



Joseph G. Darling  
President

September 17, 2009

Dear valued ConMed Linvatec customer:

You may have recently become aware of two voluntary medical device recalls of ConMed Linvatec's earlier-generation Hall® Battery Powered Instruments (handpieces) and MC5057 cables, due to self-activation in certain circumstances. In order to make sure that the correct information is circulating, I want to communicate directly to you, our valued customer, concerning precisely which products are subject to the recalls, the actions we are taking to facilitate these recalls, and to address questions that have been raised by some of our customers.

Both recalls were undertaken voluntarily by ConMed Linvatec after discussion with the FDA to accelerate and expand mitigation plans. On September 10, 2009, we sent recall notifications to all customers with affected handpieces and cables. These notifications included forms that allow us to confirm the specific devices in your possession. Once we receive these completed forms from your facility, our Customer Service department will contact you to schedule a return date for your affected handpieces and cables. All items will be scheduled for return within the next 6-8 months. **Please note, the Company believes it is safe for you to use your handpieces and cables if you follow the mitigation guidelines (page 2).** If you have products that are subject to the recall, they will be replaced with new cables or refurbished handpieces at no charge.

For your convenience, mitigation guidelines are outlined on page 2. These guidelines also can be found in our user manuals. By following these guidelines, your staff can minimize any potential risks associated with these devices as noted in this recall action. You also should reread the *Instructions for Use* for these devices, especially the service, warnings and cautions sections.

It is important for our customers to know that, to date, out of the 12,205 affected cables in use today, there have been five (5) reports of failure, resulting in two (2) user injuries. To date, out of the 14,579 affected handpieces shipped since 2002, there have been 22 reported self-activation failures — with no injuries. For details, please refer to page 2.

I can assure you this is our top priority as we work to handle servicing of your product(s) as quickly and efficiently as possible. Our goal is to provide timely and accurate information, as well as minimize any inconvenience to you and your staff. I appreciate your patience and understanding as we work to remedy this situation. We have established the following dedicated Customer Service line to field any questions or concerns you may have: 1(800) 535-8536. You may also contact this line if you are unsure whether you have products that are affected.

We sincerely appreciate your business and continued support.

A handwritten signature in black ink that reads "Joe Darling". The signature is written in a cursive, flowing style.

# Background of ConMed Linvatec recalls

*The following is the background of events that led to ConMed Linvatec's two recent field actions:*

## **BATTERY POWERED INSTRUMENTS (HANDPIECES)**

### **PRO5000 and PRO6000 family of handpieces**

- There have been **NO** reported injuries related to this recall.
- 22 failures have been reported SINCE 2002. In a significant portion of these 22 failures, the handpiece self activated at a very slow (less than 200 rpm) speed.

## **CABLES**

### **MC5057 Cables**

- A risk of self-activation will occur ***ONLY*** if there is a failure of certain MC5057 cables when used with PowerPro<sup>®</sup> Electric Large Bone handpieces, or with the 5020-027 MicroChoice<sup>®</sup> Modular handpiece. All of these handpieces are pistol-grip handpieces, which are used primarily in large-bone orthopedic, arthroscopic ACL, hand, foot, and sternotomy applications.
- There have been five (5) reports of failure in these devices, resulting in two (2) injuries. Both occurred in 2006 and both were treatable injuries to the hospital staff.
  - One injury was a result of improper handling of the instrument, where the individual grabbed the device by the operating end of the handpiece — contrary to ***Instructions for Use***.
  - The second injury resulted in a minor cut, which required a Band-Aid.
- **PLEASE NOTE:** This recall ***does not*** affect the Apex<sup>®</sup>, Advantage<sup>®</sup>, or Advantage Turbo<sup>®</sup> shavers, or the E9010 handpieces, as each of these have a dedicated cable and are, therefore, not used with the MC5057 cable.

### **How do I know if my product is affected?**

- If you received a letter that was sent to your Risk Management office and/or to your Materials Management office, your product is affected. If you did not receive a letter, your product is **NOT** affected.

## **RISK MITIGATION**

The following risk mitigation activities should be taken until your handpiece(s) or cable(s) have been returned after scheduling by Customer Service.

### **Handpieces:**

- **Warning: When battery is installed, avoid contact with moving parts. Insert battery and test preoperatively, away from the surgical site.**

### **Cables:**

- Follow instructions included in your handpiece manual that read: **Always inspect cord for signs of excessive wear or damage. If wear or damage is found, discontinue use and replace immediately.**