



THERAPEUTIC
GOODS
ADMINISTRATION

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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 2025/2002
EXPIRY DATE 30/1/03

Devices : 2.00 x Margron Mini Stem

Supplier : Portland Orthopaedics
44 McCauley Street
MATRAVILLE NSW 2000

Fax : (02)

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

Dr Ronald Sekel
Medical Centre
St George Private Hospital
1 South Street
KOGARAH NSW 2217

Fax : (02 9587 1014)

in the treatment of : [REDACTED]
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.

Dr Martin Witenden-Devitt
Medical Adviser
Conformity Assessment Branch

Notification : Original to Portland Orthopaedics
Copy to Dr Ronald Sekel

31 October 2002