



The Prince of Wales Hospital

STOMAL THERAPY AND WOUND SERVICES  
THE PRINCE OF WALES HOSPITAL  
RANDWICK NEW SOUTH WALES  
AUSTRALIA

**BURNAID<sup>®</sup>**

**WOUND**

**TRIAL**

**2004**



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## CONTENTS

<u>PAGE</u>	<u>CONTENT</u>
1.	CONTENT
2.	AIM & BACKGROUND OF TRIAL
4.	BURNAID-WOUNDAID PRODUCT
6.	BURNAID EVALUATION
7.	BURNAID TRIAL CASE SYNOPSIS
15.	CONCLUSION



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## AIM AND BACKGROUND OF TRIAL

The active ingredient of BURNAID Hydrogel is 4% Melaleuca Oil or more commonly known as Tea Tree Oil (TTO). *Melaleuca alternifolia* is unique to Australia and its natural habitat is in small pockets of low-lying swamp area throughout New South Wales (Carson & Riley 1992). TTO has been well document as an antiseptic and disinfectant agent as early as the 1920's and 30's. Humphery (1930) published one of the first scientific papers summarizing personal experiences of therapeutic applications of the oil. These included the cleansing and dressing of dirty wounds with oil solutions as well commercially available products in the 1920's that were used to disinfect and dress a large diabetic ulcer, which healed without further infection (Halford 1936).

Post World War II slump in the TTO industry stopped all production of commercial products. The essential oil of *M. alternifolia*, or Tea Tree Oil, has enjoyed increased medicinal use in recent years. BURNAID traditionally has been used as a gel for the first aid treatment of burn injuries and has been commercially available world wide for over a decade. Large numbers of published in-vivo and in-vitro studies have indicated that TTO exhibit strong antimicrobial properties and animal studies have proven excellent results in wound healing.



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BURNAID was used as a hydrogel on a variety of wounds throughout the general surgical and medical wards as well as outpatient clinics in the Prince of Wales Hospital, a large adult tertiary hospital, within the South East Sydney Area Health Services.

Wounds treated with BURNAID Hydrogel varied widely from a range of leg ulcers, pressure related wounds, spider bites and various infective wounds. The trial was conducted over a three-month period from June 04 – August 04.



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## BURNAID – WOUNDGEL

Burnaid Hydrogel – Wound gel is manufactured by RYE PHARMACEUTICALS PTY LTD Australia and supplied by M.R.RESCUE PTY LTD Australia for the purposes of this trial.

BURNAID Gel consists of in excess of 90% water trapped in a proprietary gel, containing 4% Melaleuca Oil (Tea Tree Oil). BURNAID Gel and Dressings are approved for sale under US FDA, European Union CE, Australian TGA, NZ – MOH, and throughout selected countries in Asia and the Middle East (BURNAID Technical Report 2004).

### INFECTION CONTROL

Testing of Burnaid Burn Gel Tubes (4% Melaleuca Oil) in accordance with British Pharmacopoeia Preservative Test indicated Burnaid passed the test.<sup>1</sup>

<b>Culture</b>	<b>Control Count</b>	<b>0 hr</b>	<b>6 hr</b>	<b>24 hr</b>	<b>48 hr</b>
S. aureus	1.9x10 <sup>7</sup>	8.4 x 10 <sup>5</sup>	<10	<10	<10
Ps. aeruginosa	4.7x10 <sup>6</sup>	3.6 x 10 <sup>5</sup>	<10	<10	<10
C. albicans	5.1x10 <sup>6</sup>	4.0x10 <sup>5</sup>	<100	<100	<100
A. niger	2.9x10 <sup>6</sup>	4.7x10 <sup>5</sup>	3.8x10 <sup>5</sup>	2.6 x 10 <sup>5</sup>	<100



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Testing of Burnaid Gel (4% Tea Tree Oil) by the Department of Microbiology, Repatriation General Hospital, Concord, Sydney, for activity against a number of organisms expressed as zones of inhibition, indicated activity against all organisms.<sup>ii</sup>

<b>ORGANISM</b>	<b>ZONE OF INHIBITION (mm)</b>
C. albicans	5
C. tropicalis	11
Staph. aureus 3	40
Staph. aureus 4	47
E. coli 5	30
E. coli 6	24

<sup>i</sup> Schwartzkoff C. Bioassay, Lillyfield NSW Australia. Paper presented to symposium on modern phytotherapy – the clinical significance of tea tree oil and other essential oils – Macquarie University Sydney 1989; 54-65.

<sup>ii</sup> Levy J. Repatriation General Hospital Concord, NSW Australia. Work conducted on Bu maid Gel. 1992.

## **SAFETY**

### ***Toxicity, Skin Irritation and Sensitisation***

In-vivo studies conducted on Burnaid indicate a Draize irritation index of 0 for acute dermal irritation, indicating a non-irritant. Skin sensitization studies indicated slight intradermal irritation reactions, although no sensitization properties are shown. Oral toxicity studies indicate the LD50 to be greater than 10g/Kg - indicating a very low potential toxicity. Burnaid Gel 4% was evaluated as a very mild eye irritant using the Draize procedure.<sup>ii</sup>

21-day cumulative irritancy testing of a 10% Melaleuca Oil formulation conducted on humans indicated that in general low percentage formulations used topically such as Burnaid would appear to pose little risk of skin irritation when applied under normal conditions.<sup>ii</sup>

## **STERILITY**

Burnaid Dressings are gamma irradiated at a minimum dosage of 25Kgys. Independent review of the radiation sterilization practices and laboratory testing procedures used on Burnaid gave a Sterility Assurance Level (SAL) of greater than  $10^{-6}$  – ensuring compliance as a sterile medical device under FDA and European Union Sterile Devices Codes.<sup>ii</sup>

(BURNAID Technical Condensed report 2004)



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## **Burn Aid Evaluation**

We have found Burn Aid to be:

- Effective in debriding wounds
- Soothing for the patient – all patients have described it as being very comfortable as soon as it was applied to the wound
- It does not macerate good skin
- Helps to cut down on the smell with Malodorous wounds
- Worked very well as an ‘anti-microbial’ on one chronic wound whereas a silver dressing which had previously been used was ineffective in ‘kick-starting’ healing and cutting down on malodour
- Used on one fungating wound with good results – patient found it soothing and it did ‘cut down’ on malodour



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## BURNAID TRIAL CASE SYNOPSIS

### CASE 1: Patient BJ

He has a PMH of Diabetes, Peripheral Vascular Disease (PVD) and below knee amputation.

This patient had a heel wound from a pressure sore that had developed whilst he was a patient at POWH. This was surgically debrided and the patient refused any further surgery and stated that he wanted to have his wound treated by dressings.

This patient is an outpatient.

**March – June 2004:** the wound had halved in size, and had healthy granulation tissue evident using a dressing called Vacutex.

**June 18<sup>th</sup> 2004** -I saw the wound and it had not reduced in size since the previous month and was malodorous and so the dressing was changed to Aquacel AG

**July 9<sup>th</sup> 2004** – the wound was unchanged in size and was still malodorous and so the dressing was changed to Burnaid gel (the gel was impregnated into gauze and this was applied to the cavity) NAD dressing and mesorb

**July 16<sup>th</sup> 2004** – the wound had reduced in size in one week and was no longer malodorous. The patient stated that the odour was much reduced after even the first dressing change.



**Figure 1A**  
**9 July 2004**



**Figure 1B**  
**Note: wrong date on ruler**  
**16 July 04**

Wound prior to BURNAID

One week with BURNAID



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## Case 2: Patient DP

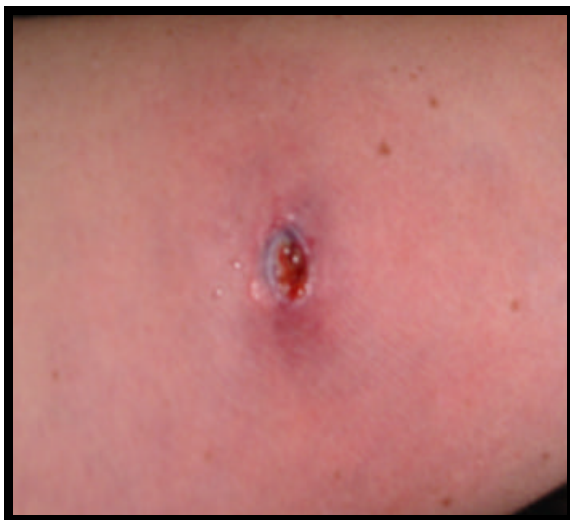
This patient had a white tail spider bite in June

Vacutex were used for 1 month and the necrotic centre of the wound 'cleaned up' and the wound was granulating well

In the space of 2 weeks there was little change in the wound and although it was clean there was no reduction in size of the wound

**July 2004** – patient dressing was changed to Burnaid gel and the wound reduced in size in 24 hours and healed in 3 days

### Figure 2A: Prior to BURNAID



**Figure 2B: Wound after BURNAID** – reduction in size after 24 hours healed 72 hours.



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## Case 3: Patient AV

This patient has a history of PVD and Diabetes with a previous Below Knee Amputation. When he came into hospital he had 2 necrotic toes and there was thick green slough over his toes and ankle. The skin on the ankle was very macerated due to incorrect usage of solosite gel. Within 1 week the maceration had cleared up on the ankle and the ulcers were also looking much better. The ankle wound was grafted 10 days after admission and the graft took 100%

**Figure 3A: Prior to BURNAID 6 July 2004**



**Figure 3B: After BURNAID 14.7.2004**



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## **CASE 4: Patient JR**

This patient had a very sloughy RT Saphenous vein graft site following Coronary Artery Grafts (CAG's).

Solosite gel was used for 1 month with no visible effect

Burnaid gel used with effect apparent within a few days

Patient transferred to Port Macquarie Hospital – have asked for follow-up photos but have received nothing.



**Figure 4A: 29 June 2004 Wound after 1 month use of Solosite gel**



**Figure 4B: 8 July 2004 Wound after a few days treated with BURNAID**



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## CASE 5: Patient LB

Patient came in through Emergency Department with a very 'sloughy/orange leg ulcer that was highly exudating. He was febrile with a temp of 39C, and it was believed that the leg ulcer was the cause of his fever. Has a history of NIDDM. He had had an angiogram in the last 2 weeks, which showed no evidence of PVD. Patient was also on IV Antibiotics for 5 days.

I would not usually use Burnaid gel on a wound that was heavily exudating but thought it was worthwhile to try and reduce the bacterial load

The ulcer has reduced in size in the last 7 days using Burnaid gel. It was 10cm x 6 cm initially and in 7 days has reduced to 7.5x5.5 cm. LB is now an outpatient and will be seen weekly by the Stomal therapy and wound care CNC.

**Figure 5A: 14 July 2004 Wound on admission**



**Figure 5B: One week with BURNAID – Reduction in size 2-3 cm**



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## CASE 6: Patient TT

Patient has Diabetes, Chronic renal failure- awaiting transplant – having PD.

Sustained a wood chopping injury to leg which resulted in a haematoma and it became necrotic – had surgical drainage. Burnaid to leg daily since 29-6-04 which has cleaned it up considerably.

Patient now an outpatient and is seen weekly by the Stomal therapy and wound care CNC.

**Figure 6A: 29 June 2004**

After Surgical Drain



**Figure 6B: 14 July 2004**

Progress with BURNAID



**Figure 6C: 27 July 2004**

Clean wound and new tissue granulation with BURNAID



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## CASE 7: Patient BR

Patient has a Hx of Quadriplegia and was nursed in a head brace

Patient sustained a pressure sore on the back of his head Vacutex was used to 'de-slough' the wound which is now clean but it is down to bone

Burnaid Gel commenced 15-7-04

*\_(Will be a miracle if it works on this but thought it worth trying for the 'comfort' properties it has).*

**Figure 7A: 24 June 2004**

Vacutex to de-slough wound



**Figure 7B: 27 July 2004**

BURNAID started 15.7.04



**Figure 7C: 10 August 2004**

Progress with BURNAID





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### CASE 8: Patient AT

Patient is a new paraplegic transferred from another hospital with a pressure sore on her head. She was wearing a neck brace and also had not had any nutrition to speak of for 15 days during which time this developed.

Vacutex used initially but patient found it too painful so Burnaid was then used from 7-7-04. Wound smaller in size with both granulation and epithelial tissue evident. Patient finds it much more comfortable.

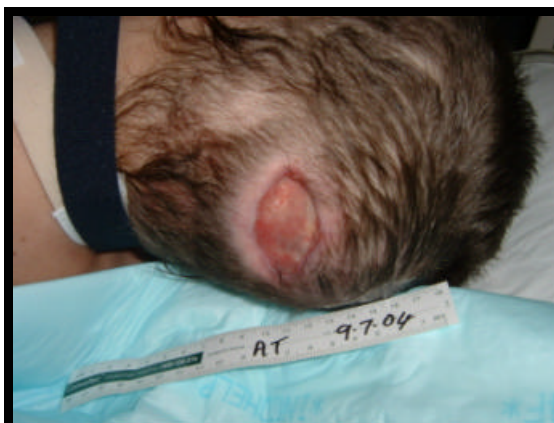
#### Figure 8A: Wound on Admission –

Vacutex commenced



#### Figure 8B: 9 July 2004

BURNAID started 7 July 2004



#### Figure 8C: 10 August 2004



BURNAID has decreased size of wound – granulation & epithelial tissue evident.



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BURNAID wound Hydrogel trial conducted by the Stomal Therapy and Wound Department for the Prince of Wales Hospital Randwick Sydney New South Wales.

Thank you to all staff and patients who participated in the BURNAID trial.

BURNAID wound trial conducted and reported by Carol Stott CNC Stomal Therapy and Wound Department Prince of Wales Hospital.

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