

8 September 2021

Essure Implant Devices 2002 to August 2021

1. From 2002 to date, how many did the Trust implant patients with Essure.

Belfast Trust implanted 1422 Essure devices from 2004 to 2016. Please note that we have identified some coding issues and so the numbers recorded may not be accurate, although we are confident that no Essure device was inserted past 2016.

2. How many leaflets were handed out to patients with Essure?

All patients who had an insertion of Essure discussed at their Gynaecology Outpatients appointment would have received an Essure information leaflet.

We are unable to advise of numbers because, as well as those who were subsequently added to waiting lists for Essure insertion, there may also have been others who decided to have another form of contraception.

3. Did the Trust receive a copy of the letter stating that Bayer never renewed the CE mark after 1st September 2017 and to discontinue using and stopping fitting patients with the Essure device?

I can confirm Belfast Trust did receive this letter.

4. Did the Trust issue a patient information sheet to any patient telling them that the CE mark was no longer in use letter dated 6/8/2017

Belfast Trust is not aware of any such information sheet being issued. Belfast Trust had stopped offering Essure in 2016.

5. How many patients did the Trust refer to the Private sector for Essure sterilisation?

Belfast Trust did not refer any patients to the private sector for Essure sterilisation.

6. How many patients had hysterectomies due to Essure sterilisation from 2002?

Approximately nine patients have had a hysterectomy for Essure removal.

7. Did any patients receive a card after getting Essure sterilisation done?

Belfast Trust do not know what card you are referring to and so are unable to provide this information.

8 September 2021

8. If patients were issued with a card after Essure, how many did the Trust give out?

As per Q7 response, Belfast Trust is unable to provide this information.

9. Did the Trust use this a sterilisation as any form of conception other than sterilisation?

Belfast Trust are unable to answer this question, as we are do not know what information is being sought.

10. Why did the Trust never recall patients with Essure sterilisation after so many adverse side effects?

The Trust decided a recall was not required following a review of the information that was available to them at the time regarding this device.