Materialise TMJ Total Arthroplasty System

Patient Information Leaflet

Product

Product Category	Total Temporomandibular Joint Prosthesis (36042)	
Brand name	Materialise TMJ Total Arthroplasty System	
Model codes	CMF.TMJ11D, CMF.TMJ11H CMF.TMJ12D, CMF.TMJ12H CMF.TMJ13D, CMF.TMJ13H CMF.TMJ14D, CMF.TMJ14H	
Material	Temporal Component: • Temporal base plate (Titanium alloy Ti6Al4V) • Fossa (UHMWPE) • Anchor screw (Titanium alloy Ti6Al4V) Mandibular Component: • Mandibular plate (Titanium alloy Ti6Al4V) • Condylar head (Cobalt-Chromium alloy) Note that the TMJ System is containing Cobalt which is a hazardous substance, but scientific evidence supports that medical devices manufactured from cobalt alloys do not cause an increased risk of cancer or adverse reproductive effects.	
Legal Manufacturer	materialise innovators you can count on	Materialise N.V. Technologielaan 15 3001 Leuven Belgium www.materialise.com/en/medical/patient-information

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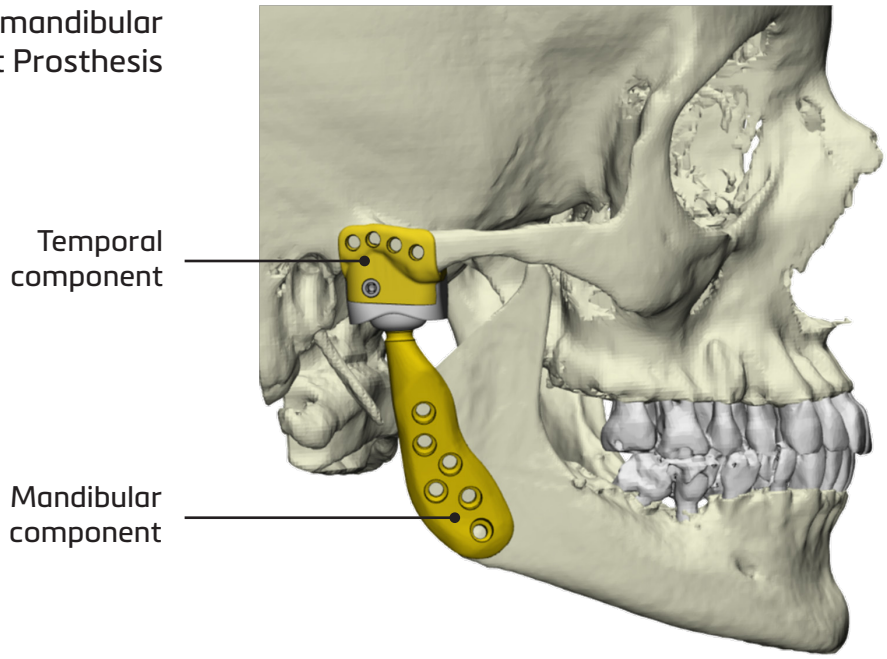
Total Temporomandibular Joint Prosthesis



What is this medical device used for?

The Materialise TMJ System is a patient-specific medical device that is implanted during a surgical procedure. It replaces the temporomandibular (TMJ) joint; this is the joint that connects the lower jaw to the skull. Each Materialise TMJ System is made uniquely for a particular patient, based on the patient's specific anatomy. The Materialise TMJ System is designed based on a pre-operative surgical plan in 3D, generated from a computed tomography (CT) scan.

The Materialise TMJ System is intended to replace the natural TMJ joint and consists out of multiple components that are implanted on the skull and lower jaw to create a new artificial joint.

What do you need to know?

Safety

For safe use of the TMJ System, patients must carefully follow the instructions provided by their healthcare practitioner as the level of care required differs with each case.

Medical examinations

There is a possibility that the TMJ System can affect the results of computer tomography ((CB)CT) or magnetic resonance imaging (MRI) scans.
The TMJ System impact on safety in the (CB)CT is currently unknown.
Non-clinical testing has demonstrated that the TMJ System is MR conditional, which means that a patient with this device can be safely scanned in a MR system if the conditions described in the MRI Conditionality section of the IFU are taken into account.
Therefore, patients must inform their healthcare practitioner when (CB)CT or MRI scans are needed to avoid the possibility of patient harm.

What are the possible side effects?

As with all surgeries, there are possible side effects:

- The TMJ System may come loose due to poor fixation following the surgical procedure;
- Superficial and/or deep infection;
- Allergic and/or sensitivity reactions to implanted material;
- Rupture or displacement of the components in case a device in case of excesive loading;
- Pain, discomfort and / or abnormal sensation due to the presence of the device;
- Vicious consolidation;
- Pseudarthrosis;
- Growth restriction or alteration;
- Deformity of adjacent soft-tissue;
- Fracture due to complications with surgical instrumentation and implant placement;
- Neurological complications occasioned during surgery.

When to contact healthcare practitioner?

Preventive monitoring or maintenance of the device itself is not required.
Please consult your healthcare practitioner for guidelines in terms of medical examinations or follow-ups.

Please consult your healthcare practitioner in case one or more of the following events occur:

- Acute pain at the implantation site.
- Skin redness, inflammation, or infection at the implantation site.

What about the expected lifetime of your medical device?

There are no expected effects of aging on a TMJ System. The TMJ System was mechanically validated to cover a period of 10 years.

Post-operative precautions:

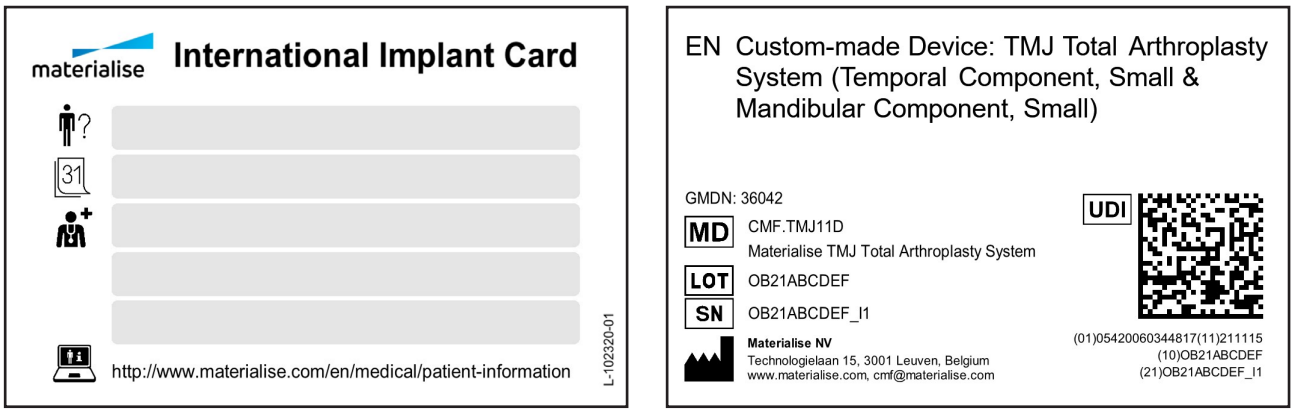
Warn the patient of the postoperative precautions to take to ensure optimal treatment outcome.

- Treat quickly and effectively any infection even benign due to haematogenous risk of contamination.
- Be attentive to any sign of pain at the implantation site.
- Monitor the patient in accordance to the frequency and protocol defined by the surgeon.
- Avoid any excessive loading of the TMJ System to avoid mechanical issues or a disfunctioning of the articular joint. A decision to remove TMJ System components must be determined by the surgeon.

Information to allow the identification of the implanted device

In order to save the identifiable details of your particular implanted device, you will receive an "International Implant Card". Your surgeon will complete it with information specific to your surgery.

It will allow you to contact your surgeon and to find information on the device readily available online.



This card is representative, and information may differ according to the country in which the implant was purchased.

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	DESCRIPTION OF SYMBOL
	Full name of the patient
	The date the implant was placed
	The name and address of the health care centre or doctor who performed the implantation
	Website where a patient can obtain additional information on the implant
MD	Name of the implant *(MD = Medical Device)*
LOT	Lot number of the implant
SN	Serial number of the implant
UDI	Reference number of the implant *(UDI = Unique Device Identifier)*
	Name and address of the legal manufacturer of the implant

This is version 1 of this document, issued in March 2022.