



# RECHARGEABLE SICURDRILL

## *USER'S MANUAL*



## Table of revision

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Rev.	Description
01	Revision according to Regulation (EU) 2017/745 on medical devices



Translation of original instructions

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## Use this device correctly and safely

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### **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 the 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

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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.

# Precautions for use

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## 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

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- **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 and disconnect the power cord.**

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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# 1.

# BEFORE USE

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## 1.1 Intended use

The rechargeable Sicurdrill is intended as an electric motor that allows the rotation of the Regeneracons / 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. To use the Sicurdrill in a sterile way it is recommended to always wrap the Sicurdrill with the COVER accessory manufactured by HBW .

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.

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## 1.2 Device configuration

- 1 Rechargeable Sicurdrill device (product code SICURDRILL 2.0)
- 1 USB cable

### 1.2.1 ACCESSORIES

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

- code 10126 connects the Sicurdrill to the Rigeneracons code 7945DS
- code 10127 connects the SICURDRILL to the Rigeneracons code 7945AS, 7945RS, 7945OS, 7945TS and Adipecons (code 79560S).

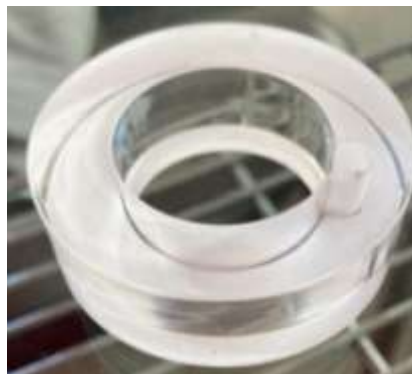
SICURLID is a sled intended to place the Rigeneracons/Adipecons devices and to permit the connection with the adapter Sicurstick.

All these accessories are NOT supplied with the rechargeable Sicurdrill device but are supplied within Rigeneracons/Adipecons kits.





## Sicurdrill and Accessories













### 1.2.2 USB cable

The product comes with a USB cable for charging.

### 1.3 Labels and symbols

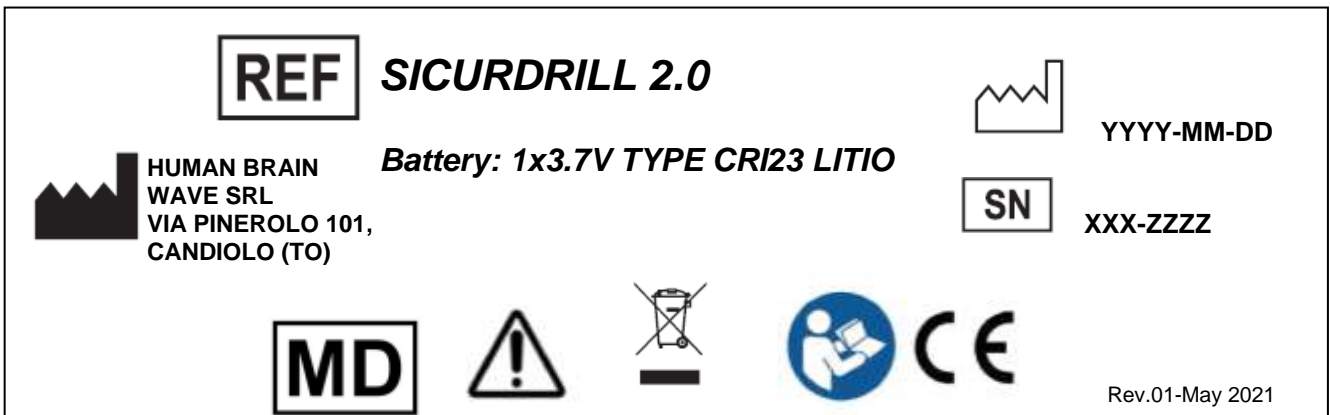
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To draw the attention of users, there are labels and instructions affixed to the device. If labels come off, characters fade or become unreadable, contact HBW or your authorized distributor.

	Manufacturer
	Date of manufacture
	Refer to the instruction manual
	Product code
	Symbol of the crossed-out bin WEEE directive
	Attention
	CE conformity marking
	Serial number
	Switching on
	Medical device

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Label on the device



## 1.4 Packaging contents

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Remove the contents of the shipping box, then check the contents of the package in the nylon pouch.

- 1 Rechargeable device
- 1 USB cable
- 1 cardboard with the indication to download the user's manual

# 2.

# OPERATIONAL PROCEDURE

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## 2.1 Overview of operations

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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. Applied the sterile cover around the Sicurdrill device (for the use in the operation room make sure that the part protruding from the cover does not come into contact with the other sterile parts for not prejudice the sterility);
3. Insert the Sicurstick to connect the Rigeneracons/Adipecons device with the Sicurdrill;
4. Place the Rigeneracons/Adipecons devices into the Sicurlid and connect the pivot with the Siicurstick;
5. Press the start button to enable rotation; if the device properly works, the yellow led on the top of the device starts to flash;
6. The cycle will last one minute, the interruption is automatic and not changeable;
7. At the end of the cycle, separate the components.

## 2.2 Battery charging

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- The lithium battery of the rechargeable sicurdrill device must be recharged using exclusively the USB 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 red to green.

## 2.3 Errors and warning

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- The red led does not light up: the battery is not charging. Verify the correct insertion of USB cable.
- The yellow led on the top of the device does not flash: the device does not work. Recharge the battery for at least 1 hour. Otherwise, contact the technical assistance of the manufacturer /distributor
- The rotation lasts 1 minute and cannot be absolutely interrupted before.

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# 3.

# MAINTENANCE

## 3.1 Maintenance and cleaning

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- Carry out an overhaul of the rechargeable Sicurdrill every 2000 work cycles.
- No ordinary maintenance by the operators is envisaged
- No installation is required
- Check the integrity of the USB 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

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- 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
- Machinery Directive 2006/42/EC
- Low Voltage Directive (LVD) 2014/35/EU
- Regulation (EU) 2017/745 on medical devices

### 4.2 Results EMC test

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EMC emission classification: Class I, group B

Type of test	Reference standard	Test results
Measurement of radiated emissions	EN 55011 :16/ A1 :17 *	Pass
Immunity to EM Radiated Fields	EN 61000-4-3 :06 / A1 :08 /A2 :10 * EN 60601-1-2 :15 *	Pass
Immunity to electrostatic discharges	EN 61000-4-2 :09	Pass
Immunity to magnetic field at industrial frequency	EN 61000-4-8 :10 *	Pass

### 4.3 Product specifications

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#### Operating conditions

Rotation time: 1 minute

Ambient temperature: + (0 ÷ 40) °C

Atmospheric pressure: (70 ÷ 106) kPa

#### Conditions of transport and storage

Ambient temperature: (-20 ÷ +60) °C

Atmospheric pressure: (70 ÷ 106) kPa

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# 5.

# DISPOSAL OF THE DEVICE

## 5.1 Disposal

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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 and all the accessories (COVER, Sicurlid and Sicurstick) are not come with the rechargeable Sicurdrill.**