UNITED ARAB EMIRATES
MINISTRY OF HEALTH

الإمارات العربية المتحدة
وزارة الصحـــــــة

التاريخ: 21/10/2014
الرقم: 2014/1209/ >

السادة الأفاضل/ مدراء المناطق الطبية المحترمين
السادة الأفاضل / مدراء المستشفيات الحكومية و الخاصة المحترمين
تحية طيبة وبعد،

م/ تقارير السلامة للوسائل الطبية
THERMOCOOL SF NAV Catheter Family
من إنتاج شركة Biosense Webster- Johnson & Johnson Inc.

حفاظا على المصلحة العامة وصحة المجتمع، نود أن نلفت انتباهكم الى توصيات الشركة المصنعة والتي يجب إتخاذها عند إستخدام المنتجات المذكورة أعلاه، والتي تستخدم في عمليات القسطرة في القلب، وذلك لمنع حدوث الأعراض الجانبية التالية:

- ثقب في القلب (Cardiac perforation and tamponade)
- الناسور في الأذينين-المريء (Atria-esophageal fistula)

توصيات الشركة المصنعة:

1. عدم استخدام القوة المفرطة لدفع أو سحب القسطرة عند مواجهة مقاومة من الطرف الآخر لمنع حدوث ثقب في القلب
2. عدم استخدام جهاز استشعار درجة الحرارة لمراقبة درجة حرارة الأنسجة. لأن جهاز درجة الحرارة يُظهر درجة حرارة قطب التبريد (cooled electrode) ، وليس درجة حرارة الأنسجة
3. لتقليل خطر الناسور في الأذينين-المريء ، ينبغي اتخاذ تدابير وقائية عند قطع وإخراج القسطرة من الأذين الأيسر بالقرب من المريء.

ولمزيد من المعلومات عن هذه المنتجات يرجى الاطلاع على الموقع:
http://www.mhra.gov.uk/home/groups/fsn/documents/fieldsafetynotice/con404455.pdf

علما بأن هذه المنتجات غير مسجلة في إدارة التسجيل و الرقابة الدوائية بوزارة الصحة و لكن حرصا منا على سلامة المرضى ارتأت الإدارة إبلاغكم بذلك لاتخاذ الإجراءات اللازمة إن وجدت لديكم.
وفي حال حدوث أي أعراض جانبية يرجى ملئ الإستمارة الخاصة بالآثار الجانبية للدواء ADR والمتوفرة على الموقع http://www.cpd-pharma.ae ، أو الإتصال على العناوين التالية:
هاتف: 6117391 - 02 أو 6117642 - 02 أو فاكس6313742- 02 أو البريد الالكتروني: pv @moh.gov.ae

و تفضلوا بقبول فائق الاحترام و التقدير.

د. أمين حسين الأميري
وكيل الوزارة المساعد لسياسة الصحة العامة والتراخيص

صدر بديوان عام الوزارة/ابوظبي بتاريخ: 9/ 2014

نسخة:

– معالي / وزير الصحة	الموقر
– سعادة / وكيل وزارة الصحة	.. المحترم ،،،
– سعادة / المدير العام لهيئة الصحة – أبو ظبي	.. المحترم ،،،
– سعادة / المدير العام لهيئة الصحة – دبي	.. المحترم ،،،
– سعادة / وكيل الوزارة المساعد لقطاع المستشفيات	.. المحترم ،،،
– سعادة / وكيل الوزارة المساعد لقطاع المراكز والعيادات الصحية	.. المحترم ،،،
– سعادة / مدير المكتب الطبي/وزارة شؤون الرئاسة	.. المحترم ،،،
– سعادة / المدير التنفيذي لمدينة دبي الطبية	.. المحترم ،،،
– سعادة / مدير إدارة سلاح الخدمات الطبية/القوات المسلحة	.. المحترم ،،،
– سعادة / مديرة إدارة الدواء	.. المحترمة ،،،

مدير ادارة الدواء

Biosense Webster

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT FIELD SAFETY NOTICE

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

Catalog Numbers: D-1313-XX-S, D-1315-XX-S, D1317-XX-S, D1318-XX-S
All Lot Numbers

April 1, 2014

The purpose of this communication is to inform you of certain observations acquired through our routine post-market surveillance process regarding the uni-directional and bi-directional THERMOCOOL® SF NAV Catheter Family. As part of our commitment to you as a user of these products, Biosense Webster believes you would have an interest in and benefit from this information.

Indications and use

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

Reported rate of adverse events

Biosense Webster has identified a higher frequency of spontaneously reported adverse events related to cardiac perforations and atrio-esophageal fistula (AEF) with the uni-directional and bi-directional THERMOCOOL® SF NAV Catheter Family during the time period of January 2010 to December 2013 as compared to other navigational THERMOCOOL® Ablation Catheters (Table 1). A total of nine (9) deaths have been reported as a consequence of these adverse events with the THERMOCOOL® SF NAV Catheter Family. Six (6) deaths were attributed to AEF & three (3) were attributed to cardiac perforation. None of these reported events were related to any reported device malfunction during the mapping and ablation procedures.

Table 1: Reported adverse event rate for irrigated navigational THERMOCOOL® Catheters (Jan 2010 – Dec 2013)

	THERMOCOOL® SF NAV	NAVISTAR® THERMOCOOL®	EZ STEER® THERMOCOOL® NAV	THERMOCOOL® SMARTTOUCH® NAV
Cardiac perforations (%)	0.2%	0.04%	0.16%	0.09%
AEF (%)	0.007%	0.0005%	0	0.003%
*Death (number)	9	1	1	2

*Number of death as a consequence of cardiac perforation or AEF.

- **Cardiac perforation and tamponade:** The majority of associated events were related to ablation of atrial fibrillation (AF) procedures and although most events occurred during ablation, small number of events occurred during mapping. Two large international surveys[1,2], providing information on current real world practices for AF ablation, reported a cardiac perforation rate of 1.31% (in 20,825 procedures) and 1.3% (in 1,410 patients) respectively.

[1] Cappato R, Calkins H, Chen SA, Davies W, Iesaka Y, Kalman J et al. Updated worldwide survey on the methods, efficacy, and safety of catheter ablation for human atrial fibrillation/clinical perspective. Circ Arrhythmia Electrophysiol 2010;3: 32–8.

[2] Arbelo E, Brugada J, Hindricks G, Maggioni A, et al. ESC-EURObservational Research Programme: the Atrial Fibrillation Ablation Pilot Study, conducted by the European Heart Rhythm Association. Europace (2012) 14, 1094–1103.

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***Tel:** 02 746 3000*

- **Atrio-esophageal fistula:** These reported events of AEF occurred during ablation in the left atrium mainly for AF indication in most of the cases. Atrio-esophageal fistula has been reported in the literature as a rare complication of percutaneous catheter ablation of AF. Surveys on catheter ablation of AF as well prevalence of AEF reported a rate of 0.01 - 0.07%.[1,3,4]

Potential cause of reported adverse events

Spontaneous adverse event reporting to manufacturers has known limitations with possible underreporting of adverse events. Further reducing the estimated spontaneous event rate is the use of the number of devices distributed as the calculation denominator rather than the number of procedures. As a result of these limitations Biosense Webster continues its investigation to assess potential contributing factors to the relatively higher reported adverse events of cardiac perforation/tamponade and AEF associated with the use of the THERMOCOOL® SF NAV Catheters.

While Biosense Webster's ongoing investigation has not identified a definitive cause for this observed difference in frequency of adverse events for our uni-directional and bi-directional THERMOCOOL® SF NAV Catheter Family, two (2) factors should be considered in relation to these reported adverse events.

- The increased stiffness and the related handling properties of the THERMOCOOL® SF NAV Catheter Family may contribute to the risk for perforation.
- Due to the enhanced cooling feature of the THERMOCOOL® SF NAV Catheter, application of the same power settings, guided by temperature feedback, as previously used with other navigational THERMOCOOL® Catheters may result in relatively deeper lesions and potentially contributes to higher rate of AEF and cardiac perforations.

Biosense Webster is committed to address the two (2) identified factors via a labeling update and a worldwide training to all physicians using the THERMOCOOL® SF NAV Catheters following dissemination of this Field Safety Notice to our customers and the applicable regulatory authorities.

Due to the enhanced cooling feature of the THERMOCOOL® SF NAV Catheter, operators should use lower power limits with the THERMOCOOL® SF NAV Catheter compared to other navigational THERMOCOOL® Ablation Catheters if the tip temperature was used to guide power delivery during ablation.

We would like to reinforce the following from the Warnings and Precautions in the Instructions for Use (IFU) for the THERMOCOOL® SF NAV Catheter Family models:

- When using the Biosense Webster THERMOCOOL® SF NAV Diagnostic/Ablation Deflectable Tip Catheter with conventional systems (using fluoroscopy to determine catheter tip location), or with the CARTO® EP Navigation System, careful catheter manipulation must be performed in order to avoid cardiac damage, perforation or tamponade. Catheter advancement should be done under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. The firmness of the braided tip dictates that care must be taken to prevent perforation of the heart.
- Do not use the temperature sensor to monitor tissue temperature. The temperature sensor located within the tip section of the catheter does not reflect either electrode-tissue interface or tissue temperature due to the cooling effects of the saline irrigation of the electrode. The temperature displayed on the RF generator is the temperature of the cooled electrode, not tissue temperature. The temperature sensor is used to verify that the irrigation flow rate is adequate. Before initiating the application of RF current, a decrease in electrode temperature confirms the onset of saline irrigation of the ablation electrode. Monitoring the temperature from the electrode during the application of RF current ensures that the irrigation flow rate is being maintained.

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[3] Cappato R, Calkins H, Chen SA, Davies W, Iesaka Y, Kalman J et al. Prevalence and causes of fatal outcome in catheter ablation of atrial fibrillation.JACC 2009: 53: 1798–1803.

[4] Nair KK, Shurrab M, Skanes A, Danon A, Birnie D et al. Prevalence and risk factors for AEF after percutaneous radiofrequency catheter ablation of atrial fibrillation: The Canadian experience.J Interv Card Electrophysiol 2014: 39(2): 139–1443.

- To minimize risk of atrio-esophageal fistula, precautionary measures should be taken when ablating on the posterior wall of the left atrium in proximity to the esophagus.

Based on Biosense Webster's investigation, including a medical evaluation of the health risk profile from the post-market reports, Biosense Webster believes the overall benefit risk profile of these catheters remains in an acceptable range when used as directed in the indicated populations.

As Biosense Webster regrets any inconvenience this Field Safety Notice may cause, we present this information to you as part of our shared commitment to the safety of your patients. Please share this information with any of your staff involved in utilizing the THERMOCOOL® SF NAV Catheters in mapping and ablation procedures.

Actions Requested on Your Part:

- Read this Field Safety Notice carefully.
- Review, complete, sign and return the attached Acknowledgement Form confirming your understanding of this notice in accordance with the instructions listed on the form.
- Pass this Field Safety Notice on to anyone in your facility that needs to be informed, including appropriate clinical personnel involved in the use of the THERMOCOOL® SF NAV Catheters.
- Retain a copy of this Field Safety Notice with the subject product.
- Maintain awareness of this Field Safety Notice.

Additional Information:

For questions related to this Field Safety Notice and the Acknowledgement Form please contact your local Biosense Webster representative.

Please return the completed acknowledgement form to Biosense Webster according to the instructions at the bottom of the form.

The 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.

Respectfully yours,

Mina Ghajar
Vice President
Quality and Regulatory Compliance

Ahmed Abdelaal
Director
Medical Affairs and Medical Science

Product Code Reference Table

Biosense Webster, a division of Johnson & Johnson Medical NV/SA
Leonardo Da Vincilaan 15, BE – 1831 Diegem - Belgium
Tel: 02 746 3000

Product Description	Manufacturing Catalog No	EU Product Code
THERMOCOOL® SF NAV Bi Directional Catheter (compatible with CARTO® 3 System)	D-1313-01-S	BNI35DDCT
	D-1313-02-S	BNI35FFCT
	D-1313-03-S	BNI35JJCT
	D-1313-04-S	BNI35FJCT
	D-1313-05-S	BNI35DFCT
	D-1313-06-S	BNI35BBCT
	D-1313-07-S	BNI35BDCT
	D-1313-08-S	BNI35BFCT
	D-1313-09-S	BNI35DJCT
THERMOCOOL® SF NAV Bi Directional Catheter (compatible with CARTO® XP System)	D-1317-01-S	BNI35DDH
	D-1317-02-S	BNI35FFH
	D-1317-03-S	BNI35JJH
	D-1317-04-S	BNI35FJH
	D-1317-05-S	BNI35DFH
	D-1317-06-S	BNI35BBH
	D-1317-07-S	BNI35BDH
	D-1317-08-S	BNI35BFH
	D-1317-09-S	BNI35DJH
THERMOCOOL® SF NAV Uni Directional Catheter (compatible with CARTO® XP System)	D-1318-01-S	D131801
	D-1318-02-S	D131802
	D-1318-03-S	D131803
	D-1318-04-S	D131804
THERMOCOOL® SF NAV Uni Directional Catheter (compatible with CARTO® 3 System)	D-1315-01-S	D131501
	D-1315-02-S	D131502
	D-1315-03-S	D131503
	D-1315-04-S	D131504

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