

Medical Device Alert

Action

Ref: MDA/2009/080 Issued: 09 December 2009 at 14:30

Device

Ultrasound transducer probes with an internal lumen used for taking transrectal prostate biopsies.

All manufacturers.

Problem	Action
<p>Potential onward transmission of abnormal prion protein, the putative infective agent in variant Creutzfeldt Jakob disease (vCJD), when ultrasound transducer probes with an internal lumen are used for taking transrectal prostate biopsies on men at risk of vCJD.</p> <p>The needle that passes through the internal lumen of a reusable ultrasound probe could transfer the abnormal prion protein from rectal lymphoid tissue, via the outside surface of the biopsy needle, onto the internal lumen of the ultrasound probe. Any attempt at subsequent decontamination of the internal lumen would not be successful due to the inability of any current decontamination process to reliably eliminate or destroy abnormal prion protein.</p>	<p>Review the advice given in the Advisory Committee on Dangerous Pathogens (ACDP) TSE Working Group's alert to urological surgeons 'Transrectal prostatic biopsy in men at risk of variant CJD', published on the Department of Health's website.</p> <p>The ACDP TSE Working Group and CJD Incidents Panel advise the following: 'Patients at risk of vCJD requiring transrectal prostatic biopsy should have the procedure performed by means of single use equipment that runs alongside (rather than through) the ultrasound probe. Where a unit does not have such equipment and intends to carry out a biopsy procedure on a patient at risk of vCJD, their options are as follows:</p> <ul style="list-style-type: none"> • To refer the patient to a unit offering an alternative technique that does not pose a risk of contaminating the internal channels with traces of biopsy tissue • To borrow the alternative equipment from another unit • To undertake the procedure with equipment that has internal biopsy channels, and then quarantine the reusable components of that equipment after decontamination. It must be accepted that this equipment would be unlikely to return to general use, except for dedicated re-use in the same patient.'
<h3>Action by</h3>	
<p>All staff who carry out prostate biopsies.</p>	
<h3>CAS deadlines</h3>	
<p>Action underway: 31 December 2009 Action complete: 26 February 2010</p>	

[Link to full Medical Device Alert](#)

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