SD

SMALL DIAMETER Implant

C-TECH IMPLANT

SD

SMALL DIAMETER implant

EC Certificate
Full Quality Assurance System
No. G1 15 10 93599 003
Manufacturer: C-TECH IMPLANT SRL
Via Cesare Battisti 2
40123 Bologna
ITALY
Facility(ies): C-TECH IMPLANT SRL
Via Cesare Battisti 2, 40123 Bologna, ITALY
Product Category(ies): Dental implants, accessories for dental implants
Report No.: ITA2801184
Valid from: 2015-11-09
Valid until: 2020-11-08
Date, 2015-10-20
Hans-Heiner Junker
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
Page 1 of 1
TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany
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CERTIFICATE
No. Q1N 15 09 93599 001
Holder of Certificate: C-TECH IMPLANT SRL
Via Cesare Battisti 2
40123 Bologna
ITALY
Certification Mark:
Scope of Certificate: Design and development, management of production and trade of dental implants and accessories
Applied Standard(s): EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.
Report No.: ITA2800402S
Valid from: 2015-10-06
Valid until: 2016-11-04
Date, 2015-10-12
Hans-Heiner Junker
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All of the materials produced by C-TECH follow a validated procedure, which includes surface treatment and packing as well, in conformity with European and international directives EN ISO 13485:2003/AC:207 and 93/42/EEC relative to medical devices.

Precision dental solutions

C-Tech Implant is a dynamic company with aggressive growth, producing components and product lines primarily for dental implantology.

International presence

With production and management based in Italy, C-Tech Implant is active in all major world markets and is distributed in over 25 countries.

Scientific research, advanced technology, simplification

C-Tech Implant differentiates itself with attention to research and the application of high technology to its products, all while maintaining a simplicity of insertion and ease of use.

C-Tech Implant incorporates the latest trends in implantology but provides very practical surgical and prosthetic solutions aimed at offering the practitioner and the patient optimal results.

High quality standards

C-Tech Implant products are made to the highest standards governing the manufacturing and management of European medical and dental components.
Up to date audits and certifications assure that these standards are vigilantly maintained.

Training & advice

Dental professionals are assisted by the rich knowledge and experience of C-Tech Implant personnel and through C-Tech courses and training sessions.
During these courses the professional is able to learn the latest methods of implant placement and reconstruction.

Mission statement

The goal of C-Tech Implant is to provide the highest level of quality for technologically advanced products at reasonable prices in order to allow the dental practitioner to find solutions for the broadest range of patients.

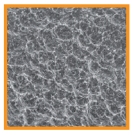
SMALL DIAMETER implant

Prosthetic choice
Choice between square or o-ball head depending on fixed or removable applications.

Micro grooving
The lower aspect of the implant collar is endowed with micro grooves to help maintain cortical bone.

Fine threading
The fine thread SD implants are designed to facilitate the placement in hard bone.

SEM 1000x



Passivated surface
The implant surface is blasted with aluminum oxide and then subjected to progressive etching using citric acid.
This surface treatment accelerates the osteointegration process by providing a greater and more uniform area of contact between bone and implant while favoring an immediate implant load.

Implant body
The anatomically shaped implants are produced from medical grade 5 titanium.

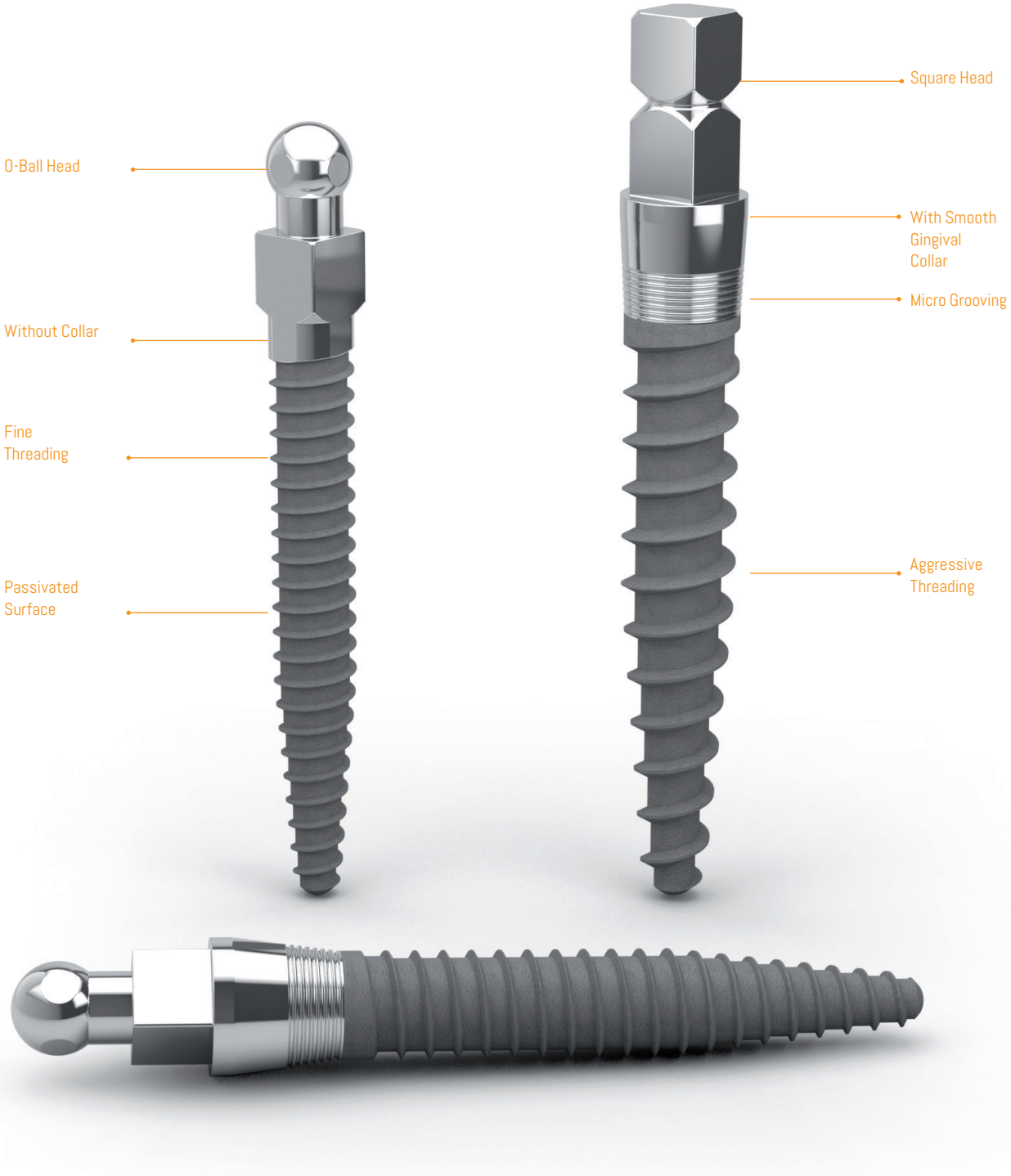
Smooth collar
The top aspect of every collared implant is smooth so as to better accommodate soft tissue.

Aggressive threading
The aggressive thread SD implants are designed for the added compression and surface area required in soft bone placement.

Collared and non-collared models
C-tech provides SD models with and without gingival collars, allowing the practitioner to better address cases with differing gingival thicknesses.

Double helix threading
The revolutionary double threads, unique in their nature, allow for ease of insertion and optimal primary stability.
This advantage simplifies the work of the oral surgeon and reduces considerably the time of insertion.
The thread has a particular 90° degrees beveled profile: whose shape, angle and depth are specifically conceived to increase contact surface with the bone.
It reduces the invasive process and improves at the same time the osseointegration.

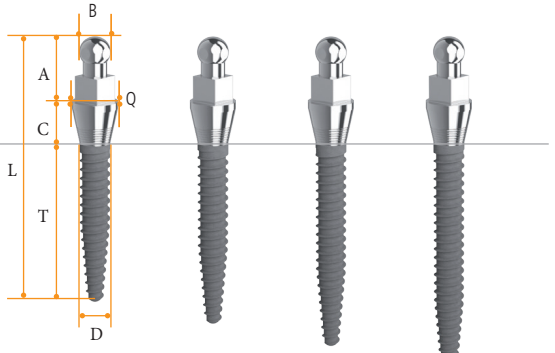
SMALL DIAMETER Implant



Dental Implant

SD implant ø1.8 fine thread implants

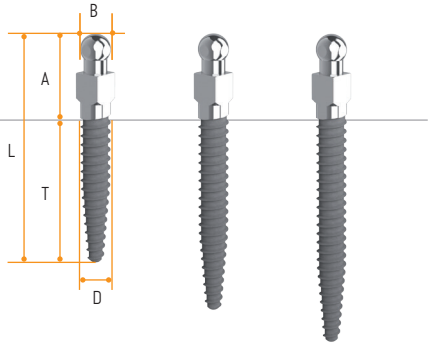
D	L	T	C	A	Q	B	item#
1.8	16.3	10	2.5	3.8	2.6	1.8	CAB-10
	17.8	11.5					CAB-115
	19.3	13					CAB-13
	21.3	15					CAB-15
	24.3	18					CAB-18



CAB-10 10 mm | CAB-115 11.5 mm | CAB-13 13 mm | CAB-15 15 mm

SD implant ø1.8 fine thread implants

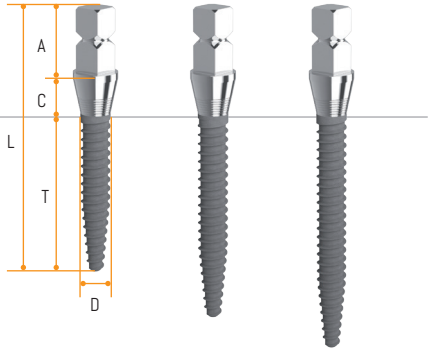
D	L	T	A	B	item#
1.8	13.9	10	3.9	1.8	NAB-10
	16.9	13			NAB-13
	18.9	15			NAB-15



NAB-10 10 mm | NAB-13 13 mm | NAB-15 15 mm

SD implant ø1.8 fine thread implants

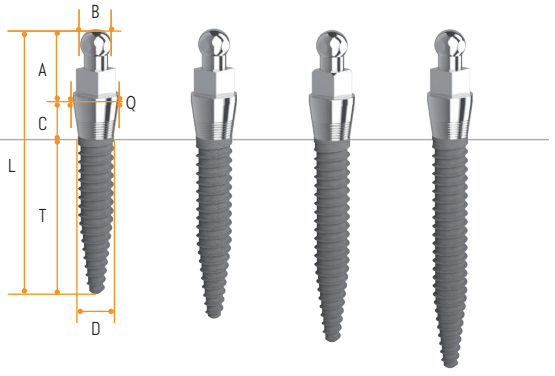
D	L	T	C	A	item#
1.8	16.3	10	2.5	3.8	SAB-10
	19.3	13			SAB-13
	21.3	15			SAB-15



SAB-10 10 mm | SAB-13 13 mm | SAB-15 15 mm

SD implant ø2.1 fine thread implants

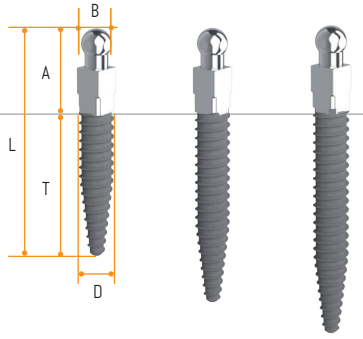
D	L	T	C	A	Q	B	item#
2.1	16.3	10	2.5	3.8	2.6	1.8	IAB-10
	17.8	11.5					IAB-115
	19.3	13					IAB-13
	21.3	15					IAB-15
	24.3	18					IAB-18



IAB-10 10 mm | IAB-115 11.5 mm | IAB-13 13 mm | IAB-15 15 mm

SD implant ø2.1 fine thread implants

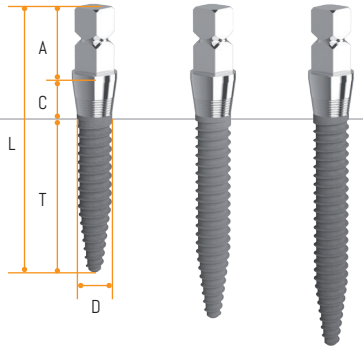
D	L	T	A	B	item#
2.1	13.9	10	3.9	1.8	NIAB-10
	16.9	13			NIAB-13
	18.9	15			NIAB-15



NIAB-10 10 mm | NIAB-13 13 mm | NIAB-15 15 mm

SD implant ø2.1 fine thread implants

D	L	T	C	A	item#
2.1	16.3	10	2.5	3.8	SIAB-10
	19.3	13			SIAB-13
	21.3	15			SIAB-15

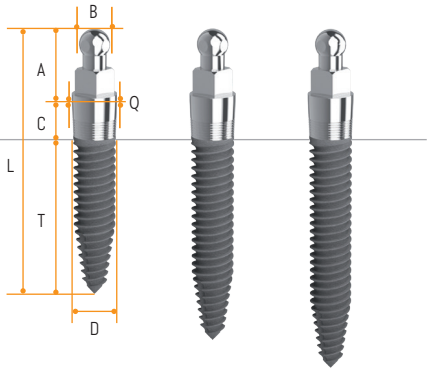


SIAB-10 10 mm | SIAB-13 13 mm | SIAB-15 15 mm

Dental Implant

SD implant ø2.5 fine thread implants

D	L	T	C	A	Q	B	item#
2.5	16.3	10	2.5	3.8	2.6	1.8	MC/25/10
	19.3	13					MC/25/13
	21.3	15					MC/25/15



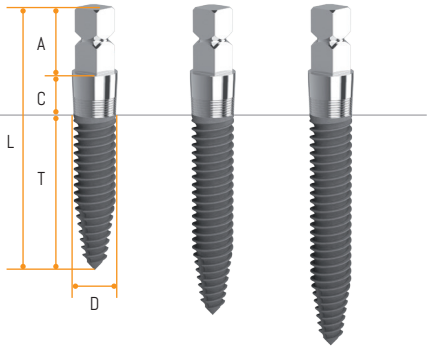
MC/25/10
10 mm

MC/25/13
13 mm

MC/25/15
15 mm

SD implant ø2.5 fine thread implants

D	L	T	C	A	item#
2.5	16.3	10	2.5	3.8	MCA/25/10
	19.3	13			MCA/25/13
	21.3	15			MCA/25/15



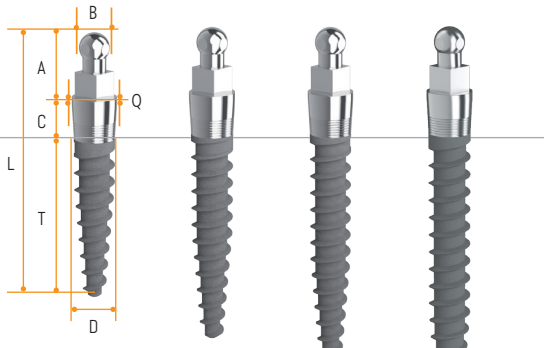
MCA/25/10
10 mm

MCA/25/13
13 mm

MCA/25/15
15 mm

SD implant ø24 aggressive thread implants

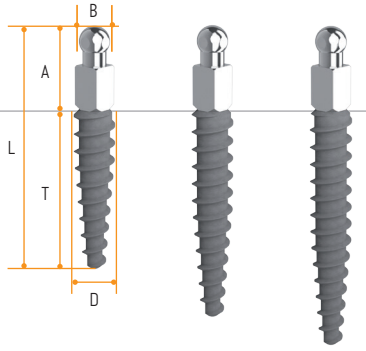
D	L	T	C	A	Q	B	item#
24	16.3	10	2.5	3.8	2.6	1.8	MAB-10
	19.3	13					MAB-13
	21.3	15					MAB-15
	24.3	18					MAB-18



MAB-10 10 mm | MAB-13 13 mm | MAB-15 15 mm | MAB-18 18 mm

SD implant ø24 aggressive thread implants

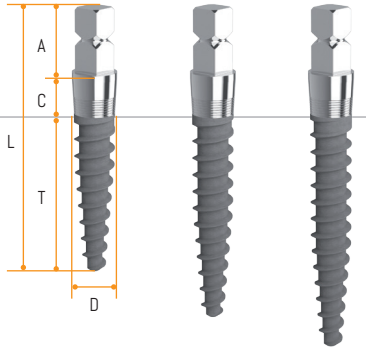
D	L	T	A	B	item#
24	13.9	10	3.9	1.8	NMAB-10
	16.9	13			NMAB-13
	18.9	15			NMAB-15



NMAB-10 10 mm | NMAB-13 13 mm | NMAB-15 15 mm

SD implant ø24 aggressive thread implants

D	L	T	C	A	item#
24	16.3	10	2.5	3.8	SMAB-10
	19.3	13			SMAB-13
	21.3	15			SMAB-15



SMAB-10 10 mm | SMAB-13 13 mm | SMAB-15 15 mm

Prosthetic components

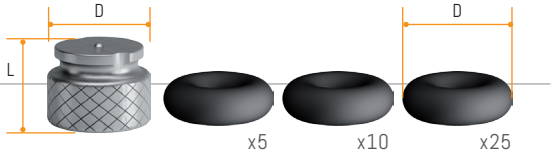
Caps soft retention

D	L
4.7	3.5

Material: Titanium grade 5

O-Ring	D
	44

Material: FDA Buna



MCH-1 soft | MC-3005B O-RING 5 pieces | MC-3005B/10 O-RING 10 pieces | MC-3005B/25 O-RING 25 pieces

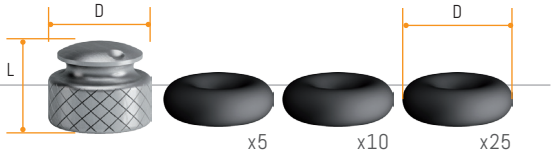
Caps medium retention

D	L
4.3	3.1

Material: Titanium grade 5

O-Ring	D
	3.8

Material: FDA Buna



MCH-2 medium | MC-3005 O-RING 5 pieces | MC-3005/10 O-RING 10 pieces | MC-3005/25 O-RING 25 pieces

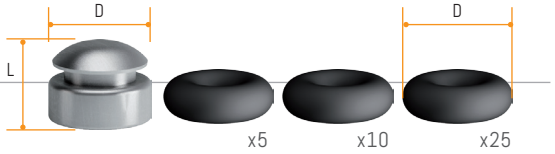
Caps hard retention

D	L
4	3.1

Material: Titanium grade 5

O-Ring	D
	3.8

Material: FDA Buna



MCH-3 hard | MC-3005 O-RING 5 pieces | MC-3005/10 O-RING 10 pieces | MC-3005/25 O-RING 25 pieces

Straight abutment

Only for O-ball heads implants

D	L
4.3	94

Material: Titanium grade 5

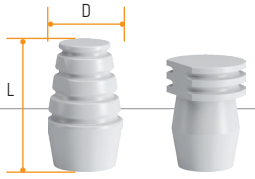
MC-3010

O-ball transfer caps

Only for O-ball heads implants

D	L	item#
4.0	7	MC-3013
4.5	64	MC-3014

Material: PUM



MC-3013 | MC-3014

Castable cap for square head and O-ball

D	L
4	6

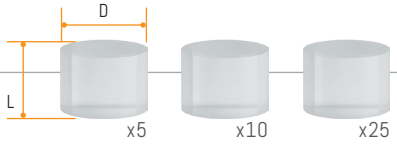
Material: Plexiglass

MC-3006

PVC protection

D	L
3.5	4

Material: PVC



MC-3008
5 pieces

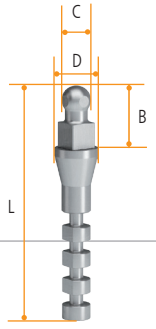
MC-3008/10
10 pieces

MC-3008/25
25 pieces

Collared analog

D	L	C	B
2.6	15.8	1.8	3.8

Material: Titanium grade 5

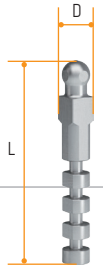


MC-3007

Non collared analog

D	L
2.0	15.8

Material: Titanium grade 5

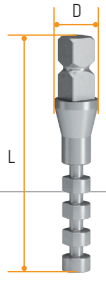


MC-3012

Collared square analog

D	L
2.6	15.8

Material: Titanium grade 5



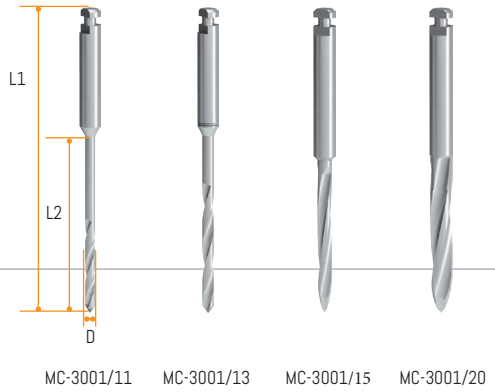
MCA-1007

Instrumentation

Drills

D	L1	L2	item#
1.1	33.3	14.3	MC-3001/11
1.3			MC-3001/13
1.5		17.5	MC-3001/15
2.0			MC-3001/20

Material: Stainless steel



MC-3001/11 MC-3001/13 MC-3001/15 MC-3001/20

Butterfly driver

D	L
8.5	7

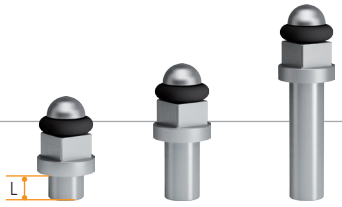
Material: Stainless steel

MC-3002

Adapters

L	item#
4	MC-3003S
8	MC-3003M
12	MC-3003L

Material: Stainless steel

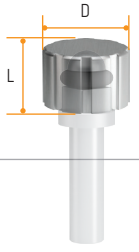


MC-3003S Short MC-3003M Medium MC-3003L Long

Finger adapter

D	L
12	8.6

Material: Stainless steel



CT-E7002
for ratchet drivers

Bone calipers

Material: Stainless steel

MC-3015

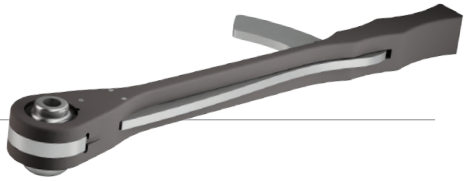
Torque wrench up to 50Ncm

Material: Stainless steel

CT-8010

Torque wrench PEEK

Material: Stainless steel and PEEK



CT-8010PEEK

Ratchet without torque

Material: Stainless steel

MC-00376

Surgical Protocol

Case planning

Following evaluation of the patient and the corresponding panoramic radiographs, the type and number of implants and planned placement sites are established. There should be a minimum of 4 implants for mandibular cases and a minimum of 6 for maxilla cases. The implant planning transparency is used to establish the implant length. A minimum of 5mm between each implant needs to be maintained to allow space for the housings. In mandibular cases the implants should be placed starting with a minimum of 7mm anterior of the mental foramen. Following implant site planning the sites are transferred to the gingiva and marked with sterile marker or bleeding points.

Pilot site drilling and initial insertion

A locator drill can be used to initiate the pilot hole, especially if the ridge is a narrow or knife edge. The drill is placed over the sites and lightly pumped up and down till the cortical plate is perforated. The drill should provide sterile irrigation. Unless the crestal bone is sharp or defective there will be no need to raise a flap or make an incision. In the case of average hardness of the bone, then the drill depth should be approximately 1/3 the length of the implant. In the case of hard bone then the depth should be extended to ¾ of the length of the implant.

The implant is removed from the sterile vial and the tip of the implant is placed into the drilled site, using the implant mount cap as initial driver. The implant is driven into the bone exerting downward pressure and clockwise motions. Once the bone has been engaged the resistance will become too great to proceed further, it is now time to disengage the cap from the implant and proceed to the next instrument.

Continuing the insertion with the butterfly driver

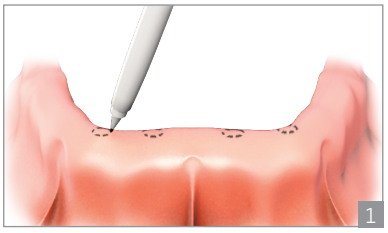
Following the initial insertion one will use the butterfly driver, which allows for applying more torque. It should be possible to seat the implant completely with this instrument but should the implant not be completely seated and further advancement is not possible due to resistance one will then require the torque ratchet for final seating.

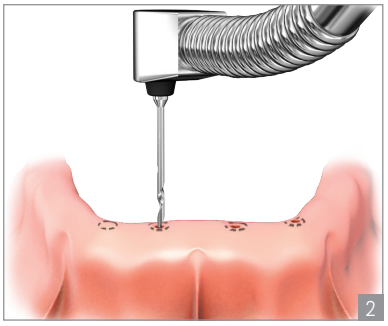
Final implant seating

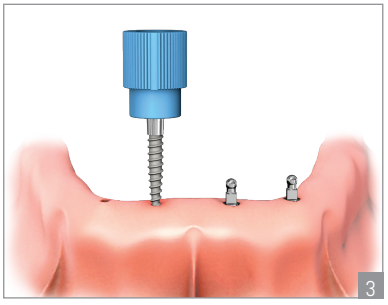
Final seating is accomplished through use of the torque wrench. The torque wrench should be set to 35 Ncm. The ratchet adapter is inserted into the opening at the end of the ratchet with the female aspect of the adapter protruding. The adapter is then fitted over the top of the implant, engaging the square part beneath the O-ball.

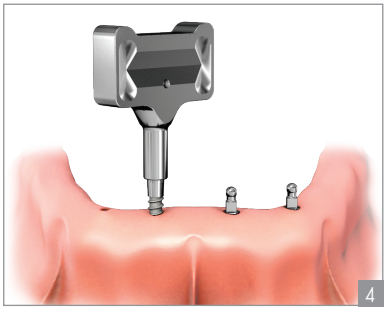
A finger should be placed over the end of the wrench in order to stabilize the insertion and prevent lever action on the end of the implant. The wrench is moved in quarter turn increments, pausing 7 seconds in between each turn, thus allowing the bone to expand.

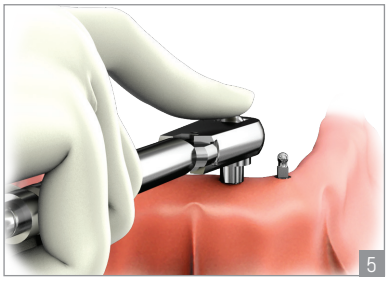
The implant is considered primarily stable once 35-45NcM has been achieved. The implant is completely seated once the O-ball and the square part beneath are the only parts protruding from the gingiva. If primary stability has been achieved prior to achieving final seating, then the implant should be slowly backed out and the pilot drill should be used to deepen the osteotomy site.

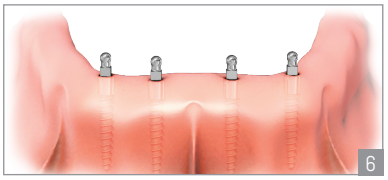












Prosthetic Protocol

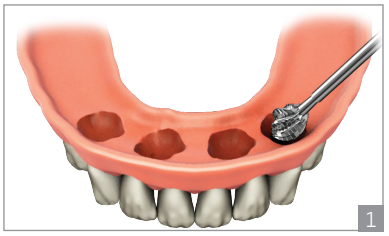
Following proper prosthetic protocol is essential to case success

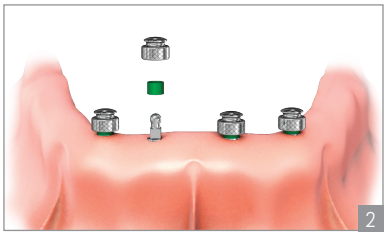
The base of the denture is relieved in order to freely accommodate the heads of the implants and the housings seated on the o-balls. The denture should be relieved until the housings no longer come into contact with the ceiling of the denture base.
The denture should be cleaned thoroughly of all acrylic powder residue.

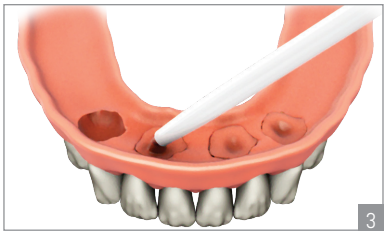
Take the PVC sleeve and, using a scalpel or scissors, cut off 1.5mm lengths corresponding to the quantity of set implants. Slip the cut lengths of tubing around the necks of the implant heads and into the gingiva but below the implant o-ball. Fit the housings over all O-ball heads, the tubing should not obstruct the full seating of the housings over the O-balls. Using cold curing acrylic, apply small amounts to the tops of the housings and fill the hollowed trough of the denture base with the acrylic.

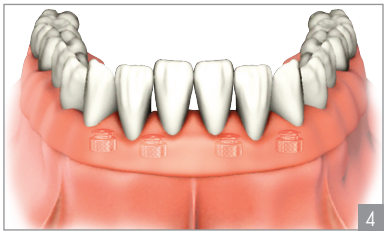
Set the denture over the housings in the patient's mouth. Have the patient bite down on the denture in a normal occlusion with normal pressure.

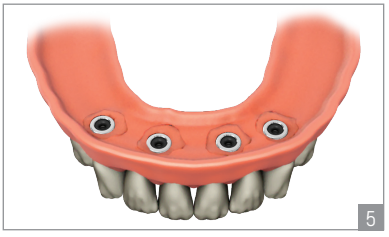
The acrylic will require approx 8 minutes to set, after which the denture is removed and excess acrylic is trimmed polished away.











SD Kit

MC-00075SC

Torque wrench
CT-8010

Butterfly driver
MC-3002

Drills
MC-3001/11
MC-3001/13

Adapters
MC-3003S
MC-3003L

Each surgical kit is equipped with 2 drills; customers can chose drills between ø 1.1 , 1.3, 1.5, 2.0

English version

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