



CMF Implant

Patient Information Leaflet



Product

Product Category	Implant cranio-maxillo-facial (CMF) - 46644 (AU)	
Brand name	TruMatch® CMF Titanium 3D Printed Implant	
Model codes	SD980.101, SD980.102, SD980.103, SD980.105, SD980.106, SD980.107, SD980.108, SD980.109	
Material	Commercially pure Titanium	
Legal Manufacturer		Materialise N.V. Technologielaan 15 3001 Leuven Belgium www.materialise.com/en/medical/patient-information
Distributor		Johnson & Johnson Medical Pty t/a DePuy Synthes 1-5 Khartoum Road North Ryde NSW 2113 Australia

What is this medical device used for?

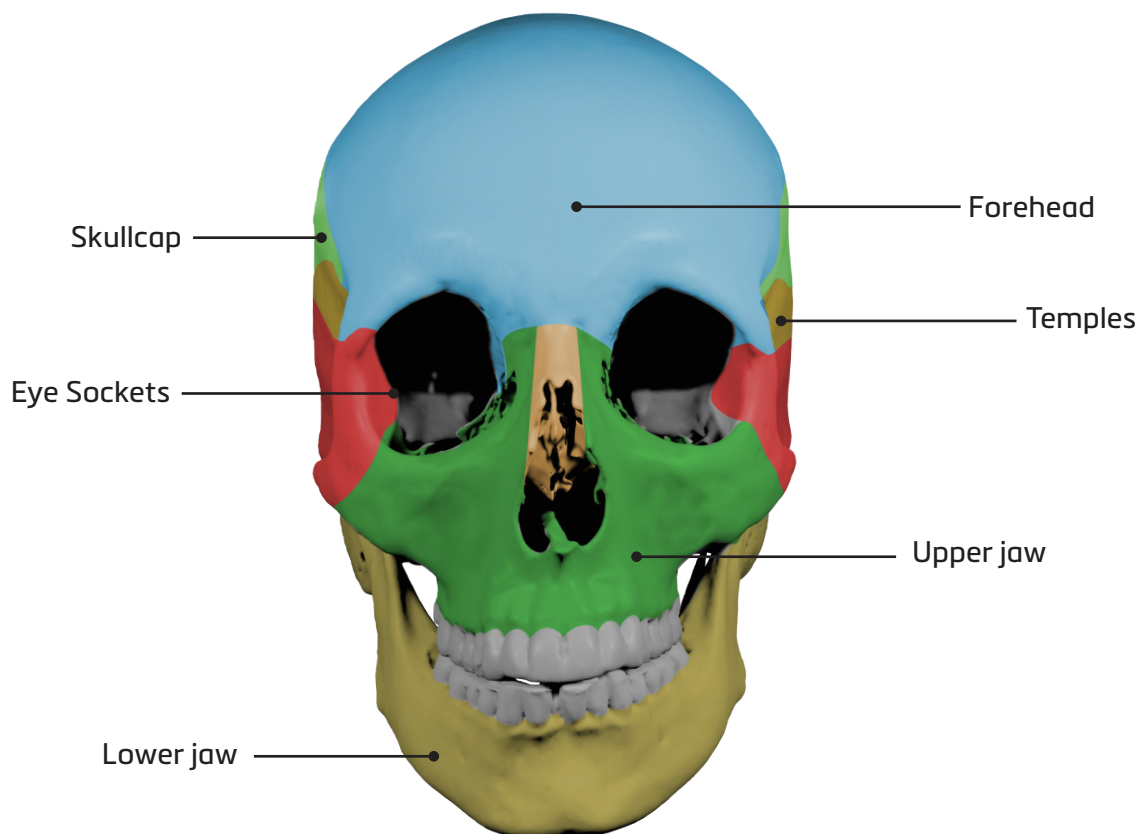
The Cranio-Maxillofacial (CMF) Titanium implant is a patient-specific medical device that is implanted on the skull. Each CMF Titanium implant is made exclusively for a particular patient, so no two CMF Titanium implants are alike. CMF Titanium implants' designs are based on a preoperative plan generated from a computed tomography (CT) scan.

The CMF Titanium implant is intended for surgical operations on bones located in the skullcap and face.

The TRUMATCH CMF Titanium 3D Printed implants are intended for children, adolescents and adults.

It is meant for bone reconstruction and bone defect restorations of the skullcap, forehead, temples, eye sockets, and upper and lower jaws. This includes all defects caused by traumatic injury, tumor removal, and genetic diseases.

The implant can also be used to increase facial structure volume for aesthetic purposes.



What do you need to know?

Safety

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

There are no specific operating instructions for the use of the CMF implant, **except the recommendation to avoid heavy stress on the implant during the healing phase according to its location (e.g. eating hard food, impact through a fall).**

Testing done on the implant has shown that residuals from the manufacturing process do not pose a risk to the patient. Additionally, the implant goes through a sterilization process before coming in contact with patients.

Medical examinations

There is a possibility that the CMF implant can affect the results of computer tomography (CT) or magnetic resonance imaging (MRI) scans.

The implant's impact on safety in the CT or MRI environment is currently unknown, so patients must inform their healthcare practitioner when 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 including pain, swelling, bruising, bleeding, and infection.

Other risks include:

- Insufficient bone reconstruction (osteolysis, osteomyelitis, osteoporosis), inhibited revascularization (the process of new blood vessels forming properly), or infection that may result in deformation or implant failure.
- Delayed or insufficient fracture healing that may cause implant failure.
- Discomfort or abnormal sensation related to the implant. This usually resolves itself but can take weeks or months. Some people have a permanent change in sensation of the area surrounding the implantation site.
- Sensitivity to material or allergic reaction to implant — when suspected, material sensitivity tests are performed prior to implantation.

Any serious incident that occurs in relation to the device should be reported to the manufacturer (cmf@materialise.com) and to the Therapeutic Goods Administrations (www.tga.gov.au)

What do you need to know?

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 CMF implant. The CMF implant has been mechanically tested to withstand the 3 to 4 months during which the bone and vascular system around the implant site need to adequately heal. After this period, the implant should become correctly integrated and sustained by its surroundings.



Avoid heavy stress on the implant during the healing phase of the bones (3 to 4 months) as it may cause implant failure.

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.

International Implant Card	
	
	
	
	
	http://www.materialise.com/en/medical/patient-information
L-101422-01	

Cranio-maxillo-facial implant (CP Ti)	
MD	SD980.101 TRUMATCH CMF Titanium 3D printed Implant GMDN: 46644
LOT	MU20-ABC-DEF
UDI	
 Materialise NV Technologielaan 15, 3001 Leuven, Belgium www.materialise.com cmf@materialise.com	
(01)05420060381010(11)200312(10)MU20-ABC-DEF	

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

SYMBOL	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
UDI	Reference number of the implant (UDI = Unique Device Identifier)
	Name and address of the legal manufacturer of the implant

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