

INTERIM (DRAFT)

LABORATORY REPORT: DIR 25692

DEVICE:

Poly Implant Prosthese (PIP) breast explants as per Device Incident Report (DIR 25692). Two implants were received - left and right breast - from Dr Pouw

DEVICE TYPE: SILICONE GEL FILLED BREAST IMPLANT

Manufacturer: PIP

Sample Number: 1202000756 , 1202000967

Implant One

Sample Number: 1202000756

DEVICE MARKING.

350 cc

38206

003

DEVICE AS RECEIVED CONDITION.

The implant is yellow in appearance has tissue residue on the patch side, easily removed with gentle rub. Implant has visible air pocket, but has no rupture, no perforation.

WEIGHT

370.76g (total weight with two bags of approximately 11.35g).

GEL APPEARANCE

The Shell was cut and peeled away from the shell. The gel looks curdled and gummy and separates easily from the shell. The appearance of the gel is quite different to other implants observed to date. The appearance is like the gel has been "chopped up."

Most PIP gels examined to date hold the shape of the implant when the shell is peeled away and remain cohesive. Sample number 1202000756 does not retain the shape of the implant when the shell is peeled away and is "runny".

The appearance may be explained by mechanical damage during implantation. The TGA should check with reporting surgeon when the implants were put in, the reason it was taken out and any other information that may explain the appearance of the gel.

Implant Two**Sample Number:** 1202000967**DEVICE MARKING.**

350 cc

34606

128

DEVICE AS RECEIVED CONDITION.

The implant is yellow but less yellow in colour than sample number 1202000756. The surface is clean and there is no evidence of tissue residue or wetness. There is no separation of the gel from the shell, no ruptures, no perforations.

WEIGHT

371.59g (total weight with two bags of approximately 11.35g).

GEL APPEARANCE

The Shell was cut and peeled away from the shell. The gel looks curdled and gummy and separates easily from the shell. The appearance of the gel is quite different to other implants observed to date. The appearance is like the gel has been “chopped up.”

Most PIP gels examined to date hold the shape of the implant when the shell is peeled away and remain cohesive. Sample number 1202000756 does not retain the shape of the implant when the shell is peeled away and is “runny”.

The appearance may be explained by mechanical damage during implantation. The TGA should check with reporting surgeon when the implants were put in, the reason it was taken out and any other information that may explain the appearance of the gel.

FURTHER TESTING PLANNED

The gel was removed as a whole piece after the shell was cut along part of the perimeter; for tensile testing at a later date.

The gel was divided into two samples and placed in jars one for later cohesion test the other for further sampling if required.

Two glass vials of gel were taken for later chemical testing. No oil to sample on this implant.

LIST OF PHOTOGRAPHS

- 1- Left and right implants as received showing difference in yellowing – Neither implant was ruptured but one showed signs of delamination of the shell from the gel (marked “>”)
- 2- Appearance of gel once the shell was peeled away both implants were similar.
- 3- Appearance of gel from a separate implant retrieval (more “cohesive” retained shape after peeling off the shell)

