

**DRAFT**

a Johnson &amp; Johnson company

DePuy International Ltd  
 St. Anthony's Road  
 Leeds LS11 8DT  
 England

March 2005

To: The Hospital – CHIEF EXECUTIVE, The CLINICAL DIRECTOR-ORTHOPAEDIC THEATRES,  
 The THEATRE MANAGER-ORTHOPAEDIC THEATRES,  
 The SAFETY LIAISON OFFICER

**Subject: Advisory Notice - Updates of Charite Centerline Insertion Tip Instruments**

**Product Type: Spinal Orthopaedic Instrument**

Dear Customer:

This letter is to advise you that we have decided to replace your present version of the Centerline instruments with improved devices. The **Centerline** instruments being removed from your set(s) and replaced at no cost to you are the following product codes:

Product Description	Product Code
Endplate Insertion Tip, Size 2	2869-20-002
Endplate Insertion Tip, Size 3	2869-20-003
Endplate Insertion Tip, Size 4	2869-20-004
Endplate Insertion Tip, Size 5	2869-20-005

*Note: The current Centerline Spreading and Insertion Forceps instrument (product code 2869-14-000) should remain in your instrument set for distraction and trialing.*

Enhancements were made to the insertion tips to improve overall performance. These enhancements have resulted in better fit and alignment of the insertion, increasing overall rigidity and reducing the amount of lateral play in the tips. This may minimize intra-operative placement adjustments of the endplates used in the Charité Artificial Disc System. We received feedback from a small number of sites, that while superior to the original Charité instruments, the lateral play in the Centreline inserter sometimes required extra time to assure the best possible alignment of the implants.

Your DePuy Spine Representative is arranging for this replacement as soon as possible and in many cases, this replacement has already been completed. The updated **Centreline TDR** instruments are marked with the following product codes:

Product Description	Product Code
Endplate Insertion Tip, Size 2	2891-52-200
Endplate Insertion Tip, Size 3	2891-52-300
Endplate Insertion Tip, Size 4	2891-52-400
Endplate Insertion Tip, Size 5	2891-52-500

# **DRAFT**

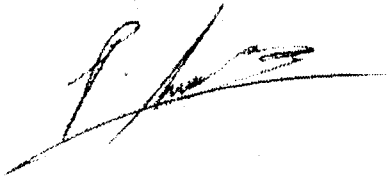
Additionally, new Spreading and Insertion Forceps (product code 2891-52-000). will be provided for use with the new Endplate Insertion Tips.

If you have already received these instruments, please check to insure that you have sent back the earlier version (i.e., those product codes noted in the upper table) to your DePuy Spine representative. If you no longer have the earlier version, then no further action necessary.

DePuy Spine believes that you will find this enhanced instrumentation further improves the placement of the endplates and hopes that you find our efforts in this continuous quality improvement to be helpful.

If you have further enquiries regarding this matter please do not hesitate to contact your local DePuy Spine Account Manager or myself at the above address.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'P. Arnott', with a long horizontal flourish extending to the right.

Paul Arnott  
On behalf of DePuy