



THE RISK ASSOCIATED WITH MEDICAL DEVICES CONTAINING OVINE OR CAPRINE MATERIALS

Issue and Background

1. The Medicine and Healthcare products Regulatory Agency (MHRA) have completed a survey of medical devices containing ovine or caprine materials to identify if there is a need for a risk assessment for the transmission of TSEs.
2. The MHRA analysis has identified twelve products containing ovine or caprine materials. The products are categorised into three groups: wool containing products, *in vitro* diagnostic reagents, and vascular grafts. Devices in the first two categories do not make contact with human tissues and are considered low risk (see [Annex 1](#)). The third category, which contains vascular grafts are considered low risk also as the grafts are generated from ovine collagen from animals bred in Australia, a country with a current geographical BSE risk level 1¹.
3. A table from the WHO guidelines on transmissible spongiform encephalopathies in relation to biological and pharmaceutical products is provided in Annex 2 which lists tissues with no detectable infectivity.

¹ EU Scientific Steering Committee. Report on the assessment of the geographical BSE -risk of Australia (2000).

**TSE RISKS ASSOCIATED WITH MEDICAL DEVICES CONTAINING
OVINE OR CAPRINE MATERIALS**

MHRA has identified 12 types of medical devices containing ovine material. They can be divided into the following three groups:

1. Fabrics containing wool, such as elastic bandages and pads. Several products are on the market. Because they only contain wool and contact only intact skin, they are classified as low risk medical devices. Thus, although manufacturers must make a declaration of conformity with the Essential Requirements for safety and performance contained in the European Medical Devices Directive, no independent verification of the manufacturer’s risk analysis is required.
2. *In vitro* diagnostic reagents prepared from whole sheep’s blood. These materials do not come into contact with patients.
3. Vascular grafts. A range of three implantable devices, comprising glutaraldehyde-fixed ovine collagen on a polyester scaffold. The collagen is laid down *in situ* on a polyester tube or patch implanted in the abdominal cavity of a sheep. They are sourced from Australia.

A breakdown of the number of devices in each of the above categories is shown in Table 1. Only the implantable vascular grafts and patch, sourced from Australia, have any tissue contact.

Table 1. Medical devices known to incorporate non-viable materials of ovine or caprine origin.

	Ovine	Caprine
Total number of medical device types incorporating animal tissues	12	0
Number of device types intended to come into contact with human tissue ^a	3	
Of which:		
Number sourced from a tissue with detectable infectivity ^b	0	
Number sourced from a country where scrapie is present ^c	0	

^a Excludes devices contacting intact skin only (e.g. elastic bandages) and non-contact devices (e.g. *in vitro* diagnostic devices).

^b Excludes tissues identified as without infectivity by Table IC of 2003 WHO Guidelines. None of the musculo-skeletal tissues tested (including skeletal muscle, heart/pericardium and skin) have been shown to have detectable infectivity.

^c Excludes tissues sourced from countries widely regarded as being free of scrapie