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01-50-1000
FORM Y-PKG-114
Date: 3-07-05

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 n=158		Total Cases Left Side 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
Mean	**8.5**	**4.6**	**3.7**	**3.4**	**3.1**	**3.4**	**2.8**	**3.5**	**4.0**	**3.7**
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
Mean	**8.5**	**4.4**	**3.5**	**3.2**	**3.0**	**3.2**	**2.8**	**3.4**	**4.3**	**3.2**
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)

Measured in millimeters (mm)										
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
Mean	**20.1**	**24.9**	**28.5**	**29.4**	**30.1**	**29.6**	**29.3**	**28.4**	**28.9**	**26.8**
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
Satisfied* Or better	**98%**	**97%**	**96%**	**97%**	**98%**	**99%**	**99%**	**100%**	**100%**
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
Yes %	190 **99%**	178 **98%**	175 **99%**	148 **97%**	125 **98%**	84 **99%**	45 **94%**	20 **100%**	14 **100%**
Unsure	2	0	0	0	0	1	0	0	0
No data	19	22	20	26	33	34	29	23	18
LTF[1]	1	1	2	3	3	4	4	4	3
Total n possible	213	204	199	179	164	123	81	47	35

[1] 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) #	Cases (n=224) %	Joints (n=329) #	Joints (n=329) %
1. Permanent removal of fossa component: 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 %
2. Removal (non-permanent)[1] of mandibular component: 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 %
3. Permanent removal of mandibular component: a. Larger component causing a dislocation removed and replaced with smaller component	1	0.4%	1	0.3%
4. Permanent removal of total joint: 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 %
Permanent removal	10	4.5 %	11	3.3 %
Non-permanent removal	5	2.2 %	9	2.7 %
TOTAL	**15**	**6.7 %**	**20**	**6.1%**

[1] 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) #	Cases (n=224) %	Joints (n=329) #	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
Total Cases	**94**	**42.0%**	**136**	**41.3%**
Total Incidence	(107)	(47.8)		

* 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 trepid 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:
Biomet U.K. Ltd.
Waterton Industrial Estates
Bridgend, South Wales
321CF 3AX, U.K.

Total TMJ Replacement System

Patient Information

This Patient Information is for informational purposes to help explain issues regarding TMJ surgery. Always consult your physician for an explanation of your specific problem and for their recommendations and instructions.

What is the Temporomandibular Joint (TMJ)?

It is the joint in your jaw, which allows you to open and close your mouth. It is similar to a ball and socket but it can also slide. The ball portion is the mandibular condyle (jaw) and the socket portion is the fossa. There is a disc between the two bone segments, which allows the condyle to slide smoothly during a range of motion or while opening your mouth. Muscles keep the joint together and provide the force required to move your jaw.

What is Temporomandibular Joint Disease (TMD)?

Any jaw joint problems are commonly referred to as TMJ but this is simply the joint itself. TMD is the joint that is diseased and needs repair. Various factors can cause TMD which result in restricted jaw movement and pain. Some symptoms include pain in your jaw, headaches, earaches, popping of your jaw, difficulty opening and locking of the jaw (closed or open), or dizziness.

What is the Total TMJ Replacement System?

The Total TMJ Replacement System is a "ball and socket" type prosthetic joint similar to a hip implant. The following implants, which make up the Total TMJ Replacement System, are made of common materials with over 30 years of successful use in orthopedic joint replacement.

1. *Condyle (also called mandibular) implant*
   The condyle implant is made of metal Cobalt-Chromium-Molybdenum (Co-Cr-Mo) alloy or Titanium (Ti-6AL-4V) alloy. Both implants have a roughened titanium porous coating on the implant surface that contacts bone. Co-Cr-Mo alloy contains nickel.
2. *Fossa Implant*
   The Fossa implant is made of a hard, plastic polyethylene. The fossa is made of molded polyethylene that has shown excellent wear resistance during mechanical testing.
3. *Screws*
   Both the condyle and fossa implants are attached to bone using titanium alloy screws.

How are the majority of TMD patients treated?

The vast majority of patients with TMD do not require surgery. They can be treated conservatively with one or a combination of the following:

- soft diet
- hot/cold pack applications
- mouth splints
- physical therapy
- anti-inflammatory medications
- muscle relaxants
- analgesics (pain medications)
- dental treatment including:
    - bite adjustments
    - restorations
    - orthodontics

Only those patients who have a "mechanical" problem inside the joint itself (a dislocated disc) that does not respond to conservative care, may be candidates for surgery.

What types of surgery are performed in the TMJ?

Oral and maxillofacial surgeons basically have these surgical options:

- Arthroscopy
- Arthroplasty (open joint surgery)
- Total joint replacement
- Partial joint replacement

Arthroscopy is a procedure where a small endoscope is place inside the joint for diagnostic purposes and to treat inflammation and discs that are "stuck" in position or displaced. For more serious disorders where the disc is badly displaced an open arthroplasty can be performed to repair, reposition or remove the disc. Only in cases where there is severe late-stage degeneration of the disc and condyle is total joint replacement considered.

Who is a candidate for the Total TMJ Replacement System?

Candidates are patients who have finished growing and have TMJ problems along with one of the following indications:

- Arthritic conditions: e.g. osteoarthritis, rheumatoid arthritis, or traumatic arthritis
- Ankylosis (an abnormal fusion of the joint)
- Revision procedures where other treatments have failed
- Avascular necrosis (death of tissue due to poor blood supply)
- Multiply operated joints
- Fracture
- Functional deformity
- Benign neoplasms (non-malignant abnormal new growth of tissue)
- Malignancy
- Joints with severe bony changes
- Developmental abnormality (birth defect)

What are the contra-indications for the Total TMJ Replacement System?

- Patients with an active infection
- Patients who do not have enough bone and/or deformed bone or good quality bone to support the device
- Patients requiring partial TMJ joint reconstruction only
- Known allergic reaction to any of the materials used in the implants including nickel.
- Patients with mental or neurologic conditions who are unwilling or unable to follow postoperative care instructions
- Patients who are still growing
- Patients with severe hyper-functional habits (e.g. clenching, grinding etc.)
- Patients with an active foreign body reaction

What are the possible complications?

The following risks are associated with the use of a total TMJ system.

- 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

- Foreign body or allergic reaction to implant components
- Wearing through of the fossa material
- Facial swelling and/or pain
- Facial nerve problems
- Removal of tissue
- Heterotopic bone formation (bone found in an abnormal place)
- Neuroma formation (abnormal growth of nerve tissue)
- Ear problems
- Dislocation
- Placement of an implant in one joint only may result in harmful effects to the joint on the opposite side.
- Placement of an implant may produce an improper relationship between teeth surfaces that should contact during biting

What have been the results with the use of the Total TMJ Replacement System?

Clinical Study Summary

A clinical study began in the United States in 1995 and was designed to document patient outcome after implantation of the Total TMJ Replacement System. 119 unilateral (one side) and 105 bilateral (both sides) cases were included only after appropriate non-surgical treatment and/or previous implant failure. The average patient follow-up was 28.7 months (range: 0.4-91.7 months) with 85 patients having follow-up data at the 3 years study endpoint.

A total of 224 cases received 329 total joints. Overall, patients improved by having a decrease in pain, increase of function, increase in maximal incisal opening (MIO), and satisfaction with their outcome.

The Total TMJ Replacement System has not been studied in pregnant women or children, therefore, the safety and effectiveness for these patients is not known. The safety and effectiveness of revision surgery using a second set of Total TMJ Replacement System implants is not known.

What should I expect after surgery?

"Reasonable expectations" after TMJ implant surgery as stated can include:

- An increased mouth opening
- Pain reduction
- Improved chewing ability

Outcomes are dependent upon the severity of the disease, the number and type of previous treatments, the condition of the patient, and patient compliance with postoperative instructions.

What precautions should I take after TMJ surgery?

1. Follow your surgeon's postoperative instructions, especially those related to physical therapy, diet, and medication. See your surgeon for scheduled follow-up visits including annual visits after the first year.
2. Avoid the following:

- hard, crunchy, or tacky food
- contact sports
- activities that may damage your implants

3. If you have to have other surgeries, not related to your TMJ surgery, please tell your doctor that you had a TMJ surgery. Your doctor will need to know this to prescribe an antibiotic to prevent infection from the new surgery. An infection can cause a problem with your TMJ implants.

What rehabilitation do I need after surgery?

Rehabilitation regimens can vary among physicians and generally include a home-based regimen of jaw stretching with a plastic, hand-held device within 48 hours of surgery. You may require more or less rehabilitation, depending on the seriousness of your TMJ disease. The length of time for your rehabilitation will depend on how much jaw movement you had before surgery. Rehabilitation may last from about 6 weeks to 6 months following implant surgery.

Call your doctor if you experience any of the following:

1. Excessive swelling
2. Sudden pain
3. Sudden less opening of your mouth and/or locking
4. Impact to your face and/or head such as from an automobile accident

Surgeon Training:

All surgeons are required to have prior training with the use of this device both by hands-on and educational course instruction.

Patient and manufacturer responsibilities

1. Request that your implants be returned to Walter Lorenz Surgical, Inc. at the following address, if all or part of the implants are removed for any reason.
2. Notify Walter Lorenz Surgical, Inc. and your surgeon if you change your mailing address so that you can be contacted if necessary with information regarding your implants. The FDA requires Walter Lorenz Surgical, Inc. to have your current address on file to be able to contact you at any time after your surgery.

For more information contact:
Walter Lorenz Surgical, Inc.
1520 Tradeport Dr.
Jacksonville, Fl. 32218
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