

restore the pelvic floor



A non-invasive, safe and effective treatment that improves pelvic floor muscle contraction and diminishes urine loss in pelvic floor disorders¹

innovo[®]
RESTORE THE FLOOR

“INNOVO® has changed my life for the better. I no longer have ‘the fear’ and don’t have to use liners anymore.”

Anne B, 51 years, lived with mixed incontinence for 10 years



Pelvic floor disorders can adversely affect quality of life

- Pelvic floor disorders occur when the muscles supporting pelvic organs such as the bladder become weak or damaged
- Pelvic floor disorders can cause embarrassment and adversely affect quality of life, as a weak pelvic floor or an inability to properly contract the pelvic floor can often be root causes of urinary incontinence
- It is currently estimated that **over 5 million women in the UK experience the symptoms of urinary incontinence** and of these, half of all sufferers aged between 18 and 65 years of age are moderately or greatly bothered by it²
- **About one third of women experience urinary incontinence after giving birth, and over 65% of these women are still affected by it 12 years later³**
- **23% of women with urinary incontinence say that it reduces their activity level; 23% state that it adversely affects their sex life; and 31% dress differently because of their symptoms²**
- Whilst pelvic floor disorders mainly affect women, they can also affect men

1 in 3

women can be affected by urinary incontinence during their lifetime



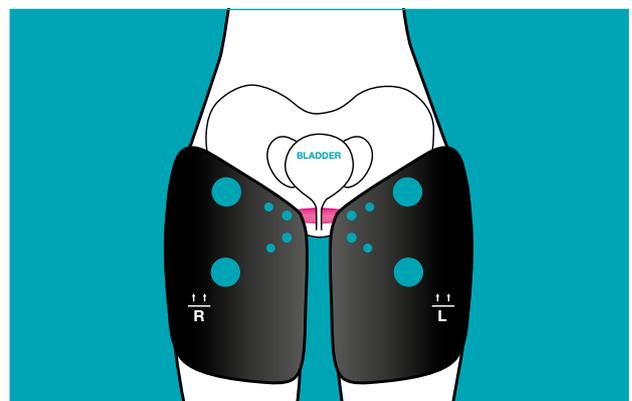
Innovotherapy, a highly effective treatment for urinary incontinence

INNOVO® has been developed by Atlantic Therapeutics*, a leading innovator in muscle conditioning and strengthening products, with a 50-year history of delivering effective, clinically proven restorative health solutions in muscle rehabilitation and conditioning.

INNOVO® has been developed to treat the root causes of urinary incontinence and Innovotherapy is the name of the treatment it delivers. It features two treatment programmes, **one that focuses on improving pelvic floor muscle contraction and the other on calming an overactive bladder.** Depending on the type of urinary incontinence (stress, urge or mixed), patients and their healthcare clinician can choose the most appropriate programmes and parameters.

Innovotherapy is a non-invasive, safe and effective form of electrical muscle stimulation. It is clinically proven to improve pelvic floor muscle contraction and diminish urine loss in pelvic floor disorders.¹

Using an INNOVO® hand-held controller that is attached to a two part wearable garment, Innovotherapy produces highly focused, accurately coordinated and effective pelvic floor muscle contractions that help rehabilitate the pelvic floor musculature. Targeted impulses are sent via conductive pads producing over 180 perfect contractions per session. Users can actually feel their entire pelvic floor muscles being "lifted" without having to do any voluntary activation.



INNOVO® stimulates the nerve tree as it branches throughout the pelvic floor

For those using Innovotherapy to treat:

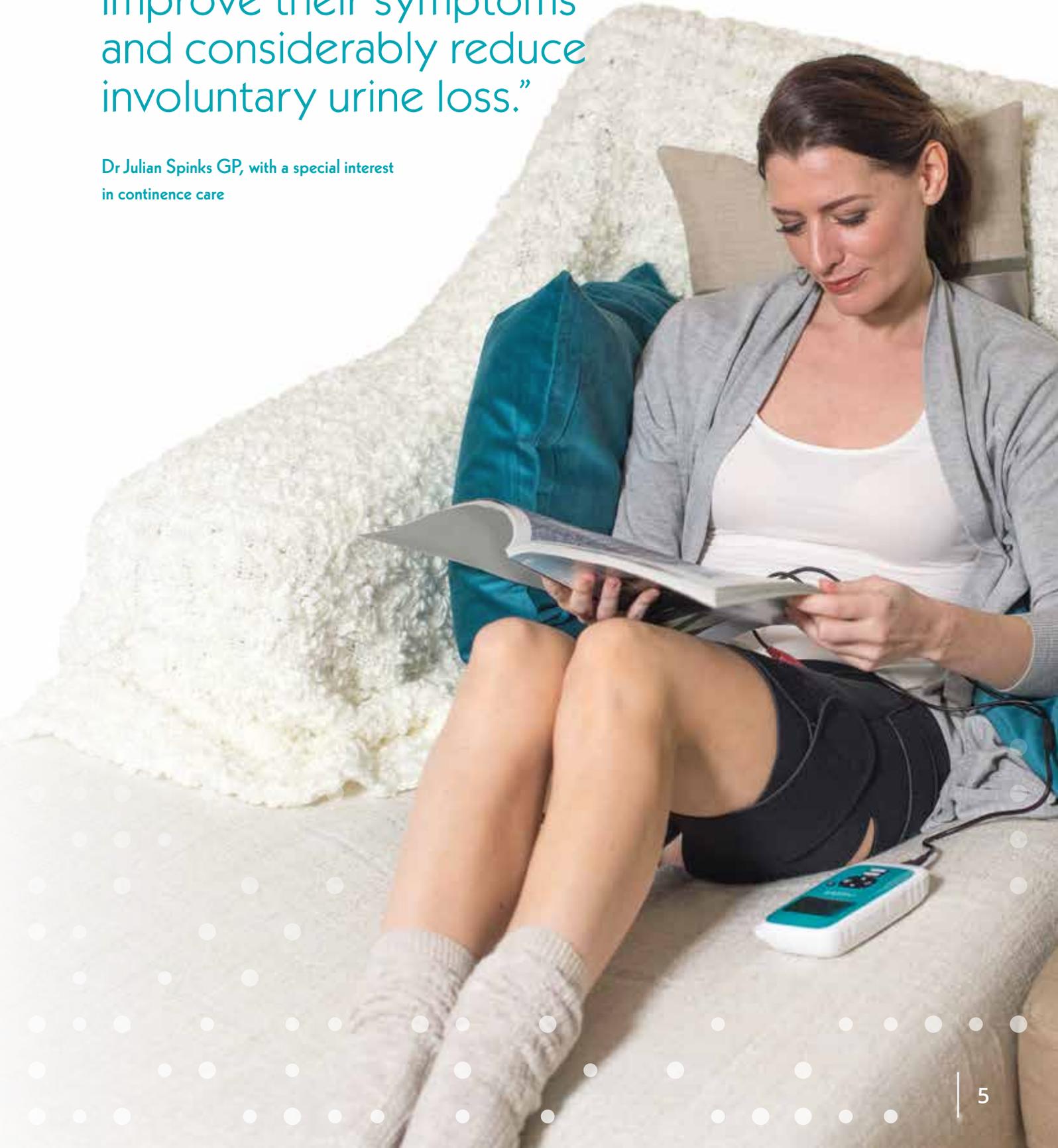
- Stress incontinence, it will strengthen the pelvic floor
- Urge incontinence, it will help calm an overactive bladder
- Mixed incontinence, it will alternate the stress and urge treatment to strengthen and calm

*Atlantic Therapeutics is the Uro/Gynaecology Division of Bio-Medical Research Limited (BMR)



“INNOVO® offers an innovative, non-invasive solution to women, enabling them to improve their symptoms and considerably reduce involuntary urine loss.”

Dr Julian Spinks GP, with a special interest in continence care



Innovotherapy decreases urinary loss

A 26-week pilot study of women with stress urinary incontinence who followed the Innovotherapy treatment regimen found significant improvement in their symptoms:

1-hour stress test

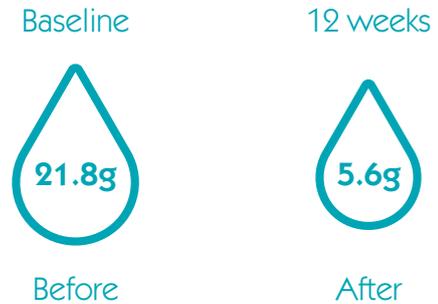
Average urine loss — weight of pad



A significant improvement in the amount of involuntary urine leaked in **93% of INNOVO® users** after 4 weeks of treatment, where **60% were defined as dry**.¹

24-hour test

Average urine loss — weight of pad



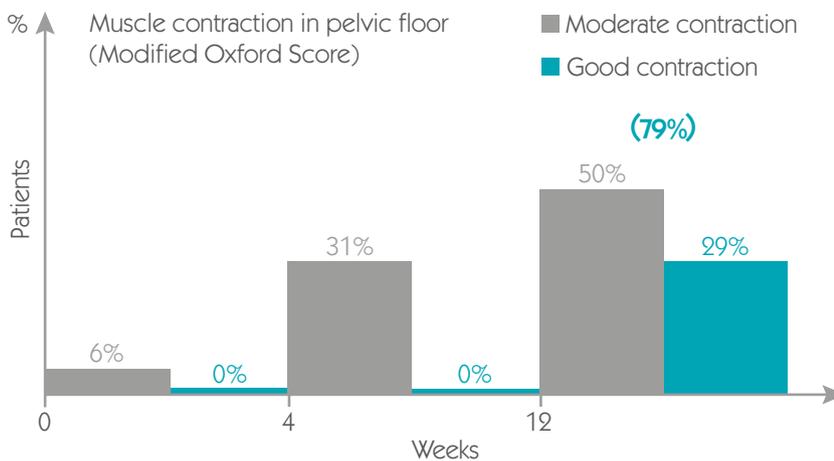
An average **74% reduction** in involuntary urine loss over 24 hours after 12 weeks of treatment, where **86% of INNOVO® users were defined as dry or almost dry**.¹

Innovotherapy improves muscle contractility

The study with patients who followed Innovotherapy for 12 weeks showed:

- An improvement in the Modified Oxford Score (standing position) after treatment with Innovotherapy, where **79% of patients had good or moderate pelvic floor muscle contractions at 12 weeks**, compared with 6% at baseline¹

Improvement in contractility upon treatment



Patients' pelvic floor muscle contractility improved over 12 weeks of INNOVO® treatment

Ultrasound imaging performed on patients throughout the application of Innovotherapy for 8 weeks showed:

- An increase in the ability to volitionally contract the pelvic floor while standing, for all patients (below), which resulted in cranial encroachment on the bladder by the pelvic floor muscle⁴
- Patients had better awareness of the pelvic floor at cessation of stimulation⁴



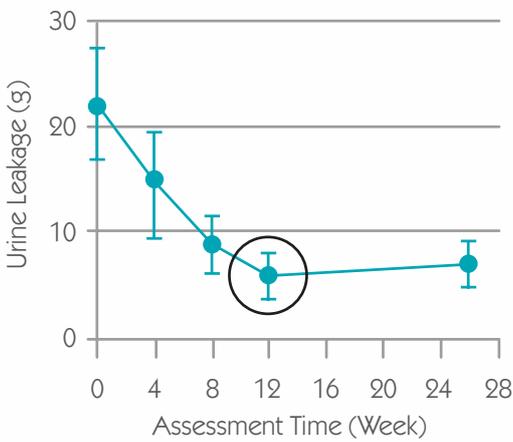
a. Pelvic floor muscle (PFM) at rest followed; **b.** attempt at volitional pelvic floor contraction which results in Valsalva and caudal motion (arrow down); **c.** PFM at rest; **d.** PFM contraction elicited by INNOVO® while standing, resulting in cranial encroachment of PFM on the bladder (arrow up).

Adapted from Maher *et al*, 2012.⁴

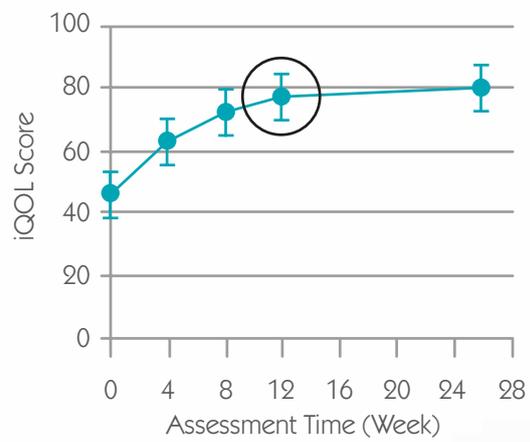
Innovotherapy significantly improves quality of life

- An improvement in incontinence quality of life score after 12 weeks of treatment with **Innovotherapy** compared with baseline (mean score 47 at baseline compared with 81 at 26 weeks)¹

Improvement in 24-hour pad weight test
Patient scores



Improvement in incontinence quality of life
Patient scores



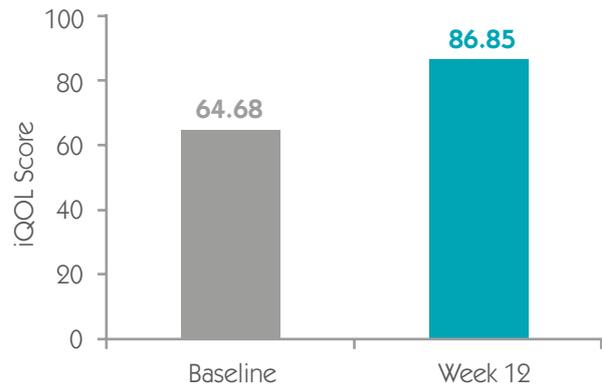
Treatment with Innovotherapy significantly improves the quality of life scores and reduces urine leaks over a 26-week period



A prospective observational study on the impact of Innovotherapy on urinary incontinence and quality of life, in which 48 patients from four French therapy centres participated for a period of 12 weeks, showed:

- **An improvement in incontinence quality of life score after 12 weeks of treatment with Innovotherapy** compared with baseline (mean score 64.68 at baseline compared to 86.85 at 12 weeks)⁵

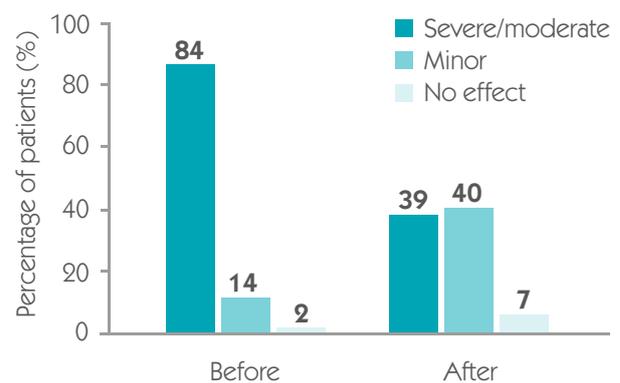
Incontinence quality of life scores improves over a 12 week period

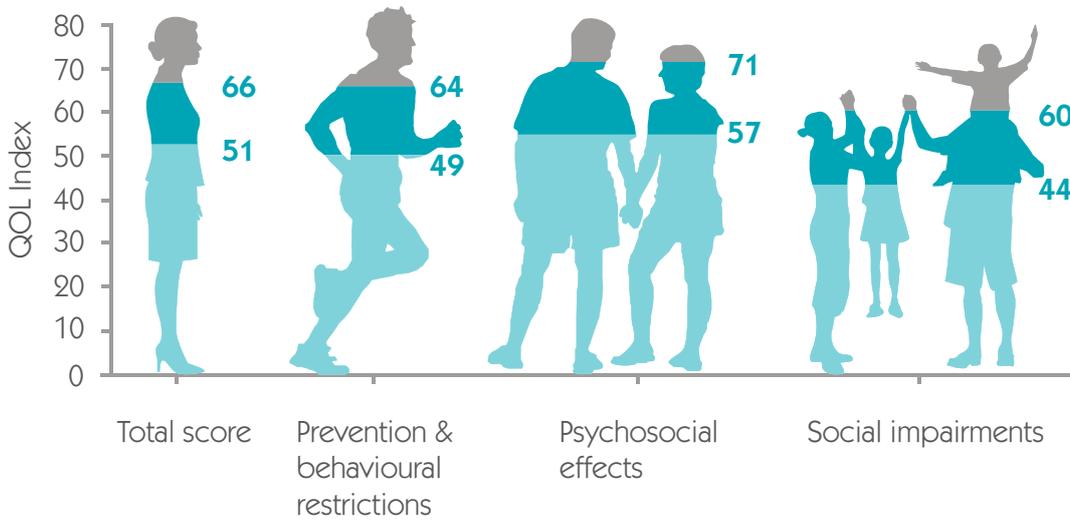


An observational study on the impact of Innovotherapy on urinary incontinence and quality of life, in which 104 patients from 25 German therapy centres participated for a period of 14 weeks, showed:

- **A significant reduction in the proportion of patients whose everyday lives were severely or moderately affected by urinary incontinence** and a consequent increase in patients only mildly affected by it⁶

Reduction of severe and moderate impact of urinary incontinence upon everyday life following Innovotherapy treatment



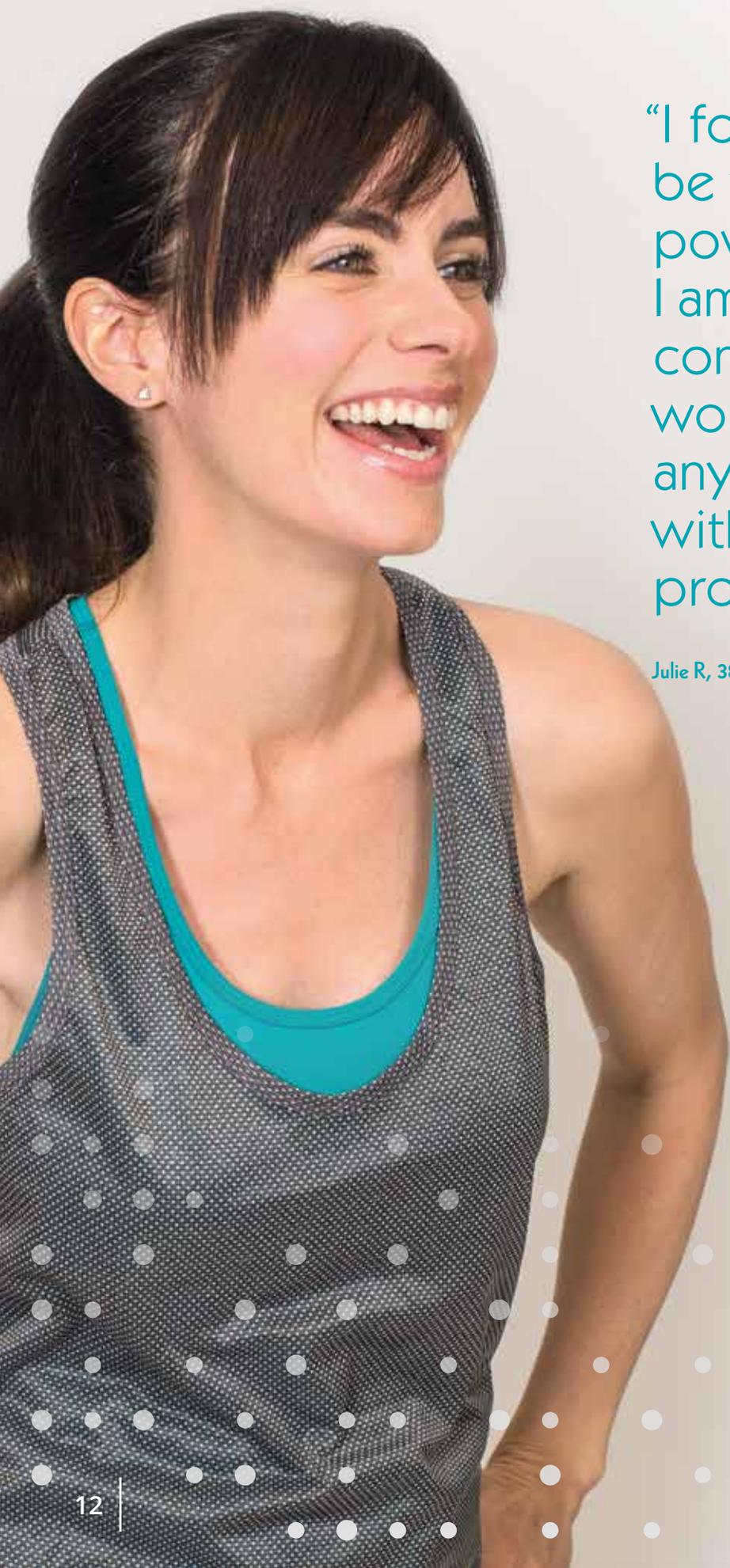


- On this scale, **the quality of life index has improved from 51 to 66 points** (average of points) with similar improvements in the individual domains of 'prevention and behavioural restrictions', 'psychosocial effects', and 'social impairments'⁶

“INNOVO® has changed my life,
I can play with my children again.”

Melinda, 34, young mum



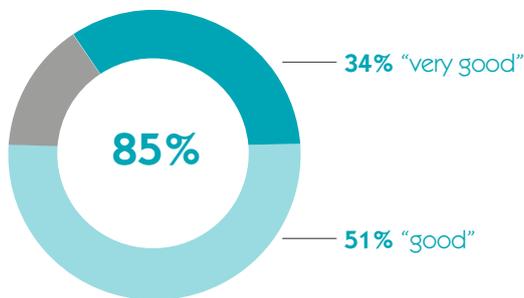


“I found the device to be very user-friendly, powerful and effective. I am now running with confidence, and I would recommend it to anyone who is suffering with incontinence problems.”

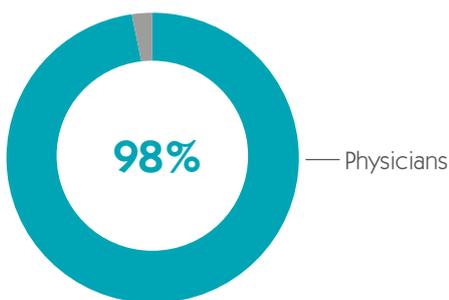
Julie R, 38

Good compliance with Innovotherapy, and recommended by doctors

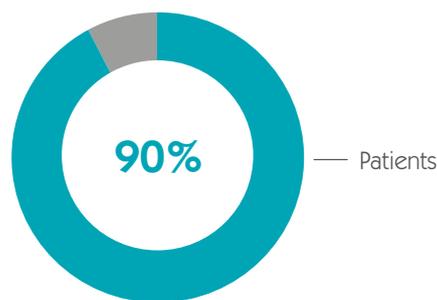
- Very good (34%) or good (51%) compliance with Innovotherapy in 85% of patients as perceived by the doctors participating in the study⁶



- Clinician and patient satisfaction when prescribing and using Innovotherapy



98% of physicians would recommend INNOVO[®] to colleagues (n=60)⁶



90% of patients would recommend INNOVO[®] to others (n=86)⁶

Benefits to patients

INNOVO® is highly effective

- **After 4 weeks of treatment, 93% of users showed 'significant improvement'** (greater than 50% reduction) in the amount of involuntary urine leaked and 60% were defined as dry¹
- **After 12 weeks of treatment, 86% of subjects were defined as 'dry' or 'almost dry'** with an average reduction of 74% in the amount of involuntary urine lost over 24 hours¹
- **An improvement in incontinence quality of life score was seen after 12 weeks of treatment with Innovotherapy** compared with baseline (mean score 47 at baseline compared to 81 at 26 weeks)¹

The results from INNOVO® observational studies confirm that:

- The quality of life of users significantly improves after treatment with the device
- Male patients can benefit as much as females
- Doctors, physiotherapists and patients alike would all recommend Innovotherapy⁶

INNOVO® is safe

- INNOVO® has been extensively tested and approved by all relevant European safety authorities
- When used in accordance with instructions, Innovotherapy is safe and has no known side-effects (see list of contraindications and warnings)
- **Over half a million treatments have already been completed by thousands of patients across Europe**

INNOVO® is comfortable

- INNOVO® is a garment based, non-invasive device. No invasive vaginal or anal electrode probes are involved
- It offers a comfortable and convenient treatment experience in the privacy of the patient's own home
- Stimulation intensity can be easily and precisely adjusted for each individual user and for each application
- The INNOVO® garment is made of breathable and skin-friendly material
- It is available in various sizes (Small, Medium and Large) to suit a wide range of male and female shapes

INNOVO® can be used by a wide range of patients

- Innotherapy can be widely used and offers a wide range of benefits to post-pregnancy, sporty, pre and post-menopausal as well as post-prostatectomy patients experiencing urinary incontinence

Post-pregnancy	Sporty Women	Menopause	Post-Prostatectomy
Restore the floor			
Effective solution, home based therapy, non-invasive, accurate, strengthen, prevention			

- Innotherapy can be fine-tuned to meet the patient’s needs and requirements. Three types of treatment regimens are available to treat stress, urge and/or mixed incontinence

Stress Incontinence

Mon	Tue	Wed	Thur	Fri	Sat	Sun
Prog. 1	Off	Off				

Urge Incontinence

Mon	Tue	Wed	Thur	Fri	Sat	Sun
Prog. 2	Off	Prog. 2	Off	Prog. 2	Off	Off

Alternate use of stress and urge programmes every other day to obtain a mixed schedule

Mon	Tue	Wed	Thur	Fri	Sat	Sun
Prog. 1	Prog. 2	Prog. 1	Prog. 2	Prog. 1	Prog. 2	Off

INNOVO® offers stress, urge and mixed incontinence treatment programmes

Restoring the pelvic floor, control and confidence

- INNOVO® actively treats the primary cause of urinary incontinence
- INNOVO® is clinically proven to improve muscle contractility, urinary loss and quality of life
- INNOVO® is a non-invasive, safe and effective treatment for pelvic floor disorders

References

- 1) Soeder S, Tunn R. Neuromuscular electrical stimulation (NMES) of the pelvic floor muscles using a non-invasive surface device in the treatment of stress UI (SUI); a pilot study. IUGA Poster Presentation Conference, 2013; Dublin, Ireland.
- 2) Eneil S. Incontinence and prolapse. In: *Annual Report of the Chief Medical Officer*: 2014. p. 122–123.
- 3) MacArthur C, Wilson D, Herbison P, Lancashire RJ, Hagen S, Toozs-Hobson P, et al. UI persisting after childbirth: extent, delivery, history, and effects in a 12-year longitudinal cohort study. *International Journal of Obstetrics and Gynaecology* 2015 (Epub ahead of print).
- 4) Maher RM, Caulfield B. A novel externally applied neuromuscular stimulator for the treatment of stress UI in women – a pilot study. *Neuromodulation* 2013; 16(6): 590-594.
- 5) Bio-Medical Research (BMR) Health. Summary results: NT Vital compact French registry study (n=48), September 2015.
- 6) Bio-Medical Research (BMR) Health. Results: observational study on the treatment of stress, urge and mixed incontinence using NEUROTECH VITAL™, April 2013 - February 2014.

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