



Agence française de sécurité sanitaire  
des produits de santé

*Agenc*  
Le Directeur Général  
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To Competent Authorities for Tissues and Cells in the EU

## Alert regarding an AFSSAPS request for recall of bone products supplied by "Ost-Developpement"

### Background

Bone donations to the OsteoCentre Bulgaria (OCBG) are sent to Osteotech Inc located in New Jersey USA for processing. The finished products (Grafton DBM) are sent to "Ost-Developpement" based in Clermont-Ferrand in France and from there are distributed in France, Bulgaria, Italy and Spain. Following recent inspections in Bulgaria and France, Afssaps has decided to suspend (temporary decision) the importation and exportation of tissues by "Ost-Developpement", where the bone donations originate from OCBG, and has requested the recall and the quarantine of all products distributed that were produced from donations collected in Bulgaria.

### Reason for this Regulatory Action

A joint unannounced inspection was conducted (from 3rd to 7th of november 2008 according with the EUSTITE inspection guideline), by Afssaps and the Bulgarian Executive Agency of Transplantation, at 3 procurement establishments and OCBG (tissue bank) in Sofia. Since then, Afssaps has conducted an inspection at Ost-Developpement in France from 10th to 11th of december.

The inspection in Bulgaria highlighted 1 critical deficiency and 10 major deficiencies that were not in compliance with the French regulation and the EU directives on tissues and cells. These deficiencies were related to procurement activities. There were serious concerns regarding traceability and validity of blood samples labelling and donor records. During the inspection it was not possible for the inspectors to cross-check donor record information recorded by the tissue bank (OCBG) with the original medical chart data.

### Management of the Recall

The recall will be managed by Ost-Developpement, with supervision by Afssaps. Competent Authorities in Bulgaria, Spain and Italy are invited to oversee the management of the recall by Ost-Developpement in those countries.

### Important Note

Osteotech in New Jersey (USA) also exports products from OCBG donations directly to the following countries: Germany (Merete Gmbh) ; South Africa (Orthomedics ; Combined medical specialities) ; Saoudl Arabia (Elite care med. Services ; Al Amin Medical Instruments) ; Austria (Crosstec Gmbh) ; Chili (Schering Plough Compania Ltda) ; Cyprus (Matina med-pharm Ltd) ; South Korea (Resource tissue bank ; Jae il medical corporation ; Hana Meditech co Ltd) ; Spain (ortoimplant ; Zimmer dental iberica) ; Florida / USA (Bioproperu) ; Greece (Ebedent) ; Israel (Biohorizons Israel) ; Italy (Xmedica ; Marca service ; Staumann Italia) ; Malaysia (Spine Innovations SDN BHD) ; Mexico (Exsemed ; Biomedical) ; Netherlands (Arsis medical) ; Portugal (Shortes) ; United Kingdom (Biohorizons Ltd ; Osteotec Ltd) ; Singapore (SDPS Asia Ltd) ; Switzerland (Laubscher Gmbh) ; Turkey (Medikon ic dis tic. Alim satim koll) ; Venezuela (Hospal Medica CA).

**Further Action**

Afssaps intends to re-inspect Ost-Developpement procurement activities once the company confirms that appropriate corrective and preventive actions have been taken to allow the lifting of this action.

**Further Information**

For further information please contact :

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