

**MATERIAL CHANGE NOTIFICATION**  
**Ball strip material on Amalgatome® MD Blade**  
**Part # X100457**

**Date: November 29, 2017**

Dear Valued Exsurco Medical Customer,

Please review the below communication summary regarding a change in the color and material to the “ball strip” on the Amalgatome MD blade.

**Product Change:**

The ball bearing strip color and material will be changing from a WHITE ball and ball strip to a BLUE ball and ball strip. The Amalgatome MD Sterile, Single use Blade, which is exclusively used with the Amalgatome MD Skin Recovery Device (Cadaveric Use Only) is the only part that is impacted. No additional components of the blade material or design are impacted. The material changed from an Acetal to a medical grade Nylon to allow sterilization using gamma irradiation.

**Material Validation:**

Exsurco Medical has performed all the required material compatibility testing for this change, including sterilization and bio-compatibility. Test results are on file at Exsurco. Based on the results, Exsurco has approved the implementation of the new material into the X100457 ball strip. The material changed from an Acetal to a medical grade Nylon to allow sterilization using gamma irradiation.

**Summary:**

There is no impact to the Amalgatome MD product performance from this change. This change will be effective starting mid-December 2017 lots going forward starting with **X-0000000000066**.

For your convenience a picture is provided below with the Old AMD blade and the New AMD Blade.



*Figure 1: Picture of Old AMD Blade*



*Figure 2: Picture of New AMD Blade*

Thank you for your ongoing support and business with Exsurco Medical, Inc.  
Please feel free to call me with any questions at the number below.

Best Regards,

Linda Sopko  
Product Manager  
PH: 440-204-3286