ORIGIN®

Implants and instruments for total knee replacement

Author	Reviewer	QA Approval
Bruno PAIS Clinical Affairs Specialist	Bojana GANNEVAT Clinical Affairs Manager	Nicolas GUIGNET VP RA & QA
Visa: *Date :* 20-MAY-2022	*Visa:* *Date :* 20-MAY-2022	*Visa:* *Date :* 20-May-2022

I. COVER PAGE

Clinical Investigation Title	Performance and safety evaluation of the ORIGIN® PS knee prosthesis and the KNEE-PLAN® Set ORIGIN® instruments
Clinical Investigation Plan Number, version and date	CLIN-G-008 12.NOV.2018 VERSION 2.0
Report Document Version	21 December 2021 version 0.1
Study design	Observational / Prospective / Multicentric / Non-comparative / Single arm PMCF study
Evaluated Devices	The ORIGIN® PS devices are made of a Total Knee Prosthesis (femoral component, tibial insert, tibial tray and patellar component) and of instruments (including patient-specific and/or single use cutting guides and instruments). A preoperative planification is made before the surgery based on patient's CT-scan
Sponsor Local representative	Symbios Orthopédie SA Avenue des Sciences 1 1400 YVERDON LES BAINS, Suisse Symbios France SAS, Rue d'Arsonval, 14 – 69680 Chassieu, France
Key Collaborators	Dr. Michel Bonnin, Orthopedic surgeon Dr. Tarik Ait Si SELMI, Orthopedic surgeon, Professor Carsten Tibesku, Orthopedic surgeon
Report date	20-MAY-2022

II. SUMMARY

Clinical Investigation title	Performance and safety evaluation of the ORIGIN® knee prosthesis and the KNEE-PLAN® Set ORIGIN® instruments
Protocol Date / Version:	CLIN-G-008 12.NOV.2018 VERSION 2.0
Study date of initiation	06.DEC.2018
Completion date	Ongoing clinical study –estimated closure date: 01.APR.2029
Brief Introduction	This is a prospective, non-comparative, single arm, multicentric, observational, post-market study. The study is performed in Germany, and in France. 434 subjects were implanted within this study with ORIGIN PS System and were included upon eligibility assessment. The enrolment period is completed and had occurred at the time of the medical examination. It was assumed that the subjects' treatments and follow-up visits will be performed per standard of the investigational site in Germany and in France. The 2 years follow-up visits were performed between 06.DEC 2020 to 25.AUG 2021 As each implanted subject is to be followed for 10 years, the estimated study duration is approximately about 240months, excluding the time required for preparing the final report. (A loss of approximately 10% is expected at the end of the study) The completion of a clinical investigation will coincide with the last visit of the last subject (supposed to be after 10 years follow-up visit: - First patient in: 06.DEC: 2018 - Last patient in: 25.AUG 2020 - And when follow-up is complete for the clinical investigation, expected completion in DEC 2028 (last patient last visit) - Study closure: expected approximate date: APRIL-2029
Study Purpose:	The study objective is to assess clinical safety and device performance outcomes of the ORIGIN System used in routine hospital practice in a large patient cohort treatment of total knee arthroplasty.
Study design:	Observational / Prospective / Multicentric / Non-comparative / Single arm PMCF study
Sample size description	Patients who have provided consent for participating in this study and met the protocol eligibility criteria will be enrolled into this observational non comparative prospective multicentric study.
Statistical Methods	The primary objective of the study is to evaluate the prosthesis revision rate (all reasons of revision) at 10 years. The hypothesis is that the revision rate

	at 10 years of the ORIGIN® prosthesis is equivalent to the revision rate in the state of the art: 7% at 10 years follow-up (survival = 93%). Evaluation of a sample size: (minimum required) A sample size of 139 patients provided 80% power to detect a difference between the preoperative and the postoperative value at each review (3-6 months, 1 year, 3 years, 5 years, 7 years, and 10 years of follow-up) with a two-sided α risk of 5%. The chosen precision is 5%. Assuming a drop-out or loss to follow-up rate of 10%, the calculation of the 5% confidence interval of the survival rate has allowed to estimate the minimum number of procedures to include in this study: the targeted sample size was adjusted to 155 patients. The Kaplan-Meier survival analysis will be used to estimate the cumulative incidence of revision of ORIGIN® knee prosthesis at 10 years of follow-up after the total knee arthroplasty.
Results	The results will be presented in a table containing the following information: - Patient population: n=434 - Implanted devices, surgery dates - Demographics, indications and follow-up - Performance results - Safety results
Conclusion	The main objective is to collect relevant clinical data related to pain, knee flexion, the knee function, the quality of life and the performance of implants and instruments. • The performance and safety data pertaining to the ORIGIN® PS l devices are consistent with the state of the art – ODEP benchmark (2.5% to 3.5% at 1 year, 4% to 6% at 5 years and 5% to 7% at 10 years): • The revision rate of ORIGIN® PS is 0.9% at 2.7 years of follow-up • As a comparison, the revision rate of FIRST® Fixed (similar and equivalent devices) is 2.3% at 5.8 years of follow-up (as detailed in the CER 5000-07.01) • The clinical data allows to demonstrate the conformity to the General Requirements related to performance and safety, the acceptable benefit/risk profile and the acceptability of side-effects • The benefit/risk profile is acceptable according to current knowledge/state of the art
Report date	20.MAY.2022 (Summary Report)

III. RESULTS

1.1 Devices Description

a) a description of the study devices

Implants				
Basic UDI-DI	Symbios reference	Product name	EMDN code	Product class
N/D	5000 1100	ORIGIN PS Femur Cemented	P0909030101	☒ Class III
N/D	5000 310X	ORIGIN PS Fixed Insert	P090903020202	☒ Class III
N/D	5000 2100	ORIGIN PS Fixed Tibia Monobloc Cemented	P090903020104	☒ Class III
Statistics N/D	5000 410X	ORIGIN Patella	P09099001	☒ Class III
Instruments				
Basic UDI-DI	Symbios reference	Product name	EMDN code	Product class
N/D	9000 0031	Drill pin - Ø 3.2 mm x 70 mm	N/D	☒ Class IIa
N/D	9000 400X	Stop drill bit	N/D	☒ Class IIa
N/D	9000 780X	ORIGIN Patella trial component	N/D	☒ Class IIa
N/D	9005 0000	ORIGIN KNEE-PLAN® Guides	N/D	☒ Class IIa
N/D	9005 0011	ORIGIN PS Femur Set	N/D	☒ Class IIa
N/D	9005 0012	ORIGIN PS Tibia Set	N/D	☒ Class IIa
N/D	9005 0013	ORIGIN PS Tibia Modular Set	N/D	☒ Class IIa
N/D	9005 0021-25	ORIGIN PS Impaction Set	N/D	☒ Class IIa
N/D	9005 0026-30	ORIGIN Impaction Set	N/D	☒ Class IIa
N/D	9000 0019	Drill pin adapter	N/D	☒ Class I
N/D	9000 0003	Resection controller	N/D	☒ Class Ir
N/D	9000 0008	EM alignment rod	N/D	☒ Class Ir
N/D	9000 0010	Pin removal forceps	N/D	☒ Class Ir
N/D	9400 0001	Patella cutting clamp	N/D	☒ Class Ir
N/D	9400 0002	Patella compression clamp	N/D	☒ Class Ir
N/D	9400 2001-05	ORIGIN® Drill tip	N/D	☒ Class Ir
N/D	PD000069	Compression tip	N/D	☒ Class Ir

b) The intended use of the devices

Intended use/purpose	The ORIGIN® PS devices including a femoral component, a tibial insert, a tibial tray and a patellar component (optional) are intended to be used in first intention total knee arthroplasty under general anesthesia by trained orthopedic surgeons and their operating team.

Target population	The ORIGIN® PS devices are intended to be used for performing primary cemented total knee replacement in patients suffering from non-inflammatory degenerative or inflammatory knee joint disease
N patients using the device	Estimated N patients corresponding to the total sales of ORIGIN® PS and devices
Description of the device	The ORIGIN® PS are a postero-stabilized (PS) knee prosthesis Both devices include a cemented femoral component, a fixed tibia insert component (proposed in two thicknesses), a fixed cemented tibial tray component and a cemented patellar component. The implantation of an ORIGIN® requires a specific disposable knee instrumentation (ORIGIN® KNEE-PLAN ® Guides, ORIGIN® PS Femur Set, ORIGIN® PS Tibia Set and Knee Impaction Set) as well as conventional instrumentation (ADD-ON Instrumentation). The ORIGIN® KNEE-PLAN® Guides are patient-specific cutting guides with their corresponding bone models. The ORIGIN® PS Femur set and the ORIGIN® PS Tibial set are patient-specific instrumentations used with the Knee Impaction Set, not patient-specific.
Applicable IFU reference	IFU 201 (Implants) IFU 211 (Single-use instruments) IFU 212 (Impaction instruments)

1.2 Clinical Data

Clinical data pertaining to the use of ORIGIN® PS devices are compiled in the following table (Data updated as of 10-MAY-2022), and contain:

- Patient population: n=434
- Implanted devices, surgery dates
- Demographics, indications and follow-up
- Performance results
- Safety results

			country	*FR & DE*		
				ORIGIN PS PMCF study		
				Clin-G-008 Last update 10.05.2022		
Study			n followed-up	434		
			Status	n	%	
			Deaths	7	1.6%	
			Revised	4	0.9%	
			Unrevised	430	99.1%	
Components and instr	Femoral	ORIGIN® PS Femur Cemented		434		
	Tibial insert	ORIGIN® PS Fixed Insert		434		
	Tibial insert size	6mm		330		
		8mm		84		
	Tibial tray	ORIGIN® PS Tibia Monobloc Cemented		434		
	Patellar compon	FIRST® Patella		0		
		ORIGIN® Patella Cemented		118		
Patients, indications and follow-up	Demographics	% males		47%		
		% females		53%		
		Mean age (years)		70.9		
		Mean weight (kg)		80.6		
		Mean height (cm)		168.5		
		Mean Body Mass Index		28.3		
	Indications	Osteoarthritis		90%		
		Avascular necrosis		2%		
		Post laxity		3%		
		Rheumatoid arthritis		1%		
		Post infection		0%		
		Post-traumatic arthritis		4%		
		Other		0%		
	Follow-up	First surgery date		06.12.2018		
		Last surgery date		25.08.2020		
		Mean follow-up (years)		2.7		
		Max follow-up (years)		3.4		
Performance and safety	Performance	STEP		Preop	3-6 months	1 Year	3 Years
		KSS Knee Score / 100		30.3	92.6	95.1	94.9
		Last FU KSS Knee > 85.5		90.8%			
		KSS Function score / 100		54.3	93.3	96.9	93.0
		Last FU KSS Function > 72.5		93.8%			
		Knee flexion (degrees)		118.4	121.3	127.5	129.4
		Forgotten joint score (FJS) /100		15.7	50.6	65.3	69.1
		Oxford Knee Score / 48		21.6	36.3	40.2	41.0
		Patients satisfaction / 10		NA	8.6	9.5	8.9
	Safety	n followed-up		434			
		Intraoperative complications		n		%	
		Fracture		1		0.2%	
		Patellar injury		0		0.0%	
		Patella tendon avulsion		0		0.0%	
		Ligament injury		0		0.0%	
		Other		0		0.0%	
		TOTAL		1		0.2%	
		n followed-up		434			
		Postoperative adverse events		Rev	%	NOT REV	%
		Infection		1	0.2%	0	0.0%
		Progressive arthritis		0	0.0%	0	0.0%
		Femoral aseptic loosening		0	0.0%	0	0.0%
		Tibial aseptic loosening		1	0.2%	0	0.0%
		Patellar aseptic loosening		0	0.0%	0	0.0%
		Pain		0	0.0%	15	3.5%
		Stiffness		1	0.2%	10	2.3%
		Malalignement		0	0.0%	0	0.0%
		Instability		0	0.0%	0	0.0%
		Dislocation-subluxation		0	0.0%	0	0.0%
		Periprosthetic fracture		1	0.2%	3	0.7%
		Wear		0	0.0%	0	0.0%
		Tibial lysis/soft tissue reaction		0	0.0%	1	0.2%
		Femoral lysis		0	0.0%	0	0.0%
		Component dissociation		0	0.0%	0	0.0%
		Implant fracture		0	0.0%	0	0.0%
		Patellar clunk / problems		0	0.0%	0	0.0%
		Wound dehiscence		0	0.0%	1	0.2%
		Heterotopic ossification		0	0.0%	0	0.0%
		Insert spin-out		0	0.0%	0	0.0%
		Other reason		0	0.0%	3	0.7%
		TOTAL reasons for revision		4	0.9%	33	7.6%
		TOTAL revision of all ORIGIN components		4	0.9%	NA	
		Mean follow-up (years)		2.7			

1.3 Clinical Data - Conclusion

The ORIGIN® PS devices are followed-up in a post-market clinical follow-up study (CLIN-G-008). This study is related to 434 primary total knee replacements, performed between 2018 and 2020. Indications are coherent with instructions for use. The mean follow-up is 2.7 years.

a) Performance

(a) Implants

The KSS KNEE scores of the ORIGIN® PS devices are consistent with the performance claim (KSS KNEE score > 85.2 points) related to pain, mobility, flexion and alignment:

- The KSS KNEE score of the ORIGIN® PS devices is significantly improved at 1, and 3 years (mean score: 94.9/100 is excellent) compared to preoperative value (mean score: 30.3/100 is poor).
- The rate of patient with a KSS KNEE higher than 85.2 at 3 years is 90.8%

The KSS FUNCTION score of the ORIGIN® PS devices is consistent with the performance claim (KSS FUNCTION score > 72.5 points) related to walking, stairs and used of walking aids:

- The KSS KNEE score of the ORIGIN® PS devices significantly improved at 3 years (mean score: 93/100 is excellent) compared to preoperative value (mean score: 54.3/100 is poor).
- The rate of patient with a KSS KNEE higher than 72.5 at 3 years is 93.8%

The Oxford Knee Score (pain, walking, stairs) for the ORIGIN® PS devices is significantly improved at 3 years (mean score: 41/100 is excellent) compared to preoperative value (mean score: 21.8/100 is poor).

The Forgotten Joint Score (perception of the patient about their knee) for the ORIGIN® PS devices is significantly improved at 3 years (mean score: 69.1/100 is very good) compared to preoperative value (mean score: 15.7/100 is poor).

- The clinical data are validated for n=434 procedures with a follow-up of more than 2 years.

(b) Instruments:

The rate of accuracy within ±3° for the ORIGIN® PS devices is consistent with the performance claim (the femoral component with an accuracy of 75% in the frontal position, and the tibial component with an accuracy of 80% in the frontal position and 65% in the sagittal position:

- The rate of accuracy within ±3° for the Alpha angle is 96% (frontal component in the frontal position), for the Beta angle is 92% (tibial component in the frontal position), and for the Tibial slope is 98% (tibial component in the frontal position).

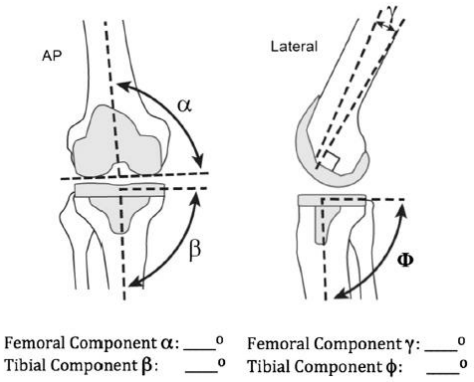
The performance claim for the instruments is assessed by the accuracy (within ±3°) of the implant position:

- "To implant the femoral component (within ±3°), the accuracy is 75% for the frontal position."
- "To implant the tibial component (within ±3°), the accuracy is 80 %for the frontal position and 65 % for the sagittal position."

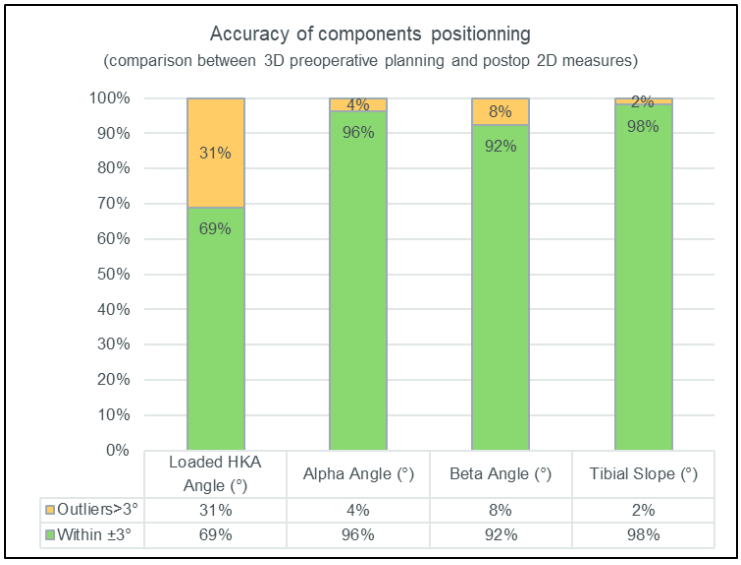
Regarding the performance of **ORIGIN®** instruments is higher than the expected claim for:

→ the femoral component in the frontal position (**96% > 75%)**

→ the tibial component in the frontal position (**92% > 80%)** and the sagittal position (**98% > 65%**)



Accuracy within ±3°	Within ±3°	Outliers>3°
Loaded HKA Angle (°)	69%	31%
Alpha Angle (°)	96%	4%
Beta Angle (°)	92%	8%
Tibial Slope (°)	98%	2%



According to the Knee Society Radiographic Evaluation System[1] :

[1] Meneghini RM, et al, Development of aModern Knee Society Radiographic Evaluation SystemandMethodology for Total

b) Safety

The revision rate of the ORIGIN® PS devices is consistent with the state of the art – ODEP benchmark System (2.5% to 3.5% at 1 year, 3.5% to 5.5% at 3 years, 4% to 6% at 5 years and 5% to 7% at 10 years):

Details about per-operative complications (n=1):

→ Femoral fracture (n=1)

Details about postoperative complications (n=33) → revisions (n=4)

n followed-up	434			
Postoperative adverse events	**Rev**	**%**	**NOT REV**	**%**
Infection	1	0.2%	0	0.0%
Tibial aseptic loosening	1	0.2%	0	0.0%
Pain	0	0.0%	15	3.5%
Stiffness	1	0.2%	10	2.3%
Periprosthetic fracture	1	0.2%	3	0.7%
Tibial lysis/soft tissue reaction	0	0.0%	1	0.2%
Wound dehiscence	0	0.0%	1	0.2%
Other reasons	0	0.0%	3	0.7%
TOTAL reasons for revision	**4**	**0.9%**	**33**	**7.6%**
TOTAL revision of all ORIGIN components	**4**	**0.9%**	**NA**	
Mean follow-up (years)	2.7			

→ Other reasons (n=3) → swelling (n=1), progressive arthritis (n=1), low back pain (n=1)

At a mean follow-up of 2.7 year:

→ The per-operative complications (n=1) → revision rate is 0.2%

→ The postoperative complications (n=4) → revision rate is 0.9%

The postoperative complications (n=33) rate without revision is 7.6%

- The revision rate of ORIGIN® PS devices is 0.9% at a mean follow-up of 2.7 years.
- The clinical data are validated for n=434 procedures with a follow-up of more than 2 years.

Knee Arthroplasty, J Arthroplasty (2015)

B. Surgeon

1. CV of the approver surgeon

PROF. DR. CARSTEN TIBESKU

BAHNHOFPLATZ 1. 94315 STRAUBING

DIPLOMA

Jahrgang 1972 Schulbildung und Zivildienst in Paderborn/Westfalen
1992 – 1998 Studium der Humanmedizin in Münster/Westfalen und Zürich/Schweiz
1999 Arzt im Praktikum in Zentrum für Kniechirurgie, ATOS Klinik, Heidelberg
2000 – 2005 Facharztausbildung an der Klinik und Poliklinik für Allgemeine Orthopädie der Westfälischen Wilhelms-Universität Münster
2005 – 2007 Oberarzt an der Klinik für Orthopädie und Rheumatologie der Philipps-Universität Marburg
2007 – 2017 niedergelassener Arzt und Partner im sporthopaedicum Straubing und Regensburg
2010 Ernennung zum außerplanmäßigen Professor an der Medizinischen Fakultät der Philipps-Universität Marburg
seit 2017 niedergelassener Arzt in der KniePraxis Prof. Tibesku, Straubing

MEMBERSHIPS

Gründungsmitglied der European Knee Society (EKS)
Deutsche Gesellschaft für Endoprothetik (AE)
European Knee Associates (EKA)
Deutsche Kniegesellschaft (DKG)
Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC)
Norddeutsche Orthopädenvereinigung (NOV)
Vereinigung Süddeutscher Orthopäden (VSO)
International Affiliate Member of the American Academy of Orthopaedic Surgeons (AAOS)
European Society of Sports Traumatology, Knee Surgery and Arthroscopy (ESSKA)

PUBLICATIONS (KNEE SURGERY ONLY)

1. Reduced joint-awareness in bicruciate-retaining total knee arthroplasty
compared to cruciate-sacrificing total knee arthroplasty
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K.
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9. A comparison of conventional and patient-specific instruments in total knee
arthroplasty
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11. Benefits of using customized instrumentation in total knee arthroplasty:
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Tibesku C.O. Hofer P. Portegies W. Ruys C.J.M. Fennema P.
Archives of Orthopaedic and Trauma Surgery (2013) 133:3 (405-411). Date of
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12. Frontal plane alignment after total knee arthroplasty using patient-specific
instruments
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International Orthopaedics (2013) 37:1 (45-50). Date of Publication: January
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13. Femoro-tibial kinematics after TKA in fixed- and mobile-bearing knees in the
sagittal plane
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Daniilidis K. Skwara A. Vieth V. Fuchs-Winkelmann S. Heindel W. Stückmann V.
Tibesku C.O.
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16. In vitro kinematics of human native knees a database of 60 specimens
Labey L. Bellemans J. Chevalier Y. El-Zayat B. Fuchs-Winkelmann S.
Heesterbeek P. Heyse T. Kowalczewski J. Okon T. Pianigiani S. Tibesku C.
Vandenneucker H. Victor J. Wymenga A. Innocenti B.
Journal of Biomechanics (2012) 45 Supplement (S394). Date of Publication: 1
Jul 2012

2. Declaration of interest of the approver surgeon

symbios

Avenue des Sciences 1
1400 YVERDON LES BAINS
Switzerland

Declaration on Interests of the approver surgeon

I hereby declare the following conflicts of interests:

Employment by the manufacturer (SYMBIOS Orthopédie SA)	☐ YES ☒ NO
Participation as a monitor in clinical studies of the device	☐ YES ☒ NO
Participation as an investigator in clinical studies of the device[1]	☒ YES ☐ NO
Participation in pre-clinical testing of the device (cadaver testing)	☐ YES ☒ NO
Grants sponsored by the manufacturer	☐ YES ☒ NO
Travelling or hospitality (beyond what is reasonably necessary for the work)	☐ YES ☒ NO
Interest in connection with the manufacturing of the device or its constituents	☐ YES ☒ NO
Interest in connection with intellectual property (patents, copyrights, royalties)	☒ YES ☐ NO

Name : Carsten TIBESKU

Function : Orthopaedic surgeon

Date : 01. 10. 2021

Signature :

APPROVAL BY THE MANUFACTURER:

Name : Nicolas GUIGNET

Function: VP Regulatory Affairs & Quality

Date : 11-Oct-2021

Signature :

[1] CLIN-G-008 study (ORIGIN® knee prosthesis and the KNEEPLAN® Set ORIGIN® instruments)

3. Approval of the document by the orthopaedic surgeon

Approval of the document by an orthopaedic surgeon

FIRST NAME: CARSTEN

LAST NAME: TIBESKU

SPECIALTY: ORTHOPÄDIE, SPORTMEDIZIN, PHYSIKALISCHE THERAPIE, MANUELLE THERAPIE, SPEZIELLE SCHMERZTHERAPIE

HOSPITAL: KNIEPRAXIS

CITY: STRAUBING

COUNTRY: GERMANY

EXPERIMENTED USER OF ORIGIN © DEVICES: ☒ YES ☐ NO

SURGEON'S COMMENTS (not mandatory):

Date: 20.05.2022

Signature: