

URGENT: VOLUNTARY PRODUCT FIELD CORRECTION NOTIFICATION
Herbst® Appliance made with Universal Nuts

Dear Valued Customer:

This is to inform you of a voluntary product field action involving Herbst® Appliances made with Universal Nuts. Please refer to the attached addendum which lists the Invoices affected. These appliances were manufactured from July 9th, 2014 through December 31st, 2014 and from January 13th, 2015 through January 16th, 2015. Our records indicate that you received at least one of these devices that have the potential to be affected by this issue. **PLEASE NOTE: NO OTHER SPECIALTY APPLIANCES PRODUCTS ARE INVOLVED IN THIS FIELD ACTION.**

Reason for the Field Action:

Specialty Appliances has received a limited number of reports of fractures of the threaded nut on the upper component of the Herbst appliance. Based on the company's investigation to date, the stainless steel used to manufacture some of the threaded nuts on the upper portion of the appliance is susceptible to corrosion and wear and predisposed to experience a higher than anticipated rate of fracture which may affect the integrity of the screw/nut interface. To date, for Herbst Appliances that have been clinically delivered, an incidence rate of approximately .51% has been reported and in none of the reported cases did a patient experience injury.

This field action is being made with the knowledge of the Food and Drug Administration.

Risk to Health:

Our analysis indicates that it is a small proportion of devices that will experience corrosion and wear, and that, if the fracture occurs, it will be some time greater than 30 days after clinical delivery. We are thus providing this notification to you, as a precautionary measure, so that you can best manage your patients who currently have the Herbst Appliance installed. Because these devices are manufactured to patient specific parameters, continued use of an affected Herbst Appliance that experiences fracture carries the greatest risk that the patient may swallow a Herbst screw or broken pieces of the nut. We are **not** asking you to remove and return any Herbst appliance that has already been cemented in a patient unless you observe indications that the device is experiencing corrosion and is at risk for fracture or the device has actually fractured.

A device that is experiencing corrosion is at risk for fracture and can be identified by the visual appearance of the nut area. A device that has fractured can be identified by a portion of the nut deforming and subsequently not being able to hold the Herbst screw securely. The Herbst screw will possibly turn inside the nut and not tighten completely; therefore it may possibly fail to hold the Herbst mechanism in place properly.

We understand there are issues and risks involved in removing the Herbst Appliance and since these risks may be greater than the risks of actual failure, we believe those risks are properly balanced by asking you to specifically monitor your patients for signs of corrosion of the nuts at every follow-up visit at the time intervals you deem to be appropriate. In the event a patient contacts your office regarding possible breakage of their Herbst Appliance, we recommend examining the appliance immediately and checking for the condition described above.

Although Specialty Appliances has not received reports of fracture of the lower component, we nonetheless ask you to also monitor the lower component for signs of corrosion. In the event that you observe signs of corrosion or fracture, please contact customer service at (800) 522-4636 or your sales representative immediately so that we can provide you with a replacement device at no cost to you or your patient.

Instructions to Customer:

Please take the following actions to assist us in executing this field action:

1. Complete and return the enclosed **Field Corrective Action Response Form**. This form contains important information about the devices we have provided to you that are subject to this field action. This information is essential in order to maintain field action effectiveness information required by FDA. It must be returned to us *even if you do not have any appliances in your possession*. We have attached a list of cases shipped to you that are affected by this issue. Our customer service representatives can assist you in completing this form and they may be reached at 678-513-4408.
2. Please return the completed **Field Corrective Action Response Form** via facsimile to (678) 513-7345, or via email to arlen.hurt@specialtyappliances.com. Should you have any Herbst® appliances yet to be delivered to your patient, please call 678-513-4408 from 8 a.m. to 4:30 p.m. (Eastern Time) to receive instruction as to how to return it to Specialty Appliances.
3. Monitor your patients for signs of corrosion on both the upper and lower components at every follow-up visit. We do not recommend prophylactic removal of the appliance due to the low probability that a fracture will occur and if the appliance does fracture, the risk of patient injury is low.
4. In the event that you observe signs of corrosion or a fracture, please contact our customer service at 678-513-4408 or your sales representative immediately so that we can provide you with a replacement appliance at no cost to you or your patient.

We deeply regret the inconvenience that this field action has or will cause you and appreciate your understanding as we take this action to ensure patient and customer satisfaction. If you have questions or need help, please contact your local sales representative or customer service at 678-513-4408. We can also be reached via email at arlen.hurt@specialtyappliances.com.

Thank you for your support. We are committed to providing you with product that meets the quality standards that you expect from Specialty Appliances.

Sincerely,

Scott Huges

Scott Huges
President
Enclosures



**Field Corrective Action Response Form
Herbst® Appliance made with Universal Nuts**

Please assist us in making this field action process as efficient and convenient to you as possible by completing and returning the form as soon as possible. This will serve as confirmation that you have received and understand this notification. It is imperative we receive your completed response.

Please see the attached list of cases sent to you that are affected by this issue. Please correct any information that is incorrect.

Please check ALL appropriate boxes:

- I have read and understand the field action instructions provided in the April 13th, 2015 letter.
- I will monitor my patients for signs of corrosion and contact Specialty Appliances at 678-513-4408 if I observe signs of corrosion that could lead to fracture.

Any adverse events associated with field actioned product? Yes No

If yes, please explain: _____

I certify that I have read and understood the VOLUNTARY PRODUCT FIELD CORRECTION NOTIFICATION for the Herbst® Appliance affected by this product deviation.		
Name	Signature	Title
Tel. number: ()	Email	Date

**PLEASE FAX COMPLETED RESPONSE FORM TO:
OR MAIL TO:**

(678) 513-7345
Specialty Appliances
4905 Hammond Industrial Drive
Cumming, Georgia 30041
arlen.hurt@specialtyappliances.com

OR EMAIL A SCANNED COPY TO: