

# LABELING

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01-50-1000  
FORM Y-PKG-114  
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**TOTAL TEMPOROMANDIBULAR JOINT (TMJ) REPLACEMENT SYSTEM**  
**Essential Prescribing Information (EPI)**

**CAUTION:**

Federal Law (USA) restricts this device to sale, distribution, or use, by or on the order of a physician.

**DESCRIPTION:**

The Total Temporomandibular Joint (TMJ) Replacement System is implanted in the jaw to functionally reconstruct a diseased and/or damaged temporomandibular joint. The Total TMJ Replacement System is a two-component system comprised of mandibular condyle and glenoid fossa components. Both components are available in multiple sizes as right and left side specific designs and are attached to bone by screws. Included in the system are trials, instruments and instrument cases.

**MATERIALS:**

Mandibular Component – Cobalt-Chromium-Molybdenum (Co-Cr-Mo) alloy with titanium alloy coating or Titanium (Ti-6Al-4V) alloy with titanium alloy coating

Fossa Component – ultra high molecular weight polyethylene (UHMWPE)

Screws – Titanium alloy

Trials: mandibular – aluminum  
fossa – Radel® plastic

Instruments: TMJ flat diamond rasp, TMJ diamond burs, TMJ double-ended drill guide,  
retractors – stainless steel

Instrument Case – stainless steel, silicone, Radel® plastic

**INDICATIONS:**

The Total Temporomandibular Joint Replacement System is indicated for reconstruction of the temporomandibular joint. The reconstruction is necessary due to one of the following diagnoses:

1. arthritic conditions: osteoarthritis,  
traumatic arthritis  
rheumatoid arthritis
2. ankylosis including but not limited to recurrent ankylosis with excessive heterotopic bone formation,
3. revision procedures where other treatments have failed (e.g. alloplastic reconstruction, autogenous grafts)
4. avascular necrosis
5. multiply operated joints
6. fracture
7. functional deformity
8. benign neoplasms
9. malignancy (e.g. post-tumor excision)

10. degenerated or resorbed joints with severe anatomic discrepancies
11. developmental abnormality

**CONTRAINDICATIONS:**

1. Active or chronic infection.
2. Patient conditions where there is insufficient quantity or quality of bone to support the components.
3. Systemic disease with increased susceptibility to infection.
4. Patients with extensive perforations in the mandibular fossa and/or bony deficiencies in the articular eminence or zygomatic arch that would severely compromise support for the artificial fossa component.
5. Partial TMJ joint reconstruction.
6. Known allergic reaction to any materials used in the components.  
NOTE: Patients with known or suspected nickel sensitivity should not have Co-Cr-Mo devices implanted since this material contains nickel.
7. Patients with mental or neurological conditions who are unwilling or unable to follow postoperative care instructions.
8. Skeletally immature patients.
9. Patients with severe hyper-functional habits (e.g. clenching, grinding etc.)
10. Patients with a foreign body reaction due to previous implants.

**WARNINGS:**

1. Mandibular and fossa components are provided STERILE. DO NOT RESTERILIZE.
2. Screws, trials, instruments and instrument cases are provided NON-STERILE. CLEAN AND STERILIZE BEFORE USE.
3. DO NOT USE if there is a loss of sterility of the devices.
4. DO NOT USE damaged implants and only use implants that are packaged in unopened or undamaged containers.
5. DO NOT USE the individual components of this total system (e.g. mandibular components, fossa components, or screws) for partial joint reconstruction.
6. Bone cement or other grouting agents should not be used when implanting these devices. Safety and efficacy have not been established for the use of bone cement or other grouting agents with these implants.
7. DO NOT USE IN CHILDREN. The Total TMJ Replacement was designed for skeletally mature patients.

**PRECAUTIONS:**

The device is limited to surgeons who are adequately trained in the use of the device through hands-on and educational course work. In all cases sound medical practice is to be followed and the surgeon must select the type of device appropriate for treatment.

The patient is to be warned that the system does not replace normal healthy bone in their TMJ and they may continue to have chronic pain and limited range of motion. The system can break or loosen as a result of stress, activity, or trauma. Patients with severe hyper-functional habits may have an undesirable outcome. The presence of existing mandibular and/or zygomatic arch screws or screw holes may compromise fixation. Note that placement of the implant in one joint only may result in harmful effects to the joint on the opposite side. Placement of the implant may produce an improper relationship between teeth surfaces that should contact during biting. The patient is to be made aware of surgical risks and possible adverse effects prior to surgery and

warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.

Specialized instruments/trials are designed for use with the Total TMJ Replacement System to aid in the accurate implantation of the components. DO NOT USE trials/instruments or cases that are disfigured, cracked, corroded, or otherwise damaged. Instruments/trials are subject to wear with normal usage and are susceptible to fracture when exposed to extensive use or excessive force. All trials/instruments and cases should be regularly inspected for wear or disfigurement. These should be disposed of appropriately.

#### **ADVERSE EVENTS:**

Adverse events that may occur following placement of the Total TMJ Replacement System are listed below. See Tables 7 and 8 for more detailed information on adverse events from the clinical trial.

- Removal of components(s) including, but not limited to the following:
  - implant changes caused by loading and/or wear
  - degenerative changes within the joint surfaces from disease or previous implants
  - implant materials producing particles or corroding
- Loosening or displacement with or without removal of the implant
- Infection (systemic or superficial)
- Foreign body or allergic reaction to implant components
- Fossa wear through
- Facial swelling and/or pain
- Facial nerve dysfunction
- Excision of tissue
- Heterotopic bone formation
- Neuroma formation
- Ear problems
- Dislocation

#### **CLINICAL STUDIES:**

A prospective clinical study began in the United States in 1995 and was designed to document patient outcomes after implantation of the Total TMJ Replacement System. Unilateral and bilateral patients were enrolled only after non-surgical treatment and/or previous implant failure. Listed in Table 1 are the diagnoses of patients in the study. Many patients had more than 1 diagnosis so the % totals are more than 100%.

**TABLE 1**  
**Diagnosis**

	Total Cases Right Side		Total Cases Left Side	
	n=158		n=171	
	n	%	n	%
1. Osteoarthritis	93	28%	107	30%
2. Rheumatoid Arthritis	9	3%	12	3%
3. Traumatic Arthritis	60	18%	64	18%
4. Malignancy	0	0%	0	0%
5. Benign Neoplasm	1	0%	1	0%
6. Functional Deformity	9	3%	9	2%
7. Revision: partial implant	8	2%	11	3%
8. Revision: total implant	45	14%	49	14%
9. Avascular Necrosis	42	13%	42	12%
10. Ankylosis	46	14%	50	14%
11. Fracture	16	5%	16	4%

A total of 224 cases received 329 joints. Overall patients demonstrated decrease pain, increase function, increase in maximal incisal opening (MIO), and satisfaction with their outcome. See the following Tables 2-8, which summarize the clinical outcome.

**TABLE 2**  
**Jaw Pain Intensity**

Visual Analog Scale (0 = none, 10 = most intense pain imaginable)										
Jaw Pain	Pre-op n=224	1 mo. n=193	3 mo. n=181	6 mo. n=177	1 yr n=150	1.5 yr n=128	3 yrs n=85	4 yrs n=48	5 yrs n=20	6 yrs n=14
<b>Mean</b>	<b>8.5</b>	<b>4.6</b>	<b>3.7</b>	<b>3.4</b>	<b>3.1</b>	<b>3.4</b>	<b>2.8</b>	<b>3.5</b>	<b>4.0</b>	<b>3.7</b>
No data	0	19	22	20	26	33	34	29	23	18
Death/ Removal	0	1	1	2	3	3	4	4	4	3
Total n possible	224	213	204	199	179	164	123	81	47	35

**TABLE 3**  
**Interference with Eating**

Visual Analog Scale (0 = none, 10 = excruciating)										
Interference with Eating	Pre-op n=224	1 mo. n=193	3 mo. n=181	6 mo. n=177	1 yr n=150	1.5 yr n=128	3 yrs n=85	4 yrs n=48	5 yrs n=20	6 yrs n=14
<b>Mean</b>	<b>8.5</b>	<b>4.4</b>	<b>3.5</b>	<b>3.2</b>	<b>3.0</b>	<b>3.2</b>	<b>2.8</b>	<b>3.4</b>	<b>4.3</b>	<b>3.2</b>
No data	0	19	22	20	26	33	34	29	23	18
Death/ Removal	0	1	1	2	3	3	4	4	4	3
Total n possible	224	213	204	199	179	164	123	81	47	35

**TABLE 4**  
**Maximal Incisal Opening (MIO)**

<b>Measured in millimeters (mm)</b>										
MIO	Pre-op n=224	1 mo. n=193	3 mo. n=181	6 mo. n=177	1 yr n=150	1.5 yr n=128	3 yrs n=85	4 yrs n=48	5 yrs n=20	6 yrs n=14
<b>Mean</b>	<b>20.1</b>	<b>24.9</b>	<b>28.5</b>	<b>29.4</b>	<b>30.1</b>	<b>29.6</b>	<b>29.3</b>	<b>28.4</b>	<b>28.9</b>	<b>26.8</b>
No data	0	19	22	20	26	33	34	29	23	18
Death/ Removal	0	1	1	2	3	3	4	4	4	3
Total n possible	224	213	204	199	179	164	123	81	47	35

**TABLE 5**  
**Patient Satisfaction** (\* includes enthusiastic, very satisfied, and satisfied)

% of joints	1 mo. n=286	3 mo. n=265	6 mo. n=256	1 yr n=215	1.5 yr n=190	3 yrs n=118	4 yrs n=66	5 yrs n=28	6 yrs n=19
<b>Satisfied* Or better</b>	<b>98%</b>	<b>97%</b>	<b>96%</b>	<b>97%</b>	<b>98%</b>	<b>99%</b>	<b>99%</b>	<b>100%</b>	<b>100%</b>
No data	42	51	53	72	85	80	73	51	28
Death/ Removal	1	1	2	3	3	4	4	4	3
Total n possible	329	317	311	290	278	202	143	83	50

**Table 6**  
**In Hindsight, Would You Choose to Have This Surgery?**

% of patients	1 mo. n=193	3 mo. n=181	6 mo. n=177	1 yr n=150	1.5 yr n=128	3 yrs n=85	4 yrs n=48	5 yrs n=20	6 yrs n=14
<b>Yes</b>	190	178	175	148	125	84	45	20	14
<b>%</b>	<b>99%</b>	<b>98%</b>	<b>99%</b>	<b>97%</b>	<b>98%</b>	<b>99%</b>	<b>94%</b>	<b>100%</b>	<b>100%</b>
Unsure	2	0	0	0	0	1	0	0	0
No data	19	22	20	26	33	34	29	23	18
LTF <sup>1</sup>	1	1	2	3	3	4	4	4	3
Total n possible	213	204	199	179	164	123	81	47	35

<sup>1</sup> LTF = Lost to follow-up (either death or permanent removal of all components)

**Table 7**  
**Adverse Events Requiring Device Removal**

Device Removals	Cases (n=224)		Joints (n=329)	
	#	%	#	%
<b>1. Permanent removal of fossa component:</b> a. One due to aseptic necrosis b. Two due to infection c. One due to swelling d. One due to heterotopic bone removal	5	2.2 %	6	1.8 %
<b>2. Removal (non-permanent)<sup>1</sup> of mandibular component:</b> a. Two bilateral removals of heterotopic bone b. One due to dislocation c. Two due to reposition for malocclusion	5	2.2 %	9	2.7 %
<b>3. Permanent removal of mandibular component:</b> a. Larger component causing a dislocation removed and replaced with smaller component	1	0.4%	1	0.3%
<b>4. Permanent removal of total joint:</b> a. One unilateral patient requested removal due to pain and swelling after 6 months b. Three removals due to infection	4	1.8 %	4	1.2 %
<b>Permanent removal</b>	10	4.5 %	11	3.3 %
<b>Non-permanent removal</b>	5	2.2 %	9	2.7 %
<b>TOTAL</b>	<b>15</b>	<b>6.7 %</b>	<b>20</b>	<b>6.1%</b>

<sup>1</sup> Mandibular components were taken out in the operating room for removal of heterotopic bone or re-positioning and then were placed back in the joint.

**Table 8**  
**Adverse Events Not Requiring Device Removal**

Adverse Events	Cases (n=224)		Joints (n=329)	
	#	%	#	%
Reflex Sympathetic Dystrophy (RSD)	1	0.4	1	0.3
Excision of tissue (excluding neuroma and/or heterotopic bone)	4 (10)*	1.8 (4.5)	6	1.8
Heterotopic bone excision	4 (9)	1.8 (4.0)	6	1.8
Chronic severe masseter muscle spasms	2	0.9	3	0.9
Motor vehicle accident (MVA) - increased pain regardless of facial impact	14	6.3	22	6.7
Facial trauma (excluding MVA)	9	4.0	10	3.0
Head trauma with no jaw involvement	2	0.9	3	0.9
Neuroma excision	12 (13)	5.4 (5.8)	15	4.6
Death (all unrelated)	3	1.3	3	0.9
Coronoidectomy	16 (17)	7.1 (7.6)	25	7.6
Unrelated disease diagnosis (multiple sclerosis, Multiple myeloma, meningitis)	3	1.3	5	1.5
Abscess (stitch/facial/intraoral)	3	1.3	5	1.5
Skin infection (not in area of prosthesis)	1	0.4	2	0.6
Dislocation (mandible)	1	0.4	1	0.3
Ear infection (two with tympanic membrane perforation)	5	2.2	8	2.4
External ear canal problems: 1. Perforation 2. Granulation formation	2	0.9	2	0.6
Scalp alopecia from anesthesia tubing pressure	1	0.4	2	0.6
Muscle tenderness	1	0.4	2	0.6
Decreased range of motion	1	0.4	1	0.3
Allergy to resorbable sutures	1	0.4	2	0.6
Contralateral Subcondylar osteotomy for pre-existing disease	1	0.4	1	0.3
Patient reported episodic "floaters" in right eye	1	0.4	2	0.6
Dysesthesia of pre-auricular scar	1	0.4	1	0.3
Ankylosis	2	0.9	3	0.9
Facial numbness	1	0.4	2	0.6
Loose fossa screw	1	0.4	2	0.6
Fistula	1	0.4	1	0.3
<b>Total Cases</b>	<b>94</b>	<b>42.0%</b>	<b>136</b>	<b>41.3%</b>
<b>Total Incidence</b>	<b>(107)</b>	<b>(47.8)</b>		

\* These numbers in parenthesis ( ) are the incidence

## **PATIENT COUNSELING INFORMATION:**

Discussion of the following points is recommended prior to surgery.

- The importance of prompt medical attention if they experience unusual swelling in the area of the implant.
- The risks associated with a total TMJ system (see Warnings and Adverse Events).
- Post-operative pain relief and return of function varies from patient to patient.
- Additional treatment may be required including but not limited to extended physical therapy, bite splint, dental braces, and/or orthognathic and reconstructive surgery .

## **HOW SUPPLIED:**

The Total TMJ Replacement System mandibular and fossa components are supplied sterile in individual packages. Screws, trials, and instruments are supplied non-sterile and must be sterilized prior to surgical use. See the following autoclave recommendations under Sterility.

## **REUSABLE TMJ INSTRUMENT CASE CLEANING METHOD**

The TMJ Instrument Case is comprised of two cases: the smaller trial case fits into the larger instrument case. The smaller trial case holds unused screws and hand rinsed trials. The unoccupied space is intended for larger surgical instruments.

### **NOTE: DO NOT ALLOW SOILED INSTRUMENTS/TRIALS TO DRY.**

- Immerse or use damp towels with deionized or distilled water to keep soiled instruments/trials moist prior to cleaning.
- For instruments/trials contaminated with blood and body fluids (e.g. protein), use of an enzyme product is recommended to facilitate cleaning.
- Use of a residue free detergent is recommended.
- Mechanical cleaning (i.e. washer-disinfection/washer-decontamination equipment) using equipment designed for medical devices is recommended. Automatic washers/disinfectors should be operated as instructed by the manufacturer.

### **Cleaning Instructions using an Automatic Washer/Disinfector and Detergent**

1. Disassemble reusable instruments from powered hand piece (powered hand pieces not supplied by Walter Lorenz Surgical, Inc.).
2. Pre-rinse by hand  
Remove gross contamination from all soiled instruments/trials under cool to tepid running tap water using an instrument brush to scrub all surfaces of each instrument/trial until visibly clean. Wear protective gloves and goggles during this step.
3. Loading the TMJ Instrument Case  
After visually removing gross contamination, the instruments/trials are placed into the TMJ Instrument Case. The trials along with unused screws are placed into the smaller trial case. The larger surgical instruments should fit into the remaining space so that the lid of the case is easily clamped over the top. If the lid of the case will not close, the case is overloaded. Remove excess instrumentation and clamp the lid over the top of the case.

*Warning: Use the TMJ Instrument Case only with instruments/trials of the Total TMJ Replacement System.*

Pre-wash cycle: optional (if not available, proceed to instruction #4)

Do not use detergent in this cycle. Pre-wash in deionized or distilled water.

*Minimum cycle parameters: 4 minutes at 49° C or 120° F*

4. Wash Cycle

Use a residue free detergent per manufacturer's instructions.

*Minimum cycle parameters: 12 minutes at 49° C or 120° F*

5. Final Rinse/Thermal Disinfect Rinse

**DO NOT USE cleansing agents during this final cycle.**

After the wash cycle, a final rinse cycle using deionized water for a *minimum of 4 minutes at 30° C or 86° F* or a thermal disinfect cycle at an elevated temperature of *85° C or 185° F* should be used.

6. Visual Inspection

At the end of the cleaning cycle, visually inspect the instruments to ensure they are "visually clean". If they are not, repeat cleaning instructions 2-6.

**Warning:** Do not, under any condition, reuse titanium screws that entered the operative site. Sterilized unused screws that did not enter the operative site can be cleaned as above and re-sterilized using the steam (autoclave) sterilization parameters below.

**Precaution for reusable trials, instruments and instrument cases:**

**DO NOT USE** trials/instruments or cases that are disfigured, cracked, corroded, or otherwise damaged. All trials/instruments and cases should be regularly inspected for wear or disfigurement. These should be disposed of appropriately.

**STERILITY:**

The Total Temporomandibular Joint Replacement System mandibular and fossa components are sterilized by exposure to a minimum of 25 kGy of gamma irradiation. **DO NOT RESTERILIZE.**

**Screws, trials, and the TMJ Instrument Case containing instruments are supplied non-sterile and should be wrapped with an FDA cleared sterilization wrap prior to steam sterilization in order to maintain sterility.**

*The following autoclave recommendations are for sterilization of screws, trials, and the TMJ Instrument Case containing instruments used with the Total TMJ Replacement System.*

Pre-Vacuum Steam Sterilization:

Temperature: 270° - 275° F (132° - 135° C)

Time: Fifteen (15) minutes

Drying Time: Fifteen (15) minutes

**Authorized Representative:**

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