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## Study Summary

# Temporary Implantable Nitinol Device for Benign Prostatic Hyperplasia-related Lower Urinary Tract Symptoms: Over 48-month Results

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**Amparore D, De Cillis S, Schulman C, Kadner G, Fiori C, Porpiglia F**


## Conclusion

iTind™ device provided significant and durable symptom reduction and improved IPSS-QoL for >48 months post treatment. No late postoperative complications were reported beyond 36 months of follow-up. Surgical re-treatment rate for >36 months was 4%.


## Objective and Indication

To follow up on the >48-month (50-79 months) results of patients treated with iTind device for lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).

## Design

**Prospective, single-arm, Multicenter, International Clinical Study**

Assessment at baseline, 1, 3, 6 months, 12, 24, 36 and >48 months postoperatively. OR-time, pain, postoperative complications, functional results (IPSS, Qmax, PVR, QoL), sexual and ejaculatory function (two yes/no questions) were assessed up to 36 months. >48-month outcomes are assessed via IPSS, IPSS-QoL, change in medication, need for surgical re-treatment and adverse events.

## Subjects

81 men with symptomatic benign prostatic obstruction (BPO) and IPSS ≥10, Qmax <12ml/s, prostate volume <75ml were originally enrolled. Fifty out of these 81 (62%) patients at 3/9 sites (Italy, Switzerland, and Belgium) continued the follow-up beyond 36 months. Due to the COVID-19 pandemic, the over 48-month follow-up was amended: Each patient was assessed once during 50-79 months postoperatively telephonically.

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## Results

- >48 months results were available for 41 patients: 5 subjects were lost to follow-up and 2 died (unrelated to iTind™ device placement). Two subjects required surgical re-treatment (1 TURP; 1 ThuLEP).
- iTind device treatment showed significant improvement in symptoms: IPSS was reduced by 45.3% (P<0.0001) and IPSS-QoL improved by 45.1% (P<0.0001) from baseline to 79 months post-procedure; with a mean±SD of 11.26±7.67 and 2.10±1.41 points, respectively.
- No complications occurred from 36 up to 79 months and no patient required additional medication.

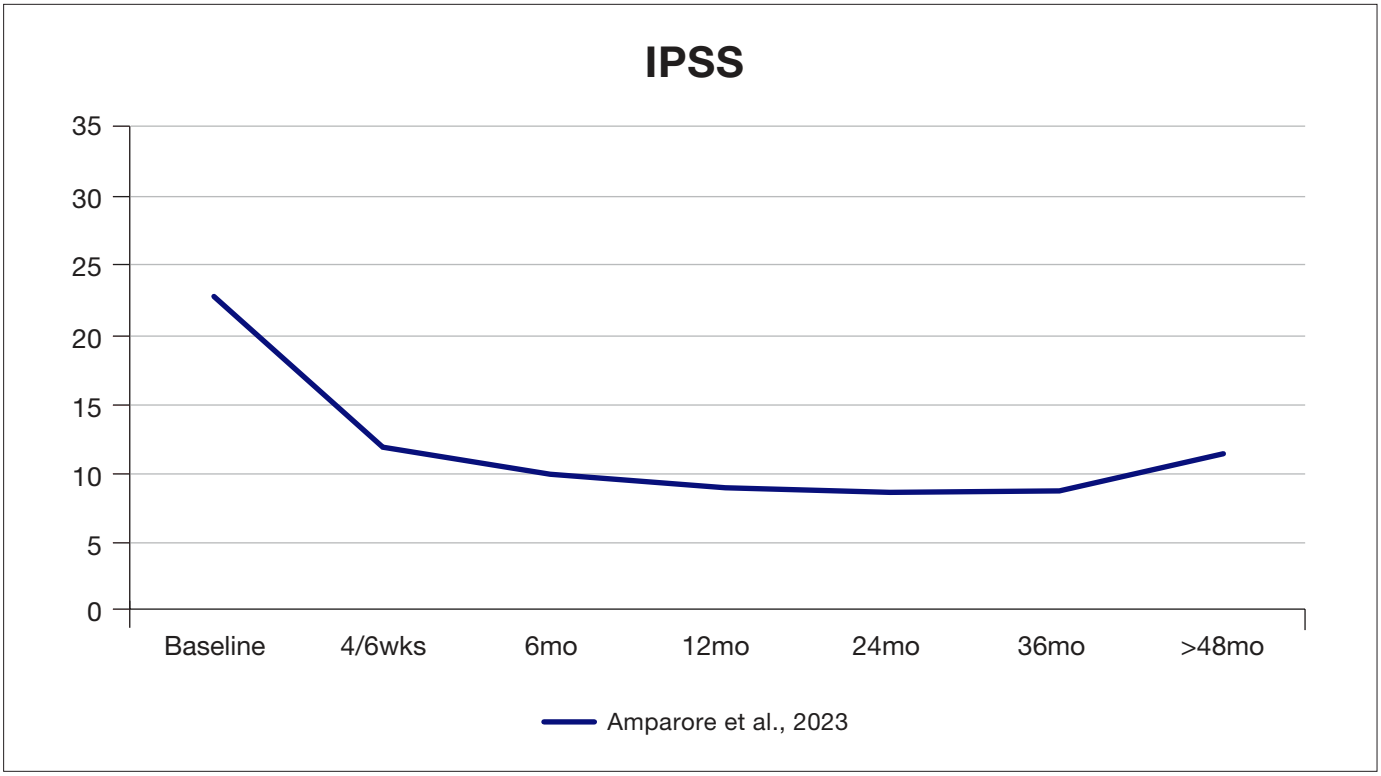


**Figure 1:** Improvement of IPSS over time. ITT analysis set. OPEN ACESS LINK*

* Graph created by Olympus, based on the data in the given publication.

Implantation of the iTind™ device may cause urinary urgency, pelvic discomfort, dysuria or hematuria. In rare cases, the iTind™ device may cause urinary tract infection or acute urinary retention.



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