

QUICK ALERT TISSUES AND CELLS

Origin: Competent Authority for Tissues and Cells of Belgium

Date: 23 October 2008

The presence, or previous history, of malignant disease, except for primary basal cell carcinoma, carcinoma in situ of uterine cervix, and some primary tumors of the central nervous system that have to be evaluated according to scientific evidence, is a criterion for exclusion of donors for tissue or cells (Commission Directive 2006/17/EC).

The US Company Wright Medical Technologies (WMT - <http://www.wmt.com/>) supplies "Allomatrix" bone implants to a bone tissue bank in Belgium. Donors are selected by WMT according to US standards. These standards allow, based on the advice of the medical director, the procurement and distribution of tissues from donors with a history of cancer.

The Allomatrix bone implants are delivered to the Belgian bone tissue bank on the condition that the donors of the implants, and the implants themselves, fulfill the requirements (legal, quality standards) of Belgium and the European Union. This excludes implants procured from donors with a history of cancer.

By error WMT has distributed in the period of 20/02/2008 to 09/2008 to the Belgian tissue banks - and probably to other European tissue establishments - Allomatrix bone implants (*Allomatrix Bone Putty* and *Allomatrix injectable putty*) from 8 donors that did not fulfill that requirement.

This error was detected by WMT on 07/10/2008. The stocks of Allomatrix bone implants were immediately put in quarantine and distributed implants were recalled.

Lots withdrawn from distribution:

Lot Number	Donor
084104170	044610
084105263	044610
066349066	051769
106386699	052140
017402385	060028
106386700	060114
117502725	070791
117511296	070805
068645130	083418
018527071	073837
018541452	075638
068653208	080151
048597786	081397
068648552	081528
078678937	083545

The company WMT asked the Belgian bone bank to stop the delivery and implantation of these implants in the European Union.

Allomatrix bone implants may also be imported to tissue establishments in other EU member states and therefore this quick alert.