

CLINICIAN'S

Non-Cast Application Guide C

1. Before starting, Physician has to mark on skin an "X" over fracture site, to ensure accurate placement of Transducer holder for every treatment. Patient / Clinician will need to ensure this point is reproducible for each treatment. An indelible marker may assist.



2. Place strap with Transducer holder over fracture site and stabilise securely using the Hook and Loop fasteners. It is vital that Transducer holder be held securely over site to be treated, to ensure Transducer is accurately positioned.

3. Open Transducer holder by pushing two turquoise tabs on either side of Transducer holder towards centre.



4. Hold Transducer and place a small amount of ultrasound gel on the Transducer face, approximately 1.5cm diameter.

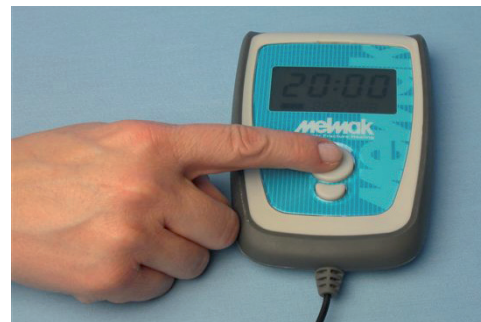


Place ultrasound Transducer through Transducer holder. Ensure cable is routed through cut out on cap and secure by closing cap.



The spring mechanism on the cap provides light pressure to the Transducer. It ensures good contact to the gel and skin over the treatment area for ultrasound transmission.

5. Press ON/OFF button to start treatment. Timer will illuminate and count down from 20 minutes and then turn off automatically.



AFTER TREATMENT HAS COMPLETED

6. Undo strap and remove Transducer head from treatment site. Clean gel from Transducer head, strap and skin with soft cloth. Pack Melmak Device into carry case for safe keeping.

MELMAK COMPONENTS



ACCESSORIES



ULTRASOUND GEL

250 gram bottle. Gel must be applied to ultrasound Transducer head prior to all treatment to enable ultrasound signal to pass from Transducer through skin to the fracture site. Only use Gel supplied by your local Melmak Distributor.



ASSEMBLED TRANSDUCER HOLDER & STRAP

Used to position ultrasound Transducer over fracture site



FELT

For cast application



MELMAK DESKTOP SOFTWARE CD (for clinician use only)

Patient / Device Management PC-based Program



USB CABLE

Used for charging Melmak Device via PC or for connection to PC for set up or data logging. Length 1m. (Consider references to USB cable & charging via PC).



BATTERY CHARGER (including adaptors)

USB Cable is used for charging the internal non-replaceable battery of the Melmak Device. Length 1.8m. For international use multiple adaptors are supplied.



INSTRUCTIONS FOR USE MANUAL

Operation instructions

I. Indications and Intended Use

The Melmak Device is indicated for the treatment of fresh bone-fractures and established non-unions excluding treatment of the skull and the vertebral column. The location and type of fracture will influence results.

This non-invasive treatment can only be prescribed by a Physician or other Health Professional.

II. Safety Instructions

The Melmak Device is intended for non-invasive use only, and should only be used as prescribed by a Physician or other Health Professional for its intended use.

The Operating Guide must be followed accurately. The Melmak Device is to be used only with Melmak specified and supplied equipment and not in combination with other devices.

For external use only.

The Melmak Device is to be operated and stored under dry conditions.

For any queries please contact your local Melmak Distributor.

III. Rechargeable Battery & USB Connection

The Melmak Device Control Unit is powered by a non-replaceable, rechargeable Lithium-Ion (Li-On) battery pack. A medical grade battery charger with inbuilt USB connector is used to charge the internal battery. Country specific adaptor must be used.

The USB mini connector on the top edge of the Melmak Device is used for charging and for connection to a PC for data logging.

All functions of the Melmak Device will be disabled if the device

is not charged. The voltage level of the battery pack is constantly monitored by the Control Unit while operating and the voltage level is displayed on the LCD.

When the battery voltage falls below the critical battery level during a treatment session, in addition to flashing, the LCD will also show "Lo bdt" signal. When the "Lo bdt" signal is present, the current treatment will be completed but further treatments will not be possible until the Melmak Device is recharged.

During the charging process, the LCD will show the letter "P" and the animated battery symbol will be displayed.

During the charging process, the Melmak Device cannot be operated.

IV. Patient/Device Management PC-based Program

Melmak Device administrators have access to a proprietary PC-based Patient/Device Management program used to upload and download information to and from the Melmak Control Unit.

The minimum system requirements are:

- ◆ Operating System: Microsoft Windows XP/Vista/7 operating system
- ◆ 1GB of RAM
- ◆ 500MB of hard drive space
- ◆ Screen Resolution of 1280 x 1024
- ◆ Keyboard and mouse
- ◆ Unoccupied USB port

PLEASE REFER TO CLINICIAN'S MANUAL FOR FULL OPERATING CARE / INSTRUCTIONS