



2012-01-16

Dear colleagues

RE: PIP IMPLANTS

Following the recent furor regarding the PIP implant saga, there has obviously been a media frenzy thus necessitating the need to compile a policy document as regards management of these patients in South Africa. Using guidelines published by the NHS and French Authorities the available data suggest the following:

There is no evidence that PIP implants are associated with a higher risk of breast cancer than other silicone gel implants

The statistical evidence on the rate of rupture of PIP implants compared with other implants is incomplete and this risk cannot be assessed accurately

The composition of the silicone used by PIP after 2006 cannot be guaranteed to have been submitted to the same rigorous toxicological testing as is required to meet the essential requirements and as such no conclusions can be drawn about its quality in the context of breast implants

Toxicology tests in both France and the UK suggest no significant health risk to women

Only 1,7 % of women with PIP implants are known to have ruptured

With these types of blanket statements, the question then arises as to how to manage these patients and what to advise them?

All patients who have PIP implants should be contacted and reassured

In the absence of clinical symptoms of rupture, patients should not be advised to seek explantation, but should have regular follow up examinations and yearly sonar appraisals.

Concerned patients should consult a registered Plastic Surgeon, be examined clinically and in the presence of clinical symptoms of possible rupture, should be subjected to ultrasonographic appraisal of the implants.

In the presence of both intracapsular and extracapsular rupture, explantation is mandatory. Patients should then be given the option of reimplantation, explantation alone or explantation with mastopexy in the scenario of redundant skin and ptosis post explantation.

Should a patient request removal of the implants in the absence of rupture, then the risk benefit ratio should be discussed and the patient managed appropriately.

This then raises the unpleasant topic of financial obligations. Clearly at the time of implantation the surgeon had no reason to believe that he/she might be inserting faulty devices and as such, cannot be financially

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penalized for the Company's dishonesty and indiscretion. Due to the sensitive nature of the problem and in light of preserving our stature in the Health care environment, we will try to help these patients to effect necessary changes. It should be explained that we have the patients best interests at heart and are doing everything in our power to help resolve the problem.

Yours sincerely

Dr RW Robson

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