CIRCULAR NORMATIVA

Nº: 4/GDG

Data: 21/04/2008

Assunto: Alerta urgente sobre recipientes para conservação de cabeças femorais

Para: Conhecimento a todos os estabelecimentos hospitalares públicos ou privados que colham, preservem ou apliquem cabeças de fémur, Gabinetes de Coordenação de Colheita de Órgãos e Transplantação (GCCOT) e Centros de Histocompatibilidade

De: Director – Geral da ASST

Contacto na ASST. Sr.ª Dr.ª Margarida Amil

A Autoridade para os Serviços de Sangue e Transplantação (ASST) recebeu um alerta da União Europeia relativo a uma reacção adversa grave resultante de defeito de embalagem dos recipientes para colheita e conservação de cabeças femorais fornecidos pela Medfor Products Ltd., comunicada pela Autoridade de tecidos humanos do Reino Unido.

Em face da referida reacção adversa importa instituir no nosso País medidas de controlo adequadas semelhantes às adoptadas no Reino Unido relativamente aos lotes identificados no anexo à presente Circular, com vista a garantir a qualidade e segurança.

Assim, atentas as atribuições da ASST de regulação, normalização, controlo e fiscalização da actividade de colheita, análise, manipulação, armazenamento e distribuição de órgãos, tecidos e células de origem humana (cf. artigos 2.º, 8.º e 9.º do Decreto Regulamentar n.º 67/2007, de 29.05), determina-se o seguinte:

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1. Qualquer entidade pública ou privada que use produtos Medfor para colheita de tecidos deve verificar os stoks existentes, bem como os registos de produtos utilizados e respectivos números de lote.

2. Caso haja produtos não utilizados dos lotes números 11, 14 e 49, identificados em anexo à presente Circular, devem ser colocados em quarentena e contactada a Medfor em www.medfor.com.

3. Se houver produtos não utilizados dos lotes 110407 e 112307, identificados em anexo à presente Circular, que tiverem defeitos de embalagem devem ser colocados de quarentena e devolvidos à Medfor.

4. Se tiverem sido utilizados produtos de lote 111449, identificados em anexo à presente Circular, e haja suspeita de defeito na embalagem, o tecido deve ser isolado e posto de quarentena para investigação.

5. Os tecidos em relação aos quais haja suspeita de poder ter havido risco de contaminação devem ser inutilizados, a menos que se comprove por testes microbiológicos a sua segurança.

6. Quaisquer receptores potencialmente afectados e qualquer reacção adversa subsequente deve ser notificada à ASST através do endereço asst@asst.min-saude.pt

7. De igual modo as instituições devem comunicar à ASST se utilizam ou não os produtos em causa e, em caso afirmativo, remeter toda a informação relacionada com o constante nos números 1 a 5 da presente Circular Normativa.

O Director – Geral,

(João Rodrigues Pena)

HTA
Human Tissue Authority

Regulatory alert 002/2008

Medfor Femoral Head Storage Pots (S400)

Issued 14 April 2008 to all establishments licensed for human application and Competent Authorities

Scope

This alert is being issued by the Human Tissue Authority (HTA) in its role as Competent Authority under the European Union Tissue and Cells Directives. The Directives have now been implemented into UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

Issue

A Serious Adverse Event has been reported to the HTA regarding Femoral Head Storage Pots supplied by Medfor Products Ltd. The pots are supplied double wrapped in sterile packaging. On some units the seal on the outer packaging is defective/not sealed correctly, potentially rendering the external surface of the inner pack non-sterile.

This alert is to ensure that all establishments:

- using Medfor products are aware of the affected lot numbers and if required take steps to identify potentially affected donors and quarantine affected tissue;
- are aware of their obligations to report Serious Adverse Events and Serious Adverse Reactions to the HTA;
- are aware of their obligations to take steps to minimise the risk of bacterial contamination; and
- are aware of their obligations to ensure appropriate third party agreements are in place with suppliers of goods and services that could affect the quality and safety of tissues and cells.

Background

The HTA has received a Serious Adverse Event notification from a licensed establishment regarding femoral head storage pots supplied by Medfor. The affected product and lot numbers are:

Catalogue number	Medfor lot number	Dates issued	Action taken
S400	111449	Sep 07 – Jan 08	RECALLED
S400	110407	Feb 07 – Jul 07	EXERCISE VIGILANCE
S400	112307	Jan 08 – Mar 08	EXERCISE VIGILANCE
S227	All	–	EXERCISE VIGILANCE

It has been found that a number of units from lot number 111449 have a defective seal on the outer packaging. Sterility tests carried out by the manufacturer indicate that the outer surface of the inner packaging was not sterile in some affected units. Depending on the handling procedures of theatre staff this may mean a scrubbed nurse has handled a non-sterile surface.

Medfor has initiated a product recall on lot number 111449, and has issued guidance for extra vigilance in respect of two further lots, 110407 and 112307. Medfor has also issued guidance for extra vigilance on product S227, which uses the same type of packaging.

Action taken by the HTA

The HTA has contacted the reporting establishment, Medfor and the Medicines and Healthcare products Regulatory Agency (MHRA).

Actions for establishments licensed for human application

URGENT

- Any establishment using Medfor products for procurement of tissue should check their current stock and historical procurement records for the affected product and lot numbers.
- If unused products from lot 111449 are found, they should be quarantined and the Medfor recall procedure initiated – please contact Medfor for details (www.medfor.com).

- If unused products from lot 110407 and lot 112307 are found and have faulty packaging, they should be quarantined and returned to Medfor. Please also inform Hazel Lofty, HTA Regulation Manager on 020 7211 3435 or email hazel.lofty@hta.gov.uk .
- If products from lot 111449 have been used for procurement of tissue and it is suspected that the packaging may have been faulty, then tissue should be traced and quarantined immediately pending investigation. Please notify the HTA via the HTA's online Serious Adverse Event and Reaction reporting system.
  http://www.hta.gov.uk/licensing/adverse_event_and_reaction_reporting.cfm
- Affected donors and any recipients should be identified and any subsequent adverse reactions reported to the HTA.
- Establishments should carry out a risk assessment to determine the most suitable course of action with implicated tissue. Unless able to determine by further microbiological testing that irradiating tissue would be effective, or if testing and irradiating are likely to add further risk of contamination, then tissue should be disposed of. Any disposal should be in line with HTA's Codes of Practice.

ONGOING ADVICE AND GUIDANCE

All establishments are advised to refer to the manufacturer's labeling and instructions for use which states that they should check the seal on the packaging before use.

Establishments are reminded that under HTA Directions 002/2007,

- critical reagents and materials should meet documented requirements and specifications;
- all relevant data relating to products and material coming into contact with tissues and / or cells should be traceable;
- establishments must notify the HTA of any suspected serious adverse event and / or serious adverse reaction **as soon as possible** after the incident;
- where a third party procures, processes, tests, distributes, imports or exports tissues and / or cells on behalf of the Licence Holder or Designated Individual the establishment shall put in place and maintain a written third party agreement;
- where a third party supplies to the Licence Holder or Designated Individual **any goods or services** which may affect the quality or safety of tissues and / or cells the establishment shall put in place and maintain a written third party agreement.

Please contact Hazel Lofty on 020 7211 3435 or email hazel.lofty@hta.gov.uk if you would like any further advice on any of the above points or you are storing tissue which you think may be affected.

Further guidance in relation to your obligations under the European Union Tissues and Cells Directives as implemented by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 can be found by referring to HTA Directions 001/2006, 002/2007 and 004/2007.

This regulatory alert is available on the HTA website at:
www.hta.gov.uk/guidance/regulatory_alerts/regulatory_alert_002/2008.cfm