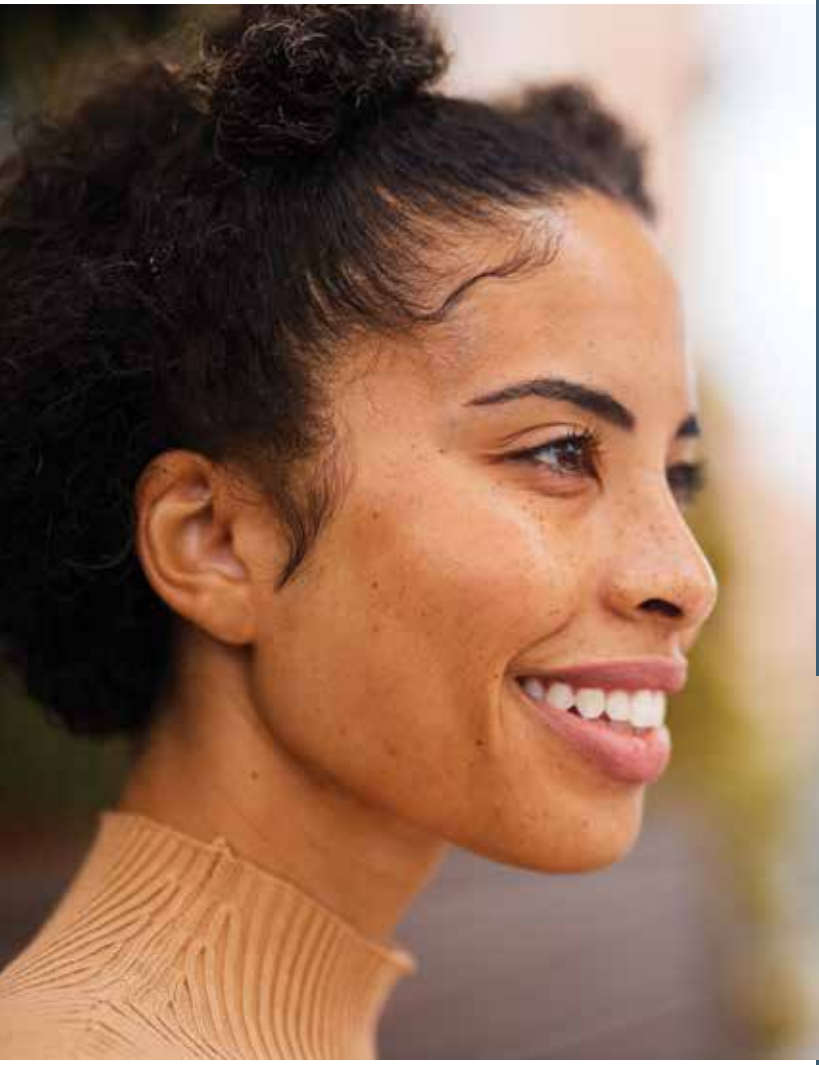
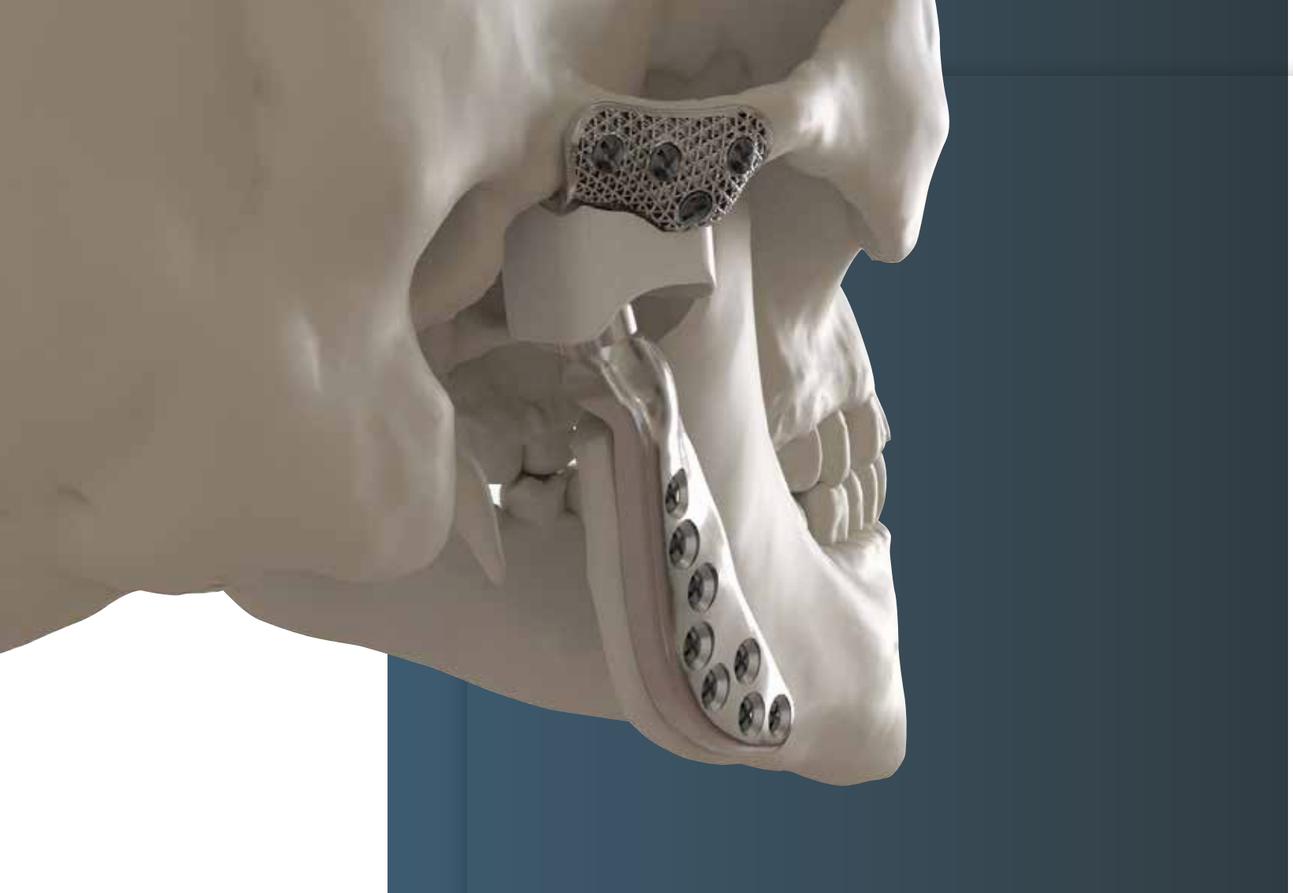
stryker

Market leading. **Always evolving.**

TMJ Concepts patient-specific implants
for optimal fit and function





Meticulously modeled

You're there for your patients when they need you most. And we're here for you. Built to spec from each patient's anatomy, our customized implants – combined with your expertise – can help create a brighter patient future with potentially less pain, more function, enhanced appearance and new-found hope.[1]

Glenoid fossa component

No two are the same; distinct designs measured and fabricated per patient

A Unalloyed titanium mesh backing

B Ultra-high molecular weight polyethylene

C Industry-exclusive posterior lip design

Mandibular component

Individually designed for unique patient anatomy

D Cobalt-chromium-molybdenum alloy condylar head

E Titanium alloy body

True original.
Genuine difference.

Precision fit and function

- Individualized implants address each patient's anatomical idiosyncrasies
- Fossa titanium mesh backing for secure screw fixation
- Lip design of the fossa helps to minimize the possibility of posterior dislocation
- Enhances preoperative planning and precision

Total assurance

- Evidence-based design backed by positive patient outcomes[1]
- Made of trusted, clinically-proven materials[2]
- Helps build patient confidence knowing implant is personalized
- Brought to you by the market leader in CMF fixation

Simplified workflow

- Helps streamline perioperative workflow since implants are tailored per patient
- Less recontouring of the bone needed[3]

Earned trust means everything

You've made us the market leader in craniomaxillofacial surgery, and you've made our TMJ Concepts patient-specific implant the gold standard in TMJ reconstruction. We continually strive to advance the services and solutions we offer to your elite subspecialty so together we can help restore form, function and hope to patients around the world.

Clinically proven. Surgeon trusted.

- 25+ years proven history
- 100+ clinical articles published
- 1,000+ patients treated annually
- Sold in 20+ countries
- Only FDA-approved patient-specific TMJ implant in the U.S.

Gold standard performance: successful function at median of 21 years[1]

- Implants still functioned well
- Zero implants removed due to material wear[1]

Reasons you prefer patient-specific implants[1,2,4]

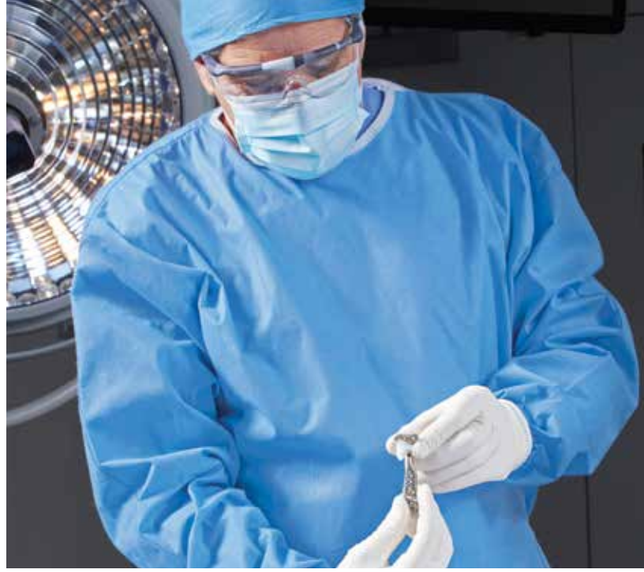
- Ease-of-use
- Improved outcomes and quality of life
- Long-term reliability

78% of surgeons prefer

patient-specific TMJ implants over off-the-shelf[4]

Customized solution, unique advantages

The face expresses your patients' personality and is vital to their senses, function, appearance, social life and more. We recognize your immense responsibility and we know quality of life is on the line. That's why we aim to provide every advantage possible via strategic features designed to give you and your patients greater ability to achieve your goals.



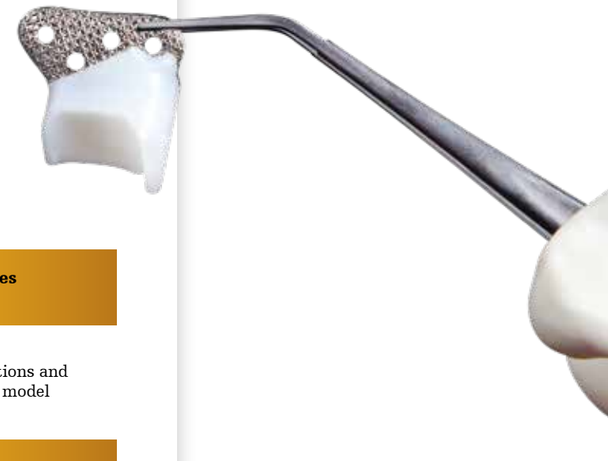
U.S. market	TMJ Concepts patient-specific implant
U.S. PMA approved	1999
Material: mandible component	Cobalt-chromium-molybdenum alloy condylar head with titanium alloy mandibular body
Material: fossa component	Ultra-high molecular weight polyethylene with an unalloyed titanium mesh backing (2 materials fused)
Customized, patient-specific implants	✓
Titanium mesh backing on fossa prosthesis	✓
Posterior lip on fossa prosthesis for condyle placement; to minimize dislocation	✓
Enhanced flexibility in occlusal correction and condyle placement (since implant is fitted to patient anatomy)	✓
Greater accounting for varied patient anatomy and scar tissue	✓
Less bone recontouring/ adjustment while surgically placing implant	✓
Enhanced approach to personalized treatment	✓

Model **solution**

Not only do we aim to improve patient quality of life, but we strive to enhance your surgical experience as well. Each patient's unique anatomy is inherent in their customized implant, helping to lighten your workload.

TMJ implants, **made to order**

Using customized implants is simple and convenient. You initiate the process, then we do the heavy lifting. Your time commitment is minimal to submit and review implant details, and your CMF representative is there to help at every stage along the way.



You	**Initiate order and upload CT images and case data to online portal**
We	Review CT scan data, plan bony resections and movements, and create an anatomical model
You	**Evaluate anatomical model images; respond with approval or modifications**
We	Create implant designs according to your input
You	**Review and approve final implant design**
We	Blend precision machining with hand crafting to meticulously shape and manufacture physical implant components precisely to patient specs
We	Sterilize the implants and ship them to your hospital along with the non-sterilized anatomical bone model for reference and final implant pictures with screw length mapping
We	Provide sales rep assistance upon delivery or at any stage throughout the order and development process

Authentic leader. **Committed partner.**

Patients tell us your expertise is the most important factor when considering TMJ reconstruction.[5,6] And together with our market-leading TMJ Concepts patient-specific implant, you can offer them a winning combination of surgical talent and technology. Your CMF representative is always standing by for assistance, call **800 962 6558**, visit **stryker.com** or scan this QR code.

Contraindications[2]

The TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis System should not be used for patients with one or more of the following conditions:

- Active or suspected infections in or about the implantation site
- Uncontrollable masticatory muscle hyperfunction (clenching or grinding) which may lead to overload and loosening of screws
- Known allergy to any of the component materials

Clinical data[2]

A total of 279 patients (465 joints) were enrolled in a post-approval study in which clinical data was collected both pre-operatively (month 0) and post-operatively at various follow-up intervals out to 5 years (month 60). Based on previous clinical studies of TMJ patients, it was anticipated that a large number would become lost to follow up. It was desired to have a cohort of at least 100 patients remaining at the 5-year evaluation time point, therefore a significantly larger number of patients were enrolled in the study. Clinical data was obtained out to 5 years on a final cohort of 128 patients (204 joints).

Pre-operative data and post-operative follow-up data were collected using a standardized data collection format. Subjective data related to pain, function of the lower jaw, and diet were obtained using a 55mm length visual analogue scale. The pain scale ranged from "no pain" at 0mm to "severest pain" at 55mm. The function scale ranged from "no loss" at 0mm to "cannot function" at 55mm. The diet scale ranged from "no restriction" at 0mm to "liquids only" at 55mm. Subjective data was also collected by asking each patient how their current quality of life compared to before they received their TMJ implants. Objective measurements of mandibular range of motion were made directly on the patients. These measurements, recorded in millimeters, included maximum interincisal opening and left and right excursion.

Results are shown for only the month 0 and month 60 evaluation time points as clinical data was not available for each patient at every intermediate follow-up interval. These clinical data show a statistically significant decrease in pain, increase in function, decrease in diet restrictions, and increase in maximum interincisal opening. A summary of the quality of life responses at month 60 is also shown.

Pain Measurement Improvement at 5 Years
(scale: 0mm = "no pain" to 55mm = "severest pain")

Month	Mean (mm)	S.D.(mm)
0	39.0	13.4
60	18.3	15.9

Function Measurement Improvement at 5 Years
(scale: 0mm = "no loss" to 55mm = "cannot function")

Month	Mean (mm)	S.D.(mm)
0	36.4	13.0
60	17.9	13.8

Diet Measurement Improvement at 5 Years
(scale: 0mm = "no restriction" to 55mm = "liquids only")

Month	Mean (mm)	S.D.(mm)
0	32.4	14.2
60	14.7	13.4

MIO Measurement Increase at 5 Years

Month	Mean (mm)	S.D.(mm)
0	25.0	11.2
60	33.4	9.2

Summary of Quality of Life Responses at 5 Years
How does your current quality of life compare to before you received your TMJ implants?

Response	Percentage of Patients
Much Better	52.3%
Better	25.8%
Same	7.8%
Worse	12.5%
Much Worse	1.6%

Several of the patients enrolled in the post-approval study that were not included in the final cohort of 128 patients had adverse events reported prior to their becoming lost to follow up or being removed from the study for another reason. The adverse event data presented below includes events reported for any of the 279 initially enrolled patients.

These types of adverse events and the rate at which they occurred as well as the quality of life responses shown above are not unexpected in this compromised patient population with many previous surgeries involving failed tissue grafts and/or failed implants from other manufacturers which may leave behind material particulates.

Adverse Events Resulting in Additional Surgery

Category	Patients (n=279)		Joints (n=465)	
	No.	%	No.	%
Chronic or recurring pain and/or swelling	4	1.4%	4	0.9%
Infection	3	1.1%	3	0.6%
Dislocation of implant components	2	0.7%	3	0.6%
Perforation or dehiscence of surrounding tissues	2	0.7%	2	0.4%
Loosening	2	0.7%	2	0.4%
Material sensitivity (reaction to implant components)	1	0.4%	2	0.4%
Malocclusion	1	0.4%	1	0.2%
Total	15	5.4%	17	3.7%

References
1. Wolford LM, Mercuri LG, Schneiderman ED, et al. Twenty-year follow-up study on a patient-fitted temporomandibular joint prosthesis: the Techmedica/TMJ Concepts device. J Oral and Maxillofacial Surgery. 2015;73(5):952-60. **2.** TMJ Concepts Sterile Implant IFU **3.** Brown ZL, Sarrami S, and Perez DE. Will they fit? Determinants of the adaptability of stock TMJ prostheses where custom TMJ prostheses were utilized. Int J Oral Maxillofacial Surgery. 2021; 50(2):220-226. **4.** 2020 TMJ pain market survey findings **5.** Stryker data on file **6.** Orthognathic surgery patient journey, qualitative research report, May 2022. Bauman Research & Consulting

Craniomaxillofacial

FAC-BR-7_Rev. None_34086
G55/PS

Printed in USA

Stryker
1941 Stryker Way
Portage, MI 49002 USA
t: 269 323 7700 f: 800 999 3811
toll free: 800 253 3210

stryker.com

Brochure intended for U.S. market only.