## Unapproved artificial organs implanted in humans

Experimental implants manufactured at University College London were sent abroad and used on patients despite not having approval for human use, an inquiry has found. The implants included an artificial windpipe, a synthetic tear duct and an arterial graft.

The inquiry, led by Stephen Wigmore of the University of Edinburgh at the request of UCL, was triggered by the university's relationship with <u>Paolo Macchiarini</u>, a surgeon at the centre of a scandal in which six of eight patients who received synthetic windpipes died.

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The inquiry found that Seifalian's laboratory was not licensed to make clinical grade devices and did not request permission to use the unlicensed devices. In a written testimony to the inquiry, Macchiarini indicated that he was not aware that the graft had not been made to clinical standard.

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In a statement, UCL said: "We deeply regret that materials that had not undergone rigorous preclinical assessment and which were not made to [approved] standards, were manufactured and supplied by Professor Alexander Seifalian's research laboratory for direct clinical use. Our governance systems should have prevented that. We also regret the wider, negative impact that this work had on the field of regenerative medicine research."

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion, and analysis. Read full, original post: Artificial organs used in operations without approval for humans