

## **ETHICS CHARTER – LIVE DEMONSTRATION**

#### **PREAMBLE**

LINNC Paris Course is medical education meeting organized around live cases transmissions, lectures and recorded cases.

The program of each edition is developed through three critical axes — Live Centres, New Technologies and Education. The aim is to provide a forum for the exchange of ideas and the sharing of experience with world-renown experts while, at the same time, offering a series of quality "take-home" messages that will have an immediate impact on the practice. To create a program of this level is a constant work in progress, and occurs from one LINNC Paris to the next, reflecting the expertise of the Editorial Board and Course Directors as well as the invaluable input of each participant.

Europa Group organises medical conferences (or "Courses"), including the LINNC Courses and Seminar in the field of Interventional neuroradiology ("LINNC Courses"). LINNC Courses have an excellent reputation within the international medical community.

During LINNC Courses, may be broadcast "LIVE Demonstrations", interventions (i) carried out in the operative room (or angiosuite) of a leading hospital selected by the LINNC Course Directors, and (ii) transmitted and commented on live during Course.

LIVE Demonstrations are not remunerated. They give the selected hospitals and their medical teams significant visibility and enhance their reputation.

LINNC meetings completely respect the rules enacted in the addendum to the WFITN Ethics Charter of 2016 regarding live demonstration. (see below Appendix 1: LIVE DEMONSTRATIONS. ADDENDUM TO THE WFITN ETHICS CHARTER OF 2016).

The hospital centre / hospital / clinic ("the LIVE Centre"), recognised for its expertise in interventional neuroradiology, was selected by LINNC Course Directors to perform one or more LIVE Demonstration(s) and has agreed to participate in this project.

## 1 LINNC COURSES AND RESPECT OF THE EDUCATION FRAMEWORK

The LIVE Centre acknowledges that by agreeing to carry out a filmed Intervention to broadcast under the terms of this Ethics Charter, it agrees to comply with the education framework and educational values of LINNC Courses before, during and after the Intervention.

It undertakes to respect the codes of conduct provided by the Europa Group teams, on behalf of the Course Directors, which are stated in the reference documents in **Appendix 1** of this Ethics Charter.

These procedures have been established to guarantee the quality of LIVE Demonstrations and to achieve the educational objectives of LINNC Courses whilst ensuring the safety of the Patients.

### 2 PREPARATION OF THE INTERVENTION

#### 2.1 Choice of Operators and the Principal Operator

The choice of Operators and medical personnel participating in the Intervention is the responsibility of the LIVE Centres, it being stipulated that:

- The identity of the **Principal Operator** of each LIVE Demonstration must be communicated sufficiently in advance to the Course Directors and the Europa Group teams (and in principle upon receipt of the official invitation as a LIVE Centre) so that Europa Group may include the Principal Operator in all preparatory stages and adjust their involvement in other parts of the scientific programme if needed.
  - In the event of a change of the Principal Operator before the Intervention, the LIVE Centre commits to inform the Course Directors and the Europa Group teams without delay, and to specify the identity of the new Principal Operator responsible for the Intervention as soon as they become aware of it.
- The Operators and medical personnel, including, where applicable, external Operators, are the sole responsibility of the LIVE Centre.
- It is the responsibility of the LIVE Centre to conclude all contracts and to carry out all necessary formalities for their Intervention, including for foreign Operators (documents necessary for visa application, work permit, etc.).

## 2.2 Patient selection and information

## 2.2.1 Patient selection

The LIVE Centre is responsible for selecting each Patient in accordance with the **Appendix 1** and in such a way as to meet the following conditions:

- The Patient case must correspond to the topic and objectives of the Scientific Session, as described by the Course Directors;
- The Patient must present an adequate therapeutic indication, enabling a good predicted result from the Intervention;
- The Patient's treatment schedule is compatible with the date of the Scientific Session concerned;
- The Patient's physical condition must enable the obtention of good quality images;
- If the Intervention cannot be done during the duration of the LIVE transmission, the LIVE Centre shall give an follow up regarding the end of the procedure before the Course ending.

The LIVE Centre commits to selecting a second Patient based on the same criteria ("emergency" patient) on whom the Intervention may be performed in an unforeseen situation (refusal of the first Patient to sign the letter of consent, need to bring the intervention forward, last minute complication, etc.).

## 2.2.2 Patient Information

The LIVE Centre commits to precisely informing the Patient about the conditions of the Intervention and its potential risks, the scientific and educational objective of the LINNC Course, and the proceedings of LIVE Demonstrations.

It undertakes to obtain the Patient's written consent prior to the Intervention, in accordance with the good clinical practices in force in their country and within their establishment.

The LIVE Centre will be responsible for developing this consent document so that it conforms to the strictest ethical and regulatory standards. The Patient must at least:

- Acknowledge that they have been informed in detail of the proceedings of the LIVE Demonstration.
- Authorise Europa Group to film the Intervention, to comment on it using the Useful Information, to broadcast it live during the Scientific Session (by projection on the LINNC Course site and simultaneous broadcasting online) and to record it.
- Authorise Europa Group, exclusively within the scope of their respective activities, to use, reproduce, represent, broadcast, use the Recording of the Intervention and the Useful Information, free of charge or against payment, on all types of media, in particular by broadcasting on the LINNC ONLINE website, globally and for the duration of its copyright protection, as provided for by the applicable texts.
- Agree to having no rights over the Recording, which is carried out without their active participation and without them being identifiable and whose possible intellectual property rights belong to Europa Group.
- Acknowledge that they participate in the LIVE Demonstration free of charge in view of the scientific and educational objective of the LINNC Course and consequently renounce any remuneration in this respect.
- Recognise and accept that the Intervention is carried out under the sole responsibility of the LIVE Centre
  and/or the Operators in charge of the Intervention and consequently refrain from seeking Europa Group's
  liability for any damage that may arise from the Intervention, regardless of its capture/broadcasting.

## 3 INTERVENTION

## 3.1 Intervention preparation and implementation

The LIVE Centre undertakes to respect, and enforce respect by the Operators, of the LINNC directives for the preparation and running of the Intervention. It will also particularly ensure that the Operators have, before the Intervention, all the Useful Information about the Patient and their condition.

The LIVE Centre agrees to ensure that the operating room equipped by the Europa Technical Team is made available to the Operators at the date and time agreed for the performance and broadcasting of the LIVE Demonstration, duly equipped with all material and human resources required for the Intervention.

The LIVE Centre will make its best efforts to ensure that the Intervention is carried out by the originally proposed Operators, in accordance with the best practices applicable for this type of intervention.

The LIVE Centre agrees that all data relating to the Patient provided by the Operators during the Intervention remains strictly anonymous.

It will ensure that the Patient's face is not visible and that the Patient is not identifiable during the operation. Europa Group agrees not to film the Patient's face or anything that may enable the Patient's identification.

Europa Group agrees to only film the Patient's organs and body parts that are strictly necessary for the presentation and explanation of the Intervention.

## 3.2 <u>Intervention commentary</u>

Before the start of the Intervention, the Principal Operator may state the name of the LIVE Centre and that of the Operators, the objectives of the Intervention, the name of the techniques and materials used. This presentation

must not include any advertising or promotional elements, nor any element not directly related to the Intervention.

To enable the Operators to focus on the Intervention, a medical coordinator present at the LIVE Centre site will be in permanent contact with a counterpart, medical coordinator, in the control office of the conference room hosting the Scientific Session, who will ensure that the images received and broadcasted are relevant and to transmit, if necessary, any required information to the Europa Technical Team.

During the Intervention, the Operators (not the Principal Operator) will liaise with the Chairpersons, Panellists through the medical coordinator, to exchange and explain about the medical strategy applied, and respond to questions from Panellists and the audience.

At the end of the Intervention, the Operators shall be at the disposal of the Chairpersons, Panellists and audience to answer their questions.

#### 4 LINKS WITH INDUSTRY – COMMERCIAL ANIMATION

The LIVE Centre declares and guarantees, under its responsibility, that its Permanent Representatives, Operators and any other person concerned within its organisation act and will act in accordance with the legal and ethical rules concerning the prior declaration of their possible conflicts of interest due to their links with healthcare industries whose business activity is related to the Intervention.

The LIVE Centre declares and guarantees that the treatment of the Patient as well as the materials and techniques used in the LIVE Demonstration will be chosen exclusively in consideration of the Patient's interest, without influence of the industry on the educational content of the LIVE Demonstration, and without influence of the relations that the LIVE Centre, Operators and any other person concerned within its organisation, may have with the health industries.

When the Scientific Session concerned is sponsored by the Industry, the LIVE Centre will work in collaboration with the industry partner in defining the educational objectives of the LIVE Demonstration; however, it agrees that the decisions made by the LIVE Centre, Operators and any person concerned within its organisation are exclusively made in the interest of the Patient.

The Parties shall not display the logos of the health industry partners or circulate presentations of industry partner products during the Intervention broadcasting.

The LIVE Centre will comply with all instructions provided by Europa Group so that the Intervention Recording may be broadcast in compliance with the applicable rules.

## 5 EVALUATION AND BROADCASTING OF THE INTERVENTION AFTER THE CONFERENCE

The LIVE Centre acknowledges and accepts that LIVE Demonstrations are evaluated by the Course Directors.

The Course Directors will determine, based on the evaluations and according to LINNC technical and educational standards, the scope and methods of the broadcasting of the Intervention Recording.

Depending on the decision made by the Course Directors, the Recording may or may not be released on the LINNC online website and may or may not be used at other LINNC events (Scientific Sessions of future LINNC Courses, LINNC Seminars, Webinars, Workshop and online learning platforms).

The LIVE Centre acknowledges that Europa Group has no obligation to broadcast the Recording after the Intervention.

# Appendix 1 - Code of conduct and guidelines for LIVE Case Operators and Panel Chairpersons- LINNC Courses



## World Federation of Interventional and Therapeutic Neuroradiology

## LIVE DEMONSTRATIONS. ADDENDUM TO THE WFITN ETHICS CHARTER OF 2016 (1)

### Contributors

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Live in-room demonstrations can be either performed within a small group of attendees inside the angiosuite, or can be broadcast live, outside the angiosuite. Both concepts of "live teaching" can be considered as valuable tools for spreading familiarity with new techniques and devices.

This charter confirms that treatments observed from inside or from outside the angio-suite, as far as they are exposed to observers or attendees or visitors, like proctoring treatments or live teaching courses, have to follow exactly the same precise ethical and organizational rules as described below. Doing "live treatments" according to the above description, should not change the strategy of the operator, which has to be based on his own practice and decision-making criteria.

Live cases broadcasting are perfectly appropriate as a teaching method, provided that:

- Patient consent to participation in such demonstrations, after detailed explanation is provided
- 2. Patient care is not compromised in order to facilitate the demonstration (for example, by delaying treatment until a visiting observer arrives), as it should be during non--broadcastedtreatments.
- 3. Any commercial or financial influence regarding the choice of technique or device is excluded, as it should be during non--broadcasted treatments.
- 4. The way a patient is treated must not be related to any company participation or advertisement to the live demonstration, as it should be during non-- broadcasted treatment.
- 5. Financial remuneration to the operator for performing live treatment is inappropriate, as it should be during non--broadcasted treatment.

The opportunity of teaching by live demonstration broadcasting, comes with the requirement to protect patients in any case through the following steps:

- The patient should be fully informed regarding his treatment and also that it will be observed and recorded for teaching purposes. Refusal of consent should in no way influence the future patient's care.
- Patient confidentiality must be protected at all times.
- All efforts to protect the patient's privacy and comfort must be taken including no visible camera or cameraman when the patient is entering or leaving the angiosuite.
- There must be a pre-established strategy for the treatment. The operator should be able to change strategy based on personal experience and judgment according to the proceedings of the procedure.
- The operator can decide at any time whether to interact or not with the panellists, either per sound connection or per video transmission. It remains operator's discretion whether to maintain or stop audio or video connection for any reason.

- LINNC Amendment: The Board of Director of LINNC has decided to not permit to the Principal Operator to interact during the live transmission. The Principal Operator will only be able to interact with the audience before and after the procedure. A medical coordination phone line is setup between the directors in the conference room and a member of the staff in the angiosuite. This staff member in charge of the medical coordination phone line can not be the Principal Operator.
- Immediate stop of the live transmission is recommended if any complication occurs, in order to preserve serenity in the management of the complication. Discussion will take place later.
- An honest discussion with the audience should take place after the treatment is completed.
- Cases for treatment should be selected only in places where the treatment indications and the devices are authorized at the time of the procedure.
- It is not acceptable to perform a "first device" procedure during live transmission. The number of cases to be done with a new technology, before the permission to move to live transmission, has to be discussed device based, in order to find a consensus.
- The operating teams have to follow their 'everyday' practice in terms of their indications, approach, treatment technique and devices.

<sup>1.</sup> Picard L, Bracard S, Rodesch G. WFITN Ethics Charter. Interventional Neuroradiology 2016; Vol 22, Issue 6, pp. 618 – 623. 10.1177/1591019916647195