



July 10, 2012

Citicon Hong Kong Limited
Unit A 11/F, Sea Bright Plaza
9-23 Shell Street
North Point HONG KONG

ATTENTION: CUSTOMER NOTIFICATION

Dear Citicon Hong Kong Limited:

Pentron Clinical would like to inform you that the current Directions for Use (DFU) for Correct Plus Bite Superfast lists a Working Time that is not indicative of the actual performance of the product. Please note the product itself has not been modified in any way, and therefore there is no change in the product performance to which you are accustomed; continue to use the product in the same manner you have in the past. The current DFU lists the Total Working Time as 25 seconds, while the material actually provides a minimum working time of 15 seconds as outlined in the chart below.

Product	Correct Plus Bite Superfast
Minimum Working Time	0:15 Seconds
Maximum Intra Oral Setting Time (from initial mix)	1:15 Minutes

There are no safety or efficacy concerns associated with Correct Plus Bite Superfast as the product will set.

The following table lists the affected units included in the scope of this correction.

Description	Part Numbers	Lot Number
Correct Plus Bite Superfast	Q34IA	All Production Lots
	Q34IC	

Please review the table above and confirm that you are aware of the correct Working Time and timing parameters as detailed in the enclosed instruction card by returning the attached reply form. **Please contact Pentron Clinical Customer Care at 1-800-551-0283 if you have any further questions.**

PENTRON CLINICAL KINDLY REQUESTS YOUR COOPERATION IN COMPLETING AND FAXING BACK THE ENCLOSED FORM IN ORDER TO CONFIRM YOUR RECEIPT OF THIS FIELD CORRECTION LETTER, REGARDLESS OF WHETHER YOU HAVE ANY PRODUCT IN YOUR INVENTORY.

If you are an authorized Pentron Clinical distributor, we request that you identify those customers that may have been shipped the affected product lot and contact these customers to inform them of the issue within forty-eight (48) hours of receipt of this notification.

Pentron Clinical sincerely apologizes for the inconvenience this situation causes you and your customers.

Thank you for your patience and support.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Wendy Carmer". The signature is written in a cursive, flowing style.

Director, Regulatory Affairs

Citicon Hong Kong Limited
Unit A 11/F, Sea Bright Plaza
9-23 Shell Street
North Point HONG KONG

Correct Plus Bite Superfast Acknowledgement Form

Description	Part Numbers	Lot Number
Correct Plus Bite Superfast	Q34IA	All Production Lots
	Q34IC	

- We acknowledge receipt of the Correct Plus Bite Superfast Field Correction Letter and acknowledge that we are aware of the correct Working Time and timing parameters as detailed below and in the enclosed instruction card. Additionally, we are aware that we must identify those customers that may have been shipped the affected product and contact these customers to inform them of the issue within forty-eight (48) hours of receipt of this notification.***

Product	Correct Plus Bite Superfast
Minimum Working Time	0:15 Seconds
Maximum Intra Oral Setting Time (from initial mix)	1:15 Minutes

Contact Person (Please Print)

Facility

Signature

Date

WE ALSO KINDLY REQUEST YOUR COOPERATION IN FAXING THIS ACKNOWLEDGEMENT FORM TO THE FOLLOWING NUMBER WHETHER OR NOT YOU HAVE ANY PRODUCT TO RETURN TO CONFIRM YOUR RECEIPT OF THIS NOTIFICATION.

714-288-4609