Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

22nd May 2023

Dear

FOI 23/318

Thank you for your email dated 02 May 2023 where you requested **updated data on adverse events that have been reported to the MHRA for the following medical devices*:* Puraplas, Dermal Roller, Cannulas and PDO Threads.**

As you may know, the MHRA has recently changed the way in which we code medical device incident reports, now using the Global Medical Device Nomenclature (GMDN). Unfortunately, incident data provided previously cannot be directly compared to the data in this response due to this change in terminology.

I can confirm that the MHRA has received **9** UK reports across **all manufacturers** for adverse events concerning peripheral intravenous cannulas (GMDN Code 64574) submitted as of 1st January 2023 to 19th May 2023 inclusive. The table below includes the reported device problems. This includes reports received from manufacturers, healthcare professionals and members of the public.

Number of Adverse incident reports for each Device Problem	
Device problem	**No. of reports**
Mechanical problem	5
Material Integrity problem	<5
Manufacturing packaging or shipping problem	<5
Unspecified	<5

I can also confirm that following your request we have conducted a search using the GMDN codes displayed in the table below, and that we have not received any reports across **all manufacturers** for adverse events submitted as of 1st January 2023 to 19th May 2023 inclusive for these products.

GMDN Codes for Devices	
GMDN Code	**Term Name**
37474	Cosmetic micro-needling roller reusable
47573	Cosmetic micro-needling roller, single use
46859	Lift thread, bioabsorbable
45322	Lift thread, non-bioabsorbable
46860	Lift thread, partially bioabsorbable
46923	Haematological concentrate system preparation kit, platelet concentration

When considering the data provided within this response, please consider the below information:

- It is important to note that the inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors.
- The majority of reports indicate an issue experienced by a single user. However, some cases may represent the same user experiencing further issues or multiple events in the same report.
- The figures provided above are not the same as complication rates.
- Reports do not necessarily represent an individual patient. Individuals may report an incident at any time after the event and people can make multiple reports at any time after the use of device and on the same issue.
- Where possible, multiple reports for the same event are linked. However, as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate.
- It should be noted that this information may include a range of recognised complications related to this type of procedure and does not necessarily indicate a fault with any particular device.
- The numbers may include reports where the incident has been taken from published literature or the report may be about notification of a safety communication.
- These numbers of reports are accurate at the time they are extracted from our database and minor changes in the numbers can occur if the reporter of the incident gives us more details later.

As with all medical devices the MHRA continues to monitor the safety and performance and encourages reporting of any adverse incidents through its Yellow Card scheme on https://yellowcard.mhra.gov.uk/.

Yours sincerely,

FOI Team
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency