Observational Study of the GORE® TAG® Thoracic Endoprosthesis in the treatment of diseases of the thoracic aorta

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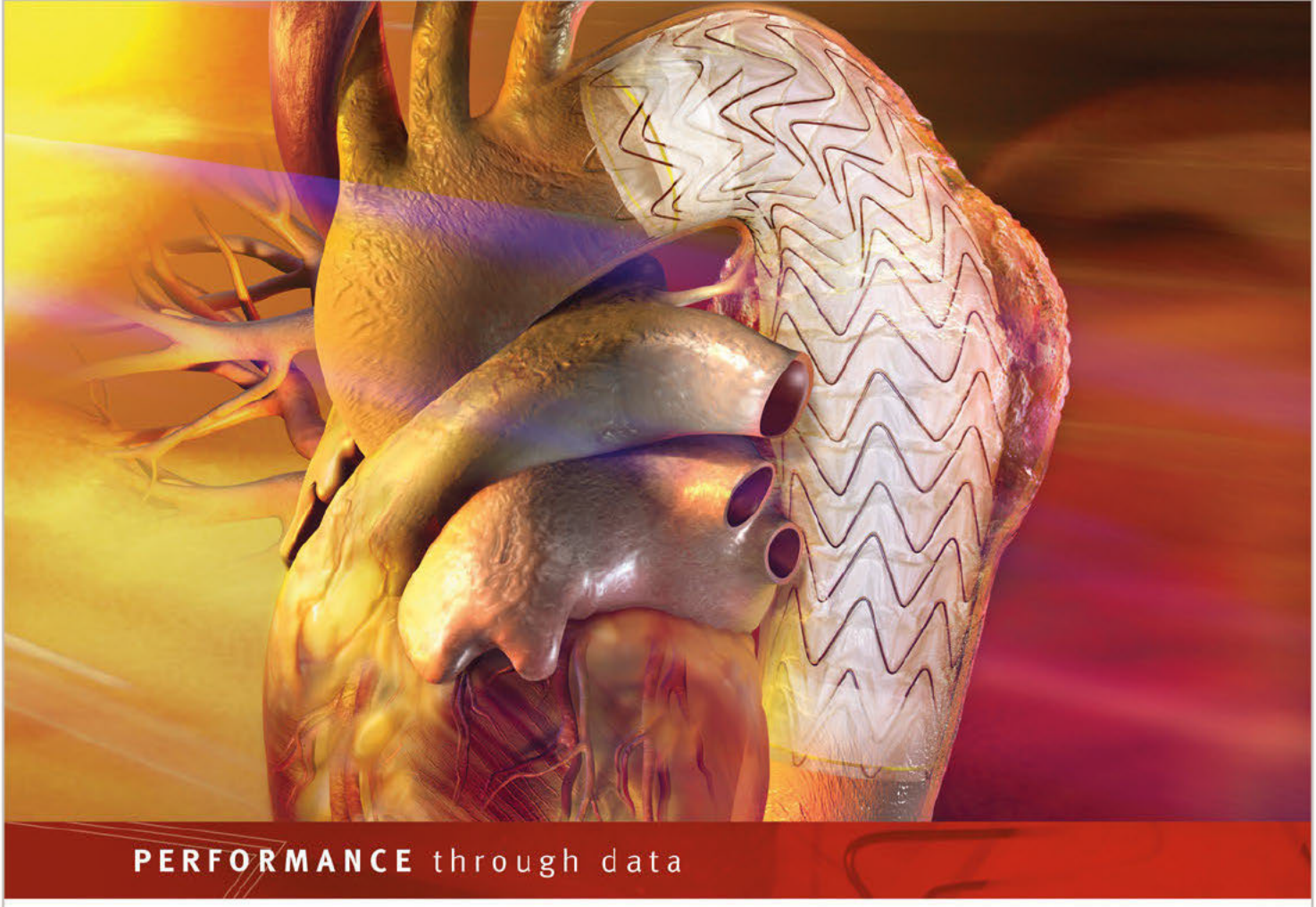
W. L. Gore & Associates, Inc.
Medical Products Division



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Observational Study of the GORE® TAG® Thoracic Endoprosthesis in the treatment of diseases of the thoracic aorta

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Observational, Prospective, Multicenter Study

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TABLE OF CONTENTS

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SUMMARY

Title

Observational Study of the GORE® TAG® Thoracic Endoprosthesis in the treatment of diseases of the thoracic aorta

Basis

The endoprosthetic treatment of diseases of the thoracic aorta, including aneurysms, dissections, penetrating ulcers and isthmus rupture, seems to provide a plausible benefit compared to surgery in terms of operative mortality and severe morbidity. However, there is inadequate data on the long-term outcome of such endoprostheses. This is why the French National Health Authority requires a 5-year follow-up as part of the reimbursement renewal process for these endoprostheses. This long-term observational study was established for this reason.

Methodology of the observational study

A French-language, prospective, multicenter, non-randomized, single-arm, open-label observational study.

Study device

The devices included in the observational study are the GORE® TAG® and Conformable GORE® TAG® Thoracic Endoprostheses, including any newer models [redacted]

Study population

Enrollment criteria:

- Any patient with a GORE® TAG® or Conformable GORE® TAG® Thoracic Endoprosthesis implant (successful or otherwise) for the treatment of a descending thoracic aortic disease.
- Patients who have previously consented to the collection and use of their personal medical information.
- 18 years or older at the time of treatment.

Exclusion criteria:

- Patients who have already received treatment with a thoracic endoprosthesis other than the GORE® TAG® and the Conformable GORE® TAG® Thoracic Endoprostheses and for whom a “revision” or repeat intervention is required.
- Patients whose clinical follow-up is not possible (e.g., patients who cannot return for control visits because they live abroad).

All eligible patients and those requiring treatment with the study endoprosthesis will be candidates for enrollment in this observational study. A patient shall be considered as

enrolled once the device, or any accessory associated with the implantation of the device, enters into the vascular system.
Provided that the patient has consented to the collection of his or her medical data by signing an informed consent form, a registry of patients who were treated with the endoprosthesis but were not included in the study will be set up at each participating center so as to document the following information: reason for non-inclusion, age, gender, presence of a life-threatening emergency, main indication for implantation, and date of implantation. For patients who refused the collection of their personal data, only the reason for non-inclusion and the date of implantation will be documented.

Number of centers and patients

A total of 160 patients shall be included in this registry, consecutively if possible.

[redacted]

Primary endpoint

The primary endpoint will be:

- The all-cause mortality rates over the long term, that is 5 years.

The 5-year mortality is defined for all deaths occurring between the time of surgery when the endoprosthesis was inserted into the arterial access and the last follow-up visit at 5 years. In the absence of a standard population, the primary endpoint will be analyzed depending on the urgency of the procedure as defined by the Scientific Committee such as:

- Existence of an aortic rupture
- Dissection complicated by malperfusion

Secondary endpoints

The secondary endpoints for assessing the usefulness of the technique at different follow-up visits (after surgery or in the month following the surgery, at 1 year, then each year thereafter) shall be:

- The exclusion rate of the aneurysm, the penetrating aortic ulcer, the false lumen or rupture site, with no endoleak, regardless of type
- The rate of neurological complications
- The rate of cardiac, renal and pulmonary complications
- The rate of device-related complications
- The rate of surgical conversion
- The rate of secondary procedures
- The rate of mortality related to the disease

A report will be submitted each year to the French National Health Authority.

Duration of the observational study

- Enrollment period for the 160 patients: 24 months
- Follow-up period for each patient: 5 years
- Total duration of the study: 7 years (84 months)

Follow-up of the observational study

The schedule and procedures for monitoring the patients included in this study shall conform with the recommendations of the French National Health Authority[2], namely annual monitoring by CT scan or MRI + X-ray for 5 years.

Monitoring schedule and procedures recommended by the French National Health Authority:

	Post-operative follow-up (D1 to D30)	**Follow-up at 1 year**	**Follow-up at 2 years**	**Follow-up at 3 years**	**Follow-up at 4 years**	**Follow-up at 5 years**
Clinical evaluation	X	X	X	X	X	X
CT scan *or* MRI + X-ray	X	X	X	X	X	X

This is an observational study, therefore there is no requirement for any specific examination or procedure outside the scope of practice of each center. This schedule and the monitoring procedures may be alleviated based on future recommendations.

Regulatory aspects

Before any patient is enrolled, this study will be subject to various required reviews and authorizations in compliance with existing regulations.

Patient information

This is an observational study; the investigator shall inform the patient about the nature and objectives of the data collection and answer all of the patient's questions. An informational note has therefore been prepared for the patients, informing them of their

rights, before their enrollment in the study. In addition, all participating patients must sign a consent form authorizing the study sponsor to collect and process their medical data in accordance with existing regulations.

Compliance with the protocol

Investigators are requested to limit the number of patients lost to follow-up insofar as possible. Deaths, neurological, cardiac, renal and pulmonary complications, as well as repeat interventions and surgical conversions should be reported to the sponsor as soon as possible via the electronic Case Report Form.

Data collection

All required data shall be provided by the centers via a secure electronic Case Report Form (eCRF) within the time limit. [redacted]

[redacted]

Database records

The study will be recorded in a public European or international database.

1 GENERAL INFORMATION

1.1 Introduction

As per the current state of evidence, the endoprosthetic treatment of diseases of the thoracic aorta, including aneurysms, dissections and isthmus rupture, seems to provide a plausible benefit in terms of operative mortality and severe morbidity, subject to a rigorous mid-term evaluation [average rate of paraplegia 2.1% (range: 0 to 7%) with endoprostheses versus 5% (range: 3 to 15%) with surgery].
Conventional treatments are surgical treatment on the one hand and/or medical treatment, on the other hand. Surgical treatment requires major surgery with initiation of a cardiopulmonary bypass and can only be provided to patients who can tolerate the surgical risk. Medical treatment mainly consists of managing the hypertension.
The therapeutic strategy varies depending on the disease concerned:

Aneurysm of the thoracic aorta:
The benchmark treatment is open surgery with implantation of the prosthesis after initiation of a cardiopulmonary bypass.
The rates of surgical morbidity and mortality are different in the elective and emergency treatments, specifically in terms of the risk of spinal cord ischemia, resulting in paraparesis or paraplegia. The operative mortality rates of descending thoracic aorta aneurysms in elective surgery vary between 6% and 15%, and are significantly higher in emergency surgery. The risk of paraparesis or paraplegia is estimated between 3% and 15%.[3]

The major complications are as follows[3] (about 5% each):

- Bleeding requiring secondary surgical revision
- Respiratory failure with prolonged respiratory aid
- Acute renal failure
- Central neurological events (stroke and coma)
- Peripheral neuropathies (sensorimotor deficits, paraparesis, paraplegia)
- Infections

The contraindications to surgery are patients over 80 years old, chronic respiratory failure, renal failure, coronary artery diseases and generalized diseases (neoplasia, etc.).[3]

Thoracic aortic dissections:
The benchmark treatment differs, depending on whether it is a type A dissection (ascending aorta origin) or a type B dissection (descending aorta origin). Type A dissections require emergency surgical treatment. For uncomplicated type B dissections, antihypertensive medical treatment is the benchmark treatment. In the event of complications, surgery is indicated. Contraindications to surgical treatment are mainly related to older patient age and cardiorespiratory issues. Acute hemiplegia or mesenteric infarction of more than 6 hours are also contra-indications for surgery[2]. In the acute phase, mortality rates for surgical treatment range between 20 and 35% and medullary complications between 10 and 20%.

Aortic isthmus ruptures and penetrating ulcers:
In the event of trauma to the thoracic aorta, the use of a thoracic aortic endoprosthesis can be especially useful for patients with multiple traumas who are often not candidates for open surgery. Their lesions can be treated with the GORE® TAG® and Conformable GORE® TAG® Thoracic Endoprostheses as a substitute for surgical treatment.

However, the data on the long-term outcome of such endoprostheses has been deemed as inadequate by the French National Health Authority (HAS). This has caused the HAS to subject any renewal for inclusion on the list of reimbursable products and services (LPPR) to the implementation of an observational follow-up study on a cohort of patients representative of the population treated under real-life conditions, with a 5-year follow-up. [redacted]

1.2 Information about the observational study device

The devices included in the observational study are the GORE® TAG® and Conformable GORE® TAG® Thoracic Endoprostheses, including any newer models [redacted]

1.2.1 Description of the GORE® TAG® Thoracic Endoprosthesis

The GORE® TAG® Thoracic Endoprosthesis is intended for the endovascular repair of the descending thoracic aorta. One or more GORE® TAG® Thoracic Endoprostheses may be used, depending on the area being treated.

[redacted]

Description of the Conformable GORE® TAG® Thoracic Endoprosthesis

The GORE® TAG® Thoracic Endoprosthesis is intended for the endovascular repair of the descending thoracic aorta. One or more GORE® TAG® Thoracic Endoprostheses may be used, depending on the area being treated.

1.2.2 Terms of use and prescription recommended by CNEDiMTS

The implantation of the GORE® TAG® and/or Conformable GORE® TAG® Thoracic Endoprostheses must be conducted in accordance with the recommendations[2] made by the French National Health Authority (HAS) specifically:

- The implantation must be performed in centers with expertise in both endovascular and surgical treatments, and with adequate technical equipment
- The implementation of a multidisciplinary study, in particular on the risk of surgical conversion and the possible use of a cardiopulmonary bypass (CPB)
- Verification of the presence of a proximal neck at least 2 cm long, allowing for the insertion of the endoprosthesis
- The need to inform patients of the benefits and disadvantages of the available repair techniques, such as open-heart surgery and endo-aortic prosthesis (EAP).
- Annual monitoring by CT scan or MRI + X-ray

The follow-up of patients in a prospective observational study is requested by CNEDiMTS. The data from this study on the implantation and monitoring of the GORE® TAG® and the Conformable GORE® TAG® Thoracic Endoprostheses will be required on renewal of registration.

2 PLAN OF THE OBSERVATIONAL STUDY

2.1 Goals of this study

The purpose of this study is to evaluate the usefulness of the technique in terms of the efficacy and safety of use of the GORE® TAG® and Conformable GORE® TAG® Thoracic Endoprostheses at 5 years, on a cohort of patients representative of the population treated under real-life conditions.

2.2 Endpoint criteria

2.2.1 Primary endpoint criteria

The primary endpoint will be:

- The all-cause mortality rates over the long term, that is 5 years

The 5-year mortality is defined for all deaths occurring between the time of surgery when the endoprosthesis was inserted into the arterial access and the last follow-up visit at 5 years. In the absence of a standard population, the primary endpoint will be analyzed depending on the urgency of the procedure as defined by the Scientific Committee such as:

- Existence of an aortic rupture
- Dissection complicated by malperfusion

2.2.2 Secondary endpoint criteria

The secondary endpoints assessing the usefulness of the technique at different follow-up visits (after surgery or in the months following the surgery, at 1 year, 2 years, 3 years, 4 years and 5 years) will be:

- The exclusion rate of aneurysm, of penetrating aortic ulcer, of false lumen or site of rupture, with no endoleak, as defined above
- The rate of neurological complications
- The rate of cardiac, renal and pulmonary complications
- The rate of device-related complications
- The rate of surgical conversion
- The rate of secondary procedures
- The rate of mortality related to the disease

Definitions:

- Migration: movement evaluated on a workstation with 3D reconstruction according to the reference examination (1st post-op imaging examination)
  - Proximal movement > 10 mm or ≤ 10 mm with coverage of a branch of the supra-aortic trunks
  - Distal movement > 10 mm or ≤ 10 mm with coverage of the celiac trunk
- Exclusion of the aneurysm:
  - No type I or type III endoleak associated with the lack of increase in the maximum diameter of the aneurysm sac > 5 mm (reference examination 1st post-operative examination)
- Exclusion of the penetrating ulcer:
  - No type I or type III endoleak associated with the lack of increase in the maximum aortic diameter compared to the ulcer > 5 mm (reference examination 1st post-operative examination)
- Exclusion of rupture site:
  - No type I or type III endoleak
- Exclusion of the false lumen (dissection):
  - Exclusion of the main entry of the dissection
  - Thrombosis of the false lumen at the endoprosthesis

- Mortality from thoracic disease is defined as any death occurring as a result of complication of aortic disease (rupture, conversion, etc.) or following any surgery intended to treat the aortic disease.

2.3 Study population

160 patients presenting with thoracic aorta disease that is amenable to the endovascular treatment of such disease with the GORE® TAG® and/or Conformable GORE® TAG® Thoracic Endoprostheses will be included in the study, consecutively if possible. The eligibility criteria will be limited in order to best represent the population treated under real-life conditions.

[redacted]

[redacted]

2.4 Outline of the observational study

This is a French-language, prospective, multicenter and non-randomized observational study. 160 patients shall be included consecutively in randomized user centers, which means that patients who are eligible for the implantation of the GORE® TAG® and Conformable GORE® TAG® Thoracic Endoprostheses who have previously signed a consent for the collection and processing of their medical data shall be included. This observational study does not change the usual schedule of patient care and monitoring. Potential limitations and biases: This observational study was designed to reduce the biases related to observational studies in the following ways:

- Its prospective nature and the requirement of a consecutive recruitment of patients in order to avoid any patient screening bias in the centers.
- The establishment of a non-inclusion register will document any patient who was not included in the study and will specify the reasons for the non-enrollment in order to detect any bias at this level.
- Since current legislation does not allow for mandatory data collection, any enrollment at a center may only be done on a voluntary basis. Therefore, a potential bias may exist at this level as is the case with all observational studies.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

2.7 Duration of the study

The duration of the study will be determined by the duration of recruiting 160 consecutive patients within 30 potential investigation centers.

- Enrollment period for the 160 patients: 24 months
- Follow-up period for each patient: 5 years
- Total duration of the study: 7 years (84 months)

3 PATIENT SELECTION

3.1 Enrollment criteria

- Any patient with a GORE® TAG® or Conformable GORE® TAG® Thoracic Endoprosthesis implant (successful or otherwise) for the treatment of a descending thoracic aortic disease.
- Patients who have previously consented to the collection and use of their personal medical information.
- **18 years or older at the time of treatment.**

3.2 Exclusion Criteria

- Patients who have already received treatment with a thoracic endoprosthesis other than the GORE® TAG® and the Conformable GORE® TAG® endoprostheses and for whom a "revision" or another intervention is required.
- Patients whose clinical follow-up is not possible (e.g., patients who cannot return for control visits because they live abroad).

All eligible patients requiring treatment with the endoprosthesis of the observational study will be candidates for enrollment in this study. A patient shall be considered as included in the observational study once the device, or any accessory associated with the implantation of the device, enters the vascular system.
Provided that the patient has consented to the collection of his or her medical data by signing an informed consent form, a registry of patients who were treated with an endoprosthesis but who were not included will be established in order to document the following information: reason for non-inclusion, age, gender, presence of a life-threatening emergency, main indication for implantation, date of implantation.
For patients who did not want their personal data to be collected, only the reason for non-inclusion and the date of implantation will be documented.

[redacted]

5 CONDUCTING THE OBSERVATIONAL STUDY

5.1 Schedule of visits

The schedule and procedures for monitoring the patients included in this study adhere to the recommendations of the French National Health Authority[2], namely annual monitoring by CT scan or MRI + X-ray for 5 years.
During this observational study, there will be no requirement for any specific examination or procedure outside the scope of practice of each center.
The monitoring schedule and procedures may be alleviated based on future recommendations.
Monitoring schedule and procedures recommended by the French National Health Authority:

	Post-operative follow-up (D1 to D30)	**Follow-up at 1 year**	**Follow-up at 2 years**	**Follow-up at 3 years**	**Follow-up at 4 years**	**Follow-up at 5 years**
Clinical evaluation	X	X	X	X	X	X
CT scan *or* MRI + X-ray	X	X	X	X	X	X

Note: Centers are requested to adhere to the visit schedule to the best of their ability. This adherence to schedule is essential for a scientific analysis of results. However, some centers may follow a different follow-up protocol (different intervals, less invasive tests such as Echo-Doppler) if no anomaly was found in the previous examination.

Investigators are requested to limit the number of patients lost to follow-up insofar as possible. If a patient misses a clinical and/or radiological follow-up, the investigator is asked to contact the patient by all possible means in order to optimize data collection. At each clinical assessment, the investigator must interview the patient (neurological, cardiac, renal and pulmonary exams) and ensure that the patient has not had any surgery since the last assessment.

5.2 Data to be collected

Data collection in the case report form can commence only after the patient has read the informational note and signed an informed consent form authorizing the collection and transmission of personal data. Data should be collected in the electronic case report form (eCRF) as soon as possible. The duly completed forms must be reviewed and signed by the investigator or any authorized individual.

[redacted]

All data related to the patient's admission, implantation procedure, post-operative hospitalization period and follow-up period (5 years) must be collected.
Any source document (surgical report, radiological examinations, laboratory tests, death certificate, etc.) submitted to the sponsor must be anonymized and bear the patient's study identification number.

These forms must be filled out for each patient:

▪ 1. Pre-operative period	▪ To be completed for each patient in order to describe his/her medical history and health status at the time of admission.
▪ 2. Implantation	▪ To be completed for each patient in order to describe the implantation procedure.
▪ 3. Post-operative period	▪ To be completed for each patient in order to describe the period between surgery and discharge from the hospital.
▪ 4. Follow-up	▪ To be completed for each follow-up visit (post-operative visit, follow-up at 1, 2, 3, 4 and 5 years). An intermediate follow-up form must be filled out for any additional assessment of either the patient or the endoprosthesis.
▪ 5. Exiting the observational study	▪ To be filled out for each patient at the completion of the study and at the end of data collection or to document any premature termination of the follow-up visits (patient lost to follow-up, patient's death, withdrawal of consent, etc.).

Forms to be completed at the onset of an event

▪ 6. Occurrence of a Serious Adverse Event	▪ To be filled for each patient at the onset of a serious adverse event (see GCP/ICH)
▪ 7. Repeat intervention	▪ To be filled out during any repeat vascular intervention (secondary endovascular or surgical procedure).
▪ 8. Complication	▪ To be completed at the onset of a complication (see paragraph E3).

Table 2: Data collection

Data	*CRF Pre-op.*	*CRF Implantation*	*CRF Post-op.*	*CRF Follow-up*	*CRF SAE*	*CRF Repeat intervention*	*CRF Study Exit*
Consent	✓						
Eligibility criteria	✓						
Imaging tests	✓		✓	✓			
Clinical history	✓						
Assessment of disease(s) and diagnosis(es)	✓						
Implantation		✓					
Information on the device used		✓					
Post-operative assessment			✓				
Post-operative follow-up at D1-D30, 1, 2, 3, 4 and 5 years				✓			
Onset of complications		✓	✓	✓	✓		
Repeat vascular intervention						✓	
Surgical conversion						✓	✓
Lost to follow-up							✓
Death					✓		✓
Lost to follow-up/ abandon							✓

Table 2 summarizes all the data that will be collected as part of this prospective observational study. This is not an exhaustive list. Please refer to the final electronic Case Report Form (eCRF).
Provided the patient has consented to the collection of his or her medical data by signing an informed consent form, a registry of patients treated with an endoprosthesis but not included in the study will be established at each participating center to document the following information: reason for non-inclusion, age, gender, presence of a life-threatening emergency, main indication for implantation and date of implantation. For patients who refused the collection of their personal data, only the reason for non-inclusion and the date of implantation will be documented.
A general form could be created for this purpose in the case report form that must be completed by the investigator throughout the study for each patient who was eligible but not included.

5.3 Adverse events

According to the primary and secondary endpoints of this study, the documentation of the adverse events shall consist of:
Adverse events related to the device and the procedure, regardless of their severity (severe side effects or not)
serious adverse events such as:

- Pulmonary complications
- Neurological complications of the central and peripheral nervous systems
- Vascular complications
- Cardiac complications
- Renal complications
- Visceral complications
- Infectious complications
- Any complication resulting in the patient's death

Imaging abnormalities, the notes/technical facts behind the clinical outcomes
These complications must be documented throughout the study; they will appear in the patient's medical record and will be collected in the form of Serious Adverse Events in the electronic Case Report Form. This form must be completed for each adverse event specific to the study, regardless of the severity or causality of the event. The information contained in this form shall include, among others, a description of the event, the date of occurrence of the event, the causal link with the device, the procedure, the measures taken and the evolution of the event.

Once informed, the investigator shall immediately send a comprehensive report of these complications to W.L. Gore & Associates, Inc. via the electronic data collection case report form, or eCRF.

5.4 End of patient participation

5.4.1 Procedure to withdraw from the study

The withdrawal procedure from the study applies when patient data are no longer collected. Discontinuation of patient data collection will occur in the following cases:

- The patient decides to withdraw from the study at any time, for whatever reason, without having to justify such a decision
- Decision made by the doctor to stop the patient's participation in the study in order to protect the patient's well-being
- Patient lost to follow-up
  Note: the patient may not be considered as being lost to follow-up by the investigator as long as the follow-up period (5 years) has not elapsed.
- Patient's death
- Normal end of the observational study

Data on patients, for whom the study endoprosthesis was introduced at the arterial access but not inserted during the initial intervention (failed installation), will be collected until the patient's withdrawal. Thereafter, a withdrawal form from the observational study must be completed.

Patients for whom the endoprosthesis will be explanted during the follow-up period should be evaluated clinically at least until the last 5-year visit.

5.4.2 Patients lost to follow-up

Several measures are taken to avoid patients from being lost to follow-up. The observational study documents handed over to investigators during the study set-up highlight the fundamental importance of patient follow-up and data collection throughout the study. The investigator will seek the means to contact the attending physician or the nearest trusted relation.
In the event of a missed visit, the investigation center shall contact the patient by phone several times (at least two documented calls) and send an appointment letter by certified mail. In the absence of a response, the attending physician will be contacted in a bid to obtain information on the patient's status and on all elements needed to trace a possible endoprosthesis related clinical event (hospitalization, surgery, etc.).
In the event that there are no results from the procedures below, then the alive/dead status of the patient must be documented in the eCRF once the investigator has confirmed it from the Epidemiological Center for the Medical Causes of Death (Cépi-DC).
Note: the patient may not be considered lost to follow-up by the investigator as long as the follow-up period (5 years) has not elapsed.

5.5 Deviations from the Clinical Investigation Plan

A deviation from the observational study (deviation from the protocol) occurs when the investigator or a member of the center involved in the observational study does not conduct the study according to the Clinical Investigation Plan, or according to existing regulations.

In this observational study where patients are treated per the standard practice of each center, a deviation report is only required in a limited number of cases. A deviation form must be completed for each deviation from the protocol, particularly in the following cases:

- If the patient does not receive proper information for the collection of his/her personal data
- Wrong version of the information note used
- Included patient does not meet all the eligibility criteria

5.6 Scientific Committee

A Scientific Committee common to all manufacturers has been established. This multidisciplinary and independent Committee is composed of one methodologist and several practitioners (vascular surgeons, interventional radiologists, etc.) the make-up of the committee being shown in APPENDIX B.

6 QUALITY CONTROL PROCEDURE

The research will be supervised according to the manager's standard operating procedures. The research shall be conducted at the investigation centers and patient care shall follow ethical and medical guidelines.

Transcribing data into the case report form

The observational study data will be recorded by the participating doctors in a notebook or an eCRF or electronic case report form. The information provided in the doctor's questionnaire should match the information in the patient's record.

Data management

Systematic coherence control procedures shall be set up and documented. Correction procedures shall be followed. For the observational study data, requests (queries) shall be issued and sent to different centers for resolution.

Quality Assurance Procedure

Quality control is carried out continuously during the various stages of error correction, according to the manager's standard operating procedures.

7 LEGAL & ETHICAL CONSIDERATIONS

7.1 CNIL [French Data Protection Agency] Declaration

This observational study shall be subject to the modified version of the Data Protection law of January 6, 1978. Before its actual commencement, the processing of data collected in the observational study shall be subject to referral to the French Advisory Committee on Information Processing in Material Research in the Field of Health (CCTIRS), and then the French Data Protection Agency (CNIL).

7.2 Information and Non-opposition Form

The investigator must inform the patient about the nature and objectives of the data collection and answer all questions. Patients must be informed of their rights, prior to their enrollment in the study, in order to be able to refuse, if they so wish, the collection and transmission of personal data.
According to existing law, an informational note must be given to the patient and an informed consent must be signed by the patient in order to collect and transmit his/her personal medical data.

7.3 Final Research Report

The final research report will be written by the sponsor. This report will be sent to each of the investigators.

8 DATA PROCESSING AND STORAGE OF RESEARCH RELATED DOCUMENTS AND DATA

Documents pertaining to research must be stored by all parties involved for a period of 15 years after the end of the research.

This indexed storage will comprise at least:

- Successive versions of the protocol (identified by the version No. and date)
- The letters of correspondence with the manager
- A completed and validated case report form for each subject enrolled
- All appendices specific to the observational study
- The final report of the observational study

The database from which the statistical analysis was drawn must also be stored by the head of analysis (hard or soft copy).

9 DATA ANALYSIS AND REPORTS

9.2 Statistical criteria for discontinuing the research

No discontinuation criterion.

9.3 How to manage missing, unused or invalid data

Missing data will be listed and presented in a tabulated form.
Patients will be considered as censored at the date of the last observation.

9.5 Right of access to data and source documents

Individuals with direct access to data in accordance with existing legislative and regulatory provisions, notably articles L.1121-3 and R.5121-13 of the Public Health Code (for example, investigators, individuals responsible for quality control, and any individuals appointed to collaborate in trials) shall take all necessary precautions to ensure the confidentiality of information relating to experimental drugs, trials, subjects involved in trials, particularly as regards their identity, and results obtained therefrom. Data collected by these people is then anonymized.

9.6 Rules relating to publication

W. L. Gore & Associates, Inc. is the proprietor of all data, analyses and results relating to the GORE® TAG® or Conformable GORE® TAG® Thoracic Endoprosthesis and these may not be used or transmitted to a third party without prior consent therefrom. However, the center is free to independently use and develop data resulting from the medical records of its own patients, as also data and information:

- That were known to the center prior to its disclosure by manufacturers
- That are or become legally accessible to the public
- That are released from the seal of confidentiality by written agreement of the manufacturer

10 EXPECTED RISKS AND BENEFITS

10.1 Risks

This study does not lead to any change in patient management. Therefore, there is no additional risk to the patients from their participation in the study.
Risks related to the implantation of a thoracic endoprosthesis, specifically the implantation of GORE® TAG® and Conformable GORE® TAG® Thoracic Endoprostheses have been described in the User's Manual delivered with each device.

10.2 Benefits

Patients in this observational study will receive the same treatment as they would have received if they had decided not to participate in this study. Therefore, there is no direct benefit related to their participation in the study.

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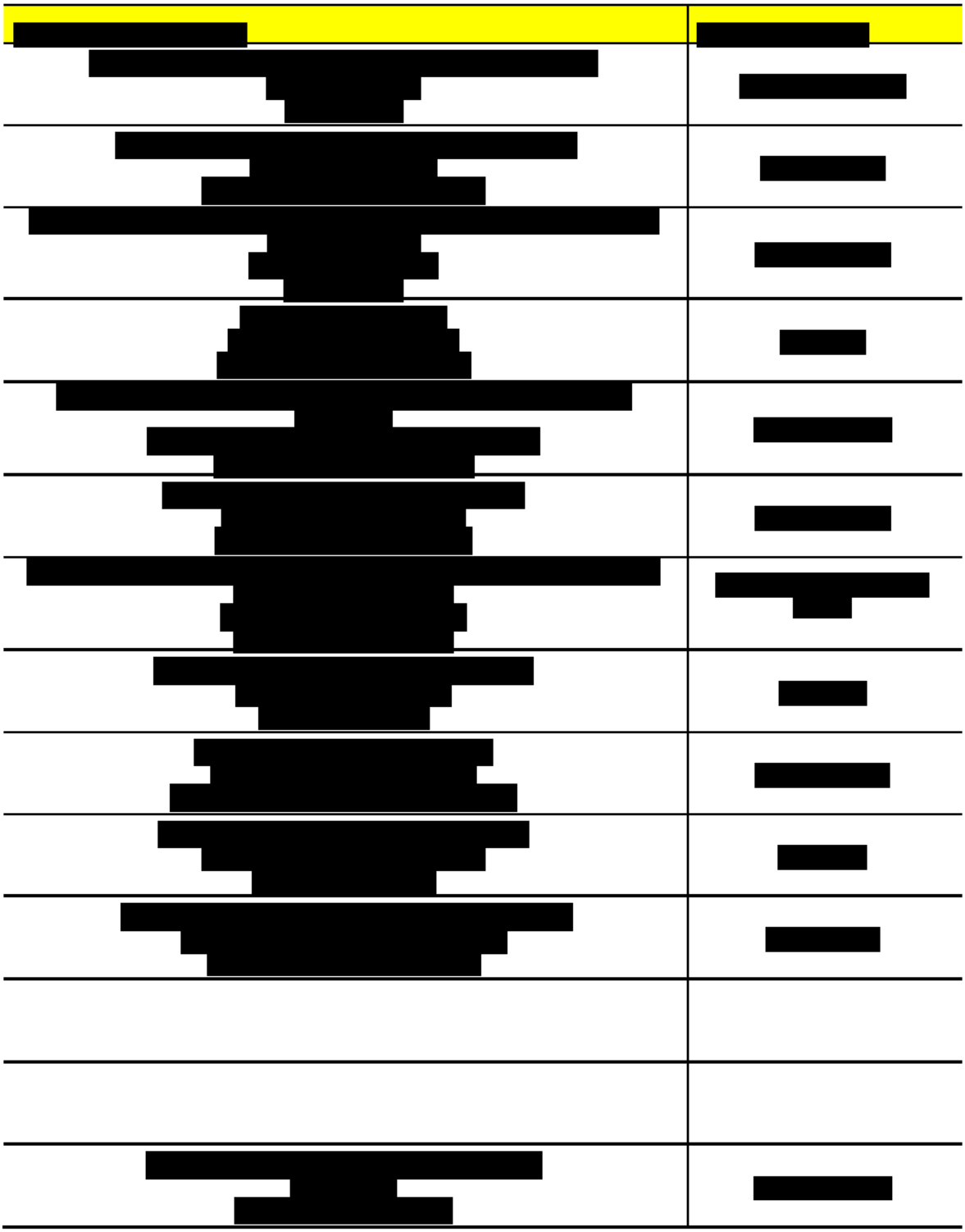
4 - Evaluation of abdominal aortic endoprostheses used for the treatment of aneurysms of the abdominal infrarenal aorta. Afssaps/HAS Report. July 7, 2009

[redacted]

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