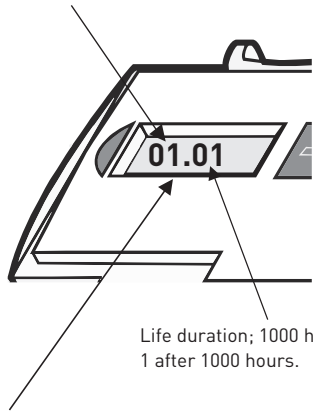


Display

Attention : This is an EXAMPLE, your device may display other numbers.

Treatment time (hours x 100) increases by 1 for every 100 hours treated (max. 10 = 1000 hours)



Life duration; 1000 hours, decreases by 1 after 1000 hours.

A flashing dot indicates that the device is working

Information in the Display

4 numerals and a flashing dot in the display, e.g. 00.01, indicate that the device is working properly.

If you hear a warning beep, you must check the display.

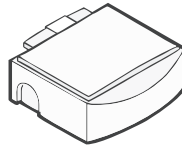
(empty display) = Change Battery.

PACE = Change Battery.

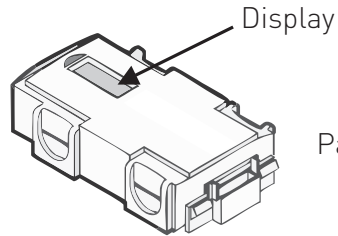
FAIL of COIL = Check the connection between the Patient Unit and the coil by disconnecting first the Battery and then the Patient Unit. Afterwards reconnect the Patient Unit and the Battery. If the FAIL or COIL warning remains: contact Ossatec

LIFE = The Patient Unit has reached its end of life duration.

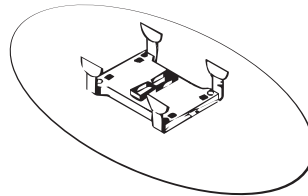
If you have any questions or faults occur, contact Ossatec:
Telephone no. +31(0)413 265 281, e-mail: info@ossatec.eu



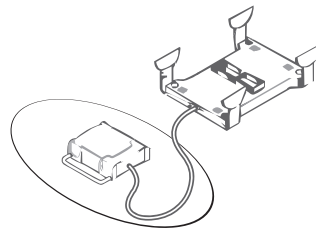
Battery



Patient Unit



Flat Coil



Flat Coil with extension lead

Specialists in non-invasive fracture management

OSSATEC



Ossatec Benelux B.V.

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I. www.ossatec.eu



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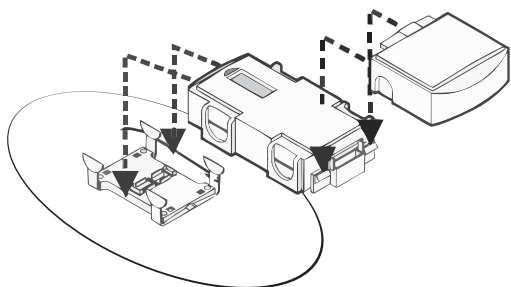
For accelerated bone fracture healing



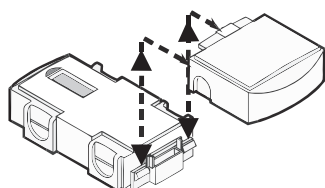
INSTRUCTIONS FOR USE

For the Patient

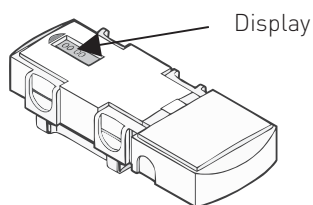
Complete Ossatec® System



Changing the Battery



1. Disconnecting/reconnecting the Battery
After connecting the system, press components together.



2. If the Battery is correctly connected, you will hear a continuous audible signal lasting for approx. 10 seconds. After this, check the display for the flashing dot [See example above].

Information about the Ossatec®

Important!

- The chance of this treatment being successful is partly dependent on your co-operation. Follow therefore the instructions given by your specialist, casting technician or Ossatec technician.
- An Ossatec treatment requires a minimum of 4 to 8 hours of stimulation per 24 hours.
- The Battery must be disconnected when the device is not in use.
- The Ossatec® is splash water resistant. The system must be removed when taking a shower.
- Progress controls will be determined in consultation with your treating consultant or clinical staff.
- When going for a control, be sure to take everything associated with the Ossatec® Bone Growth Stimulator with you.
- The Ossatec® system, including the coil, must be removed before having an x-ray.
- If the coil is incorporated into a cast, make sure the plaster technician is informed about this before removing the cast. This prevents coil damage when sawing or cutting.
- The Ossatec® system is on loan to you. You are therefore responsible for it. Any damage or costs incurred through nonchalant use can be charged.

Warning

- Disconnect the Battery when: on board an aircraft, in an ambulance, in an intensive care department, in an accident and emergency department or such departments.
- Do not damage the device or expose to temperatures higher than 45° C or lower than -10°C.
- Do not immerse the device in water
- If necessary, clean the device with a damp cloth.

Battery

3 Batteries are supplied during the installation of the device. These batteries are not rechargeable and each one will last for approximately 100 hours of treatment time. This will depend on the size of coil used for the treatment.

The Battery is easily connected and replaced as shown in "Changing the Battery".

When the last Battery is in use and there is insufficient capacity to last until the next outpatient visit, you can contact Ossatec Benelux B.V. We will send new Batteries free of charge so that the treatment can be continued without interruption. See our telephone number and email address on the other side of this instruction leaflet.

The used batteries can be disposed of at local battery disposal points.

IMPORTANT:

Avoid contact with water and exposure to temperatures above 100° C. Do not dispose of the Battery in an incinerator.


At the end of the treatment, the Patient Unit and any unused Batteries in unopened packaging can be left at the hospital or returned by post free of charge to:

Ossatec Benelux B.V.
Int. Business Reply Service
I.B.R.S./C.C.R.I. no 123
NL-5400 VB Uden
The Netherlands

More information about Ossatec®?

Go to our website: www.ossatec.eu



 Ossatec Benelux BV and is in compliance with the Medical Device 93/42/EEC. Ossatec Benelux BV is ISO 13485 certified Directive.