7. Carefully inspect the NOTE of the bone/plate. Higher torque may be required to fully engage the threads than when using a normal screw with 22mm, 2.0mm diameter Auto-Drive® screws in lengths from 4.0mm to 22.0mm, 2.0mm diameter Auto-Drive® screws in lengths from 4.0mm to 22.0mm, 2.0mm and 2.4mm diameter locking screws in lengths from 2.0mm to 16.0mm, and 2.0mm and 2.4mm diameter locking screws in lengths from 2.0mm to 16.0mm. The lateral hole will align with the screw hole on the plate and serve as a pilot hole during screw placement.

8. Drill the first hole: Select the Angulated Locking Drill Guide and insert it into the first plate hole nearest the osteotomy site, and then all remaining screws, following the previously outlined procedure. Securely tighten each screw utilizing the proper technique.

9. For illustrative procedures:
   a. Resect the desired area
   b. Place the plate back onto the osteotomy in its original position.
   c. Place the reduction forceps over the osteotomy
   d. Check all screws to ensure a secure fit in the plate.

10. Bone grafting: Use a 2.0 locking system. A vascularized bone graft must be applied to all 2.0mm constructs used in reconstructing the mandible.

Instructions for Use, Angulated Locking Screw System

3. The surgeon should have specific training, experience, and thorough familiarity with the use of rigid fixation products and techniques.

5. Drill and replace the planting screw: Insert the second screw on the opposite side of the plate or osteotomy site, and then all remaining screws, following the previously outlined procedure. Securely tighten each screw utilizing the proper technique.

9. For illustrative procedures:
   a. Resect the desired area
   b. Place the plate in its place, remove the plate and screws, taking note of each screw placement. Resect the desired area

10. Remove the plate:
   a. Once the plate is in place, remove the plate and screws, taking note of each screw placement. Resect the desired area

Instructions for Use, Mandible Lag Screw System

2. Place the template across the fracture; ensure that the fracture lines fall entirely within the limit lines of the template. 

3. Determine drill placement area and angulations. Final drill path/angle is shown by tip of sliding length gauge.

4. Position the plate:
   a. Place the plate over the fracture or osteotomy site.
   b. Use the plate holding forceps to secure the plate to the bone, if desired.

5. The use of osteotomes is contraindicated in cases of active or suspected infection

6. Measure screw length:
   a. Remove drill guide and use depth gauge to measure depth to determine osteotomy depth.

7. Drill and place the remaining screws:
   a. Insert the second screw on the opposite side of the plate or osteotomy site, and then all remaining screws, following the previously outlined procedure.

8. Drill and place the remaining screws: Insert the second screw on the plate opposite the side of the osteotomy or plate site, and then all remaining screws, following the previously outlined procedure. Securely tighten each screw utilizing the proper technique.

9. For illustrative procedures:
   a. Resect the desired area
   b. Once the plate is in place, remove the plate and screws, taking note of each screw placement. Resect the desired area

10. Remove the plate:
   a. Place the plate back onto the osteotomy in its original position.
   b. Resect the desired area
   c. Place the reduction forceps over the osteotomy
   d. Check all screws to ensure a secure fit in the plate.

11. When using the Power System Instruction for Use, irrigation when pilot drilling.

12. When using Plate Benders 220-0548 and 220-0529, note they can only be used with Reconstruction plates.

1. Expose and reduce fracture: After completing the preoperative plan, expose the fracture or osteotomy site.

2. Select and prepare implants: Select the appropriate template/plate depending on the indication. For Reconstruction plates, allow for at least 3 screws per bone segment. Orient the plate so the tip-facing the tip-facing the posterior border to the plate.

3. Determine the plate to match the anatomy. An exact match is not required when using angulated locking screws, as plate stability is not dependent on plate-to-bone contact when screws are locked. Cut and contour plate to match template form. Plates can be cut with the appropriate OsteoMed Osteotomes.

4. Position the plate:
   a. Place the plate over the fracture or osteotomy site.
   b. Use the plate holding forceps to secure the plate to the bone, if desired.

5. Drill the first hole:
   a. Select the threaded drill guide and insert it into the first plate hole nearest the fracture or osteotomy site.

6. Drill forceps insertion holes:
   a. Drills the first hole of the template's web hole and the second hole through one of the osteotomy

7. Select the appropriate plate:

8. Drill the first hole:
   a. Select the threaded drill guide and insert it into the first plate hole nearest the fracture or osteotomy site.

9. Drill and place the remaining screws: Insert the second screw on the osteotomy side of the plate or fracture site, and then all remaining screws, following the previously outlined procedure. Securely tighten each screw utilizing the proper technique.

10. Drill and replace the planting screw: Insert the second screw on the plate opposite the side of the fracture or osteotomy site, and then all remaining screws, following the previously outlined procedure. Securely tighten each screw utilizing the proper technique.

Instructions for Use, Auto-Drive® Screws

The Auto-Drive® screws are self-drilling and can be inserted in one step. Insert the screw in a TapLock™ socket and rotate the drill guide in a counterclockwise motion until the head is flush with the surface of the bone. A torque may be required to fully engage the threads with the surface of the bone.

The lateral hole will align with the screw hole on the plate and serve as a pilot hole during screw placement.

Instructions for Use, Reduction Plates & Forceps

1. Expose the fracture:

2. Place the plate onto the osteotomy site:

3. Contour and/or lag the plate:

4. Drill pilot holes:

5. Drill and replace the planting screw:

6. Drill and replace the remaining screws: Insert the second screw on the plate opposite the side of the fracture or osteotomy site, and then all remaining screws, following the previously outlined procedure. Securely tighten each screw utilizing the proper technique.

7. Place the plate back onto the osteotomy in its original position.

8. Ensure the template:

9. Check all screws to ensure a secure fit in the plate.

10. Drive the screw to compress the fracture.
6. Insert the forceps' tips into the plate until there is enough engagement between the tip of the forceps and the slot of the plate to adequately retain the plate.

6.1 One tip of the forceps must be placed in the slot and the second tip must be placed in one of the screw holes on the opposing side of the fracture.

7. Engage the reduction forceps into the mandible fracture fragments, reduce the fracture.

8. Push the plate flush with the bone and drill the first screw using the appropriate drill.

9. Use Depth Gauge to measure the screw length required.

10. Insert the required screw and drive until fully seated.

11. Place opposite side lateral screw to maintain reduction.

12. Remove forceps and place remaining screws.

13. Close per standard practice.

14. Do not use excessive force when lodging the tip into the slot.

Caution, Consult Instructions for Use.

Symbols and Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
<tr>
<td>PREVAC</td>
<td>Pre-Vacuum Steam</td>
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</table>

Cleaning
- Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasonic treatment, etc.) and recommendations for chemical detergents.
- OsteoMed recommends the following cleaning and sterilization instructions for instrumentation:
  1. Clean all instruments thoroughly using mild detergent, soft brush and warm water. Ensure that dried blood, bone chips and other deposits are removed from the instruments and sterilization tray.
  2. Thoroughly rinse all instruments and the sterilization tray with water.
  3. Arrange all the instruments in the sterilization case and ensure that the lid is in place and properly closed.
  4. Steam Autoclave per the following Sterilization Instructions.

Sterility
- Product is supplied NON-STERILE unless expressly labeled as STERILE.
- Select plates and screws are available sterile packaged (Gamma Sterilized) in 5-packs.

Pre-Vacuum Steam

<table>
<thead>
<tr>
<th>Sterilization Systems</th>
<th>MPX™ Rigid Fixation Systems - Plastic Tray</th>
<th>MPX™ Rigid Fixation Systems - Aluminum Tray</th>
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</thead>
<tbody>
<tr>
<td>Time</td>
<td>90 minutes</td>
<td>55 minutes</td>
</tr>
<tr>
<td>Dry Time</td>
<td>15 minutes</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Configuration</td>
<td>Wrapped tray</td>
<td>Wrapped tray</td>
</tr>
<tr>
<td>Wrapping Technique</td>
<td>Wrapped tray in two layers of 1-ply polypropylene wrap with towel placed between the wraps and bottom of the tray</td>
<td>Wrapped tray in two layers of 1-ply polypropylene wrap with towel placed between the wraps and bottom of the tray</td>
</tr>
</tbody>
</table>

Storage
- Sterile packaged implants should be stored at controlled room temperature out of direct sunlight. Product packaging should be inspected prior to use for signs of damage or tampering.

Caution
- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.