

CUSTOM LIFE

INDICATIONS - CustomLife is indicated for reconstruction of the maxillary and mandibular regions due to bone remodeling related to trauma or pathological factors; and rehabilitation of severe atrophy of the maxillary and mandibular region.



CONTRAINDICATIONS

- Suspected or pre-existing infections at or near the implantation site.
- Conditions of immunosuppression or that hinder the healing process (e.g. smoking, alcoholism, uncontrolled diabetes).
- Presence of qualitative or quantitative bone deficiency, or potential situation of impairment of the CustomLife support/fixation.
- Bruxism, whether primary or secondary.
- Patients with incomplete or immature bone development (e.g. children).
- Implants that present little stability, instability or damage.
- Disorders that make it difficult to adhere to medical advice during the treatment phase.
- Allergy to any component present in the implant.



INSTALLATION PROCEDURE

Step 1 : Anesthetize the patient

Step 2: Make the incision and detach the surgical flap from the area where CustomLife will be installed

Step 3: Position the surgical guide over the patient's bone surface and stabilize the guide in place with the 2.00 mm screws in the hex holes.

Step 4: Using the 1.5 mm drill, drill the circular holes, which will be the points of the subperiosteal implant.

Step 5: Prepare the bone bed following the flat surfaces of the surgical guide.

Step 6: Remove the surgical guide.

Step 7: Test the fit of CustomLife on the bone preparation performed. If necessary, make adjustments to the bone to obtain a precise fit.

Step 8: Fix the CustomLife through the most anterior holes. Any holes that are not present must be made with the 1.5 mm drill bit.

Step 9: Install the screws alternately, without tightening them completely. After positioning all the screws, apply the necessary torque for final tightening.

Step 10: Install the connectors on the CustomLife. Use the appropriate tools for installation. The torque limit for installing the connectors is 20 N.cm; values above this may cause the connector's stabilizing screw to break.

Step 11: Install the connector scarifiers . Use the appropriate tools for installation. The torque limit for installing the connectors is 10 N.cm.

Step 12: Suture the incision site.



CAUTIONS AND WARNINGS

- Custom Life system components are STERILE with the exception of connectors, as they have sterile and non-sterile models.
- SINGLE USE product. DO NOT REUSE OR REPROCESS.
- The CustomLife system must be implanted by a qualified professional, in a surgical environment and with properly sterilized instruments.
- Applying excessive loads increases the risk of deformations, cracks and fractures in the implant.
- Do not use in case of fractures or signs of fragility in the implant structure.
- Do not use the product if the packaging is damaged or the seal is broken.
- Do not use the product if found damaged.
- Do not use the product after the expiration date.
- Do not use if the model/reference presents discrepancies.
- Use only compatible products manufactured by CPMH to ensure the safety and effectiveness of the device installation.

Adverse Events

Every surgical procedure presents risks and the possibility of complications. Adverse events may include:

- ✓ Loosening, displacement or fracture of components.
- ✓ Vascular involvement.
- ✓ Feeling of pain, discomfort or annoyance.
- ✓ Edema, bruising, inflammation, infection, exfoliation, abscess formation, hyperplasia, gingival irregularities, complications associated with anesthesia
- ✓ Implant failure or exposure.

COMPONENTS

Maxilla Plates

Product Code	Description	Dimension ¹
PC-353-1	Maxillary Reconstruction Plate	15x35x20 the 35x80x45
PC-353-2	Maxillary Reconstruction Plate	15x60x20 the 35x120x45

¹In all models, the angle between rods in the same plane is 85° to 180° and the angle between rods and the base of the connections is 80° to 180°.

Jaw Plates

Product Code	Description	Dimension ¹
PC-354-1	Partial Mandible Reconstruction Plate	15x35x20 the 35x80x45
PC-354-2	Full Mandible Reconstruction Plate	15x60x20 the 35x110x45

¹In all models, the angle between rods in the same plane is 85° to 180° and the angle between rods and the base of the connections is 80° to 180°.

Connectors

Product Code	Description	Dimension ¹
EPC-710.060	Connector 0,6 mm	4,8 x 0,60 x 2,2
EPC-710.200	Connector 2,00 mm	4,8 x 2,0 x 2,2
EPC-710.400	Connector 4,00 mmL	4,8 x 4,0 x 2,2
ECP-710.600	Connector 6,00 mm	4,8 x 6,0 x 2,2

Connectors

Product Code	Description	Dimension ¹
PC-710.060t	Connector 0,6 mm	4,8 x 0,60 x 2,2
PC-710.200	Connector 2,00 mm	4,8 x 2,0 x 2,2
PC-710.400	Connector 4,00 mml	4,8 x 4,0 x 2,2
PC-710.600	Connector 6,00 mm	4,8 x 6,0 x 2,2

2.0 MM SELF-TAPPING SCREWS

Size

4 mm
5 mm
6 mm
7 mm
8 mm
9 mm
10 mm
11 mm
12 mm
13 mm
14 mm
15 mm
16 mm
17 mm
18 mm
19 mm
20 mm

Product Code

EPC- 920.104
EPC-920.105
EPC-920.106
EPC-920.107
EPC-920.108
EPC-920.109
EPC-920.110
EPC-920.111
EPC-920.112
EPC-920.113
EPC-920.114
EPC-920.115
EPC-920.116
EPC-920.117
EPC-920.118
EPC-920.119
EPC-920.120

Dimension

Ø2,0 x 04
Ø2,0 x 05
Ø2,0 x 06
Ø2,0 x 07
Ø2,0 x 08
Ø2,0 x 09
Ø2,0 x 10
Ø2,0 x 11
Ø2,0 x 12
Ø2,0 x 13
Ø2,0 x 14
Ø2,0 x 15
Ø2,0 x 16
Ø2,0 x 17
Ø2,0 x 18
Ø2,0 x 19
Ø2,0 x 20

With SLA

EPC-920.104
EPC-920.105
EPC-920.106
EPC-920.107
EPC-920.108
EPC-920.109
EPC-920.110
EPC-920.111
EPC-920.112
EPC-920.113
EPC-920.114
EPC-920.115
EPC-920.116
EPC-920.117
EPC-920.118
EPC-920.119
EPC-920.120

Dimension

Ø2,0 x 04
Ø2,0 x 05
Ø2,0 x 06
Ø2,0 x 07
Ø2,0 x 08
Ø2,0 x 09
Ø2,0 x 10
Ø2,0 x 11
Ø2,0 x 12
Ø2,0 x 13
Ø2,0 x 14
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Ø2,0 x 16
Ø2,0 x 17
Ø2,0 x 18
Ø2,0 x 19
Ø2,0 x 20

2.0 MM SELF-TAPPING SCREWS

Size

4 mm
5 mm
6 mm
7 mm
8 mm
9 mm
10 mm
11 mm
12 mm
13 mm
14 mm
15 mm
16 mm
17 mm
18 mm
19 mm
20 mm
21 mm
22 mm

Product Code

EPC-924.104
EPC-924.105
EPC-924.106
EPC-924.107
EPC-924.108
EPC-924.109
EPC-924.110
EPC-924.111
EPC-924.112
EPC-924.113
EPC-924.114
EPC-924.115
EPC-924.116
EPC-924.117
EPC-924.118
EPC-924.119
EPC-924.120
EPC-924.121
EPC-924.122

Dimension

Ø2,4 x 04
Ø2,4 x 05
Ø2,4 x 06
Ø2,4 x 07
Ø2,4 x 08
Ø2,4 x 09
Ø2,4 x 10
Ø2,4 x 11
Ø2,4 x 12
Ø2,4 x 13
Ø2,4 x 14
Ø2,4 x 15
Ø2,4 x 16
Ø2,4 x 17
Ø2,4 x 18
Ø2,4 x 19
Ø2,4 x 20
Ø2,4 x 21
Ø2,4 x 22

With SLA

EPC-924.104
EPC-924.105
EPC-924.106
EPC-924.107
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EPC-924.121
EPC-924.122

Dimension

Ø2,4 x 04
Ø2,4 x 05
Ø2,4 x 06
Ø2,4 x 07
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Ø2,4 x 14
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Ø2,4 x 16
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Ø2,4 x 21
Ø2,4 x 22



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