

URGENT: MEDICAL DEVICE CORRECTION C1014

Date: 10/04/2010

To Whom It May Concern:

This is to inform you of a **MEDICAL DEVICE CORRECTION** involving the **Software for the Sureshot Targeter**

| Affected Part and Batch Numbers |
|---|
| Item # 71692802 All Serial numbers including and prior to ACA5 |

This correction has been initiated as we have confirmed an issue with the targeting software providing erroneous targeting when used with the 13MM Left TAN/FAN nails. The nail representation on the screen is shifted slightly posterior (by approximately 1.5mm) on 13MM Left TAN/FAN nails in Sureshot Targeting software Version 2.0.1. This software offset error may lead to a drill missing the hole on the anterior side of a 13MM Left TAN/FAN nail.

The risk of a drill missing the hole in the nail would be a potential weakness of the bone if drilled multiple times, delay in surgery and/or possible damage of the nail if the hole is partially missed by the drill bit.

Action:

Please follow the instructions included in this package.

This requires your immediate attention and cooperation. Please complete this task promptly.

If you have any questions, please contact [REDACTED] at [REDACTED] or the contact information provided on the instructions.

This correction is being conducted with the knowledge of the Food and Drug Administration, so it is important for you to track all of your actions regarding this correction as they may be audited by the FDA.

We apologize for any inconvenience this may cause. However, by acting promptly to address issues such as this, you are ensuring that Smith & Nephew continues to deliver the right product to the right place at the right time.

Please complete the below acknowledging that you were made aware of this correction.

_____ Signature of Hospital Representative

_____ Date

_____ Printed Name of Hospital Representative

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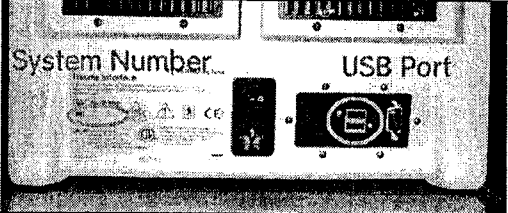
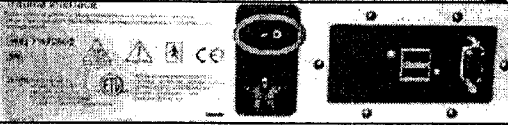
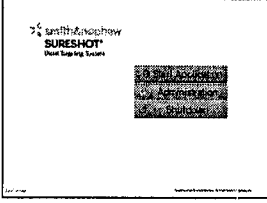
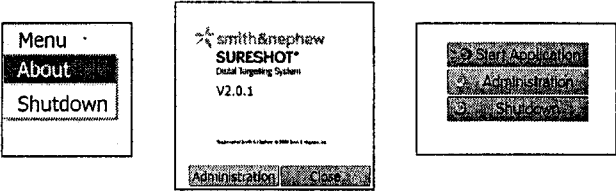
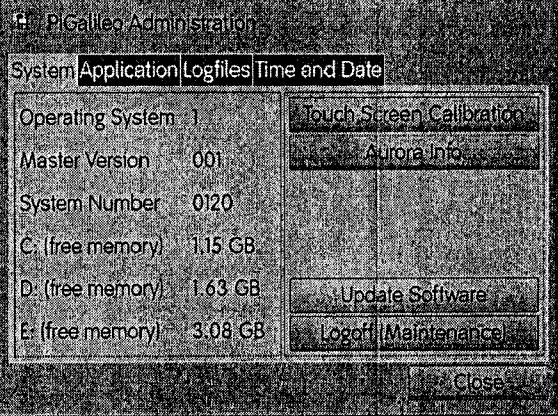
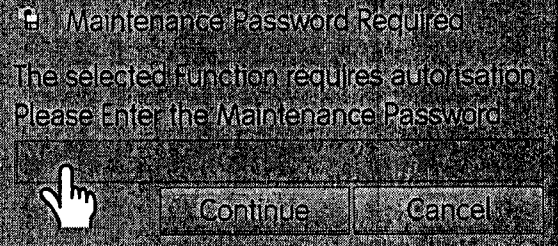
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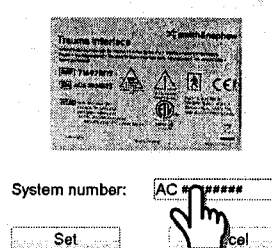
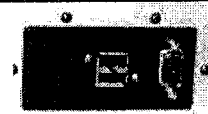

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Sureshot Targeting V2.0.2 (with Trauma Launcher V1.0.1) USB Update Instructions

| | |
|--|--|
| <p>1. Verify the following information is printed on the USB drive:</p> <ul style="list-style-type: none"> • "Sureshot Targeting V2.0.2" • "Trauma Launcher V1.0.1" |  |
| <p>2. Plug the USB drive into either of the 2 USB ports on the back of the Trauma Interface. This MUST be done before turning on power to the Interface Unit.</p> <ul style="list-style-type: none"> • Write down the System Number SN. You will need this for Step 8. |  |
| <p>3. Plug in the Interface and start system power on the back of the Trauma Interface Unit (Power on).</p> |  |
| <p>4. Does this screen appear?</p> <p>If YES: Press "Administration" then go to Step 6</p> <p>If NO: Go to Step 5</p> |  |
| <p>5. Select the following:</p> <p>Menu > About > Administrator</p> <p>"Do you want to Exit the Program" Select: YES</p> <p>Press "Administration" Button</p> <p>Note: If a "Settings Change" Windows message appears asking to restart, select: NO</p> |  |
| <p>6. Select button Update Software</p> |  |
| <p>7. Activate on-screen keyboard by touching the ORANGE INPUT FIELD</p> <p>On the on-screen keyboard, type in: update</p> <p>then press "OK"</p> <p>Press the Continue Button.</p> |  |

When completed, fax all pages to (901) 566-7835
Or email to CSOfflineTeam@smithnephew.com

Sureshot Targeting V2.0.2 (with Trauma Launcher V1.0.1) USB Update Instructions

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|---|---|
| <p>8. Write the System Number on the line below (same number from Step 2).</p> <div style="border: 1px solid black; display: flex; justify-content: space-around; width: 100px; height: 20px; margin: 5px 0;"> </div> <p>Activate on-screen keyboard by <u>touching</u> the 'System Number' field</p> <p>On the on-screen keyboard, type in System Number Press the OK button</p> <p>Press the Set button</p> |  <p style="text-align: center;">System number: AC # ####</p> <p style="text-align: center;">Set OK</p> |
| <p>9. Press the Start button to initiate the software update</p> | <div style="text-align: center;"> <h3>SURESHOT Update</h3> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid gray; padding: 5px; width: 40%;"> <p style="text-align: center; margin: 0;">Additional Software</p> <p style="font-size: small; margin: 5px 0;">Trauma Launcher V1.0.1 DistalTargeting V2.0.2</p> </div> <div style="font-size: 2em; margin: 0 10px;">➔</div> <div style="border: 1px solid gray; padding: 5px; width: 40%;"> <p style="text-align: center; margin: 0;">On System</p> <p style="font-size: small; margin: 5px 0;">Trauma Launcher V1.0.0</p> </div> </div> <div style="margin-top: 10px; display: flex; justify-content: center; gap: 20px;"> Start Exit </div> </div> |
| <p>10. If the update was successful, an Update Code will appear. Enter this Update Code below:</p> <div style="border: 1px solid black; display: flex; justify-content: space-around; width: 100px; height: 20px; margin: 5px 0;"> </div> <p>Press the OK button</p> <p style="font-size: x-small;">(if unsuccessful, please contact Technical Support using the number at the bottom of the page)</p> | <div style="text-align: center; border: 1px solid gray; padding: 10px;"> <p style="font-size: 1.2em; margin: 0;">Update was successful.</p> <p style="font-size: 1.2em; margin: 0;">Update Code '####'</p> <div style="margin-top: 10px; border: 1px solid gray; padding: 5px; width: 100px; margin: 0 auto;"> <p style="text-align: center; margin: 0;">Ok</p> </div> </div> |
| <p>11. Remove USB drive & Shutdown the system.</p> <p>(It is okay to remove the USB drive while the interface is on)</p> |  |
| <p>12. Turn the power OFF, then ON to restart application and write version below:</p> <div style="display: flex; align-items: center; margin: 5px 0;"> V <div style="border: 1px solid black; display: flex; justify-content: space-around; width: 100px; height: 20px;"> </div> </div> <p>Menu -> About</p> | <div style="display: flex; align-items: center;">  <div style="border: 1px solid gray; padding: 5px; background-color: #f0f0f0;"> <p style="margin: 0;">Menu</p> <p style="margin: 0; background-color: #333; color: white; padding: 2px;">About</p> <p style="margin: 0;">Shutdown</p> </div> </div> |

| | | | | |
|---------------------------------|-------------------------------|-------------------------------------|------------------------------------|-------------------------------|
| Type of Unit (check one): | Demo <input type="checkbox"/> | Evaluation <input type="checkbox"/> | Consigned <input type="checkbox"/> | Sold <input type="checkbox"/> |
| Sales Rep Name: | | | | |
| DM/TM/FMD: | | | | |
| Account Name (if applicable): | | | | |
| Account Number (if applicable): | | | | |
| Signature: | | | Date: | |

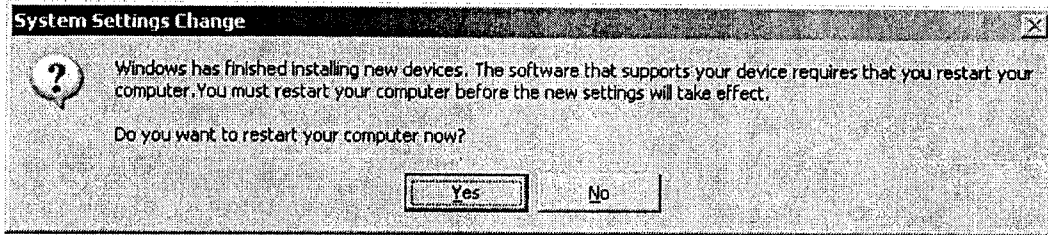
For Technical Support please call Customer Service at 1 (800) 238-7538 (Select Option 1 and then Option 2)

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Sureshot Targeting V2.0.2 (with Trauma Launcher V1.0.1)
USB Update Instructions

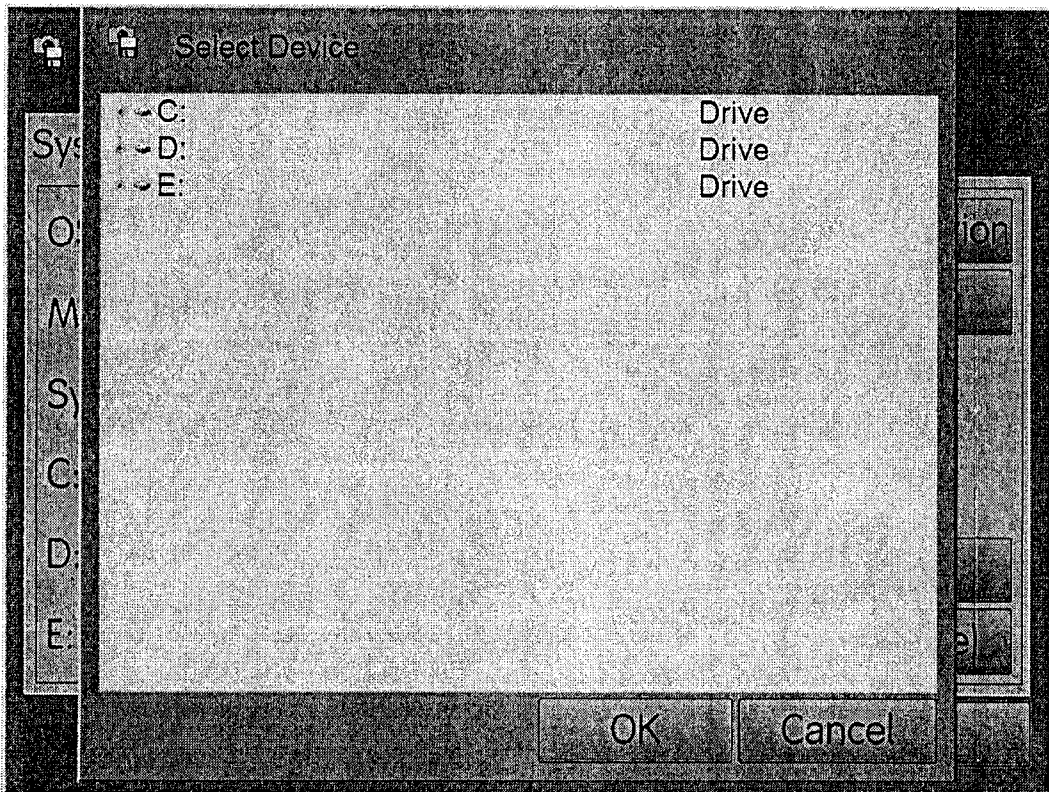
Frequently Asked Questions

Question: What should I do if this window appears?



Answer: Select "NO" and continue with the instructions

Question: What should I do if this window appears?



Answer:

- 1) Select "Cancel"
- 2) Place USB Drive in the other USB Port on the back of the System
- 3) Go back to "Step 6" and proceed. (If this does not work, reboot the system & start over)

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