

# Transport of EXOGEN Bone Healing Device aboard Passenger Aircraft

The EXOGEN Bone Healing Device contains a 3.7 VDC, single cell, 700mAh capacity, 2.59Watt hour, Lithium Ion battery pack.

According to the International Air Transport Association (IATA), referring to air travel in *Dangerous Goods Regulations, Packing Instructions 967*, "lithium-ion batteries contained in equipment" (UN 3481) passengers are permitted to carry on the EXOGEN device onto a passenger aircraft because the following conditions from Section II, batteries having a Watt-hour rating not more than 20 Watt-hours, have been met:

- Each cell and battery is of the type proven to meet the requirements of test in the *UN Manual of Tests and Criteria, Part III, subsection 38.3*.
- Cells and batteries are manufactured under the quality management program described in IATA section 3.9.2.6(e)
- Cells and batteries are protected against short circuits
- Equipment is equipped with effective means of preventing accidental activation
- The pack is afforded "strong outer protection" by the equipment in which it is contained.



**References:**

IATA Packaging Instruction 967, 54<sup>th</sup> Edition, 1 January 2013

**Summary of Indications for Use**

EXOGEN is indicated for the non-invasive treatment of osseous defects (excluding vertebra and skull) that includes the treatment of delayed unions, non-unions<sup>†</sup>, stress fractures and joint fusion. EXOGEN is also indicated for the acceleration of fresh fracture heal time, repair following osteotomy, repair in bone transport procedures and repair in distraction osteogenesis procedures.

<sup>†</sup> A non-union is considered to be established when the fracture site shows no visibly progressive signs of healing.

There are no known contraindications for the EXOGEN device. Safety and effectiveness have not been established for individuals lacking skeletal maturity, pregnant or nursing women, patients with cardiac pacemakers, on fractures due to bone cancer, or on patients with poor blood circulation or clotting problems. Some patients may be sensitive to the ultrasound gel. Full prescribing information can be found in product labeling, at [www.exogen.com](http://www.exogen.com).

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