

## Vaccines, Blood & Biologics

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### Safety & Availability (Biologics)

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## Urgent Medical Device Removal – AXP Processing Bagset-ThermoGenesis

Updated: Additional lot numbers  
DATE NOTIFICATION INITIATED:

October 24, 2008

November 13, 2008

#### PRODUCT / LOT NUMBER:

AXP Processing Bagset

Model 8-5101

Lot Numbers: 08A29, 08B13, 08B20, 08B25, 08C04, and 08C11

#### MANUFACTURER:

Thermogenesis Corporation

Rancho Cordova, CA

#### REASON:

ThermoGenesis has determined that there is a potentially serious issue associated with the use of these lots. They have become aware that particulates from the stopcock in the bagset may be released into the sterile, non-pyrogenic fluid path. While all materials used in the bagsets are biocompatible, the introduction of any particulate into the body could result in serious injury to a patient being transfused with cord blood that has been stored in these units.

#### Contact Us

##### Consumer Affairs Branch (CBER)

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