

Urgent Medical Device Correction – Immediate Action Required

Cosman Medical Nitinol RF (TCN) Reusable Electrodes

July 16, 2017

Dear Healthcare Professional:

CC Chairman Medical Board and relevant Head of Departments:

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 1 below.

Table 1: Affected Products

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

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 in the hub 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.



A wholly-owned subsidiary of Boston Scientific Neuromodulation Corp.

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.

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.

We are notifying the appropriate worldwide regulatory authorities of this correction as required. If you have any questions, please contact the company representative.

Sincerely,

Patrick Crotteau
Vice President, Quality
Boston Scientific
25155 Rye Canyon Loop
Valencia, CA 91355

1-888-8COSMAN
Cosmanorders@bsci.com

Encl: Correction Instructions
Field Correction Reply Verification Tracking Form

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to Boston Scientific Neuromodulation complaint call center at 1-866-680-1848 and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm

Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787

Fax: (800) FDA-0178

Phone: (800) FDA-1088

Correction Instructions

The Field Correction Reply Verification Tracking Form enclosed with this Customer Device Correction Notice must be completed and returned **even if you do not have any of the units remaining at your facility.**

1. **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.

2. **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.

3. **Complete and return the Field Correction Reply Verification Tracking Form.**

- Complete the enclosed Field Correction Reply Verification Tracking Form, following the directions on this page.
- Return the Field Correction Reply Verification Tracking Form:

Email: Cosmanorders@bsci.com

or

Fax to: 781-272-6563

Please email or fax your Field Correction Verification Tracking Form(s) immediately. Identify your email with "TCN Electrodes Action" in the subject line.