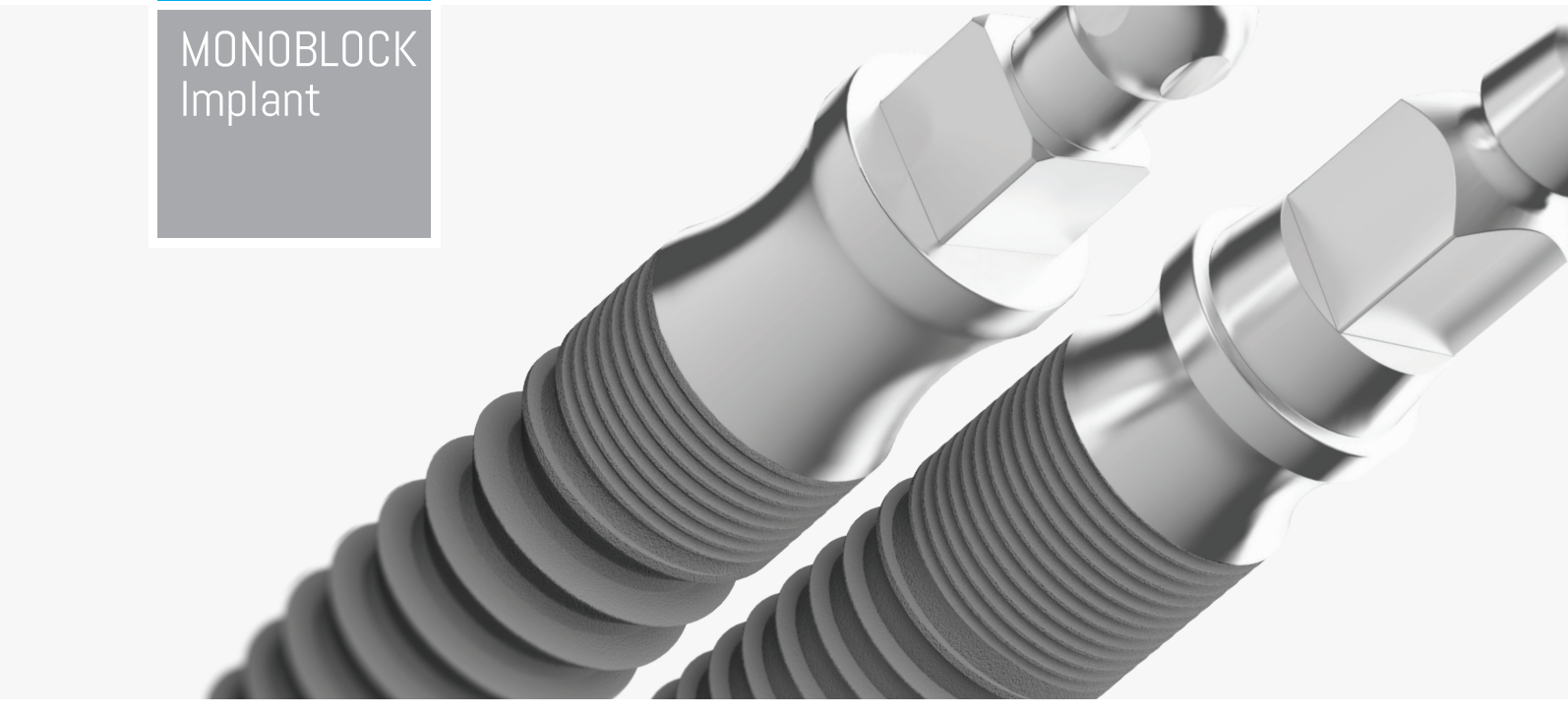
MB

MONOBLOCK Implant



C-TECH IMPLANT

MONOBLOCK 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. ITA269184

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

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.: ITA23004425

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.

MONOBLOCK implant

The C-Tech MB, Mono Block implant, provides 2 different prosthetic options as well as 2 different main body designs to meet the differing requirements of bone and soft tissue encountered in the maxilla and the mandible.

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

Support for Fixed Recontructions
A tapered head with a 4,8mm height above the 3,1mm platform offers an optimal base and structure for the fixed recontruction.

Gingival Collar
MAN-OB/MAN-TAP smooth collar provides the platform switching height to accommodate the average mandibular gingival tissue.

Mandibular Cortical Maintenance
Augmented MAN-OB/MAN-TAP micro grooving for the increased cortical height of the mandibular bone.

Low Profile Threading
Low profile threading offers surface area yet with the reduced resistance necessary for placement in the D2/D1 bone that can be encountered in the mandible.

Surface Topography
Blasted and acid etched main body surface.

Mandibular Apex
Sharp apex to facilitate advancement in D2/D1 bone.

System Compatiblity
Choice of tapered and O-ball head prosthetics.
O-ball head is compatible with SD, GL, and BL O-ball attachments

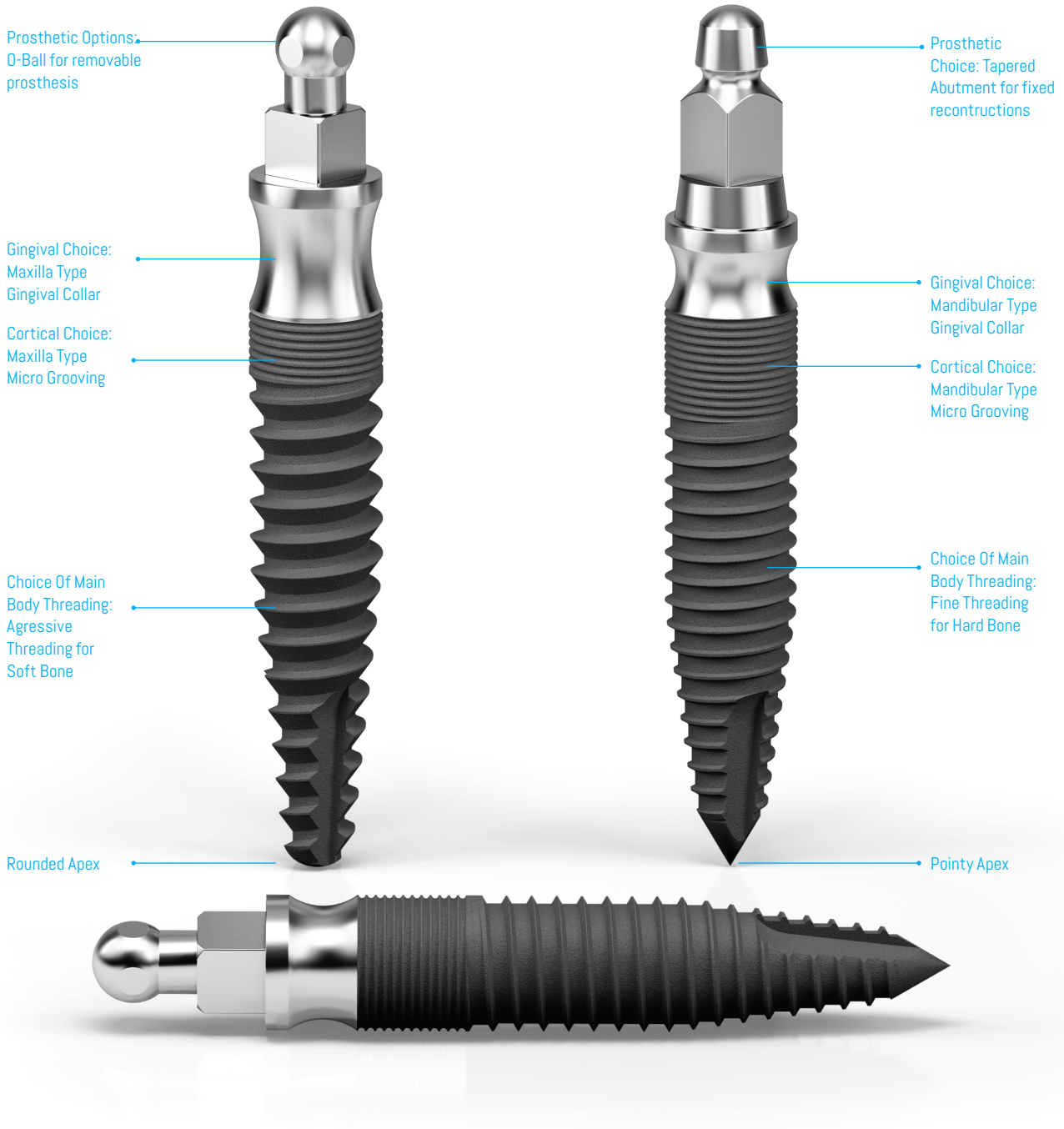
Augmented Gingival Collar
MAX-OB/MAX-TAP smooth collar platform switching fits the thicker maxillary gingival tissue

Maxilla Type Bone Micro Grooving
MAX-OB/MAX-TAP micro grooving accommodates the thinner cortical bone that is encountered in the maxilla.

Aggressive Main Body Threading
MAX-OB/MAX-TAP main body threading, agressive reverse buttress threads deliver the surface area and stability required by softer maxillary bone

Maxilla Type Apex
Rounded tip is ideal for the maxilla to prevent possible sinus perforation.

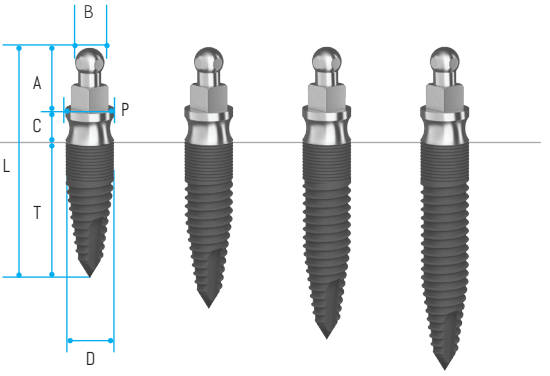
MONOBLOCK Implant



Dental Implant

MANOB

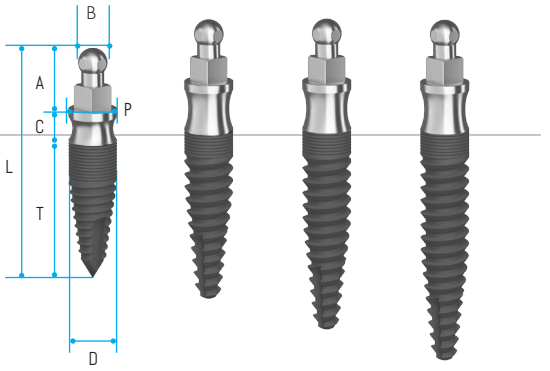
D	L	T	C	A	P	B	item#
3	14.3	9	1.5	3.8	3.1	1.8	MANOB-09
	16.3	11					MANOB-11
	18.3	13					MANOB-13
	20.3	15					MANOB-15



MANOB-09 9 mm | MANOB-11 11 mm | MANOB-13 13 mm | MANOB-15 15 mm

MAXOB

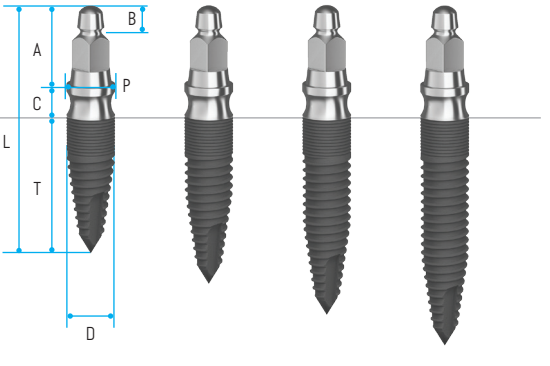
D	L	T	C	A	P	B	item#
3	15.3	9	2.5	3.8	3.1	1.8	MAXOB-09
	17.3	11					MAXOB-11
	19.3	13					MAXOB-13
	21.3	15					MAXOB-15



MAXOB-09 9 mm | MAXOB-11 11 mm | MAXOB-13 13 mm | MAXOB-15 15 mm

MANTAP

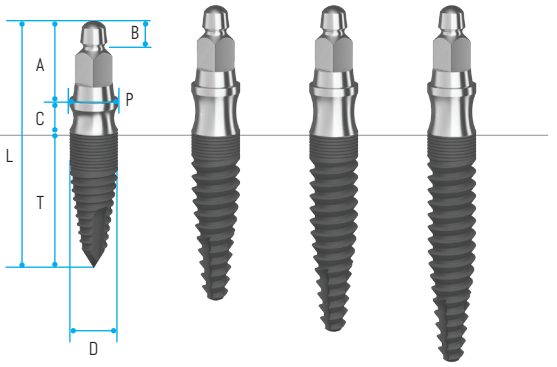
D	L	T	C	A	B	P	item#
3	15.3	9	1.5	4.8	2.3	3.1	MANTAP-09
	17.3	11					MANTAP-11
	19.3	13					MANTAP-13
	21.3	15					MANTAP-15



MANTAP-09 9 mm | MANTAP-11 11 mm | MANTAP-13 13 mm | MANTAP-15 15 mm

MAXTAP

D	L	T	C	A	B	P	item#
3	16.3	9	2.5	4.8	2.3	3.1	MAXTAP-09
	18.3	11					MAXTAP-11
	20.3	13					MAXTAP-13
	22.3	15					MAXTAP-15



MAXTAP-09
9 mm

MAXTAP-11
11 mm

MAXTAP-13
13 mm

MAXTAP-15
15 mm

Prosthetic components

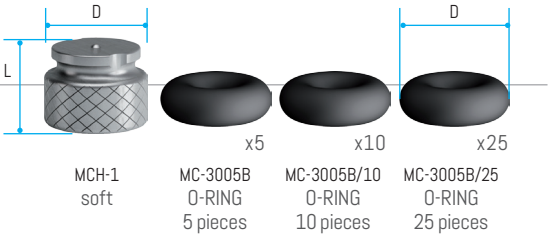
Caps soft retention

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

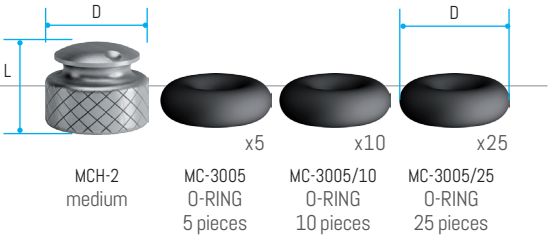
Caps medium retention

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

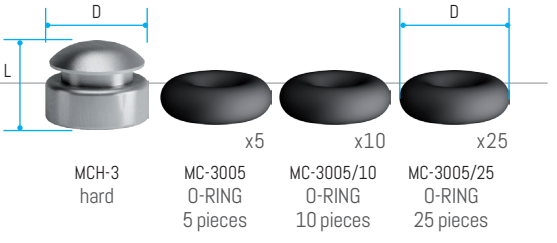
Caps hard retention

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

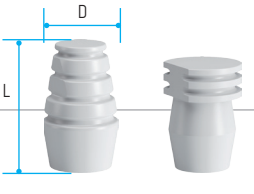
MC-3010

O-ball temporary and 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 Temporary cap | MC-3014 Transfer cap

Castable cap for square head and O-ball

D	L
4	6

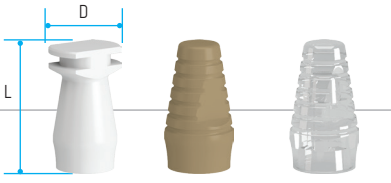
Material: Plexiglass

MC-3006

Tapered caps

D	L	item#
3	7	MB-3013
		MB-3014
		MB-3006

Material: MB-3013 - POM
MB-3014 - PEEK
MB-3006 - CPMMA



MB-3013
Tapered
impression cap

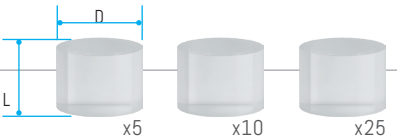
MB-3014
Tapered
temp cap

MB-3006
Tapered waxing
coping

PVC protection

D	L
3.5	4

Material: PVC



MC-3008
5 pieces

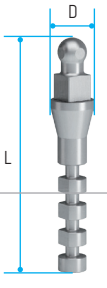
MC-3008/10
10 pieces

MC-3008/25
25 pieces

Collared analog

D	L
2.6	15.8

Material: Titanium grade 5



MC-3007

Tapered analog

D	L
3.1	17.85

Material: Titanium grade 5

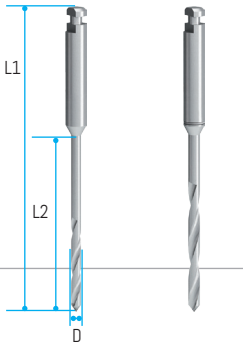
MB-ANALOG

Instrumentation

Drills

D	L1	L2	item#
1.1	33.3	14.3	MC-3001/11
1.3			MC-3001/13

Material: Stainless steel



MC-3001/11 MC-3001/13

Butterfly driver

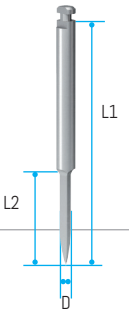
D	L
8.5	7

MC-3002

Locator drill

L1	L2	D
29	15	2.1

Material: Stainless steel

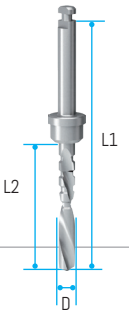


CT-2020

Initial drill

L1	L2	D
35.2	17.2	2.3

Material: Stainless steel

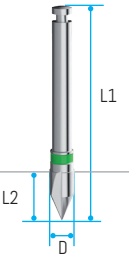


CT-1720E

Counter bore

L1	L2	D
26	6	3

Material: Stainless steel

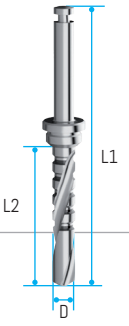


ND-1730E

Main drills

L1	L2	D
36.7	17.2	2.6

Material: Stainless steel



ND-1726E

Drill Extender

L
25

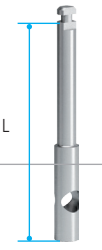
Material: Stainless steel

CT-2000

Tissue punch

L
2.8

Material: Stainless steel

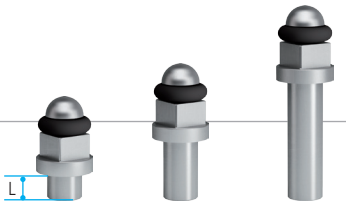


TCP-3MM

Adapters

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

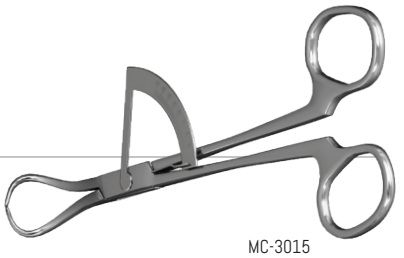
Material: Stainless steel



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

Instrumentation

Bone calipers



MC-3015

Torque wrench up to 50Ncm

CT-8010

Ratchet without torque

MC-00376

MB Kit

MC-00075SC

Torque wrench
CT-8010

Adapters
MC-3003S - MC-3003M
MC-3003L

Butterfly driver
MC-3002

Tissue punch
TCP-3MM

Locator drill
CT-2020

Drill extender
CT-2000

Initial drill
CT-1720E

Drill Stop
CTSTOP-09 CTSTOP-11 CTSTOP-13

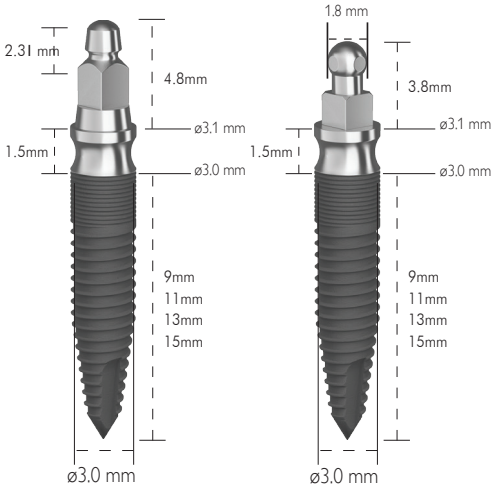
Main drill
ND-1726E

Counter bore
ND-1730E

Each surgical kit is equipped with 2 drills; customers can chose drills between Ø 1.1, 1.3, 1.5, 2.0 e 2.6 mm.

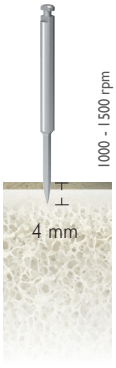
Site preparation D2/D3

MAN - TAPER / MAN - O-BALL FOR DENSITY D1/D2

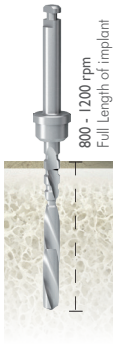


TCP - 3mm
3mm Tissue Punch

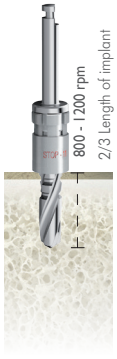
CT-2020
Locator Drill



CT-1720E
ø 2.3 mm drill

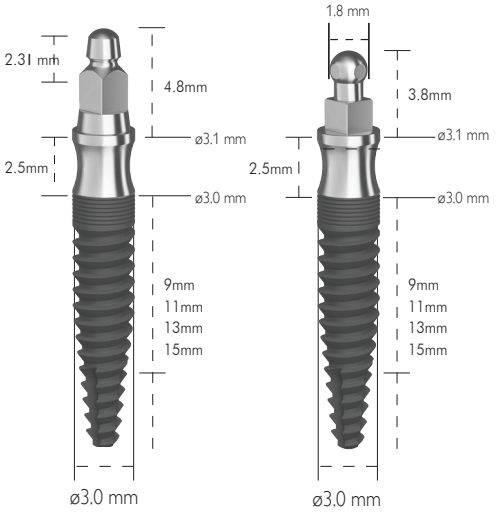


ND-1726E
ø 2.6 mm drill



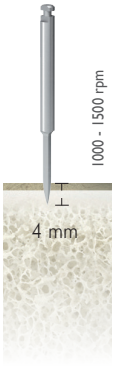
MC-3003
Ratchet adapter

MAX - TAPER / MAX - O-BALL FOR DENSITY D2/D3

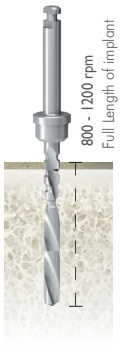


TCP - 3mm
3mm Tissue Punch

CT-2020
Locator Drill



CT-1720E
ø 2.3 mm drill

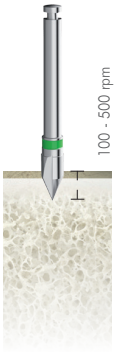


MC-3003
Ratchet adapter

D1 additional steps

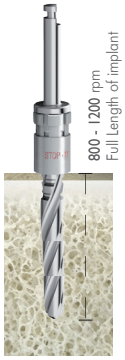
ND-1726E
ø 2.6 mm drill

CT-1730E
ø 3 mm
Counter Bore



MC-3003
Ratchet adapter

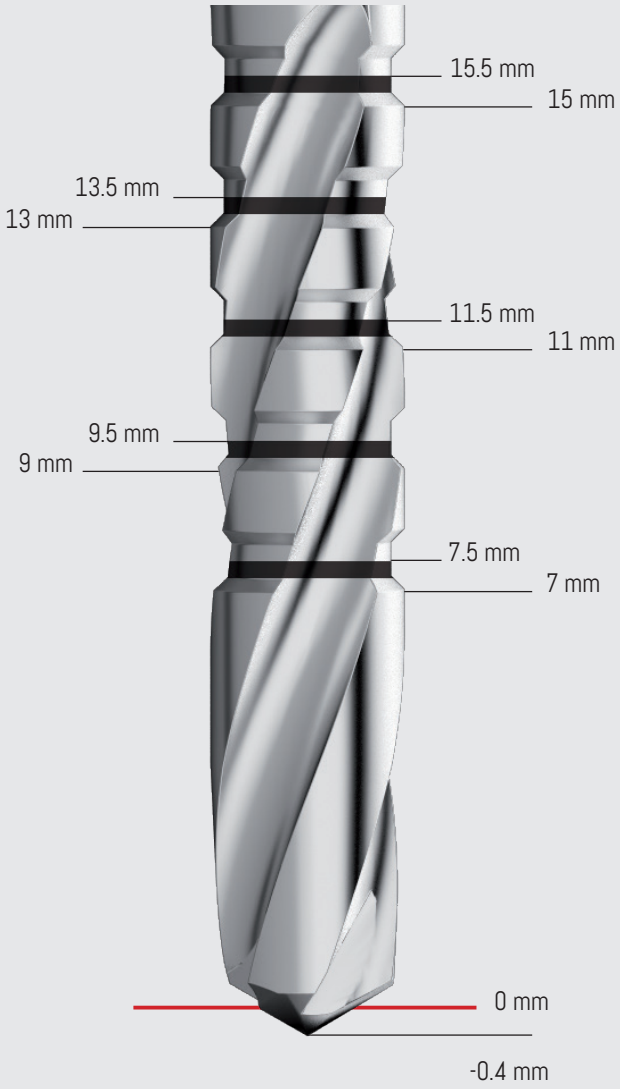
ND-1726E
ø 2.6 mm drill



MC-3003
Ratchet adapter

Explanation of Drill Marking

- The drill markings do not include the point of the drill.
- The point of the drill is 0.4 mm long, thus the drill marking of 7 mm is actually 7.4 mm from the very tip to the bottom of the first black line.
- The implant should be set approximately 1 mm sub crestally, thus for a 13 mm implant, one should drill to the 14 mm. The use of metal stop is recommended.



English version

REV. 01 / 02-2016

C-TECH
CENTURY IMPLANT TECHNOLOGIES

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