Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

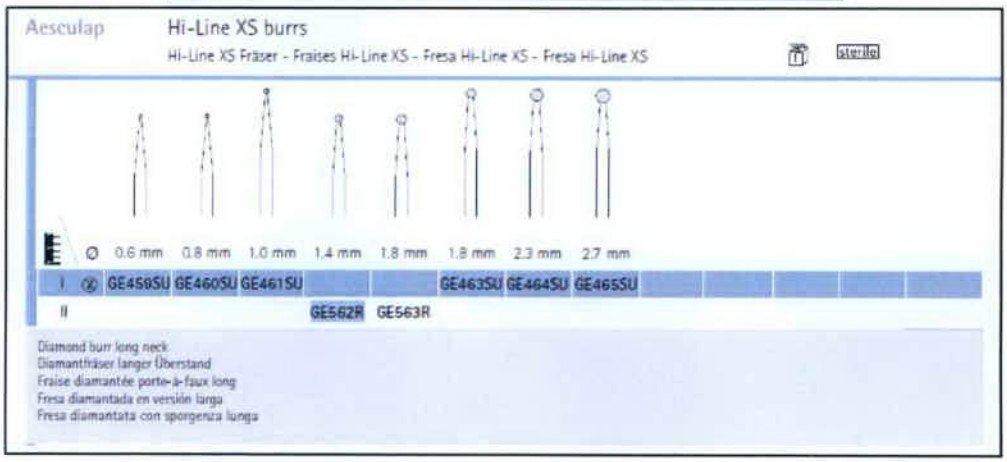
11 OCT 2017

FDA ADVISORY
No.: 2017-283

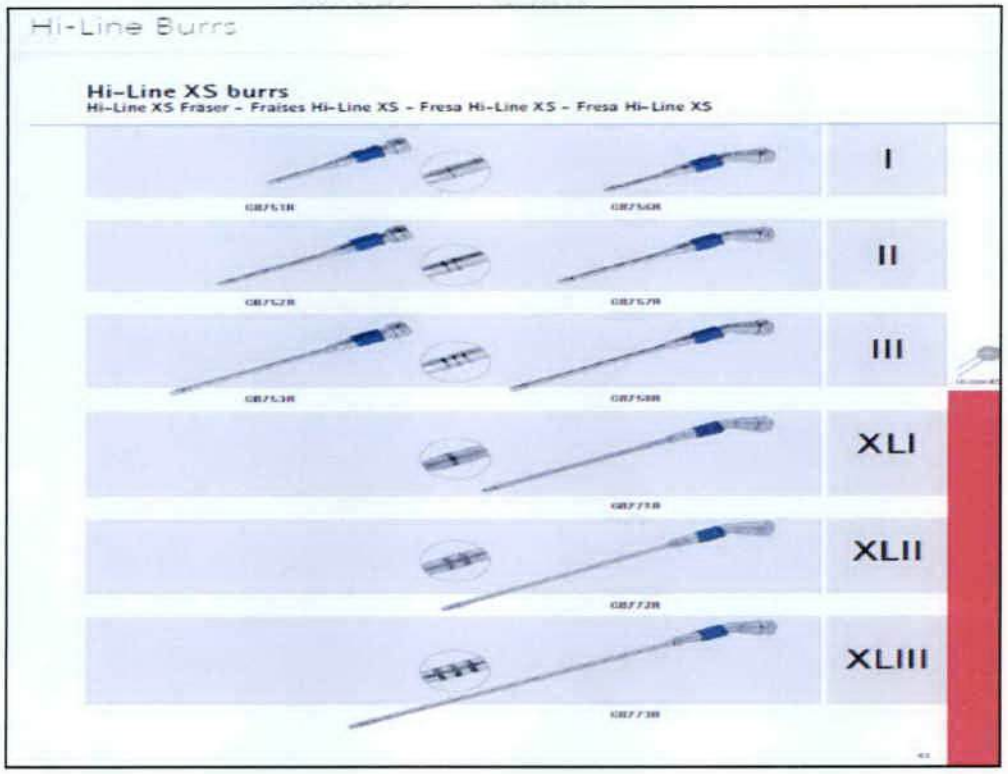
TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Recall of Diamond Burr with Coarse and Extra-Coarse Grain (Pursuant to System)**

All concerned healthcare professionals are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary recall of Diamond Burr (see photos of the product below) distributed by B. Braun Medical Supplies, Inc. Diamond Burrs are used in spine surgery and cranial neurosurgery in the area of working on hard tissue.



Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900
Website: www.fda.gov.ph
Fax +63 2 807 0751
Email: info@fda.gov.ph



The following List of affected articles:

GP161R	ELAN 4 1-RING DIAMOND BURR COARSE D2.0
GP162R	ELAN 4 1-RING DIAMOND BURR+ COARSE D2.0
GP163R	ELAN 4 1-RING DIAMOND BURR COARSE D2,3
GP164R	ELAN 4 1-RING DIAMOND BURR+ COARSE D2,3
GP165R	ELAN 4 1-RING DIAMOND BURR COARSE D3,0
GP166R	ELAN 4 1-RING DIAMOND BURR+ COARSE D3,0
GP167R	ELAN 4 1-RING DIAMOND BURR++ COARSE D3,0
GP168R	ELAN 4 1-RING DIAMOND BURR COARSE D4,0
GP169R	ELAN 4 1-RING DIAMOND BURR COARSE D5,0
GP170R	ELAN 4 1-RING DIAMOND BURR COARSE D6,0
GP321R	ELAN 4 2-RING DIAMOND BURR COARSE D2.3
GP322R	ELAN 4 2-RING DIAMOND BURR COARSE D3.0
GP323R	ELAN 4 2-RING DIAMOND BURR COARSE D4.0
GP324R	ELAN 4 2-RING DIAMOND BURR COARSE D5.0
GP325R	ELAN 4 2-RING DIAMOND BURR COARSE D6.0
GE426R	HI-LINE XS DIAMOND BURR X-CRS.I D4.5MM
GE426SU	HI-LINE XS DISP.DIAM.BURR X-CRS.I D4.5MM
GE526R	HI-LINE XS DIAMOND BURR X-CRS.II D4.5MM
GE526SU	HI-LINE XS DISP.DIAM.BURR X-CRS.II D4.5
GE626R	HI-LINE XS DIAMOND BURR X-CRS.III D4.5MM

GE626SU	HI-LINE XS DISP.DIAM.BURR X-CRS.III D4.5
GP173R	ELAN 4 1-RING DIAMOND BURR X-COARSE D3,0
GP174R	ELAN 4 1-RING DIAMOND BURR X-COARSE D4,0
GP175R	ELAN 4 1-RING DIAMOND BURR X-COARSE D5,0
GP176R	ELAN 4 1-RING DIAMOND BURR X-COARSE D6,0
GP177R	ELAN 4 1-RING DIAMOND BURR X-COARSE D7,0
GP328R	ELAN 4 2-RING DIAMOND BURR X-COARSE D4.0
GP329R	ELAN 4 2-RING DIAMOND BURR X-COARSE D5.0
GP330R	ELAN 4 2-RING DIAMOND BURR X-COARSE D6.0

The above-stated medical device products are being voluntary recalled by B. Braun Medical Supplies, Inc. 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.

It was observed that during operation particles can break out oneself from the diamond burr fall into the situs. If the particles are not detected after breaking out and thus are not removed from the wound the particles can remain to a certain extent in the patient's body.

Distributors, retailers, hospitals and all healthcare professionals/users are advised to discontinue further distribution, sale and use of the said affected medical device product.

For more information and inquiries, please email us at cdrrhr_prsdd@fda.gov.ph or call the Product Research and Standards Development Division of the FDA - Center for Device Regulation, Radiation Health and Research at 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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