



PACKAGE INSERT FOR IMPLANT DEVICES

COBRA™ CHS PLATING SYSTEM

Our Titanium Compression Hip Screw Plating System is designed for the fixation and management of fractures in the femur. In addition to dealing with femur neck, trochanteric and sub-trochanteric fractures. Our longer plates can also cope with femur shaft fractures, provided that a stable construct can be established.

These devices are designed to be used as temporary scaffolding devices whilst, the fractures are healing and they should be removed once sufficient calus formation is noted. Patients **MUST** be adequately counseled prior to surgery to clearly outline the limitations of these implants in relation to:

- a. Partial weight bearing only during the healing regime and
- b. The need to use support devices such as crutches, canes, support frames during the early healing process and after the devices are extracted. Suitable life style changes must be implemented by the patient to assist in the overall healing process.

Suggested indications:

1. Femur neck, trochanteri, sub-trochanteric and shaft fractures.

Suggested contra-indications:

1. Where an active infection is suspected/diagnosed.
2. Circumstances where a patient's ability or unwillingness to follow a non-weight bearing regime during the healing period is indicated or inferred (e.g. Mental disorder, drug intoxication, alcoholism, neuropathy).
3. Foreign body sensitivity is known or suspected. Sensitivity tests must be performed prior to surgical intervention.
4. In circumstances such as insufficient bone quality, bone volume, blood supply limitations, previous deep wound or localised infections.
5. Patients with chronic disease's such as diabetes/mellitus chronic articular rheumatism, geriatric diseases etc.
6. Patients suffering from osteoporosis, epilepsy, obesity.
7. Our implants must never be used in conjunction with another manufactures implants.

Warnings and precautions relating to pre, per and post operative management.

Pre-operative

1. Patient profile and or any predisposition as outlined in both the suggested indications and contra-indications are to be thoroughly reviewed.
2. As in the success of any surgical technique, careful patient review/planning coupled with pro-active evaluation of the implants efficacy, will contribute to the success of this technique.
3. Always ensure that a full range of sterile implants are available at the time of the procedure including a complete set of dedicated instruments.
4. All implants are to be handled with care. No modifications of any kind should be entertained. While handling, ensure that no damage is caused or noticed. Dents, scratches etc. may impair the efficacy of the implant.
5. The surgeon should be familiar with the implants and related instrumentation prior to undertaking the procedure. Any trial fitting etc. should be undertaken to ensure both familiarity and efficacy of the implant and instrumentation being employed.
6. Allergies and other reactions to Titanium, although rare and infrequent, should be considered, tested (Where appropriate) and ruled out, prior to surgery.
7. In addition to the range of dedicated instruments, access and familiarity to theatre equipment such as image intensifiers etc. is highly recommended.
8. Surgeons should acquire competency with handling and using our range of implants and familiarity with our recommended surgical technique etc. prior to attempting surgery. In all cases it is recommended that surgeons acquire competency in handling less demanding fractures before attempting the use of our implants in unstable and other difficult fractures.

Pre-operative

1. Always ensure that a full range of implants and instrumentation are available in theatre. Choosing the correct type and length of implant will clearly determine the final outcome of this procedure.
2. Do not modify any of our implants in any way. If the implant is scratched or damaged in any way, return the items to the appropriate authority.
3. These implants are for ONE TIME USE ONLY. Do not under any circumstances recycle these implants.
4. Always ensure that the fracture is properly aligned and reduced, as far as practicable, and that a stable construct is achieved and confirmed, using image intensifiers etc.
5. Please follow surgical technique and pay particular attention to :
 - a. Position and angulation of guide pin/drill being deployed.
 - b. Measurement of the depth of insertion of the guide pin/drill.
 - c. Choice of the appropriate size, type, neck angle of lag screws/neck assembly.
 - d. Reaming.
 - e. Development of lag screw/neck section and plate.
 - f. Drilling of cortical screw sites for the chosen plate.
 - g. Deployment of cortical screws of the correct length.
6. Pro-active judgement with regards to the successful outcome of the procedure in relation to:
 - a. Instability of the construct leading to bone shortening.
 - b. Nerve damage both pre and post operatively.
 - c. Damage to vascular supply leading to necrosis.

Post-operative

1. Surgeons should counsel all patients regarding appropriate care and lifestyle during the healing period. Strict guidelines should be provided on any activity that is likely to cause early weight bearing or active use of extremities. Patients should be made aware of the fact that any or all of these activities hinder proper healing and cause stress on the implant and can lead to other complications.
2. Periodic x-ray monitoring of the healing cycle is highly recommended. This type of clinical regime not only confirms adequate healing is in progress, but where complications arise, such as loosening, bending, non-union, fracture of the implant or changes in position, are detected early, this usually leads to prompt, appropriate corrective measures. Where complications are detected, it is important to evaluate all options available, whether it be a considered "wait and see" or, where appropriate, reduced activity and where necessary, early revision of the implant.
3. Early partial weight bearing should only be recommended where stable fractures and good bone-to-bone contact is established. In all cases, it is vital to enlist the total co-operation of the patient. It is imperative that the patient be advised to take all appropriate precautions from undertaking any activity likely to violate the healing regime.
4. Patients should be cautioned against unassisted activity without the use of aids such as crutches, slings etc.
5. Post-operative care and suitable physical therapy should be designed so as to prevent early loading of extremities, until stable fracture site is confirmed.
6. Once healing is complete, patients should be cautioned against activity that may contribute towards re-fracture of the site, even though the implant is still in place or soon after the implant is retrieved. This danger will diminish once the voids left by implant retrieval are filled completely.
7. The surgeon must make the final decision as to when the implant is to be retrieved. This decision will be by its very nature, require the consent and co-operation of the patient. This general rule however, is that devices should be removed as soon as their aid to healing is complete. In elderly or debilitated patients, this device may be left in place even after healing, as long as there is no evidence or complaint of any pain or a bursa.

STERILITY

THESE DEVICES ARE SUPPLIED STERILE. DO NOT RE-STERILISE. IF DEVICE STERILITY IS COMPROMISED, CONTACT THE MANUFACTURER.

CAUTION: United States Federal Law restricts this device to sale by or on the order of a licensed physician.

INFORMATION: For further information and support please contact your local dealer or the Customer Services Manager at:

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