

«Hospital_Name»
«Users_Name»- «Department»
«Customer_Address»
«Zip_Code» «City» - «Country_name»

Reference: 92119486-FA

xx June 2017

Field Safety Notice (for Distributor) - Urgent Medical Device Correction Cosman Medical Nitinol RF (TCN) Reusable Electrodes

Dear «Users_Name»,

Cosman Medical is implementing a voluntary action for Nitinol RF (TCN) reusable electrodes to **convert them to single use** electrodes. The TCN Electrodes were manufactured by Cosman Medical, a wholly-owned subsidiary of Boston Scientific, and affected units are labeled as Cosman. The affected product codes are provided in Table below.

Our records indicate that your facility received some of the concerned product. The **table below provides a complete list of all affected products**. Please note that **only the devices listed below are affected. No other Boston Scientific or Cosman product is involved in this Field Safety Notice. Further distribution or use of any remaining product affected by this action should cease immediately.**

Affected Product Listing

TCN-5-3M	TCN-15	TCNK-10-C
TCN-10-3M	TCN-20	TCNK-15
TCN-15-3M	TCNK-5	TCNK-15-C
TCN-5	TCNK-5-C	TCNK-20
TCN-10	TCNK-10	

Note: Cosman stainless steel (CSK) and Disposable (TCD/CU/CUR) Electrodes are not affected by this action

There have been complaints that after multiple reprocessing cycles, the epoxy resin which holds the TCN electrode can exhibit signs of damage. In some cases, this damage may result in the inability to fully remove blood and/or tissue residuals prior to cleaning and re-sterilizing the device. The failure to completely remove any blood and/or tissue from the TCN electrodes prior to re-sterilization creates a potential risk of infection and spread of blood borne pathogens to patients.

The TCN Electrode was introduced in 2009. To date, we have not received any reports of patient injury related to this issue.

COSMAN

If you have any of these affected electrodes within your inventory that have not been used, please segregate the product immediately and read the enclosed Correction Instructions before proceeding. Used TCN Electrodes should be disposed **immediately** in accordance with your institution's infectious material/biohazard waste control procedures.

INSTRUCTIONS:

1- **Check your Inventory for the products affected by this Field safety Notice.**

2- **Immediately discontinue use of devices that have already been used.**

Used TCN Electrodes should be disposed of in accordance with your institution's infectious material/biohazard waste control procedures.

3- **Please notify all your customers that have received affected product of this Field Safety Notice.** To effectively manage this Field Safety Notice, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this recall to the medical facility level.

4- **Unused/un-opened** TCN Electrodes should be identified as **single use only** (for one patient). These devices are supplied as **non-sterile** which require cleaning and sterilization prior to use. These TCN Electrodes may be used once the cleaning and sterilization steps are completed.

After **single use**, the used TCN Electrode should be disposed of in accordance with your institution's infectious material/biohazard waste control procedures.

5- **Please complete the attached Acknowledgement Form even if you do not have any product to return.**

6- **When completed, please return the Acknowledgement Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **xx July 2017**.

Your Competent Authority is being notified of this Field Safety Notice.

Cosman Medical recognizes the impact of this action on both you and your patients, and wants to reassure you that the patient safety remains our primary concern. We regret any inconvenience that this action may cause and appreciate your understanding..

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Acknowledgement Form



Please complete the form & send it to Your Local Office:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «Users_Name» - «City» - «Country_name»

Distributor Acknowledgement Form – Medical Device Correction
Cosman Medical Nitinol RF (TCN) Reusable Electrodes
92119486-FA

I acknowledge receipt of the
Medical Device Correction Notice from Cosman Medical
dated xx July 2017

and will disseminate this information to our customers.

NAME* _____ TITLE _____

Telephone _____ Email _____

Customer? SIGNATURE* _____ DATE* _____

* Required field

dd/mm/yyyy