



**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            2026/2002  
EXPIRY DATE     30/1/03

Devices :        **2.00 x Modular Extension Component**

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.**

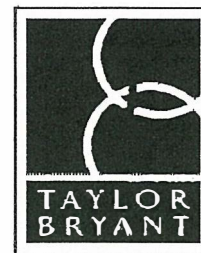
**Dr Martin Witenden-Devitt  
Medical Adviser  
Conformity Assessment Branch**

Notification : Original to Portland Orthopaedics  
Copy to Dr Ronald Sekel

31 October 2002

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## FACSIMILE TRANSMISSION SHEET



ABN 28 004 000 373

Taylor Bryant Pty Ltd  
86 Chandos Street  
St Leonards NSW 2065  
PO Box 427  
St Leonards NSW 1590  
Phone 02 9906 8355  
Fax 02 9906 8064  
[www.taylorbryant.com.au](http://www.taylorbryant.com.au)  
New Zealand Toll Free  
Phone 0800 444 597

TO: Clinical Section  
Conformity Assessment  
Branch

FROM: Matt Slade-Smith

COMPANY: TGA

DATE: 1 May 2003

FAX NO: 6232-8785

NO. OF PAGES: 2  
(INCLUDING COVER)

PHONE NO:

RE: URGENT IPU APPLICATION FORM

Urgent

For review

Please comment

Please reply

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Dear TGA,

Please find attached an IPU that we are hoping to have processed before tomorrow as this is when surgery is anticipated to take place. Also could you please fax back approval to Taylor Bryant Pty. Ltd. on (02) 9906-8064 rather than Portland Orthopaedics as it is our sales reps who will be supporting the case.

Kind Regards

Matt Slade-Smith  
Taylor Bryant Pty. Ltd.