



Australian Government
Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

ANZHSN

AN INITIATIVE OF THE NATIONAL STATE AND
TERRITORY GOVERNMENTS OF AUSTRALIA
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Horizon Scanning Technology Prioritising Summaries

**Renessa® radiofrequency micro-remodelling
treatment for female stress urinary
incontinence**

September 2006



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:

Renessa® radiofrequency micro-remodelling treatment for female stress urinary incontinence (Novasys Medical Inc., Newark, CA, USA).

Purpose and Target Group:

The Renessa radiofrequency micro-remodelling treatment is a non-surgical, transurethral treatment for women suffering stress urinary incontinence (SUI). It is used for women suffering SUI associated with bladder outlet hypermobility, with or without associated intrinsic sphincter deficiency.

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged in Australia

The Renessa RF micro-remodelling system is currently not listed in the Australian Register of Therapeutic Goods.

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		✓	
European Union		✓	

Impact Summary:

Background

Urine is produced in the kidneys then flows down the ureters into the bladder where it is stored (National Association for Continence 2005). Urination is controlled by the urinary sphincter, rings of muscles at the base of the bladder and wall of the urethra (tube that connects the bladder to the outside for urination) (Choldhan 2003, National Association for Continence 2005). When the bladder is full, relaxation of the sphincter in conjunction with contraction of the bladder muscle allows urine to flow out (National Association for Continence 2005). When urination is complete and when the bladder is not full the sphincter contracts and the detrusor relaxes (National Association for Continence 2005).

Urinary incontinence is the inability to hold urine in the bladder and prevent involuntary urine loss (Choldhan 2003). Urinary incontinence in women usually results from a variety of



causes although the most common predisposing factors include vaginal birth trauma, previous pelvic/vaginal surgery, radiation therapy and menopausal status (Choldhan 2003).

Patients can suffer from different forms of urinary incontinence, including (Choldhan 2003, National Association for Continence 2005):

- Total incontinence: the complete inability to control leakage of urine.
- Overflow incontinence: occurs when the bladder overflows when it is too full.
- Urge incontinence: urine leakage without warning, resulting from an over reactive bladder.
- Stress incontinence: leakage of urine resulting from activity that strains or stresses the bladder e.g. lifting, sneezing or exercises.

There are also various management and treatment options for sufferers of urinary incontinence. These options range from the use of sanitary pads and disposable underwear to the surgical option of an Artificial Urinary Sphincter (AUS) (National Association for Continence 2005). Although a variety of treatments are available there is a trend by both patients and physicians to express significant interest in non-surgical, less invasive methods of treatment (Sotomayor and Bernal 2003).

The Renessa system is a new treatment option using radiofrequency energy to perform micro-remodelling of the tissue in the urinary tract thought to be responsible for stress urinary incontinence. It is a non-surgical, transurethral treatment method previously used to treat disorders such as faecal incontinence and gastroesophageal reflux disease, which can be performed under conscious sedation (Sotomayor and Bernal 2005).

In contrast to RF tissue ablation which uses temperatures high enough to cause tissue necrosis and is applied on a gross scale, RF micro-remodelling uses lower temperatures (65 – 75 °C) and is applied on a microscopic scale (Sotomayor and Bernal 2003). RF tissue ablation creates a focal, microscopic denaturation of collagen without tissue necrosis, vascular or nerve injury, leading to micro-remodelling of selected areas of collagen upon cooling and healing (Sotomayor and Bernal 2003). The results are 150-200 µm diameter remodelled regions with reduced dynamic tissue compliance (Sotomayor and Bernal 2003). It is this focused micro-remodelling which makes RF micro-remodelling useful in the treatment of barrier function disorders such as SUI (Sotomayor and Bernal 2003).

Clinical Need and Burden of Disease

It is estimated that up to 70% of urinary incontinence sufferers are women, usually occurring following childbirth and menopause (Millard 1998). According to surveys, for the majority of women, treatment selection is driven by a desire for minimally invasive therapy and an expectation that the treatment will lead to an improvement in their quality of life (Sotomayor and Bernal 2005). Few women expect a cure (Sotomayor and Bernal 2005).



In Australia it is estimated that between 10% and 25% of women suffer urinary incontinence (Women's Health Queensland Wide Inc. 2003). Although women of all ages may suffer urinary incontinence, it is estimated that 40% of women aged 30 to 50 years suffer the condition (Women's Health Queensland Wide Inc. 2003). Stress urinary incontinence is the most common form and is usually caused by bladder outlet (urethral) hypermobility secondary to poor anatomic pelvic support (Rackler and Vasavada 2006). It is estimated to affect up to 20% of women over the age of 40 (Menstruation.com.au 2005).

Therefore any new minimally invasive treatments with the ability to provide a significant improvement in women's quality of life have the potential to positively impact the lives of this large proportion of women.

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

The Renessa RF micro-remodelling system received the CE Mark in April 2003 allowing Novasys Medical Inc. to market the system in European Union countries. In August 2005, the Renessa system also received approval from the US Food and Drug Administration.

Existing Comparators

- Medications (Women's Health Queensland Wide Inc. 2003):
 - Decongestants
 - Anticholinergic medication nerves to prevent bladder spasms, sometimes used for urge incontinence
- Biofeedback (Women's Health Queensland Wide Inc. 2003)
- Electrical stimulation (Women's Health Queensland Wide Inc. 2003)
- Urethral injections (e.g. collagen) (Women's Health Queensland Wide Inc. 2003)
- Surgical (Women's Health Queensland Wide Inc. 2003):
 - Vaginal repair
 - Artificial urinary sphincter
 - Colposuspension
 - Sling procedures

Estimated Cost Impact

The cost of the Renessa system was not revealed in the searches conducted.

The Medicare Benefits Schedule item numbers, reimbursements and number of claims between July 2005 and June 2006 for treatments of female urinary incontinence are outlined in Table 1.



Table 1 Year 2006 Medical Benefits Schedule of Fees for Treatment of Female Urinary Incontinence

Category	Item Number	Benefit	Number of Claims July 2005 to June 2006
Sling operation, with or without mesh or tape, for stress incontinence*	35599	\$583.79	5016
Combined synchronous abdominovaginal operation for stress incontinence (abdominal procedure)	35602	\$583.75	50
Combined synchronous abdominovaginal operation for stress incontinence (vaginal procedure)	35605	\$316.70	60
Sling procedure for bladder stress incontinence (using autologous facial sling) *	37042	\$788.70	226
Stamey or similar type needle colposuspension, with or without mesh for bladder stress incontinence	37043	\$583.75	72
Suprapubic procedure, with or without mesh for bladder stress incontinence	37044	\$598.75	827
Periurethral or transurethral injection of materials for treatment of urinary incontinence*	37339	\$207.60	652

* Indicates combined number of claims for men and women.

Efficacy and Safety Issues

List of Studies Found

Total number of studies	2
Randomised controlled trials	1
Non-randomised comparative studies	1

Both these studies were included in this summary. Papers arising from these studies are highlighted in bold in the reference list.

Safety and efficacy data from one randomised controlled trial and one non-randomised comparative study were selected for inclusion in this summary based on the use of RF micro-remodelling to treat urinary incontinence in large groups of women.

Safety

The initial study investigating the safety and efficacy of RF micro-remodelling in women was published in 2003 before the Renessa name was adopted (Sotomayor and Bernal 2003). The study aimed to establish safety and efficacy of RF micro-remodelling of the proximal



urethral and bladder outlet in women with SUI as well as determine the optimal parameters (number of lesions, location of lesions, and duration of RF delivery) required to obtain optimal results.

The study was conducted using the Novasys Medical Inc. RF micro-remodelling probe in combination with Curon Medical Inc.'s RF generator (Sunnyvale, California) at a time when perhaps the Novasys RF generator was still under development.

A total of 41 women suffering SUI associated with bladder outlet hypermobility were enrolled into one of four treatment groups at two institutions. However due to a variety of reasons including loss to follow-up and urine cultures positive for urinary tract infection, data for 37 patients were analysed for efficacy. At baseline the four groups were comparable. The groups were designed to compare different modes of delivering the RF remodelling treatment in terms of total number of lesions, location of lesions created and duration of RF delivery (See Table 2).

Table 2 RF Micro-remodelling Treatment Groups As Reported by Sotomayor and Bernal (2003)

Group	Number of Patients	Total number of Lesions	Location (Number) of Lesions	Duration of RF Delivery (min)
I	8	24	Proximal urethra (24)	7.5
II	9	36	Vesicourethral junction (12) proximal urethra (24)	10.5
III	11	48	Distal bladder outlet (24) proximal urethra (24)	12.0
IV	9	60	Distal bladder outlet (24) vesicourethral junction (12) proximal urethra (24)	15.0

Treatment was performed in an outpatient setting under conscious sedation (four exceptions requiring spinal anaesthesia) with procedural and post discharge oral antibiotics. The mean time required for the total procedure was 35 ± 13 minutes (range: 17 to 75 minutes). All women were able to be discharged on the day of the procedure after a mean recovery room time of 2 h 56 min \pm 1 h 29 min (range: 1h 5 min to 8 h 35 min). During their first 30 minutes in recovery women were asked to circle on a Lickert 10-point visual analogue scale (VAS) a score that best reflected their pain and discomfort at that point in time. Mean VAS scores did not significantly differ between treatment groups and an overall mean VAS score of 2.1 ± 2.1 (range: 0 to 7) was reported.

The study monitored the occurrence of serious adverse events (SAE) and minor clinical events (MCE) over the study period. The authors reported no device related or procedure



related SAEs either during the procedure or at any of the follow-up periods (1, 3 and 6 months). However, during the procedure, 16% of women experienced some form of a MCE. This figure rose to 73% of women during the 30 day post-procedure period (Table 3). None of the reported MCEs however were deemed serious enough to require therapeutic intervention.

Table 3 RF Micro-remodelling Procedure and 30 Day Post-procedure Minor Clinical Events (n=37)

Event	Number	Percentage
During Procedure:		
Serious adverse event	0	0
Dysuria	1	3
Gross hematuria	1	3
Anaesthetic reaction	1	3
Post Treatment (up to 30 days):		
Serious adverse event	0	0
Dysuria	23	62
Urgency or pain	19	51
Gross hematuria	16	43
Urinary retention (requiring 48 h indwelling catheterisation)	1	3

Continuing from their first paper, Sotomayor and Bernal published a second paper of the same pilot clinical trial of RF micro-remodelling in women suffering SUI detailing 12 month post-procedure results (Sotomayor and Bernal 2005).

In this publication the authors reported the absence of any SAEs up to the 12 month follow-up in all four treatment groups. During the 6 and 12 month follow-ups a total of 8% of patients reported at least one episode of dysuria while 22% reported at least one episode of urgency. No further safety information was provided.

In a recently published paper Apell and colleagues report on a prospective, controlled randomised 12 month multicenter study on the safety and efficacy of RF micro-remodelling on women suffering SUI associated with bladder outlet hypermobility (Apell *et al.* 2006). Women were randomised to either a treatment (n = 110) or sham treatment (n = 63, with modified RF generator that did not delivery any RF emissions and a sham micro-remodelling probe with no electrodes). Women remained blinded to their treatment for the duration of



the study. The treated group had micro-remodelling of 36 targets from the bladder neck to the proximal urethra.

Using a treatment regimen based on that by Sotomayor and Bernal (2003) the investigators applied RF micro-remodelling to 36 microscopic, sub mucosal, circumferential targets from the bladder neck, cranially, to the middle aspect of the proximal urethra, caudally, to patients in the treatment group. The study utilised the Novasys Medical Inc. RF generator and the Curon Medical Inc. RF generator (Fremont, California).

During the 12 month study period no serious adverse events were reported, lending support to the 6 month and 12 month observations by Sotomayor and Bernal (2003). Other adverse events, however, were documented and are listed in Table 4. Although no adverse event was statistically significant more prevalent in one group than the other, the percentage of women who had experienced dysuria and a dry overactive bladder were 5.7 and 2.3 times more prevalent in the treatment group than in the sham group respectively. The statistical tests used in the study were not reported.

Table 4 12 Month Adverse Events

Adverse event	Number (%) of treatment group events (n=110)	Number (%) of sham group events (n=63)	P value
Dysuria	10 (9.1%)	1 (1.6%)	0.06
Hematuria	1 (0.9%)	0 (0%)	1.0
Urinary retention	1 (0.9%)	0 (0%)	1.0
Urinary tract infection	5 (4.5%)	3 (4.8%)	1.0
Hesitancy	0 (0%)	1 (1.6%)	0.4
Asymptomatic detrusor over activity	2 (1.8%)	4 (6.3%)	0.2
Dry overactive bladder	8 (7.3%)	2 (3.2%)	0.3
Wet overactive bladder	11 (10%)	6 (9.5%)	1.0

Efficacy

In the studies identified a variety of outcome measures were used to determine the efficacy of the Renessa system/RF micro-remodelling including the Incontinence Quality of Life



score (IQoL), frequency of incontinence episodes, pad usage and leak point pressure (LPP). Of these, IQoL was featured in all of the studies as a clinically significant outcome measure. In all studies an improvement in the IQoL score of at least 10 points (on the 100 point scale) was used as a measure of the effect of the Renessa system/RF micro-remodelling on women's quality of life. The 10 point or greater IQoL score improvement is associated with a reduction in stress pad weight and incontinence episode frequency of at least 25% and improved patient satisfaction leading to a perceived feeling of 'much better' following treatment (Lenihan 2005, Apell et al. 2006).

For the initial study conducted by Sotomayor and Bernal (2003) the IQoL score was used as the primary measure of efficacy and was 50.4 ± 16.2 ($n = 37$) at baseline for all four treatment groups (Table 2). The authors state that there were no statistically significant differences between treatment groups in baseline IQoL scores. However, it is notable that group I's mean baseline IQoL was approximately 10 points below that in the other group and an improvement of 10 is considered to be clinically relevant. At the 6 month follow-up IQoL score improvements of at least 10 points (compared to baseline) were demonstrated by the majority of patients across the four groups. No statistical tests for this primary outcome are reported. Tests are reported for the mean change from baseline, which show that only groups II and IV demonstrated statistically significant improvements from baseline, but this may be selective reporting of significant results (Table 5).

Table 5 Improvements in IQoL Scores Following RF Micro-remodelling Treatment

Group	Mean baseline IQoL	Mean 6 month IQoL	p value	Percentage of women with ≥ 10 point increase
I	44.1	54.3	0.40	63
II	53.9	76.6	0.004	78
III	54.9	66.4	0.08	70
IV	53.6	80.6	0.02	67

At the 6 month follow-up, 38% of group I, 22% of group II, 40% of group III, and 75% of group IV patients were 'dry' (no incontinence episodes and no pad usage in 3 months prior to 6 month follow-up). This was accompanied by a 50% or greater decrease in incontinent episodes for 38%, 56%, 50% and 78% of women in groups I, II, III and IV respectively. As with the IQoL improvements however statistically significant differences over baseline were only found in group II ($p < 0.05$) and group IV ($p < 0.05$). Additionally, women in group IV experienced a statistically significant decrease in pad use ($p < 0.04$) at 6 months.

Despite being able to demonstrate the effectiveness of RF micro-remodelling on IQoL the results of this study were not able to determine whether the number of lesions created was



associated with better improvements in quality of life or the occurrence of incontinence episodes. Moreover, an association between lesion site and patient improvement was also not able to be determined, although considering the lesion sites in groups II and IV and the above results it is possible that micro-remodelling of the submucosa within the vesicourethral junction and proximal urethra may be required to obtain best results.

Unfortunately, a lack of control patients as well as the relatively low number of patients in each treatment group and lack of urodynamic data cannot eliminate the possibility that the improvements observed were not at least partially due to the placebo effect. Additionally because no urodynamic data were taken, there is the possibility that women suffering mixed incontinence rather than SUI may have accidentally enrolled in the study, thus potentially impacting on the results observed.

Despite the shortcomings of the initial experiment's 6 month results, the authors published 12 month follow-up results two years later (Sotomayor and Bernal 2005).

At the 12 month follow-up, the majority of women in all groups except group II experienced a ≥ 10 point increase in IQoL score over baseline and all groups except group I experienced a significant improvement in mean IQoL scores over baseline (Table 6).

Table 6 12 Month IQoL Score Improvements Following RF Micro-remodelling Procedure

Group (n)	Mean \pm SD 12 month IQoL improvement	p value	Percentage of women with ≥ 10 point increase
I (8)	23 \pm 29	NS	63
II (9)	16 \pm 21	0.05	44
III (10)	17 \pm 22	0.04	70
IV (9)	24 \pm 27	0.03	67

Incontinence episode frequency (IEF) and 'cure' (no incontinence episodes and no use of pads between the 6 and 12 month follow-ups) was also evaluated (Table 7). At 12 months groups I, II and IV experienced statistically significant IEF reductions over baseline ($p < 0.05$).



Table 7 12 Month IEF Reduction and Cure

Group (n)	% of women with any IEF reduction	% of women with $\geq 50\%$ IEF reduction	% of women cured
I (8)	88	63	40
II (9)	67	67	22
III (10)	70	70	40
IV (9)	89	89	67

As with the 6 month results, the 12 month results did not provide sufficient data to show the superiority of any one treatment in achieving the most desirable outcomes. However, considering all four treatment groups involved micro-remodelling of sites within the proximal urethral submucosa it is possible that micro-remodelling of this area may be necessary required for effects to be seen, although further investigation would be required.

The 12 month prospective, controlled, randomised study by Apell and colleagues in which patients received either RF micro-remodelling or a sham treatment evaluated the degree to which RF micro-remodelling improved IQoL scores by at least 10 points and LPP at 6 and 12 months following the procedure (Apell *et al.* 2005).

Following the procedure, which took approximately 20 minutes per patient (no mean or median time reported) patients were asked to indicate their level of pain and discomfort by circling a number ranging from 0 (no pain) to 10 (terrible pain) on a Lickert VAS. Patients in the treatment group recorded a mean VAS score of 1.3 ± 1.9 (range: 0 to 8) with 51% of them indicating a pain and discomfort level of zero. Compared to patients in the sham group the mean VAS scores were not statistically different from each other (mean sham group VAS scores not reported) indicating that RF micro-remodelling itself may not be the cause of any discomfort but rather the procedure.

At the 12 month follow-up 142 patients (89 from treatment group and 53 in sham group) (approximately 80%) were available for IQoL analysis. Twenty-nine patients were excluded due to loss of follow-up or protocol violations and so the analysis is not performed on the full intention-to-treat population. Forty-eight percent of women in the treatment group compared to 44% of women in the sham group demonstrated ≥ 10 point improvement in IQoL at 12 months ($p = 0.7$).

The second measure of efficacy used in this study, LPP, was available for 78% of patients and showed a statistically significant difference between the two groups at the 12 month follow-up. At the 12 month period, women in the treatment group experienced a mean increase in LPP of 13.2 ± 39.2 cm H₂O over the baseline level, while women in the sham group experienced a reduction of 2.0 ± 33.8 cm H₂O over baseline levels in the same period of time ($p = 0.022$). This improvement in LPP, an objective measure, not only supports the



IQoL results of this and previous studies but also provides evidence that the proposed mechanism of incontinence treatment on which RF micro-remodelling is based is valid.

Although published before the randomised, controlled trial by Apell *et al.* (2006), Lenihan (2005) taking into account that regions of the lower urinary tract are affected during both menopause and RF micro-remodelling conducted a retrospective analysis of the study sample in Apell *et al.* (2006) to investigate the impact of menopausal status and hormone replacement therapy (HRT) on quality of life improvements 12 months following treatment.

A comparison in twelve month incidence of ≥ 10 point IQoL improvement between post-menopausal women undergoing HRT and post-menopausal women not undergoing HRT revealed no statistically significant difference, suggesting HRT status may not significantly impact the therapeutic effect of RF micro-remodelling. Similar results comparing pre-menopausal versus post-menopausal women taking HRT, pre-menopausal versus post-menopausal women not taking HRT, and pre-menopausal versus post-menopausal (regardless of HRT status) women were also observed, suggesting that menopausal status also does not significantly impact the therapeutic effects of RF micro-remodelling.

However, it must be noted that although statistically significant differences were not observed in any of the above comparisons, the small numbers of patients in each comparative group may not have been sufficiently large enough to detect any significant differences.

Ethical Issues

No issues were identified from the retrieved literature.

Cultural or Religious Considerations

No issues were identified from the retrieved literature.

Other Issues

No issues were identified from the retrieved literature.

Conclusion:

The available evidence regarding the Renessa system and its method of action (RF micro-remodelling) so far points towards some favourable outcomes for patients undergoing this treatment. Although no serious adverse events were reported in any of the studies presented, less serious minor clinical events were reported, such as an elevated incidence of dysuria among treated patients during the study periods in the RCT by Apell *et al.* (2006). Further long term studies to establish the long term safety and efficacy of the device are required. It is therefore recommended that the following be conducted:



Horizon Scanning Report

Full Health Technology Assessment

Monitor

Archive

HealthPACT recommendation:



References:

Apell RA, Juma S, Wells WG, Lenihan JP, Klimberg IW, Kanellos A, Reilley SF. Transurethral radiofrequency energy collagen micro-remodeling for the treatment of female stress urinary incontinence. *Neurourology and Urodynamics* 2006; 25(4): 331-336.

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Search Criteria:

A search of MEDLINE, PubMed, *The Cochrane Library*, the Current Controlled Trials metaRegister, the UK National Research Register, the International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in August 2006.

Search terms used were:

'Renessa', 'Renessa system', 'Novasys', 'Novasys Medical', 'female stress urinary incontinence', 'radiofrequency female stress urinary incontinence', 'RF female stress urinary incontinence', 'radiofrequency micro-remodelling', 'RF micro-remodelling'.

This Horizon Scanning Prioritising Summary was prepared by Mr. Luis Zamora from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).