# PROTOCOL

SU017

## A 3 Years Naturalistic Cohort Survey Of Altis® Single Incision Sling System For Female Stress Urinary Incontinence

A post-marketing and multicenter prospective observational cohort study in subjects with female stress urinary incontinence

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Final Version 1.2

## > SYNOPSIS OF THE PROTOCOL

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|---|---|
| **TITLE** | A 3 Years Naturalistic Cohort Survey Of Altis® Single Incision Sling System For Female Stress Urinary Incontinence<br>A post-marketing and multicenter prospective observational cohort study in subjects with female stress urinary incontinence |
| **SPONSOR** | Coloplast Manufacturing France SAS.<br>C.A.La Boursidière<br>Hall Poitou<br>92567 LePlessis-Robinson, France |
| **DEVICE** | Altis Single Incision Sling System |
| **STUDY TYPE** | Post-market and prospective observational cohort study of subjects implanted with the Altis SIS for female stress urinary incontinence |
| **OBJECTIVES** | **Main study objective**<br>To monitor the use of Altis Single Incision Sling in a real world population.<br>To assess the clinical effectiveness (defined by the treatment success rate) and to monitor safety of Altis SIS at 12 months post device implantation in women with stress urinary incontinence.<br>Success will be regarded as optimal if the PGI-I score is rated as very much or much or a little improved and no severe/serious event has been reported.<br>**Secondary objectives**.<br>To assess the clinical effectiveness of Altis SIS over the 3 years post device implantation follow up in real subject population<br>To explore pre-surgery prognosis factors of effectiveness and failure<br>To explore impact of Altis SIS on quality of life<br>To explore impact of Altis on sexual life<br>To document emergent device-related adverse events and safety over the 3 years post device implantation |
| **POPULATION** | **Target Subject Population**<br>All subjects meeting selection criteria will be invited to participate in the registry. Participating sites are required to do their best efforts to document in the registry all enrolled subjects including those with early revision of the sling for any reason. |

**Inclusion criteria**

1. Female gender
2. At least 18 years of age.
3. Subject implanted with Altis Single Incision Sling System in the participating center, to manage Urinary Incontinence according to Urologist's diagnosis
4. Subject having received written and oral information about study objectives and having accepted that anonymous data issued from his medical dossier will be used for research purposes and will be analyzed by using computer systems. According to national regulations, a written consent to participate may be required.

**Non-inclusion criteria**

1. Subject who refuses to be included in the survey or that their medical data will be used for research purposes.
2. Indication for Altis Single Incision Sling System implantation is not for the treatment of female UI.
3. Subject already enrolled in any investigational clinical trial of any treatment (drug or device).

**Study Sample Size**

The total number of subjects enrolled is not limited. However, a minimum of 150 subjects with 12-month available data will be collected. Taking into account a global attrition rate of 20%, 180 patients are targeted for enrolment.

## CENTERS

The participating centers will include sites from at least 4 countries across Europe. The study may include sites from France, Germany, Italy and Spain but the number of countries is not limited to these countries.
Around 40 surgeons (5 cases by surgeons) are expected internationally but the number of centres that will be involved in the study is not limited.

## STUDY DESIGN

This project will be launched after the first introduction of Altis in Europe. This study is a multicenter prospective, non-interventional (i.e. naturalistic) Post-Marketing cohort follow-up of women with urinary incontinence implanted with Altis Single Incision Sling System. Patients will be recruited by specialised surgeons (urologists, gynaecologists or uro-gynaecologists) who are experienced to the implantation of Altis. They will be followed for 12 months in routine real world clinical practice except for administration of subject questionnaire(s). Routine visits will be performed approximately at baseline (peri-operative period), between 1 and 3 months (immediate post-operative period) and 12 months. An annual follow-up, each year during 2 additional years will also performed via postal questionnaires.

## DATA COLLECTION

Clinical data will be collected at baseline (preoperative and implantation), and post-operatively at each visits usually scheduled by the

surgeons. The data will be captured in an electronic data capture system (EDC).

The Data Collection Schedule below provides an outline of the desired types of clinical and subject data expected to be collected at each visit.
None of these exams are mandatory. If they are performed results will -be collected in the EDC.

| | Baseline | Operative period | First Immediate postoperative visit (2 Months ± 1 Mo)[1] | 12 Months visit (1 year ± 2 Mo)[1] | Yearly follow-up (until 3 years) |
|---|---|---|---|---|---|
| Informed consent obtained | X | | | | |
| Demographic information, urogynecologic history | X | | | | |
| Body Mass Index | X | | | X | X |
| Urodynamics/Uroflowmetry *(history)* | X | | | | |
| Urethral mobility & Prolapse anatomy | X | | | | |
| **Physician –rated assessments** | | | | | |
| Stress urinary & overactive bladder symptoms | X | | X | X | X |
| Cough stress test | X | | X | X | X[2] |
| Post void residual urine volume | X | X | X | X[3] | |
| Adverse Event assessment | | X | X | X | X |
| **Patient-reported outcomes** | | | | | |
| Number of pad/day | X | | X | X | X |
| ICIQ-UI SF & I-QOL & PISQ12 | X | | X | X | X |
| PGI-I | | | X | X | X |
| Subject satisfaction | | | X | X | X |

1 windows are given for information

2 not requested if data are obtained only by mailed questionnaires

3 not requested if the previous value is normal