Medtronic

Protocol# COVSYMB0441:

Observational Registry Study for Symbotex™ Composite Mesh in Ventral Hernia Repair

Statistical Analysis Plan

Version 1.0 [Final]
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I. Definition of Analysis Set

The Full Analysis set will be created for study purpose. Data are entered in routine in the Club Hernie database. Principal investigator sends periodically datasnapshot, for registry follow-up and/or for statistical analysis purpose.

From the global database, N=100 consecutive patients (date of surgery) operated with Symbotex™ **composite** mesh for Ventral Hernia Repair and satisfying the following criteria will form the Full Analysis Set (FAS):

- patients informed by surgeon with a written information notice of the nature of the observational registry study
- age ≥ 18 years of age
- Date of surgery ≥ 25JUN2014

The Full Analysis Set will be used for Primary and Secondary endpoints measurement (combining Performance and Safety parameters).

II. General Methodology

Statistical analysis will be descriptive.

- Continuous variables will be summarized using descriptive statistics, specifically the mean, standard deviation, median, minimum and maximum.

- Categorical variables will be summarized using frequencies and percentages.

For each parameter, the number of missing values will be reported.

Subject disposition and follow-up, as well as Demographic and Baseline characteristics of patients will be described, additionnaly to primary and secondary endpoints, as defined below.

III. STUDY ENDPOINTS DEFINITION AND MEASURES

a. Primary Endpoint

Primary endpoint focus on complications (including recurrence) occuring during procedure, and in short, mid and long-term following ventral hernia repair. More precisely primary endpoint includes:

1. Peri-operative complications
2. Post-operative complications such as anticipated device related complications as pain, recurrence, complications related to adhesions, wound complications, other postoperative complications, SAEs…
3. All complications

b. Secondary Endpoint(s)

Secondary endpoints include descriptive analysis of the following parameters, measured during surgery procedure and/or during the whole follow-up (up to 24 months):

1. Surgical technique and mesh fixation
2. Operative time
3. Ease of use / mesh manipulability assessment by surgeons

4. Length of hospital stay
5. Quality of life and patient satisfaction
6. Surgeon satisfaction
7. VAS (pain) score

Parameters related to hernia and mesh characteristics will be measured on any hernia (one or more, repaired with Symbotex™ composite mesh), or any Symbotex™ composite mesh (one or more) used on patients from Full Analysis Set.

IV. INTERIM ANALYSES

4 interim analyses will be run for communication purpose, according the following calendar:

- September 2014
- February 2015
- August 2015
- August/September 2016

V. REPORTING OUTPUT

All outputs will be produced using SAS® version 9.2.
Tables and listings will be produced as PDF files and Courier New font size 9 bold or upper

Outputs will be ordered in the order that they appear in the textual sections of the plan i.e. disposition outputs first, followed by protocol deviations, baseline outputs, compliance outputs, effectiveness outputs and safety outputs.

The listings will be ordered by site, subject and visit as applicable, unless otherwise stated.