970/18



#### **CONSULTING AGREEMENT**

This consulting agreement (the "Agreement"), with effective date 40.9. 2018 (the "Effective Date"), is entered into:

## **BETWEEN:**

**TERUMO EUROPE NV,** a company incorporated under the laws of Belgium, with registered office at Interleuvenlaan 40, 3001 Leuven, Belgium, registered with the Crossroad Bank of Companies under the number 0408.270.327 ("**Terumo**");

**Fakultni Nemocnice Plzen**, with registered office at Alej Svobody 80, 30460 Plzen, Czech Republic, represented by MUDr. Václav Šimánek, Ph.D. in his capacity of director (the "Institution");

### AND

**MUDr. Marian Kohut,** Consultant Cardiac Surgeon, born on [xx/xx/1981], with official domicile in xxx, Plzeň xxx, Czech Republic, with license to practice medicine no.xxx issued by the Medical Chamber in Czech Republic, (the "**Consultant**");

Terumo, Institution and Consultant are hereinafter referred to as the "Parties" or individually as a "Party".

### **WHEREAS**

- A. Terumo is a developer, manufacturer, supplier, distributor and service provider in the field of medical devices, primary drug containers and drug delivery devices.
- B. Terumo is active in the field of Cardiac Surgery and has discussed with the Institution and the Consultant a demonstration and training program concerning Endoscopic Vein Harvesting with the TERUMO VirtuoSaph Plus system.
- C. Terumo, Institution and Consultant have agreed that the Institution and the Consultant shall perform services for Terumo according to the terms and conditions set forth below at the Institution's Premises.



### **NOW IT HAS BEEN AGREED AS FOLLOWS:**

## 1. Scope of the work

- 1.1. Organization of trainings and proctorships upon Terumo's request: The Institution and the Consultant undertakes to provide assistance to Terumo and, in particular, to provide the work, support and services related to demonstration and training programs organized by Terumo at Institution's premises as set out in Annex 1 to the Agreement (the "Services").
- 1.2. Provision of trainings and/or proctorships upon Terumo's request: the demonstration and training programs, including proctorships, will be carried out by the Consultant, MUDr. Marian Kohut, who is working at the Cardiac Department of the Fakultni Nemocnice Plzen under the Head of the Cardiac Department, xxx,

#### 2. Manner of Performance

- 2.1. The Institution and the Consultant guarantee that (i) they have the requisite expertise, ability, contacts and legal right to render the Services in an efficient manner; (ii) they will perform the Services under its full liability; (iii) there is no conflict with internal regulations of the Institution; and (iv) they are not bound by outstanding obligations or agreements which are inconsistent or in conflict with the performance of this Agreement by the Institution and the Consultant.
- 2.2. The Institution and the Consultant represent and warrant that the Services will be performed with due care and diligence, respecting (i) all applicable laws, rules and regulations, (ii) Terumo's code of conduct (Sakura rules and Code of Business Compliance) which it declares to have received before signing this Agreement and (iii) such rules of conduct as may be added by Terumo from time to time. The Institution and the Consultant agree not to do anything which may adversely affect Terumo's reputation or interests.

#### 3. Term

3.1. This Agreement shall commence on the Effective Date and terminate on 31 July 2019.

### 4. Compensation

- 4.1. Terumo will pay the Institution the fees and expenses described in Annex 2. Terumo will make payments in Euro of accepted invoices on the bank account of the Institution specified in Annex 2.
- 4.2. The Institution will be responsible for all taxes and charges to be paid on the fees or payments to the Institution. The reimbursement of expenses and the eventual use of Terumo's equipment and property will always be according to Terumo's internal policies and guidelines.

# 5. Confidentiality

5.1. In the course of this Agreement, it is possible or anticipated that the Institution and the Consultant will learn of, and have access to (whether orally, via site visits or in writing), information that Terumo regards as confidential or proprietary, such as information and/or data relating to Terumo or its affiliated companies its business, affairs, researches, knowhow, trade secrets, intellectual property rights, processes, products, drawings, designs, study results, formulas, manufacturing methods, techniques, raw materials, sources of supply, applications for particular technologies, vendor lists, customer lists, employee lists, management systems, financial information, pricing, sales and marketing plans



("Confidential Information"). The results of the Services are also considered as Confidential Information under this Agreement.

- 5.2. The Institution and the Consultant shall maintain Confidential Information in strict confidence and not disclose any Confidential Information, in whole or in part, to any third party. The Institution and the Consultant shall use the Confidential Information in accordance with this Agreement and not use it for any other purpose than the performance of this Agreement.
- 5.3. Notwithstanding the foregoing, however, Confidential Information shall not include information which: (a) was in the public domain or subsequently becomes part of the public domain, otherwise than through a breach of this Agreement; (b) was lawfully known to or in the possession of the Institution and/or the Consultant prior to the Effective Date and with respect to which the Institution and the Consultant do not have any obligation of confidentiality; (c) becomes available to the Institution and the Consultant from a source other than Terumo, which source is not bound by any obligation of confidentiality to Terumo in relation to such information; or (d) was or is developed by the Institution and/or the Consultant independently of any disclosure of information hereunder.
- 5.4. Within fifteen (15) calendar days following the written request by Terumo, the Institution and the Consultant shall, at Terumo's option, return to Terumo, destroy and/or erase all hard and soft copies of any Confidential Information. Destruction or erasure of all Confidential Information will be certified to Terumo by the Institution and the Consultant.
- 5.5. The confidentiality undertakings contained herein shall survive the termination of this Agreement for a period of ten (10) years.
- 5.6. The parties agree that there will not be any transfer of patient's personal data. Furthermore, Terumo ensures that it will not collect, process or use in any other form any patients' personal data.

### 6. Independent Contractor

- 6.1 The relationship of the Parties under this Agreement shall be and remain one of independent contractors, and neither the Institution nor the Consultant are employees or agents of Terumo. The Institution and the Consultant shall have no authority to assume or create obligations on Terumo's behalf, and shall not take any action which has the effect of creating the appearance of having such authority. The Institution and the Consultant shall bear and be solely responsible for the payment of all expenses for the operation of the Institution's and the Consultant's office and activity.
- 6.2 The Institution and the Consultant acknowledge that their participation to this Agreement is not linked to any obligation to use, prescribe or purchase Terumo products.

### 7. Ownership of Work and Developments

7.1 Terumo shall be the owner of all results, including information, deliverables, materials, software, database, intellectual property rights and know-how, of whatever nature, whether or not they can be protected, which would be generated, produced, obtained, developed, conceived or otherwise created by one of the Parties in connection with this Agreement (the "Work"). Therefore, the Institution and the Consultant shall provide Terumo with all materials, equipment and documentation being part of the Work. In addition, to the extent permitted by law, the Institution and the Consultant irrevocably assign and transfer to Terumo any and all intellectual property rights (including, without any limitation, copyright, database rights, trademarks, patents, and design rights) attached to the Work. This assignment includes, amongst others, the right of reproduction, communication to the



public, adaptation, and translation of the Work and/or one of its elements (such as but not limited to pictures and graphic elements) for Terumo or its affiliated companies. Terumo can thus copy, record, adapt, print, publish the Work on whatever support or translate it into any language.

- 7.2 In the event Terumo should decide to protect intellectual property rights attached to the Work, the Institution and the Consultant will provide to Terumo all required assistance in this respect. The Institution and the Consultant also undertake to provide any assistance to Terumo to defend and protect such intellectual property rights before the courts or in any judicial or non-judicial procedure, as well as to assist Terumo to ensure and prove the validity of the transfer of intellectual property rights attached to the Work. The Institution and the Consultant shall not at any time infringe, contest, dispute or question such intellectual property rights nor aid others in doing so, directly or indirectly.
- 7.3 The Institution and the Consultant hereby acknowledge and accept that any indemnity or compensation for the transfer of the intellectual property rights is already included in the fees set forth in this Agreement and that these fees constitute sufficient and adequate payment for the aforementioned transfer.
- 7.4 No license or transfer of intellectual property rights is granted to the Institution and the Consultant. It is understood that the Institution and the Consultant are not entitled to re-use the Work for any other purpose than the performance of this Agreement, nor for the benefit of any third party without Terumo's prior written consent.

### 8. Termination

- 8.1 Terumo may terminate this Agreement at any time and without any compensation in case:
  - (i) the Institution and/or the Consultant fail to perform any of their obligations under the Agreement and if such failure is not remedied within thirty (30) days following a written notice sent by Terumo to the Institution and/or the Consultant depending on who has failed to perform their contractual obligations; or
  - (ii) the Institution and/or the Consultant are in winding up, liquidation, insolvency, cessation of payment, bankruptcy or any analogous proceedings.
- 8.2 Terumo may terminate this Agreement, at any time, for any reason, with a thirty (30) days prior written notice to the Institution and the Consultant. If Terumo so terminates, the Institution and/or the Consultant shall be entitled to:
  - (i) compensation only for the Services actually provided up and until the date of Terumo's termination, increased by the amount corresponding to services scheduled in the following month, less all such payments already made by Terumo to the Institution or to the Consultant under this Agreement; and
  - (ii) reimbursement of all expenses effectively incurred under this Agreement in so far such expenses relate to the Services and are demonstrated to have been incurred before the date of Terumo's termination notice.

Such compensation and reimbursement of expenses shall be the Institution's and the Consultant's sole and exclusive remedy for Terumo's termination of the Agreement according to this paragraph.

8.3 In case of risk to public health or request by health authorities, Terumo may, without delay and without any compensation, suspend or terminate this Agreement

### 9. Notification and authorization

9.1 The Institution and the Consultant declare and warrant that he has fulfilled all notification requirements and obtained all authorizations that are required by applicable laws, regulations or code of conducts or necessary in relation to the performance of this Agreement.



- 9.2 The Institution and the Consultant commit themselves to notify Terumo without any delay in the event it receives an opinion or decision from any competent body that could negatively impact the performance of this Agreement.
- 9.3 The Parties declare and warrant that they shall comply with all transparency and anti-gift obligations required by law, regulations or codes of ethics applicable to the Parties. Each Party shall provide the other Party with all information reasonably required to comply with such obligations. According to such obligations, a Party might have to publish the existence and/or the content of this Agreement on a public website and/or to communicate this Agreement to a Physician Association or another entity for information, opinion or authorization. The Parties shall proceed to such publication and/or communication only to the extent required by applicable law, regulations or codes of ethics.

## 10. Data protection

10.1. Terumo will collect the Institution's or Consultant's personal data that are contained in this Agreement, as well as personal data provided voluntarily by the Institution or the Consultant (e.g. in email communications).

Terumo may use the Institution or Consultant's personal data for the performance of this Agreement, to comply with applicable transparency and anti-gift laws or regulations, to interact with the Consultant and respond to its queries and requests, to ensure the ongoing accuracy and relevance of the Consultant's data, for research or survey purposes, to send the Consultant invitations to events organized by Terumo, to share with the Consultant information that might be of interest for the Consultant, to inform the Consultant about Terumo's products and/or services (the Consultant can freely oppose to such use at any time), and/or to comply with law, regulation, a public authority request or a court order.

Terumo will use the Institution or Consultant's personal data in compliance with and within the limits provided by the applicable laws and regulations. The Consultant's data may be transmitted outside the European Economic Area, as well as to Terumo's affiliated companies or to third parties in order to carry out processing for Terumo.

Terumo may store the Institution or Consultant's personal data as long as necessary or useful and appropriate to comply with applicable legal standards.

The Institution or Consultant are entitled to have access to the Institution's or Consultant's personal data hold by Terumo and to require Terumo to correct, amend or delete such information if it is demonstrated to be inaccurate, incomplete or unnecessary. However, the Institution and Consultant acknowledge that he cannot oppose to publications or communications of its personal data that are required by law.

10.2. In case Terumo entrusts the Institution or Consultant with the processing of personal data, the Institution or Consultant have to ensure that it shall process such personal data in compliance with the European General Data Protection Regulation and any other data protection law applicable to the Institution or Consultant. The Institution or Consultant can process such personal data only on written instructions from Terumo and is responsible for ensuring appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction, accidental loss, alteration, or unauthorized disclosure or access.

The Institution or Consultant may use personal data provided by Terumo only for the performance of this Agreement or to comply with law, regulation, a public authority request or a court order.



The Institution or Consultant may store personal data provided by Terumo as long as necessary to comply with this Agreement and applicable legal standards.

# 12. Assignment

- 11.1 Neither Party may assign its rights or delegate its obligations under this Agreement without the express written consent of the other Party, except to one of its Affiliates.
- 11.2 This Agreement will be binding and inure to the benefit of the Parties hereto and their respective heirs, successors and permitted assigns.

### 13. Notices

12.1 Any notice under this Agreement shall be given in writing and in English to the relevant Party and may be delivered by hand or by registered letter with acknowledgment of receipt to the address stated in this Agreement to the attention of its legal department, or to such other address and persons as may from time to time be notified in accordance with this Article.

## 14. Entire agreement

13.1 This Agreement contains the entire agreement between the Parties and supersedes all pre-existing agreements between the Parties with respect to its subject matter. Any modification to this Agreement shall only be effective if made in writing and signed by the Parties. The general terms and conditions of the Institution are expressly excluded.

## 15. No waiver

14.1 No failure to exercise and no delay in exercising, any right, power or remedy under this Agreement will operate as a waiver. Nor will any single or partial exercise of any right, power or remedy preclude any other or further exercise of that or any other right, power or remedy.

# 16. Severability

- 15.1 If any provision in this Agreement is held to be illegal, invalid or unenforceable, in whole or in part, under any applicable law, then such provision or part of it shall be deemed not to form part of this Agreement. The legality, validity or enforceability of the remainder of this Agreement shall not be affected.
- 15.2 In such case, each Party shall use its best efforts to immediately negotiate in good faith a valid replacement provision that is as close as possible to the original intention of the Parties and has the same or as similar as possible economic effect.

## 17. Governing Law and Jurisdiction

- 16.1 This Agreement and any non-contractual obligations arising out of or in connection with it is governed by and construed in accordance with Czech law, with the exclusion of its conflict of law principles to the extent that they would refer to foreign law.
- 16.2 Any dispute which the Parties are unable to settle amicably in connection with this Agreement or any non-contractual obligations arising out of or in connection with it shall be submitted to the sole jurisdiction of the courts of Prague.



In witness whereof, this Agreement has been executed in as many counterparts as Parties, by duly authorized representatives on behalf of the Parties, and shall be in full force and effect as of the Effective Date.

Terumo Europe NV

[The Institution]

Name:

Title: 10 -09- 20:8

Date MUDr. Václav Šimánek, Ph.D.

# Annexes:

Annex 1: The Services

Annex 2: Payment of fees and expenses



### Annex 1

#### The Services

# 1. Scope of the Services

1.1 Organization of trainings and proctorships by the Institution:

The "Services" described under clause 1.1 shall mean work, support and services such as the use of the premises for trainings and demonstrations related to TERUMO's VirtuoSaph and VirtuoSaph Plus endoscopic vein harvesting systems, upon Terumo's request.

- In the framework of the trainings, demonstrations and/or workshops, surgical teams from other institutions will visit FN Hospital Plzen to learn about TERUMO VirtuoSaph and VirtuoSaph Plus endoscopic vein harvesting (EVH) system in routine use.
- These workshops shall be organized on written request of TERUMO upon agreement with FN PLZEN EVH TEAM.
  - Number of attendants per workshop: maximum 5 visitors (clinicians from other hospitals or TERUMO associates).
  - Content of workshops:
    - presentations on EVH technique, VirtuoSaph and VirtuoSaph Plus product, tips & tricks,
    - 1-3 EVH case observations in the operating room.
- The duration for these workshops shall vary from 1-2 days per visitor group.
- The Institution will make sure that at least one VirtuoSaph and VirtuoSaph Plus case will be performed per day of the workshop at the Institution's premises.

The Institution agrees that FN Plzen EVH team will provide clinical follow-up trainings/proctorship in the institution of the visitors (= external) in order to support them during their introduction phase of EVH. These external trainings are not subject of this contract and will be organized by separate agreements.

To hold the training, the Institution or the Consultant must have informed and collected the consent of the patients participating in the training. The patients shall be therefore informed in advance about the workshop and/or training and will sign an Informed consent form.

1.2 Provision of trainings and proctorships by the Consultant:

The "Services" described under clause 1.2 shall mean the provision and leadership by the Consultant, Dr. Kohut, of clinical trainings and proctorships upon Terumo's request in Fakultni Nemocnice Plzen in order to support invited clinicians from other hospitals and/or Terumo associates during their introduction phase of endoscopic vein harvesting techniques using the TERUMO VirtuoSaph or VirtuoSaph Plus system. Activities shall include:



- 1 3 EVH case observations/day for trainees
- 1 tips & tricks session

In the case of live cases, the Consultant shall properly inform the subjects concerning the training and collect their consent through an informed consent form to be signed prior to the participation in the training. Without this consent form, the live case training cannot take place.

# 2. Reporting

The Consultant shall ensure that Terumo is kept informed about the status and results of the Services. Such information will be provided in writing to Terumo. The Consultant shall provide Terumo with progress reports on a regular basis, as well as with a final report to be submitted one month after the provision of the services.



### Annex 2

# Payment of fees and expenses

### 1. Fees

- 1.1 For the Services performed by the Institution and the Consultant to the satisfaction of Terumo, the Institution is entitled to the following compensation, including Tax/VAT, upon receipt of a proper invoice:
  - € 450/day. The cost breakdown is as follows:
    - o 225 € for the Services performed by the Institution described in clause 1.1
    - o 225 € for the Services performed by the Consultant described in clause 1.2.

Except for what is stipulated below, the fees include all necessary disbursements and expenses of the Institution and the Consultant necessary and advisable for the performance of the Services – for example protective work aids, etc..

# 2. Payment conditions

Invoices are payable by Terumo sixty (60) days invoice date.

Terumo will make the payment of the Services performed by the Institution and the Consultant after the corresponding invoice on the official bank account of the Institution:

Name of the account holder: [Fakultní nemocnice Plzeň]

Address of the account holder: [Edvarda Beneše 1128/13, 305 99 Pilsen, Czech Republic]

Account number: [33739311/0710]

IBAN code: [CZ21 0710 0000 0000 3373 9311]

Bank name: [ČNB]

Bank Address: [Na Příkopě 28, 11503 Praha 1, 00669806, CZ00669806]

Swift/BIC code: [CNBACZPP]

## 3. Expenses

The agreed fees under point 1 above include all necessary disbursements and expenses of the Institution and the Consultant for the performance of the Services.