

Ref: 24-943

Freedom of Information Request

27 December 2024

By Email

Dear Sir/Madam

Thank you for your request for information under the Freedom of Information Act 2000. The Trust's response is as follows:

We can confirm that we do hold the information you are requesting

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:

1. Name: Viola Joji Mathew

2. Job Title: Consultant

3. Hospital: University Hospitals Bristol and Weston NHS Foundation Trust

- 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? No
- 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? None

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?

Due to the range in size and shape of the Simpson Shelf Vaginal, it has been used when other flexible or compressible pessaries are not successful.

- 7. Are the ranges of sizes of the Simpson Shelf Vaginal Pessary from 51mm 101mm adequate for your patient population?
 Yes.
- 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 Simpson Shelf Vaginal Pessary has been useful when a more rigid device is needed to control pelvic organ prolapse, particularly a more advanced prolapse and in patients who are unable to have surgery due to complex medical comorbidities, or in patients who opt for conservative management; we would recommend it's use to other clinicians, however, as with any pessary used for pelvic organ prolapse, the clinician or practitioner would have to assess each patient on an individual basis, taking the patient's requirements into consideration.

This concludes our response. We trust that you find this helpful, but please do not hesitate to contact us directly if we can be of any further assistance.

If, after that, you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to:

Data Protection Officer
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
BS1 3NU

Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Publication

Please note that this letter and the information included/attached will be published on our website as part of the Trust's Freedom of Information Publication Log. This is because information disclosed in accordance with the Freedom of Information Act is disclosed to the public, not just to the individual making the request. We will remove any personal information (such as your name, email and so on) from any information we make public to protect your personal information.

To view the Freedom of Information Act in full please click here.

Yours sincerely

Freedom of Information Team University Hospitals Bristol and Weston NHS Foundation Trust