

National Registry for Hip and Knee Replacement

Organization and function

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SIRIS Partner Organizations



ANQ

Swiss National Association for Quality Development in Hospitals and Clinics



H+ Die Spitäler der Schweiz (H+ The Hospitals of Switzerland)

Umbrella organization of public and private hospitals, clinics, and care institutions

SWISS MEDTECH

Swiss Medtech

Industry organization for Swiss medical technology



santésuisse

Industry organization for Swiss health insurers



swiss orthopaedics

Swiss Society of Orthopaedics and Traumatology

Swiss Implant Registry SIRIS

Background

The Swiss Implant Registry SIRIS exists to promote quality of treatment in the field of medical implants. By measuring the hard endpoint of “**implant exchange**”, the service life of prostheses can be monitored throughout Switzerland. Analysis of the data collected makes it possible to identify factors that affect the service life.

The Federal Office of Public Health (FOPH) welcomes the establishment of an independent implant registry; it is in accordance with the formal inclusion of the **obligation for quality assurance** in Art. 58 of the Health Insurance Act (KVG).

The registry

Medical registries make a valuable contribution to the detailed evaluation of long-term implant and treatment quality and serve as an **early warning system** for product defects or process failures.

In Switzerland, approximately 22,000 artificial hip joints and 18,000 artificial knee joints are implanted each year. These products are produced or sold by approximately 16 companies. They are implanted by around 800 physicians, who carry out the procedures in about **157 hospitals** (see page 11).

Sponsorship

The foundation for quality assurance in medical implants SIRIS is an **independent**, non-profit organization. It was founded in August 2007 by swiss orthopaedics, Swiss Medtech and santésuisse, and subsequently established the Swiss Implant Registry SIRIS.

Mandate

Since 2012, the SIRIS registry for hip and knee joint prostheses has formed part of the **ANQ review plan**¹ and has been **compulsory** for hospitals that have signed the National Quality Agreement and that list these two procedures in the catalog of services they offer. As a result of this, today over 95% of all hip and knee replacements are recorded in the SIRIS registry each year.

SIRIS founding members

<p>swiss orthopaedics</p> <p>Swiss Society of Orthopaedics and Traumatology</p>	<p>Swiss Medtech</p> <p>Industry organization for Swiss medical technology</p>	<p>santésuisse</p> <p>Industry organization for Swiss health insurers</p>
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¹ The Swiss National Association for Quality Development in Hospitals and Clinics (ANQ) coordinates and implements quality measurements in acute care, rehabilitation and psychiatry. The results enable transparent comparability at a national level. On the basis of these findings, hospitals and clinics can develop targeted measures to improve their quality. Members of ANQ include the hospital organization H+, santésuisse, the Swiss social insurance providers, the cantons and the Swiss Conference of Health Directors.

Organization

Responsibility

The SIRIS Foundation Board is the main responsible body. Relations between the ANQ, the registry operator SwissRDL of the University of Bern and the SIRIS foundation are contractually governed.

Foundation Board

The Foundation Board is composed of two representatives from each of the following professional associations.

H+ Die Spitäler der Schweiz

Umbrella organization of public and private hospitals, clinics, and care institutions

santésuisse

Industry organization for Swiss health insurers

Swiss Medtech

Umbrella organization for Swiss medical technology

swiss orthopaedics

Swiss Society of Orthopaedics and Traumatology

Cooperation with the ANQ

As a result of incorporating the SIRIS registry for hip and knee joint prostheses into the **ANQ review plan**, today over 95% of all hip and knee replacements are recorded in the SIRIS registry each year. This partnership has also managed to secure financing for the registry. Members of ANQ include the hospital organization Hplus, santésuisse, the Swiss social insurance providers, the cantons and the Swiss Conference of Health Directors.

Financing

The National Quality Agreement requires hospitals to pay a contribution to SIRIS (per hip or knee replacement). An **independent trust company** issues an invoice (quarterly) to each hospital for their SIRIS contribution, based on the delivery details reported by the implant manufacturers.

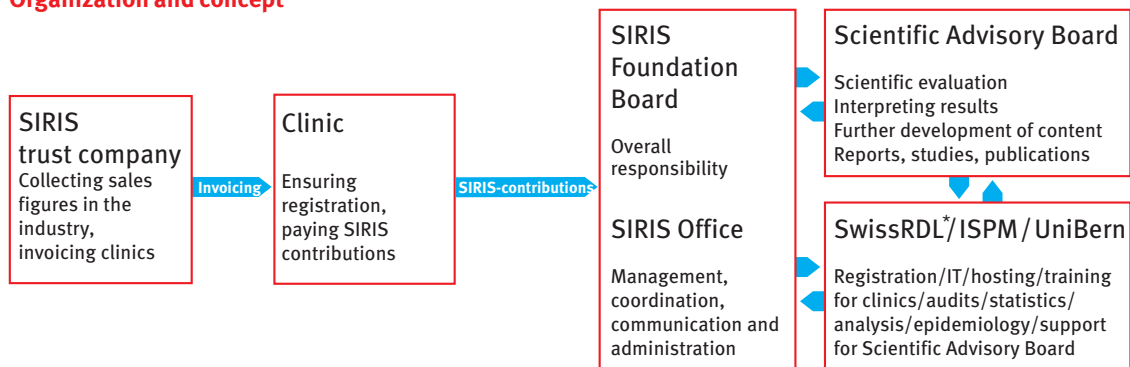
Technical implementation

SwissRDL, a part of the ISPM at the University of Bern, handles the technical implementation, support for hospitals, data management and statistical evaluation on behalf of the SIRIS foundation. The hardware and software components are regularly checked for security, data protection and integrity as well as undergoing further development.

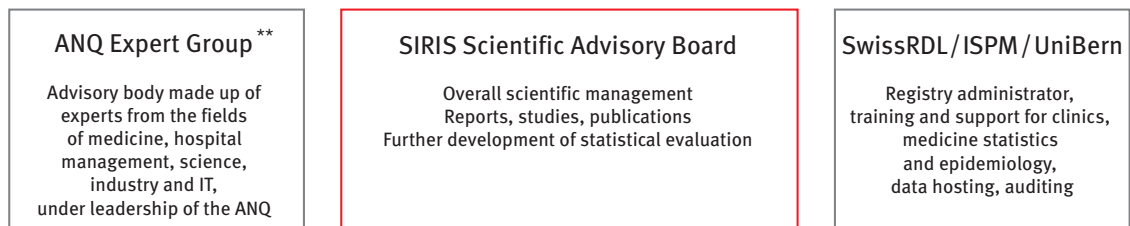
Scientific evaluation

The **SIRIS Scientific Advisory Board** is responsible for data analysis, studies, publications and the annual SIRIS report. The **SIRIS Expert Group** assists the board in an advisory capacity under the leadership of the ANQ. Further evaluations and topics are developed collaboratively. The SIRIS Foundation Board is the main responsible body.

Organization and concept



Scientific evaluation



* SwissRDL – medical Registries and Data Linkage, a part of the ISPM – Institute for Social and Preventive Medicine, at the University of Bern
 ** National Association for Quality Development in Hospitals and Clinics; ANQ members include the hospital organization H+, santésuisse, the cantons and the Swiss social insurance providers.

Collection of data

Clinical data

Patient names, type of procedure, date, surgeon and health institution as well as patient characteristics (sex, age, height, weight, Charnley class), diagnosis and technical details of the operation (surgical approach, positioning, devices) are collected by means of a questionnaire. Each questionnaire can be filled out by the surgeon, their assistant or – based on the surgical report – by the clerical staff. The questionnaires are completed within minutes and vary depending on the implant used (knee or hip, primary prosthesis, revision or follow-up).

The hospital obtains the patient's consent to have their data collected. The patient is entitled to refuse to have the data about their procedure stored.

Data transfer and data protection

The SIRIS registry facilitates a streamlined, cross-institutional tracking of implants, without infringing upon the personal rights of patients. The specific architecture of the server environment and the data encryption ensures the traceability of implants, or patients. The social insurance number is never saved; after being encrypted in the browser it is deleted and only the hash code generated from it remains in the registry.

A plan to link the SIRIS registry to the Swiss deaths registry is in development. Connecting the two registries is vital to assessing the service life of different implants.

Implant data

The correct identification of the **implants** used in connection with a particular procedure requires the documentation of certain data. All implant components used are recorded and can be assigned to the corresponding patient/procedure in the SIRIS database.

Types of collection

To make the collection of data as easy as possible for hospitals, there are several possibilities:

Submission of paper forms

There are entry forms available for each area (hip, knee, primary, revision, follow-up). The front side of the form is for patient details and clinical data; on the back there is space for stickers taken from whichever products were used. This questionnaire is sent to the institute operating the registry (SwissRDL) or submitted online by the hospital administration.

Online submission

Using a password, the orthopedist can access their data collection in the SIRIS registry directly (MEM-doc). Patient and operation data is then entered online by the physician and/or the hospital administration.

Submission using an integration of the hospital information system (HIS)

Submission within the hospital's own HIS and transfer direct to the SIRIS registry using the interface

Submission using the SIRIS app

Online and offline submission via app; transfer direct to the SIRIS registry using the interface.

Paper forms

The image displays various forms and app interfaces for the SIRIS register. On the left, there are paper forms for 'HÜFTE' (Hip) and 'KNIE' (Knee) primary prostheses, including sections for patient data, diagnosis, previous operations, and operation details. On the right, there are screenshots of the SIRIS app. The top screenshot shows the 'Operation' form, and the bottom screenshot shows the 'Übersicht' (Overview) screen for a knee revision case, displaying patient ID, date of surgery, and implant details.

Scope of collection

Basic questionnaire for primary prostheses (required)

- Pathology (diagnosis, previous operations)
- Procedure (date, side of the body and type of procedure)
- Technology (conventional, minimally invasive, computer-assisted)
- Fixation of components (type of fixation, cementing technique and cement)
- Implant data via bar code scanner/sticker/entry

Questionnaire for follow-up procedures (optional)

- Date of follow-up
- Condition of the implant
- No implant data necessary

Questionnaire for revisions (required)

- Pathology (reason for revision/diagnosis)
- Remaining information same as in basic questionnaire

Online submission

SIRIS app

Data access and analysis

Security

The implant registry is not publicly accessible. Appropriate technical and organizational measures for guaranteeing the confidentiality, availability and accuracy of the data have been taken to protect it against unauthorized use.

Regulations for use

The regulations define the group of people entitled to use the data, the scope of access rights and the fees for use. In general, the broad-based **data regulations of the ANQ** also apply for SIRIS.

All documents can also be found at www.siris-implant.ch, under “Downloads > Administratives” (in German).

Patient data

As a strict principle, personal data can only be viewed by the attending physicians, hospitals and institutes that are tasked with managing the registry and **required to maintain absolute confidentiality**. Access to the data in a fully anonymized form is possible as long as the request required for this is approved by the foundation.

The data protection provisions of the **Swiss Confederation** are fully observed. Patients can view their data at any time and request its deletion if necessary.

Access by orthopedists and hospitals

Every orthopedist and every hospital can view the data they have provided and compare it with the **anonymized overall data** (benchmark). The Foundation Board decides on further use of data and data sets. The Board also has the duty to publish a public annual report on the implant registry and the results of the data analysis. The right to first publication belongs to the ANQ.

Data sovereignty

The hospitals remain the owners of the raw data. The foundation owns the data collection and all intellectual property rights to it. The patients are granted **right of access** to information in response to a corresponding request, **free of charge** and at any time, as stipulated in the data privacy law.

Reporting

Quarterly reports

Cumulative analyses are issued quarterly for each hospital and made available for download by the SIRIS administrators of the respective hospital. The fourth-quarter report includes an overview of the year. The reports describe the main variables collected in the registry for the respective hospital and compare these with the data pool of the 157 hospitals in Switzerland participating in SIRIS.

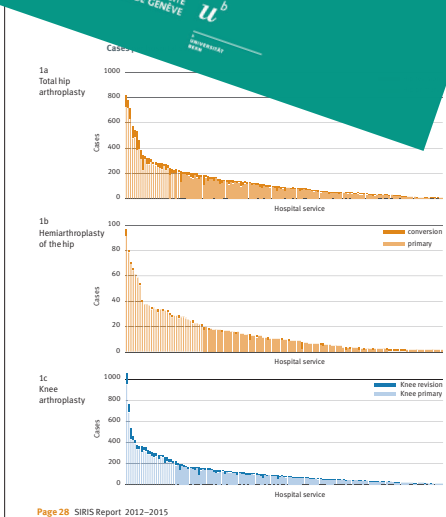
Annual SIRIS report

The SIRIS foundation, swiss orthopaedics, the University of Bern, the University of Geneva and other experts participate in the extensive annual report – which is written in English. The report provides information about the current state of hip and knee joint replacements in Switzerland and provides a wealth of new information.

Annual ANQ summary

Every year the ANQ publishes a review of the main findings from the extensive SIRIS report. This review is announced in a press release and is available in German, French and Italian. It can be downloaded at www.anq.ch/akutsomatik/messengergebnisse.

Annual SIRIS report



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5. Hip arthroplasty

5.1 Primary total hip arthroplasty

Among the 57 718 primary THAs documented over the entire data collection period, 52% were performed in women (Table 7). The mean age was 68 years. One-third of the interventions were performed in patients aged between 65 and 74, one-third in patients aged below 65 years and one-third in patients aged 75 years and older. On average, men were younger (66 years old) than women (70 years old) at the time of surgery. In 85% of cases the diagnosis was primary osteoarthritis, in 9% secondary osteoarthritis, and in 6% surgery was performed following a fracture. The proportion of primary osteoarthritis changed from 86% in 2012 to 84.3% in 2015, whereas the proportion of fractures changed from 5% in 2012 to 6.3% in 2014/15. Table 7 also shows BMI and morbidity state (ASA class) results following the collection of this data for the first time in 2015.

Table 7 Primary total hip arthroplasty: Baseline patient characteristics by year 2012-2015. BMI and ASA class data are only available from 2015 onwards

	2012	2013	2014	2015	All	
N	6627	16886	17117	17088	57718	
Women [%]	50.5	52.2	52.5	52.6	52.2	
Mean age (SD)	All 67.2 (12.3)	67.9 (12.1)	68.3 (12.2)	68.6 (11.6)	68.1 (12.0)	
Women	68.8 (12.0)	69.7 (11.8)	70 (11.9)	70.4 (11.3)	69.9 (11.7)	
Men	65.6 (12.3)	65.9 (12.1)	66.4 (12.2)	66.6 (11.7)	66.2 (12.1)	
Age group [%]	<45	3.9	3.3	3.3	2.6	3.2
45-54	10.1	9.9	9.2	9.8	9.7	
55-64	23.3	21.9	21.3	21.3	21.7	
65-74	32.7	33.5	33.4	33.4	33.4	
75-84	25.2	25.5	26.6	26.1	26.0	
85+	4.9	5.8	6.2	6.6	6.1	
Mean BMI (SD)				27.1 (5.0)	27.1 (5.0)	
BMI [%]	<18.5			1.8	1.8	
18.5-24.9				35.0	35.0	
25-29.9				39.2	39.2	
30-34.9				16.8	16.8	
35-39.9				5.4	5.4	
40+				1.7	1.7	
Morbidity state [%]	ASA 1			14.7	14.7	
ASA 2				51.3	51.3	
ASA 3				22.8	22.8	
ASA 4				0.5	0.5	
unknown				10.6	10.6	
Diagnosis [%]	Primary OA	86.0	85.4	85.6	84.3	85.2
Secondary OA		9.0	9.0	8.2	9.4	8.9
Fracture		5.0	5.6	6.3	6.3	5.9

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Quarterly reports for each hospital



Annual ANQ report



Security concept

SIRIS documentation concept

The documentation platform, consisting of a central server and external modules, was developed with data separation in mind. The MEMdoc central server, located at the University of Bern, stores the main software applications and the central database, including all study definitions and the anonymized data from the clinical studies.

All identity-related data (demographic data of users, hospitals and patients) is saved on the SIRIS module servers. There is no direct connection between the central server and the module servers to ensure the security and privacy of both systems. The data is only displayed together in the browser.

Data validation

Flexible options have been developed to meet individual needs with regard to the shared use of data and access. Data quality is automatically monitored through the systematic validation of incoming data. Data is checked for **completeness and plausibility**. When required, the user will see an on-screen notification prompting them to correct or complete the data. You can find the validation concept (in German) at www.siris-implant.ch › Downloads › Administratives.

Data separation

Incoming data is separated. Only the **anonymized patient number** (pat. no.), the internal identification number for the user, the hospital, the department and the module are sent to the MEMdoc central server. They are linked to the SIRIS doc module server using internal identification numbers. **Clinical data never passes through the module server.** The only demographic data stored on the central server is the patient's year of birth and sex. This allows **epidemiological evaluation** to be carried out on the entire data collection.

Registering hospitals and clinics

Asana Gruppe AG, Spital Menziken	Hôpital Riviera, Site de Chablais Monthey	SMN SA, Clinique de Valère, Sion
Asana Gruppe, Spital Leuggern	Hôpital Riviera, Site de Riviera Montreux	SMN SA, Clinique Générale Ste-Anne SA, Fribourg
Berit Klinik, Speicher	Hôpital Riviera, Site de Riviera Vevey	SMN SA, Clinique Montbrillant, La Chaux-de-Fonds
Center da Sandà, Engiadina Bassa CSEB, Scuol	Hôpitaux Universitaires de Genève (HUG)	SMN SA, Hôpital de la Providence, Neuchâtel
Centre Hospitalier Universitaire Vaudois CHUV, Lausanne	Insel Gruppe AG, Inselspital, Bern	SMN SA, Klinik Villa im Park AG, Rothrist
CIC Groupe Santé SA, Clinique CIC Riviera Centre, Clarens	Inselgruppe AG, Spital Aarberg	SMN SA, Privatklinik Bethanien, Zürich
CIC Groupe Santé SA, Valais, Saxon	Inselgruppe AG, Spital Münsingen	SMN SA, Privatklinik Lindberg, Winterthur
Clinica Luganese SA, Lugano	Inselgruppe AG, Spital Riggisberg	SMN SA, Privatklinik Obach AG, Solothurn
Clinica Santa Chiara SA, Locarno	Inselgruppe AG, Spital Tiefenau, Bern	Solothurner Spitäler AG, Bürgerspital Solothurn
Clinique de la Source, Lausanne	Kantonales Spital und Pflegeheim Appenzell	Solothurner Spitäler AG, Kantonsspital Olten
Clinique des Grangettes SA, Chêne-Bougeries	Kantonsspital Aarau AG	Solothurner Spitäler AG, Spital Dornach
Clinique Générale Beaulieu, Geneva	Kantonsspital Baden AG	Spital Affoltern, Affoltern a. A.
EHC, Hôpital de Morges	Kantonsspital Baselland, Standort Bruderholz	Spital Altstätten
eHnv, Hôpital St-Loup, Pompaples	Kantonsspital Baselland, Standort Laufen	Spital Bülach
eHnv, Hôpital Yverdon-les-Bains	Kantonsspital Baselland, Standort Liestal	Spital Davos AG
EOC, Ospedale regionale di Bellinzona (San Giovanni)	Kantonsspital Glarus AG	Spital Einsiedeln
EOC, Ospedale regionale di Locarno (La Carità)	Kantonsspital Graubünden, Chur	Spital Emmental AG, Burgdorf
EOC, Ospedale regionale di Lugano (Civico e Italiano)	Kantonsspital Nidwalden, Stans	Spital Emmental AG, Langnau
EOC, Ospedale regionale di Mendrisio (Beata Vergine)	Kantonsspital Obwalden, Sarnen	Spital Grabs
Flury Stiftung, Spital Schiers	Kantonsspital St. Gallen, Spital Flawil	Spital Lachen AG
Gesundheitszentrum Fricktal AG, Spital Laufenburg	Kantonsspital St. Gallen, Spital Rorschach	Spital Limmattal, Schlieren
Gesundheitszentrum Fricktal AG, Spital Rheinfelden	Kantonsspital St. Gallen, Standort St. Gallen	Spital Linth, Uznach
Groupement Hospitalier de l'Ouest Lémanique GHOL, Nyon	Kantonsspital Uri, Altdorf	Spital Männedorf AG
GZO AG Spital Wetzikon	Kantonsspital Winterthur	Spital Muri
Hirslanden AndreasKlinik Cham, Zug	Klinik Gut, Fläsch	Spital Oberengadin, Samedan
Hirslanden Bern AG, Klinik Beau-Site, Bern	Klinik Gut, St. Moritz	Spital Schwyz
Hirslanden Bern AG, Klinik Permanence, Bern	Klinik Hirslanden Zürich	Spital STS AG, Spital Thun
Hirslanden Bern AG, Klinik Salem, Bern	Klinik Hohmad, Thun	Spital Thurgau AG, Kantonsspital Frauenfeld
Hirslanden Clinique La Colline SA, Geneva	Klinik Pyramide am See AG, Zürich	Spital Thurgau AG, Kantonsspital Münsterlingen
Hirslanden Klinik Aarau	Klinik Seeschau AG, Kreuzlingen	Spital Thusis
Hirslanden Klinik am Rosenberg, Heiden	Klinik Siloah AG, Gümligen	Spital Uster
Hirslanden Klinik Belair, Schaffhausen	Klinik St.Georg Goldach AG	Spital Walenstadt
Hirslanden Klinik im Park, Zürich	La Tour Réseau de Soins SA, Hôpital de la Tour, Meyrin	Spital Zofingen
Hirslanden Klinik St. Anna AG, Lucerne	Lichtensteinisches Landesspital, Vaduz	Spital Zollikerberg
Hirslanden Klinik St. Anna AG, Meggen	Lindenhofgruppe, Klinik Sonnenhof, Bern	Spitäler fmi AG, Spital Frutigen
Hirslanden Klinik Stephanshorn, St. Gallen	Lindenhofgruppe, Lindenhofspital Bern	Spitäler fmi AG, Spital Interlaken
Hirslanden Lausanne SA, Clinique Bois-Cerf, Lausanne	Luzerner Kantonsspital LUKS, Lucerne	Spitäler Schaffhausen. Kantonsspital
Hirslanden, Klinik Birshof AG, Münchenstein	Luzerner Kantonsspital LUKS, Sursee	Spitalregion Fürstenland Toggenburg, Spital Wattwil
Hôpital du Jura bernois SA, Site de Moutier	Luzerner Kantonsspital LUKS, Wolhusen	Spitalregion Fürstenland Toggenburg, Spital Wil
Hôpital du Jura bernois SA, Site de Saint-Imier	Merian Iselin Klinik, Basel	Spitalregion Rheintal Werdenberg Sarganserland,
Hôpital du Jura, Site de Delémont	Nouvelle Clinique Vert-Pré SA, Conches-Genève	Spitalregion Rheintal Werdenberg Sarganserland,
Hôpital du Pays-d'Enhaut, Château-d'Oex	Praxisklinik Rennbahn AG, Muttenz	Spitalverbund Appenzell Ausserrhodon, Heiden
Hôpital du Valais (RSV), Martigny	Privatklinik Linde AG, Biel	Spitalverbund Appenzell Ausserrhodon, Herisau
Hôpital du Valais (RSV), Sion	Regionalspital Surselva AG, Ilanz	Spitalzentrum Biel AG
Hôpital du Valais SZO, Spital Brig	Réseau Santé Balcon du Jura RSB, St. Croix	SRO AG, Spital Langenthal
Hôpital du Valais SZO, Spital Visp	Rosenklinik, Rapperswil	St. Claraspital AG, Basel
Hôpital fribourgeois HFR, Hôpital cantonal, Fribourg	Schulthess Klinik, Zürich	Stadtspital Triemli, Zürich
Hôpital fribourgeois HFR, Site de Riaz	See-Spital, Horgen	Stadtspital Waid, Zürich
Hôpital fribourgeois HFR, Site de Tafers	See-Spital, Kilchberg	Universitätsklinik Balgrist, Zürich
Hôpital intercantonal de la Broye HIB, Payerne	SMN SA, Clinica Ars Medica, Gravesano	Universitätsspital Basel USB
Hôpital neuchâtelois HNE, Site de la Chaux-de-Fonds	SMN SA, Clinique de Genolier	Universitätsspital Zürich
Hôpital neuchâtelois HNE, Site de Pourtalès, Neuchâtel	SMN SA, Clinique de Montchoisi, Lausanne	Zuger Kantonsspital AG, Baar

schweizerisches implantat-register
registre suisse des implants


sirIS

**SIRIS – Foundation for
Quality Assurance in Medical
Implants**

c/o conidea GmbH
Waldheimstrasse 22
3604 Thun

Tel. +41 33 335 02 79

info@siris-implant.ch
www.siris-implant.ch