

## Stronger rules needed on medical devices

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The Consumers Health Forum welcomes the Senate committee call for stronger measures to reduce the risk of another medical device disaster like that with transvaginal mesh which caused so much pain and disability to thousands of Australian women.

The Senate Community Affairs References Committee has made 13 recommendations which cover the range of complex issues and practices raised by transvaginal mesh procedures.

“What the report highlights is the need for rigour and scrutiny in the introduction of a device like mesh, the requirement for effective training including for the possible removal of mesh devices and close surveillance of the performance of such products,” the CEO of the Consumers Health Forum, Leanne Wells, said.

“We would like to see the medical profession and specialists in this area take effective action to ensure that consumers’ faith in medical advice and oversight is well-placed.

“We support the position that mesh should be the last resort and other measures should be fully explored first. This is not to deny women the choice of having a mesh implant but this must be linked to improved informed consent.

“We acknowledge work the Therapeutic Goods Administration has already commenced on medical devices namely the introduction of patient device cards and consumer device information leaflets. These will begin to take effect with new urogynaecological devices from 1 December.

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“We also like the report’s emphasis on improving informed consent processes to check that women fully understand the procedure and the potential risks and side effects.

“Throughout the testimony from affected women it became clear that many had not had a proper conversation with their specialist and did not understand the nature of the procedure, that it was permanent or that there might be adverse side effects,” Ms Wells said.

ENDS

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