



HIGHLAND METALS INC.
www.highlandmetals.com

419 Perrymont Avenue
 San Jose, CA 95125, United States
 Phone: 1-408-271-2955
 Fax: 1-408-271-2962

Urgent Field Safety Notice – Mislabeled Product

Dato: January 3, 2014

Customer: AARHUS UNIVERSITET

Country: Denmark

Email: mmunk@odont.au.dk; JYTTEKARNBAK@HOTMAIL.COM **Fax Number:** 011 45 89424161

Product Name:	SuperElastic NiTi Archwires
HMI Identifier:	CAR 897
Type of Action:	Notification

1: Incident Details and Affected Devices:

Detail	Specific Detail
Country of Manufacture:	USA
Date HMI Notified of Incident:	December 6, 2013
Description of Incident:	Product may be mislabeled; <ul style="list-style-type: none"> • Product labeled as “Upper” may contain “Lower” archwires with a red midline mark. • Product labeled as “Lower” may contain “Upper” archwires with a black midline mark.
Possible risk to patients associated with previous use of affected devices:	If the incorrect wire is used on a patient the device may not function as intended and be inefficient in the treatment of the patient. This may require intervention by the doctor to replace the wire.
Period when affected devices were sold in Country*:	From November 1, 2013 to December 9, 2013

Part Number	Part Description	Lot Number	Label Form	Actual Form
11100141124	SE Niti 014 Nat U 100	41756	Upper	Lower
11100141144	SE Niti 014 Nat L 100	41760	Lower	Upper
11100141145	SE Niti 014 Nat L 10	41760	Lower	Upper
11100161124	SE Niti 016 Nat U 100	41684	Upper	Lower
11100161125	SE Niti 016 Nat U 10	41684	Upper	Lower
11100161144	SE Niti 016 Nat L 100	41679	Lower	Upper

- Action concerning lots or parts of lots only – explain why other devices are not affected:
Other samples made during the period of the incident have all been checked and confirmed to contain correct product as per label.

2: Customer Distribution of Affected Devices:

Invoice No	Invoice Date	Part Number	Lot Number	Qty (pks)	UOM
51746	11/8/2013	11100141124	41756	1	100 pk
51746	11/8/2013	11100141144	41760	1	100 pk

3: The Following Action is Required:

Action Required	Specific Detail	Due Date
<input checked="" type="checkbox"/> Identify and review the products received as per Section 2.	Please check archwire form. Archwires with a red midline mark are lower form, while those with a black midline mark are upper form.	Jan 10, 2014

4: Transmit this Notice as Follows:

- This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which this action has an impact.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

HMI Contacts:

Quality

Name: Eveline Carr
Title: Quality Administrator
Email: eveline@highlandmetals.com

Customer Services

Name: Jennifer Jones
Title: Customer Services Manager
Email: jennifer@highlandmetals.com

Organization: Highland Metals Inc
Address: 419 Perrymont Avenue
San Jose, CA 95125, United States
Phone: 1-408-271-2955

Acknowledgement of Receipt and Action:

I hereby acknowledge the receipt of this notification issued by Highland Metals Inc.

- The product listed in Section 2 has been checked and packs are CORRECTLY labeled.
- The product listed in Section 2 has been checked and packs are INCORRECTLY labeled.
- I wish to keep the products.
- I wish to return the product to HMI to get a refund.
HMI will arrange a call tag to have product returned to HMI at no expense to you. Your account will be credited for the returned devices upon receipt by HMI.
- Please send replacement products for the original order.
There will be no shipping charge (including duties and taxes) for replacement product.

Signature: _____

Name: _____

Company: AARHUS UNIVERSITET

Date: _____

Please fax back to HMI on +1-408-271-2962 or scan and email to quality@highlandmetals.com