Anticipation and innovation. These two qualities have made Biomet Microfixation an industry leader. Founded by Walter Lorenz more than thirty years ago, Biomet Microfixation offers instrumentation, plating systems and related products for a wide range of surgical procedures.

Biomet Microfixation incorporates Biomet’s 30 years of Orthopedic total joint experience into the design and materials utilized in both TMJ Replacement Systems.

**Stock Design**

Biomet Microfixation’s Stock TMJ replacement system has been manufactured and clinically used since July 1995 under an approved investigational device exemption (IDE) from the FDA. In this 10 year IDE study, our stock prosthesis proved to be compatible for 88% of patients. Today, over 2,500 implants have been implanted worldwide.

**Patient Matched Design**

In today’s TMJ market, traumatic reconstructive cases or extreme anatomical variations may require the development of a patient matched implant (PMI). Combining the precision of patient specific positioning guides developed from an MRI with the latest web technology allows for a state-of-the-art, custom fit implant.

**PMI are Ideal for Patients:**

- With a severe deformity in the applied anatomy
- With compromised bone in the ramus or zygomatic arch
- Requiring simultaneous orthognathic corrections
- Requiring large resections of the applied anatomical areas

“*Alloplastic TMJ reconstruction consistently makes a difference for the patient.*”

- Dr. Esben Aagaard - Odense University Hospital, Denmark

Patient missing large part of mandible requiring extensive changes to the mandible and fossa components.

**Stock vs. Patient Matched Cases**

*For those rare, complex cases Biomet’s Patient Matched Implant is your solution.*
Surgeon Testimonials

The resulting fit and post operative outcomes of Biomet’s Patient Matched Implants in patients with complex anatomic deformities or simultaneous occlusal corrections have been very gratifying. It has helped make a significant and predictable difference in patients with severely challenging problems.

Dr. David Psutka - Senior Staff Surgeon, Mount Sinai Hospital, Toronto, Ontario Canada

The Biomet Microfixation Total Joint Prosthesis has proven to be a superb device in 9 years of use in our program. It is a great addition to have the opportunity to now offer a custom “Patient Matched” prosthesis for complex reconstructions. I like the capabilities of being directly involved in the design process using internet technology and being assured of a precise fit; all to the benefit of our special patient population.

Dr. Gerald Baker - Director and Head of OMS Division, Mt. Sinai Hospital, Toronto, Ontario Canada

Being a part of the design process is not only exciting but it also gives me more confidence that my surgery will go very smoothly and precisely.

Dr. Esben Aagaard - Odense University Hospital, Denmark

Patient Testimonials

One surgeon told me there was not anything I could do for my jaw problems. But I couldn’t open my mouth and was in serious pain. With a second opinion and Biomet’s Patient Matched Implants, I finally found my solution.

I have my life back after having Biomet’s Patient matched Implants. I can now enjoy actual meals again. More importantly, my husband and children have their wife and mom back!

- Lori Murphy, Toronto, Ontario - Canada

Biomet’s Patient Matched Implant gave me a new beginning. Now I can plan my future without pain in my daily life!

- Female Patient, 21 years old, Denmark

With the great results from my Biomet Patient Matched Implants, I’m left (lightheartedly) asking my surgeon, ‘Why didn’t we do this replacement procedure 20 years ago?’

- Female Patient, 48 years old, Denmark

* Patients requested that their identity not be revealed.

While the surgeon and patient testimonials are true, these results are not necessarily typical, indicative or representative of all TMJ patients. The Patient Matched Joint Replacement prosthesis has been used successfully in achieving mobility and cosmesis in many patients. However, as with any implant device, there are surgical and post-operative factors which ultimately may result in unpredictable variable outcomes, including levels of mobility and pain. These factors include, but are not limited to, the patient’s pre and post-operative health conditions, bone quality, number of surgical procedures, and adherence to instructions regarding the procedural guidelines. Due to these variables, it is not possible to predict or warrant specific results or patient satisfaction.
Innovative Manufacturing Process

**Patient Matched Fossa**

**Step 1.**
Using our state-of-the-art, 5-Axis robotic machine, raw material is cut to the precise size and length.

**Step 2.**
Using computerized numeric control programming, our 5-Axis robotic machine mills the patient specific contour of the fossa socket and flange.

**Step 3.**
Once each implant is produced, a meticulous inspection of the articulating surface and the anatomical compatibility is performed.

**Patient Matched Mandibular**
Development Process

Typical Development Timeline

1. **Send CT Scan**
   - Week 1

2. **Web Conferencing and Surgical Planning**
   - Week 2

3. **Implant Approval**
   - Week 3

4. **Implant Manufactured**
   - Week 4

5. **Implants Shipped**
   - Week 5

*This time frame will vary based on surgeon response time.*
Patient Matched Capabilities

**Surgical Planning via Web Conference**
- Reduces development process steps and time
- Provides an interactive forum with direct anatomical and implant visualization
- Final implant design is verified

**Operative Guides**
- Burring guides
- Cutting guides
- Implant placement guides

**Bite Splints**
- Ensures proper occlusion when simultaneously performing orthognathic adjustments
- Dental impressions required

**Screw Length Charts**
- Illustrates depth of bone
- Provides screw length recommendations
- States the distance from top of condylar head to skull base for post-operative referencing on CT scan.

**ClearView® Model: Intra-Operative Reference**
- Shows location of nerves
- Shows outline of proper placement for the implant

**Fossa Design Options**
- Anterior and posterior lip capabilities to prevent joint dislocation or condylar shifting
Web Conference Feature

**Web Conference Call**
- Significantly reduces the total time needed to complete the project
- Provides an interactive forum with direct anatomical and implant visualization
- Allows for surgeon and engineer discussions and dual maneuvering capabilities
- Surgeon shows precise modifications or adjustments of the implant and verifies the final design

**Surgeon Designed. Patient Matched.**

Using the Biomet Patient Matched TMJ prosthesis gives me the opportunity to work with the designing engineers via an innovative web conference, providing direct input into each implant’s design.

- Dr. David Psutka, Senior Staff Surgeon, Mount Sinai Hospital, Toronto, Canada
If you are interested in utilizing Biomet Microfixation’s Patient Matched Implant program, please send in the following forms:

- **Patient CT Scan Scan**
- **Design Input Form**
- **Prescription Form for Custom Products**

Send forms electronically or fax to Medical Modeling

Email: info@medicalmodeling.com
Phone: 888.273.5344  •  Fax: 303.273.6463

Contact Biomet Microfixation for online CT Data Uploading Instructions or visit www.medicalmodeling.com.
Warnings and Precautions

Caution
This product is for use outside of the United States and is only available in certain countries where special access has been granted for use. These warnings and precautions should be adhered to in all countries utilizing these implants.

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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 burrs, 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:
- Arthritic conditions: osteoarthritis, traumatic arthritis, rheumatoid arthritis
- Ankylosis including but not limited to recurrent ankylosis with excessive heterotopic bone formation
- Revision procedures where other treatments have failed (e.g. alloplastic reconstruction, autogenous grafts)
- Avascular necrosis
- Multiply operated joints
- Fracture
- Functional deformity
- Benign neoplasms
- Malignancy (e.g. post-tumor excision)
- Degenerated or resorbed joints with severe anatomic discrepancies
- Developmental abnormality

Contraindications
- Active or chronic infection.
- DO NOT USE the individual components of this total system (e.g. mandibular components, fossa components, or screws) for partial joint reconstruction.
- 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.
- DO NOT USE IN CHILDREN. The Total TMJ Replacement was designed for skeletally mature patients.
What fascinates you about the body is also what drives us. That’s why we’re always pushing the boundaries of engineering to make products that help you keep the human form as glorious as it was intended. To learn more about our breadth of products, call 800-874-7711 or visit us online at biometmicrofixation.com. We’d love to join you in a conversation about the future.