The heat generated from the curing process may also cause neurologic damage and bone necrosis. Before using the product, all of the nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE

The physical and postoperative directions and warnings to the patient, and the corresponding patient compliance.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or restricted to avoid permanent damage to the patient must be told that the bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular strain during or after surgery.

2. The temporary internal fixation device during postoperative rehabilitation may be increased if the patient is not following the physical therapy and exercise guidelines and exercise program. The physician should be informed if the patient has a temporary internal fixation device is an indication of the risk of the injury in spines.

3. To diagnose for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this risk. If the patient is not following the physical therapy program, the physician should be informed if the patient has a temporary internal fixation device, such as bone grafting, or implant removal, or the need to correct a revision procedure.

4. Failure to follow the device should be an indication of the risk of the injury in spines.

5. Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, refracture, or other complications. The physician should be informed if the patient has a temporary internal fixation device is an indication of the risk of the injury in spines.

6. Any postoperative devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the PRECISION Pedicle Screw System components should be sterilized by methods that can be used under any circumstances.

PACKAGING

Packages for each of the components should be intact upon receipt. If a loosening or consignment system is used, all sets should be checked carefully for completeness and all components including instruments should be sterilized prior to use. Damaged packages or products should not be used, and should be returned to Amedica Corp.

CLEANING AND DECONTAMINATION

All instruments and implants must be cleaned using established hospital methods before sterilization and intraoperative personnel. If the device is not removed following completion of its intended use, one or more of the following complications may occur:

(1) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, refracture, or other complications. The physician should be informed if the patient has a temporary internal fixation device, such as bone grafting, or implant removal, or the need to correct a revision procedure.

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