PRECAUTIONS:
- Ensure that all components needed for the operation are available in the surgical theatre.
- Inspection is recommended prior to surgery to determine if implants have been contaminated or damaged during storage.
- Handle instruments with care. Instruments should be examined for wear or damage prior to surgery.
- Avoid surface damage to the implant and discard all damaged or mishandled implants.
- After the procedure check the proper positioning of all implants using an image intensifier. Correct positioning of the implant parts is extremely important for the outcome (see surgical manual).
- Do not use components from Swecan in combination with components from other manufacturer’s systems.

ADVERSE EFFECTS:
- Pain, discomfort, abnormal sensations, nerve damage, soft tissue damage, infections, necrosis of bone, bone resorption, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.
- Treatment failure such as fracture or loosening of the implant may occur due to excessive activity, prolonged loading upon the device, incomplete healing, delayed union, non-union or excessive force exerted on the implant during insertion.
- Implant migration and/or loosening may occur.
- Material sensitivity, histological or allergic reaction resulting from implantation of a foreign material may occur.
- Abrasion of the prosthesis surface and the development of osteolysis due to a foreign body reaction.
- Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.
- Surgery intervention maybe required to treat adverse effects. This may involve exchange of a screw, removal of a prosthesis and conservative treatment.
- Stiffness, tendinitis or transient neuropathy.

POSTOPERATIVE CARE INSTRUCTIONS:
- Postoperative care is extremely important. The patient must be cautioned about the use, limitations and possible adverse effects of this implant. The patient must also be warned that the implant and/or treatment might fail if he/she neglects the postoperative care instructions.
- The implant affects the patient’s ability to carry loads and he/she must be general living circumstances. For this reason, each patient needs individual instructions on correct behaviour after implantation.
- The device is not designed to immediately withstand the stress of weight bearing, load bearing or excessive activity.
- Explain the need to report unusual changes in the implantation area as well as falls or accidents even if the device or the surgical area did not appear to be harmed at the time.
- The patient should be warned that the device cannot fully replicate a healthy anatomical joint.

STERILITY:
The implants are provided sterile. Sterile devices have been exposed to a minimum dose of 25.0 kGy gamma irradiation. If either the implant or the package appears damaged, or if sterility is questioned for any reason, the implant shall not be used.

CLEANING AND DISINFECTION:
The instruments should be disassembled before cleaning. Cleaning shall be performed in accordance with ISO 15883. Cannulated instruments must be visually inspected after cleaning.

STERILIZATION AND RE-STERILIZATION:
The instruments shall be sterilized and re-sterilized by using a validated sterilization process in accordance with ISO 17665. Sterile packaging shall be done in accordance to ISO 11607-1.

Do not re-sterilize the implants because this could lead to surface damages.

STORAGE INSTRUCTIONS:
Store in a cool dry place and keep away from direct sunlight.

SYMBOLS USED ON THIS PRODUCT:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilized using irradiation</td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td>Do not reuse</td>
<td>Consult instruction for use</td>
</tr>
<tr>
<td>Caution</td>
<td>Do not re-sterilize</td>
</tr>
<tr>
<td>Non-sterile</td>
<td></td>
</tr>
</tbody>
</table>