Codman

Urgent Field Safety Notice (FSN)

Product Name: **Codman (and Formerly MICRUS) NEUROPATH Guiding Catheters**

FSCA-identifier: **Our ref: SR1-1022046453**

Type of Action: Field Safety Notice **and Field Safety Corrective Action**

Date: January 11, 2013

Attention: Trust Chief Executives, Surgery,
Theatre and Interventional Neuro Radiology Laboratories
General Managers – Private Sector Hospitals

Affected devices: *Codman (and formerly MICRUS) NEUROPATH Guiding Catheters*

Part numbers:

GMC60900000	NEUROPATH 6Fx90 GUIDING CATH MPC
GSM50900000	NEUROPATH 5Fx90 GUIDING CATH S2
GHH60900000	NEUROPATH 6Fx90 GUIDING CATH HH
GHH51000000	NEUROPATH 5Fx100 GUIDING CATH HH
GMC51000000	NEUROPATH 5Fx100 GUIDINGCATH MP
GMD60900000	NEUROPATH 6Fx90 GUIDING CATH MPD
GMD51000000	NEUROPATH 5Fx100 GUIDINGCATH MP
GST61000000	NEUROPATH 6Fx100 GUIDING CATH ST
GSM51000000	NEUROPATH 5Fx100 GUIDING CATH S2
GCB61000000	NEUROPATH 6Fx100 GUIDINGCATH MC
GSM61000000	NEUROPATH 6Fx100 GUIDING CATH S2
GCB51000000	NEUROPATH 5Fx100 GUIDINGCATH MC
GCB50900000	NEUROPATH 5Fx90 GUIDING CATH MCV
GMC50900000	NEUROPATH 5Fx90 GUIDING CATH MPC
GMD61000000	NEUROPATH 6Fx100 GUIDINGCATH MP
GMD50900000	NEUROPATH 5Fx90 GUIDING CATH MPD
GST51000000	NEUROPATH 5Fx100 GUIDING CATH ST
GST50900000	NEUROPATH 5Fx90 GUIDING CATH ST
GST60900000	NEUROPATH 6Fx90 GUIDING CATH ST
GHH50900000	NEUROPATH 5Fx90 GUIDING CATH HH
GCB60900000	NEUROPATH 6Fx90 GUIDING CATH MCV
GSM60900000	NEUROPATH 6Fx90 GUIDING CATH S2
GHH61000000	NEUROPATH 6Fx100 GUIDING CATH HH
GMC61000000	NEUROPATH 6Fx100 GUIDINGCATH MP

Lot No/Serial No: All lots of all product codes still within expiry dating

The above NEUROPATH Guiding Catheters, used for intravascular introduction of interventional/diagnostic devices, are being recalled. This Field Safety Corrective Action is being initiated because our testing has shown that the packaging is insufficient to withstand certain transportation methods, and this could result in damage to the sterile package. To prevent the potential use of non-sterile product, Codman is recalling NEUROPATH lots manufactured in the last three years,

Root Cause:

The root cause stems from insufficient packaging that did not withstand current standards of transit testing without damage to the sterile pouch. .

Action Required

- Acknowledge receipt of this Field Safety Notice to verify that you have been made aware of this possible issue and report unused items to be returned.
- Return any unused items to your local Codman offices as requested by this notice.
- Return the acknowledgement form to your Codman sales representative or local Codman office.

Corrective Action

We are in the process of taking corrective actions to prevent re-occurrence.
We regret the need to undertake this action and we thank you for your cooperation.

Distribution of this Field Safety Notice:

Please share this information with any staff that may use these products.

Contact Information:

Consult with your local sales representative if you have questions concerning this notice.

Authorized European Representative Contact Reference Person:

Donal Hempenstall

tel: 44.1344.871186
fax: 44.1344.324687

This FSCA has/will be sent to the appropriate Regulatory Agency.

Codman

Field Safety Notice Acknowledgement Form

Ref: FSN: SR1-1022046453

The undersigned acknowledges receipt of the subject Field Safety Notice in reference to the Codman (and formerly MICRUS) NEUROPATH Guiding Catheter

Date: _____

Name (please print):_____

Signature:_____

Hospital Name: _____

City and Country:_____

Please Complete:

Please check YES or No and if YES, please identify Lot and Quantity to return:

_____ YES, I do have one or more NEUROPATH catheters affected by this recall

Lot/Quantity: _____ /__ _____/___ (add additional page, if needed)

_____ NO, I do not have any Codman NEUROPATH Guiding Catheters affected by this recall.

Please return this completed form to your local Codman Sales Representative or fax to: [NOTE: Add Local Fax Number Here]