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## Lyodura

Lyodura was a medical product used in neurosurgery that has been shown to transmit Creutzfeldt-Jakob disease, a degenerative neurological disorder that is incurable, from affected donor cadavers to surgical recipients. Lyodura was introduced in 1969 as a product of B. Braun Melsungen AG, a leading hospital supply company based in Germany.

The product was used as a quick and effective patch material for surgery on the brain. It was a section of freeze-dried tissue that could be stored for extended periods on hospital shelves and made ready for use simply by soaking it in water for a few minutes.

What was not known by the consumer was the origin of the source material, the efficacy of its processing methods, and the danger of its use.

The raw material for Lyodura was the dura mater of a human corpse. The tissue would usually be harvested during an autopsy and then sold to the manufacturer after neurological diseases were linked to the use of Lyodura, an investigation determined that the manufacturer had obtained the donor tissue by black market methods. Autopsy staff would remove the tissue from cadavers, regardless of whether the deceased's family had agreed to an autopsy or not, and sell it in quantity to representatives of the manufacturer. Due to this illegal method of collection, no record of patient history accompanied the tissue to production.

Large quantities of the harvested tissue would be mass sterilized in a heated vat. The tissue would then be freeze dried and packaged for purchase. The manufacturer believed that its sterilization procedure was sufficiently powerful to render any tissue harmless and was therefore unconcerned about cross-contamination from CJD-containing tissue to other tissue in the same sterilization vat. It is now believed that almost all Lyodura product was tainted with Creutzfeldt-Jakob disease through this process.

An award-winning documentary was produced on the subject. The Canadian Broadcasting Corporation's The Fifth Estate segment, "Deadly Harvest", dealt with the product's history, sale in Canada, and health effects worldwide. According to the documentary, there have been more than 70 CJD-related deaths in Japan since Lyodura's distribution. The product has since been banned for use in Canada.

Cadaveric dura mater graft-associated CJD (dCJD) accounts for a common form of iatrogenic CJD. A report summarizes the epidemiologic features of 154 cases of dCJD identified in Japan during 1975-2017; these cases account for >60% of dCJD cases reported worldwide.

The unusually high prevalence of dCJD in Japan was first reported in 1997. In 2008, a single brand of graft (Lyodura [B. Braun Melsungen AG, Melsungen, Germany]), frequently used as a patch in neurosurgical procedures, was identified as the probable vehicle of transmission.

No international recall of the implicated Lyodura occurred, the product had a relatively long shelf life, and the grafts were used frequently in Japanese patients with non-life-threatening conditions. Since 2008, additional cases have been ascertained, reflecting the identification of previously missed cases and the occurrence of new cases with longer latency periods (interval from exposure to symptom onset) for dCJD (up to 30 years), underscoring the importance of maintaining surveillance for dCJD <sup>1)</sup>.

1)

Ae R, Hamaguchi T, Nakamura Y, Yamada M, Tsukamoto T, Mizusawa H, Belay ED, Schonberger LB. Update: Dura Mater Graft-Associated Creutzfeldt-Jakob Disease - Japan, 1975-2017. MMWR Morb Mortal Wkly Rep. 2018 Mar 9;67(9):274-278. doi: 10.15585/mmwr.mm6709a3. PubMed PMID: 29518068; PubMed Central PMCID: PMC5844283.

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