



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

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AN INITIATIVE OF THE NATIONAL, STATE AND  
TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

## Horizon Scanning Technology Prioritising Summary

Bioabsorbable joint implants (PLA96) for the  
treatment of rheumatoid arthritis

April 2004



**ASERNIP/S**

**Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
College of Surgeons**



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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

**Name of Technology:**

Bioabsorbable Joint Implants (PLA96)

**Purpose and Target Group:**

The implant may benefit people suffering from rheumatoid arthritis as the porous scaffolding of the implant can be penetrated by living tissue to form a new joint.

**Stage of Development (in Australia):**

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

The bioabsorbable joint implant (PLA96) is not listed or registered in the Australian Register of Therapeutic Goods (ARTG).

**International Utilisation:**

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely Diffused
Finland	✓		

**Impact Summary:*****Background***

Rheumatoid arthritis is a chronic disease that results in inflammation of the lining of joints (synovium) and/or other internal organs, which initiates an autoimmune response that destroys surrounding bone and cartilage. The involved joint then loses its shape and alignment, resulting in pain and loss of movement.<sup>1</sup>

Typically reconstruction of the joints uses silicon implants; however, problems with the durability of the implants<sup>2</sup> have led to the development of bioreconstructive implants that produce a new joint (neojoint) through the penetration of a porous scaffold with living tissue and eventual bioabsorption of the implant.<sup>3</sup>

***Clinical Need and Burden of Disease***

Rheumatoid arthritis affects approximately 3% of the Australian population, and is more prevalent in women. It is a progressive disease that tends to occur between the ages of 25 and 50 years.<sup>1</sup>



Rheumatoid arthritis is recognised as one of the major reasons of people leaving work early and hence affects peoples' social activity and work capacity.<sup>1</sup>

### ***Estimated Speed, Geographic and Practitioner Use Patterns of Diffusion in the Health System***

Professor Pertti Tormala and colleagues, in Finland, first trialled the technique five years ago and to date they have used it in over 100 patients with rheumatoid arthritis. The surgeons have recently received European Union funding to expand their study trials and it is now being tested in Finland, Sweden, Germany, Italy and Turkey.<sup>4</sup>

### ***Existing Comparators***

- Swanson Silicon Implants

### ***Estimated Cost Impact***

The costs associated with this new product are not available. The cost of traditional joint implants in Australia is also not available. However, the reimbursement cost as stated by the Medicare Benefits Schedule for interphalangeal or metacarpophalangeal joint repair using synthetic implants (procedure only) is approximately \$470.00.<sup>5</sup>

### ***Efficacy and Safety Issues***

Safety and efficacy data exist from only one case series study.

Honkanen and colleagues<sup>3</sup> reported on 23 rheumatoid arthritis patients who underwent PLA96 implants and were followed up after one year. Pain alleviation was achieved, with an improvement in a range of motion. Average ulnar deviation was 26 degrees preoperatively compared to 6 degrees at follow-up. Volar subluxation was evident in 56% of patients preoperatively and only 6% at the 1-year follow-up. This is the first report of the formation of a living, functional joint.

### ***Ethical Issues***

No issues were identified from the retrieved material.

### ***Cultural or Religious Considerations***

No issues were identified from the retrieved material.

### ***Other Issues***

No issues were identified from the retrieved material.

### **Conclusion:**

Very limited evidence exists on the safety and efficacy of the PLA96 Bioabsorbable joint implants. Long-term safety and efficacy data from controlled trials would be needed before this procedure could be widely accepted.



- Horizon Scanning Report       Full Health Technology Assessment  
 Monitor       Archive

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### Search Criteria:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials  
metaRegister, UK National Research Register, International Network for Agencies for  
Health Technology Assessments, relevant online journals and the Internet was conducted in  
December 2003.



Search terms used were: 'bioabsorbable and joint and implant', 'PLA96', 'Tormala P' and 'metacarp\$ and arthroplasty'