

**Aesculap AG
Quality Management**

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Date: March 27th, 2017

**Field Safety Corrective Action (FSCA): Product Recall
Product: Diamond burr with coarse and extra-coarse grain (pursuant to system)**

Dear Sir or Madam,

With this letter, we would like to inform you that Aesculap AG is initiating a global voluntary product recall of diamond burrs with coarse and extra-coarse grain pursuant to system. The use of these tools under some conditions can result in the release of particles from the diamond coating, which may not be discovered by the user. To date, no damage to patients has been connected to this.

Please send the relevant product with the enclosed return form back to Aesculap AG. You will receive a credit item immediately. Please find the article numbers in question in the file appended.

Should you have any question concerning this Field Safety Corrective Action, please contact

Please fill in your local contact

For any product related request, do not hesitate to contact our product manager „Neurosurgery“:

Please fill in your local contact

Please make sure that all users of the above-mentioned products in your organization and other persons who need to be informed have gained knowledge of this FSCA. In the event that you have issued devices to a third party, please forward a copy of this information letter to the contact person stated below. Please keep this information letter at least to such time as this matter has been resolved. The German Federal Institute for Drugs and Medical Devices has received a copy of this FSCA.

Chairman of Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:
Prof. Dr. Hanns-Peter Knaebel
(Chairman)
Dr. Jens von Lackum
Dr. Joachim Schulz

Corporate Office: Tuttlingen
Register Court: Stuttgart HRB 726261
VAT reg. no. DE812160059
WEEE-Reg.-No. DE 65109852

Bank Account:
Deutsche Bank AG Tuttlingen
BLZ 653 700 75 Konto 21 22 000 00
IBAN DE44 6537 0075 0212 2000 00
SWIFT / BIC DEUTDE33
Baden-Württembergische Bank
BLZ 600 501 01 Konto 487 1905
IBAN DE31 6005 0101 0004 8719 05
SWIFT / BIC SOLADEST

Address:
Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Germany

Page 2 to the letter of March 27th, 2017

Please fill out the feedback form attached and send it back to the contact person stated therein.

Should you have an affected product, please return it with the enclosed "**Product Recall Form**"

We regret the inconvenience caused by the implementation of these actions and thank you for your understanding and cooperation.

Sincerely,

Aesculap AG

FEEDBACK FORM (FSCA)
Diamond burr with coarse and extra-coarse grain (pursuant to system)

We request the return of this form either by fax or e-mail addressed to:

Please fill in local contact data

- We do not have any of the affected products.
- We do have affected products and will send them back to the Aesculap AG with the enclosed return form.

HOSPITAL _____

CITY _____

NAME _____

DEPARTMENT _____

PHONE NO. _____

SIGNATURE

DATE

Appendix

coarse	
GP161R	ELAN 4 1-RING DIAMOND BARR COARSE D2.0
GP162R	ELAN 4 1-RING DIAMOND BARR+ COARSE D2.0
GP163R	ELAN 4 1-RING DIAMOND BARR COARSE D2,3
GP164R	ELAN 4 1-RING DIAMOND BARR+ COARSE D2,3
GP165R	ELAN 4 1-RING DIAMOND BARR COARSE D3,0
GP166R	ELAN 4 1-RING DIAMOND BARR+ COARSE D3,0
GP167R	ELAN 4 1-RING DIAMOND BARR++ COARSE D3,0
GP168R	ELAN 4 1-RING DIAMOND BARR COARSE D4,0
GP169R	ELAN 4 1-RING DIAMOND BARR COARSE D5,0
GP170R	ELAN 4 1-RING DIAMOND BARR COARSE D6,0
GP321R	ELAN 4 2-RING DIAMOND BARR COARSE D2.3
GP322R	ELAN 4 2-RING DIAMOND BARR COARSE D3.0
GP323R	ELAN 4 2-RING DIAMOND BARR COARSE D4.0
GP324R	ELAN 4 2-RING DIAMOND BARR COARSE D5.0
GP325R	ELAN 4 2-RING DIAMOND BARR COARSE D6.0

extra coarse	
GE426R	HI-LINE XS DIAMOND BARR X-CRS.I D4.5MM
GE426SU	HI-LINE XS DISP.DIAM.BARR X-CRS.I D4.5MM
GE526R	HI-LINE XS DIAMOND BARR X-CRS.II D4.5MM
GE526SU	HI-LINE XS DISP.DIAM.BARR X-CRS.II D4.5
GE626R	HI-LINE XS DIAMOND BARR X-CRS.III D4.5MM
GE626SU	HI-LINE XS DISP.DIAM.BARR X-CRS.III D4.5
GP173R	ELAN 4 1-RING DIAMOND BARR X-COARSE D3,0
GP174R	ELAN 4 1-RING DIAMOND BARR X-COARSE D4,0
GP175R	ELAN 4 1-RING DIAMOND BARR X-COARSE D5,0
GP176R	ELAN 4 1-RING DIAMOND BARR X-COARSE D6,0
GP177R	ELAN 4 1-RING DIAMOND BARR X-COARSE D7,0
GP328R	ELAN 4 2-RING DIAMOND BARR X-COARSE D4.0
GP329R	ELAN 4 2-RING DIAMOND BARR X-COARSE D5.0
GP330R	ELAN 4 2-RING DIAMOND BARR X-COARSE D6.0