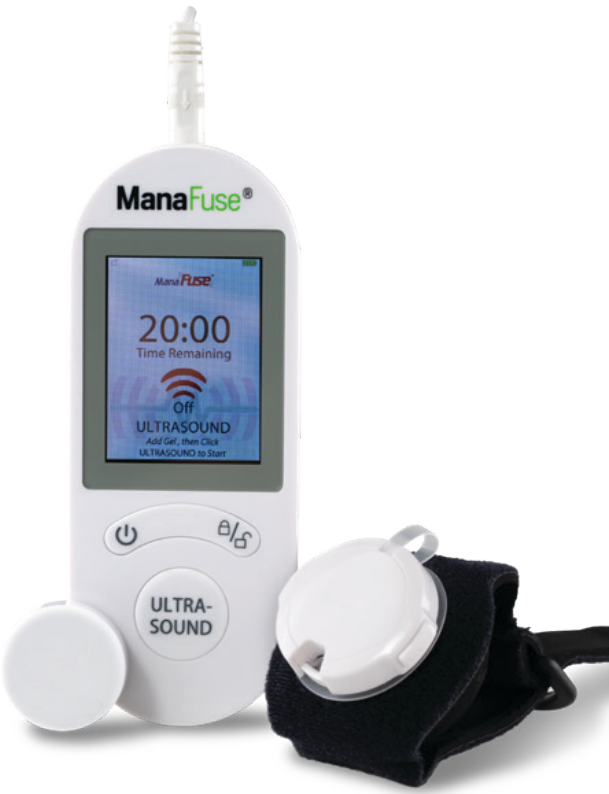
enovis™

Parent Company of DJO, LLC

20 MINUTES. ONCE DAILY.

Bone Growth Stimulation for the treatment of indicated* fresh fractures and fracture nonunion.

Low Intensity Pulsed Ultrasound



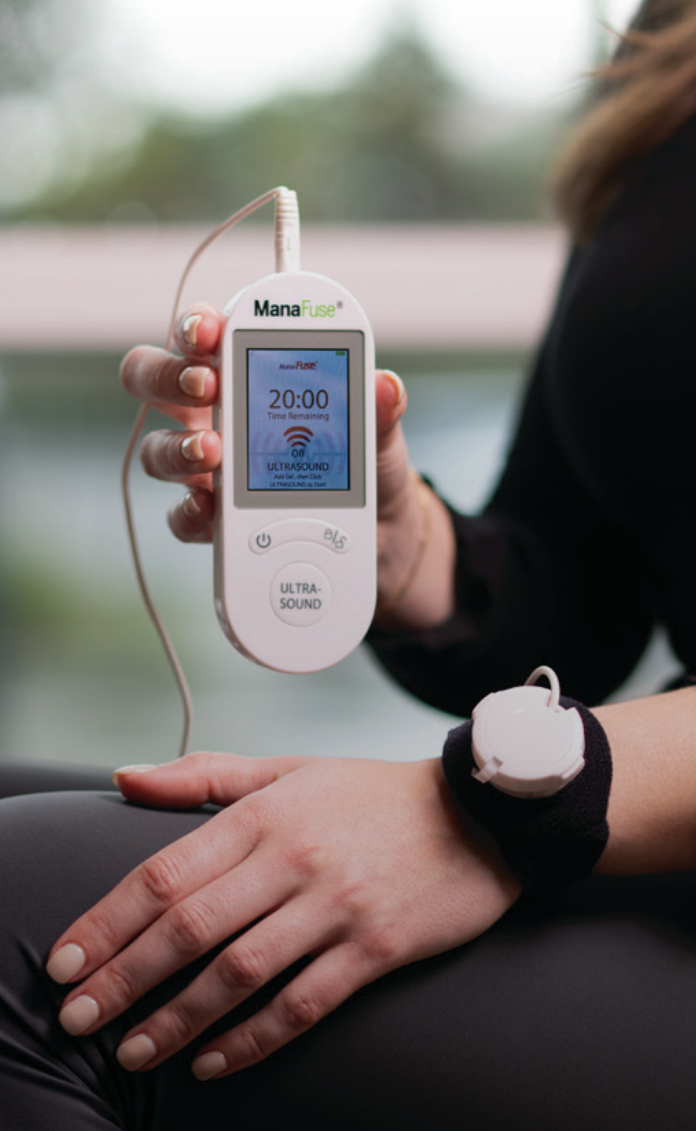
HOW DOES IT WORK?

The Manafuse™ bone growth stimulator is a nonsurgical treatment prescribed by your physician to help heal your bone fracture. The stimulator emits a Low Intensity Pulsed Ultrasound Stimulation (LIPUS) that, when placed directly on the skin over your bone fracture, assists in activating the body's natural healing process. As reported in published data, Manafuse LIPUS technology offers statistically significant improvement in fracture healing when used as indicated.

If your fracture has been immobilized with a cast, you may require a window in your cast to properly apply the Manafuse treatment. Your device includes a strap to assist in keeping the transducer head comfortably and appropriately placed on the skin directly over your fracture. The strap and lightweight nature of the design allow you to perform daily activities while undergoing treatment but always check with your physician before performing activity while treating. You should not feel Manafuse LIPUS therapy during your treatment.

It is very important that you use your Manafuse device daily as prescribed. The Manafuse device will allow you to treat your fracture for 20 minutes per day for up to 343 days. While you have the flexibility to treat at any time you choose, it is recommended that you perform treatment at approximately the same time each day. Your device will track your daily treatment and your doctor may ask you to bring the device to your follow-up visits to check your usage history.

Your doctor will closely monitor your progress and will let you know when you no longer need to use your Manafuse device. Typically, treatment is continued until your fracture has healed. Once you have completed your treatment, you may choose to keep the device or return it to Enovis for recycling or proper disposal. Manafuse is a single-patient use device and may not be passed to other patients.



HOW EFFECTIVE IS THE MANAFUSE LIPUS TECHNOLOGY?

Individual patient results may vary. The following summarizes published data related to outcomes associated with use of LIPUS technology.

- In a prospective, randomized, double-blind, placebo-controlled study of 67 tibial fresh fractures, LIPUS treatment accelerated healing by 38% - a difference of more than 8 weeks.[1]
- In a prospective, randomized, double-blind, placebo-controlled study of 61 distal radius fractures, LIPUS treatment accelerated healing by 38%.[2]
- A study of Low-Intensity Pulsed Ultrasound for the treatment of nonunion fractures reported an 86% heal rate with an average healing time of 5 months. The average age of the fracture at the initiation of treatment was 14.3 months.[3]

WILL MY INSURANCE COVER IT?
Insurance policies are different depending on the plan you have. The Manafuse™ bone growth stimulator is covered by the majority of health plans including Medicare and workers compensation plans; specific coverage criteria must be met.

DOES Enovis™ PREAUTHORIZE THE DEVICE WITH MY INSURANCE COMPANY?
If pre-authorization is required, Enovis™ will verify your eligibility and benefit levels to obtain a pre-authorization from the payer of record.

WHAT HAPPENS IF MY INSURANCE COMPANY DENIES THE CLAIM?
In the event the insurance carrier denies coverage, the claim will be forwarded to our appeals processing department on your behalf. Depending upon the outcome, Enovis™ may contact you to arrange payment options.

For more information, contact your local sales representative or call Enovis™ Customer Service at **(800) 263-6004**

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ARE THERE KNOWN SIDE EFFECTS OF LIPUS?
There are no known side effects related to the use of this device. Thousands of patients have been prescribed Low Intensity Pulsed Ultrasound to help heal their fractures. Please refer to your package insert to review additional information about your prescribed device.

CAN I WEAR THE MANAFUSE IF I AM PREGNANT?
The safety of the Manafuse is not known if you are pregnant or nursing. Therefore, if you are pregnant or nursing, you should consult your doctor before using the Manafuse.

CAN I USE THE MANAFUSE IF I HAVE A PACEMAKER?
The operation of active, implantable devices, such as cardiac pacemakers, may be adversely affected by close exposure to the Manafuse device. Your physician should advise you or anyone who would be near you during treatment to be evaluated by their attending cardiologist or implant physician before starting treatment with the Manafuse device.

CAN I TRAVEL WITH MY MANAFUSE?
Yes. Although not commonly required, before you travel you may request a letter from our Customer Service Support department or your Enovis™ Sales Representative that will explain what the device is and how it operates. You can also keep your user manual available to quickly and easily identify the device for any security personnel.

HOW OFTEN WILL I NEED TO CHARGE MY MANAFUSE?
A fully charged battery should last for 10 hours. You should fully charge your Manafuse device prior to your initial use. A charging cable is provided with your device. The Micro-USB plug end of the charger cord plugs into the bottom of the device. The other end plugs into the adapter, which plugs into a wall outlet. The charger requires a standard US 120 VAC, 60Hz, household electrical outlet. A "low battery" symbol will appear on the LCD screen on your remote indicating that the battery needs to be charged.

WHAT DO I DO WITH THE DEVICE WHEN I AM FINISHED USING IT?
After your treatment is complete and your doctor says you no longer need to use your Manafuse, you may dispose of the device yourself according to your local governing ordinances and recycling plans. You may also contact our Customer Support department (800.263.6004) for help with device disposal. The Manafuse is not reusable. Each device is for single-patient use only and cannot be re-sold or used on multiple patients.

MANAFUSE™ BONE GROWTH STIMULATION BRIEF PRESCRIBING INFORMATION

***INDICATION:** The ManaFuse™ system is indicated for the non-invasive treatment of established nonunions excluding skull and vertebra, and for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature adult individuals when these fractures are orthopedically managed by closed reduction and cast immobilization.

CONTRAINDICATIONS: There are no known contraindications.

References:

1. Heckman JD, Ryaby JP, McCabe J, Frey J, Kilcoyne RF. Acceleration of tibial fracture-healing by non-invasive, low-intensity pulsed ultrasound. J Bone Joint Surg Am. 1994;76(1):26-34. doi:10.2106/00004623-199401000-00004
2. Kristiansen TK, Ryaby JP, McCabe J, Frey JJ, Roe LR. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. A multicenter, prospective, randomized, double-blind, placebo-controlled study. J Bone Joint Surg Am. 1997;79(7):961-73. doi:10.2106/00004623-199707000-00002
3. Nolte PA, van der Krans A, Patka P, Janssen IM, Ryaby JP, Albers GH. Low-intensity pulsed ultrasound in the treatment of nonunions. J Trauma. 2001;51(4):693-703. doi:10.1097/00005373-200110000-00012
4. PMA P210016 1/17/2025

Your Account Representative:

NAME: _____

CONTACT: _____

Visit our website to learn more and for full prescribing information

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