MODIFIED “REMEEX” RE-ADJUSTABLE SLING PROCEDURE: 2 YEARS FOLLOW UP – OUTCOMES AND SAFETY PROFILES.

Hypothesis / aims of study
Besides recent achievements in the treatment of stress incontinence (SUI) with mid-urethral sling procedures, 15 – 25% of patients remain incontinent and up to 10% develop voiding dysfunctions. The effectiveness of surgeries decreases if they are performed in the recurrent cases. Unfortunately, most of slings don’t allow readjustment of its position/tension after the initial placement. In contrary, modified “Remeex” re-adjustable sling procedure not only allow for immediate adjustment of the position/tension of the sling in closest to physiological conditions but also allow for delayed re-adjustment in case of failure. Aim of the study was to investigate the outcomes and safety profiles of modified TRT (Tension Free Re-adjustable Tape, Remeex, Neomedic) for the treatment of primary and recurrent SUI.

Study design, materials and methods
150 consecutive women with urodynamically confirmed SUI undergone TRT - Remeex procedure. Patients were with primary as well as recurrent stress urinary incontinence. Length of the follow up was between 2 to 24 months after the surgery. We used objective measures (cough test, UD) and patients’ self-reported impression of improvement.

Results
TRT - Remeex procedure was modified with placement of the regulator under the abdominal fascia but over the rectus muscles instead of recommended by company supra-fascial placement. Prior to use of modified technique, 2 patients developed infectious abscess in the site of implanted regulator. In first patient 2 weeks after implantation and in second patient 2 months after implantation. One patient developed rejection of the regulator with aseptic abscess 18 months after implantation. In all patients the regulator was removed and sling sutures were tied without tension over the abdominal fascia. That allowed preserving continence in these patients. After modification and sub-fascial TRT – Remeex placement, there were no cases of infection or regulator rejection. 98% of patients with primary TRT – Remeex placement/adjustment were considered to be cured. They didn’t have SUI symptoms and didn’t demonstrate SUI signs. 2% of patients required delayed re-adjustment and were cured of SUI thereafter. There were no cases of urinary retention. There were no cases of any intra-operative complications.

Concluding message
Modified TRT – Remeex mid-urethral re-adjustable sling procedure is highly effective and safe in patients with SUI, including cases recurrent stress urinary incontinence. Modified sub-fascial TRT – Remeex placement allowed significant reduction of the device infection/rejection rate.

References
1. “Externally Readjustable Device to Regulate Sling Tension in Stress Urinary
2. “Long-Term Evaluation of Safety and Efficacy of the ContaSure (Remeex) Female Adjustable

Specify source of funding or grant  None
Is this a clinical trial?  No
What were the subjects in the study?  HUMAN
Was this study approved by an ethics committee?  No
This study did not require ethics committee approval because  Not investigational device or comperative study. Just follow up collection data
Was the Declaration of Helsinki followed?  Yes
Was informed consent obtained from the patients?  Yes