Medtronic

URGENT FIELD SAFETY NOTICE

Hancock™ II Bioprosthesis

Recall

Product Name	Model Number	Serial Number
Hancock II Bioprosthesis	T510 (Mitral)	B887929, B896723, B896730, B914146, B818699, B654768, B694390
Hancock II Bioprosthesis	T505 (Aortic)	B167637, B217329, B217330, B217347, B192698

June 2019

Medtronic Reference: FA874

Dear Physician or Healthcare Professional,

On May 22, 2019, Medtronic initiated a verbal communication of an Urgent Field Safety Notice for specific distributed units of Hancock II Bioprostheses (surgical heart valves). This notice is a follow-up to that verbal notification provided to your facility, where Medtronic requested that you put unused affected products in quarantine.

Medtronic has determined that a total of fifteen (15) affected devices were distributed worldwide, which were mislabeled with an incorrect size. In all cases, the actual surgical heart valves are larger than what was indicated on the boxes and jar labels. When an incorrect size valve (too big) is implanted there is a potential for deformation or subvalvular obstruction which could lead to regurgitation and/or stenosis. **Through 28 MAY 2019, Medtronic has received two complaints of a mislabeled valve observed during the implant procedure. To date there have been no (0) reported patient complications.**

Patient Recommendations:
Medtronic does not recommend any further actions for patients already treated with the listed devices. The management or follow-up would include your normal protocol procedures post-surgical heart valve implantation.

Customer Instructions:
Medtronic's records indicate that your facility has received one or more of the listed heart valves. As a result, Medtronic requests that you immediately take the following actions:

1. Identify and quarantine all unused product as listed above in your inventory.
2. Return all unused listed product in your inventory to Medtronic. Your local Medtronic Representative can assist you in the return and replacement of this product as necessary.

This notice needs to be passed on to all those who need to be aware within your organization.
Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter If you have any questions regarding this communication, please contact your Medtronic Representative at 040-7117555.

Sincerely,

Rick Paauw
Manager RA/QA & EHS

LET'S TAKE HEALTHCARE
FURTHER, TOGETHER