The W. Lorenz Surgical Bi-Phase System is a convenient external fixation solution for your mandible fracture needs. It allows the surgeon to fixate a mandibular fracture with no major incisions, making this technique ideal for areas with significant soft tissue loss. The Bi-Phase device serves as the patient’s mandible until the fracture site has completely healed. The procedure not only requires less O.R. time, but also remains a cost effective alternative to traditional plating.

**Indications for Mandibular Use**

- Multiple Fractures
- Bone Resections
- Reconstructive Procedures
- Comminuted Fractures
After the surgeon has determined the appropriate amount and size of bone screws, they are then applied to each side of the unreduced mandible fracture or mandibular defect. By using the open side of the trocar handle (01-0005) the proper placement of the screws can be determined. The hexagon wrench (01-0011) can be used to drive each screw properly into the mandible.

1. To allow for temporary reduction of the fracture, the screw holding assembly (01-0022) is attached to one screw on each side of the fracture. Tighten the clamp with the hexagon wrench, using the opposite side that was used for the bone screws.

2. Tightening of the rod is achieved by using the same side of the hexagon wrench that was used for the screws. Once the splint has been stabilized, the mechanism is ready for acrylic cement application.
The photos and information presented in this brochure are to demonstrate the clinical technique utilized by Dr. Gregory W. Hueler who is familiar with the Bi-Phase System and its application. As the manufacturer of this device, Walter Lorenz Surgical does not practice medicine and does not recommend this device and surgical procedures to any specific individual patient. The surgeon who performs any implant procedure must determine the appropriate device and surgical procedure for each individual patient. For product information, including indications contraindications, warnings, precautions, and potential adverse effects, see package insert or visit our website at www.lorenzsurgical.com or call 1-800-874-7711.

Information contained in this brochure is intended for surgeon information only and is not intended for patient distribution.

4. The appropriate amount of *acrylic cement is determined by adjusting the *acrylic cement tray assembly (01-0014) proportionately to the length of the splint. The *acrylic cement should then be poured into the tray and removed when a putty-like consistency has been achieved.

5. The *acrylic cement putty should now be placed over all the screws, allowing enough room for the bone screw nuts to be added.

6. The bone screw nuts (01-0030) can now be applied to each screw using the hexagon wrench. After the *acrylic cement has hardened, the fracture and splint should be completely secured and the surgery is complete.

*(not included with the Bi-Phase System)
### Bi-Phase Fixation System (01-0010) includes:

<table>
<thead>
<tr>
<th>QTY</th>
<th>Part #</th>
<th>Description</th>
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<tbody>
<tr>
<td>5</td>
<td>01-0001</td>
<td>Bi-Phase Assembly</td>
</tr>
<tr>
<td>1</td>
<td>01-0005</td>
<td>Bi-Phase Trocar Handle</td>
</tr>
<tr>
<td>1</td>
<td>01-0006</td>
<td>Bi-Phase Trocar</td>
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<tr>
<td>1</td>
<td>01-0007</td>
<td>Bi-Phase Drill Guide</td>
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<tr>
<td>1</td>
<td>01-0011</td>
<td>Bi-Phase Hex Wrench</td>
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<tr>
<td>1</td>
<td>01-0014</td>
<td>Acrylic Cement Tray Assembly</td>
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<tr>
<td>4</td>
<td>01-0019-02</td>
<td>Bi-Phase Cap</td>
</tr>
<tr>
<td>1</td>
<td>01-0019-02</td>
<td>Bi-Phase Lateral Rod 13cm</td>
</tr>
<tr>
<td>1</td>
<td>01-0020</td>
<td>Bi-Phase Lateral Rod 9cm</td>
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<tr>
<td>1</td>
<td>01-0022</td>
<td>Bi-Phase Screw Holding Assembly</td>
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<tr>
<td>4</td>
<td>01-0025</td>
<td>Bi-Phase Short Screw Ti, 4.2cm</td>
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<td>4</td>
<td>01-0029</td>
<td>Bi-Phase Medium Screw Ti, 5.1cm</td>
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<tr>
<td>12</td>
<td>01-0030</td>
<td>Bi-Phase Bone Screw Nut Ti</td>
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<td>4</td>
<td>01-0035</td>
<td>Bi-Phase Long Screw Ti, 6.4cm</td>
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<td>01-0039</td>
<td>Bi-Phase Bone Screw Nut Ti</td>
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<tr>
<td>2</td>
<td>03-4086</td>
<td>2.3 x 80mm Drill</td>
</tr>
<tr>
<td>2</td>
<td>915-2047</td>
<td>2.2 x 105mm Drill</td>
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### Bi-Phase Fixation System (optional parts)

<table>
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<tr>
<th>QTY</th>
<th>Part #</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>01-0015</td>
<td>Acrylic Cement Tray Channel (Part of 01-0014)</td>
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<tr>
<td>1</td>
<td>01-0016</td>
<td>Acrylic Cement Tray Insert (Part of 01-0014)</td>
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<tr>
<td>1</td>
<td>01-0017</td>
<td>Replacement Sliding Stop (Part of 01-0014)</td>
</tr>
<tr>
<td>1</td>
<td>01-0032</td>
<td>Thumb Screw, Acrylic Cement Tray (Part of 01-0014)</td>
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METALLIC INTERNAL FIXATION DEVICES
ATTENTION OPERATING SURGEON

ALL INSTRUCTIONS MUST BE READ CAREFULLY PRIOR TO CLINICAL USE

DESCRIPTION
Walter Lorenz Surgical, Inc. manufactures and distributes a variety of internal fixation devices intended to aid in the alignment and stabilization of bone in the oral cranio-maxillofacial skeletal system. Instrumentation has been designed specifically for use with each system of implants.

Implant Material: Commerically Pure Titanium, ASTM F-67
Titanium 6Al 4V Alloy, ASTM F-136

INDICATIONS
These devices are implantable bone plates and bone screws for oral, cranio-maxillofacial procedures including:
1. Fractures
2. Osteotomies, including orthognathic procedures
3. Reconstructive procedures
4. Revision procedures where other treatments or devices have failed

CONTRAINDICATIONS:
1. Active infection
2. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
3. Patients with limited blood supply, insufficient quantity or quality of bone, or latent infection.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS
1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
2. Nonunion or delayed union, which may lead to breakage of the implant.
3. Migration, bending, fracture or loosening of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Increased fibrous tissue response around the fracture site and/or the implant.
8. Necrosis of bone.
9. Inadequate healing.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain, which may not be related to the implant.

WARNINGS
Internal fixation devices aid the surgeon in the alignment and stabilization of the oral cranio-maxillofacial skeletal bone for fixation of fractures, osteotomies and reconstructive procedure. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand unsupported stress placed upon the device by full load bearing. Internal fixation devices are internal splints, or load sharing devices that align the fracture until normal healing occurs. If there is delayed union, nonunion, or incomplete healing of bone, the implant can be expected to bend, break, or fail. Therefore, it is important that immobilization of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. The size and shape of bones and soft tissue place limitation on the size and strength of implants. Surgical implants are subject to repeated stresses in use, which can result in fatigue fracture. Factors such as the patient’s activity level, and adherence to load bearing instructions have an effect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and metallurgical aspects of the surgical implants.

1. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalies that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants.
2. Correct handling of implants is extremely important. Implants should be modified only when necessary. Modifications or excessive contouring of implants may weaken the implant and contribute to breakage. Notches or scratches put in the implant during the course of surgery may contribute to breakage.
3. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.
4. Implants may be removed after fracture has healed. Implants can loosen, fracture, corrode, migrate, or cause pain. If an implant remains implanted after complete healing, the implant may cause stress shielding, which may increase the risk of refracture in an active patient. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Adequate postoperative management to avoid refracture should follow implant removal.
5. Adequately instruct the patient. Postoperative care is important. The patient’s ability and willingness to follow instruction is one of the most important aspects of successful fracture management. Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure since these patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports and braces that are intended to immobilize the fracture site and limit load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, and load bearing. The patient is to be made aware and warned of general surgical risks, complications, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.
6. 1.0 mm and 1.5 mm plates and screws are not designed to be used as the sole means of fixation in the mandible.

PRECAUTIONS
Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in a different patient.

Instruments are available for each implant system to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Walter Lorenz recommends that all instruments be regularly inspected for wear and disfigurement.

Surgical instruments must be used only for the device systems for which they are designed. Use of other manufacturer instruments can involve incalculable risks for the implant and instrument, thereby potentially endangering the patient, user, or third party.
Warning and Precautions for use of the Bi-Phase System

Bone Plates
Bone plates may need to be contoured to the surface of the bone by bending the plates with a bending instrument.
1. Care must be taken to achieve the appropriate contour with as few bends as possible. Repeated bending of titanium increases the risk of fracture.
2. Sharp angles and small bending radii must be avoided to reduce the risk of the device breaking.
3. The bending instruments must be used with care because they can cause damage to the implant. The operating surgeon should always inspect the implant after bending for damage, which may include dents or deformed screw holes. These defects can lead to breakage of the implant. Deformed screw recesses due to bending may impair the proper fit of the screw head.
4. Cutting bone plates may increase the risk of failure of the implant. If the operating surgeon elects to cut a plate, care must be taken to cut in such a way to maintain adequate strength, support, and fixation for the intended use. Cutting a plate between the screw holes is the preferred method to maintain strength characteristics. Sharp edges should be smoothed to avoid soft tissue damage or irritation. When cutting a plate, extra care must be taken to prevent the portion being cut from projecting towards the patient, user, or third party.

Templates:
Templates are instruments used to achieve the proper contour of a bone plate.
• Do not implant a template.

Bone Screws:
• The screwdriver, which has been designed, for a particular system of screws must always be used to be sure that proper screwdriver/screw head connection is achieved.
• Incorrect alignment or fit of the screwdriver to the screw head may increase the risk of damage to the implant or screwdriver.
• Excessive torque can cause the screw to fracture.

Twist Drills:
1. Twist drills are labeled for single use only.
2. When using twist drills, appropriate cooling is necessary to aid in the prevention of injury to bone, skin and tissue. It should be combined with low speed drilling to prevent risks of bone demineralization, possible loosening of the bone screw and injury to the patient.
3. The manufacturers instructions for the hand piece used with the twist drill must be followed. The manufacturer of the handpiece may recommend proper speeds to avoid failures such as breakage of the twist drill.
4. Excessive force may cause unusual stress conditions and result in breakage or fracture of the device.
5. Breakage of twist drills may result in injury to the patient, the user, or third party.

Drill Guides and Cannulas
Drill guides and cannulas are provided to assist the operating surgeon in guiding the twist drill and to aid in the protection of the patient, user and third parties. Drill guides and cannulas should be properly irrigated to prevent risks of injury to the patient.

Depth Gauges:
Depth gauges are used to measure the hole drilled into the bone and assist in proper selection of the length of screw to be used. It is recommended to use a depth gauge designed for the system of screws being used since screw head thickness varies between the systems. The depth gauges indicate the entire length of the screw, which corresponds to the labeling. Plate thickness and screw seating in the plate is already taken into account.

STERILITY
Unless supplied sterile, metallic internal fixation devices must be sterilized prior to surgical use. Unused implants can be re-sterilized. Where specified, do not use implants after expiration date. Following is a recommended minimum cycle for steam sterilization that has been validated by W. Lorenz under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of recommended minimum cycle parameters described below.

Pre-vacuumed Steam Sterilization (Hi-VAC) Wrapped:
Temperature: 270 ° Fahrenheit (132 ° Celsius)
Time: Four (4) minutes
Drying Time: Thirty (30) minutes MINIMUM

Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. Since W. Lorenz is not familiar with individual hospital handling methods, cleaning methods and bioburden, W. Lorenz cannot assume responsibility for sterility even though the guideline is followed.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Operating Surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities which they are involved in the handling and use of this product.

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