Regulation of Medical Robots in Switzerland

The Example of Robotic Applications in Minimally Invasive Surgery

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Abstract: The use of robotic applications is a growing trend in Switzerland's healthcare sector. For example, robots have been broadly in use in minimally invasive surgery. Robotic applications in minimally invasive surgery are an *information-driven* and *safety-critical technology* governed, amongst others, by data protection as well as medical device regulations. Doctors must make sure they understand how such robots process patient-specific information to comply with the relevant provisions of data protection regulations, which include, in the opinion of the authors, the requirement to seek informed patient consent. Robotic applications in minimally invasive surgery are (normally) medical devices under Swiss law. In this respect, the revised Therapeutic Product Act leads to a tightening of medical device regulations and an increase of the barriers to market entry for medical device manufacturers.

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I. Introduction

Robots are perceived as one of the most transformative technologies of the 21st century and have a huge societal and economic impact.[1] Indeed, robots have already reached and transformed many industries: agriculture, manufacturing in the automotive industry, entertainment, rescue as well as home services.[2] The use of robotic applications is also a growing trend in Switzerland's healthcare sector.[3] The variety of robotic applications used in healthcare today is remarkable.[4] For example, robots have been broadly in use in minimally invasive surgery. Such robotic applications have the advantage to facilitate minimally invasive operations, to reduce blood loss and the length of time spent in hospital following a surgery, resulting in less pain and fewer post-operative com-

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1 BECKER HEIDRUN/SCHEERMESSER MANDY/FRÜH MICHAEL/TREUSCH YVONNE/AUERBACH HOLGER/HÜPPI RICHARD ALEXANDER/MEIER FLURINA, Robotik in Betreuung und Gesundheitsversorgung, Zürich 2013, 5; BEKEY GEORGE A., Current Trends in Robotics, in: LIN PATRICK/ABNEY KEITH/BEKEY GEORGE A. (editors), Robot Ethics: The Ethical and Social Implications of Robotics, Cambridge MA 2012, 17, 17; LEENES RONALD/PALMERINI ERICA/KOOPS BERT-JAAP/BERTOLINI ANDREA/SALVINI PERICLE/LUCIVERO FEDERICA, Regulatory challenges of robotics, in: Law, Innovation and Technology 2017, 1, 15.

2 Cf. MAIER HELMUT, Grundlagen der Robotik, Berlin 2016, 15; LENZEN MANUELA, Künstliche Intelligenz: Was sie kann & was uns erwartet, München 2018, 97 et seqq.; ROBOTICS BUSINESS REVIEW, 5 Industries that Robotics Have Disrupted Drastically, available at www.roboticsbusinessreview.com (visited on 20th December 2019).

3 GÜNTHER JAN-PHILIPP, Quantensprung durch Roboter im Gesundheitsbereich: Bericht zum Panel an der Tagung "Roboterrecht" vom 28. und 29. Oktober 2016 des FAA-HSG, AJP 2017, 265, 265.

4 For more details and references see KLEIN BARBARA/GRAF BIRGIT/ SCHLÖMER INGA FRANZISKA/ROSSBERG HOLGER/RÖHRICHT KARIN/ BAUMGARTEN SIMON, STIFTUNG MÜNCH (Hrsg.), Robotik in der Gesundheitswirtschaft: Einsatzfelder und Potenziale, Heidelberg 2018, 12 et seqq.

plications.[5] Therefore, it does not surprise that experts predict an increase in small to medium-sized (surgical) procedures executed by autonomous robots in the future.[6] In spite of these remarkable advantages, there are concerns pertaining to the use of robots in healthcare, in particular regarding minimally invasive surgery. These concerns include high financing costs of robotic applications, potential loss of data protection and patient security.[7]

In the literature, robotic applications used in minimally invasive surgery are referred to either as "medical robots" or as "surgical robots".[8] In this article, we show that robotic applications in minimally invasive surgery are robots according to the so-called "sense-think-act paradigm" (cf. II.A.). They are service robots (cf. II.B.), they are used in the healthcare sector and are a subgroup of the so-called medical robots (cf. II.C.).

This article aims at an analysis of the relevant data protection and medical device regulations applicable to the introduction and use of robotic applications in minimally invasive surgery. As far as can be seen, there are no articles in Switzerland analyzing the legal requirements for such medical robots. This is astonishing because robotic applications used in minimally invasive surgery have been on the market in Switzerland for years. For example, the "Kantonsspital St. Gallen" has been using such robots for almost 10 years.[9] In the US, they have been used since the 1990s.[10]

After having categorized robotic applications for minimally invasive surgery (cf. II.), we will analyze Swiss data protection and medical device regulations (cf. III.) and finish off with a conclusion (cf. IV.).

II. Categorization of Robotic Applications in Minimally Invasive Surgery

A. Robotic Applications in Minimally Invasive Surgery as Robots According to the "Sense-Think-Act Paradigm"

Any legal regulation relating to robots presupposes that we know what we mean by "robot". But there is neither a consensus among roboticists how to define robots[11] nor a legal definition for robots. According to the roboticists' "sense-think-act paradigm" a robot is *"a machine that senses, thinks, and acts*. Thus, a robot must have sensors, processing ability that emulates some aspects of cognition, and actuators".[12] Robotic applications used in minimally invasive surgery consist of an ergonomic input station (the so-called "operator"), which contains a 3D-monitor for visual reproduction and sensors for recording hand movements as well as several actuators ("teleoperators"),[13] which carry the 3D-endoscope and several surgical instruments (executed by the surgeon).[14] Therefore, robotic applications used in minimally invasive surgery fulfill the "sense-think-act paradigm" and are robots.

B. Robotic Applications in Minimally Invasive Surgery as Service Robots

Certain product safety regulations relate to sub-categories of robots, i.e. *industrial robots* and *service robots*. The "International Federation of Robotics" (IFR) divides robots into these two categories and bases its use of the term industrial robot on the definition of the "International Organization for Standardization" (ISO).[15] This classification is valuable from a legal point of view because it can provide possible starting points for the legal analysis of robotic applications (e.g., in the area of the applicability of product safety regulations).

According to ISO 8373[16], an industrial robot is defined as an "automatically controlled, reprogrammable multipurpose manipulator programmable in three or more axes". In comparison to an industrial robot, a service robot is defined as "a robot that performs useful tasks for humans or equipment excluding industrial automation application. [...] The classification of a robot into industrial robot or service robot is done according to its intended application".[17] Robots used in the healthcare sector in general and robotic applications in minimally invasive surgery in particular are normally seen as service robots because they "support the functioning of impaired indi-

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5 ROBOTICS BUSINESS REVIEW (Fn. 2); SHARKEY NOEL/SHARKEY AMANDA, Robotic surgery and ethical challenges, in: GOMES PAULA (ed.), Medical Robotics: minimally invasive surgery, Cambridge 2012, 276, 276.

6 KLEIN BARBARA ET AL. (Fn. 4), 160 et seq. Cf. further BECKER HEIDRUN ET AL. (Fn. 1), 179 et seq.; MAIER HELMUT (Fn. 2), 40.

7 GÜNTHER JAN-PHILIPP, AJP 2017 (Fn. 3), 265.

8 Cf. II.C.2 (Fn. 42).

9 KANTONSSPITAL ST. GALLEN, KLINIK FÜR UROLOGIE, available at https://www.kssg.ch/urologie (visited on 20th December 2019).

10 DOMBRE ETIENNE/DE MATHELIN MICHEL/TROCCAZ JOCELYNE, Characteristics and State of the Art, in: TROCCAZ JOCELYNE (ed.), Medical Robotics, London 2012, 1, 7.

11 BEKEY GEORGE A. (Fn. 1), 17.

12 BEKEY GEORGE A., Autonomous Robots: From Biological Inspiration to Implementation and Control, Cambridge 2005, 2; BEKEY GEORGE A. (Fn. 1), 18. Cf. also WILDHABER ISABELLE, Die Roboter kommen – Konsequenzen für Arbeit und Arbeitsrecht, ZSR 2016, 315, 316.

13 BAYLE BERNHARD/BARBÉ LAURENT, Tele-manipulation, in: TROCCAZ JOCELYNE (ed.), Medical Robotics, London 2012, 269, 272; ORTMAIER TOBIAS, Roboterassistierte minimal-invasive Chirurgie, in: SCHLAG PETER MICHAEL/EULENSTEIN SEBASTIAN/LANGE THOMAS (Hrsg.), Computerassistierte Chirurgie, München 2011, 267, 271.

14 ORTMAIER TOBIAS, 267, 271 et seq.

15 INTERNATIONAL FEDERATION OF ROBOTICS, Topics and Definition, available at https://ifr.org/service-robots/products (visited on 20th December 2019).

16 ISO 8373:2012, Robots and robotic devices – Vocabulary.

17 INTERNATIONAL FEDERATION OF ROBOTICS, Service Robots, available at https://ifr.org/service-robots/products (visited on 20th December 2019).

viduals, rehabilitation of patients, care and medical intervention of patients".[18] In other words, robotic applications used in minimally invasive surgery have a support function. They are not being used to completely replace, but to *assist medical staff* (i. e., the surgeon).[19] There is no need to worry about robots replacing humans on a big scale here.

In essence, the classification of robots into industrial robot or service robot depends on whether a robot is industrial. From a legal standpoint, we doubt that this binary distinction of robots is appropriate as a basis for product safety regulations, particularly due to the wide variety of robots.[20] For example, a robotic application in minimally invasive surgery and a robot vacuum cleaner are both service robots, even though it is obvious that a medical robot requires other safety requirements than a robot vacuum cleaner.[21] Thus, recent scholarship in law has sought to capture the wide range of robotic applications by using new criteria to classify robots, for example the structured environment of a robot (i. e., Locomat performs tasks in a structured environment)[22] and its ability to learn and make decisions.[23]

C. Robotic Applications in Minimally Invasive Surgery as a Form of Medical Robots Used in the Healthcare Sector

In this section, we show that medical robots are being used in the healthcare sector and that robotic applications in minimally invasive surgery are a subcategory of medical robots.

1. Medical Robots as a Category of Robotic Applications Used in the Healthcare Sector

Commercially, robotic applications have not fully succeeded in the healthcare sector yet.[24] Nevertheless, their economic potential is huge.[25] For example, according to ABB's internal research, more than 60,000 non-surgical robots are expected to be working in hospitals by 2025.[26] Therefore, it is not surprising that ABB, having already applied robotics and automation within the automotive, electronics, food as well as beverage and logistics industry, has recently opened a new global research hub for healthcare robotics in order to break into the non-surgical healthcare market.[27]

There is no legal definition of what is meant by robotic applications used in the healthcare sector. However, in the absence of a legal definition, technical terms may be used differently by lawyers. This can lead to misunderstandings and confusions. Therefore, it may be helpful to refer to definitions from the robotics literature as a starting point for the legal analysis of robotic applications used in the healthcare sector.

Robotic applications used in the healthcare sector can be described as "the domain of systems able to perform coordinated mechatronic actions (force or movement exertions) on the basis of processing of information acquired through sensor technology, with the aim to support the functioning of impaired individuals, rehabilitation of patients, care and medical intervention of patients and also to support individuals in prevention programmes".[28] Thus, robotics for healthcare encompasses an impressively wide variety of robotic applications. Therefore, there are efforts in literature to categorize robotic applications used in the healthcare sector. For example, MAURITS BUTTER ET AL. divide healthcare robots into the following categories: (1) Robot assisted preventive therapies and diagnosis (e.g., RP-7 by InTouch Technologies that is a medical mobile platform to treat patients remotely); (2) Robotic Assistive Technology (e.g., intelligent lower extremities prosthesis); (3) Robots supporting professional care (e.g., RIKEN to carry humans); (4) Robotics for rehabilitation treatment (e.g., Locomat by Hocoma to support the patient's walking); (5) Robotics for medical interventions (e.g., robotic devices for minimally invasive surgery).[29] Based on this subdivision, two findings can be derived: First, robots for medical interventions form a separate category within the robotic applications used in the healthcare sector. However, we will use the terminology of *medical robots* instead, by which we mean robotic applications that belong to the 5th category according to the classification of MAURITS BUTTER ET AL.[30] Second, medical robots must be distinguished from "Personal Care Robots". This second finding is relevant from a legal perspective. In

18 BUTTER MAURITS ET AL., Robotics for Healthcare: Final Report, 2008, 12, available at https://repository.tudelft.nl/view/tno/uuid:beddf38c-e88c-4d2a-8394-e7234d9b3e8a.

19 TAYLOR RUSSELL H./MENCIASSI ARIANNA/FICHTINGER GABOR/FIORINI PAOLO/DARIO PAOLO, Medical Robotics and Computer-Integrated Surgery, in: SICILIANO BRUNO/KHATIB OUSSAMA (editors), Springer Handbook of Robotics, 2nd ed., Berlin 2016, 1657, 1660.

20 WILDHABER ISABELLE/LOHMANN MELINDA F., Roboterrecht – eine Einleitung, AJP 2017, 137 et seq.

21 WILDHABER ISABELLE/LOHMANN MELINDA F., AJP 2017 (Fn. 20), 137.

22 LOHMANN MELINDA F., Roboter als Wundertüten – eine zivilrechtliche Haftungsanalyse, AJP 2017, 152, 153 et seq.

23 WILDHABER ISABELLE/LOHMANN MELINDA F., AJP 2017 (Fn. 20), 137 et seq. Cf. also MAIER HELMUT (Fn. 2), 26, who proposes other criteria.

24 GÜNTHER JAN-PHILIPP, AJP 2017 (Fn. 3), 265.

25 euRobotics, Robotics 2020: Multi-Annual Roadmap, 29, available at www.eu-robotics.net; INTERNATIONAL FEDERATION OF ROBOTICS, Executive Summary World Robotics 2018 Service Robots, 12, available at https://ifr.org/free-downloads/.

26 ROBOTICS BUSINESS REVIEW, A Closer Look at ABB's New Research Hub for Healthcare Robotics, available at www.roboticsbusinessreview.com (visited on 20th December 2019).

27 ROBOTICS BUSINESS REVIEW (Fn. 26).

28 Cf. BUTTER MAURITS ET AL. (Fn. 18), 12.

29 BUTTER MAURITS ET AL. (Fn. 18), 36 et seqq. Cf. further KLEIN BARBARA ET AL. (Fn. 4), 12 et seqq.

30 Cf. for the definition of medical robots II. C. 2.

contrast to certain robots supporting professional care or for rehabilitation treatment that qualify as "Personal Care Robots" (ISO 13482:2014), medical robots qualify as medical devices, which are subject to stricter regulation (cf. III. B.).[31] Finally, medical robots based on artificial intelligence must be distinguished from wholly *software-based* artificial intelligence which exerts no agency in the physical world.[32] Therefore, such robots may be considered as *hardware-based* (embodied) artificial intelligence.[33] In other words, purely *software*-based AI applications used in medicine are not robots (according to the "sense-think-act paradigm"). However, software-based artificial intelligence is also very important in modern medicine, e. g. to treat cancer.[34]

2. Robotic Applications in Minimally Invasive Surgery as a Subcategory of Medical Robots

This section aims to clarify the question of whether robotic applications in minimally invasive surgery are a subcategory of medical robots. For this purpose, it is necessary to determine first what we understand by medical robots. The clarification of the term may provide guidance, for example, to determine the applicability of legal provisions in the area of the procedures for assessing conformity under medical device regulations.

There is no generally scientifically accepted definition of medical robots.[35] However, the term "medical robot" refers to robotic applications that are intended to support the work of surgeons, for example by providing the necessary precision work in surgical procedures.[36] Therefore, such robots are part of the so-called "computer-assisted surgery" or "computer aided surgery". This term refers to surgical concepts and methods in which computer or robot technology is used to plan an operation.[37] If medical robots are understood on the basis of this term, then robotic applications in minimally invasive surgery are to be regarded as a subcategory of medical robots. Medical robots are also being used in other surgical disciplines (e. g. neurosurgery, surgical orthopaedics, interventional and diagnostic radiology and microsurgery).[38] For example, the "Da Vinci Surgical System" by Intuitive Surgical Inc. (USA)[39] is one of the most successful robotic systems used in minimally invasive surgery, i. e. to remove the prostate because of prostate cancer ("radical prostatectomy"). Another robotic application (with semi-autonomous functions) in the field of robotic applications in minimally invasive surgery is the so-called "CyberKnife" by Accuracy[40] which is in actual use for the treatment of brain cancer.[41] These robots used for medical interventions are described in literature as *medical robots* or *surgical robots*.[42]

In the following section, we will describe the data protection and medical device regulations for medical robots using the example of robotic applications in minimally invasive surgery. The findings of this legal analysis can basically be transferred to other types of medical robots.

III. Swiss Data Protection and Medical Device Regulations for Robotic Applications in Minimally Invasive Surgery

A. Swiss Data Protection Regulations

A robotic application in minimally surgery, such as the "Da Vinci Surgical System", is an *information-*

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31 WILDHABER ISABELLE/LOHMANN MELINDA F., AJP 2017 (Fn. 20), 138 et seq.

32 BUTTER MAURITS ET AL. (Fn. 18), 12 ; RICHARDS NEIL M./SMART WILLIAM D., How should the law think about robots?, in: CALO RYAN/FROOMKIN A. MICHAEL/KERR IAN (editors), Robot Law, Cheltenham/Northhampton 2016, 3, 6; WILDHABER ISABELLE/LOHMANN MELINDA F., AJP Praxis 2017 (Fn. 20), 135, 135 et seq.

33 WINFIELD ALAN, Robotics: A very short introduction, Oxford 2012, no. 8.

34 For more details and references see FRAUNHOFER-GESELLSCHAFT, Künstliche Intelligenz in der Medizin, available at www.fraunhofer.de (visited on 20th December 2019); HAENSSLE HOLGER A. ET AL., Man against machine: diagnostic performance of a deep learning convolutional neural network for dermoscopic melanoma recognition in comparison to 58 dermatologists, Annals of Oncology 2018, 1 et seqq.; THOMPSON REID F. ET AL., The Future of Artificial Intelligence in Radiation Oncology, International Journal of Radiation Oncology 2018, 247 et seq. Cf. for a jurisprudential analysis of AI in healthcare (in relation to European law) SCHÖNBERGER DANIEL, Artificial intelligence in healthcare: a critical analysis of the legal and ethical implications, International Journal of Law and Information Technology 2019, 171 et seqq.

35 Cf. WAHRBURG JÜRGEN/SAHM STEPHANIE/SCARPIN DOMINIK/SCHLIMBACH MARC/SCHNEIDER HANS-CHRISTIAN, Autonome und interaktive Medizinroboter, in: SCHLAG PETER MICHAEL/EULENSTEIN SEBASTIAN/LANGE THOMAS (Hrsg.), Computerassistierte Chirurgie, München 2011, 225, 226.

36 CHRISTALLER THOMAS/WEHNER JOSEF, Autonomie der Maschinen – Einführung in die Diskussion, in: CHRISTALLER THOMAS/WEHNER JOSEF (Hrsg.), Autonome Maschinen, Wiesbaden 2003, 9, 19; HAUN MATTHIAS, Handbuch Robotik: Programmieren und Einsatz intelligenter Roboter, 2. Aufl., Berlin 2013, 11.

37 MAIER HELMUT (Fn. 2), 41.

38 DOMBRE ETIENNE/POIGNET PHILIPPE/PIERROT FRANÇOIS, Design of Medical Robots, in: TROCCAZ JOCELYNE (ed.), Medical Robotics, London 2012, 141, 143 et seq.; SCHWEIKARD ACHIM/ERNST FLORIS, Medical Robotics, Cham 2015, 333 et seqq.

39 KOSE M. FARUK, Robotic gynecologic surgery – introduction, in: KILIC SAMI GOKHAN/ERTAN KUBILAY A./KOSE M. FARUK (editors), Robotic Surgery: Practical Examples in Gynecology, Berlin 2014, 3, 6 et seq.; MAIER HELMUT (Fn. 2), 41; ROBOTICS BUSINESS REVIEW (Fn. 2).

40 KLEIN BARBARA ET AL. (Fn. 4), 160.

41 SHARKEY NOEL/SHARKEY AMANDA, 276, 278.

42 Cf. MOREAU-GAUDRY ALEXANDRE/CINQUIN PHILIPPE, Medical Robotics in the Service of the Patient, in: TROCCAZ JOCELYNE (ed.), Medical Robotics, London 2012, 55, 55 et seqq.; TAYLOR RUSSELL H./MENCIASSI ARIANNA/FICHTINGER GABOR/FIORINI PAOLO/DARIO PAOLO, 1657, 1657 et seqq.; WINFIELD ALAN (Fn. 33), no. 35.

driven technology collecting and processing patient-specific information.[43] Whenever a robotic application collects and processes personal data about identified or identifiable individuals, data protection law is relevant. In order to describe the data protection requirements for such robots, it must first be clarified which data protection law applies to data processing by robotic applications in minimally invasive surgery. Second, we outline the general principles of data protection. Third, we show that Big Data-based and network-based robotic applications in minimally invasive surgery may contradict certain general principles of data protection.

1. Applicability of Data Protection Law

The applicability of data protection law is a complex issue: In Switzerland, data protection law in healthcare is based on a *multi-level system* that comprises the federal and cantonal regulations. The reason for this is that the Swiss Constitution (Cst.)[44] does not give the Federation a comprehensive competence regarding data protection.[45] As a consequence, the cantons have the right and obligation to regulate the data processing by cantonal (and communal) organs (cf. Art. 3 and Art. 42 Cst).[46] Therefore, as a general rule, data processing by cantonal (and communal) hospitals relating to robotic applications used in minimally invasive surgery is *usually regulated by cantonal data protection legislation,* whereas the Swiss Federal Act on Data Protection (FADP)[47] is applicable as soon as personal data is being processed by such robots in private medical practices and private hospitals (cf. Art. 2 para. 1 lit. a FADP).[48] However, there are some derogations from this aforemen-

tioned general rule.[49] As a result, there might be difficulties distinguishing between the applicability of the FADP and the cantonal data protection legislation creating legal uncertainty.[50] Materially, the cantonal data protection legislation is based on the FADP,[51] mitigating the implications of the identified legal uncertainty. The data protection requirements for robotic applications in minimally invasive surgery are described in the next section using the example of the FADP.

2. Data Protection Requirements for Robotic Applications in Minimally Invasive Surgery

a) General Principles of Data Protection in the FADP

The FADP is applicable as soon as private parties or federal government process information about an identified or identifiable (natural or legal) person (cf. Art. 2 para. 1 lit. a and lit. b FADP and Art. 3 lit. a FADP).[52] Whenever information about a patient is being collected or processed, the *general principles of data protection* must be (cumulatively) fulfilled, no matter whether the personal data is processed by a medical person or by a robotic application in minimally invasive surgery (cf. Art. 4, Art. 5 para. 1 as well as Art. 7 para. 1 FADP). Hence, the FADP is based on the *principle of technology neutrality.*[53]

Information about a patient is data relating to health. Health data directly or indirectly provides information on the physical, mental or psychological state of health of a natural person. Such health data may have negative consequences for the persons concerned.[54] Health data constitutes *sensitive personal data* in the

43 TAYLOR RUSSELL H./MENCIASSI ARIANNA/FICHTINGER GABOR/FIORINI PAOLO/DARIO PAOLO, 1657, 1658.

44 Federal Constitution of the Swiss Confederation of 18 April 1999 (Cst, SR 101).

45 EPINEY ASTRID/CIVITELLA TAMARA/ZBINDEN PATRICK, Datenschutzrecht in der Schweiz: Eine Einführung in das Datenschutzgesetz des Bundes, mit besonderem Akzent auf den für Bundesorgane relevanten Vorgaben, Freiburg 2009, 18; RUDIN BEAT, Die datenschutzrechtliche Umsetzung von Schengen in den Kantonen, in: BREITENMOSER STEPHAN/GLESS SABINE/LAGODNY OTTO (Hrsg.), Schengen in der Praxis: Erfahrungen und Ausblicke, Zürich 2009, 213, 215; SCHWEGLER IVO, Informations- und Datenschutzrecht, in: MÜLLER MARKUS/FELLER RETO (Hrsg.), Bernisches Verwaltungsrecht, 2. Aufl., Bern 2013, 325, 343.

46 BELSER EVA MARIA, Die Kompetenzverteilung zwischen Bund und Kantonen, in: BELSER EVA MARIA/EPINEY ASTRID/WALDMANN BERNHARD, Datenschutzrecht: Grundlagen und öffentliches Recht, Bern 2011, 298, 299; RUDIN BEAT, Datenschutz und E-Government, in: BUSER DENISE (Hrsg.), Neues Handbuch des Staats- und Verwaltungsrechts des Kantons Basel-Stadt, Basel 2008, 1083, 1089.

47 Federal Act on Data Protection of 19 June 1992 (FADP, SR 235.1). Swiss Parliament is currently debating the total revision of the FADP. Cf. DIE BUNDESVERSAMMLUNG – DAS SCHWEIZER PARLAMENT, Datenschutzgesetz. Totalrevision und Änderung weiterer Erlasse zum Datenschutz (17.059), available at www.parlament.ch (visited on 20th December 2019).

48 For more details and references see RÜTSCHE BERNHARD, Datenschutzrechtliche Aufsicht über Spitäler, Zürich 2012, 41 et seqq.

49 AEBI-MÜLLER REGINA E./FELLMANN WALTER/GÄCHTER THOMAS/RÜTSCHE BERNHARD/TAG BRIGITTE, Arztrecht, Bern 2016, 22 et seq.; GÄCHTER THOMAS/RÜTSCHE BERNHARD, Gesundheitsrecht: Ein Grundriss für Studium und Praxis, 4. Aufl., Basel 2017, 73.

50 BRUNNER STEPHAN C., Mit rostiger Flinte unterwegs in virtuellen Welten?, Jusletter vom 4. April 2011, no. 24.

51 BERGER KURZEN BRIGITTE, E-Health und Datenschutz, Diss. Zürich 2004, 99; CASANOVA THOMAS, Datenverknüpfungen in ausgewählten Bereichen: Gesundheitswesen, in: EPINEY ASTRID/PROBST THOMAS/GAMMENTHALER NINA (Hrsg.), Datenverknüpfungen: Problematik und rechtlicher Rahmen, Zürich 2011, 41, 42; EPINEY ASTRID/FASNACHT TOBIAS, Zu den datenschutzrechtlichen Vorgaben für Errichtung und Betrieb von Informationssystemen: Unter besonderer Berücksichtigung der Bearbeitung besonders schützenswerter Personendaten und der Zugriffsberechtigung und am Beispiel des Klienten-Informationssystems für Sozialarbeit (KiSS), Fribourg 2014, 6.

52 THOUVENIN FLORENT/HETTICH PETER/BURKERT HERBERT/GASSER URS, Remembering and Forgetting in the Digital Age, Cham 2018, 18.

53 BELSER EVA MARIA/NOUREDDINE HUSSEIN, Datenschutzgesetzgebung im Überblick, in: BELSER EVA MARIA/EPINEY ASTRID/WALDMANN BERNHARD, Datenschutzrecht: Grundlagen und öffentliches Recht, Bern 2011, 411, 428.

54 SPRECHER FRANZISKA, Datenschutz im Gesundheitsbereich: Aktuelle Entwicklungen, in: KIESER UELI/PÄRLI KURT/UTTINGER URSULA (Hrsg.), Datenschutztagung 2018, Zürich/St. Gallen 2019, 137, 141.

sense of Art. 3 lit. c no. 2 FADP. The FADP provides for higher requirements for the processing of health data in some cases.[55]

As Florent Thouvenin demonstrated, the general data protection principles of data processing originate from the field of *public law*.[56] Therefore, some of these general principles of data protection (e. g., the principle of proportionality stipulated in Art. 4 para. 2 FADP) may not have the same meaning if private parties process personal data in the direct interest of the data subject.[57] This insight is important in the context of robotic applications used in minimally invasive surgery, as personal data is usually collected in the *interest* of *patients* (and not for purely economic purposes). In our opinion, the applicability of the general principles of data protection (in particular with regard to the principle of purpose limitation according to Art. 4 para. 3 FADP as well as the principle of proportionality according to Art. 4 para. 2 FADP) should therefore be less strict, as long as personal data is being processed by robotic applications in the interest of the patient.

b) Big Data-Based Robots and the Principles of Purpose Limitation and of Proportionality

Robotic applications can use *"Big Data"* analytics tools.[58] "Big Data" can be understood as a process consisting of collecting, integrating, interpreting data and using interpretation results.[59] The comparison of the patient's data with data from other patients is characteristic for "Big Data" in the medical context.[60] It is not simple to find out if a robotic application used in minimally invasive surgery is based on Big Data. A robot based on Big Data may run the risk of breaching the *principle of purpose limitation* (cf. Art. 4 para. 3 FADP).[61] Therefore, medical persons need to make sure they know (with the support

of IT specialists) *how* a robotic application processes patient-specific information. For example, if a patient's data is linked to data from other patients for scientific purposes, the patient's data may be processed for other purposes than the one it was originally collected for. Furthermore, robotic applications in minimally invasive surgery based on Big Data may also infringe the *principle of proportionality* according to Art. 4 para. 2 FADP, since these robots will process more than the personal data required to treat the patient.[62]

Whenever robotic applications in minimally invasive surgery process patient's data contrary to the general principles of data protection, this data processing constitutes an unlawful breach of privacy unless it is justified by the consent of the injured party or by an overriding private or public interest or by law (cf. Art. 12 para. 2 lit. a in conjunction with Art. 13 para. 1 FADP). Therefore, we recommend the medical person to seek *consent* from the patient before collecting and processing their personal data by a robotic application in minimally invasive surgery working with Big Data. As shown, information about a patient is data relating to health (cf. Art. 3 lit. c no. 2 FADP). As a result, the consent has to be given *voluntarily* on the provision of adequate information as well as *expressly* (cf. Art. 4 para. 5 FADP).

c) Cloud- and Network-Based Robots in the Field of Tension to Art. 10a and Art. 6 FADP

Robotic applications in minimally invasive surgery may also be connected to a *cloud* via a *network* such as the Internet or Intranet for data transmission and processing[63] depending on the type of robot. It is a complex issue to understand the data transmission and processing of a cloud- and network-based robot without the support of IT specialists, particularly when it comes to the question of what people have access to personal data. The processing of data relating to health by (foreign) third parties via cloud- and network-based robots may be in contradiction with *data processing by third parties* (cf. Art. 10a FADP), *cross-border disclosure* (cf. Art. 6 FADP) as well as to *violation of professional secrecy* (cf. Art. 321 of the Swiss Criminal Code[64]), because unauthorized third parties may have access to the information about the relevant patient.[65] As a result, we advise to process

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55 Cf. for example III. A. 2. b).

56 Thouvenin Florent, Erkennbarkeit und Zweckbindung: Grundprinzipien des Datenschutzrechts auf dem Prüfstand von Big Data, in: Weber Rolf H./Thouvenin Florent (Hrsg.), Big Data und Datenschutz – Gegenseitige Herausforderungen, Zürich 2014, 61, 69 et seqq.

57 Cf. in relation to the principle of proportionality Baeriswyl Bruno, Art. 4 FADP, no. 30, in: Baeriswyl Bruno/Pärli Kurt (Hrsg.), Stämpflis Handkommentar zum Bundesgesetz über den Datenschutz vom 19. Juni 1992 (Datenschutzgesetz, DSG), Bern 2015.

58 Cf. Taylor Russell H./Menciassi Arianna/Fichtinger Gabor/Fiorini Paolo/Dario Paolo, 1657, 1658.

59 Riedl Reinhard, Welchen Regulierungsbedarf schaffen die Paradigmenwechsel von Big Data?, Jusletter IT vom 21. Mai 2015, no. 19.

60 Riedl Reinhard, Jusletter IT vom 21. Mai 2015, no. 14.

61 Cf. Sprecher Franziska, Datenschutz und Big Data im Allgemeinen und im Gesundheitsrecht im Besonderen (1/2), Zeitschrift des Bernischen Juristenvereins 2018, 482, 508 et seq.; Thouvenin Florent, 61, 67 et seqq.; Weber Rolf H., *Big Data:* Herausforderungen für das Datenschutzrecht, in: Epiney Astrid/Nüesch Daniela (Hrsg.), Big Data und Datenschutzrecht, Zürich 2016, 1, 7 et seq.

62 Cf. Aebi-Müller Regina E./Fellmann Walter/Gächter Thomas/Rütsche Bernhard/Tag Brigitte (Fn. 49), 439.

63 Cf. Song Dezhen/Goldberg Ken/Chong Nak-Young, Networked Robots, in: Siciliano Bruno/Khatib Oussama (editors), Springer Handbook of Robotics, 2nd ed., Berlin 2016, 1109, 1121 et seqq. Cf. for network-based robots Niemeyer Günter/Preusche Carsten/Stramigioli Stefano/Lee Dongjun, Telerobotics, in: Siciliano Bruno/Khatib Oussama (editors), Springer Handbook of Robotics, 2nd ed., Berlin 2016, 1085, 1086; Ortmaier Tobias, 267, 271.

64 Swiss Criminal Code of 21 December 1937 (SR 311.0).

65 Cf. Wohlers Wolfgang, Auslagerung einer Datenbearbeitung und Berufsgeheimnis (Art. 321 StGB), Zürich 2016, 6 et seqq.

personal data with the help of a robot connected to a network solely with the *patient's consent* (cf. Art. 321 no. 2 of the Swiss Criminal Code).

B. Swiss Medical Device Regulations

Robotic applications, such as the "Da Vinci Surgical System", are *safety-critical systems*[66]: they may injure patients or medical staff by performing medical tasks. For this reason, it is crucial to have an effective regulation with provisions averting dangers arising from such robots. In Switzerland, the product safety regulation of *medical devices* is essentially based on the Federal Act on Medicinal Products and Medical Devices (TPA)[67] and the Medical Devices Ordinance (MedDO)[68], amongst others. Therefore, it must be first clarified whether robotic applications used in minimally invasive surgery are medical devices in the sense of the TPA (and MedDO). Second, we present the medical device legal requirements for robotic applications used in minimally invasive surgery which are regarded as medical devices in the sense of the TPA.

Legal developments in medical device regulations have been quite dynamic in recent times. The National Council and the Council of States adopted unanimously the partial revision of the TPA on 22 March 2019 and it should enter into force in the first half of 2020.[69]

1. Robotic Applications in Minimally Invasive Surgery as Medical Devices?

The TPA is only applicable to a robotic application in minimally invasive surgery if it is a *medical device*. Medical devices are defined as "products [...] which are intended to have, or are presented as having, a medical use and whose principal effect is not obtained with a medicinal product" (cf. Art. 4 para. 1 lit. b rev.TPA). Therefore, a robotic application in minimally invasive surgery is a medical device in Swiss law if its use is *medical* and its action is *not* obtained with a *medicinal product*. For example, the "Da Vinci Surgical System" performs medical tasks such as the removal of the prostate (e. g., in the case of prostate cancer), which qualifies as medical use. It may be difficult, in practice, to distinguish between robots with and without medical use,[70] especially because the legal term "medical use" in the sense of the TPA is based on the concept of a disease which is not

a genuinely legal concept. In contrast to medicinal products, medical devices achieve their intended principal medical effect mainly not by pharmacological, immunological or metabolic means, but by mechanical, physical or physicochemical means.[71] In this respect, the "Da Vinci Surgical System" is not a medicinal product because it achieves its medical effect by mechanical means. The "Da Vinci Surgical System" used in minimally invasive surgery is a medical device because it is clearly based on medical use and it is not a medicinal product (cf. Art. 4 para. 1 lit. b rev.TPA). As a result, the TPA and MedDO are applicable to the "Da Vinci Surgical System".

2. New Obligations for the Manufacturers of Robotic Applications Used in Minimally Invasive Surgery

The revised TPA leads to a *tightening* of medical device regulations and an increase of the barriers to market entry for medical device manufacturers.[72] Thus, the "rev.TPA" provides, e. g., a duty to register robotic applications used in minimally invasive surgery and to identify them (cf. Art. 47 rev.TPA). Manufacturers must now assign a *unique product identification* ("UDI") to the robotic application used in minimally invasive surgery and register such a ("rev. TPA") robot in an information system to be set up (cf. Art. 62c rev.TPA) or in the European database for medical devices ("Eudamed"). Furthermore, the "rev. TPA" stipulates a duty for manufacturers of robotic applications used in minimally invasive surgery to prepare technical documentation (cf. Art. 47a rev. TPA) and a duty to introduce and maintain a quality management system (cf. Art. 47b rev.TPA).[73]

The entry into force of the MedDO is also planned for the first half of 2020.[74] The draft consultation of the MedDO contains the obligation for manufacturers to employ at least one person in their organisation who has the necessary expertise in the field of medical devices and is responsible for compliance with the relevant regulatory requirements.[75]

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66 Taylor Russell H./Menciassi Arianna/Fichtinger Gabor/Fiorini Paolo/Dario Paolo, 1657, 1665.

67 Federal Act on Medicinal Products and Medical Devices of 15 December 2000 (Therapeutic Products Act, TPA, SR 812.21).

68 Medical Devices Ordinance of 17 October 2001 (MedDO, SR 812.213).

69 Bundesamt für Gesundheit (BAG), Revision des Medizinprodukterechts, available at www.bag.admin.ch (visited on 20th December 2019). Cf. III. B. 2.

70 Wildhaber Isabelle/Lohmann Melinda F., AJP 2017 (Fn. 20), 138 et seq. with regard to ISO 13485:2016.

71 Eggenberger Stöckli Ursula, Gesundheitsrecht: Heilmittel, in: Biaggini Giovanni/Häner Isabelle/Saxer Urs/Schott Markus (Hrsg.), Fachhandbuch Verwaltungsrecht: Expertenwissen für die Praxis, Zürich 2015, 573, 586; Gächter Thomas/Rütsche Bernhard (Fn. 49), 223; Wildhaber Isabelle, Zum Begriff des Medizinprodukts, in: Rütsche Bernhard (Hrsg.), Medizinprodukte: Regulierung und Haftung, Bern 2013, 9, 16.

72 Kesselring Felix/Reudt-Demont Janine, Eckpunkte der neuen Medizinprodukte-Regulierung, LSR 2019, 183, 191.

73 Cf. Kesselring Felix/Reudt-Demont Janine, LSR 2019 (Fn. 72), 185 et seq.

74 Bundesamt für Gesundheit (BAG), Erläuternder Bericht zur Totalrevision der Medizinprodukteverordnung und Verordnung über klinische Versuche mit Medizinprodukten (neue Medizinprodukte-Regulierung), Bern 2019, 9, available at www.bag.admin.ch.

75 Bundesamt für Gesundheit (Fn. 74), 30 et seq.

3. Placing on the Market of Robotic Applications Used in Minimally Invasive Surgery

The TPA regulates different legal aspects regarding placing on the market, distribution and monitoring of a medical device.[76] Medical devices do not require an official authorization in contrast to medicinal products;[77] instead they must *get a certification.*[78] The conformity assessment by the legal manufacturer and market surveillance by Swissmedic replace an official approval in order to guarantee the safety and efficacy of medical devices in Switzerland.[79] Medical devices are divided into different classes (I, IIa, IIb und III) for this conformity assessment. In view of the high level of detail of the *classification rules* and their adaptation to the *concrete purpose* of the respective product, the classification of a robotic application used in minimally invasive surgery must be determined in the concrete individual case and cannot be determined in general.[80] To get certified, the manufacturer of a robotic application used in minimally invasive surgery must prove that this robot is in line with the *essential legal requirements* (cf. Art. 45 para. 2 TPA).[81] These essential legal requirements do not include detailed technical rules. It is difficult for the manufacturer of robotic applications in minimally invasive surgery to know whether their product complies, as these essential legal requirements are too *vague* and too *open.*[82] Therefore, *technical standards* of private standardization bodies substantiate these essential requirements.[83] For example, SN EN ISO 13485:2016 ("Medical devices – Quality management systems – Requirements for regulatory purposes") as well as DIN EN 80601-2-78:2018 ("Medical Electrical Equipment – Part 2–78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation") (available as a draft) are two technical standards which stipulate safety requirements for robotic applications in minimally invasive surgery. However, as these standards are only "soft law", the manufacturer of a robotic application in minimally invasive surgery is not legally obliged to fulfill these technical standards.[84] Compliance by manufacturers with the (designated) technical standards gives rise to the *rebuttable presumption* that a robotic application used in minimally invasive surgery meet the essential safety and performance requirements.[85]

4. Product Monitoring of Robotic Applications in Minimally Invasive Surgery

Product monitoring after placing a robotic application in minimally invasive surgery on the market is an essential part of the medical devices regulation concept. The manufacturer of a robotic application in minimally invasive surgery must introduce and maintain a *product tracking system* ("post-market surveillance system"). The manufacturer must actively and systematically collect, record and analyse data on the quality, performance and safety of the robotic applications in minimally invasive surgery throughout its lifetime in order to identify and take any measures necessary to avert danger or improve the robot.[86] It is unclear if the manufacturer of a robotic application in minimally invasive surgery must carry out an on-the-spot inspection. If there is a *concrete suspicion* of endangering a person's health, the manufacturer must carry out an on-the-spot inspection. In our opinion, an effective product tracking system requires a *close collaboration* between the manufacturer and the users of a robotic application used in minimally invasive surgery by sharing product-specific information in order to reduce potential health risks.

IV. Conclusion

Robotic applications in minimally invasive surgery such as the "Da Vinci Surgical System" are an *information-driven* and *safety-critical technology.* There-

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76 Wildhaber Isabelle (Fn. 71), 9.

77 Cf. Art. 9 para. 1 TPA. Cf. for the authorisation of medicinal products Bratschi Peter/Eggenberger Stöckli Ursula, Bundesgesetz über Arzneimittel und Medizinprodukte (Heilmittelgesetz): Gesetzestext mit Erläuterungen, Bern 2002, 8 et seqq.; Gächter Thomas/Rütsche Bernhard (Fn. 49), 228 et seqq.; Poledna Tomas/Berger Brigitte, Öffentliches Gesundheitsrecht, Bern 2002, no. 318 et seqq.; Richli Paul, Regelungsschwerpunkte des Heilmittelgesetzes, unter besonderer Berücksichtigung formeller Rechtsfragen, in: Eichenberger Thomas/Poledna Tomas (Hrsg.), Das neue Heilmittelgesetz, Zürich/Basel/Genf 2004, 47, 55 et seqq.

78 The fact that medical devices do not require state approval in Switzerland is not a matter of course. US law, for example, subjects medical devices to a state approval procedure in the area of marketing. Cf. Von Manger-Koenig Jörg, Inverkehrbringen von Medizinprodukten in den USA, in: Rütsche Bernhard (Hrsg.), Medizinprodukte: Regulierung und Haftung, Bern 2013, 131, 141 et seqq.

79 Bratschi Peter/Eggenberger Stöckli Ursula (Fn. 77), 19; Eggenberger Stöckli Ursula, Gesundheitsrecht: Heilmittel, in: Biaggini Giovanni/Häner Isabelle/Saxer Urs/Schott Markus (Hrsg.), Fachhandbuch Verwaltungsrecht: Expertenwissen für die Praxis, Zürich 2015, 573, 615; Gächter Thomas/Burch Stephanie, Inverkehrbringen von Medizinprodukten in der Schweiz und in der EU, in: Rütsche Bernhard (Hrsg.), Medizinprodukte: Regulierung und Haftung, Bern 2013, 93, 100.

80 Cf. BaslerKomm/Meier, Art. 45 HMG, no. 64.

81 Bratschi Peter/Eggenberger Stöckli Ursula (Fn. 77), 97.

82 BaslerKomm/Meier, Art. 45 HMG, no. 22.

83 Fuchs Philippe, (Berechtigte) Sicherheitserwartungen bei Medizinprodukten, Sicherheit & Recht 2016, 122, 124; Gächter Thomas/Burch Stephanie (Fn. 79), 101 et seq.

84 BaslerKomm/Meier, Art. 45 HMG, no. 25 and no. 86; Gächter Thomas/Burch Stephanie (Fn. 79), 102; Jacobs Theo, Normen und Richtlinien, in: Hilgendorf Eric/Günther Jan-Philipp (Hrsg.), Robotik und Gesetzgebung: Beiträge der Tagung vom 7. bis 9. Mai 2012 in Bielefeld, Baden-Baden 2013, 73, 75.

85 Cf. BaslerKomm/Meier, Art. 45 HMG, no. 24; Bundesamt für Gesundheit (Fn. 74), 16; Philippe Fuchs, Sicherheit & Recht 2016 (Fn. 83), 124.

86 Cf. Art. 47b para. 2 rev.TPA; Bundesamt für Gesundheit (Fn. 74), 34.

fore, data protection law as well as medical device regulations govern this robot type, such as the "Da Vinci Surgical System". Whenever such robots collect and process information of a patient based on Big Data, we recommend the doctor to seek consent from the patient. The same goes for robotic applications used in minimally invasive surgery connected to a cloud via a network. Doctors must make sure they understand (with the support of IT specialists) how these robots process patient-specific information to comply with the relevant provisions of data

protection law. Robotic applications in minimally invasive surgery, such as the "Da Vinci Surgical System", are (normally) medical devices under Swiss law. As a result, the provisions of the TPA and MedDO are applicable. Manufacturers of robotic applications in minimally invasive surgery must introduce and maintain a product tracking system. An effective product tracking system requires a close collaboration between the manufacturer and users of the "Da Vinci Surgical System" in order to reduce potential health risks.