

IMPORTANT INFORMATION

Please read before use.



Orthofix OsteoTite Bone Screws With Hydroxyapatite Coating

INDICATIONS:

Orthofix OsteoTite Bone Screws are indicated for use in association with the external fixation of bone.

CAUTION:

Federal (USA) law restricts this device to sale by or on the order of a physician.



ORTHOFIX Srl

Via Delle Nazioni 9 - 37012 Bussolengo (Verona) - Italy

Telephone 0039-0456719000 - Fax 0039-0456719380



INSTRUCTIONS FOR USE:

⚠ See Manual 1 “Orthofix External Fixation: Basic Considerations” for correct technique of screw insertion.

Orthofix OsteoTite Bone Screws are plasma-sprayed with a thin coating of hydroxyapatite over the threaded portion. This coating has been shown in clinical trials to enhance fixation at the pin-bone interface and to reduce the incidence of pin loosening. Furthermore, osseointegration with direct contact between the bone and the screw thread was seen on histologic examination.

CONTRAINDICATIONS:

Orthofix OsteoTite Bone Screws are not designed or sold for any use except that indicated.

WARNINGS:

Orthofix OsteoTite Bone Screws are a SINGLE USE (ⓧ) device.

Do not attempt to re-sterilize.

STERILE: | | | |---------|---| | STERILE | R | |---------|---|

Orthofix OsteoTite Bone Screws are provided STERILE. The device is sterilized by gamma irradiation. **Contents of package STERILE unless opened or damaged. If package is opened or damaged, DO NOT USE.**

RETURNS:

Contact your local distributor. Include return authorization number (U.S.A. only), a written description of the problem, name and telephone number of contact person at your facility. Be sure to include area code, stating clearly the place of origin.

WARRANTY:

Suitability for use of the medical device for any surgical procedure shall be determined by the user. Orthofix Srl. and Orthofix Inc. shall not be liable for incidental or consequential damage of any kind.