

Results of Randomised Controlled Trial of Bulkamid® versus Tension-free Vaginal Tape Published

January 2020: Contura is pleased to report that the 1 year results of the 1st ever randomised controlled trial (“RCT”) to compare the effectiveness and safety of patients with stress urinary incontinence (“SUI”) treated with Bulkamid to those treated with Tension-free Vaginal Tape (“TVT”) have been published in The Journal of Urology.

This investigator-initiated trial was conducted at the Helsinki University Central Hospital in Finland, a global centre of excellence for SUI and other pelvic floor surgeries. With 224 patients recruited into the study, the results showed that Bulkamid achieved similar levels of patient satisfaction compared to TVT with regard to the median visual analogue scale scores, and that almost all peri-operative complications and all serious complications at 1-year were associated with the tension-free vaginal tape operation. The authors conclude that Bulkamid can be offered as 1st line treatment post conservative measures in women with primary stress urinary incontinence. More details on the study can be found at <https://www.ncbi.nlm.nih.gov/pubmed/31479396>.

Commenting on the results, Ieva Ankorina Stark, Chief Scientific Officer of Contura said: ***“This is a 1st of its kind study. With a subjective cured and improved rate of 92% and an average patient satisfaction VAS score of 85 out of 100, this independent randomised controlled trial provides strong evidence that Bulkamid should be offered to as a 1st choice for the women with primary SUI.”***

These study results come at a time where the use of TVT’s for SUI is coming under increasing scrutiny with an adverse safety profile emerging from all over the world.

Rakesh Tailor, Director of Contura commented: ***“There is a degree of patient apprehension with the currently available treatments for SUI. With its excellent safety and effectiveness profile, Bulkamid represents a 1st line treatment for women with SUI. These patients should be presented with the options available to them and when weighing up the benefits with the risks, the evidence shows that the majority of women prefer Bulkamid.”***

About Bulkamid

Bulkamid is a soft hydrogel that consists of 2.5% polyacrylamide and 97.5% water. Once injected, Bulkamid provides additional volume to the urethra and acts as a scaffold for cells to grow through, helping to provide long lasting relief of SUI symptoms.

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About Female Stress Urinary Incontinence

SUI is very common among women of all ages and increases with age. Other contributing factors include childbirth, obesity or some form of a pelvic floor disorder. SUI is caused by a weakness in the pelvic floor, preventing the urethra (the tube that urine comes out of) from closing fully when sudden pressure is put on the bladder. This can allow urine to leak out during normal daily activities for example when coughing, laughing, walking or exercising.

About Contura

Contura is headquartered in London and has its manufacturing facility in Copenhagen, Denmark. It specialises in the distribution and sale of healthcare products, both pharmaceuticals and medical devices, focused primarily in women's health. Its lead products are Bulkamid[®], Aquamid[®], Regurin[®] XL and Cystistat[®]. It also has a number of ongoing development programmes focused upon additional uses of its proprietary hydrogel technology, such as Arthrosamid[®] for the treatment of osteoarthritis in the knee. Contura has an established sales and marketing infrastructure in the leading European and worldwide markets, either through its own sales force or through distribution partners. It has its own offices in the UK, Denmark, Germany, France and Italy, currently employing around 50 staff worldwide.

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