

Customer Advisory Letter

19th March 2007

**PRODUCT: 585039 Irrigating Cystotome curved [Joyce] .40 x 16mm
Lot number 6275397
Note that this Advisory Letter applies to this lot number only.**

Dear Customer:

I am writing to notify you that some products contained within the blisters are not as identified on the outside label. The product actually contained within the blister is 585093 – Cystotome Irrigating [Simcoe] Angled .40mm. This product is angled whereas product 585039 has a radius form. The gauge size and end profiles of both cystotome products are identical. Out of a total batch size of 1,220, a total of 355 products (29% of the batch) are of the incorrect (angled) type.

We have conducted a clinical assessment and have concluded that the differences between the curved and angled versions of the 27g cystotome represent a very small risk to the patient. Before the cystotome comes into contact with the patient, it would be apparent that the cystotome is angled and not curved. The only potential hazard would be if a surgeon chooses to use the angled cystotome instead of the curved cystotome, and cannot adapt their technique to account for the change. This decision would be made prior to contact with the eye, as the surgeon would visualise the cystotome prior to contact.

Although the risk to the patient is very small, we recognise that you may prefer to use the curved version of this cystotome, therefore if you require replacements we can provide you with shelf stock of the correct version of these cystotomes.

We apologise for any inconvenience this issue may cause you or your staff. Please do not hesitate to contact the undersigned if you have any further questions in this regard.

Yours sincerely,


Regulatory & Quality Assurance Manager
BD Ophthalmic Systems