V IMPLANT REMOVAL

The surgeon must take the final decision on implant removal. It is recommended that an implant, used as an aid for healing should be removed once its services are over, particularly in younger and more active patients

VI POST OPERATIVE CARE

A patient must be made aware of the limitations of metallic implants and take precautions to avoid unnecessary stress to implant.

No partial weight bearing or non-weight bearing device can be expected to withstand the unsupported stresses of full weight bearing or excessive muscular activity when there is an un-united tracture.

Bone union is a must and the patient must restrict his activities to assist in healing.

VII SECOND HAND IMPLANTS

Used implants, even if they appear un-damaged, may have internal and external Defects. It is possible that individual stress analysis each part fails to reveal the accumulated stress on the metals as a result of use within the body. This may ultimately lead to implant failure.

Every implant must be discarded after use and should never be re-used. It should be bent & then disposed of properly so that it becomes unfit for reuse. While disposing it of, it should be ensured that the discarded implant does not pose any threat to children, stray animals and environment.

VIII CAUTION

Implant components from one manufacture should not be used with those of another. Implants from each manufacture may have metal and design differences so that the use in conjunction with different devices may lead to inadequate fixation or corrosion of the implant due to generation of peizo currents.

IX PACKAGING DISPOSAL

The packaging material of this device if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such a way that it is out of reach of children andstray animals.

X STERILITY

GREENS SURGICALS (P) LTD.. Bone Plates and Bone Screws are supplied Non-Sterile.

Check the integrity of the packaging and labelling before opening the pack.

Remove the device from the pack before sterilization.

Implants are recommended to be sterilized, using steam autoclaving process regularly used in the hospitals and clinics.

The following two methods have been validated and recommended by the company:

Method:	**Steam Sterilization (Autoclaving)**
Temperature	**121 Degree Centigrade**
Exposure Time:	**15 Minutes**

XI USE

Qualified & specialized trained surgeons only should use this device.

STORAGE

Store in a dry place.

PRODUCT INFORMATION DISCLOSURE:

GREENS SURGICALS (P) LTD.. HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND MANUFACTURE OF THESE PRODUCTS. GREENS SURGICALS (P) LTD. EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. GREENS SURGICALS (P) LTD.. WILL NOT BE LIABLE FOR ANY INCIDENT OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM THE USE OF THE DEVICES. GREENS SURGICALS (P) LTD.. NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE DEVICES.

INFORMATION

Should any information regarding the implants or their use be required, please contact your representative or distributor or contact the manufacturers direct.

Details of various Symbols used in Labeling

	Do not reuse
	Batch code
	Date of manufacture YYYY-MM
	Consult Instructions for Use
	Manufacturer
	Use by YYYY-MM
	Non-Sterile
	Catalogue number
	Keep Dry
	Keep Away from Sunlight
	Do not use if package is damaged

EC REP	EC Representative Address
MAT	Material Grade Stainless Steel like 316L, 316LVM, Titanium TiAl6V4
QTY	Quantity in the package

DEVICE SYSTEM NAME:

GREENS SURGICALS (P) LTD. **Bone Screws**

DEVICE DECRIPTION:
The bone screw system consists of non-sterile bone screw implants. The plates are the devices, used to fasten the bones for the purpose of fixation of fractured bones.

The **GREENS SURGICALS (P) LTD.**Bone Screws are differentiated by the manner in which they are fastened on the bone, their function, their size and the type of bone they are intended to be used for.

- Five Types of Screws:
  Cortical (cortex)
  Cancellous
  Malleolar
  Cannulated
  DHS (Dynamic Hip Screws) only for DHS and DCS Plates.

These screw variants can be provided with locking compression thread types as well as regular types.

Type of Recess	**:**	**Hexagonal.**
Diameter Range	**:**	**1.5mm to 7.3mm.**
Length Range	**:**	**6mm to 150mm.**

MATERIALS: THESE DEVICES CAN BE MADE IN THE FOLLOWING MATERIALGRADES

STAINLESS STEEL: 316L, 316LVM ALLOY

TITANIUM ALLOY. TiAl6V4

INDICATIONS FOR USE:
GREENS SURGICALS (P) LTD. Bone Screws are provided non-sterile. The bone screws when used in combination with plates are intended for treating fractures of various bones in combination with corresponding bone plates including the clavicle, pelvis, scapula, long bone (humerus, ulna, radius,

femur, tibia and fibula), and small bone (metacarpals, metatarsals, phalanges).

CONTRA INDICATIONS:

The implant should not be used in a patient who has currently, or who has a history of:

- Local or Systemic acute or chronic inflammation.
- Active infection or inflammation.
- Suspected or documented metal allergy or intolerance.
- Symptomatic Arthiritis.

WARNING:

Serious Post-operative complications may occur from the use of implant in a patient who-

- **Lacks good general physical condition**
- **Has severe osteoporosis**
- **Demonstrates anatomical or physiological anomalies.**
- **Has immunological response, sensitization or hypersensitivity for foreign materials.**
- **Do Not Re-Use. Do not re-process. The device is not designed for re-processing. Reprocessing of the medical device intended for single use devices may lead to degraded performance or a loss of functionality. The cleaning and disinfection / sterilization for re-processing of these single use devices has not been validated nor any authentic information is available. So re-process of the single use device is not allowed.**

Adequate knowledge of Surgical Techniques, proper selection and placement of implants and post-operative patient care are important considerations while performing an orthopaedic surgical procedure. Therefore it is essential that the implants are used by a qualified Medical Practitioner only.

NOTE: It is the responsibility of the surgeon to discuss, with the patient, the precautions, possible risks, warnings, consequences, complications and adverse reactions which may occur as a result of the surgical procedure and implantation of the device(s).

The patient should be informed that the life expectancy of the device is unpredictable and once implanted, successful results cannot be

guaranteed if adequate care and precautions are not taken. The screws can be used alone as well upon the selection and decision of the surgeons performing surgeries.

If adverse effects happen, it may necessitate re-operation, revision or removal surgery, arthrodesis or the involved joint and/or amputation of the limb.

MRI COMPATIBILITY:
The GREENS SURGICALS (P) LTD.. Bone Screws have not been evaluated for safety and compatibility in the MR environment. The GREENS SURGICALS (P) LTD.. Bone Screws have not been tested for heating or migration in the MR environment.

I SELECTION OF THE PATIENT

During selection of patients the following factors have to be considered:

a) Immunological intolerance
Immunological intolerance may occur in some patients. Where material sensitivity is suspected, appropriate foreign body tests should be performed

b) Degenerative Diseases
In the case of patients suffering from degenerative diseases, this can get aggravated during implantation, and will decrease the expected life of the implant. In such cases surgery can be considered only as a temporary relief.

c) Mental illness
Mental illness or schizophrenia may cause patients to ignore the limitations and precautions of the implanted material, leading to implants fracture and complication

d) Alcohol and Drug Addiction
The patients, addicted to alcohol and drugs, ignore, during the state of stupor or during the stage of withdrawal, the necessary precautions for the use of implants. This may result in complications of implants fracture.

e) Obesity
An obese patient produces abnormal stresses leading to increased load on the implant which ultimately results in failure of the implant.

f) Activity
If the patient indulges in an activity involving significant muscular strain in the implanted region, the result may be failure of the implant.

II SELECTION OF THE IMPLANT/IMPLANT SYSTEM
For successful implantation, the selection of the proper size, the Selection of the bone screw is very important.

The size and the shape of the human bones puts limitations of and strength of implants during fracture management and re-constructive surgery. The Doctor/Orthopedic Surgeon has to select the appropriate implant depending upon the application, which should also be free from any apparent corrosion or any manufacturing defect.

III HANDLING OF IMPLANT/IMPLANT SYSTEM
The plate should conform to the shape of the bone. Any inequality should be adjusted by accurate shaping of the plate. To fit the bone is not recommended as the screws are instantly subjected to a strong expelling force. Hence, plate contouring should be done by the plate benders designed for this purpose.

Care should be taken that there are no scratches or distortions sharp edges at the site of the screw hole.

These may cause defects on surface finish and result in improper device performance.

IV IMPORTANT
The screws, even if properly fixed may fatigue and break. Breakage may be due to unstable implant fixation or insufficient support.

If the screw is not properly centred as it is being tightened, there will be a tendency for the countersink in the plate to force it to one side, thereby damaging the good threads already cut in the bone and producing a strain which will probably lead to necrosis and early loosening of the screw.