

Uris
Implant System





OMNI

Implant System

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OMNI
Implant System

Versatile Prosthetic Options

powered by TruAbutment



Stock
Abutment



Custom
Healing
Abutment



Custom
Abutment



All-on-T
Custom
MUA



T:LOC
Custom
Removable



ASC
Angulated
Screw Channel

11° Morse Taper

- Creates hermetic seal.
- Elimination of microgap.
- Reduction of micro-movements and screw loosening.

Platform Switching

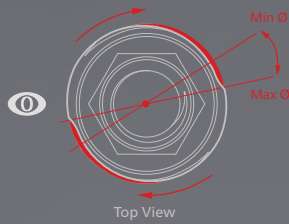
- Reduction of peri-implant bone loss.
- Greater magnitude with increased diameter.
- Aids in maintaining biological width without disruption during clinical functions.
- Beveled feature facilitates bone growth above the shoulder.

Cutting Edge

- Triple cutting edge.
- Self-tapping.

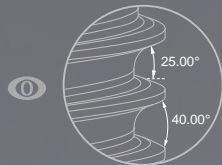
SEM x500

Preserves more of the peri-implant bone, stabilizes more of the soft tissues, reduces the microgap size found in the abutment-implant connection and proper geometry for narrower mesio-distal edentulous spaces.



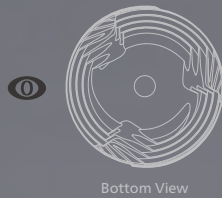
Blood pockets

- 6.5 ~12 % Reduction: Reduction of stress / pressure points.
- Creation of "blood pockets" promotes bone growth during osseointegration.
- Gradual distribution of force along the cortical plate.



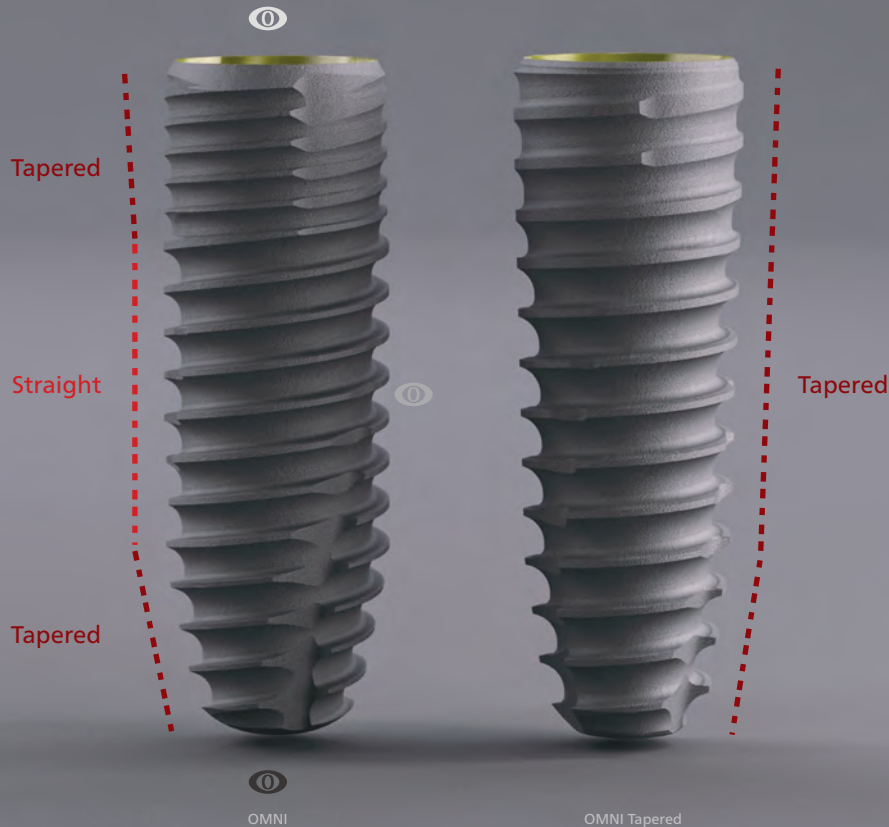
Thread Design

- The bite of the thread features two-stage ramp.
- Allows for gradual bone condensing for wide range of bone conditions.
- Even insertion while protecting bone structure.



Apex design

- Aggressive triple cutting edge allows for adjustable implant orientation during manual insertion for optimal final placement.
- Round apex to protect sinus floor, nerve canal or other anatomical structures.



- Hybrid design provides best features of both straight and tapered implants.
- Coronal taper with unique design aids in initial stability, load dissipation and reduces stress/strain on the crestal bone.
- The body and apical design assist in guiding the implant to the desired position while providing bone density distribution.

OMNI Fixture

N Hex 1.95

Length

D Ø3.0



Length

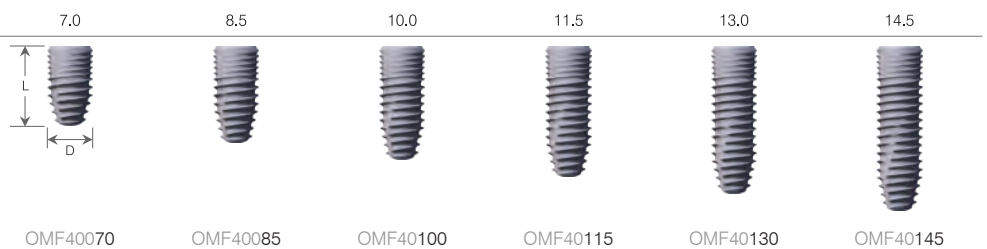
D Ø3.5



R Hex 2.5

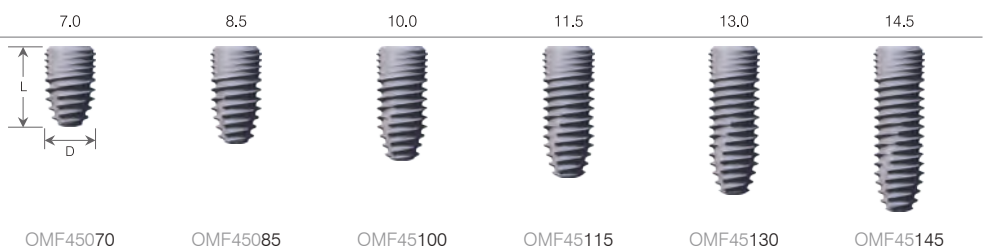
Length

D Ø4.0



Length

D Ø4.5



Length	7.0	8.5	10.0	11.5	13.0	14.5
D Ø5.0						
	OMF50070	OMF50085	OMF50100	OMF50115	OMF50130	OMF50145

Length	7.0	8.5	10.0	11.5
D Ø5.5				
	OMF55070	OMF55085	OMF55100	OMF55115

Length	7.0	8.5	10.0
D Ø6.0			
	OMF60070	OMF60085	OMF60100

Length	7.0	8.5	10.0
D Ø6.5			
	OMF65070	OMF65085	OMF65100

OMNI

Tapered

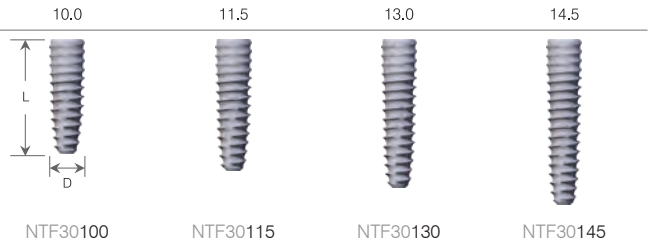
(Unit: mm)

Packing Unit: OMNI Tapered Fixture+Cover Screw

N Hex 1.95

Length

D Ø3.0



Length

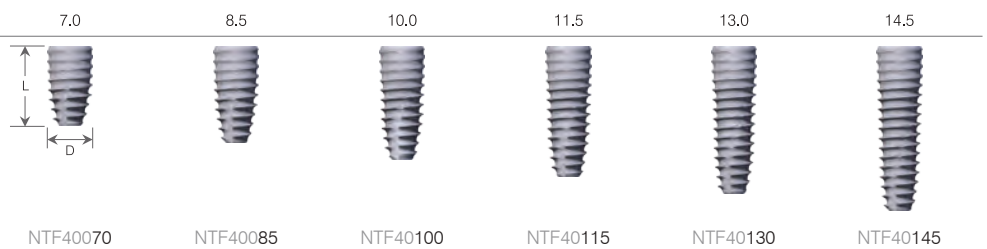
D Ø3.5



R Hex 2.5

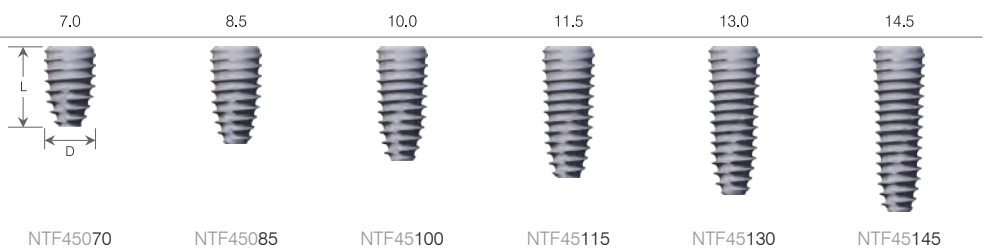
Length

D Ø4.0



Length

D Ø4.5



Length	7.0	8.5	10.0	11.5	13.0	14.5
D Ø5.0						
	NTF50070	NTF50085	NTF50100	NTF50115	NTF50130	NTF50145

Cover

Screw

Hex driver : 1.27 | Torque : 5~10 Ncm

*Not Sold Individually



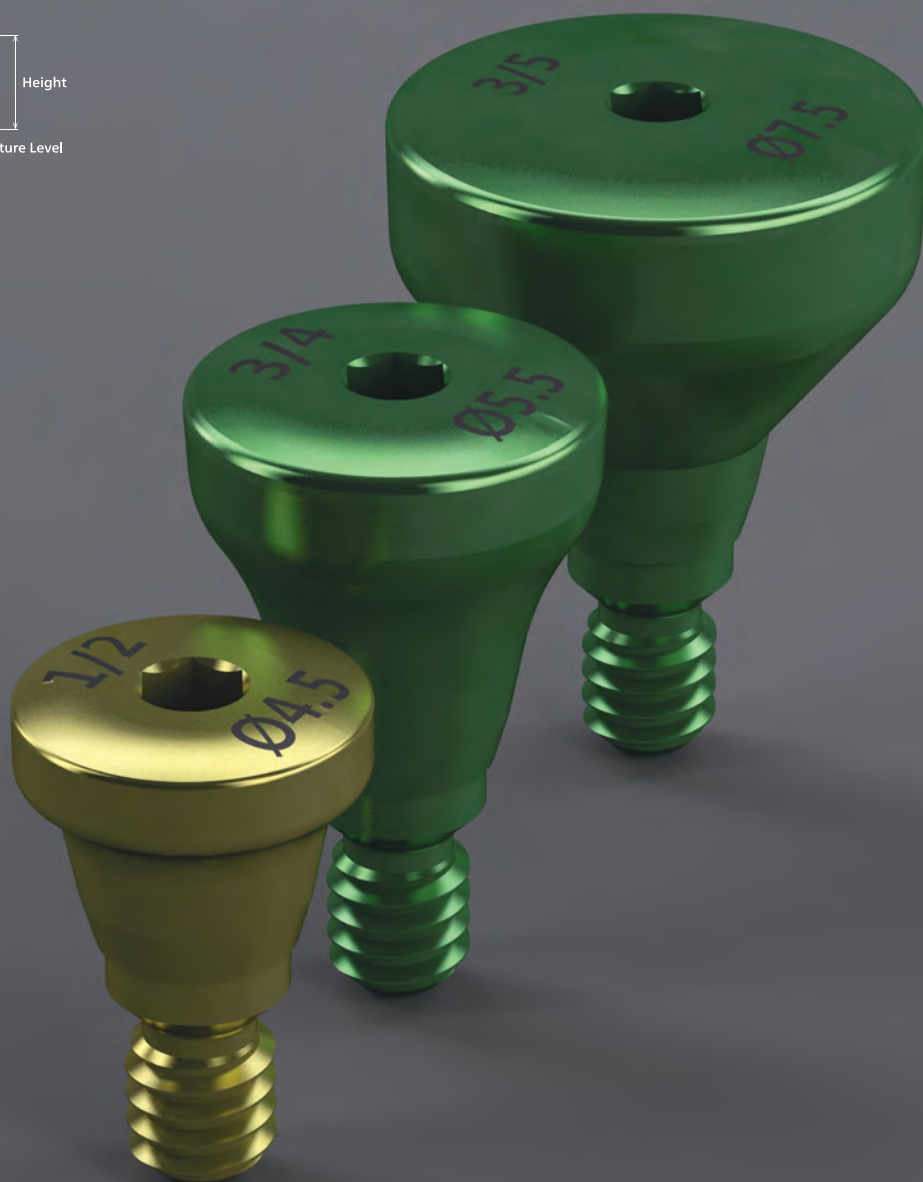
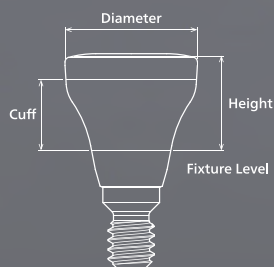
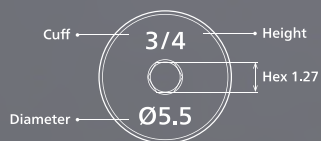
UCS16



UCS20

Healing Abutment

Hex driver : 1.27
Torque : 5~10 Ncm



Healing Abutment

(Unit: mm)

N

Cuff/Height	1.0 / 2.0	2.0 / 3.0	3.0 / 4.0	4.0 / 5.0	5.0 / 7.0	2.0 / 2.0
D Ø4.0						
	UHAN4012	UHAN4023	UHAN4034	UHAN4045	UHAN4057	UHAN4022

Cuff/Height	1.0 / 2.0	2.0 / 3.0	3.0 / 4.0	4.0 / 5.0	5.0 / 7.0	2.0 / 2.0
D Ø4.5						
	UHAN4512	UHAN4523	UHAN4534	UHAN4545	UHAN4557	UHAN4522

R

Cuff/Height	1.0 / 2.0	2.0 / 3.0	3.0 / 4.0	4.0 / 5.0	5.0 / 7.0	2.0 / 2.0
D Ø4.0						
	UHA4012	UHA4023	UHA4034	UHA4045	UHA4057	UHA4022

Cuff/Height	1.0 / 2.0	2.0 / 3.0	3.0 / 4.0	4.0 / 5.0	5.0 / 7.0	2.0 / 2.0
D Ø4.5						
	UHA4512	UHA4523	UHA4534	UHA4545	UHA4557	UHA4522

Cuff/Height	1.0 / 2.0	2.0 / 3.0	3.0 / 4.0	4.0 / 5.0	5.0 / 7.0	2.0 / 2.0
D Ø5.5						
	UHA5512	UHA5523	UHA5534	UHA5545	UHA5557	UHAN5522

Cuff/Height	1.0 / 2.0	2.0 / 3.0	3.0 / 4.0	4.0 / 5.0	5.0 / 7.0	2.0 / 2.0
D Ø6.5						
	UHA6512	UHA6523	UHA6534	UHA6545	UHA6557	UHA6522

Cuff/Height	1.0 / 2.0	2.0 / 3.0	3.0 / 5.0	2.0 / 2.0
D Ø7.5				
	UHA7512	UHA7523	UHA7535	UHA7522

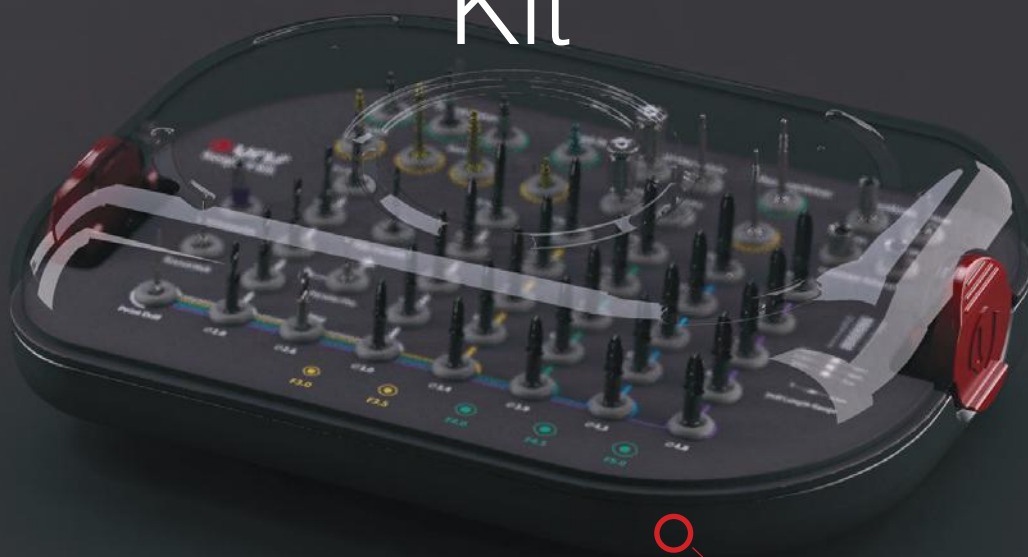
Surgery

Instruments

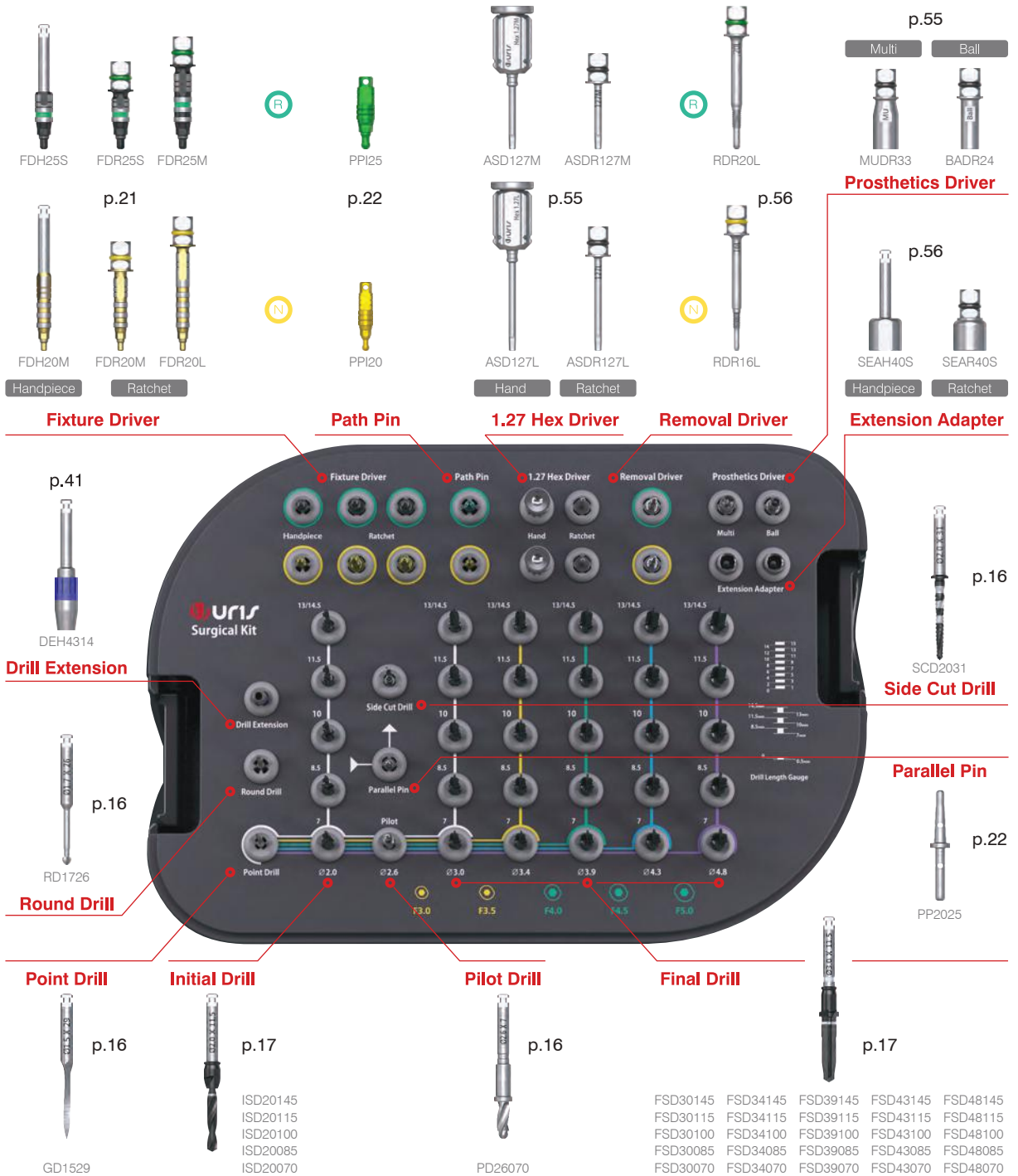


Surgical Instruments

Surgical Kit



SKA 01



Lower

p.53

Torque Wrench



TW40

Depth Gauge



DGMW75

Titanium Bowl



TB4762

Wide Surgical Kit



WSK 01



Final Drill
Ø5.3

FSD53070

FSD53085

FSD53100

Final Drill
Ø5.8

FSD58070

FSD58085

FSD58100

p.19

Final Drill
Ø6.2

FSD62070

FSD62085

FSD62100



Tapered Surgical Kit

TSK 01

**Pilot Drill
Long Type**



SPD30L



SPD35L



SPD40L



SPD45L



SPD50L



p.20

**Pilot Drill
Short Type**



SPD30S



SPD35S



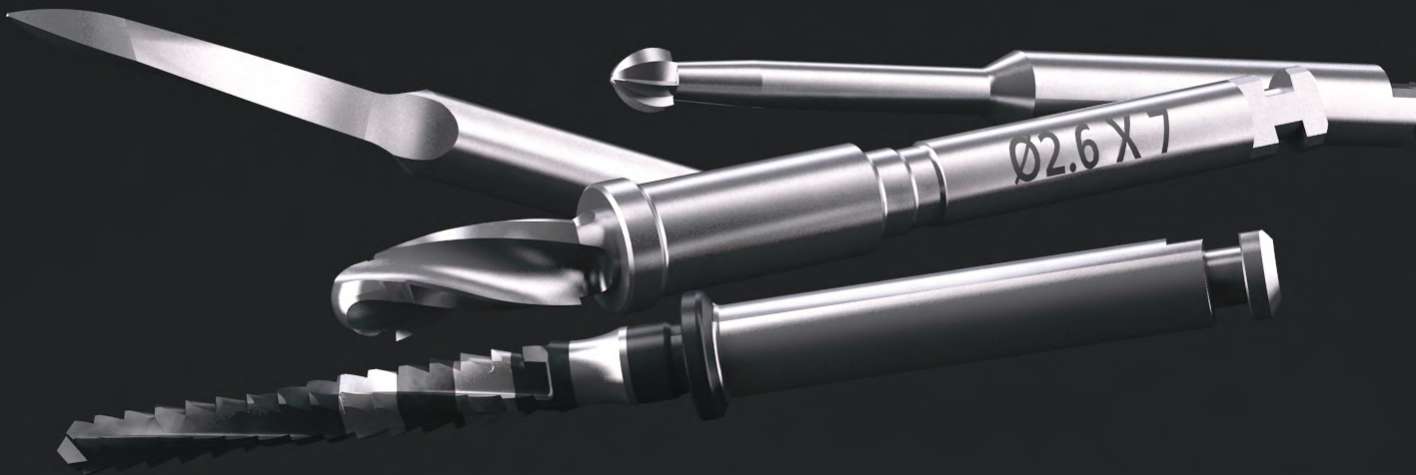
SPD40S



SPD45S



SPD50S



Point Drill

Drills through the cortical bone to create an ideal path for the next drills at the selected site.
800~1200 rpm (must use with saline water)



GD1529

Round Drill

Levels out the uneven bone and removes the remaining gingiva residue.
800~1200 rpm

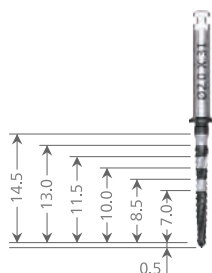


RD1726

Side Cut Drill

Drills with the side blade to modify the drilling path.
800~1200 rpm

(Unit: mm)



SCD2031

Pilot Drill

Expands cortical bone to let the final drill enter the path easily.
800~1200 rpm







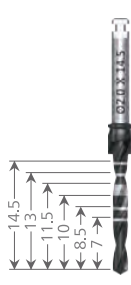
PD26070



Initial Drill

Expands the prepared site and used according to the chosen fixture's length.
800~1200 rpm





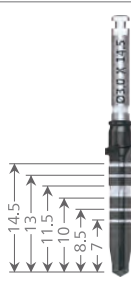
(Unit: mm)





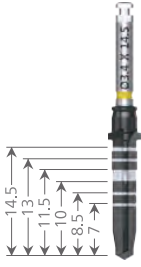
Length	7.0	8.5	10.0	11.5	13.0/14.5
D Ø2.0					
	ISD20070	ISD20085	ISD20100	ISD20115	ISD20145





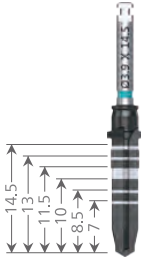
Final Drill





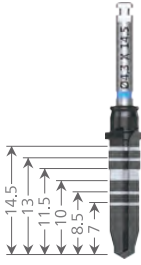
The last drill used to place the URIS fixture and is available for each fixture diameter/length and bone density.
800~1200 rpm





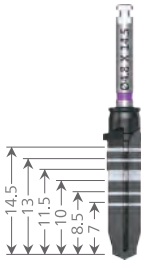
(Unit: mm)




Length	7.0	8.5	10.0	11.5	13.0/14.5
D Ø3.0					
	FSD30070	FSD30085	FSD30100	FSD30115	FSD30145




Length	7.0	8.5	10.0	11.5	13.0/14.5
D Ø3.4					
	FSD34070	FSD34085	FSD34100	FSD34115	FSD34145

Length	7.0	8.5	10.0	11.5	13.0/14.5
D Ø3.9					
	FSD39070	FSD39085	FSD39100	FSD39115	FSD39145

Length	7.0	8.5	10.0	11.5	13.0/14.5
D Ø4.3					
	FSD43070	FSD43085	FSD43100	FSD43115	FSD43145

Length	7.0	8.5	10.0	11.5	13.0/14.5
D Ø4.8					
	FSD48070	FSD48085	FSD48100	FSD48115	FSD48145

Length	7.0	8.5	10.0
D Ø5.3	 <p>FSD53070</p>	 <p>FSD53085</p>	 <p>FSD53100</p>

Length	7.0	8.5	10.0
D Ø5.8	 <p>FSD58070</p>	 <p>FSD58085</p>	 <p>FSD58100</p>

Length	7.0	8.5	10.0
D Ø6.2	 <p>FSD62070</p>	 <p>FSD62085</p>	 <p>FSD62100</p>



Pilot Drill

The last drill used to place the URIS tapered fixture and is available for each tapered fixture diameter/length and bone density.

800~1200 rpm

(Unit: mm)

Diameter

Ø3.0

Ø3.5

Ø4.0

Ø4.5

Ø5.0

Short Type



SPD30S



SPD35S



SPD40S



SPD45S



SPD50S

Long Type



SPD30L



SPD35L



SPD40L



SPD45L



SPD50L



Fixture

Driver

*Caution: Must torque after fully engaging into the fixture securely to avoid any breakages.

Handpiece



FDH20S



FDH20M



FDH20L



FDH25S



FDH25M



FDH25L

Ratchet



FDR20S



FDR20M



FDR20L



FDR25S



FDR25M



FDR25L

Parallel

Pin

Indicates and confirms the bone preparation location.



PP2025

Path

Pin

Confirms the path, the gingiva depth & the hex direction of the prosthetic connection after the placement.



PPI20



PPI25

OMNI Fixture

Surgical Drilling Protocol



Required



Use at your discretion



Requires a drill that is 1.5 mm shorter than the fixture

Implant Ø3.0 x 11.5mm

Bone Quality

Soft



Normal



Hard



Drill

Point Drill

Initial Drill
Ø2.0

Pilot Drill
Ø2.6







Final Drill
Ø3.0



11.5mm









Implant Ø3.5 x 11.5mm









Bone Quality					
Soft		●	●		
Normal		●	●	●	
Hard		●	●	●	⊙
Drill					
	Point Drill	Initial Drill Ø2.0	Pilot Drill Ø2.6	Final Drill Ø3.0 Ø3.4	
					
11.5mm					

● Required ○ Use at your discretion ⊙ Requires a drill that is 1.5 mm shorter than the fixture

Implant Ø4.0 x 11.5mm









Bone Quality					
Soft		●	●	●	
Normal		●	●	○	●
Hard		●	●	○	●
Drill					
	Point Drill	Initial Drill Ø2.0	Pilot Drill Ø2.6	Final Drill Ø3.0 Ø3.4 Ø3.9	
					
11.5mm					

Implant Ø4.5 x 11.5mm

Bone Quality								
Drill	Soft	●	●	○	●			
	Normal	●	●	○	●	●		
	Hard	●	●	○	●	●	⊙	
		Point Drill	Initial Drill Ø2.0	Pilot Drill Ø2.6	Ø3.0	Final Drill Ø3.4	Ø3.9	Ø4.3
								
11.5mm								

● Required ○ Use at your discretion ⊙ Requires a drill that is 1.5 mm shorter than the fixture











Implant Ø5.0 x 11.5mm

Bone Quality								
Drill	Soft	●	●	○	●	●		
	Normal	●	●	○	●	●	●	
	Hard	●	●	○	●	○	●	⊙
		Point Drill	Initial Drill Ø2.0	Pilot Drill Ø2.6	Ø3.0	Ø3.4	Final Drill Ø3.9	Ø4.3
								
11.5mm								

OMNI Wide Fixture

Surgical Drilling Protocol

Implant Ø5.5 x 11.5mm











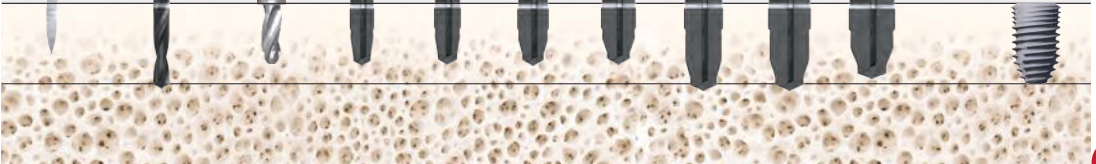
Bone Quality									
Soft		●	●	○	●	●	●		
Normal		●	●	○	●	●	●	●	
Hard		●	●	○	●	○	●	●	⊙
Drill	Point Drill	Initial Drill Ø2.0	Pilot Drill Ø2.6	Ø3.0	Ø3.4	Ø3.9	Ø4.3	Ø4.8	Ø5.3
									
11.5mm									

● Required

○ Use at your discretion













⊙ Requires a drill that is 1.5 mm shorter than the fixture

Implant Ø6.0 x 10.0mm

Bone Quality										
Soft		●	●	○	●	●	●	●		
Normal		●	●	○	●	●	●	●	●	
Hard		●	●	○	●	○	●	●	●	⊙
Drill	Point Drill	Initial Drill Ø2.0	Pilot Drill Ø2.6	Ø3.0	Ø3.4	Ø3.9	Ø4.3	Ø4.8	Ø5.3	Ø5.8
										
10.0mm										

- Required ○ Use at your discretion ⊙ Requires a drill that is 1.5 mm shorter than the fixture

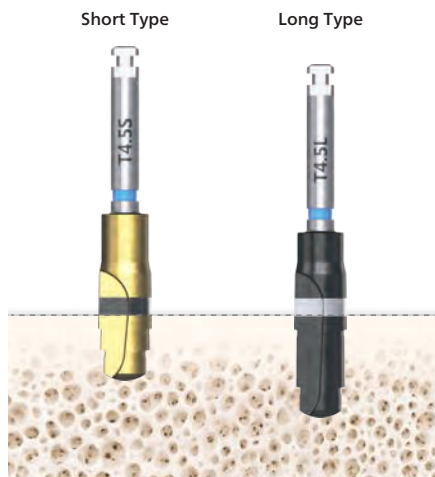
Implant Ø6.5 x 10.0mm

Bone Quality											
Soft	●	●	○	●	●	●	●	●			
Normal	●	●	○	●	●	●	●	●	●		
Hard	●	●	○	●	○	●	●	●	●	⊙	
Drill	Point Drill	Initial Drill Ø2.0	Pilot Drill Ø2.6	Ø3.0	Ø3.4	Ø3.9	Ø4.3	Ø4.8	Ø5.3	Ø5.8	Ø6.2
											
10.0mm											

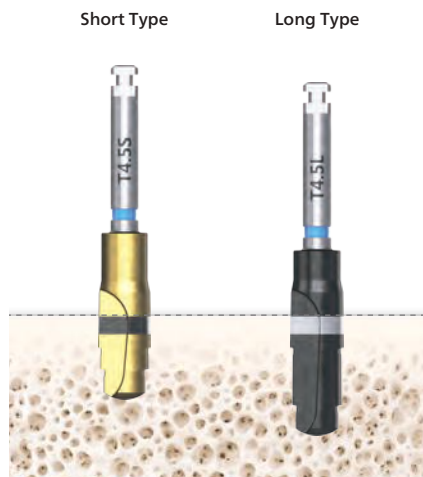
OMNI Tapered Fixture

Surgical Drilling Protocol

Normal Bone

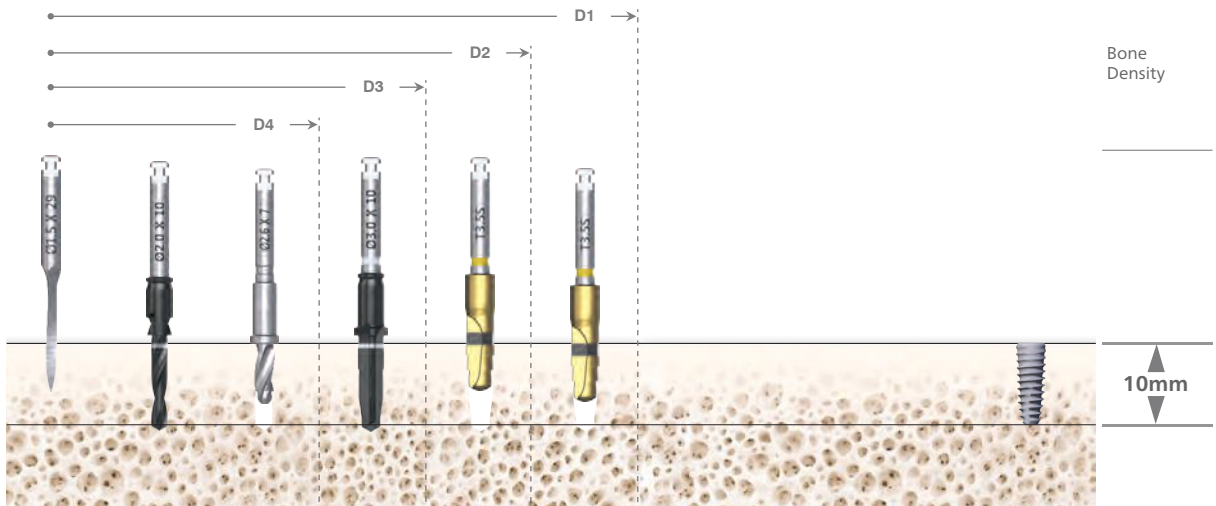


Hard Bone



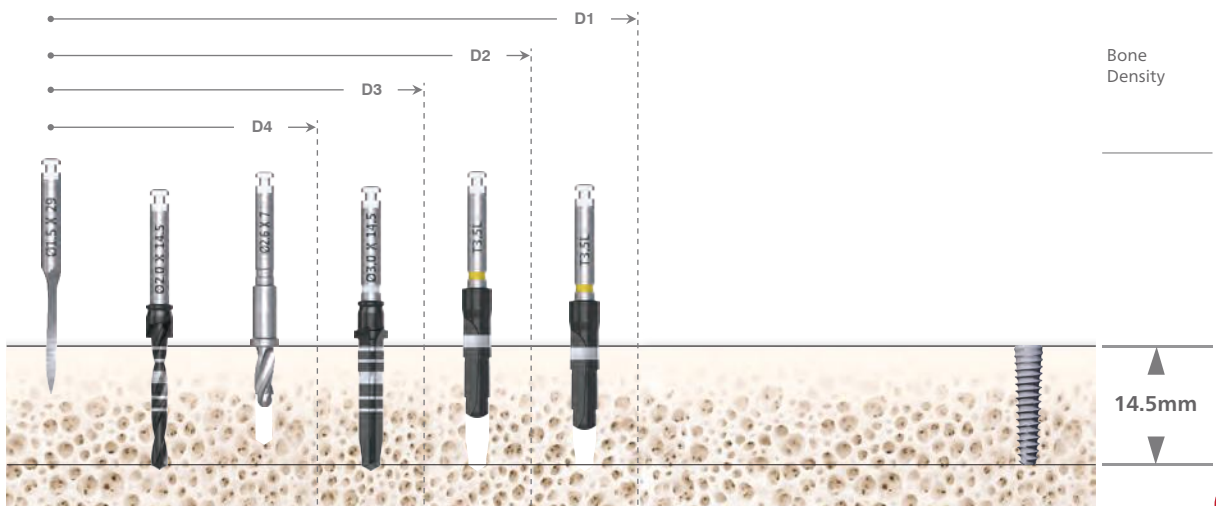
Implant Ø3.5 x 10mm

Point Drill	Initial Drill	Pilot Drill	Final Drill	Pilot Drill	
Ø1.5	Ø2.0	Ø2.6	Ø3.0	T3.5	T3.5
29	10	7	10	Short	Short



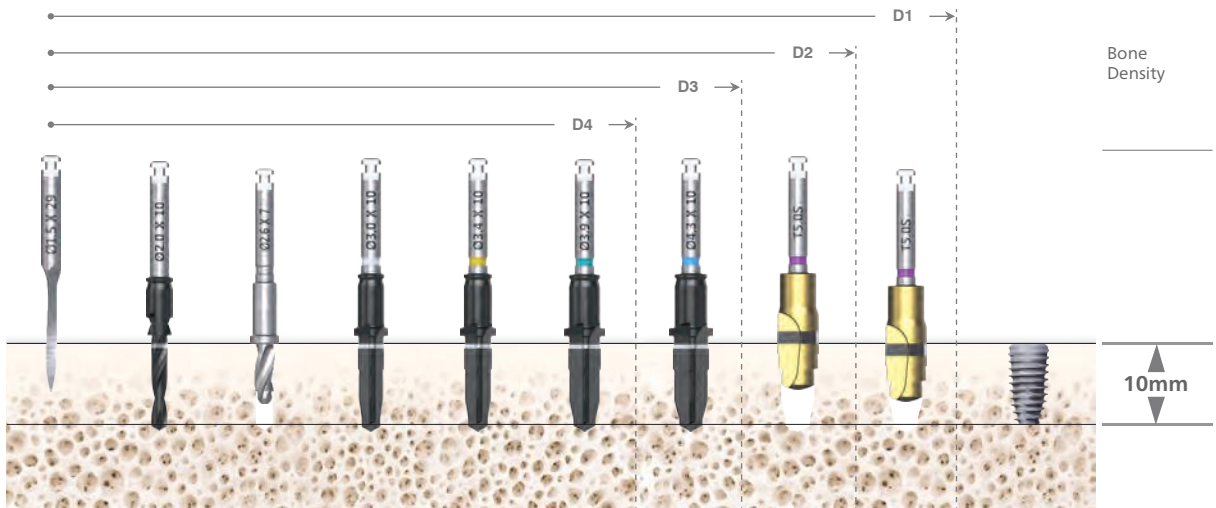
Implant Ø3.5 x 14.5mm

Point Drill	Initial Drill	Pilot Drill	Final Drill	Pilot Drill	
Ø1.5	Ø2.0	Ø2.6	Ø3.0	T3.5	T3.5
29	14.5	7	14.5	Long	Long



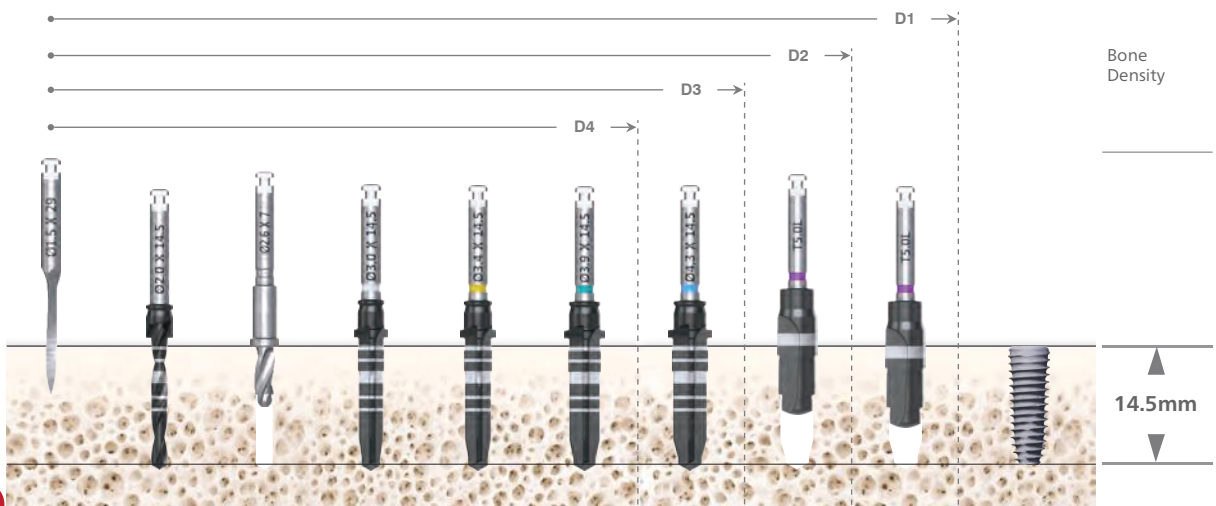
Implant Ø5.0 x 10mm

Point Drill	Initial Drill	Pilot Drill	Final Drill				Pilot Drill	
Ø1.5	Ø2.0	Ø2.6	Ø3.0	Ø3.4	Ø3.9	Ø4.3	T4.5	T4.5
29	10	7	10	10	10	10	Short	Short



Implant Ø5.0 x 14.5mm

Point Drill	Initial Drill	Pilot Drill	Final Drill				Pilot Drill	
Ø1.5	Ø2.0	Ø2.6	Ø3.0	Ø3.4	Ø3.9	Ø4.3	T5.0	T5.0
29	14.5	7	14.5	14.5	14.5	14.5	Long	Long



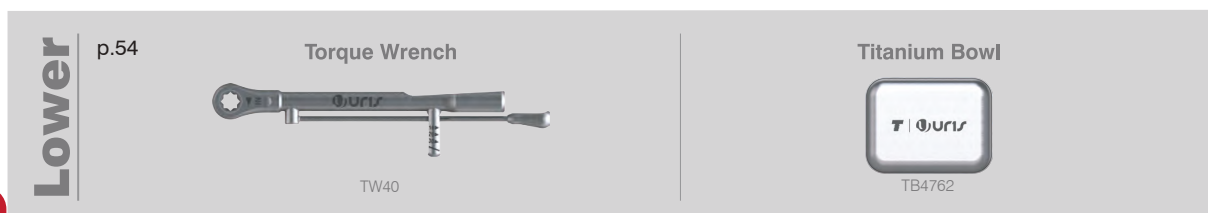
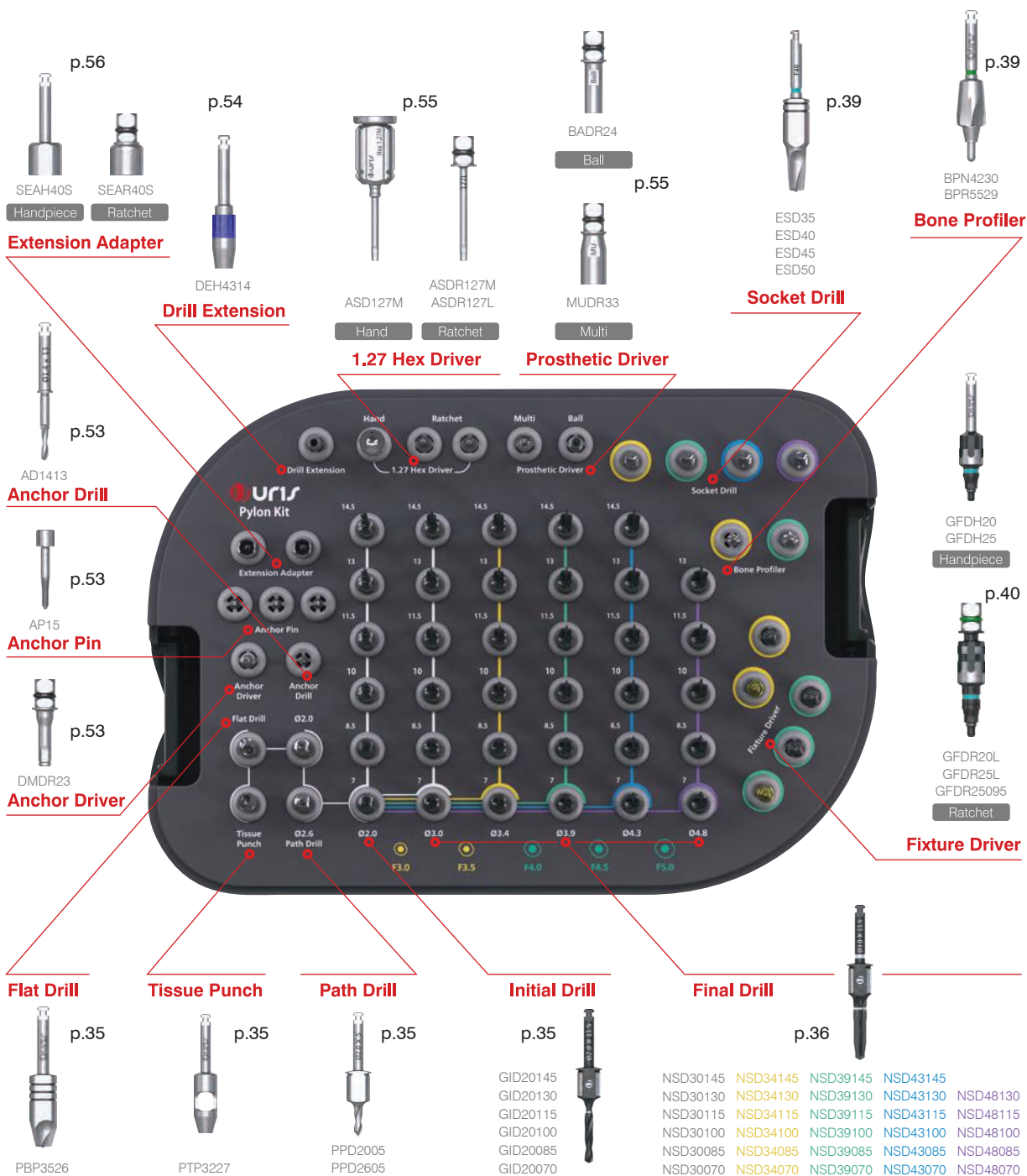


Surgical Guide Instruments

Pylon Kit



NKA 01



Surgical Guide Instruments

Pylon Plus Kit



PPK 01

p.35



PBP5027

Flat Drill 5.0

p.35



GID20160

GID20175

Initial Drill



Final Drill



NSD30175
NSD30160

NSD34175
NSD34160

NSD39175
NSD39160

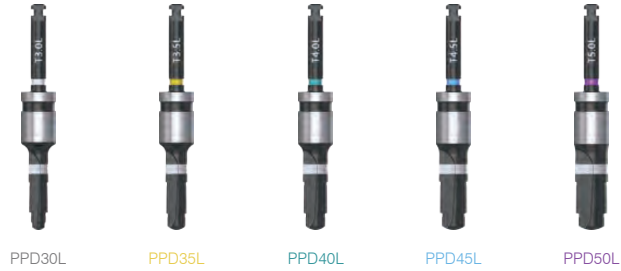
NSD43175
NSD43160

p.36

Tapered Pylon Kit

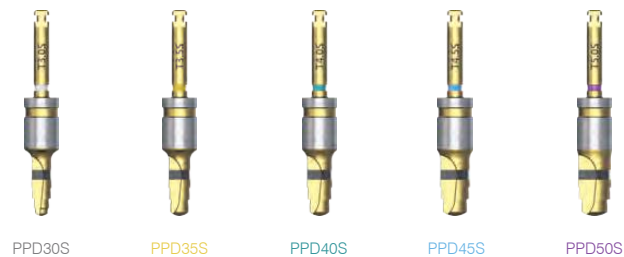


**Pilot Drill
Long Type**



p.20

**Pilot Drill
Short Type**

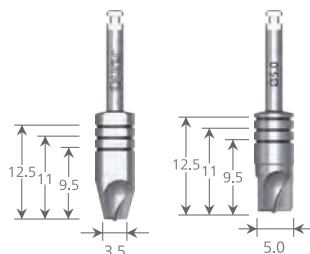




Flat Drill

Flattens out uneven bone and also removes remaining gingiva residue after tissue punching.

(Unit: mm)



PBP3526

PBP5027

Tissue Punch

Removes soft tissue during a flap-less surgery.

(Unit: mm)

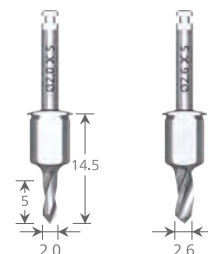


PTP3227

Path Drill

Increases the accuracy of the drilling path.

(Unit: mm)



PPD2005

PPD2605

Tissue Punch / Path Drill / Initial Drill

Low speed: 50~100 rpm; within 5 seconds with high torque | High speed: 800~1200 rpm (use irrigation)

Initial Drill

Expands the drilling path by the chosen fixture's length.

(Unit: mm)

Length 1	7.0	8.5	10.0	11.5	13.0	14.5	16.0	17.5
Length 2	17.0	18.5	20.0	21.5	23.0	24.5	26.0	27.5

D Ø2.0



GID20070

GID20085

GID20100

GID20115

GID20130

GID20145

GID20160

GID20175




Final Drill


Used as the last drill to place an URIS fixture and is selected according to the fixture diameter and bone density.

Low speed: 50~100 rpm; within 5 seconds with high torque

High speed: 800~1200 rpm (use irrigation)

(Unit: mm)

Length 1	7.0	8.5	10.0	11.5	13.0	14.5	16.0	17.5
Length 2	17.1	18.6	20.1	21.6	23.1	24.6	26.1	27.6
D Ø3.0								
	NSD30070	NSD30085	NSD30100	NSD30115	NSD30130	NSD30145	NSD30160	NSD30175

Length 1	7.0	8.5	10.0	11.5	13.0	14.5	16.0	17.5
Length 2	17.1	18.6	20.1	21.6	23.1	24.6	26.1	27.6
D Ø3.4								
	NSD34070	NSD34085	NSD34100	NSD34115	NSD34130	NSD34145	NSD34160	NSD34175

Length 1	7.0	8.5	10.0	11.5	13.0	14.5	16.0	17.5
Length 2	17.1	18.6	20.1	21.6	23.1	24.6	26.1	27.6

D Ø3.9



Length 1	7.0	8.5	10.0	11.5	13.0	14.5	16.0	17.5
Length 2	17.1	18.6	20.1	21.6	23.1	24.6	26.1	27.6

D Ø4.3



Length 1	7.0	8.5	10.0	11.5	13.0
Length 2	17.2	18.7	20.2	21.7	23.2

D Ø4.8





Pilot Drill

Used as the last drill to place an URIS Tapered fixture and is selected according to the Tapered fixture diameter and bone density.
 Low speed: 50~100 rpm; within 5 seconds with high torque
 High speed: 800~1200 rpm (use irrigation)

(Unit: mm)

Diameter

Ø3.0

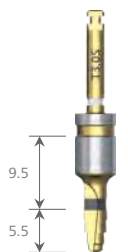
Ø3.5

Ø4.0

Ø4.5

Ø5.0

Short Type



PPD30S



PPD35S



PPD40S

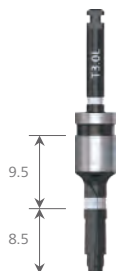


PPD45S



PPD50S

Long Type



PPD30L



PPD35L



PPD40L



PPD45L



PPD50L



Socket Drill

Cuts the ridge of the extracted site by the fixture's diameter size, preventing drill slippage caused by remaining bone residue.
800~1200 rpm

(Unit: mm)

Diameter

Ø3.5

Ø4.0

Ø4.5

Ø5.0



ESD35



ESD40



ESD45



ESD50

Bone Profiler

Contours the bone around the coronal aspect to facilitate full seating of the abutment after removing the surgical guide.
800~1200 rpm

(N)

(R)



BPN4230



BPR5529

Fixture Driver

A tool that delivers the fixture.

Handpiece

*Caution: Not recommended on hard bone. Do NOT torque over 25 Ncm and should not drill deeper than 6.5 mm.
Needs to be torqued with a ratchet driver as the final step.



GFDH20



GFDH25

Ratchet

Recommended Torque Value: 30 Ncm ~ 45 Ncm



GFDR20S



GFDR20L



GFDR25S



GFDR25L

Ratchet

Recommended Torque Value: 30 Ncm ~ 45 Ncm

Stopper



GFDR20095



GFDR20110



GFDR20125



GFDR25095



GFDR25110



GFDR25125

Sleeve



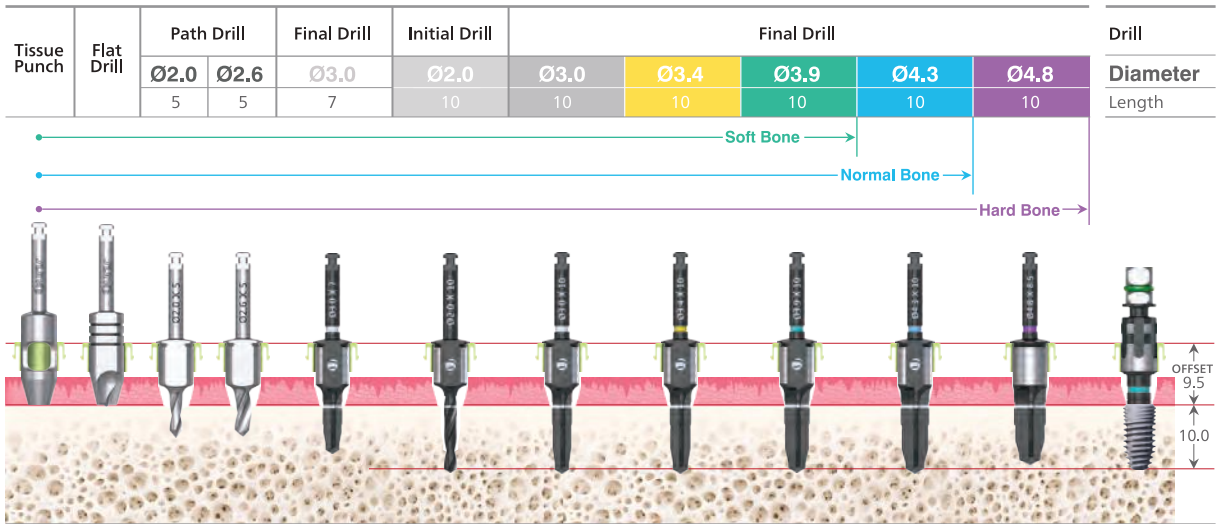
NS53GR

OMNI Fixture

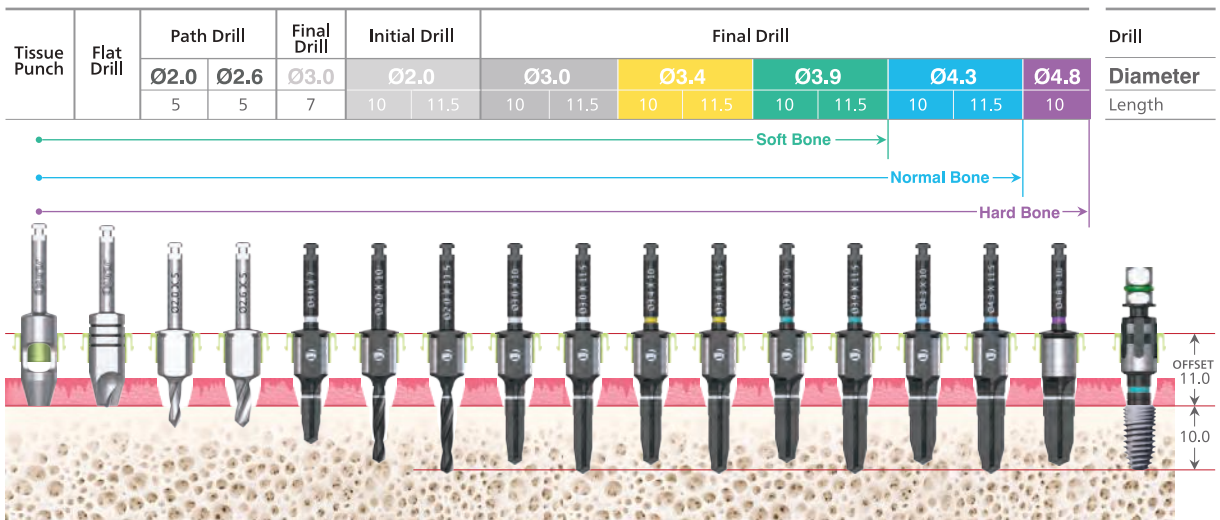
Guided Surgery Drilling Protocol

Implant Ø5.0 x 10.0mm

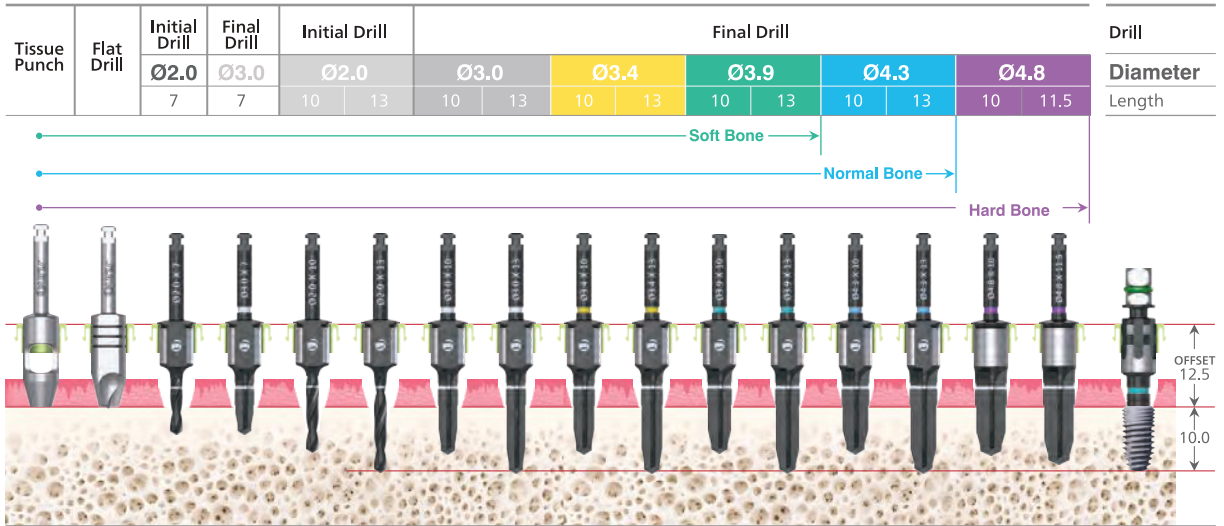
Guide Sleeve Offset 9.5



Guide Sleeve Offset 11.0



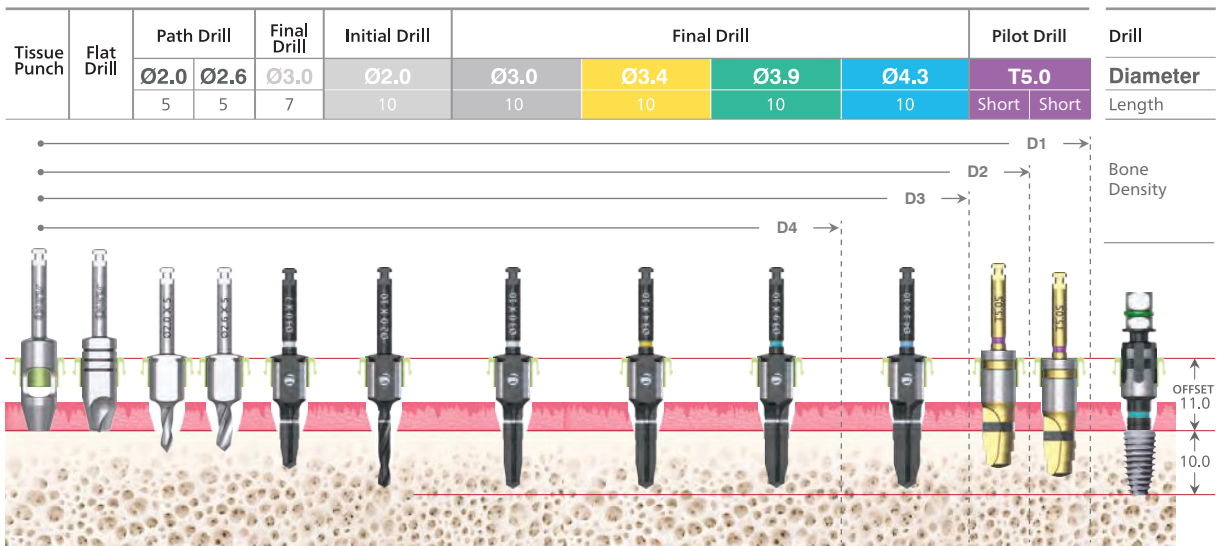
Guide Sleeve Offset 12.5



OMNI Tapered Fixture

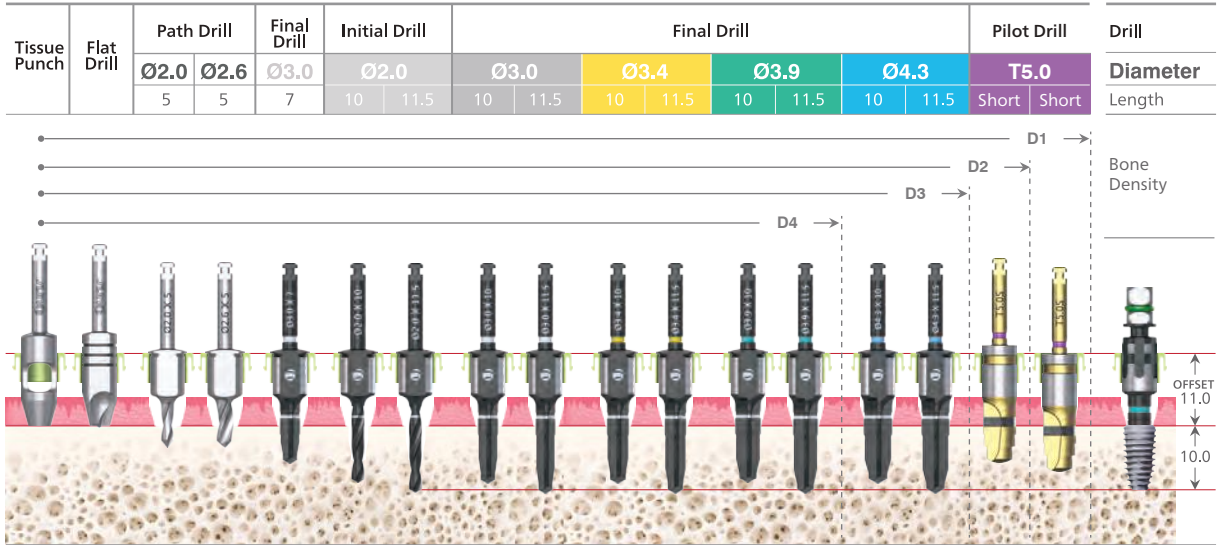
Guided Surgery Drilling Protocol

Guide Sleeve Offset 9.5

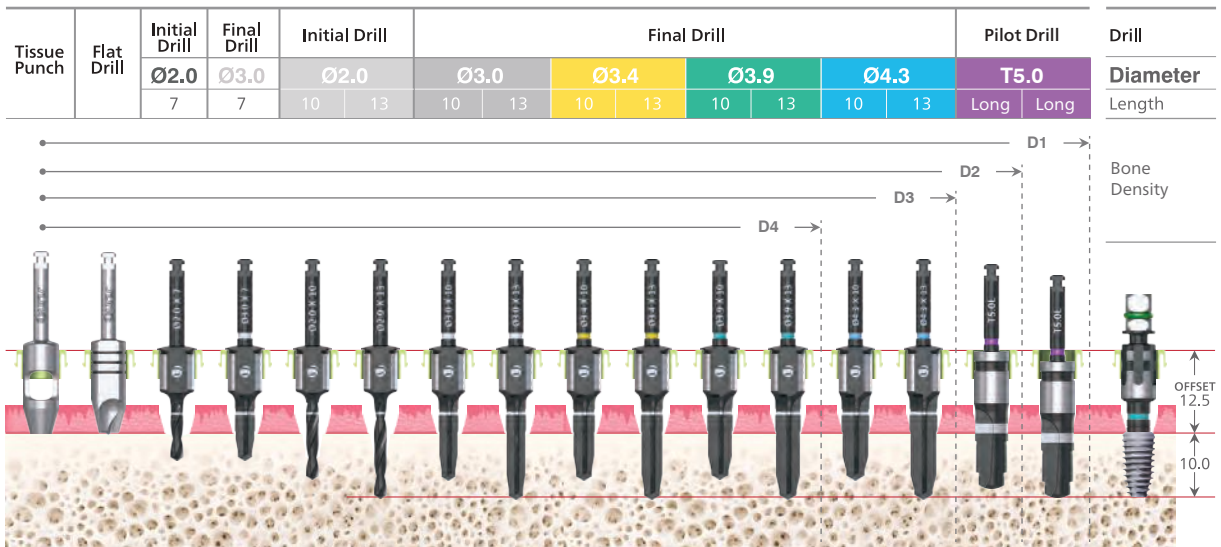


Implant Ø5.0 x 10.0mm

Guide Sleeve Offset 11.0



Guide Sleeve Offset 12.5





Surgical Guide Instruments

Pylon Crestal Sinus Kit





PSK 01



Initial Drill

Enlarges the osteotomy site. Do NOT drill deeper than 0.5~1.0 mm directly below the maxillary sinus floor.
 Low speed: 50~100 rpm; within 5 seconds with high torque
 High speed: 800~1200 rpm (use irrigation)

(Unit: mm)

Length	12.0	13.0	14.0	15.0	16.0
D Ø2.0					
	PSID20120	PSID20130	PSID20140	PSID20150	PSID20160

Step Drill

Used after the D2.0 initial drill to enlarge the osteotomy site. Do NOT drill deeper than 0.5~1.0 mm directly below the maxillary sinus floor.
 Low speed: 50~100 rpm; within 5 seconds with high torque
 High speed: 800~1200 rpm (use irrigation)

(Unit: mm)

Length	12.0	13.0	14.0	15.0	16.0
D Ø2.7					
	PSMD27120	PSMD27130	PSMD27140	PSMD27150	PSMD27160










Sinus Drill

Used to approach the sinus membrane and should drill 1~2 mm deeper than the step drill.

Low speed: 50~100 rpm; within 5 seconds with high torque (*Drill while applying pressure)

High speed: PROHIBITED

(Unit: mm)





Length	13.0	14.0	15.0	16.0	17.0	18.0	21.0
D Ø3.2							
							
	PSRD32130	PSRD32140	PSRD32150	PSRD32160	PSRD32170	PSRD32180	PSRD32210

Final Drill

Used with a surgical guide after bone grafting.

Low speed: 50~100 rpm; within 5 seconds with high torque

(Unit: mm)

Length	15.5	18.0	Length	15.5	18.0
D Ø3.9			D Ø4.3		
					
	PSFD39155	PSFD39180		PSFD43155	PSFD43180



Membrane Elevator **Carrier**

Delivers the membrane elevator.
Needs to be engaged onto a handle.



PHME6537

Membrane **Elevator**

Lifts sinus membrane with hydraulic pressure.
Needs to be engaged onto a carrier.



PSME8027

Membrane Elevator **Tube**

A transparent silicon tube.
Outer D4.0/Inner D2.0/Length 300 mm | Autoclave before use | Single use only



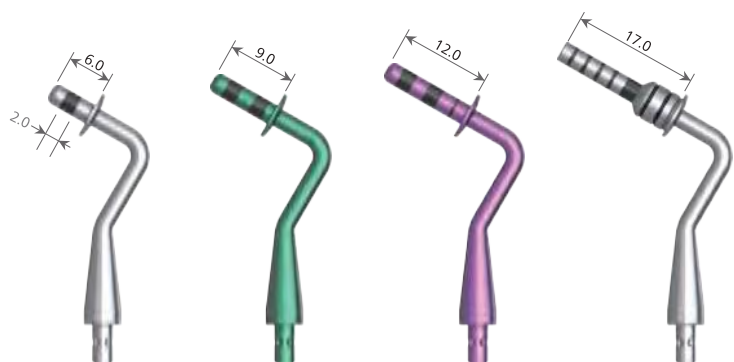
PSMET00



Bone Condenser

Inserts bone graft materials into inferior wall once the wall is completely opened.
Used after removing the surgical guide.

(Unit: mm)



PSBC28060

PSBC28090

PSBC28120

PSBC28170

Depth Gauge

Measures depth with measurement markings at the tip.

(Unit: mm)



PSDG28195

Bone Condenser Handle

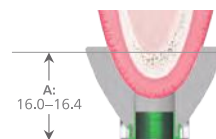


PSBC9095

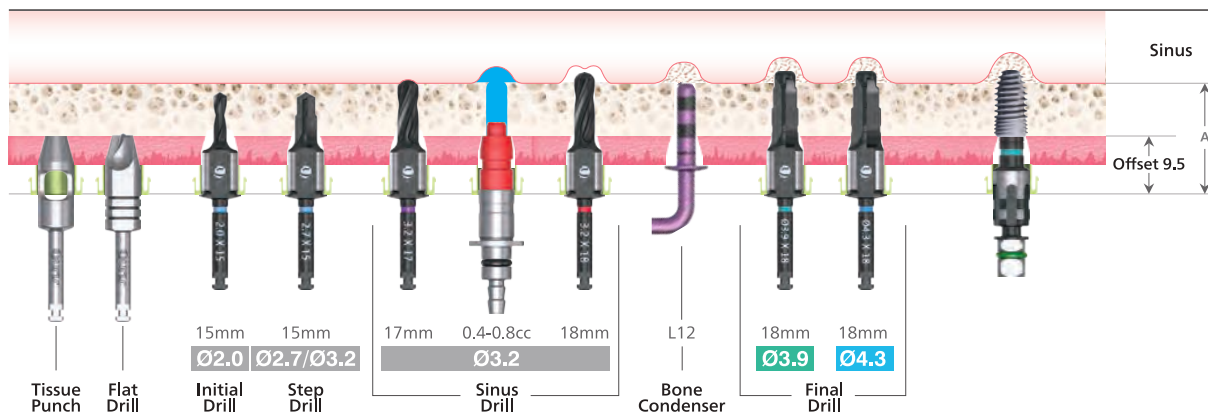
Pylon Crestal Sinus Kit

Guide Drilling Protocol

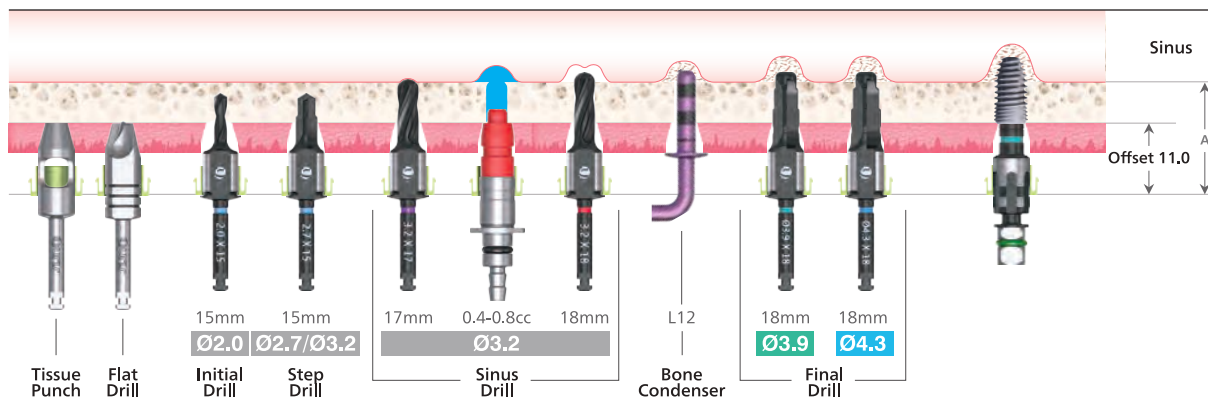
Implant Ø5.0



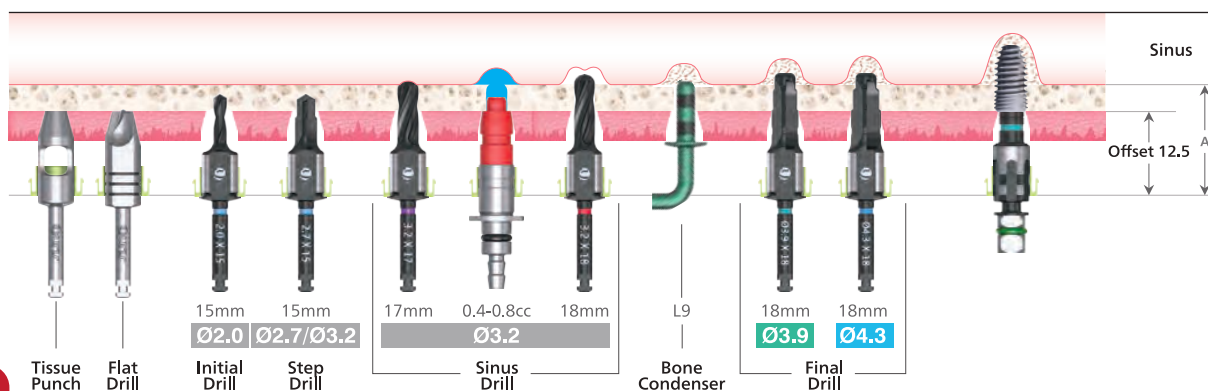
Guide Sleeve Offset 9.5



Guide Sleeve Offset 11.0



Guide Sleeve Offset 12.5



Pylon Anchor Kit



PAK 01

p.53



PAI2007

Fixation Pin

p.53



PADH23

Anchor Driver



Fixation Screw



p.53



PAF095N



PAF110N



PAF125N



PAF095R



PAF110R



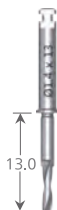
PAF125R



Anchor Drill

Drills a hole on the bone for the anchor pin.

(Unit: mm)



AD1413

Anchor Pin

Holds the surgical guide onto the bone. Mostly used in an edentulous case.

(Unit: mm)

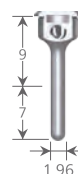


AP15

Fixation Pin

Holds the surgical guide after the 2.0 drill before the fixture delivery.

(Unit: mm)



PAI2007

Fixation Screw

Holds the surgical guide after the fixture delivery.

(Unit: mm)

Offset

9.5

11.0

12.5



PAF095N



PAF110N



PAF125N



PAF095R



PAF110R



PAF125R

Anchor Driver

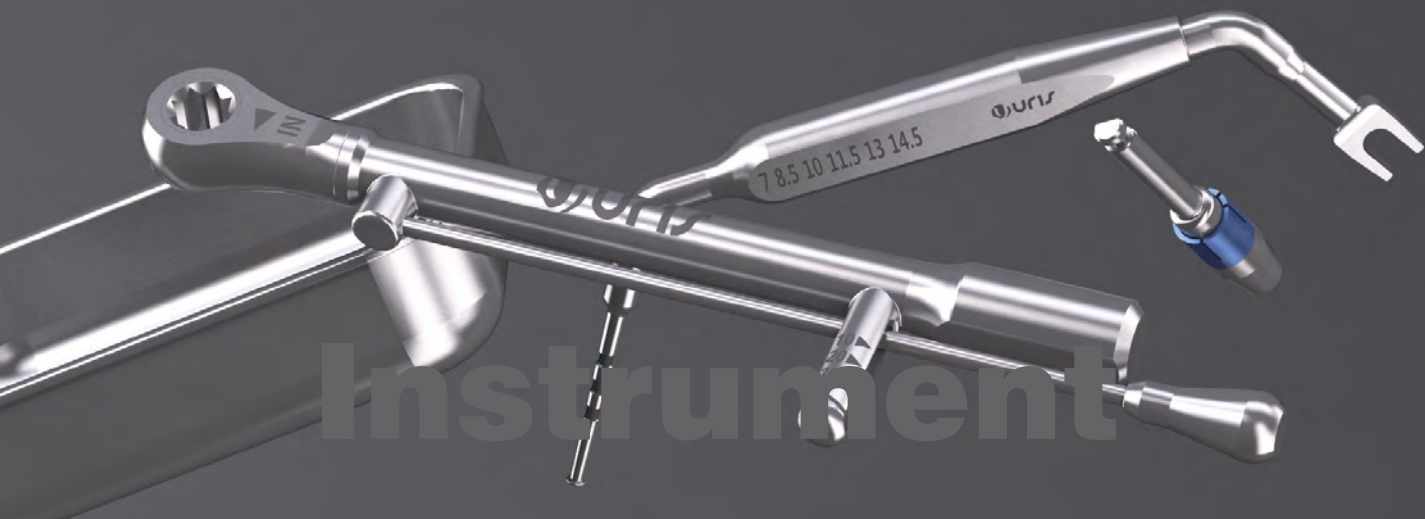
Tightens down the anchor pin.



Ratchet
DMDR23



Hand
PADH23



Drill **Extension**



DEH4314

Torque **Wrench**



TW40

Depth **Gauge**

Measures the depth of a drilling hole.



DGMW75

Titanium **Bowl**



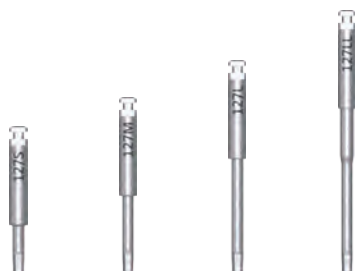
TB4762



1.27 Hex Driver

*Caution: Must be properly engaged and used at the recommended torque value.

Handpiece



ASDH127S ASDH127M ASDH127L ASDH127LL

Ratchet



ASDR127S ASDR127M ASDR127L ASDR127LL

Hand



ASD127M ASD127L

Ball Driver

Compatible
with
Ball abutments.



BADR24

Multi-Unit Driver

Compatible
with Straight
Multi-Unit abutments.



MUDR33

T:LOC Straight Driver

Compatible
with
TLOC abutments.



TLC-TLSD13

Angulated Screw Channel

Driver

***Caution:**
Must be properly engaged and torqued at the recommended torque value of 20~25 Ncm within 25°.

Handpiece



AADH135S AADH135M AADH135L

Ratchet



AA DR135S AADR135M AADR135L

Hand



ASD135M ASD135L

Removal

Driver

Used to remove the abutment off of the fixture. Must be inserted upright and tightened clockwise.



RDR16S



RDR16L



RDR20S



RDR20L

Extension

Adapter

Extends the instrument's length.

(Unit: mm)

Handpiece



SEAH40S



SEAH40L

Ratchet



SEAR40S

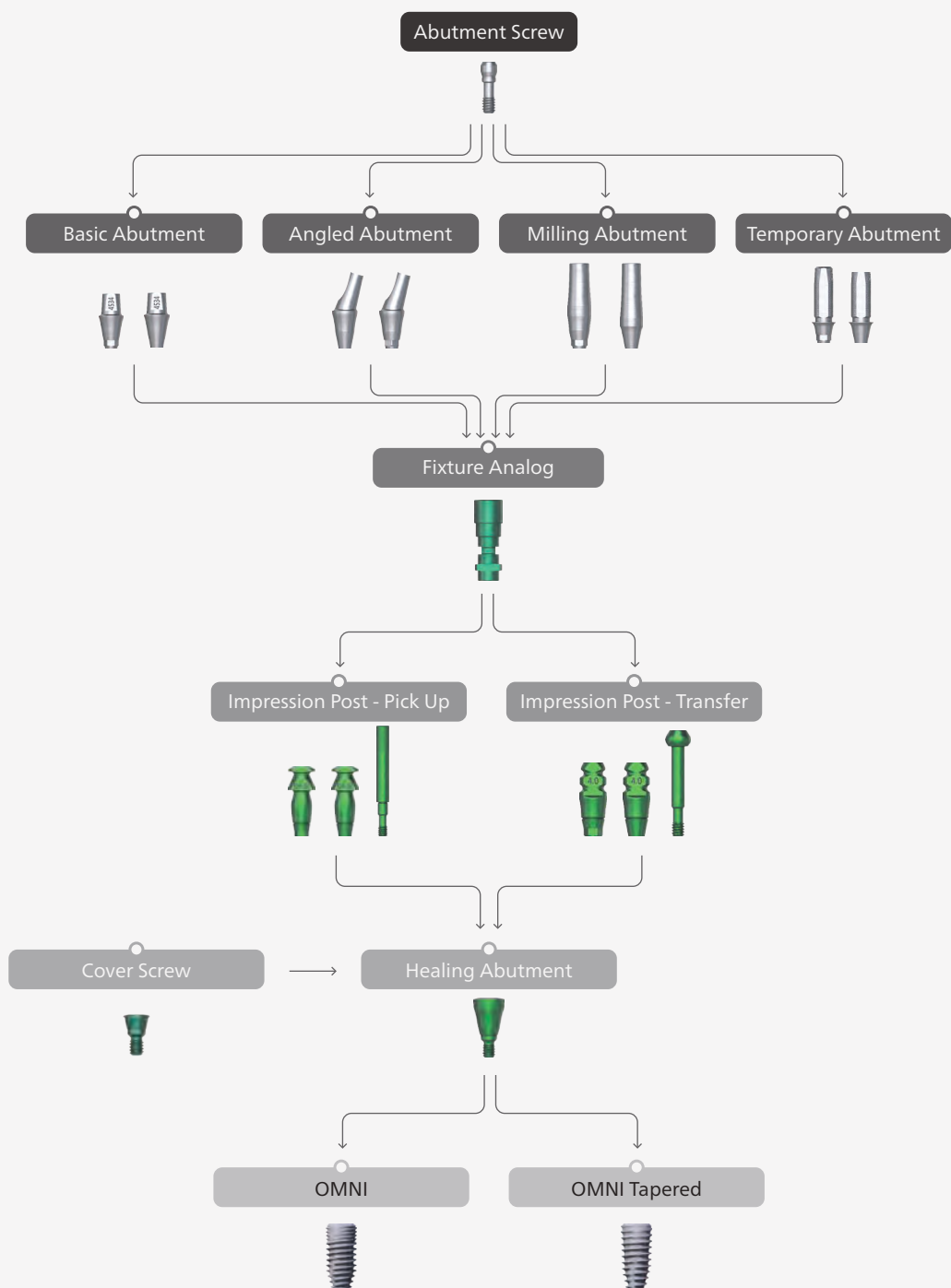


SEAR40L

Prosthetics

Fixture Level Impression

Flowchart



Basic Abutment

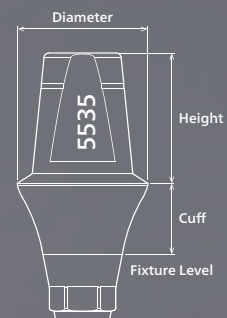
Hex Type

Hex driver : 1.27

Torque: Narrow[20 Ncm]/Regular[30 Ncm]

Packing unit : Basic Abutment_Hex Type + Abutment Screw







Order Code : ex) UDA 5534H









Basic Abutment






(Unit: mm)















Cuff		1.0	2.0	3.0	4.0	5.0	6.0
D Ø4.0							
							
Height	4.0	UDAN4014H	UDAN4024H	UDAN4034H	UDAN4044H	UDAN4054H	UDAN4064H
	5.5	UDAN4015H	UDAN4025H	UDAN4035H	UDAN4045H	UDAN4055H	UDAN4065H
	7.0	UDAN4017H	UDAN4027H	UDAN4037H	UDAN4047H	UDAN4057H	UDAN4067H

Cuff		1.0	2.0	3.0	4.0	5.0	6.0
D Ø4.5							
							
Height	4.0	UDAN4514H	UDAN4524H	UDAN4534H	UDAN4544H	UDAN4554H	UDAN4564H
	5.5	UDAN4515H	UDAN4525H	UDAN4535H	UDAN4545H	UDAN4555H	UDAN4565H
	7.0	UDAN4517H	UDAN4527H	UDAN4537H	UDAN4547H	UDAN4557H	UDAN4567H



Cuff		1.0	2.0	3.0	4.0	5.0	6.0
D Ø4.5							
							
Height	4.0	UDA4514H	UDA4524H	UDA4534H	UDA4544H	UDA4554H	UDA4564H
	5.5	UDA4515H	UDA4525H	UDA4535H	UDA4545H	UDA4555H	UDA4565H
	7.0	UDA4517H	UDA4527H	UDA4537H	UDA4547H	UDA4557H	UDA4567H

Cuff	1.0	2.0	3.0	4.0	5.0	6.0	
D Ø5.5							
							
Height	4.0	UDA5514H	UDA5524H	UDA5534H	UDA5544H	UDA5554H	UDA5564H
	5.5	UDA5515H	UDA5525H	UDA5535H	UDA5545H	UDA5555H	UDA5565H
	7.0	UDA5517H	UDA5527H	UDA5537H	UDA5547H	UDA5557H	UDA5567H
Cuff	1.0	2.0	3.0	4.0	5.0	6.0	
D Ø6.5							
							
Height	4.0	UDA6514H	UDA6524H	UDA6534H	UDA6544H	UDA6554H	UDA6564H
	5.5	UDA6515H	UDA6525H	UDA6535H	UDA6545H	UDA6555H	UDA6565H
	7.0	UDA6517H	UDA6527H	UDA6537H	UDA6547H	UDA6557H	UDA6567H

Basic Abutment

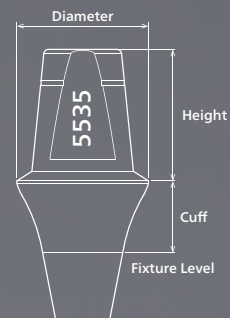
Non Hex Type

Hex driver : 1.27

Torque: Narrow[20 Ncm]/Regular[30 Ncm]

Packing unit : Basic Abutment_Non Hex Type + Abutment Screw







Order Code : ex) UDA 5534N









Basic Abutment

(Unit: mm)





Cuff		1.0	2.0	3.0	4.0	5.0	6.0
D Ø4.0							
Height	4.0	UDAN4014N	UDAN4024N	UDAN4034N	UDAN4044N	UDAN4054N	UDAN4064N
	5.5	UDAN4015N	UDAN4025N	UDAN4035N	UDAN4045N	UDAN4055N	UDAN4065N
	7.0	UDAN4017N	UDAN4027N	UDAN4037N	UDAN4047N	UDAN4057N	UDAN4067N

Cuff	1.0	2.0	3.0	4.0	5.0	6.0	
D Ø4.5							
Height	4.0	UDAN4514N	UDAN4524N	UDAN4534N	UDAN4544N	UDAN4554N	UDAN4564N
	5.5	UDAN4515N	UDAN4525N	UDAN4535N	UDAN4545N	UDAN4555N	UDAN4565N
	7.0	UDAN4517N	UDAN4527N	UDAN4537N	UDAN4547N	UDAN4557N	UDAN4567N



Cuff	1.0	2.0	3.0	4.0	5.0	6.0	
D Ø4.5							
Height	4.0	UDA4514N	UDA4524N	UDA4534N	UDA4544N	UDA4554N	UDA4564N
	5.5	UDA4515N	UDA4525N	UDA4535N	UDA4545N	UDA4555N	UDA4565N
	7.0	UDA4517N	UDA4527N	UDA4537N	UDA4547N	UDA4557N	UDA4567N

Cuff		1.0	2.0	3.0	4.0	5.0	6.0
D Ø5.5							
Height	4.0	UDA5514N	UDA5524N	UDA5534N	UDA5544N	UDA5554N	UDA5564N
	5.5	UDA5515N	UDA5525N	UDA5535N	UDA5545N	UDA5555N	UDA5565N
	7.0	UDA5517N	UDA5527N	UDA5537N	UDA5547N	UDA5557N	UDA5567N

Cuff		1.0	2.0	3.0	4.0	5.0	6.0
D Ø6.5							
Height	4.0	UDA6514N	UDA6524N	UDA6534N	UDA6544N	UDA6554N	UDA6564N
	5.5	UDA6515N	UDA6525N	UDA6535N	UDA6545N	UDA6555N	UDA6565N
	7.0	UDA6517N	UDA6527N	UDA6537N	UDA6547N	UDA6557N	UDA6567N

Impression

Post

Pick Up Type

Hex driver : 1.27

Packing unit : Impression Post_Pick Up Type + Screw

Order Code : ex) UIPP 4511H

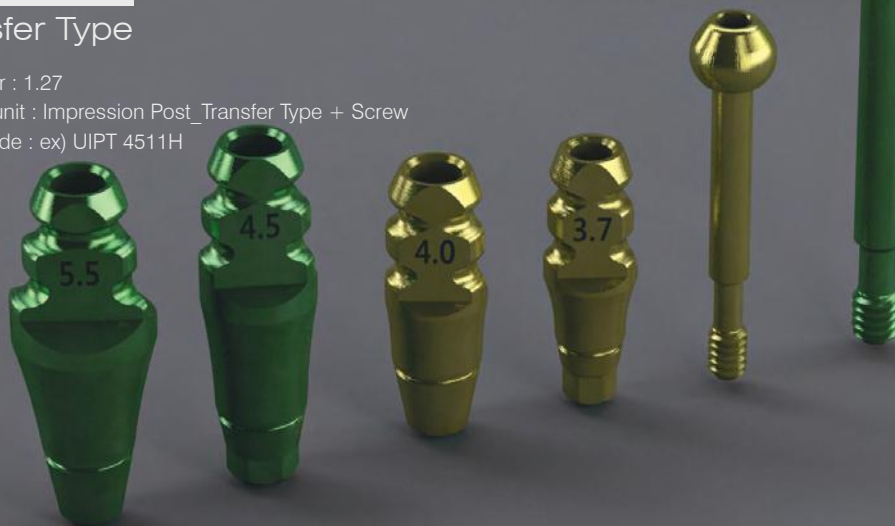


Transfer Type

Hex driver : 1.27

Packing unit : Impression Post_Transfer Type + Screw

Order Code : ex) UIPT 4511H



Fixture

Analog



Impression

Post

Pick Up Type

(Unit: mm)

N

Height

11.0

15.0

D Ø3.7

Hex

Non-Hex

Hex

Non-Hex



UIPPN3711H



UIPPN3711N



UIPPN3715H



UIPPN3715N

R

Height

11.0

15.0

Hex

Non-Hex

Hex

Non-Hex



UIPP4011H



UIPP4011N



UIPP4015H



UIPP4015N

D Ø4.0

D Ø4.5

D Ø5.5

UIPP4511H

UIPP4511N

UIPP4515H

UIPP4515N

UIPP5511H

UIPP5511N

UIPP5515H

UIPP5515N

Impression

Post

Transfer Type

(Unit: mm)

N

Height

11.0

15.0

D Ø3.7

Hex



UIPTN3711H

Non-Hex



UIPTN3711N

Hex



UIPTN3714H

Non-Hex



UIPTN3714N

R

Height

11.0

15.0

Hex



UIPT4011H

Non-Hex



UIPT4011N

Hex



UIPT4014H

Non-Hex



UIPT4014N

D Ø4.0

D Ø4.5

D Ø5.5

UIPT4511H

UIPT5511H

UIPT4511N

UIPT5511N

UIPT4514H

UIPT5514H

UIPT4514N

UIPT5514N

Fixture

Analog

N



UDAG35

R



UDAG40

Angled Abutment 17°

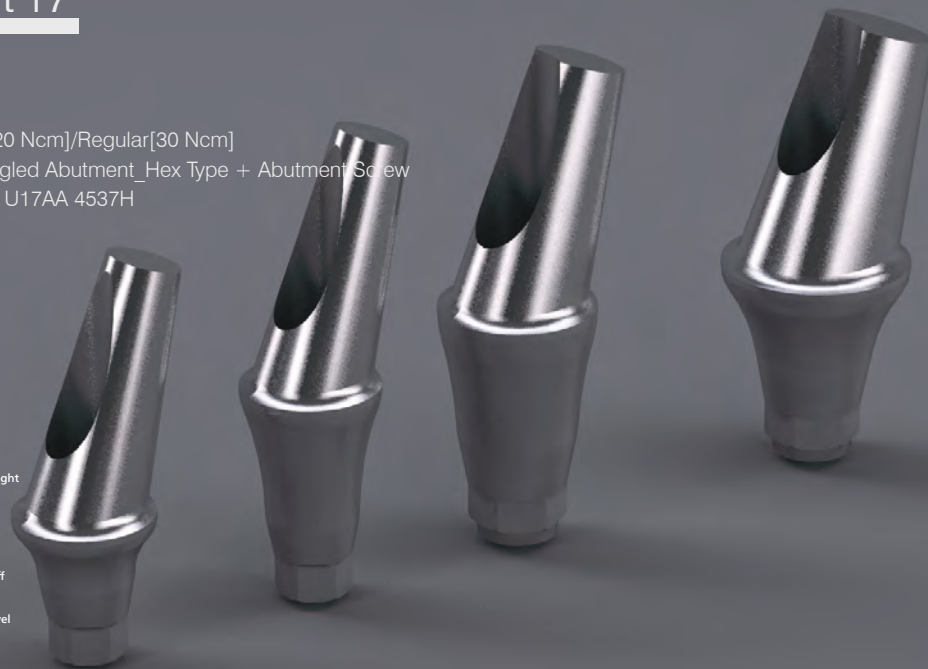
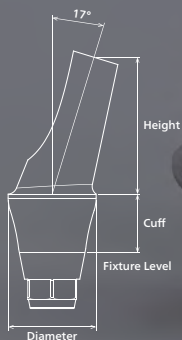
Hex Type

Hex driver : 1.27

Torque: Narrow[20 Ncm]/Regular[30 Ncm]

Packing unit : Angled Abutment_Hex Type + Abutment Screw

Order Code : ex) U17AA 4537H



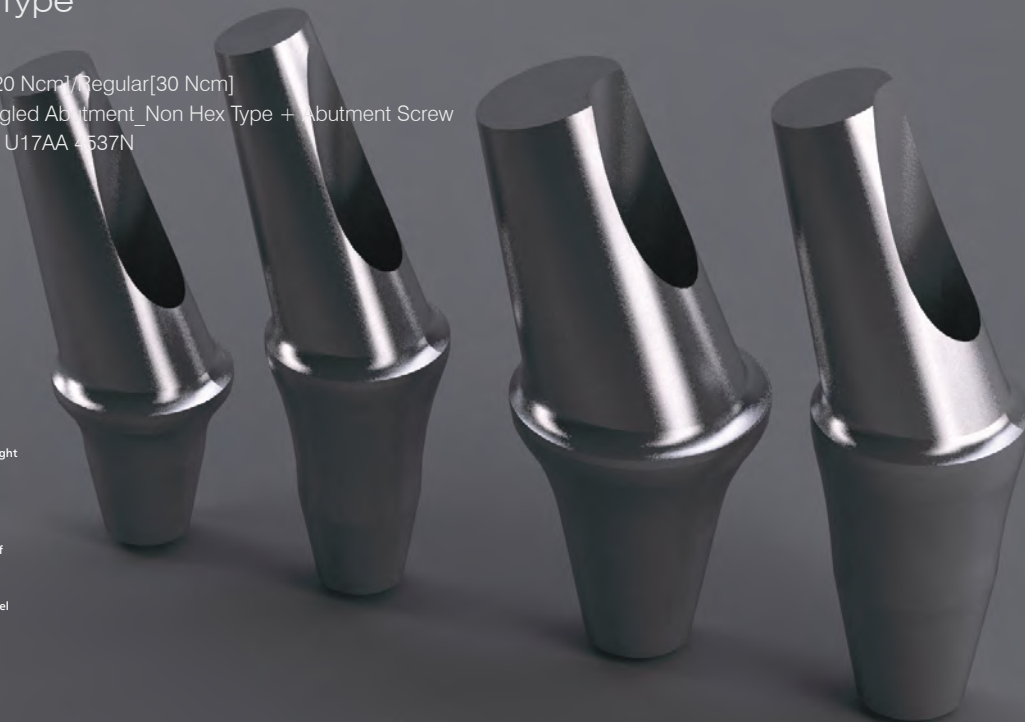
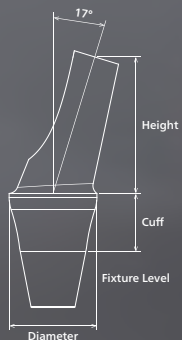
Non Hex Type

Hex driver : 1.27

Torque: Narrow[20 Ncm]/Regular[30 Ncm]

Packing unit : Angled Abutment_Non Hex Type + Abutment Screw

Order Code : ex) U17AA 4537N



Angled Abutment 17°

(Unit: mm)



(Bottom View / Scale 1:2.5)



Cuff	2.0	3.0	4.0	5.0
D Ø4.0				
				
	U17AAN 4027H	U17AAN 4037H	U17AAN 4047H	U17AAN 4057H



Cuff	2.0	3.0	4.0	5.0
D Ø4.5				
				
	U17AA 4527H	U17AA 4537H	U17AA 4547H	U17AA 4557H

Cuff	2.0	3.0	4.0	5.0
D Ø5.5				
				
	U17AA 5527H	U17AA 5537H	U17AA 5547H	U17AA 5557H

N

Cuff	2.0	3.0	4.0	5.0
D Ø4.0				
				
	U17AAN 4027N	U17AAN 4037N	U17AAN 4047N	U17AAN 4057N

R

Cuff	2.0	3.0	4.0	5.0
D Ø4.5				
				
	U17AA 4527N	U17AA 4537N	U17AA 4547N	U17AA 4557N

Cuff	2.0	3.0	4.0	5.0
D Ø5.5				
				
	U17AA 5527N	U17AA 5537N	U17AA 5547N	U17AA 5557N

Milling Abutment

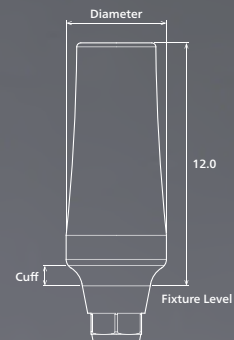
Hex Type

Hex driver : 1.27

Torque: Narrow[20 Ncm]/Regular[30 Ncm]

Packing unit : Milling Abutment_Hex Type + Abutment Screw

Order Code : ex) UMI 5010H



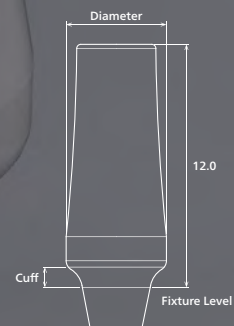
Non Hex Type

Hex driver : 1.27

Torque: Narrow[20 Ncm]/Regular[30 Ncm]

Packing unit : Milling Abutment_Non Hex Type + Abutment Screw

Order Code : ex) UMI 5010N





Milling



Abutment

(Unit: mm)





Cuff	1.0	3.0
D Ø4.0		
	UMIN 4010H	UMIN 4030H







Cuff	1.0	3.0
D Ø4.0		
	UMIN 4010N	UMIN 4030N





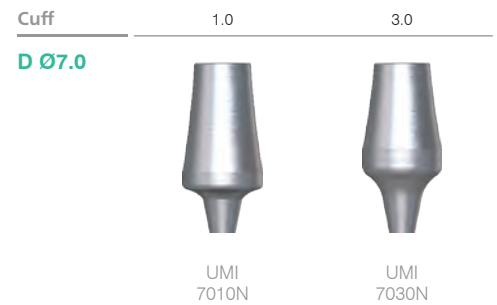
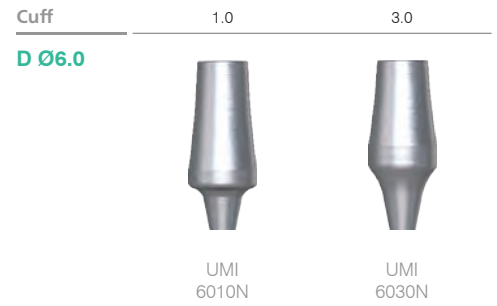
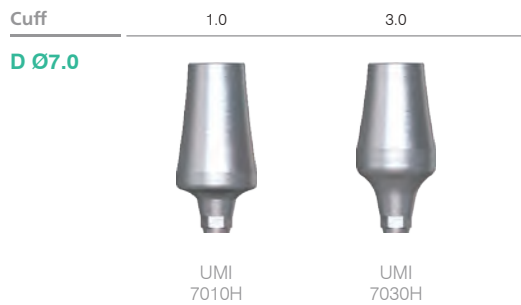
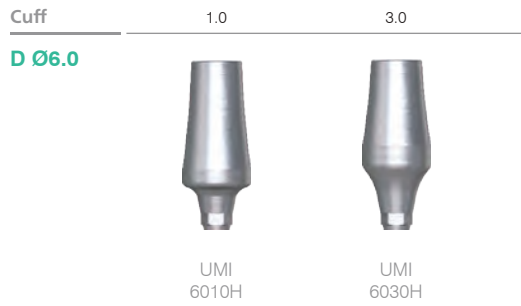
Cuff	1.0	3.0
D Ø4.0		
	UMI 4010H	UMI 4030H



Cuff	1.0	3.0
D Ø4.0		
	UMI 4010N	UMI 4030N

Cuff	1.0	3.0
D Ø5.0		
	UMI 5010H	UMI 5030H

Cuff	1.0	3.0
D Ø5.0		
	UMI 5010N	UMI 5030N



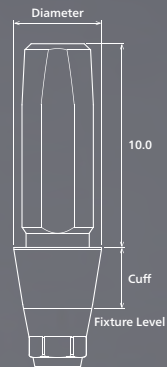
Temporary Abutment

Hex driver : 1.27

Torque: 20 Ncm

Packing unit : Temporary Abutment + Abutment Screw

Order Code : ex) UTA 4310H





Temporary



Abutment

(Unit: mm)





Cuff	1.0	3.0
D Ø3.7		
		
UTAN 3710H		UTAN 3730H





Cuff	1.0	3.0
D Ø3.7		
		
UTAN 3710N		UTAN 3730N



Cuff	1.0	3.0
D Ø4.3		
		
UTA 4310H		UTA 4330H



Cuff	1.0	3.0
D Ø4.3		
		
UTA 4310N		UTA 4330N

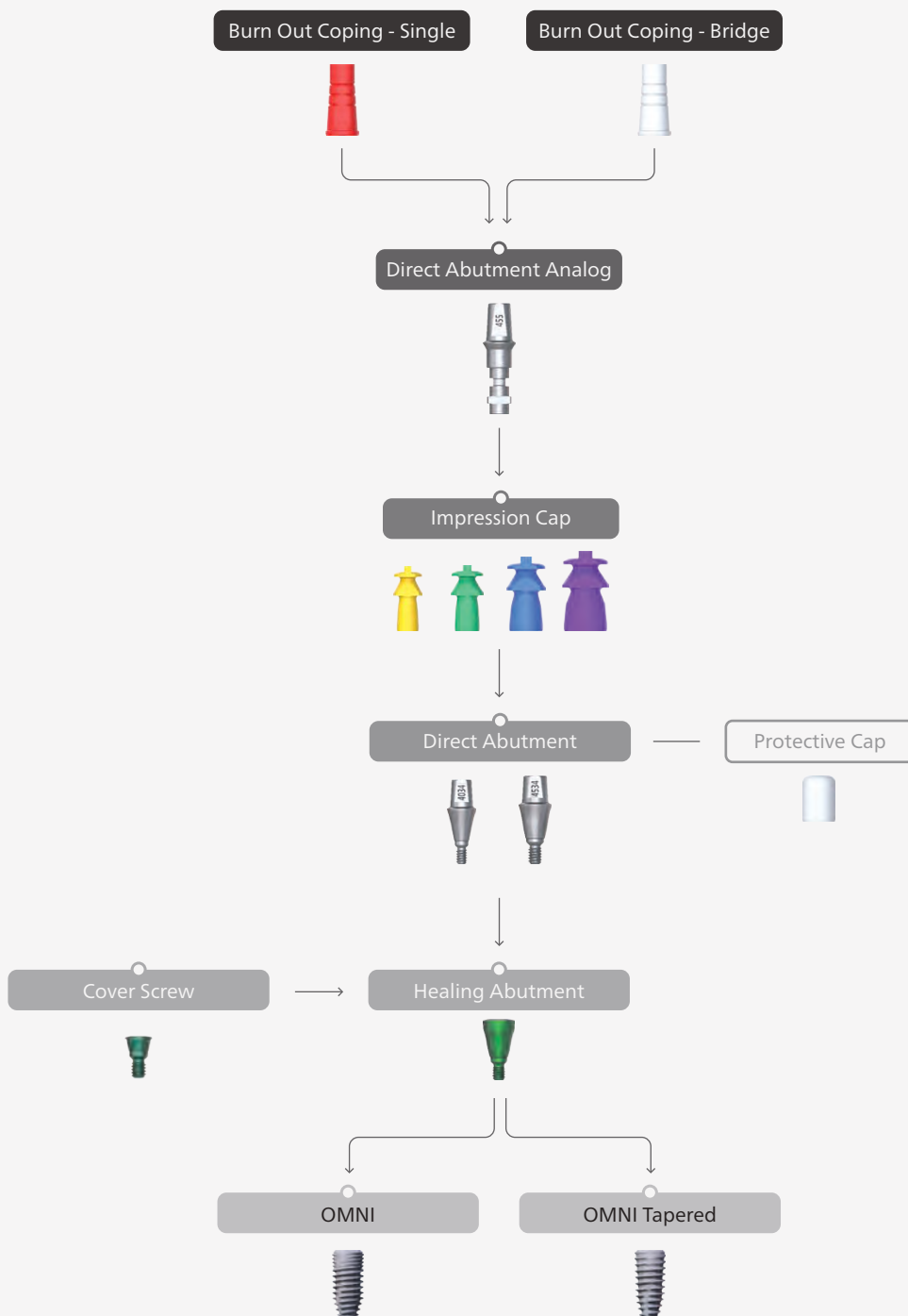
Abutment

Screw

	
UAS16H	UAS20H

Abutment Level Impression

Flowchart



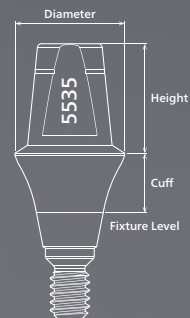
Direct Abutment

Hex driver : 1.27

Torque: Narrow[20 Ncm]/Regular[30 Ncm]

Packing unit : Direct Abutment







Order Code : ex) UDA 5534









Direct Abutment







(Unit: mm)















Cuff	1.0	2.0	3.0	4.0	5.0	6.0	
D Ø4.0							
							
Height	4.0	UDAN4014	UDAN4024	UDAN4034	UDAN4044	UDAN4054	UDAN4064
	5.5	UDAN4015	UDAN4025	UDAN4035	UDAN4045	UDAN4055	UDAN4065
	7.0	UDAN4017	UDAN4027	UDAN4037	UDAN4047	UDAN4057	UDAN4067

Cuff	1.0	2.0	3.0	4.0	5.0	6.0	
D Ø4.5							
							
Height	4.0	UDAN4514	UDAN4524	UDAN4534	UDAN4544	UDAN4554	UDAN4564
	5.5	UDAN4515	UDAN4525	UDAN4535	UDAN4545	UDAN4555	UDAN4565
	7.0	UDAN4517	UDAN4527	UDAN4537	UDAN4547	UDAN4557	UDAN4567



Cuff	1.0	2.0	3.0	4.0	5.0	6.0	
D Ø4.5							
							
Height	4.0	UDA4514	UDA4524	UDA4534	UDA4544	UDA4554	UDA4564
	5.5	UDA4515	UDA4525	UDA4535	UDA4545	UDA4555	UDA4565
	7.0	UDA4517	UDA4527	UDA4537	UDA4547	UDA4557	UDA4567

Cuff	1.0	2.0	3.0	4.0	5.0	6.0	
D Ø5.5							
							
Height	4.0	UDA5514	UDA5524	UDA5534	UDA5544	UDA5554	UDA5564
	5.5	UDA5515	UDA5525	UDA5535	UDA5545	UDA5555	UDA5565
	7.0	UDA5517	UDA5527	UDA5537	UDA5547	UDA5557	UDA5567

Cuff	1.0	2.0	3.0	4.0	5.0	6.0	
D Ø6.5							
							
Height	4.0	UDA6514	UDA6524	UDA6534	UDA6544	UDA6554	UDA6564
	5.5	UDA6515	UDA6525	UDA6535	UDA6545	UDA6555	UDA6565
	7.0	UDA6517	UDA6527	UDA6537	UDA6547	UDA6557	UDA6567

Protective Cap



Impression Cap









Burn Out Coping









Protective Cap

(Unit: mm)

Height	4.0	5.5	7.0
D Ø4.0			
	UDAC4004	UDAC4005	UDAC4007

Height	4.0	5.5	7.0
D Ø4.5			
	UDAC4504	UDAC4505	UDAC4507

Height	4.0	5.5	7.0
D Ø5.5			
	UDAC5504	UDAC5505	UDAC5507

Height	4.0	5.5	7.0
D Ø6.5			
	UDAC6504	UDAC6505	UDAC6507

Impression

Cap

(Unit: mm)

Diameter

Ø4.0

Ø4.5

Ø5.5

Ø6.5



UDAIC40



UDAIC45



UDAIC55



UDAIC65

Burn Out

Coping

(Unit: mm)

Single

Ø4.0

Ø4.5

Ø5.5

Ø6.5



UDABC40S



UDABC45S



UDABC55S



UDABC65S

Bridge

Ø4.0

Ø4.5

Ø5.5

Ø6.5



UDABC40B



UDABC45B



UDABC55B



UDABC65B

Direct Abutment

Analog



Direct Abutment

Analog

(Unit: mm)

Height	4.0	5.5	7.0
D Ø4.0	 <p>UDAG404</p>	 <p>UDAG405</p>	 <p>UDAG407</p>

Height	4.0	5.5	7.0
D Ø4.5	 <p>UDAG454</p>	 <p>UDAG455</p>	 <p>UDAG457</p>

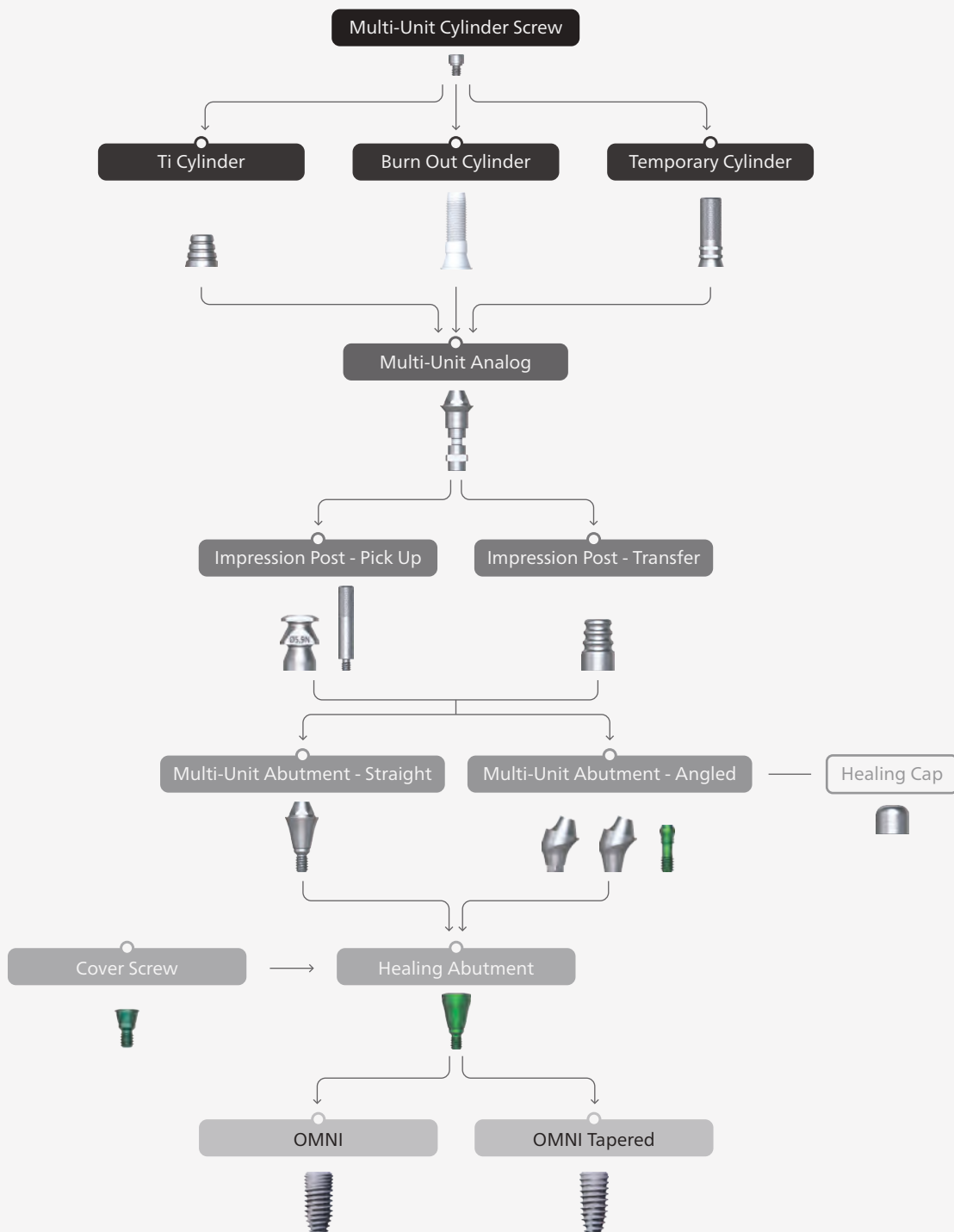
Height	4.0	5.5	7.0
D Ø5.5	 <p>UDAG554</p>	 <p>UDAG555</p>	 <p>UDAG557</p>

Height	4.0	5.5	7.0
D Ø6.5	 <p>UDAG654</p>	 <p>UDAG655</p>	 <p>UDAG657</p>

Abutment Level Impression

Multi-Unit Abutment & Components

Flowchart



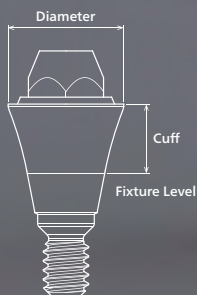
Multi-Unit Abutment

Straight Type

Torque: Narrow[20 Ncm]/Regular[30 Ncm]

Packing unit : Multi-Unit Abutment _Straight Type + Holder

Order Code : ex) UMA 5030



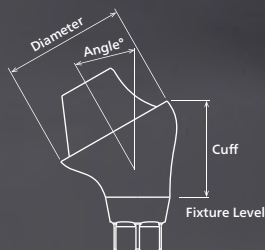
Angled Type

Hex driver : 1.27

Torque: Narrow[20 Ncm]/Regular[30 Ncm]

Packing unit : Multi-Unit Abutment _Angled Type + Multi Abutment Screw + Holder

Order Code : ex) U17MA 5030H



Multi-Unit

Abutment

Straight Type

(Unit: mm)



Cuff

1.0

2.0

3.0

4.0

5.0

6.0

D Ø5.0



UMAN5010



UMAN5020



UMAN5030



UMAN5040



UMAN5050



UMAN5060



Cuff

1.0

2.0

3.0

4.0

5.0

6.0

D Ø5.0



UMA5010



UMA5020



UMA5030



UMA5040



UMA5050



UMA5060

Multi-Unit

Abutment

New Angled Type

(Unit: mm)



Cuff / Angle	3.0 / 17°	4.0 / 17°	5.0 / 17°	4.0 / 29.5°	5.0 / 29.5°	6.0 / 29.5°
D Ø5.0						
	U17MUAN 5030H	U17MUAN 5040H	U17MUAN 5050H	U30MUAN 5040H	U30MUAN 5050H	U30MUAN 5060H



Cuff / Angle	3.0 / 17°	4.0 / 17°	5.0 / 17°	4.0 / 29.5°	5.0 / 29.5°	6.0 / 29.5°
D Ø5.0						
	U17MUAR 5030H	U17MUAR 5040H	U17MUAR 5050H	U30MUAR 5040H	U30MUAR 5050H	U30MUAR 5060H

Abutment

Screw



UAS16H



UAS20H

Multi-Unit Components

● Each comes with 1 Multi-Unit Screw

Multi-Unit
Burn Out Cylinder
Torque: 20 Ncm



Multi-Unit Temporary Cylinder
Torque: 20 Ncm



Multi-Unit Ti Cylinder
Torque: 20 Ncm



Impression Post
Transfer Type



Multi-Unit Analog



Multi-Unit Healing Cap
Torque: 20 Ncm



Screw



Impression Post
Pick Up Type



Multi-Unit **Healing Cap**



UMHC50

Multi-Unit **Ti Cylinder**



UMTIC50N

Multi-Unit
Cylinder Screw



Multi-Unit **Burn Out Cylinder**



UMBC50N

Multi-Unit
Cylinder Screw



Multi-Unit **Temporary Cylinder**



UMTC50N

Multi-Unit
Cylinder Screw



Multi-Unit **Cylinder Screw**



UMCS16



UMCS16(5)

Impression **Post**

Pick up



UMIPP50N

Transfer



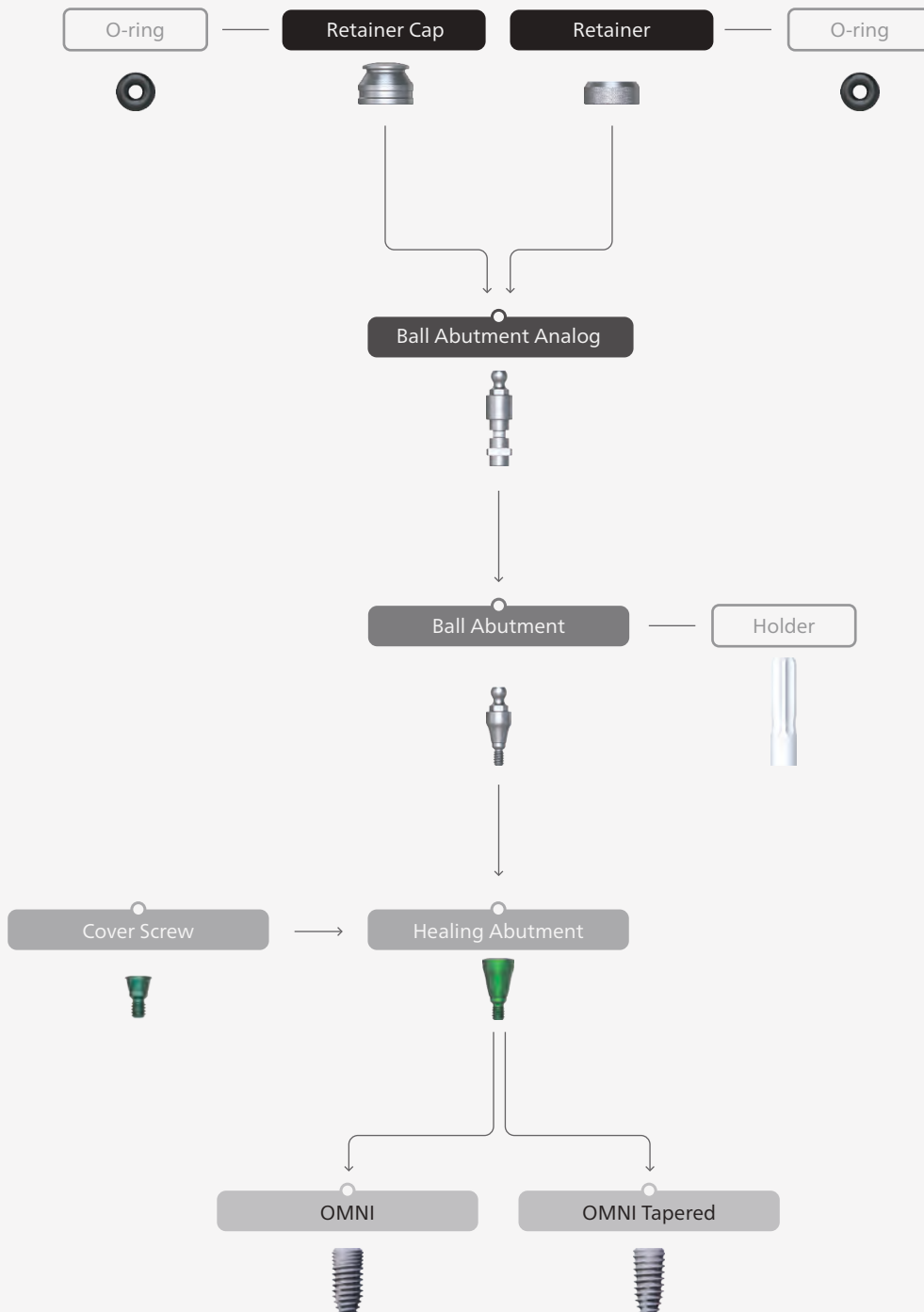
UMIPT50

Multi-Unit **Analog**



UMAG50

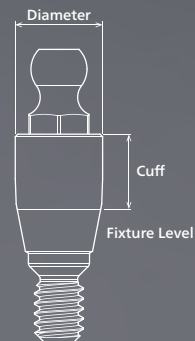
Abutment Level Impression **Overdenture - Ball Abutment** Flowchart



Ball

Abutment & Components

For Overdenture Implant
 Torque: Narrow[20 Ncm]/Regular[30 Ncm]
 Packing unit : Ball Abutment + Holder
 Order Code : ex) UBA 3030



Ball Abutment

(Unit: mm)



Cuff	1.0	2.0	3.0	4.0	5.0	6.0
D Ø3.5						
	UBAN3510	UBAN3520	UBAN 3530	UBAN3540	UBAN3550	UBAN3560



Cuff	1.0	2.0	3.0	4.0	5.0	6.0
D Ø3.5						
	UBA3510	UBA3520	UBA3530	UBA3540	UBA3550	UBA3560

Components

Retainer Cap



UBSC35

Retainer



UBSO35

O-ring



GOR4515K

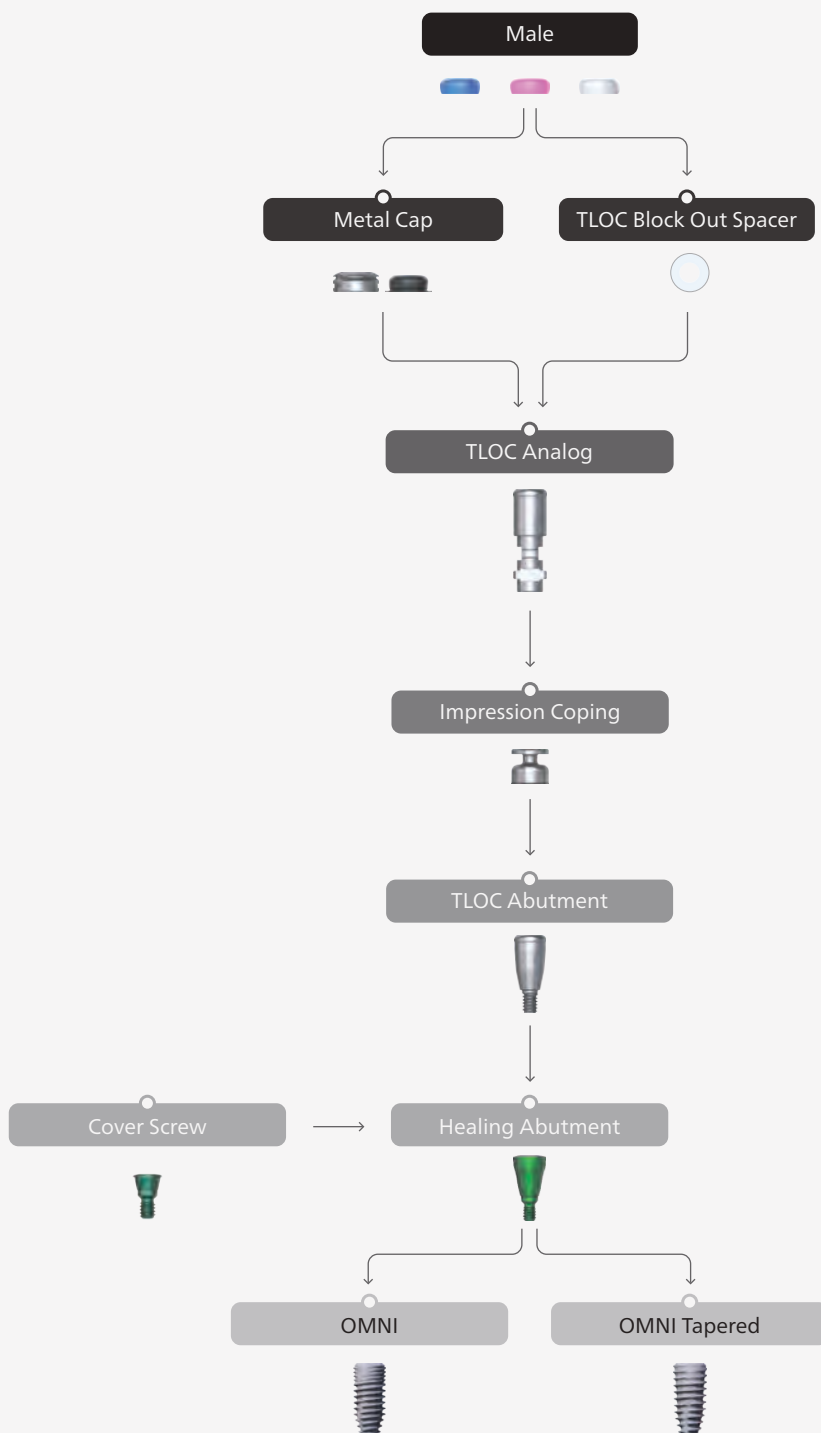


UBAG35

Ball Abutment Analog

Abutment Level Impression **Overdenture - T:LOC Abutment**

Flowchart



T:LOC

Abutment & Components



Black Processing Replacement Male
TLC-PRM56K



TLOC Analog
UBAG 35



Block Out Spacer
TLC-PRM56K



TLOC Impression Coping
UBAG 35



Retention Replacement Male
TLC-RRM478B



TLOC Titanium Cap
TLC-TC5423







TLOC

Abutment

(Unit: mm)



Cuff	1.0	2.0	3.0	4.0	5.0	6.0
D Ø3.8						
						
	UTLAN3810	UTLAN3820	UTLAN3830	UTLAN3840	UTLAN3850	UTLAN3860



Cuff	1.0	2.0	3.0	4.0	5.0	6.0
D Ø3.8						
						
	UTLAR3810	UTLAR3820	UTLAR3830	UTLAR3840	UTLAR3850	UTLAR3860

TLOC Component

Set



TLC-CST(6)

TLOC
Titanium Cap

*Not Sold Individually



TLC-TC5423

Black Processing
Replacement Male

*Not Sold Individually



TLC-PRM56K

Retention
Replacement Male

*Not Sold Individually



TLC-RRM478B

1.5lb



TLC-RRM47P

3.0lb



TLC-RRM47T

5.0lb

Block Out
Spacer

*Not Sold Individually



TLC-PRM56K

TLOC
Impression Coping



UTLTP55

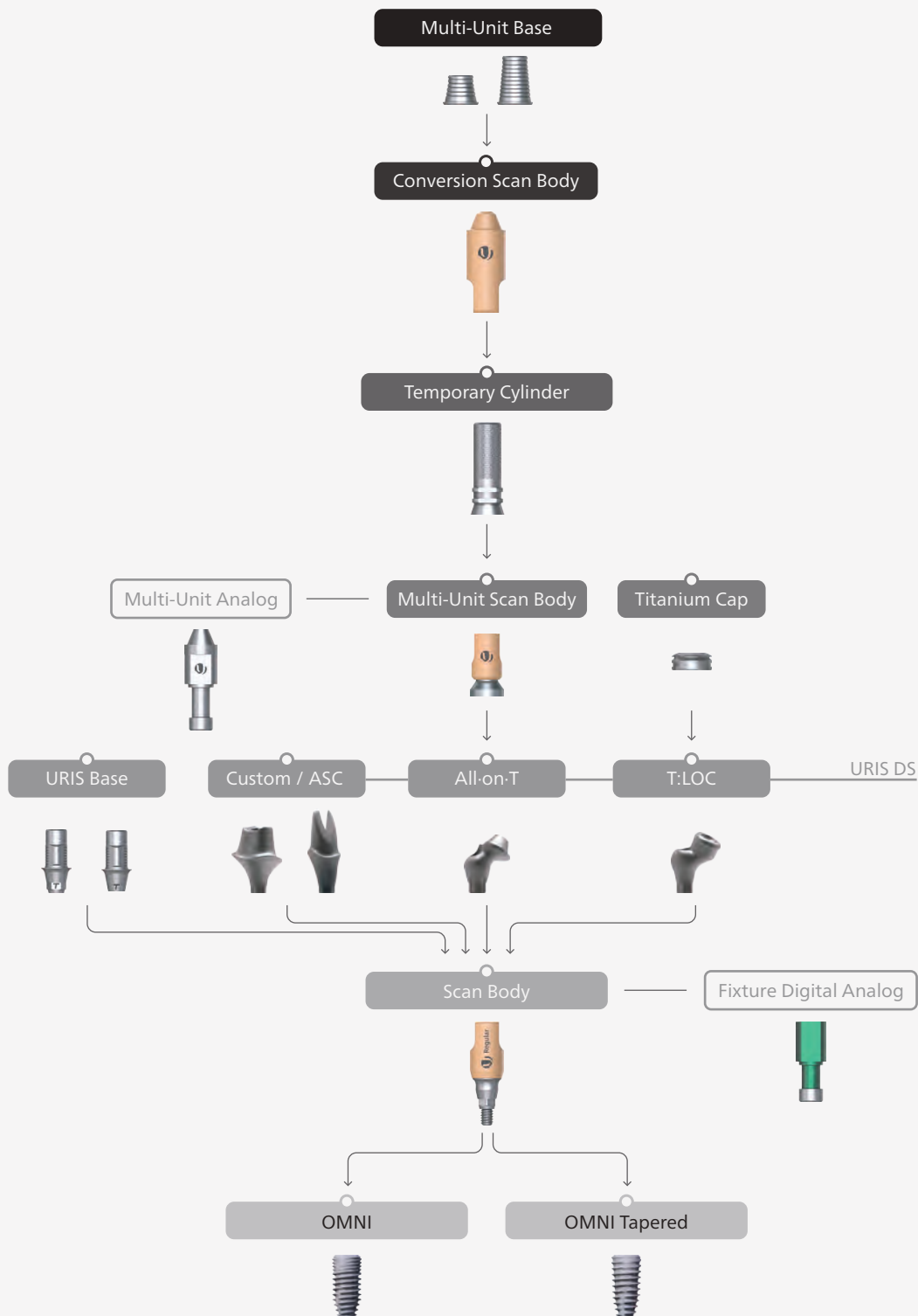
TLOC
Analog



UTLAG38

Digital Impression & Components

Flowchart



URIS
DS

Custom

ASC

All•on•T

T:LOC

URIS
DS



UCAN 20H



UCAR 25H



UCAN 20N



UCAR 25N

URIS
Base



Fixture
Digital Analog



URIS
Scan Body



URIS

Base

(Unit: mm)



Cuff/Height	1 / 3.5	1 / 5.5
-------------	---------	---------

D Ø4.0



UBN4013HA



UBN4015HA



Cuff/Height	1 / 3.5	1 / 5.5
-------------	---------	---------

D Ø4.5



UBR4313HA



UBR4315HA



Cuff/Height	GH 1 / 3.5	GH 1 / 5.5
-------------	------------	------------

D Ø4.0



UBN4013NA



UBN4015NA



Cuff/Height	1 / 3.5	1 / 5.5
-------------	---------	---------

D Ø4.5



UBR4313NA



UBR4315NA

for CEREC

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Cuff	1	2	3	4
------	---	---	---	---

D Ø4.0

S Type



UBN4008HS



UBN4018HS



UBN4028HS



UBN4038HS



Cuff	1	2	3	4
------	---	---	---	---

D Ø4.5

L Type



UBR4508HS



UBR4518HS



UBR4528HS



UBR4538HS

URIS

Scan Body

(N)



UNSB45105

(R)



URSB50103

Fixture

Digital Analog

(N)



UDAG35D

(R)



UDAG40D

Scan Post

for CEREC

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Cuff

1

2

3

4

D Ø4.0



USPN4008



USPN4018



USPN4028



USPN4038

Cuff

1

2

3

4

D Ø4.5



USPR4508



USPR4518



USPR4528



USPR4538

Packing unit : Scan Post + Scan Cap + Abutment Screw | Order Code : ex) USPN 4018

Scan Cap



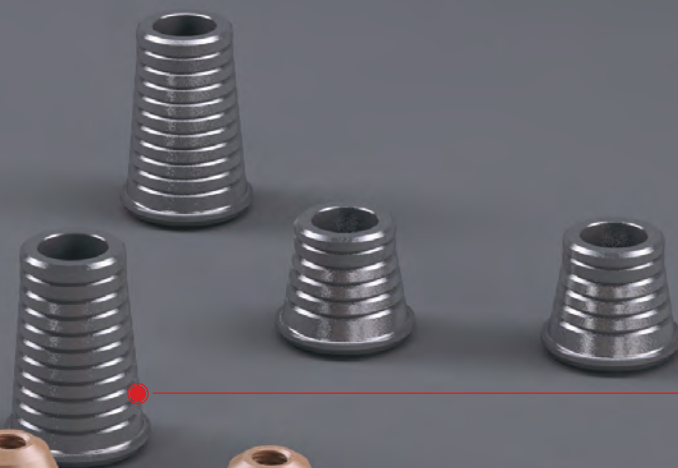
CMM-SSC4



CMM-SSC4(5)

Multi-Unit

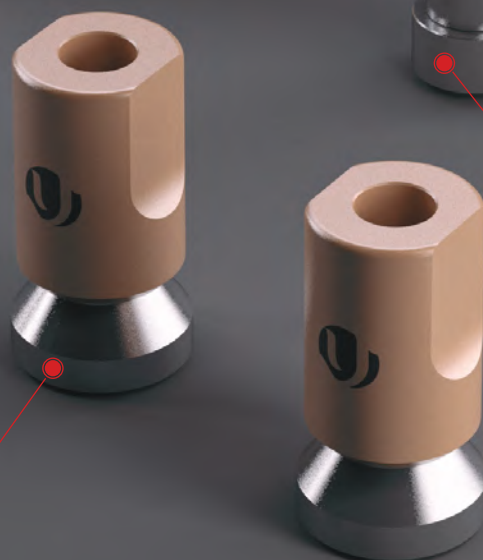
Digital Components



Multi-Unit Base
UMUB 50L



Multi-Unit Conversion Scan Body
UMCSB 50



Multi-Unit Scan Body
UMSB 50



Multi-Unit Digital Analog
UMDLA 50

Multi-Unit **Base**

Multi-Unit
Cylinder Screw



UMUB50L

Multi-Unit
Cylinder Screw



UMUB50S

Multi-Unit **Scan Body**

Multi-Unit
Cylinder Screw



UMSB50

Multi-Unit **Digital Analog**



UMDLA50

Multi-Unit Conversion **Scan Body**

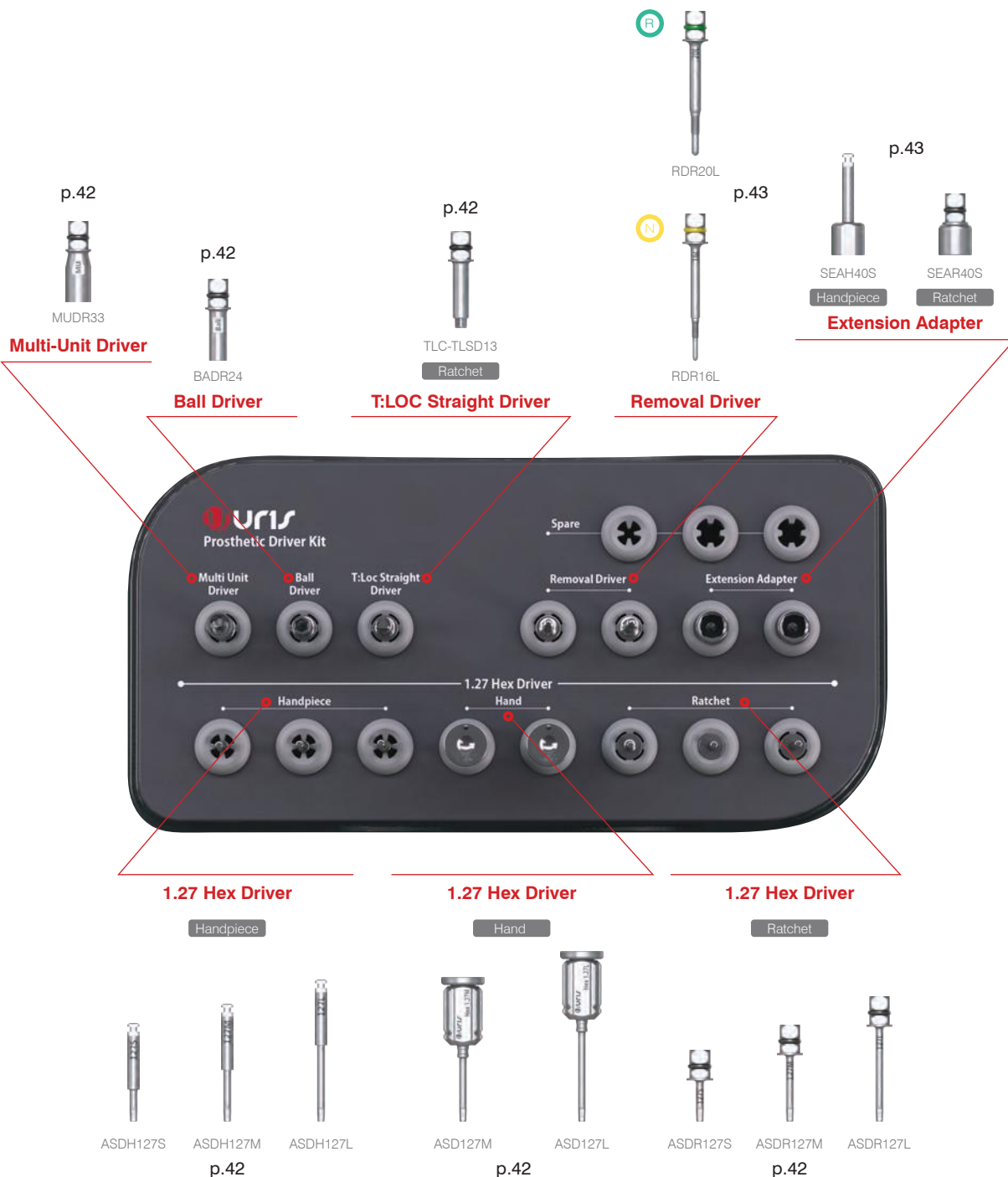


UMCSB50



Prosthetic Driver Kit

PDK 01



Lower

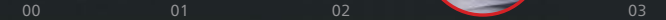
p.41

Torque Wrench



TW40

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Instructions for use

EN

Dental Implant, Fixtures, URIS OMNI System

Valid only in United States

IFU_UOI0004, Revision 02, Document valid as of May-4-2018

2 – 4



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www.urisimplants.com

Device Description

URIS OMNI System fixtures are dental implants made of Unalloyed Titanium, grade 4 (ASTM F67) intended for use in partially or fully edentulous mandibles and maxillary, in support of single or multiple-unit restorations. The surface is SLA (Sandblasted, Large grit and Acid etched) treated and is provided sterile. It consists of two implant lines, the OMNI and the OMNI Tapered, with corresponding cover screws, healing abutments and prosthetic abutments. The OMNI Tapered implant has a tapered wall with a single thread design. The OMNI is straight walled with smaller threading at the coronal end, and bigger threading at the apical end. Both implant lines have two platform sizes, Narrow (Ø 3.5 mm) and Regular (Ø 4.0 – Ø 6.5 mm). Both implant lines share the following diameters and lengths:

Ø 3.5 x 8.5, 10, 11.5, 13, 14.5mm (L)
 Ø 4.0 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
 Ø 4.5 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
 Ø 5.0 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
 Ø 5.5 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
 Ø 6.0 x 7, 8.5, 10mm (L)
 Ø 6.5 x 7, 8.5, 10mm (L).

URIS Prosthetic System is made of titanium alloy (Ti-6Al-4V ELI) intended for use as an aid in prosthetic restoration. It consists of Cover screw, Healing abutment, Direct Abutment, Basic abutment, Angled abutment, Milling abutment, Temporary abutment, and Abutment screw. The surface of cover screw and healing abutment are anodized in yellow and green.

Device Component	Diameters (Ø)	Lengths	Angulation
Cover Screw	2.78/3.48mm	4.875/5.375mm	-
Healing Abutments	4.0/4.5/5.5/6.5/7.5mm	Cuff Height: 1.0mm~5.0mm	-
Direct Abutments	4.0/4.5/5.5/6.5mm	Cuff Height: 1.0mm~6.0mm	-
Basic Abutments	4.0/4.5/5.5/6.5mm	Cuff Height: 1.0mm~6.0mm	-
Angled Abutments	4.0/ 4.5/5.5mm	Cuff Height: 2.0mm~5.0mm	17°
Milling Abutments	4.0/5.0/6.0/7.0mm	Hex Type: 14.1/14.85mm Non-Hex Type: 13.9/14.85mm	-
Temporary Abutments	3.7 / 4.3mm	Cuff Height: 1.0mm~3.0mm	-
Abutment screw	1.9/2.3mm	7.2/7.7mm	-

Fixtures and cover screw are provided sterile and other prosthetics are provided non-sterile. All non-sterile products must be sterilized by end users before use.

Indications for Use

URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillary, in support of single or multiple-unit restorations including: cemented-retained, screw-retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Instructions for operation and use

A. Preparation before use

- Before clinical use, the clinician must be well acquainted with the surgical procedure of the product, and has to inform the patient about the limitations of the implant system. The patient should also be well aware of any functional and aesthetic limitations of the implant.
- Because proper selection and fixation of the implant are closely related to the

life-span of the implant, the clinician must follow the indications, contraindication, cautions and recommendations.

- Handling procedures must be followed in order to prevent potential damage to the implant. Damage to the implant and/or patient may occur without careful review of the patient's condition and establishment of proper diagnosis and restorative plans.
- The clinician must select the appropriate device based on careful review of the patient's X-ray picture and overall condition.
- Check the products' expiration date and condition of the packaging for any visible damages.
- Since the product is packaged aseptically, do not use if the packaging is damaged or torn.
- Be sure to properly maintain the hygiene standards and preparatory state of the surgical instruments in order to prevent the use of contaminated instruments which may lead to complications and/or implant loss.
- Inspect for any foreign-material before use.

B. Instructions and procedural sequence

During the diagnosis and planning, you must exclude any patient with local lesions or other contraindications and choose candidates who have proper bone condition to undergo implant surgery. Before proceeding to surgery, you must sterilize operation room and patient's oral cavity and perioral area thoroughly. After proper draping, perform local anesthesia and make an incision on the implant site and form a flap. Expose the implant site sufficiently and proceed to implant surgery.

(1) Implant site preparation

To implant the fixture, various drills are used in sequence for site preparation during osteotomy. To place the fixture accurately in the selected site, a hole must be made according to the size of the artificial dental prosthesis, using the respective instruments (drilling, tapping). Rotatory speed during these procedures must be adjusted taking the recipient bone condition and type of equipment used into consideration. The maximum permissible rotatory speed for the drill is generally 1,000~1,500rpm and 20~30rpm for the tap drill. The procedure should be performed using adequate normal saline to reduce the generation of heat on the bone tissue.

(2) Placing the fixture

Pick up the fixture from the sterile vial using the Fixture Driver and Adapter and place the fixture into the osteotomy. Install the fixture at low speed (25 rpm) under profuse irrigation and the maximum torque set at 45 Ncm. Allow the implant to work its way into the osteotomy. Avoid applying unnecessary pressure.

NOTE: The final recommended torque at seating should be 20~40Ncm for the URIS OMNI System.

Excessively high insertion torque may cause necrosis of the peri-implant bone in the receiving site which may result in implant failure.

(3) Inserting the cover screw

After the fixture has been placed, attach the cover screw using a driver below 10Ncm torque. Make sure there are no foreign bodies inside and suture the operation site.

(4) Connecting the abutment

Osseo-integration of the fixture requires 3~4 months for the mandible and 6~8 months for the maxilla. After this period, expose the implant and connect the healing abutment to enhance mucosal healing.

(5) Prosthesis attachment

After a healing period of between 2~4 weeks, connect the impression post to obtain an impression and manufacture a dental mockup. Deliver the final prosthesis.

Cautions

(1) Cautions during use

- 1) The operation must be performed by a well-trained, qualified dental specialist.
- 2) While performing the osteotomy, you must follow the procedure outlined in the catalog and the fixture should be adequately implanted.
- 3) Ensure that the soft tissue does not interfere with the connection between the fixture and prosthesis by verifying complete and proper seating.
- 4) All instruments and tooling used during the procedure must be maintained in good condition and care must be taken so that instrumentation does not damage implants and/or other components. Therefore, inspect the condition of the instruments before every operation.
- 5) The product is provided sterile via gamma ray sterilization, therefore, it is recommended to be opened prior to immediate use.
- 6) If the package has been damaged, discard the product since the aseptic condition has been compromised.

(2) Contraindications

1) Intraoral contraindications

- A. In cases with insufficient bone tissue where severe bone resorption is predicted.
Or if there is insufficient remaining bone for early-fusion in the proximal tooth extraction wound.
- B. Disorder in mastication or functional relation
- C. Pathologic condition of the alveolar bone
- D. Prior radiotherapy on jawbone
- E. Xerostomia
- F. Pathologic change of oral mucosa (vitiligo, lichen planus, stomatitis)
- G. Macroglossia
- H. If vital anatomical structures are nearby
- I. Cellulitis in surrounding soft tissues
- J. If there are not sufficient soft tissues or its condition is poor

2) Transient contraindications

- A. Acute inflammatory disease or infection
- B. Pregnancy
- C. Temporary effect of specific drugs (anticoagulant, immune-suppressant)
- D. Mental, physical fatigue

3) Psychological contraindications

- A. Poor compliance
- B. Alcohol or other substance abuse
- C. Neurosis, psychosis patient
- D. Troublesome patient

4) General medical contraindications

- A. General/nutritional condition - age (obesity, cachexia, 5year survival rate)
- B. Current medications (corticosteroid, long-term antibiotic treatment)
- C. Metabolic disorder (pubertal diabetes, overt hyperglycemia (>300mg/dl))
- D. Hematologic disorder (disorder of RBC, WBC, coagulation)
- E. Cardiovascular diseases (arteriosclerosis, overt hypertension (>300mmHg))
- F. Metabolic disorder of skeletal system
(osteomalacia, Paget's disease, menopausal osteoporosis)
- G. Connective tissue disease (dermatosclerosis, rheumatoid arthritis)
- H. Implant as potential infection focus (prosthetic valve, bacterial endocarditis)

(3) Warnings

- 1) Implant operation should be performed by a skilled dental surgeon because mishandled procedures may damage the implant or recipient bone
- 2) Implant is not to be recycled and should be used for its original purpose
- 3) Damaged or mishandled implant should be removed
- 4) Inappropriate implant selection and improper implantation site or unstable fixation may shorten the life-span of the implant
- 5) Defective product should be withdrawn
- 6) Handle the implant carefully to prevent any damage or deformation
- 7) Warning: Small diameter implants and angled abutments are not recommended

for the molar region of the mouth.

(4) POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS

General complications after intraoral implant surgery include local hemorrhage, edema and hematoma. Transient loss of taste, sense and masticatory function may occur. Additionally, following complications may develop:

- Iatrogenic trauma of surrounding tissues (lower alveolar nerve injury or sensory change, injury or hemorrhage in maxillary sinus or nasal cavity)
- Insufficient or failed bony fusion
- Wound dehiscence on sutured site
- Delayed recovery, edema due to anesthesia
- Mucositis around implant due to insufficient adhesive soft tissue
- Incomplete implant placement due to insufficient bone removal or overt compression
- General hypersensitivity reaction

MR Statement

The URIS OMNI System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of URIS OMNI System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Sterility

All dental implants (fixture) and cover screw are supplied sterile and are labeled "STERILE". All products sold sterile are for single-use before the expiration date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize.

End-User Sterilization Information

All prosthetic abutments are provided non-sterile and must be sterilized before use. To correctly sterilize the products, use a steam sterilizer with pre-vacuum process, at a temperature of steam sterilizer at 132° C for 4 minutes, wrap and dry for 20 minutes with a validated cycle according to the standard ISO 17665-1 following the autoclave manufacturer instructions.

	Pre-Vacuum Autoclave
Temperature	132° C
Exposure Time	4 minutes
Dry Time	20 minutes

Note: The validated procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79.

Storage











The product has to be stored in its original package in a dry place at room temperature.

Handling

- This product is a disposable sterilized medical instrument and should therefore not be reused.
- Packing must be opened prior to surgery in a clean area.
- Discard if wrapping has been opened, even if product is unused.
- Do not use the product if the shelf life has expired.
- Opened products cannot be returned to the manufacturer or distributor.
- Manufacturer and distributor have no responsibility for products re-sterilized by users.

LABELING SYMBOLS

Symbols may be used on some international package labeling for easy identification.

	Do not reuse
	Use by date
	Batch code
	Date of manufacture
	Non-Sterile
	Catalogue number
	Caution, consult accompanying documents
	Manufacturer
	Consult instructions for use
	Do not use if package is damaged
Rx Only	Prescription only

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Instructions for use

EN

Dental Implant, Fixtures, URIS OMNI Narrow System

Valid only in United States

IFU_UOI0014, Revision 00, Document valid as of Oct-08-2020

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Device Description

URIS OMNI Narrow System fixtures are dental implants made of Unalloyed Titanium, grade 4 (ASTM F67) intended for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors. The surface is SLA (Sandblasted, Large grit and Acid etched) treated and is provided sterile. It consists of two implant lines, the OMNI and the OMNI Tapered, with corresponding cover screws, healing abutments and prosthetic abutments. The OMNI Tapered implant has a tapered wall with a single thread design. The OMNI implant has straight wall with smaller threading at the coronal end, and bigger threading at the apical end. Both implant lines have Narrow (Ø 3.15 mm) platform sizes. Both implant lines share the following diameters and lengths.

Ø 3.15 x 10, 11.5, 13, 14.5mm (L)

URIS Prosthetic System is made of titanium alloy (Ti-6Al-4V ELI) intended for use as an aid in prosthetic restoration. It consists of Ball Abutment, Retainer Cap, Retainer, T LOC Straight Abutment, T Loc Titanium Cap, Multi-Unit Straight Abutment, Multi-Unit Angled Abutment, Multi-Unit Healing Cap, Multi-Unit Ti Cylinder, Multi-unit temporary cylinder, Multi-Unit Base, Multi-Unit Cylinder screw, URIS DS, URIS Base. No additional angulation is to be included in the when using a coping or cylinder (i.e., Multi-unit Ti Cylinder, Multi-unit Temporary Cylinder, Multi-unit Base) with any of the Multi-unit Abutments.

Cover screw and healing abutment are anodized in yellow or green.

Device Component	Diameters (Ø)	Lengths	Angulation
OMNI Fixtures	3.15mm	10~14.5mm	
OMNI Tapered Fixtures	3.15mm	10~14.5mm	
Ball Abutments	3.5mm	Cuff Height: 1.0~6.0mm	
Retainer Cap	5.1mm	3.9mm	
Retainer	5.1mm	2.1mm	
TLOC Straight Abutments	3.8mm	Cuff Height: 1.0~6.0mm	
TLOC Titanium Cap	5.4mm	2.3mm	
Multi-Unit Straight Abutments	5.0mm	Cuff Height: 1.0mm~6.0mm	
Multi-Unit Angled Abutments		Cuff Height: 3.0mm~5.0mm	17°
		Cuff Height: 4.0mm~6.0mm	29.5°
Multi-Unit Healing Cap	5.1mm	4.5mm	
Multi-Unit Ti Cylinder	5.0mm	5.0mm	
Multi-unit Temporary Cylinder	5.0mm	12mm	
Multi-Unit Base	5.0mm	4.35/7.35mm	
Multi-unit Cylinder screw	1.6mm	3.3mm	
URIS DS	Ø3.8~ Ø 5.5mm	6~11mm	0~25°
URIS Base	4.0mm/4.3mm	Cuff Height: 1.0/2.0mm	

Fixtures and cover screw are provided sterile and other prosthetics are provided non-sterile. All non-sterile products must be sterilized by end users before use.

URIS Base consists of a two-piece abutment, where the titanium base is a pre-manufactured abutment that will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment) that composes the final abutment. URIS Base is made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. It is compatible with the following systems:

URIS Base is provided non-sterile therefore must be sterilized after the cementation of the zirconia superstructure on the URIS Base.

Design Limitation for Zirconia superstructure

Design parameter	Design Limit
Minimum and Maximum abutment angle	0~15°
Minimum and Maximum Cuff Height	0.5~5 mm
Minimum and Maximum diameter at abutment/implant interface	5.0mm~ 8.0mm
Minimum Thickness	0.4 mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4 ~6 mm

URIS DS abutment as a patient matched titanium abutment compatible with both URIS OMNI System (K172100) and URIS OMNI Narrow System (subject).

Design Limitation for URIS DS

Design parameter	Design Limit
Minimum and Maximum Gingival Height	0.5~4mm
Minimum and Maximum diameter at abutment / implant interface	3.8~5.5mm
Minimum and Maximum length of abutment	6~11mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4~8mm
Minimum wall thickness at abutment / implant interface	0.4mm
Minimum and Maximum abutment angle	0~25°

Indications for Use

URIS OMNI Narrow System is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

The URIS OMNI Prosthetic abutments are intended for use with URIS OMNI dental implants to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.

All digitally designed abutments and/or coping for use with URIS OMNI Prosthetic abutments are intended to be sent to a TruAbutment-validated milling center for manufacture

A. Preparation before use

- 1) Before clinical use, the clinician must be well acquainted with the surgical procedure of the product, and has to inform the patient about the limitations of the implant system. The patient should also be well aware of any functional and aesthetic limitations of the implant.
- 2) Because proper selection and fixation of the implant are closely related to the life-span of the implant, the clinician must follow the indications, contraindication, cautions and recommendations.
- 3) Handling procedures must be followed in order to prevent potential damage to the implant. Damage to the implant and/or patient may occur without careful review of the patient's condition and establishment of proper diagnosis and restorative plans.
- 4) The clinician must select the appropriate device based on careful review of the patient's X-ray picture and overall condition.
- 5) Check the products' expiration date and condition of the packaging for any visible damages.
- 6) Since the product is packaged aseptically, do not use if the packaging is damaged or torn.
- 7) Be sure to properly maintain the hygiene standards and preparatory state of the surgical instruments in order to prevent the use of contaminated instruments which may lead to complications and/or implant loss.
- 8) Inspect for any foreign-material before use.

B. Instructions and procedural sequence

During the diagnosis and planning, you must exclude any patient with local lesions or other contraindications and choose candidates who have proper bone condition to undergo implant surgery. Before proceeding to surgery, you must sterilize operation room and patient's oral cavity and perioral area thoroughly. After proper draping, perform local anesthesia and make an incision on the implant site and form a flap. Expose the implant site sufficiently and proceed to implant surgery.

(1) Implant site preparation

To implant the fixture, various drills are used in sequence for site preparation during osteotomy. To place the fixture accurately in the selected site, a hole must be made according to the size of the artificial dental prosthesis, using the respective instruments (drilling, tapping). Rotatory speed during these procedures must be adjusted taking the recipient bone condition and type of equipment used into consideration. The maximum permissible rotatory speed for the drill is generally 1,000~1,500rpm and 20~30rpm for the tap drill. The procedure should be performed using adequate normal saline to reduce the generation of heat on the bone tissue.

(2) Placing the fixture

Pick up the fixture from the sterile vial using the Fixture Driver and Adapter and place the fixture into the osteotomy. Install the fixture at low speed (25 rpm) under profuse irrigation and the maximum torque set at 45 Ncm. Allow the implant to work its way into the osteotomy. Avoid applying unnecessary pressure.

NOTE: The final recommended torque at seating should be 20~40Ncm for the URIS OMNI System.

Excessively high insertion torque may cause necrosis of the peri-implant bone in the receiving site which may result in implant failure.

(3) Inserting the cover screw

After the fixture has been placed, attach the cover screw using a driver below 10Ncm torque. Make sure there are no foreign bodies inside and suture the operation site.

(4) Connecting the abutment

Osseo-integration of the fixture requires 3~4 months for the mandible and 6~8 months for the maxilla. After this period, expose the implant and connect the healing abutment to enhance mucosal healing.

(5) Prosthesis attachment

After a healing period of between 2~4 weeks, connect the impression post to obtain an impression and manufacture a dental mockup. Deliver the final prosthesis.

Cautions

(1) Cautions during use

- 1) The operation must be performed by a well-trained, qualified dental specialist.
- 2) While performing the osteotomy, you must follow the procedure outlined in the catalog and the fixture should be adequately implanted.
- 3) Ensure that the soft tissue does not interfere with the connection between the fixture and prosthesis by verifying complete and proper seating.
- 4) All instruments and tooling used during the procedure must be maintained in good condition and care must be taken so that instrumentation does not damage implants and/or other components. Therefore, inspect the condition of the instruments before every operation.
- 5) The product is provided sterile via gamma ray sterilization, therefore, it is recommended to be opened prior to immediate use.
- 6) If the package has been damaged, discard the product since the aseptic condition has been compromised.

(2) Contraindications

1) Intraoral contraindications

- A. In cases with insufficient bone tissue where severe bone resorption is predicted. Or if there is insufficient remaining bone for early-fusion in the proximal tooth extraction wound.
- B. Disorder in mastication or functional relation
- C. Pathologic condition of the alveolar bone
- D. Prior radiotherapy on jawbone
- E. Xerostomia
- F. Pathologic change of oral mucosa (vitiligo, lichen planus, stomatitis)
- G. Macroglossia
- H. If vital anatomical structures are nearby
- I. Cellulitis in surrounding soft tissues
- J. If there are not sufficient soft tissues or its condition is poor

2) Transient contraindications

- A. Acute inflammatory disease or infection
- B. Pregnancy
- C. Temporary effect of specific drugs (anticoagulant, immune-suppressant)
- D. Mental, physical fatigue

3) Psychological contraindications

- A. Poor compliance
- B. Alcohol or other substance abuse
- C. Neurosis, psychosis patient
- D. Troublesome patient

4) General medical contraindications

- A. General/nutritional condition - age (obesity, cachexia, 5year survival rate)
- B. Current medications (corticosteroid, long-term antibiotic treatment)
- C. Metabolic disorder (pubertal diabetes, overt hyperglycemia (>300mg/dl))
- D. Hematologic disorder (disorder of RBC, WBC, coagulation)
- E. Cardiovascular diseases (atherosclerosis, overt hypertension (>300mmHg))

- F. Metabolic disorder of skeletal system
(osteomalacia, Paget's disease, menopausal osteoporosis)
- G. Connective tissue disease (dermatosclerosis, rheumatoid arthritis)
- H. Implant as potential infection focus (prosthetic valve, bacterial endocarditis)

(3) Warnings

- 1) Implant operation should be performed by a skilled dental surgeon because mishandled procedures may damage the implant or recipient bone
- 2) Implant is not to be recycled and should be used for its original purpose
- 3) Damaged or mishandled implant should be removed
- 4) Inappropriate implant selection and improper implantation site or unstable fixation may shorten the life-span of the implant
- 5) Defective product should be withdrawn
- 6) Handle the implant carefully to prevent any damage or deformation
- 7) Warning: Small diameter implants and angled abutments are not recommended for the molar region of the mouth.

(4) POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS

General complications after intraoral implant surgery include local hemorrhage, edema and hematoma. Transient loss of taste, sense and masticatory function may occur. Additionally,

following complications may develop:

- Iatrogenic trauma of surrounding tissues (lower alveolar nerve injury or sensory change, injury or hemorrhage in maxillary sinus or nasal cavity)
- Insufficient or failed bony fusion
- Wound dehiscence on sutured site
- Delayed recovery, edema due to anesthesia
- Mucositis around implant due to insufficient adhesive soft tissue
- Incomplete implant placement due to insufficient bone removal or overt compression
- General hypersensitivity reaction

MR Statement

The URIS OMNI System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of URIS OMNI System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Sterility

All dental implants (fixture) and cover screw are supplied sterile and are labeled "STERILE". All products sold sterile are for single-use before the expiration date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize.

End-User Sterilization Information

All prosthetic abutments are provided non-sterile and must be sterilized before use. To correctly sterilize the products, use a steam sterilizer with pre-vacuum process, at a temperature of steam sterilizer at 132° C for 4 minutes, wrap and dry for 20 minutes with a validated cycle according to the standard ISO 17665-1 following the autoclave manufacturer instructions.

	Pre-Vacuum Autoclave
Temperature	132° C
Exposure Time	4 minutes
Dry Time	20 minutes

Note: The validated procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79.

Storage











The product has to be stored in its original package in a dry place at room temperature.

Handling

- This product is a disposable sterilized medical instrument and should therefore not be reused.
- Packing must be opened prior to surgery in a clean area.
- Discard if wrapping has been opened, even if product is unused.
- Do not use the product if the shelf life has expired.
- Opened products cannot be returned to the manufacturer or distributor.
- Manufacturer and distributor have no responsibility for products re-sterilized by users.

LABELING SYMBOLS

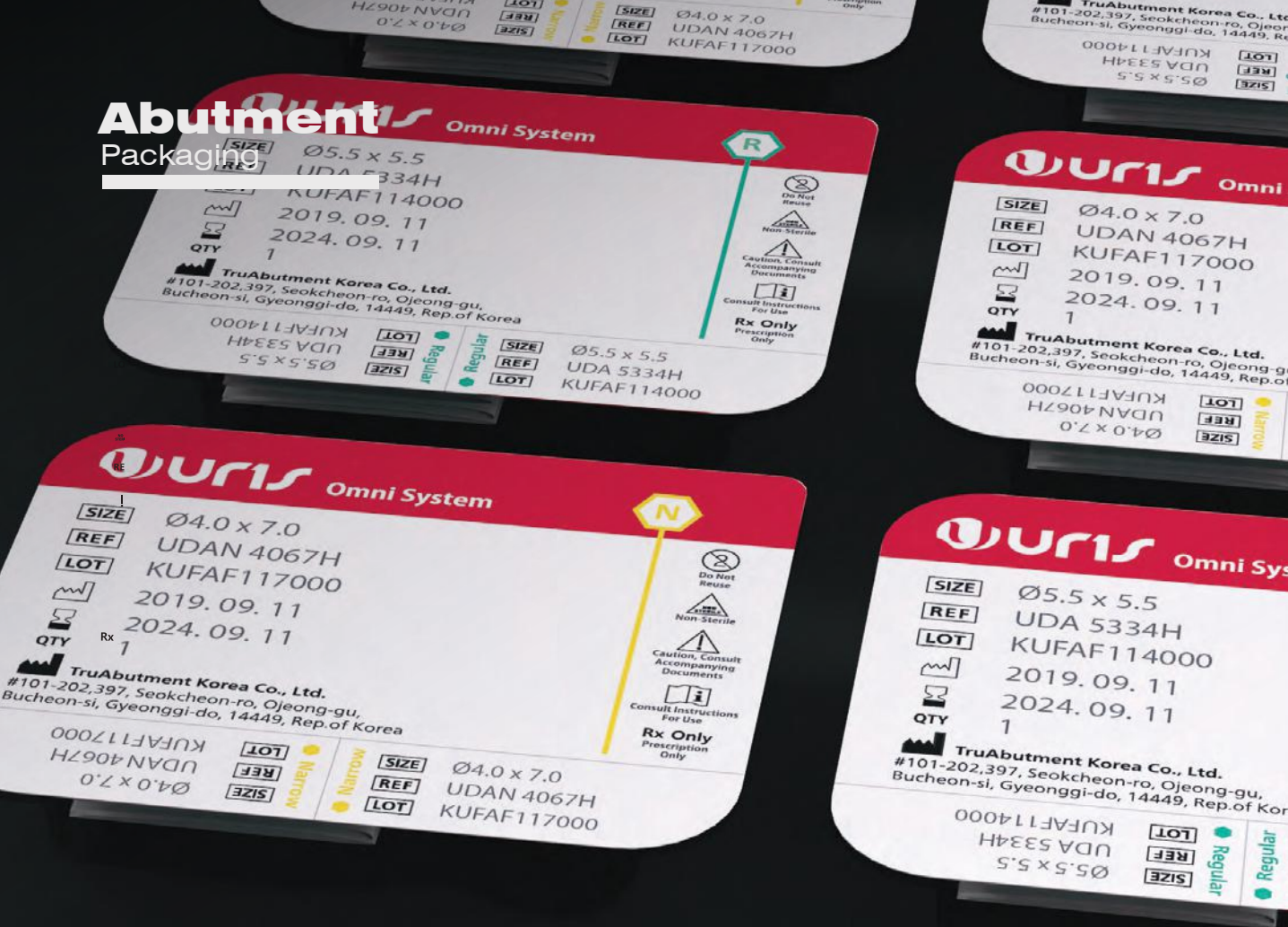
Symbols may be used on some international package labeling for easy identification.

	Do not reuse
	Use by date
	Batch code
	Date of manufacture
	Non-Sterile
	Catalogue number
	Caution, consult accompanying documents
	Manufacturer
	Consult instructions for use
	Do not use if package is damaged
Rx Only	Prescription only

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Abutment Packaging



Abutment Screw

Instruction

Abutment





Instructions for use

EN

Dental Implant, Abutments, URIS OMNI System

Valid only in United States

IFU_UOI0005, Revision 02, Document valid as of May-4-2018

2 – 4



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Device Description

URIS OMNI System fixtures are dental implants made of Unalloyed Titanium, grade 4 (ASTM F67) intended for use in partially or fully edentulous mandibles and maxillary, in support of single or multiple-unit restorations. The surface is SLA (Sandblasted, Large grit and Acid etched) treated and is provided sterile. It consists of two implant lines, the OMNI and the OMNI Tapered, with corresponding cover screws, healing abutments and prosthetic abutments. The OMNI Tapered implant has a tapered wall with a single thread design. The OMNI is straight walled with smaller threading at the coronal end, and bigger threading at the apical end. Both implant lines have two platform sizes, Narrow (Ø 3.5 mm) and Regular (Ø 4.0 – Ø 6.5 mm). Both implant lines share the following diameters and lengths:

Ø 3.5 x 8.5, 10, 11.5, 13, 14.5mm (L)
 Ø 4.0 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
 Ø 4.5 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
 Ø 5.0 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
 Ø 5.5 x 7, 8.5, 10, 11.5, 13, 14.5mm (L)
 Ø 6.0 x 7, 8.5, 10mm (L)
 Ø 6.5 x 7, 8.5, 10mm (L).

URIS Prosthetic System is made of titanium alloy (Ti-6Al-4V ELI) intended for use as an aid in prosthetic restoration. It consists of Cover screw, Healing abutment, Direct Abutment, Basic abutment, Angled abutment, Milling abutment, Temporary abutment, and Abutment screw. The surface of cover screw and healing abutment are anodized in yellow and green.

Device Component	Diameters (Ø)	Lengths	Angulation
Cover Screw	2.78/3.48mm	4.875/5.375mm	-
Healing Abutments	4.0/4.5/5.5/6.5/7.5mm	Cuff Height: 1.0mm~5.0mm	-
Direct Abutment	4.0/4.5/5.5/6.5mm	Cuff Height: 1.0mm~6.0mm	-
Basic Abutments	4.0/4.5/5.5/6.5mm	Cuff Height: 1.0mm~6.0mm	-
Angled Abutments	4.0/ 4.5/5.5mm	Cuff Height: 2.0mm~5.0mm	17°
Milling Abutments	4.0/5.0/6.0/7.0mm	Hex Type: 14.1/14.85mm Non-Hex Type: 13.9/14.85mm	-
Temporary Abutments	3.7 / 4.3mm	Cuff Height: 1.0mm~3.0mm	-
Abutment screw	1.9/2.3mm	7.2/7.7mm	-

Fixtures and cover screw are provided sterile and other prosthetics are provided non-sterile. All non-sterile products must be sterilized by end users before use.

Indications for Use

URIS OMNI System is indicated for use in partially or fully edentulous mandibles and maxillary, in support of single or multiple-unit restorations including; cemented-retained, screw-retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

Restorative Components:

1. Abutments

The abutments are used to restore a dental implant, acting like the base for the prosthesis. They are available in different shapes and sizes to respond to different needs. It should maintain at least 4mm from the abutment platform to avoid damaging the abutment screw:

• Titanium Abutments

There are four types of titanium abutments available:

- Basic Abutments: None of the Basic abutments are to be used as titanium base abutments or as part of a hybrid abutment (e.g. part of a two-piece abutment). Basic abutments are full size abutments and are to be used straight. No angular correction or divergence is allowed by any additional copings, or modifications.
- Angled Abutments: In general, they are angled at 17°, which can be adapted to the majority of clinical cases.
- Milling Abutments: Intended to be milled by hand and are intended to be used straight. No angular correction or divergence is allowed.
- Temporary Abutments: Intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement-retained restorations. Maximum duration for use of Temporary Abutment is less than six months. Temporary restorations should be out of occlusion.

2. Screws

The screws are made from Ti-6Al-4V ELI (ASTM F136), recommended for its biocompatibility, its mechanical strength and hardness. It serves to attach the abutment or prosthesis to the implant (clinical screw) or to the laboratory analogue (laboratory screw).

Recommendations for its specific use include:

The screws are single-use only. It is not recommended to use the screws again after their removal, not even in the laboratory, due to the possible deterioration of their behavior. It is vitally important to not use clinical case screws that have been previously used in a dental laboratory. It is important to verify the compatibility of the implant model to be used. You should avoid causing any damage around the area where the implant is connected, so care must be taken if carving or machining in this area. Radiography is recommended in the height of the junction of the union with the perpendicular axis of said union, once the implant is fixed, for verification.

Torque

Only the implant manufacturer's recommended torque is to be used.

Ncm	Abutments (Narrow Connection)
5~10	Cover Screw, Healing Abutments,
20	Basic Abutments, Direct Abutments, Angled Abutments, Milling Abutments, Temporary Abutments
Ncm	Abutments (Narrow Connection)
5~10	Cover Screw, Healing Abutments,
20	Temporary Abutments
30	Basic Abutments, Direct Abutments, Angled Abutments, Milling Abutments, TruBase

Warnings:

The instructions given are insufficient if used as the only reference for the use of the cited components. These elements should only be inserted by dentists who have been fully trained in the insertion of dental implants. The use of these products without any prior specific knowledge can lead to component failure and may require implant removal. The safety of our products is guaranteed only when they are used exclusively by trained professionals. Read the instructions carefully on the labels of the products, where you will find the basic guidelines. Keep a record of the products used in the patient's personal medical booklet, stating the name of the product, the reference number, and the lot number. Please inform URIS Implants of any defects or complications related to any of its products. All URIS OMNI System products are solely for single use. To reuse the single-use products may lead to a possible deterioration of the characteristics of the product, which in turn can lead to an elevated risk in gum or tissue infection and deterioration in the patient's health. In general, implant component's placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships

reappraisal of the treatment option may be considered. There is a risk of accidental inhalation and/or ingestion of the products when they are used, therefore it is necessary to carefully hold onto the products in case of intraoral applications. The patient should be made aware of any limitations in his/her treatment, and the need for maintenance, for example, the need to seek medical assistance if any symptoms or side effects arise. It should be recommended to the patient to conduct regular dental check-ups for maintenance of the URIS OMNI System products. The products are not sterilized when sold, and therefore, it is recommended to clean and sterilize the products before their use.

* Warning: Small diameter implants and angled abutments are not recommended for the molar region of the mouth.

Contraindications:

It is contraindicated placing dental implants in patients:

- Medically unfit for an oral surgical procedure
- With inadequate bone volume unless an augmentation procedure can be considered
- In whom adequate sizes, numbers or desirable position of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Allergic or hypersensitive to titanium alloy (grade 5).

MR Statement

The URIS OMNI System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of URIS OMNI System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

End-User Sterilization Information

All prosthetic abutments are provided non-sterile and must be sterilized before use. To correctly sterilize the products, use a steam sterilizer with pre-vacuum process, at a temperature of steam sterilizer at 132° C for 4 minutes, wrap and dry 20 minutes with a validated cycle according to the standard ISO 17665-1 following the autoclave manufacturer instructions.

	Pre-Vacuum Autoclave
Temperature	132° C
Exposure Time	4 minutes
Dry Time	20 minutes











Note: The validated procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79.

Storage

The product has to be stored in its original package in a dry place at room temperature.

LABELING SYMBOLS

Symbols may be used on some international package labeling for easy identification.

	Do not reuse
	Use by date
	Batch code
	Date of manufacture
	Non-Sterile
	Catalogue number
	Caution, consult accompanying documents
	Manufacturer
	Consult instructions for use
	Do not use if package is damaged
Rx Only	Prescription only

**TruAbutment Korea Co., Ltd.**

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Instructions for use

EN

Dental Implant, Abutments, URIS OMNI System & Prosthetics

Valid only in United States

IFU_UOI0015, Revision 00, Document valid as of Oct-8-2020

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Device Description

URIS OMNI Narrow System fixtures are dental implants made of Unalloyed Titanium, grade 4 (ASTM F67) intended for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors. The surface is SLA (Sandblasted, Large grit and Acid etched) treated and is provided sterile. It consists of two implant lines, the OMNI and the OMNI Tapered, with corresponding cover screws, healing abutments and prosthetic abutments. The OMNI Tapered implant has a tapered wall with a single thread design. The OMNI implant has straight wall with smaller threading at the coronal end, and bigger threading at the apical end. Both implant lines have Narrow (Ø 3.15 mm) platform sizes. Both implant lines share the following diameters and lengths.

Ø 3.15 x 10, 11.5, 13, 14.5mm (L)

URIS Prosthetic System is made of titanium alloy (Ti-6Al-4V ELI) intended for use as an aid in prosthetic restoration. It consists of Ball Abutment, Retainer Cap, Retainer, T LOC Straight Abutment, T Loc Titanium Cap, Multi-Unit Straight Abutment, Multi-Unit Angled Abutment, Multi-Unit Healing Cap, Multi-Unit Ti Cylinder, Multi-unit temporary cylinder, Multi-Unit Base, Multi-Unit Cylinder screw, URIS DS, URIS Base. No additional angulation is to be included in the when using a coping or cylinder (i.e., Multi-unit Ti Cylinder, Multi-unit Temporary Cylinder, Multi-unit Base) with any of the Multi-unit Abutments.

Cover screw and healing abutment are anodized in yellow or green.

Device Component	Diameters (Ø)	Lengths	Angulation
OMNI Fixtures	3.15mm	10~14.5mm	
OMNI Tapered Fixtures	3.15mm	10~14.5mm	
Ball Abutments	3.5mm	Cuff Height: 1.0~6.0mm	
Retainer Cap	5.1mm	3.9mm	
Retainer	5.1mm	2.1mm	
TLOC Straight Abutments	3.8mm	Cuff Height: 1.0~6.0mm	
TLOC Titanium Cap	5.4mm	2.3mm	
Multi-Unit Straight Abutments	5.0mm	Cuff Height: 1.0mm~6.0mm	
Multi-Unit Angled Abutments		Cuff Height: 3.0mm~5.0mm	17°
		Cuff Height: 4.0mm~6.0mm	29.5°
Multi-Unit Healing Cap	5.1mm	4.5mm	
Multi-Unit Ti Cylinder	5.0mm	5.0mm	
Multi-unit temporary Cylinder	5.0mm	12mm	
Multi-Unit Base	5.0mm	4.35/7.35mm	
Multi-unit Cylinder screw	1.6mm	3.3mm	
URIS DS	Ø3.8~ Ø 5.5mm	6~11mm	0~25°
URIS Base	4.0mm/4.3mm	Cuff Height: 1.0/2.0mm	

Fixtures and cover screw are provided sterile and other prosthetics are provided non-sterile. All non-sterile products must be sterilized by end users before use.

URIS Base consists of a two-piece abutment, where the titanium base is a pre-manufactured abutment that will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment) that composes the final abutment. URIS Base is made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. It is compatible with the following systems:

URIS Base is provided non-sterile therefore must be sterilized after the cementation of the zirconia superstructure on the URIS Base.

Design Limitation for Zirconia superstructure

Design parameter	Design Limit
Minimum and Maximum abutment angle	0~15°
Minimum and Maximum Cuff Height	0.5~5 mm
Minimum and Maximum diameter at abutment/implant interface	5.0mm~ 8.0mm
Minimum Thickness	0.4 mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4 ~6 mm

Design Limitation for URIS DS

Design parameter	Design Limit
Minimum and Maximum Gingival Height	0.5~4mm
Minimum and Maximum diameter at abutment / implant interface	3.8~5.5mm
Minimum and Maximum length of abutment	6~11mm
Minimum and Maximum length of abutment post (length above the abutment collar/gingival height)	4~8mm
Minimum wall thickness at abutment / implant interface	0.4mm
Minimum and Maximum abutment angle	0~25°

INDICATIONS FOR USE

URIS OMNI Narrow System & Prosthetic is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

RESTORATIVE COMPONENTS:**1. ABUTMENTS**

The abutments are used to restore a dental implant, acting like the base for the prosthesis. They are available in different shapes and sizes to respond to different needs. It should maintain at least 4mm from the abutment platform to avoid damaging the abutment screw:

Titanium Abutments

There are five types of titanium abutments available:

- Ball Abutment: Ball abutment is a type of extra coronal attachment mechanism used with dental

Implants to retain an overdenture.

- **TLOC Straight Abutment:** T Loc Straight Abutment allows to have a low profile, i.e. low vertical height, they may be used for all types of removable complete dentures.
- **Multi-unit Abutment:** Multi-Unit abutment is used for screw-retained bridges and full-arch restorations. Straight and angulated Multi-Units are available. Abutments with a post length of less than 4mm is only available for multi-unit cases.
- **URIS DS:** URIS DS is designed and produced specifically for the patient using CAD/CAM technology taking into account the angle of the implant applied to the patient. Abutments with a post length of less than 4mm is only available for multi-unit cases.
- **URIS Base:** URIS Base are products which are used for the digital acquisition of an implant position and for the restorative supply of implants. The URIS Base product comprises two individual
- **Components:** Titanium base and Abutment Screw. Abutments with a post length of less than 4mm is only available for multi-unit cases.

2. SCREWS

The screws are made from Ti-6Al-4V ELI (ASTM F136), recommended for its biocompatibility, its mechanical strength and hardness. It serves to attach the abutment or prosthesis to the implant (clinical screw) or to the laboratory analogue (laboratory screw).

RECOMMENDATIONS FOR ITS SPECIFIC USE INCLUDE:

The screws are for single-use only. It is not recommended to use the screws again after their removal, not even in the laboratory, due to the possible deterioration of their behavior. It is vitally important to not use clinical case screws that have been previously used in a dental laboratory.

It is important to verify the compatibility of the implant model to be used. You should avoid causing any damage around the area where the implant is connected, so care must be taken if carving or machining in this area. Radiography is recommended in the height of the junction of the union with the perpendicular axis of said union, once the implant is fixed, for verification.

Torque

Only the implant manufacturer's recommended torque is to be used.

Ncm	Abutments (Narrow Connection)
20	Ball Abutments, Multi-Unit Angled Abutments, Multi-Unit Straight Abutments, TLOC Straight Abutments, URIS DS, URIS Base.
Ncm	Abutments (Regular Connection)
30	Ball Abutments, Multi-Unit Angled Abutments, Multi-Unit Straight Abutments, TLOC Straight Abutments, URIS DS, URIS Base.
Ncm	Components
20	Multi-Unit Temporary Cylinder, Multi-Unit Ti Cylinder, Multi-Unit Base.

Warnings:

The instructions given are insufficient if used as the only reference for the use of the cited components. These elements should only be inserted by dentists who have been fully trained in the insertion of dental implants. The use of these products without any prior specific knowledge can lead to component failure and may require implant removal. The safety of our products is guaranteed only when they are used exclusively by trained professionals. Read the instructions carefully on the labels of the products, where you will find the basic guidelines. Keep a record of the products used in the patient's personal medical booklet, stating the name of the product, the reference number, and the lot number. Please inform URIS Implants of any defects or complications related to any of its products. All URIS OMNI Narrow System products are solely for single use. To reuse the single-use products may lead to a possible deterioration of the characteristics of the product, which in turn can lead to an elevated risk in gum or tissue infection and deterioration in the patient's health. In

general, implant component's placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered. There is a risk of accidental inhalation and/or ingestion of the products when they are used, therefore it is necessary to carefully hold onto the products in case of intraoral applications. The patient should be made aware of any limitations in his/her treatment, and the need for maintenance, for example, the need to seek medical assistance if any symptoms or side effects arise. It should be recommended to the patient to conduct regular dental check-ups for maintenance of the URIS OMNI Narrow System products. The products are not sterilized when sold, and therefore, it is recommended to clean and sterilize the products before their use.

* Warning: Small diameter implants and angled abutments are not recommended for the molar region of the mouth.

Contraindications:

It is contraindicated placing dental implants in patients:

- Medically unfit for an oral surgical procedure
- With inadequate bone volume unless an augmentation procedure can be considered
- In whom adequate sizes, numbers or desirable position of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Allergic or hypersensitive to titanium alloy (grade 5).

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The URIS OMNI System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of URIS OMNI System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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All prosthetic abutments are provided non-sterile and must be sterilized before use. To correctly sterilize the products, use a steam sterilizer with pre-vacuum process, at a temperature of steam sterilizer at 132° C for 4 minutes, wrap and dry 20 minutes with a validated cycle according to the standard ISO 17665-1 following the autoclave manufacturer instructions.

	Pre-Vacuum Autoclave
Temperature	132° C
Exposure Time	4 minutes
Dry Time	20 minutes











Note: The validated procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79.

Storage

The product has to be stored in its original package in a dry place at room temperature.

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Symbols may be used on some international package labeling for easy identification.

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Instructions for use

EN

Dental Implant, Instruments

Valid only in United States

IFU_UOI0007, Revision 00, Document valid as of Apr-1-2019

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URIS OMNI System Instruments are manually powered devices intended to aid the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid the fitting of endosseous dental implants or abutments, aid the fabrication dental prosthetics, and used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. These devices include drills, screwdrivers, torque wrenches, implant placement and removal tools, laboratory pieces used for fabrication of dental prosthetics.

General Principles of Surgical Tool Management

1. Because all surgical tools are provided in a non-sterile condition, they must be cleansed and sterilized before use.
Caution - Incorrect cleansing and sterilizing processes cause corrosion and damage to the tools and if used directly, can cause second infection.
2. The recommended number of use of a drill is 20~30 times based on the bone status, and must be replaced if the blade has been damaged or transformed.
Caution - If a damaged drill is used, heat necrosis may occur
3. When managing the surgical tool, one must wear a mask and a glove to prevent infection.

Before sterilization

1. To prevent contaminants such as blood, tissue cell or bone residue from attaching to the surface of the instruments, the instruments must be immersed in an antiseptic solution immediately after use.
2. When using antiseptic solution, to prevent corrosion or bronzing, follow the directions given by the manufacturer for the antiseptic concentration and the duration of the instrument immersion in the antiseptic.
Check Concentration : Completely liquify the concentrate before placing the instruments in the antiseptic solution.
Immersion Duration : The instruments must not be immersed more than a day.
3. The instruments must be fully immersed in the antiseptic solution.
4. To decrease in sterilizing power and to prevent corrosion, the antiseptic solution must be replaced every day.

Before rinse

To prevent protein from clotting in 45°C, the instruments must be rinsed in running cold water.

Caution

Cleanse the instruments right after preliminary rinse

Sterilization

1. Must only use antiseptic solution that is FDA and CE approved, and follow the manufacturer's directions.
2. When cleansing metal instruments, corrosion free antiseptic solution and cleansing product use is recommended.
3. For safety, always wear personal protection gear such as gloves, glasses, and masks.
4. The user is responsible for the sterilization and management of the instrument.
5. Restriction and limitation of the instrument reuse:
 - With repetition of cleansing, the life expectancy of all instruments will decrease. If the instruments show corrosion, transformation or discoloring of the marking area, they have exceeded the safety criteria that is required for use.
 - Product with a disposable mark cannot be reused.
 - Tungsten carbide burs, plastic composition and NiTi instruments can be damaged with hydrogen peroxide and aluminum material instruments can be damaged by caustic soda solution.
 - Do not use acid solution (pH < 6) and alkaline solution (pH > 8).

Caution

After use, if the contaminants such as residual bone or blood stain are not completely removed, it may lead to corrosion; therefore, all separable instruments must all be disassembled before the cleansing process.

Cleanse / Dry

1. Contaminants must be completely removed using a soft brush.
Do not use a wire brush or stainless material brush, and do not put too much pressure.
2. Immerse the products in the antiseptic solution of their characteristics and clean with an ultrasonic cleaner. However, do not cleanse different materials together. Also, when immersing the instruments in the ultrasonic cleaner, make sure that the instruments do not touch each other.
3. Make sure that debris is not visible.
 - Products that are fractured or transformed must be discarded.
 - One should follow the recommendations for the level of concentration or the length of time provided by the manufacturer.
 - The antiseptic solution must not include aldehyde, di- or tri-ethanolamines components to control the corrosion.
4. After cleaning, the products must be rinsed with distilled water or deionized water for at least a minute. If the antiseptic solution contains corrosion inhibitor, rinsing before placing in the sterilizer is recommended.
5. To prevent corrosion or water stain on the instruments, completely dry with a dryer or filtered compressed air
6. To prevent corrosion, decrease in sterilizing power, and contamination, antiseptic must be supplemented every day.

Caution

If the instruments are not properly rinsed, residue is left behind, or not properly dried, the sterilization process might discolor or corrode the instruments, and therefore the whole process must be repeated.

Caution

Corrosion may start if debris such as blood stain or bone residue is not completely removed. They must be cleansed right after use and the debris must be completely removed when cleaning.

Check

Check on the instruments for faults (fracture, transformation or corrosion). If necessary, assemble the instruments.

Contaminated instruments must be cleansed or disinfected. Transformations that may affect the safety, performance or tolerance of the instruments in other words; bent, damaged (fractured or corroded), or faulty products (discoloration of marking area or loss) must be destroyed.

Packaging

1. Check on the dry status of the instruments and pack in the sterilized wrapping paper.
2. On the sterilized wrapping paper, attach a direction tape to check the date of sterilization. Check the expiration date on the sterilized wrapping paper. Wrapping paper must be able to withstand up to 141°C that coincides with the EN ISO 11607.

Pasteurization

1. The product is packaged cleaned and sterilized before use. To correctly sterilize the products, use a steam sterilizer with pre-vacuum process at a temperature of steam sterilizer at 132°C for 4 minutes Then dry for 20 minutes with a validated cycle according to the standard ISO 176651 following the auto-clave manufacturer instructions.
2. Instruments and plastic components must be sterilized according to their packaging label.
 - Sterilizer must coincide with the requirements of EN 13060 and EN285.
 - Sterilization process must regard the ISO 11607.
 - Follow the sterilization process and maintenance process of the sterilizer provided by the manufacturer.
 - Efficiency management (proper packaging, no humidity level and sterilization dashboard).

Caution









- The products must not touch the inner part of the sterilization equipment, and the sterilization degree must be lower than 150°C
- If they were not cleansed, not properly dried, or has been corroded, separate them from the rest or remove the faults.
(Do not sterilize the corroded instruments together with the noncorroded products)
- For sterilization, use only salt-free water or distilled water as the solution.
(Do not use tap water)
- Check if the instruments are fully dried and do not leave them in a place with high moisture.

Storage

Instruments must be stored in a sterilized container in a dry and clean environment. If the packaging is opened or damaged, the instruments' sterilization status cannot be guaranteed

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