

**URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE – VOLUNTARY FIELD REMOVAL**

**Biosense Webster, a division of Johnson & Johnson Medical NV/SA
THERMOCOOL SMARTTOUCH® SF Catheter Family**

Catalog No: D134801, D134802, D134803, D134804, D134805, D134701, D134702, D134703

Lot Numbers: See Appendix 1 for list of affected lots.

November 24, 2014

Dear Doctor,

The purpose of this communication is to inform you that Biosense Webster, a division of Johnson & Johnson Medical NV/SA (“Biosense Webster”) is initiating a voluntary field removal for certain lots of THERMOCOOL SMARTTOUCH® SF Catheter (Catalog No: D134801, D134802, D134803, D134804, D134805, D134701, D134702, D134703). This letter provides important information about the affected products and instructions on how you can return the product to Biosense Webster.

Overview:

Biosense Webster has identified an opportunity in the production process of the THERMOCOOL SMARTTOUCH® SF Catheter which can lead to an incomplete weld of the tip shell. To date, there have been no patient injuries, adverse events, or customer complaints reported as a result of this defect. However, based on the potential risk of tip shell detachment, we are initiating a voluntary field removal of the THERMOCOOL SMARTTOUCH® SF Catheter units for the lots specified in Appendix 1.

Details on Affected Devices:

Indications for Use:

The Biosense Webster THERMOCOOL SMARTTOUCH® SF Navigation Catheter and related accessories are indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a radiofrequency generator, for cardiac ablation.

Actions Requested on Your Part:

- Read the “Description of the Problem” section below carefully.
- Immediately identify and set aside all affected products in a manner that ensures the product will not be used. Maintain a copy of this letter with the affected THERMOCOOL SMARTTOUCH® SF Catheters until all affected units are returned to Biosense Webster.
- Sign and return the attached Voluntary Field Removal Certification Form in accordance with the instructions listed on the form.
- Arrange for return of all affected units of the THERMOCOOL SMARTTOUCH® SF Catheters that you may have in your inventory per the instructions on the Voluntary Field Removal Certification Form.
- Pass on this notice to anyone in your facility that needs to be informed.
- Maintain awareness of this notice until all affected products have been returned to Biosense Webster.

Available Assistance:

For questions related to this issue, product return, and the Voluntary Field Removal Certification Form please contact your Biosense Webster sales representative.

The relevant European Regulatory Agencies and Notified Bodies have been notified and are aware that Biosense Webster is voluntarily providing this information. Other regulatory agencies are being notified as applicable.

Biosense Webster regrets any inconvenience that this communication may cause. The health and safety of our patients is our first priority. We know that you place high value in our products and we appreciate your cooperation in this matter.

Respectfully yours,



Vadim Kastin
Worldwide Director of Quality Assurance
Biosense Webster, Inc.

APPENDIX 1A: LIST OF AFFECTED LOTS FOR PART NUMBER D134701

| Lot Number | Lot Number | Lot Number | Lot Number | Lot Number | Lot Number | Lot Number | Lot Number |
|------------|------------|------------|------------|------------|------------|------------|------------|
| 16109575L | 17030260L | 17050102L | 17071793L | 17094394L | 17109349L | 17113767L | 17117496L |
| 16112946L | 17030261L | 17050103L | 17071795L | 17094395L | 17109350L | 17113768L | 17117642L |
| 17000306L | 17035265L | 17050104L | 17075110L | 17094396L | 17109351L | 17113769L | 17117644L |
| 17005952L | 17035266L | 17050105L | 17075111L | 17096173L | 17109352L | 17113770L | 17117645L |
| 17007089L | 17035267L | 17050717L | 17075112L | 17098694L | 17111645L | 17113771L | 17117646L |
| 17010765L | 17035269L | 17050719L | 17075113L | 17098696L | 17111646L | 17113996L | 17117647L |
| 17010766L | 17035270L | 17050721L | 17075879L | 17098699L | 17111647L | 17113997L | 17118086L |
| 17012444L | 17035985L | 17050722L | 17075880L | 17098702L | 17111648L | 17113998L | 17118094L |
| 17012445L | 17035986L | 17050742L | 17079829L | 17098705L | 17112144L | 17113999L | 17118095L |
| 17015865L | 17035987L | 17055756L | 17079830L | 17098709L | 17112145L | 17114000L | 17118096L |
| 17015866L | 17035988L | 17055758L | 17080107L | 17099670L | 17112146L | 17114001L | 17118099L |
| 17015867L | 17040940L | 17055759L | 17080108L | 17099672L | 17112147L | 17115912L | 17118100L |
| 17015868L | 17041674L | 17055760L | 17080109L | 17099674L | 17112148L | 17115913L | 17118101L |
| 17019786L | 17041675L | 17055761L | 17081204L | 17099675L | 17112149L | 17115914L | 17118103L |
| 17019787L | 17041676L | 17055762L | 17081209L | 17099677L | 17112150L | 17115915L | 17118587L |
| 17021233L | 17041677L | 17055763L | 17081211L | 17102481L | 17112705L | 17116731L | 17118588L |
| 17021234L | 17041678L | 17055764L | 17085302L | 17102482L | 17112709L | 17116733L | 17118589L |
| 17024791L | 17041679L | 17055765L | 17085303L | 17102484L | 17112714L | 17116734L | 17118591L |
| 17024792L | 17041680L | 17055766L | 17085612L | 17102485L | 17112715L | 17116735L | 17118593L |
| 17027101L | 17041681L | 17060291L | 17086940L | 17103589L | 17112716L | 17116742L | 17121315L |
| 17027191L | 17045718L | 17060292L | 17086941L | 17103591L | 17112717L | 17116743L | 17121319L |
| 17027192L | 17045719L | 17060778L | 17086942L | 17104388L | 17112718L | 17116744L | 17121323L |
| 17027193L | 17045720L | 17060779L | 17089494L | 17104389L | 17112719L | 17116745L | 17121329L |
| 17027194L | 17045721L | 17060780L | 17089501L | 17104390L | 17112720L | 17116746L | 17121330L |
| 17027195L | 17045722L | 17065358L | 17089502L | 17104391L | 17112721L | 17116748L | 17122813L |
| 17027196L | 17045723L | 17065359L | 17089503L | 17107769L | 17112723L | 17117487L | 17122818L |
| 17030253L | 17046555L | 17065811L | 17089504L | 17107770L | 17112724L | 17117488L | 17122824L |
| 17030254L | 17046556L | 17065812L | 17089505L | 17107771L | 17112725L | 17117490L | 17122825L |
| 17030255L | 17046557L | 17065813L | 17090426L | 17107772L | 17113762L | 17117491L | 17122826L |
| 17030256L | 17046558L | 17071775L | 17090427L | 17108451L | 17113763L | 17117492L | 17122828L |
| 17030257L | 17046559L | 17071777L | 17090428L | 17108452L | 17113764L | 17117493L | 17123880L |
| 17030258L | 17046559L | 17071780L | 17094391L | 17108453L | 17113765L | 17117494L | 17123883L |
| 17030259L | 17046560L | 17071782L | 17094392L | 17108454L | 17113766L | 17117495L | 17123885L |



APPENDIX 1B: LIST OF AFFECTED LOTS FOR PART NUMBER D134702

| Lot Number | Lot Number | Lot Number | Lot Number | Lot Number | Lot Number |
|------------|------------|------------|------------|------------|------------|
| 16109573L | 17035271L | 17056882L | 17075117L | 17095489L | 17108456L |
| 16112947L | 17035272L | 17056883L | 17075156L | 17096175L | 17108457L |
| 16112948L | 17035275L | 17056884L | 17075881L | 17096176L | 17108458L |
| 17000307L | 17035318L | 17056885L | 17075882L | 17096177L | 17109355L |
| 17005953L | 17035319L | 17056886L | 17075883L | 17096178L | 17109356L |
| 17007090L | 17035989L | 17056887L | 17079831L | 17096179L | 17109357L |
| 17011460L | 17035990L | 17056888L | 17079832L | 17096180L | 17109358L |
| 17011461L | 17035991L | 17056890L | 17080110L | 17099251L | 17111649L |
| 17012446L | 17035992L | 17060293L | 17080111L | 17099252L | 17111650L |
| 17014583L | 17041714L | 17060294L | 17080112L | 17099680L | 17111651L |
| 17014584L | 17041715L | 17060781L | 17081213L | 17099682L | 17111652L |
| 17017257L | 17041716L | 17060782L | 17081215L | 17099684L | 17113199L |
| 17017258L | 17041717L | 17060783L | 17081216L | 17099686L | 17121946L |
| 17019790L | 17041718L | 17060784L | 17081221L | 17099687L | 17121947L |
| 17019791L | 17041719L | 17060785L | 17085304L | 17100774L | 17121948L |
| 17021235L | 17041720L | 17060786L | 17085630L | 17100775L | 17121949L |
| 17021236L | 17041721L | 17065360L | 17085631L | 17100776L | 17121950L |
| 17024793L | 17041722L | 17065361L | 17085632L | 17100777L | 17121951L |
| 17024794L | 17046561L | 17065814L | 17085633L | 17102488L | 17121953L |
| 17027197L | 17046562L | 17065815L | 17086943L | 17102501L | 17121955L |
| 17027198L | 17046563L | 17065816L | 17086945L | 17102504L | 17121956L |
| 17027199L | 17046564L | 17065817L | 17086946L | 17102523L | 17122345L |
| 17027200L | 17046565L | 17065818L | 17086947L | 17103592L | 17122347L |
| 17027201L | 17046566L | 17065819L | 17090069L | 17103593L | 17122349L |
| 17027202L | 17050106L | 17071785L | 17090070L | 17103594L | 17123230L |
| 17027203L | 17050107L | 17071786L | 17090071L | 17103595L | 17123231L |
| 17030262L | 17050108L | 17071789L | 17090429L | 17104392L | 17123232L |
| 17030263L | 17050109L | 17071792L | 17090430L | 17104393L | 17123235L |
| 17030264L | 17050723L | 17071796L | 17090431L | 17104394L | 17123237L |
| 17030265L | 17050724L | 17071797L | 17091266L | 17104395L | 17123738L |
| 17030266L | 17050728L | 17071798L | 17091267L | 17107773L | 17123891L |
| 17030267L | 17050731L | 17071799L | 17091268L | 17107774L | |
| 17030268L | 17050741L | 17075114L | 17091269L | 17107775L | |
| 17030269L | 17056880L | 17075115L | 17091270L | 17107776L | |
| 17030270L | 17056881L | 17075116L | 17095488L | 17108455L | |

APPENDIX 1C: LIST OF AFFECTED LOTS FOR PART NUMBER D134703

| Lot Number | Lot Number | Lot Number | Lot Number | Lot Number | Lot Number |
|------------|------------|------------|------------|------------|------------|
| 16109574L | 17000308L | 17007091L | 17010768L | 17017256L | 17091271L |
| 16112950L | 17005954L | 17010767L | 17017255L | 17090432L | |

APPENDIX 1D: LIST OF AFFECTED LOTS FOR PART NUMBER D134801

| Lot Number | Lot Number | Lot Number | Lot Number | Lot Number |
|------------|------------|------------|------------|------------|
| 17005955L | 17007092L | 17022201L | 17086948L | 17086949L |

APPENDIX 1E: LIST OF AFFECTED LOTS FOR PART NUMBER D134802

| Lot Number | Lot Number | Lot Number | Lot Number | Lot Number |
|------------|------------|------------|------------|------------|
| 17005956L | 17007093L | 17022206L | 17091272L | 17091273L |

APPENDIX 1F: LIST OF AFFECTED LOTS FOR PART NUMBER D134803

| Lot Number | Lot Number | Lot Number | Lot Number | Lot Number |
|------------|------------|------------|------------|------------|
| 17005957L | 17122350L | 17123741L | 17123744L | |
| 17007094L | 17122351L | 17123742L | 17124089L | |
| 17086159L | 17122352L | 17123743L | 17124090L | |

APPENDIX 1G: LIST OF AFFECTED LOTS FOR PART NUMBER D134804

| Lot Number | Lot Number | Lot Number | Lot Number | Lot Number | Lot Number | Lot Number |
|------------|------------|------------|------------|------------|------------|------------|
| 17005958L | 17015871L | 17071801L | 17090072L | 17099689L | 17103598L | 17109425L |
| 17007095L | 17015872L | 17071803L | 17090073L | 17099691L | 17103599L | 17109426L |
| 17011452L | 17056893L | 17071805L | 17090074L | 17100778L | 17104396L | 17112151L |
| 17011453L | 17056894L | 17075884L | 17090457L | 17100779L | 17104397L | 17112152L |
| 17011454L | 17056895L | 17075885L | 17090458L | 17100780L | 17108274L | 17113200L |
| 17011455L | 17060295L | 17076527L | 17091274L | 17100781L | 17108277L | 17113201L |
| 17014575L | 17060296L | 17076528L | 17095490L | 17103460L | 17108279L | 17122353L |
| 17014576L | 17060297L | 17079833L | 17095491L | 17103461L | 17108283L | 17122354L |
| 17014577L | 17065820L | 17079834L | 17095492L | 17103462L | 17108460L | 17126973L |
| 17014578L | 17065821L | 17080113L | 17095493L | 17103463L | 17108462L | 17126974L |
| 17015869L | 17065822L | 17080114L | 17096181L | 17103596L | 17108463L | 17126991L |
| 17015870L | 17071800L | 17085305L | 17096182L | 17103597L | 17108465L | |

APPENDIX 1H: LIST OF AFFECTED LOTS FOR PART NUMBER D134805

| Lot Number | Lot Number | Lot Number | Lot Number | Lot Number | Lot Number | Lot Number |
|------------|------------|------------|------------|------------|------------|------------|
| 16109570L | 17019781L | 17035979L | 17050100L | 17071766L | 17084482L | 17100786L |
| 16109571L | 17019783L | 17035980L | 17050101L | 17071769L | 17084483L | 17100787L |
| 16109572L | 17021237L | 17035981L | 17050715L | 17071772L | 17085636L | 17102526L |
| 16112951L | 17021238L | 17035982L | 17053141L | 17071808L | 17085637L | 17102527L |
| 16112952L | 17021240L | 17035983L | 17053143L | 17071809L | 17086950L | 17102528L |
| 16112953L | 17021241L | 17035984L | 17053145L | 17071810L | 17086951L | 17102529L |
| 16112954L | 17022187L | 17038891L | 17053147L | 17071811L | 17089464L | 17102530L |
| 17000309L | 17022189L | 17038892L | 17053148L | 17074859L | 17089465L | 17102531L |
| 17000310L | 17022191L | 17038893L | 17053150L | 17074860L | 17089466L | 17103600L |
| 17000311L | 17022193L | 17038894L | 17053152L | 17074861L | 17089491L | 17103601L |
| 17000312L | 17024795L | 17038895L | 17053154L | 17074862L | 17089492L | 17103602L |
| 17001579L | 17024796L | 17038896L | 17053156L | 17074863L | 17089493L | 17103603L |
| 17001580L | 17024812L | 17041723L | 17053157L | 17074877L | 17090437L | 17104661L |
| 17001581L | 17024814L | 17041724L | 17056899L | 17074878L | 17090455L | 17104662L |
| 17001582L | 17027204L | 17041725L | 17056900L | 17074879L | 17091275L | 17104663L |
| 17001583L | 17027205L | 17041726L | 17056901L | 17075886L | 17091276L | 17104664L |
| 17001584L | 17027206L | 17041727L | 17056902L | 17075887L | 17091277L | 17104665L |
| 17001585L | 17027207L | 17041728L | 17058896L | 17076529L | 17091278L | 17104666L |
| 17005959L | 17027208L | 17044066L | 17058897L | 17076530L | 17094385L | 17107777L |
| 17005960L | 17027209L | 17044072L | 17058898L | 17078439L | 17094386L | 17107778L |
| 17007096L | 17027210L | 17044076L | 17058899L | 17078440L | 17094387L | 17107779L |
| 17007097L | 17027211L | 17044077L | 17058900L | 17078441L | 17094388L | 17107780L |
| 17010770L | 17031114L | 17044078L | 17058901L | 17078442L | 17094389L | 17107781L |
| 17010772L | 17031115L | 17044081L | 17058902L | 17078443L | 17094390L | 17107782L |
| 17011456L | 17031116L | 17045724L | 17058903L | 17078444L | 17096183L | 17108264L |
| 17011457L | 17031117L | 17045725L | 17058904L | 17078462L | 17096185L | 17108581L |
| 17011458L | 17031118L | 17045726L | 17064482L | 17078485L | 17096186L | 17108582L |
| 17011459L | 17031119L | 17045727L | 17064483L | 17078486L | 17096187L | 17108583L |
| 17012448L | 17031120L | 17045728L | 17064484L | 17078487L | 17096188L | 17109427L |
| 17012449L | 17031121L | 17045729L | 17064485L | 17080116L | 17098603L | 17109428L |
| 17014579L | 17031122L | 17048464L | 17064486L | 17081225L | 17098650L | 17109429L |
| 17014580L | 17031123L | 17048465L | 17064487L | 17081231L | 17098651L | 17109430L |
| 17014581L | 17031124L | 17048466L | 17064488L | 17084474L | 17098665L | 17109431L |
| 17014582L | 17031125L | 17048467L | 17064489L | 17084475L | 17098666L | 17109432L |
| 17017251L | 17034348L | 17048468L | 17065823L | 17084476L | 17099694L | |
| 17017252L | 17034349L | 17048469L | 17071741L | 17084477L | 17099695L | |
| 17017253L | 17034350L | 17048470L | 17071757L | 17084478L | 17100782L | |
| 17017254L | 17034351L | 17048471L | 17071759L | 17084479L | 17100783L | |
| 17019779L | 17034352L | 17048472L | 17071762L | 17084480L | 17100784L | |
| 17019780L | 17034353L | 17048473L | 17071764L | 17084481L | 17100785L | |