

# Report Form

## Field Safety Corrective Action

Medical Devices Vigilance System  
(MEDDEV 2.12/1 rev 5)

| <b>1. Administrative information</b>   |                        |
|--|------------------------|
| <b>Destination</b>   |                        |
| Name of national competent authority (NCA)<br>Medical Device Bureau, Ministry of Health Malaysia   |                        |
| Address of national competent authority<br>Level 5, No. 26, Boulevard Plot 3C4, Precinct 3, 62675 Putrajaya, MALAYSIA  |                        |
| Date of this report<br>13.07.2011  |                        |
| Reference number assigned by the manufacturer  |                        |
| Incidence reference number and name of the co-ordinating national competent authority (if applicable)<br>Unknown   |                        |
| Identify to what other national competent authorities this report was also sent<br>US; DE; FR; SE; ES; KR; FI; AT; DK; NO; CA; IT; JP; IN; CH; UK; NL; CN; HK; GR; EG; TR; PE;<br>BE; CL; AU; IL; TH; MY; TW; QA; KW; OM |                        |
| <b>2 Information on submitter of the report</b>  |                        |
| Status of submitter  |                        |
| <input checked="" type="checkbox"/> Manufacturer   |                        |
| <input type="checkbox"/> Authorised representative within EEA  |                        |
| <input type="checkbox"/> Others (identify the role):   |                        |
| <b>3 Manufacturer information</b>  |                        |
| Manufacturer name<br>Microm International GmbH   |                        |
| Manufacturer's contact person<br>Roland Johe   |                        |
| Address<br>Otto Hahn Str. 1a   |                        |
| Postal code<br>69190   | City<br>Walldorf       |
| Phone<br>+49-6227-836450   | Fax<br>+49-6227-836115 |
| E-mail<br>roland.johe@thermofisher.com   | Country<br>Germany     |
| <b>4 Authorised representative information</b>   |                        |
| Name of the authorised representative  |                        |
| The authorised representative's contact person   |                        |
| Address  |                        |
| Postal code  | City                   |
| Phone  | Fax                    |
| E-mail   | Country                |

| 5 National contact point information |         |
|--------------------------------------|---------|
| National contact point name          |         |
| Name of the contact person           |         |
| Address                              |         |
| Postal code                          | City    |
| Phone                                | Fax     |
| E-mail                               | Country |

| 6 Medical device information                   |                              |
|--|------------------------------|
| Class  |                              |
| <input type="checkbox"/>                       | AIMD Active implants         |
| <input type="checkbox"/>                       | MDD Class III                |
| <input type="checkbox"/>                       | MDD Class IIb                |
| <input type="checkbox"/>                       | MDD Class IIa                |
| <input type="checkbox"/>                       | MDD Class I                  |
| <input type="checkbox"/>                       | IVD Annex II List A          |
| <input type="checkbox"/>                       | IVD Annex II List B          |
| <input type="checkbox"/>                       | IVD Devices for self-testing |
| <input checked="" type="checkbox"/>            | IVD General                  |
| Nomenclature system (preferable GMDN)          |                              |
| EDMS   |                              |
| Nomenclature code                              |                              |
| 23-06-02                                       |                              |
| Nomenclature text                              |                              |
| Microtomes                                     |                              |
| Commercial name/brand name/make                |                              |
| HM 355S  |                              |
| Model number                                   |                              |
| HM 355S  |                              |
| Serial number(s) and/or lot/batch number(s)    |                              |
| 44478 - 51485 (1 instrument in your market)    |                              |
| Software version number (if applicable)        |                              |
| Manufacturing date/expiry date (if applicable) |                              |
| 2009-03-25 until 2011-07-06                    |                              |
| Accessories/associated device (if applicable)  |                              |
| Notified body (NB) ID- number                  |                              |
| NA   |                              |

| 7 Description of FSCA   |
|---|
| <p>Background information and reason for the FSCA</p> <p>On 2011-03-04 we were informed that a user at FHC Moore Regional Hospital in USA was injured while changing the specimen on a rotary microtome.</p> <p>After stopping motorized cutting the movement of the specimen was stopped in the highest possible position. This behavior is in accordance with the defined procedure. Then the user started exchanging the specimen without following the safety recommendations described in the user manual (activation of the hand wheel brake and the safety bracket on the blade holder). The non-braked specimen moved down and the user was injured on the finger, because the blade in the blade holder was not protected by the safety bracket.</p> <p>Furthermore we were informed on 2011-03-24 about a similar incident at JPS Health Network in USA. On 2011-03-10 also a user was injured on his finger while changing the specimen. According to the report we assume that also in this case the safety measures described in the user manual were not activated during the incident.</p> |

Description and justification of the action (corrective/preventive)  
Based on the results of the present investigation, we clearly see the root cause in non-compliance with the safety instructions in the manual.  
Therefore we see the right measure in an optimization of the manual, which specifically highlights the safety aspects. In addition, we have developed a Quick Reference Card (QRC) to support the cognitive memory which provides specific safety information for the daily use. This QRC should be placed in direct proximity of the device.  
With immediate effect starting 2011-07-07 these changes will be enclosed in all new instruments. We will provide this updated documentation also for all users of mentioned instruments in the field.

Advice on actions to be taken by the distributor and the user  
Follow all in the user manual described safety measures.

Attached please find  
 Field Safety Notice (FSN) in English (already provided)  
 FSN in German language  
 Others (please specify):

Time schedule for the implementation of the different actions  
The shipping of the referred documentation starts immediately.  
We plan to complete the implementation in 2011.

These countries within the EEA and Switzerland are affected by this FSCA  
Within EEA and Switzerland:  
 AT     BE     BG     CH     CY     CZ     DE     DK     EE     ES  
 FI     FR     GB     GR     HU     IE     IS     IT     LI     LT  
 LU     LV     MT     NL     NO     PL     PT     RO     SE     SI  
 SK

Candidate Countries:  
 HR     TR

All EEA, Candidate Countries and Switzerland

Others:  
AU; CA; CL; CN; EG; HK; IL; IN; JP; KR; KW; MY; OM; PE; QA; TH; TW; US

These countries outside the EEA and Switzerland are affected by this FSCA

**8 Comments**

I affirm that the information given above is correct to the best of my knowledge.

.....  
Signature

Roland Johe  
Name

Walldorf  
City

2011-07-13  
Date

*Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.*