



## URGENT FIELD SAFETY NOTICE

### DLP® Single Stage Venous Cannulae

December 14, 2012

**Medtronic Reference: FA534**

Dear Valued Customer,

Medtronic would like to inform you that the *Instructions for Use* for the DLP® Single Stage Venous Cannulae are in the process of being updated. The current precaution statement found below referencing ventricular assist procedures will be identified as a contraindication in the updated *Instructions for Use*:

- DO NOT USE THIS PRODUCT FOR EXTENDED TERMS SUCH AS VENTRICULAR ASSIST PROCEDURES.

Medtronic has received two reports of patient deaths due to product failure during use in ventricular assist procedures, which are outside the indications for use.

*These cannulae are intended for collection of venous blood from the right side of the heart via the superior or inferior vena cava during cardiopulmonary bypass surgery up to six hours or less.*

We request that you inform others within your organization of this notice as appropriate.

We appreciate your attention to this letter. If you have any questions related to this issue, please contact your local Medtronic Representative Gulf Medical Co at 966 2 6512828.

Sincerely,

Abd Saoud

Business Manager

Structural Heart / Middle East