Freedom of Information Request	FOI 23-344	17 August 2023

Your request
You requested the following:

1a. Is any of the product(s) purchased/used in your hospital contain Chitin/Chitosan (e.g. surgical sutures, materials in wound healing/tissue engineering/dentistry/drug delivery)?
If the answer to Q1a is Yes then skip to Q2a.
If the answer to Q1a is No then:

1b. Do you plan on utilizing products containing Chitin/Chitosan in the next two years?
If the answer to Q1b is No, you may skip the rest of the questionnaire
If the answer to Q1b is Yes, answer Q2a and then you may skip the rest of the questionnaire.

2a. What product(s) do you have in the hospital (or intend to purchase) that contains Chitin/Chitosan?

2b. For each product listed in response to Question Q2a, could you please provide the following details:
- The product's brand name.
- The purpose of the product and in which department it is used.
- The approximate volume of the product used/purchased over the last financial year (1st April 2022 – 31st March 2023).

3. Has the hospital received any complaints or filed any cases of side effects from using the Chitin/Chitosan product(s) mentioned above? If so, please provide detail of the following:
a) Number of cases in years 2020, 2021, 2022 and 2023
b) description of the most three common side effects
c) Which product(s) caused the most commonly seen side effects

4. Is there any limitation(s), certification(s), or regulatory requirement(s) that are bounded when utilizing Chitin/Chitosan in the hospital (i.e. ISO standards or Ethics, etc)? If so, please specify.

5. Is the hospital currently or will be promoting any new products containing chitin or chitosan?

Our response
1. Our response for question 1a is yes.
2. Our response for questions 2a and 2b is provided in the table below:

Products that contain Chitin/Chitosan	Haemostatic Gauze
Product Brand name	ChitoGauze
Purpose of the product	Haemostatic properties
Department	Grange University Hospital (GUH) Emergency Department (ED) and Ward B
Approximate volume used/purchased	22 units

3. We have not received any complaints or cases of side effects. Therefore, we do not hold any information for points 3a-3c.
4. The item must be supplied with a valid CE Mark demonstrating conformance to the Medical Devices Directive (MDD) and Medical Device Regulation (MDR) and must be manufactured and distributed under ISO 13485. The item must also meet the requirements set out below.
    - Must be non-granular
    - Items must be a continuous roll impregnated with Chitosan
    - Items must be within strong packaging that is easily opened
    - Items must not cause an exothermic reaction
    - Items must be able to be used on patients with a known shellfish allergy
    - Standard Chitosan products must act within 3 minutes
    - Fast Acting Chitosan products must act within 1 minute
    - Must be sterile and individually wrapped

5. No