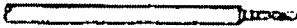



ANSPACH®

March 31, 2011

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Devices Affected:

Catalog	Lot Numbers
S-1504TD Twist Drill for 1.5 mm x 4 mm Screw. Use with SHORT Attachment 	D293037349 D323038110 D363039140
TURQ-434-4 Twist Drill for 1.5 mm x 4 mm Screw. Use with B-TURQUOISE Attachment 	D323038131 D343038845

Dear Valued Customer:

The Anspach Effort, Inc. is providing this communication to inform you of a voluntary Product Removal of sterile, single-use cutting burs used with Black Max, XMax, microMax, microMax Plus, eMax, eMax2 and eMax2 Plus High Speed Drill Systems. Our records indicate that you have received product that is part of the voluntary removal.

Description of the Problem:

This removal is being conducted because it is possible that the fluted portion of the bur may be 2 mm longer than indicated on the product label (actual 6 mm instead of the 4 mm). The diameter of the bur was not affected. As a result a hole drilled using this bur would accept a 4 mm long screw, but it would potentially be 2 mm deeper than the screw.

Even though we have not received any reports of incidents or adverse events related to this problem, we are taking this action to prevent any potential incidents in the future.

Report Number: 1045834-03/28/11-002R
The Anspach Effort, Inc
4500 Riverside Drive, Palm Beach Gardens, Florida 33410
Phone (561) 627-1080 • Fax (561) 627-3120
Toll Free Phone (800) 327-6687 • Toll Free Fax (800) 327-6661

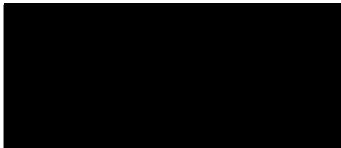
ANSPACH[®]

Customer Immediate Actions:

1. Screen your inventory immediately for any of the batches listed above.
2. If you have any of the products listed contact Anspach Customer Support at (800) 327-6887 to arrange for their immediate return and replacements.
3. Complete the attached reply form indicating how many of each part number is being returned and confirming your receipt of this letter. Return the completed form by fax to the number provided on the form. Returning the form promptly will prevent you from receiving repeat notices. If you distribute any of the products to other services or facilities, please forward this information as appropriate.

We apologize for any inconvenience that this Product Removal may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact Anspach Customer Support at (800) 327-6887.

Sincerely,



Manager, Quality Systems