TGA THERAPEUTIC GOODS ADMINISTRATION
PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8615 Facsimile: (02) 6232 8785

Department of Health and Aged Care

Therapeutic Goods Act (1989) - Exemption from Registration

Notice of approval under Section 19(1)(a)
Individual Patient Use (IPU)

IPU No
EXPIRY DATE 7/8/0

Devices : 2.00 x Poly Implants Prosthesis (PIP) - Silicone

Supplier : Precise Medical Supplies
P O Box 421
PADDINGTON NSW 2021 Fax : (02 9211827

This formal notice of approval applies to the supply of the above device to:

Dr

NSW Fax : (02

in the treatment of : 14/3/40
subject to the following conditions :

1. The clinical use of the device is that stated in the application for approval;
2. The doctor and patient/guardian accept responsibility for the outcome of the therapy **and the patient/guardian gives informed consent in the use of an unregistered device.**
3. Details of adverse events with the use of the device are to be reported to the Therapeutic Device Incident Reporting Scheme;
4. The supplier will retain records of the distribution of the device for a period of at least 5 years;
5. The use of the device shall be regarded as experimental, and the principles set out in the National Health and Medical Research Council's Statement on Human Experimentation shall be observed;
6. Special conditions:

   Detailed records of the procedure are kept, and the patient/guardian agrees to these records being included in any future clinical trial documentation.

   When this approval is provided to allow the replacement of a damaged device, the 'TGA Medical Device Incident Report' must be completed and returned to Conformity Assessment Branch. Blank Incident Report forms can be obtained by calling 1800 809 361. 'Consent forms' and 'Record of Operation forms' should be completed and attached to the patient's hospital medical records. Blank forms can be obtained by calling 02 6232 8679.

8 May 2001