

**URGENT FIELD
SAFETY NOTICE**

Subject: Indications for DURA-GUARD, PERI-GUARD, and VASCU-GUARD

Dear Customer,

Synovis and Baxter Healthcare would like to remind our customers of the approved indications for use for the DURA-GUARD, PERI-GUARD, and VASCU-GUARD products. This notification is being sent due to two recent reports involving use of the incorrect product during surgery.

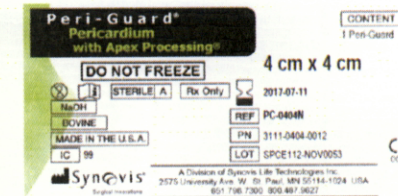
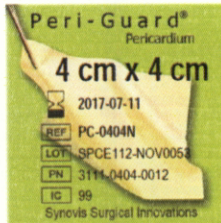
Please note that DURA-GUARD appears in a grey and white package with a graphic of a brain (example pictured right), and has the following approved indication:

For use as a dura substitute for the closure of dura mater during neurosurgery.



Please note that PERI-GUARD appears in a green and white package (example pictured right) and has the following approved indications:

For use as a prosthesis for pericardial closure and soft tissue deficiencies which include: defects of the abdominal and thoracic wall, hernias (diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal and umbilical), and intracardiac and great vessel repair.



Please note that VASCU-GUARD appears in a green and white package (example pictured right) and has the following approved indication:

For use in peripheral vascular reconstruction including the carotid, renal, iliac, femoral, profunda and tibial blood vessels and arteriovenous access revisions.



Only DURA-GUARD is indicated for use as a dura substitute.

Please note that you are not being asked to return any product, and no further action is required. You can continue to use DURA-GUARD, PERI-GUARD, and VASCU-GUARD according to their Instructions for Use.

If you provide this product to other services/facilities/departments, please forward this information as appropriate to ensure correct **DURA-GUARD, PERI-GUARD, and VASC-GUARD** utilization in your institution.

If you have any questions regarding the use of the DURA-GUARD and PERI-GUARD products, please contact Surecall Baxter Medical Information on +0044 1635 206345 or email surecall@baxter.com

Sincerely,

Les Vincent,
Senior Quality Director
Baxter Healthcare Corporation

