

CMR Surgical Registry: Patient information and informed consent

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Information for patients

About us

We (CMR Surgical Ltd) are a UK-based surgical-device company who have developed a new robotic system to help perform minimal-access (keyhole) surgery. Our aim is to make the benefits of this surgery accessible to more people across the world.

Versius

Our new system, known as Versius, makes keyhole surgery easier to perform. Versius is controlled by a surgeon at a console (workstation). The surgeon uses the console to perform surgery by controlling up to four instruments at a time.



Figure 1: The Versius® Surgical Robotic System

To monitor how safe Versius is for patients, we have launched a surgical registry (the CMR Surgical Registry). The registry will also provide a database of how surgeons are using Versius.

We will use the registry to collect important information about every operation a surgeon performs using Versius. (For example, what operation was carried out, how long it took, and how the patient recovered afterwards.)

We are asking every hospital and surgeon who uses Versius to take part in the registry and collect information from every operation they carry out.

The registry is important to us because:

- we take our responsibility for patient safety very seriously;
- by law, surgical-device companies must monitor the safety of devices such as Versius;



- we want to use the information in the registry to help us make changes to Versius and how surgeons use it (and these changes will benefit more patients in the future); and
- we want to support and promote academic research to make robot-assisted surgery even safer.

In line with international recommendations and best practice, a description of the registry is available on the ISRCTN website at <https://www.isrctn.com/>. The ISRCTN website makes available to the public an international list of clinical research studies and registries.

Why are you giving me information about the registry?

Your surgeon has recommended that you have an operation using Versius and they would like to be able to share information about you and your operation with us.

What does it mean if I agree to share my information?

It means that your surgeon and clinical team will be able to share some information about your surgery with us. This may be on paper or in electronic form.

What information would my surgeon share?

Your surgeon and clinical team will share information that is already in your medical records. They will share only limited information. They will not share any information that could directly identify you (for example, your name, date of birth or address) or information that is not relevant to your operation.

They will share basic information about you (for example, your age, sex, height and weight), your diagnosis and surgical history, and details of your surgery and any complications you might experience after your operation.

What will happen next?

Your surgeon will ask you to sign a consent form giving your permission for them to share your information.

If you give your permission, your surgeon or clinical team will provide information from your medical records to the registry. If they cannot find all the information from your medical records, they may ask you for more information at your regular clinic visits or over the phone. They may, for example, call you 90 days after your operation to check on your progress.

Do I have to agree to share my information?

No, sharing your information with us is completely voluntary. You can decide whether you want to or not, and your decision will not affect the care and treatment you receive.

Will you keep my information confidential?

Yes. We, your surgeon and the clinical team will keep the information shared in the registry confidential, private and protected.

Your surgeon and clinical team will provide your information to the registry using a unique identification number. We will not know which number refers to you and we will not be given any details that could directly identify you, such as your name, address, date of birth or hospital number. Only your surgeon or clinical team will be able to match you with your identification number.

We tightly control access to all the information we collect, and we restrict access in line with international best practice and local data standards.

Where do you store the registry information?

We are committed to following best practice relating to healthcare information, and keep to all local laws and regional data-storage requirements.

Your information will be held securely by your surgeon at your hospital, at our UK offices and on our UK-based healthcare data safe haven server.

How do you keep the information in the registry secure?

The registry follows relevant regulations and industry standards to make sure that the information is kept confidential and secure.

Access to the registry is managed by strict controls (including password access for electronic systems) and is only given to appropriate members of your clinical team and our data- and registry-management teams.

Who will use the information in the registry?

We and your hospital will use the information in the registry. We will only share information with approved partners who meet our high privacy and security standards. These approved partners include:

- academic research institutions and research study staff;
- medical and surgical associations and organisations, other non-profit organisations, and healthcare providers;
- surgeons, clinical teams and hospitals who use Versius, local medical ethics committees and institutional clinical review boards; and
- companies that have a contract with us to provide services (for example, technical companies that need information from the registry to meet specific terms in our contract).

Our partners will only be allowed to use the information after our registry management team and steering committee (a panel of external advisors, which may include doctors, data-protection experts and those without expert knowledge of data protection (lay people)) have reviewed a project plan to make sure it is appropriate (for example, a detailed plan explaining what information they would like access to and why). In some cases, this will also mean that the information will only be shared after it is further anonymised and grouped (for example, they will only be given access to information that has been put into categories and



that cannot be linked to any other information). Approval from an appropriate research ethics review board may also be needed before information is released for research.

What will you use the information in the registry for?

We follow data-protection requirements when processing the information shared with the registry, and we will use it for the following.

1. To meet our legal requirements as a medical-device company

We will:

- carry out official safety monitoring of Versius and report the results to our medical-device licensing bodies;
- prepare reports for external governing bodies, for example, government agencies, health insurers and regulatory groups;
- allow governing bodies and government agencies, for example the USA Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA), access to the registry if they request this in order to check facts and our reports; and
- follow any other law or regulation that relates to sharing information.

2. To meet our responsibility for patient safety and the safe use of Versius

We will:

- review and analyse all information that is shared with us, to make sure that Versius is used safely and appropriately;
- monitor how Versius performs, to make sure that effective technical support is provided; and
- produce clinical reports to share with your surgeon, clinical team and hospital to demonstrate how Versius is being used (for example, reports on the number of operations carried out compared with other hospitals).

3. To help guide product research and development

We will:

- provide clinical context (for example, what operations are most commonly carried out) to make informed changes and improvements to Versius;
- develop training modules to help teach surgeons and clinical teams how to use Versius; and
- provide accurate information on how surgeons around the world are using Versius to support our marketing plans.

4. To support academic and clinical research

We will:

- write documents for scientific communications and publications (for example, documents that explain how surgeons are using Versius);
- carry out research to explore and develop surgical practice and techniques; and
- provide an anonymous resource for approved research proposals.

How long will you store the information for?

The registry has no end date. We will keep your information securely for at least 15 years, in line with regulatory standards and good clinical practice.

What if I want to withdraw my permission to share my information?

You can withdraw your permission at any time by contacting your surgeon or clinical team.

After you withdraw your permission, we will not collect any new information about you. However, we will not remove information that we already have. (Information in the registry is processed for scientific research and we have the right not to delete it under the General Data Protection Regulation (GDPR) article 17 part 3(d).)

What are my rights?

Like all UK-based companies, we hold and process your information in line with the GDPR. We are a joint data controller for the registry (your hospital is also a joint data controller). Once you have given your hospital permission to share your information with us, it will begin sharing your information. We will store and process the information your hospital shares with us, in line with the permission you have given. (Our legal basis for processing your information under the GDPR is 'consent'.) As a patient with information in the registry, you have the right to be told how we store and process your information, how to access it, and how to correct it (if necessary). The table below shows which rights apply to the information that we hold about you.

Your rights	Does this apply?	Details
Right to be informed	Yes	This leaflet aims to give you all the information that you need about the registry, so that you can make a decision based on all the facts. If you have any questions, please contact your hospital direct, or contact our Data Protection Officer using the details below
Right of access	Yes	You can ask to access any information that we hold about you. Please contact your hospital direct, or contact us using the details below.

Right to correct	Yes	If you think that the information we hold about you is incorrect, you can ask us to change it. Please contact your hospital direct, or contact us using the details below.
Right to delete	No	We use the information we hold about you for scientific research to monitor the safety of Versius. Under GDPR article 17 part 3(d), this information is exempt from the right to be deleted. This means we do not have to remove this information from the registry.
Right to restrict processing	Yes	If you want to ask us to restrict how we process your information, please contact your hospital direct, or contact us using the details below.
Right to transfer information	No	We will not hold any information in the registry that you have given us yourself. So, this right to transfer does not apply.
Right to object	Yes	If you want to object to how we process your information, please contact your hospital direct, or contact us using the details below.

Figure 2: Your GDPR rights

If you have a request relating to your rights set out above, you can make it direct to your hospital as your hospital can identify which information in the registry relates to you. Or, you can make the request to us, but we cannot identify you from the information in the registry or identify which information in the registry relates to you. To respond to any request, we will need your permission to contact your hospital and ask for your unique identification number. If you do not want us to contact your hospital, we will not be able to deal with your request.

We will assess all requests that we receive and will send you a written reply giving the reasons for any decision.

Complaints

If you would like to complain about how we process your information in the registry, you can contact your hospital direct, or contact our Data Protection Officer using the details below.

Or you can send your complaint to the UK Information Commissioner's Office (ICO). (The ICO is an independent body in the UK that defends information rights.)

Phone: 0303 123 1113

Website: <https://ico.org.uk/make-a-complaint/>

Who organises and funds the registry?

We organise, maintain and fund the registry.

CMR Surgical Ltd
1 Evolution Business Park
Milton Road
Cambridge
CB24 9NG



Phone: 01223 755300

Website: www.cmrsurgical.com

Data Protection Officer – Email: dpo@cmrsurgical.com

Registry management team – Email: registry@cmrsurgical.com

What if I have any other questions?

Please do not hesitate to ask your surgeon or clinical team any questions that you may have about the registry.

Thank you for your interest in our registry.

We will give you a copy of this patient information leaflet for your records.



Informed consent form

We have launched a surgical registry (the CMR Surgical Registry) to observe and track how surgeons are using Versius. The main aim of the registry is to monitor patient safety.

The patient information leaflet provides details about the registry and what is involved. Please read the leaflet carefully, then read the statements below, tick the appropriate box (or boxes) and sign as appropriate.

1	I have read and understood the patient information leaflet and have had the chance to ask questions.	Yes <input type="checkbox"/>
		No <input type="checkbox"/>
2	I give permission for my surgeon and clinical team to collect, share or transfer information about me and my surgery with the CMR Surgical Registry, as described in the patient information leaflet.	Yes <input type="checkbox"/>
		No <input type="checkbox"/>

Your name

Signed

Date

Surgeon's name

Signed

Date

Thank you for your interest in our registry.

We will give you a copy of this consent form for your records.

