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RECHARGEABLE
SICURDRILL

USER'S MANUAL

CE

Rev. 02-2024

Table of revision

| Rev. | Description |
|------|--|
| 01 | Revision according to Regulation (EU) 2017/745 on medical devices |
| 02 | Revision for change of operative site and update of Electrical safety and EMC report |



Translation of original instructions



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Use this device correctly and safely



READ THIS MANUAL BEFORE USE

This user's manual includes operating procedures, safety precautions and specifications for rechargeable Sicurdrill, made by Human Brain Wave S.r.l.

Safety rules and operating procedures must be fully understood before using this device. Keep this manual handy for future reference.

Use of the device outside the intended use specified in this manual may cause unexpected adverse events or damage to the device.

There are no parts within the device that require maintenance by user.

If you have any problems or questions about your device, please contact Human Brain Wave S.r.l. or the authorized distributor.

Safety precautions

In this manual, a keyword is used to indicate the degree or level of safety alarm. The definition is as follows:

ATTENTION: Indicates a potentially dangerous situation which, if not avoided, can cause mild to moderate injuries or accidents with consequent property damage.

Even the situations indicated by "ATTENTION" may cause serious injury under certain conditions. Safety precautions must always be strictly adhered to.

Before use

WARNING

- **Never use the appliance for purposes other than those intended.**

Human Brain Wave s.r.l. denies all liability for accidents or malfunctions caused by improper use.

- **Read this manual before using the device. In particular, safety warnings and operational procedures must be fully understood. Do not use accessories that are not specified by Human Brain Wave s.r.l. for the device.**

Using the appliance outside the specified intended use may cause unexpected problems and adverse events.

- **Never change or touch the internal structure of the device.**

Malfunctions may occur.

- **Conditions of transport and storage**

Ambient temperature: $(-20 \div +60)^{\circ}\text{C}$

Atmospheric pressure: $(70 \div 106)$ kPa

- **Fully plug the USB cable into the respective USB socket.**

An incomplete connection can cause failure to recharge the battery

- **Do not use a USB cable other than the one supplied. Do not use the supplied USB cable for other tools.**

Malfunctions may occur.

- **Before connecting any cable to the device, be sure to turn off the device**

Malfunctions may occur.

- **Do not connect anything other than the USB socket to the USB cable.**

Malfunctions may occur.

- **Before transporting the device to another location, disconnect all cables.**

If the cables get caught or trampled, the device can fall, causing injury or failure.

- **Carry out visual and operational checks before using the device. Do not use the device if an error is detected.**

Using a malfunctioning device does not produce the expected results and can cause problems.

- **Be sure to use the accessories/devices specified by Human Brain Wave s.r.l.**

The use of accessories/devices not specified by Human Brain Wave s.r.l. may cause malfunctions or adverse events.



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BEFORE USE

1.1 Intended use

The rechargeable Sicurdrill is intended as an electric motor that allows the rotation of the Rigeneracons/Adipecons/kit disposable devices which in turn are devices for the temporary storage and disaggregation of biological samples taken from the patient to obtain autologous micrografts.

Indications: the rechargeable Sicurdrill is intended to be used with the accessories Sicurlid and Sicurstick to allow the connection with Rigeneracons/Adipecons devices.

Contraindications: none (it should be used according to following instructions).

Type of operator: doctor or specialist in the field.

Place of use: within professional healthcare facilities.

1.2 Packaging Content

Remove the contents of the shipping box, then check the contents including

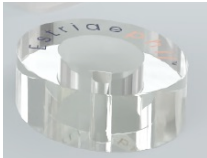
- N°1 Sicurdrill device (product code SICURDRILL 2.0)
- N°1 USB-C cable
- N. 1 Sicurstick
- N. 1 Sicurlid
- N. 1 Holder (functional support)

1.2.1 Accessories

SICURSTICKs are adapters intended to connect the Rechargeable Sicurdrill to Rigeneracons/Adipecons devices



SICURLID is a sled intended to place the Rigeneracons/Adipecons devices and to permit the connection with the adapter Sicurstick.














The **HOLDER** allows the operator to activate the rotation of the drill without the need to handle it during operation and after the procedure to store it in an orderly manner together with the accessories.



1.3 Labels and symbols

To draw the attention of users, there are labels and instructions affixed to the device. If labels come off, characters fade or become unreadable, contact HBW or your authorized distributor.

| | |
|---|---|
|  | Manufacturer |
|  | Manufacturing date |
|  | Refer to instruction manual |
|  | Product code |
|  | Symbol of the crossed-out bin WEEE directive |
|  | Direct current |
|  | Attention |
|  | CE conformity marking |
|  | Serial number |
|  | Switching on |
|  | Medical device |

2.

OPERATING PROCEDURE

2.1. Overview of operations

To ensure proper use, follow the steps below:

1. Before each use, charge the battery for at least 15 minutes using the USB cable provided;
2. Press the START button to activate the device and check that the blue LED on the lower part of the display turns on.
3. Pass the TAG (positioned on the blister of the Rigeneracons/Adipecons device) on the RFID reader located on the back part of the sicurdrill. The number 5 appears on the display.

NOTE: Once the TAG has passed, the Sicurdrill remains active for 50 minutes. After this time the Sicurdrill goes into stand-by mode for 2 minutes and it is necessary to use another TAG to reactivate it. After 2 minutes the Sicurdrill turns off and it is necessary to press the START button and pass a new TAG.

4. Use the START button to edit the number of minutes to the desired time (max 9 minutes expected).
5. Place the Rigeneracons/Adipecons in the Sicurlid slide and insert the Sicurstick into the device tree to connect to the Sicurdrill;
6. Press START for 5 seconds to start the work cycle

NOTE: The rotation of the device can be

stopped by holding down the START button for 5 seconds

7. At the end of the cycle, separate the components and recover the suspension according to what is reported in the IFU of the Rigeneracons/Adipecons devices

8. Clean the device at the end of the procedure as reported in the appropriate section

2.2 Battery charging

The lithium battery of the rechargeable sicurdrill device must be recharged using exclusively the USB-C cable supplied, which should be plugged into a standard USB socket (car charger, PC, mobile charger) 5V, with at least 0.5A.

When fully charged, the LED turns from orange to green.

2.3 Error and warning

The red led does not light up: the battery is not charging. Verify the correct insertion of USB cable.

The battery does not recharge: check that the USB cable is inserted correctly

The display does not turn on: check that you have pressed the START button or that you have read the TAG (positioned on the blister of the Rigeneracons/Adipecons devices) on the RFID reader located on the rear part of the Sicurdrill

The display could show the following errors:

3.

- E1 = TAG already used
 - A1= battery charge under 50%
 - A2= battery charge under 30%.
Recharge the device.
-
-

MAINTENANCE

3.1 Maintenance and cleaning

Carry out an overhaul of the rechargeable Sicurdrill every 500 work cycles.

No ordinary maintenance by the operators is envisaged

No installation is required

Check the integrity of the USB-C cable and, if necessary, replace it with another one provided by the manufacturer

For cleaning, use a clean cloth soaked in hydrogen peroxide or any regular disinfectant that it does not contain chlorine or its compounds, such as bleach and muriatic acid.

Dry with a clean cloth

Do not immerse the device in water or liquids in general.

Do not use steel wool or other abrasive materials that could inevitably scratch the plastic surface.

4.

STANDARDS AND SPECIFICATIONS

4.1 Applicable rules

Electromagnetic Compatibility Directive (EMC) 2014/30/EU (Compliance with the Directive has been reached with reference to EN 60601-1-2 Medical electrical equipment. Part 1: General requirements for safety – Collateral standard: Electromagnetic Compatibility - Requirements and tests. 2015

Regulation (EU) 2017/745 on medical devices

4.2 Results EMC test

EMC emission classification: Class I, group B

| Frequency | Average value (dB μ V/m) | Quasi-peak value (dB μ V/m) | Peak value (dB μ V/m) |
|---------------|------------------------------|---------------------------------|---------------------------|
| 30÷230 MHz | -- | 42-35 (3m) | -- |
| 230÷1000 MHz | -- | 42 (3m) | -- |
| 1000÷3000 MHz | 50 (3m) | -- | 70 (3m) |
| 3000÷6000 MHz | 54 (3m) | -- | 74 (3m) |

4.3 Product specification

4.3.1 Operating conditions

Rotation time: 1 minute

Ambient temperature: + (0 ÷ 40) °C

Atmospheric pressure: (70 ÷ 106) kPa

4.3.2 Condition of transport and storage

Ambient temperature: (-20 ÷ +60) °C

Atmospheric pressure: (70 ÷ 106) kPa

5.

DISPOSAL OF THE DEVICE

5.1. Disposal

The rechargeable Sicurdrill device must be disposed of in accordance with the regulations in force in the country of use.

Caution: For the correct disposal of the rechargeable Sicurdrill device, consider also applicable hospital laws and procedures relating to contaminated devices.

NOTES:

Rigeneracons/Adipecons devices are not come with the rechargeable Sicurdrill.