

## INSTRUCTIONS FOR USE OF OMNIHEX® IMPLANTS

### Caution

Federal U.S. law restricts this device to sale by, or on the order of, a licensed dentist or physician.

### Disclaimer of Liability

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### Product Description

OmniHex® Dental Implants are endosseous implants manufactured from titanium alloy. Surgical and restorative components are produced from titanium alloy as well as polymers. OmniHex® Dental Implants are compatible with the prosthetic components and surgical instrumentation of the OmniHex® Implant System. For specific product identification and contents, please refer to individual component packaging.

### Instructions for Use

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OmniHex® Dental Implant System implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

### Contraindications

Patients should be evaluated before the time of surgery for factors that put them at risk from the implant placement procedure, or that may affect healing of bone or surrounding soft tissue. Contraindications include but are not limited to: vascular conditions, uncontrolled diabetes, clotting disorders, anticoagulant therapy, metabolic bone disease, chemotherapy or radiation therapy, chronic periodontal inflammation, insufficient soft tissue coverage, metabolic or systemic disorders associated with wound and/or bone healing, use of pharmaceuticals that inhibit or alter natural bone remodeling, any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene, uncontrolled parafunctional habits, insufficient height and/or width of bone, and insufficient interarch space. Do not reuse Implant Part Dental Implants. Reuse of OmniHex® Dental Implants carries the risk of pathogenic patient cross-contamination.

### Precautions During Surgical Procedures

Minimizing tissue damage is crucial to successful implant osseointegration. In particular, care should be taken to eliminate sources of infection, contaminants, surgical and thermal trauma. Risk of osseointegration failure increases as tissue trauma increases. All drilling procedures should be performed at 2000 rpm or less under continual and copious irrigation. All surgical instruments used must be in good condition and should be used carefully to avoid damage to implants or other components. Implants should be placed with sufficient stability; however, excessive insertion torque may result in implant fracture, or fracture or necrosis of the implant site. The proper surgical protocol should be strictly adhered to. Since implant components and their instruments are very small, precautions should be taken to ensure that they are not swallowed or aspirated by the patient.

## Precautions During Prosthetic Procedures

Following successful placement of Implant Part Dental Implants, verify primary stability and appropriate occlusal loading before proceeding with the placement of a permanent or provisional prosthesis. All components that are used intraorally should be secured to prevent aspiration or swallowing. Distribution of stress is an important consideration. Care should be taken to avoid excessive loads significantly transverse to the implant axes.

## Storage & Handling

OmniHex® Dental Implants must be stored in a dry location at room temperature, in their original packaging. OmniHex® Dental Implants are packaged suspended in sterile vials. Do not handle implant surfaces directly. Users are advised to visually inspect vials to insure seals and contents are intact and in their original packaging prior to use.

## Sterility

OmniHex® Dental Implants are shipped sterile. They should not be resterilized. They are for single use only, prior to the expiration date. Do not use implants if the packaging has been compromised or previously opened.

Instruments are shipped non-sterile. Steam sterilize the surgical tray and instruments for twenty (20) minutes at 132°C/270°F minimum.

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## Warning

OMNIHEX® DENTAL IMPLANTS MAY ONLY BE USED FOR THEIR INTENDED PURPOSE IN ACCORDANCE WITH GENERAL RULES FOR DENTAL/SURGICAL TREATMENT, OCCUPATIONAL SAFETY AND ACCIDENT PREVENTION. THEY MUST ONLY BE USED FOR DENTAL PROCEDURES WITH THE RESTORATIVE COMPONENTS THEY WERE DESIGNED FOR. IF THE INDICATIONS AND USE ARE NOT CLEARLY SPECIFIED, TREATMENT SHOULD BE SUSPENDED UNTIL THESE CONSIDERATIONS HAVE BEEN CLARIFIED. THE FOLLOWING INSTRUCTIONS ARE NOT SUFFICIENT TO ALLOW INEXPERIENCED CLINICIANS TO ADMINISTER PROFESSIONAL PROSTHETIC DENTISTRY. IMPLANT PART DENTAL IMPLANTS, SURGICAL AND RESTORATIVE COMPONENTS MUST ONLY BE USED BY DENTISTS AND SURGEONS WITH TRAINING/EXPERIENCE WITH ORAL SURGERY, PROSTHETICS AND BIOMECHANICAL REQUIREMENTS, AS WELL AS DIAGNOSIS AND PREOPERATIVE PLANNING. THE IMPLANT SITE SHOULD BE INSPECTED FOR ADEQUATE BONE BY RADIOGRAPHS, PALPATIONS AND VISUAL EXAMINATION. DETERMINE THE LOCATION OF NERVES AND OTHER VITAL STRUCTURES AND THEIR PROXIMITY TO THE IMPLANT SITE BEFORE ANY DRILLING TO AVOID POTENTIAL INJURY, SUCH AS PERMANENT NUMBNESS TO THE LOWER LIP AND CHIN. PRIOR TO SURGERY, ENSURE THAT THE NEEDED COMPONENTS, INSTRUMENTS AND HELP MATERIALS ARE COMPLETE, FUNCTIONAL AND AVAILABLE IN THE CORRECT AMOUNTS. TREATMENT OF CHILDREN IS NOT RECOMMENDED UNTIL GROWTH IS FINISHED AND EPIPHYSEAL CLOSURE HAS OCCURRED. ABSOLUTE SUCCESS CANNOT BE GUARANTEED. FACTORS SUCH AS INFECTION, DISEASE AND INADEQUATE BONE QUALITY AND/OR QUANTITY CAN RESULT IN OSSEOINTEGRATION FAILURES FOLLOWING SURGERY OR INITIAL OSSEOINTEGRATION. OMNIHEX® DENTAL IMPLANTS CAN DISTORT IMAGES OBTAINED VIA MAGNETIC RESONANCE IMAGING (MRI). OSSEODENT® INC. IS NOT LIABLE FOR DAMAGES RESULTING FROM TREATMENT OUTSIDE OF OUR CONTROL. THE RESPONSIBILITY RESTS WITH THE PROVIDER.

## Treatment Plan

A complete clinical evaluation is important prior to implant surgery. Appropriate radiography should be used to determine bone availability, optimal implant location and to avoid structures such as mandibular canal, maxillary sinuses, and adjacent teeth.

## Surgical Site Preparation

Follow the corresponding drill sequence for hard (H) and soft (S) bone preparation.

### Drilling Sequence Chart

Implant Size	Pilot Drill DRILL-PD	Surgical Drill DRILL-2320	Surgical Drill DRILL-2823	Surgical Drill DRILL-3428	Surgical Drill DRILL-3834	Surgical Drill DRILL-4844	Surgical Drill DRILL-5448
3.2mmD	Soft/Hard	Soft/Hard	Hard Only				
3.7mmD	Soft/Hard	Soft/Hard	Soft/Hard	Hard Only			
4.2mmD	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Hard Only		
4.7mmD	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Hard Only	
5.2mmD	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Hard Only
5.7mmD	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard	Soft/Hard

**Step 1:** With proper irrigation, perforate the alveolar crest

**Step 2:** Pilot Drill – Employ pilot drill OSD-DRILL-PD with proper irrigation, drill a pilot hole to the appropriate depth marking on the drill. Check the orientation of the initial osteotomy using a Parallel Pin. If placing more than one implant and parallelism is desired, begin drilling the next site and align as the trajectory of the bone permits.

**Step 3:** Surgical Drills – Depending on implant diameter and the density of bone at the osteotomy site, it may be necessary to utilize one or more of the Surgical Drills to widen the osteotomy. To avoid over-preparation, widening drill diameters should be used only as necessary, and in proper succession. Select the desired Surgical Drill, accounting for the density of bone at the osteotomy site and the diameter of the implant to be placed. With proper

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### Implant Placement

**Step 1:** Implant Selection – Remove the sterile vial from its tamper-proof pouch and place it onto a sterile field.

**Step 2:** Initial Placement – Remove the implant from the vial by its plastic carrier, taking care not to touch the implant body. Transport the implant to the prepared site, and insert into the osteotomy. Rotate clockwise with applied pressure to engage the self-tapping groove. Avoid lateral forces, which can affect the angulation and final alignment of the implant. The plastic carrier will separate from the implant head upon reaching a torque threshold of approximately 15 Ncm.

**Step 3:** Advancement and Final Seating – Continue threading the implant into the osteotomy site using the preferred placement method. A minimum torque value of 35 Ncm upon final seating indicates good primary stability. Use of torque wrench OSD-WR-TRQ35 is recommended.

### Implant Positioning

The implant should be rotated at the time of placement to ensure optimal positioning of the internal hex connection. This will allow the restoring clinician to take full advantage of the anatomical abutment contours and minimize the need for abutment preparation. Adjust the final position of the implant so that any one of the six flats of the internal hex connection is oriented toward the facial.

### Cover Screw Placement

Following implant placement, use the Hex Driver OSD-HEXT-050S or OSD-HEXT-050L to unthread the Cover Screw from the plastic carrier contained in the sterile vial. Carry the Cover Screw to the implant and hand-tighten.

### Closure & Suturing

If the soft tissue was reflected, close and suture the flap utilizing the desired technique. Take a postoperative radiograph to use as a baseline, and advise the patient as to the recommended postoperative procedures.

### Second Stage Uncovering (Two Stage Surgery)

Following the appropriate healing period, make a small incision in the gingiva over the implant site to expose the Cover Screw. Use the Hex Driver to remove the Cover Screw, and place a healing abutment or temporary abutment of the appropriate height and diameter.