Instruction of use of veterinary surgical implants

Veterinary surgical implants – bone plates and screws.
Before using the implant please carefully read this instruction and surgical techniques documents. Make sure that you are familiar with the appropriate surgical technique.
IWET veterinary implants system consists of locking and non-locking plates and locking and non-locking cortical or cancellous screws.

Materials:
The material of implant is determined by the last digit of catalog number (REF).

Materials used in production of implants:

Product	REF	Material	Standard
Plates	XX.XX.1	Stainless steel 316 LVM	ISO 5832-1
	XX.XX.2	Unalloyed titanium	ISO 5832-2
Screws	XX.XX.1	Stainless steel 316 LVM	ISO 5832-1
	XX.XX.2	Ti6Al4V titanium alloy	ISO 5832-3

Intended use:
IWET veterinary implant system is intended for use in bone injury repair, bone reconstrictions an orthopedic procedures of animal bone system. It is strictly prohibited to use IWET implants in human skeleton treatment under any circumstances.

Indications:
IWET veterinary implants are indicated for surgical bone fracture repair and surgical corrections of animal osteoarticular system deformations.

Contraindications:
- open fractures with large soft tissue injuries,
- patient owners with no intention or possibility of cooperation during the treatment.
- bone inflammation, infected pseudoarthrosis and soft tissue infection in operating field.
- allergy to any metal used in implant alloy.

General adverse events:
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reaction may occur, some of the most common may include: problems resulting from anesthesia and patient positioning, thrombosis, embolism, infection, injuries of important structures including blood vessels, excessive bleeding, damage to soft tissues including swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hypersensitivity reactions, side effects associated with implant prominence, loosening, bending, or breakage of the device, malunion, non-union or delayed union which may lead to breakage of the implant, reoperation.

Device specific adverse events:
- Malunion / non-union that may be associated with:
  - Incorrect selection of the implant size for the planned application
  - Hole deformation due to plate bending
  - Construct failure due to inadequate strength design
  - Construct strength too weak for post-operative loading forces
  - Plate hole diameter too large or screw head too small
  - Insufficient screw holes left after plate has been cut
  - Reverse and repeated bending applied
- Adverse Tissue Reaction that may be associated with:
  - Instruments debris/particle created during cutting
  - Instruments debris/particle created during implantation and/or removal
- Damage to vital organs/surrounding structures that may be associated with:
  - Plate does not offer enough options for screw placement
  - Screw placement into nerve or any other critical structures
  - Screw core diameter is too small leading to screw breakage post-operatively
  - Burrs/sharp edges on edge of plate caused by plate cuting
  - Plate inadequately contoured resulting in inadequate reduction
  - Screw breaks during insertion and fragments are not retrieved
  - Screw breakage post-operatively
  - Generation of particle debris during surgical procedure
  - Screw strips bone post-operatively
  - Screw or plate migrates or deforms post-operatively
  - Improper use of implant resulting in treatment failure
  - Wrong plate selection
  - Incorrect plate/screw position resulting in irreversible damage
  - Overheating of drill bit causing thermal necrosis of bone
- • Injury to user that may be associated with:
  - Sharp edges caused during cutting of plates punctures surgical glove/hand
- Loosening that may be associated with:
  - Insufficient implant fixation
  - Screw breakage post-operatively
  - Inappropriate screw used
- Soft Tissue Damage that may be associated with:
  - Burrs/sharp edges on edge of plate
  - Screw breakage post-operatively
  - Implant loses its function post-operatively
- Systemic Infection that may be associated with:
  - Incomplete/incorrect processing leading to implantation of a non-sterile product
  - Sterile barrier compromised leading to implantation of a non-sterile product
  - Implantation of non-sterile product
  - Reuse of single use implant

Sterilization:


All IWET implant are provided in non-sterile form. Before using the implants in the surgical procedure all non sterile products must be sterilized. The user is fully responsible for sterilization process. The recommended sterilization method is steam under pressure method performed according to international standards in temperature 121°C and 1 atm pressure for 20 minutes or in temperature 134°C and 2 atm pressure for 10 minutes.

Single-use device:

Do not reuse
Products intended for single-use must not be re-used. Re-use or reprocessing may compromise the structural integrity of the device and /or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.
Contaminated implants must not be reprocessed. Any IWET implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to user protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue

Precautions:
- If contouring is necessary, the surgeon should avoid bending the device at a screw hole
- Avoid sharp bends, repetitive and reverse bending as it increases the risk of implant breakage.
- In order to determine the appropriate amount of screws needed to achieve stable construct fixation, the surgeon should consider the fracture size and shape. .
- Take care to protect soft tissue from trimmed plate edges.
- Confirm that drill bit length and diameter correspond to selected screw prior to drilling
- Always irrigate during drilling to avoid thermal damage to the bone and ensure drill bit is concentric to plate hole.

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- Drill speed rate should never exceed 1,800 rpm, particularly in dense, hard bone. Higher drill speed rates can result in:
  - thermal necrosis of the bone,
  - soft tissue burns,
  - an oversized hole, which can lead to reduced pullout force, increased ease of the screws stripping in bone and worse fixation of implant.
- Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures. Be sure to keep drill clear of loose surgical materials.
- Confirm screw length prior to implantation.
- Tighten screws in a controlled manner. Applying too much torque to the screws may cause screw/plate deformation, or bone stripping. If bone becomes stripped, remove the screw from the bone and replace it (if it is possible) with a larger screw.
- Confirm that plate positioning allows for adequate clearance of nerves and any other critical structures.

Warnings:

- Always make sure that the quality of bone tissue is sufficient in the place of plate implantation. Implantation on bone tissue of insufficient quality may result in potential threats like implant loosening and fixation failure. The user is responsible for patient health assessment and fixation device selection adequate to the patients needs.
- The surgeon should inform the owner of a patient about risks and complications that may be caused by inappropriate post operative behavior.
- The limb with the implant should not bear the same weight as the healthy limb. The owner of patient must be aware that overloading the operated limb or too much activity during the time of recovery may lead to implant damage and bone refracture that will need to be reoperated.
- Instruments, screws or cut plates have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Take care to remove all fragments that are not fixated during the surgery.
- While the surgeon must make the final decision on implant removal, we recommend to remove the devices once their service as an aid to healing is accomplished. Implant removal should be followed by adequate post-operative management to avoid refracture.

Surgical implants are indented to use by trained surgeon:

This description alone does not provide sufficient background for direct use of IWET products. It is recommend to participate in at least one training on the planned implant surgical technique.

MRI Risks warning:

Metal implants made of metallic materials such as stainless steel or titanium alloy are a contraindication to the magnetic resonance test. The residual magnetism present in those materials can cause artifacts or interference on MRI image which may lead to wrong interpretation of test results. There were no negative effects of magnetic resonance imaging on the body of a patient with a metal implant and no negative effects on the implant itself. The negative impact of metal bone implants produced by IWET is related to the accuracy and quality of MR images, which may be related to their interpretation.

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