Avante Medical Solutions Pvt. Ltd.

INSTRUCTIONS FOR USE (IFU)

The Device package contains a single-use implant of Avante medical solution Pvt. Ltd. Only trained and qualified persons should use the implants.

DESCRIPTION - The implants are artificial metal supports used to treat fractures and deformities of bones. They are manufactured as per specifications to suit the anatomy of the bones. They are used by qualified surgeons only to help support or heal the fractures of the bones. They are available in biocompatible material of either Stainless steel or Titanium alloy.

INDICATIONS: Bone Plate: Displaced intra-articular fractures – Open fracture – Polytrauma – Associated neurovascular injury – Failure of closed treatment.

Bone Screw: Cortical screw fixation is indicated when minimally invasive posterior stabilization is desired for - Degenerative instability (sagittal or coronal plane),- Augmentation of interbody constructs,- Spondylolysis,- Trauma,- Tumor/infection,- Obesity, -Osteoporosis

Nails Pins & Wire: Femoral diaphyseal fractures and distal femur fractures.- Humeral shaft fractures. - Tibial shaft fractures, proximal and distal tibia fractures.- Metaphyseal fractures.

Spinal Implants: Interbody fusion in patients with Degenerative Disc Disease -Spondylolisthesis or retrolisthesis - Discogenic back pain with degeneration of the disc. Existing painful spinal instability - Post-laminectomy spondylolisthesis.- Painful pseudoarthrosis - Potential instability- Spinal stenosis. Degenerative scoliosis.-Unstable fractures.- Augmenting anterior strut grafting - Tumor. Infection. -Stabilizing spinal osteotomies.

Dental Implants: Trauma not affecting the alveolar bone Decay without purulence Endodontic failure severe periodontal bone loss Residual root Root fracture.

CONTRAINDICATIONS: * Do not use the implant in cases of Inadequate bone quantity and/or bone quality, Hypersensitivity to metal or allergic reaction, Early or Late Inspection, both deep and / or superficial, Patients with limited blood supply, Patient within whom co-operation or mental competence is lacking, thereby reducing patient compliance.

ADVERSE REACTIONS may include but are not limited to Clinical failure (i.e. pain or injury) due to bending, loosening, breakage of implant, loose fixation, dislocation and/or migration, Pain, discomfort, and/or abnormal sensations due to the presence of the implant, Primary and/or secondary infections, Allergic reactions to implant material, Necrosis of bone or decrease of bone density, Injury to vessels, nerves and organs, Elevated fibrotic tissue reaction around the surgical area.

INSPECTION: Before use, inspect the box carefully. Do not use when Implants have scratches or seem damaged, threads are damaged. Prior to surgery check suitability of fixation of this implant with its corresponding implant, and also ensure strength of the whole assembly.

MAGNETIC RESONANCE IMAGING (MRI) Safety : In the MR environment Dental Implants have not been tested for heating or migration in the MR environment . Known risks of exposing implant devices to the MR environment include displacement, torque and radio frequency induced heating. Implant devices may also create image artifacts in MR scans. Scanning a patient who has this device may result in patient injury.

STERILIZATION RECOMMENDATIONS:

Method	Temperature	Exposure time	Pressure
Steam (autoclave)	121 Deg C.	15 Minutes	103421 Pa / 0.1 MPa / 15 psi

LABEL SYMBOLS:

	**Non-Sterile** Indicating that the device has not been sterilized.
	**Consult Instructions For Use** Note: This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device.
	**Do not re-use** Single use or use only once
	**Date Of Manufacture** Note: This symbol is accompanied by the date that the device was manufactured. The date could be year, year and month, or year, month and day, as appropriate.
	**Catalog Number** Note: This symbol be accompanied by the catalog number relevant to the device bearing the symbol.
	**Batch Code** Note: This symbol should be accompanied by the batch code relevant to the device bearing the symbol.
	**Do Not Use If Package Is Damaged** Do not use it, if the packaging is compromised.
	**Caution** This symbol is to denote that there are some warnings or precautions associated with the device, which are not otherwise found on labels.
	**Store at Room Temperature**
Qty.	**Number Of Quantity Packed.**
Material	Raw Material used for manufacturing

AVANTE	Manufacturers Company Logo.

WARNINGS: Physician note: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

- The responsibility of the proper selection of patients, implants, adequate training, experience in the choice & placement of the implant & the decision to leave or remove implant postoperatively, rests with the surgeon.
- The implants are available in variety of configurations; these shall be used in combination with related corresponding implants & instruments made by AMSPL
- If a combination of implants is used, they should be of the same MOC.
- A device that has been implanted should never be reused, reprocessed, or resterilized under any circumstances. It may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.
- Preoperative and operating procedures including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the implant.
- Further, the proper selection and the compliance of the patient will greatly affect the results.
- Failure to use the appropriate product for the application may result in a premature clinical failure. Failure to use the proper component to ensure adequate blood supply & provide rigid fixation may result in loosening, bending or cracking of the product and/ or bone fracture.
- The patient has been informed about the advantages and disadvantages of the implant & implantation procedure and about possible alternative treatments.
- The implant can fail due to excessive load, wear and tear or infection.
- The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload too early through extreme strain, work-related or athletic activities.
- Corrective surgery may be necessary if the implant fails.
- The patient must have his/her physician to carry out follow-up examinations of the implants at regular intervals.
- Store the implants in a dry and dust-free place (standard hospital environment)