B. Braun Surgical, S.A.

Enclosure 1: Customer distribution list

Customer	Reference	Box Quantity	Delivery date
[redacted]	C0023647	1	08.11.2016
	C0023647	1	08.11.2016
	C0023647	2	08.11.2016