

Information Governance
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10 December 2024

Our reference: FOI DA5767

I am responding to your request for information received 4 December 2024. This has been treated as a request under the Freedom of Information Act 2000.

I am now enclosing a response which is attached to the end of this letter. Please do not hesitate to contact me on the contact details above if you have any further queries.

Yours sincerely,

Information Rights Coordinator

If you are dissatisfied with the Trust's response to your FOIA request then you should contact us and we will arrange for an internal review of this decision.

If you remain dissatisfied with the decision following our response to your complaint, you may write to the Information Commissioner for a decision under Section 50 of the Freedom of Information Act 2000. The Information Commissioner can be contacted at:

Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF

Tel: 0303 123 1113 Web: <u>www.ico.org.uk</u>

Please note that the data supplied is not allowed to be re-used and/or published without the explicit consent of East London NHS Foundation Trust. Please contact the signatory to request permission if this is your intention

Chief Executive Officer: Lorraine Sunduza

Chair: Eileen Taylor

Request:

In line with the Freedom of Information Act (2000) we would like to understand your use and aftercare of the B. Braun Aesculap Simpson Shelf Vaginal Pessary and we would be grateful if you could respond to the following questions:

The B. Braun Aesculap Simpson Shelf Vaginal Pessary is used to relieve symptomatic prolapse of the Uterus where patients are either unwilling or unfit (chronic illness, old age) for surgery and the ring Pessary falls out. The Simpson Shelf Vaginal Pessary can be used as a stopgap, where surgery needs to be delayed or the patient requires limited relief. After initial fitting with a Medical Practitioner/ Gynaecologist, the maximum allowable time the Vaginal Pessary should be fitted without removal, for review and cleaning, is 3 months. After which the device should be cleaned and re-fitted.

Please would you respond to the following questions:

Question 1: Name:

Answer: Not applicable.

Question 2: Job Title:

Answer: Not applicable.

Question 3: Hospital:

Answer: East London NHS Foundation Trust.

Question 4: Over the last two calendar years (Jan 23 – Nov 24) has your

hospital/organisation experienced any failure of the Simpson Shelf Vaginal Pessary after implanting that relate to the materials used?

Answer: The Trust has reviewed question 4 of your request for information under the

Freedom of Information Act (FOI) 2000.

Section 1(1) of the Freedom of Information Act 2000 states:

Any person making a request for information to a public authority is entitled—
(a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and

(b) if that is the case, to have that information communicated to them.

East London NHS Foundation Trust is primarily a Mental Health and Community Health Trust and as such does not provide gynaecological

services. The Trust is therefore unable to provide a response.

Question 5: Over the last two calendar years (Jan 23 – Nov 24) has your

hospital/organisation experienced any Adverse Events that were not reported to the MHRA and what side effects or adverse events occurred?

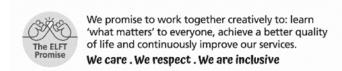
Answer: The Trust has reviewed question 5 of your request for information under the

Freedom of Information Act (FOI) 2000.

Section 1(1) of the Freedom of Information Act 2000 states:

Any person making a request for information to a public authority is entitled—
(a) to be informed in writing by the public authority whether it holds information

of the description specified in the request, and (b) if that is the case, to have that information communicated to them.



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Question 6: For the population of patients that your hospital uses an implanted Vaginal Pessary, do you feel there are other devices available that performs the same tasks as the Simpson Shelf Vaginal Pessary and which devices seem to have less adverse effects on this group of patients?

The Trust has reviewed question 6 of your request for information under the Answer: Freedom of Information Act (FOI) 2000.

> Section 1(1) of the Freedom of Information Act 2000 states: Any person making a request for information to a public authority is entitled— (a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and (b) if that is the case, to have that information communicated to them.

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Question 7: Are the ranges of sizes of the Simpson Shelf Vaginal Pessary from 51mm – 101mm adequate for your patient population?

The Trust has reviewed question 7 of your request for information under the Answer: Freedom of Information Act (FOI) 2000.

> Section 1(1) of the Freedom of Information Act 2000 states: Any person making a request for information to a public authority is entitled— (a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and (b) if that is the case, to have that information communicated to them.

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Question 8: Can you describe your experience of using the Simpson Shelf Vaginal Pessary with your patients and would you recommend its use to other clinicians at other Hospital or wider audience?

The Trust has reviewed question 8 of your request for information under the Answer: Freedom of Information Act (FOI) 2000.

> Section 1(1) of the Freedom of Information Act 2000 states: Any person making a request for information to a public authority is entitled— (a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and (b) if that is the case, to have that information communicated to them.

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