Change Notification for the UK Blood Transfusion Services

Date of Issue: 31 January 2023 **Implementation:** to be determined by each Service

Donor Selection Guidelines:

Dental Treatment and **Xenotransplantation**

No. 02 – 2023

Changes are indicated using the key below. This formatting will not appear in the final entry.

original text

«inserted text»

~~deleted text~~

The following changes apply to:

BM-DSG Bone Marrow & Peripheral Blood Stem Cell | CB-DSG Cord Blood | GDRI Geographical Disease Risk Index | TD-DSG Tissue – Deceased Donors | TL-DSG Tissue – Live Donors | **WB-DSG Whole Blood & Components**

Dental Treatment

Obligatory	**Must not donate if:** a) Less than seven days since root canal treatment, dental capping (crown or veneer), dental implants or having a tooth removed. b) Less than 24 hours since a filling, scale and polish or other superficial treatments. c) All wounds are not healed. d) There is any infection or **«the donor»** has been on antibiotics within the last seven days. e) Allogeneic human tissue (bone) has been used. f) **«Less than three months since any invasive dental treatment outside of the UK and Republic of Ireland (ROI).»**
Discretionary	a) If inspection, dental impressions or re-cementing of an existing crown or veneer only, with no requirement for further drilling or local anaesthetic, accept. ~~b) If non-allogeneic (not from another person) matrix grafts have been used (these may be autologous (the persons own), alloplastic (non biological) or approved animal), accept.~~ ~~Note it may be necessary for information concerning the type of matrix graft used to be obtained by a 'Designated Clinical Support Officer' from the surgeon performing the graft.~~ b) **«If the donor has received an autologous bone graft within the UK or ROI, accept. An autologous graft is derived from the donor's own bone.**

	c) **If the donor has been treated within the UK or ROI with graft material derived from a non-biological or approved non-human source, accept.** d) **If donor has received graft materials during dental treatment outside the UK and ROI, refer to a Designated Clinical Support Officer (DCSO).»**
See if Relevant	Infection – General Surgery Tissue and Organ Recipients
Additional Information	Dental extractions and other treatments can result in bacteria getting into the blood stream. The waiting times after treatment are to allow healing and for any bacteria that have entered the blood stream to be cleared. **«As there may be uncertainty about infection risks for invasive dental treatment performed outside the UK and ROI, a deferral period of three months is required. Invasive treatments include root canal treatments, dental capping, dental implants and tooth extractions.»** ~~*Dental work performed within the European Union should only use material and methods that are free from known infection risks. This may not be the case elsewhere and referral to a 'Designated Clinical Support Officer' may be required. Several types of protein (prion) free or demineralised animal tissue (e.g. Bio-Oss® and Bio-Gide®) have CE marking in Europe and FDA approval in the USA.*~~ **«Graft materials used in dental procedures are highly processed products, derived from autologous bone, other human bone (allogeneic), animal bone or non-biological materials.** **In the UK and ROI, any animal-derived graft material used in dental treatment is approved by regulatory authorities and can be regarded as free from known infection risks. If the donor knows that they received a product derived from an animal or non-biological source, the donor can be accepted. If the donor is unsure, advise them to check with their dentist.** **For dental surgery performed elsewhere in the world, it may be necessary to request more information about any graft products which were used.** **Donors who have had more extensive surgery on their jaw may have received a standard human bone graft. If in doubt, refer to a DCSO.»**
Information	This is a requirement of the Blood Safety and Quality Regulations 2005.
Reason for Change	~~*The entry has been updated with reference to re-cementing of existing crowns and to products used for dental implant.*~~ **«Guidance for use of non-human graft materials has been clarified and reference to individual products removed. A deferral has been added for invasive dental treatment outside the UK and ROI.»**

Xenotransplantation

Includes	Heterografts, non-human organ perfusion, xenografts and xenotransplant recipients.
Definitions	**Xenotransplantation:** Any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a non-human animal source, or (b) human body fluids, cells, tissues, or organs that have had ex vivo contact with live, non-human animal cells, tissues, or organs. Xenotransplantation products include live cells, tissues and organs. Biological products, drugs, or medical devices sourced from non-living cells, tissues or organs from non-human animals including, but not limited to, porcine insulin, porcine heart valves and acellular porcine collagen matrix ~~*(e.g. PelviSoft®, Bio-Oss®, Bio-Gide® and Surgibone®)*~~ are not considered xenotransplantation products. Inoculation **«injuries»** ~~*injury*~~ from non-human sources are not considered to be Xenotransplants.

1. Recipient	
Obligatory	Must not donate if: Material from a living non-human animal source has been directly or indirectly in contact with the donor's blood supply. This does not include animal bites.
See if Relevant	Animal Bite (Non-Human) Non-Consented Exposure to Human Body Fluids
Additional Information	Exposure to non-human animal material, particularly when the person exposed is immunosuppressed, may result in unusual infections, that would not normally affect humans, being passed on to recipients of donated material. Inoculation injury, involving non-human animals, does not fall into the category of xenotransplantation
~~*Update Information*~~	~~*This entry was last updated in:*~~ ~~*DSG-WB Edition 203, Release 10 Issue 01*~~
~~*Reason for Change*~~	~~*The entry has been updated with reference to additional products.*~~

2. Current or Former Sexual Partner of Xenotransplant Recipient	
Obligatory	**Must not donate.**
Additional Information	Sexual partners of individuals who have received a xenotransplant may potentially be at risk of acquiring an unusual

	infection that may be passed on by donated material. Because the duration of any risk is not known, deferral must be permanent.
Information	This is a requirement of the Blood Safety and Quality Regulations 2005.
~~*Update Information*~~	~~*This entry was last updated in:*~~ ~~*DSG WB Edition 203, Release 10 Issue 01*~~
~~*Reason for Change*~~	~~*The entry has been updated with reference to additional products.*~~

«Reason for Change»	**«Reference to specific products has been removed from the Definitions section»**

Dental Treatment and **Xenotransplantation** – **other WB-DSG changes:**

A-Z Index

Remove the following entries from the index:

- Bio-Gide® - Dental Treatment
- Bio-Gide® - Xenotransplantation
- Bio-Oss® - Dental Treatment
- Bio-Oss® - Xenotransplantation
- PelviSoft®
- Surgibone®

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