

Tytin Regular Set Double Spill Amalgam Capsules / Kerr Corporation/RECALL (7/14)

Reason/Information:

Kerr Corporation issued an Urgent Medical Recall on the following materiel (See Image on Message under Additional Documentation/Attachment). Reason: Kerr received complaints that the amalgam may set faster than specified in the Directions for Use. This set time discrepancy may cause the product to set before there is an opportunity to place it in the preparation or complete the carving process.

There is a low risk associated with the use of this product in that there would be a possible need to remove the set amalgam from the preparation and repeat the procedure.

Disposition/Instructions:

Action to be taken:

If you have any of the affected product, contact Kerr Corporation Customer Care at 800-537-7123 x 7076 or 714-516-7400 to receive an RMA number. The RMA will allow for a quick return and replacement or credit.

If you or your patients have experienced injury as a result of the affected product, you may voluntarily report the incident to the FDA through the MEDWATCH reporting system.

To confirm your receipt of this notification, whether you have the affected product or not (See Image on Message under Additional Documentation/Attachment) fax to: 714-288-4605.

For general questions, contact: 800-537-7123 x 7076 or 714-516-7400.

Note: Materiel shipped from November 2013 to February 2014.

Item Information:

NSN (FSC-NIIN): 6520-NS1
Part Number: 29948
Nomenclature: ALLOY AMALGAM SPHERICAL CAPSULE DENTAL HIGH COPPER
SELF-ACTIVATING DOUBLE SPILL, 600 MG, 50 CAPSULES
UI: EA
Manufacturer: KERR CORPORATION

LOT / SN:
3-1294

NOTES:

POC Contact Information:

USAMMC-E

Email: usarmy.rheinland-pfalz.medcom-usammce.list.dtd-quality-assurance@mail.mil

Phone (COMM): 011-49-6331-86-7118/7181

Phone (DSN): 495-7118

Fax: 6218

US ARMY

Email: usarmy.detrick.medcom-usamma.mbx.doc@mail.mil

Phone (COMM): 301-619-4300

Phone (DSN): 343-4300

Fax: 301-619-4468

US AIR FORCE

Email: afmoa.sgalc@us.af.mil

Phone (COMM): 301-619-4170

Phone (DSN): 343-4170

Fax: 301-619-2557

US NAVY

Email: MMQC2@MED.NAVY.MIL

Phone (COMM): 301-619-3085

Phone (DSN): 343-3085

Fax: 301-619-2473

Additional Message Recipients:

Please ensure widest dissemination of information to all interested entities.

Message Dissemination Authorization:

US AIR FORCE

AF Activities Will Take Action As Prescribed In Afi 41-209, Medical Logistics Support, Chapters 3 And 9. For Majcoms & Ngb--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.

US ARMY

See Army Regulation (Ar) 40-61, 28 January 2005, Chapter 4, And The Department Of The Army Supply Bulletin (Sb 8-75-11) For Applicable Policies And Procedures.

Additional documentation may be found [here](#).