PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

TVT-World Wide Observational Registry for Long-Term Data

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The objective of this observational study is to obtain long -term clinical and patient reported outcomes on the use of the GYNECARE family of TVT (Tension-Free Vaginal Tape) systems in women with stress urinary incontinence.

Brief Summary in Scientific Language

Sites may include patients with either the GYNECARE TVT SECUR System, GYNECARE TVT System, or the GYNECARE TVT Obturator System

Organizational Data

- DRKS-ID: **DRKS00003987**
- Date of Registration in DRKS: **2012/06/18**
- Date of Registration in Partner Registry or other Primary Registry: **2007/03/28**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT00453739 (ClinicalTrials.gov)**
- Sponsor-ID: **300-06-006 (Ethicon, Inc.)**

Health condition or Problem studied

- Free text: **Stress Urinary Incontinence**
- ICD10: **R32 - Unspecified urinary incontinence**

Interventions/Observational Groups

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **[---]***
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **[---]***
- Assignment: **[---]***
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Standing cough stress test; time frame: 12 months

Secondary Outcome

- I-QOL score; time frame: 3, 6, 12 and 24 months

Countries of recruitment

- AU **Australia**
- AT **Austria**

- CA **Canada**
- DE **Germany**
- KR **Korea, Republic of**
- SG **Singapore**
- ZA **South Africa**
- UK **United Kingdom**
- US **United States**

Locations of Recruitment

- **Universitatsfrauenklinik, Tubingen**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2007/02/27**
- Target Sample Size: **1407**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Inclusion Criteria:

- Women diagnosed with SUI who are suitable candidates for a TVT system, as according the relevant Instructions for Use (IFU).

Exclusion criteria

[---]*

Addresses

- **Primary Sponsor**

  Ethicon, Inc.

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Scientific Queries**

  Ethicon, Inc.
  David Robinson, MD

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Public Queries**

  Ethicon, Inc.
  David Robinson, MD

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

  Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2010/06/01**

Trial Publications, Results and other documents

- Trial results **Tincello DG, Botha T, Grier D, Jones P, Subramanian D, Urquhart C, Kirkemo A, Khandwala S; TVT Worldwide Registry Investigators. The TVT Worldwide Observational Registry for Long-Term Data: safety and efficacy of suburethral sling insertion approaches for stress urinary incontinence in women. J Urol. 2011 Dec;186(6):2310-5. doi: 10.1016/j.juro.2011.07.078. Epub 2011 Oct 20.; 22014817**