MEDICAL MICROINSTRUMENTS, INC. Microsurgical Study Privacy Notice - Data Protection and Confidentiality

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What is the MEDICAL MICROINSTRUMENTS, INC. Microsurgical database?

The MEDICAL MICROINSTRUMENTS, INC. Microsurgical database is the study database collecting data in Europe from patients requiring microsurgery using free flaps, replantations or lymphatic reconstructions with the aid of Symani system to perform the microsurgical anastomosis. The information in the database will be used to assess the Symani System long-term clinical performance, confirm the safety of the device and identify potential residual risks.

What information does it contain?

Starting from April 2021 a clinical database has been put in place to collect information regarding the microsurgical operations done with the Symani system within a regulated framework, namely a post-market clinical follow-up (PMCF) study. The PMCF study has been designed to collect real-life data that include details about the patients (demographics), the medical history of the disease and any concomitant morbidity, the details regarding the surgery (e.g. start/end time, prophylaxis, anticoagulant usage), the MEDICAL MICROINSTRUMENTS, INC. instruments used to perform the anastomosis and the details on the treated vessels/ducts and outcomes achieved (i.e., success/failure of the microsurgical procedure using the Symani system). The database importantly also collects any adverse event occurred from the surgery date to the latest follow-up visit as described by the study protocol. This is a vital piece of information that will help to confirm the safety of the system.

What is the legal basis for the MEDICAL MICROINSTRUMENTS, INC. Microsurgical database?

The study is part of the post-market surveillance conducted by MEDICAL MICROINSTRUMENTS, INC. on the Symami System for microsurgery in accordance with the current Medical Device Regulation (MDR 2017/745). The collected data will contribute to create clinical evidence on Symani system's safety and efficacy.

Before collecting any data, the study was approved by ethics committees (and competent authority, if needed) at each investigational site using the Sysmani system.

Who manages the MEDICAL MICROINSTRUMENTS, INC. Microsurgical database?

MEDICAL MICROINSTRUMENTS, INC. is responsible for the content of the database as Data Controller. MEDICAL MICROINSTRUMENTS, INC. can delegate Clinical Research Associate (CRA) in case of delegation of monitoring activities.

What happens to the data and who can see it?

The data are collected by the doctors, nurses, and hospital staff treating and managing the patient. Hospital computers are used to collect the information. Only an approved member of staff at the hospital can enter the data onto the MEDICAL MICROINSTRUMENTS, INC. Microsurgical database. Once the records have been entered they can be reviewed by authorized staff (both from MEDICAL MICROINSTRUMENTS, INC. and hospital) using their own approved user accounts with secure passwords. Each hospital has a dedicated account for its own patients, meaning that a specific hospital is not able to see data collected from another hospital.

The information collected is valuable as it allows clinicians and Symani system's manufacturer to assess if the technology can help with its unique features of motion scaling and hand tremor filtering, and permit to

perform microsurgery with more precision. The data will be analyzed by MEDICAL MICROINSTRUMENTS, INC. or an appointed statistician according to the analysis plan included in the study protocol.

The data will not be shared with anyone, or used for purposes other than those agreed with MEDICAL MICROINSTRUMENTS, INC. as described in the study protocol. In case of regulatory audits or inspections, the access to the MEDICAL MICROINSTRUMENTS, INC. Microsurgical database will be granted to the people who will conduct the audit or the inspections.

At the end of the five-year contract period in 2026, the MEDICAL MICROINSTRUMENTS, INC. Microsurgical data will be deleted or securely transferred to a new provider on the advice of MEDICAL MICROINSTRUMENTS, INC..

MEDICAL MICROINSTRUMENTS, INC. Microsurgical Database Server

All data points entered are held within a secure database hosted by Rackspace (sub-contracted by Dendrite) in a tier 4 data center located in the UK, and the network connection is via TLS with 256 bit encryption.

The service delivery and information governance provided complies with ISO 20000 & ISO 9001 accreditation and the security structure is aligned alongside ISO27001. The security arrangements are internally audited approximately every three months and externally audited every six months.

All servers have firewall and anti-virus software installed which is configured to use real-time scanning.

Backup Resilience

The data is securely backed-up each day. All backed up data stored is compressed, de-duplicated and encrypted within a secure off-site vault.

There are two backup vaults, the primary one is hosted locally and is then backed up to a secure secondary off-site vault hosted within a separate datacentre located at Heathrow.

Dendrite Security

Dendrite Clinical Systems is assessed against NHS Information Governance standards, which includes both physical and organisational security measures. Dendrite's toolkit assessment score is available on the IG Toolkit website (https://www.dsptoolkit.nhs.uk/OrganisationSearch/8HJ38).

The computer software program created by Dendrite that holds the MEDICAL MICROINSTRUMENTS, INC. Microsurgical data has been independently tested to ensure that it is not vulnerable to unauthorised access, or internal breaches of security.

Can I ask to see the data that the MEDICAL MICROINSTRUMENTS, INC. registry holds about me?

Requests may be made by sending a query to elisa.scaccianoce@mmimicro.com to:

1) see what data is held on the MEDICAL MICROINSTRUMENTS, INC. Microsurgical database about you,

2) delete your data on the MEDICAL MICROINSTRUMENTS, INC. Microsurgical database in case you would like to withdraw the study.