For education

SAVE GBR KIT

User Manual Ver.1

DENTIS

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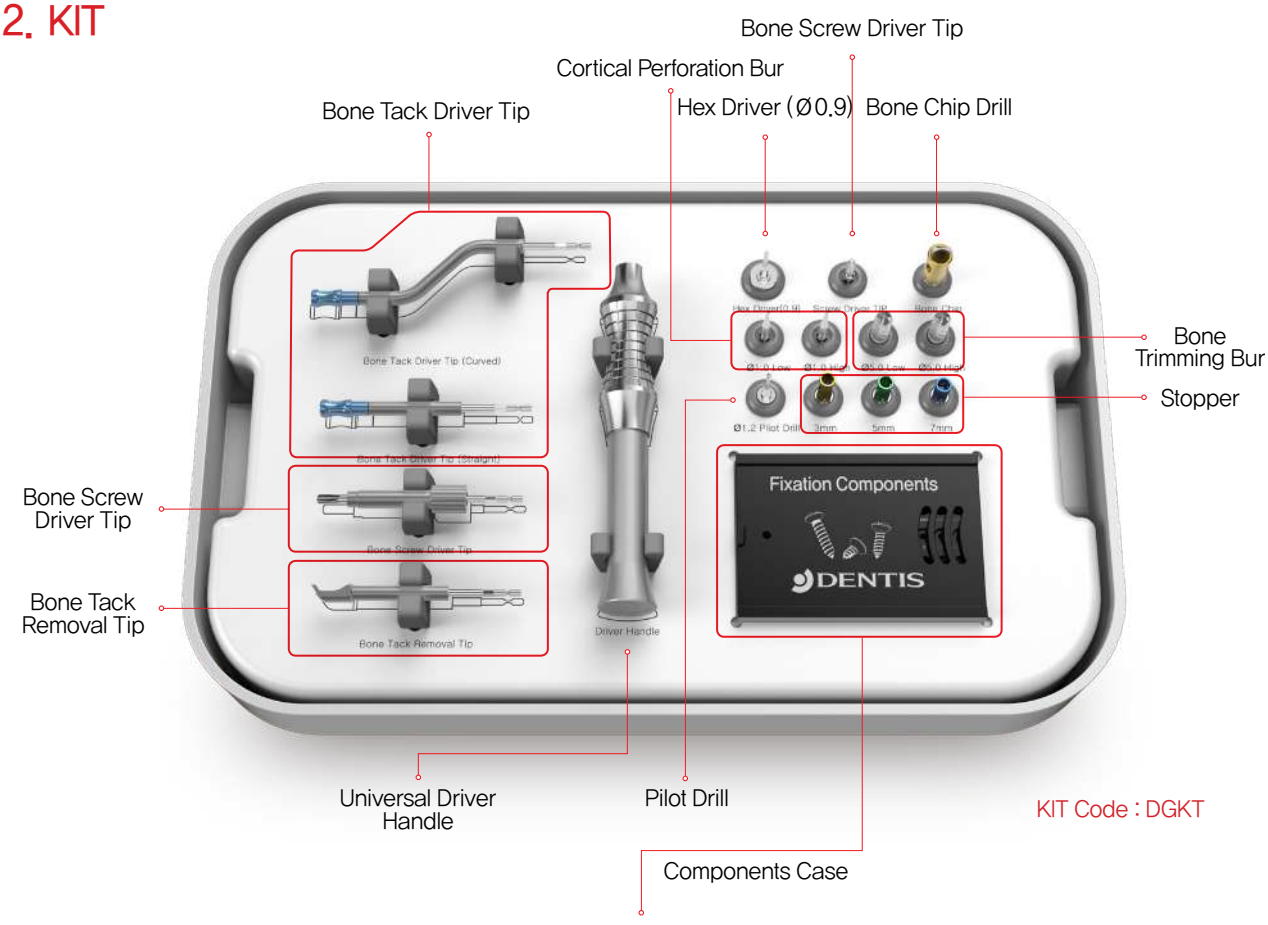
DENTIS

I. Product Overview

1. Introduction

It is an all-in-one kit that can be used in all successful GBR procedures since it is composed of various types of burs and bone tacks that are used for GBR procedures, and also driver and handle that are used for fixing the screw.

2. KIT



KIT Code : DGKT

Components Case Code : DSGSC

II. Specifications

1. Drill & Bur

Bone Chip Drill & Stopper

- This is to harvest or collect patient's own bone using drills.
- Engage bone chip drill to engine and apply stopper.
- Components : Bone chip drill, stopper
- Recommendation RPM : 300~600 RPM

Drill Diameter	Amount	Code
Ø5.0	1pcs	DGBC50

Bone Trimming Bur

- It is used to trim and contour alveolar bone for adaptation of barrier membrane or to remove granulation tissue of bony defect.

Diameter	Type	Amount	Code
Ø5.0	Straight (Low)	1pcs	DGBTB50L
Ø5.0	Contra-angle (High)	1pcs	DGBTB50H

Cortical Perforation Bur

- It is used to promote stable bone regeneration by perforating cortical bone.
- Recommendation RPM of the contra-angle bur : 1,200-1,500 RPMR
- Recommendation RPM of the straight bur : 30,000-40,000 RPM

Diameter	Type	Amount	Code
Ø1.0	Straight (Low)	1pcs	DGCPB10L
Ø1.0	Contra-angle (High)	1pcs	DGCPB10H

2. Handle & Driver

Hex Driver (Ø0.9)

• It is used when connecting the spacer and healing cap.

Drill Diameter	Amount	Code
Ø0.9	1pcs	DRHDL09

Universal Handle

• The handle that is used by being connected to the bone screw driver, tack driver and removal tip.

Amount	Code
1pcs	DGUDH

3. Bone Tack Instruments

Cortical Perforation Bur

• It is used for holding the bone tack while installing the implant.
• Separate the cover (blue part on the front) for connecting bone tack.

Type	Amount	Code
Straight	1pcs	DGBTDS
Off–set	1pcs	DGBTDC

Bone Tack Removal Tip

• It is used to remove the fixed tack.

Type	Amount	Code
Straight	1pcs	DGBTRT

4. Bone Screw & Tenting Screw Instruments

Pilot Drill

- It is used to form holes before installing the bone screw or bone tack when cortical bone is thick.
- Recommendation RPM : 800~1,500 RPM

Drill Diameter	Amount	Code
Ø1.2mm	1pcs	DGPD12

Cortical Perforation Bur

- It is connected to the pilot drill and used to control drilling depth accurately while inserting the bone screw and tenting screw.

Type	Amount	Code
3mm	1pcs	DGS03
5mm	1pcs	DGS05
7mm	1pcs	DGS07
Holder	1pcs	DGSH

Bone Screw Driver (Handle)

- It is used for holding the bone screw while installing the implant.

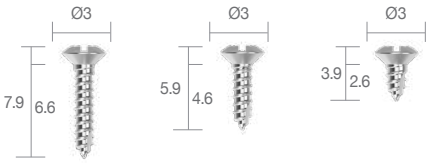
Type	Amount	Code
Universal handle	1pcs	DGBSD

Bone Screw Driver (Handpiece)

- It is used for holding the bone screw while installing the implant.
- For screw removal, rotate it in opposite direction.
- Recommendation RPM : 40~50 RPM

Type	Amount	Code
Handpiece	1pcs	DGBSDTH

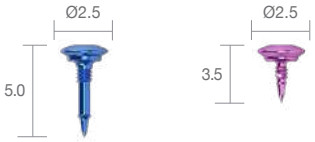
5. Fixation Components (Separately sold products)



Bone Screw

• It is a fixing screw that is used to fix the barrier membrane and it is fixed by using a designated screw driver.

Head / Thread Diameter / Length	Amount	Code
Ø3.0HD / Ø1.4TD / 3mm	1pcs	DBS1403
Ø3.0HD / Ø1.4TD / 5mm	1pcs	DBS1405
Ø3.0HD / Ø1.4TD / 7mm	1pcs	DBS1407



Bone Tack

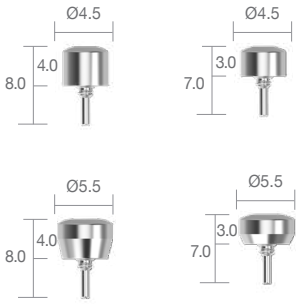
• It is used to fix the barrier membrane and it is fixed by using a designated bone tack driver and mallet for increasing fixation.

Head Diameter / Length	Amount	Code
Ø2.5 / 3.5mm	5pcs	DBT2503
Ø2.5 / 5mm	5pcs	DBT2505

Spacer

• It is used with a designated healing cap.
• A mediating structure that is connected to the implant in non–submerged type GBR.
• It is connected by using Ø 0.9 hex driver.
• Recommendation Torque Value : 12~15 NCm

Head Diameter / Length	Amount	Code
Ø4.5 / 1.5mm	1pcs	DGS4501



Healing Cap

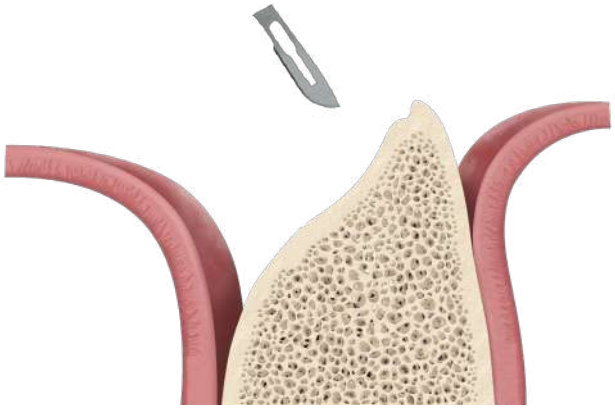
• It is used to fix barrier membrane on top of the spacer in non–submerged type GBR.
• It is connected by using Ø 0.9 hex driver.

Drill Diameter / Length	Amount	Code
Ø4.5 / 3mm	1pcs	DGHC4503
Ø4.5 / 3mm	1pcs	DGHC4504
Ø5.5 / 3mm	1pcs	DGHC5503
Ø5.5 / 4mm	1pcs	DGHC5504

III. How to Use

1. Surgical Procedure

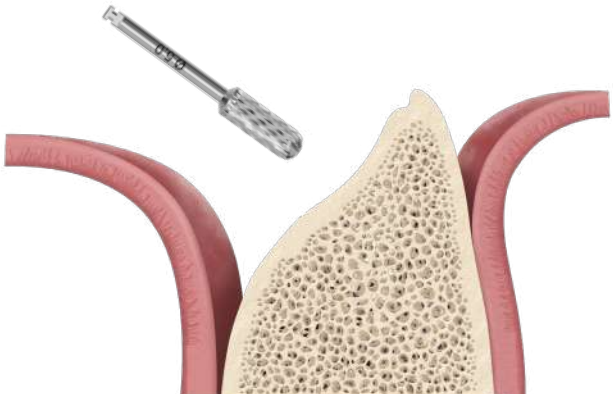
1) Incision & flap elevation



Make an incision on the gingiva of the site for implant insertion by using a blade, and separate periosteum by using periosteal elevator or similar kind instrument.

2) Bone trimming (Optional)

Bone Trimming Bur



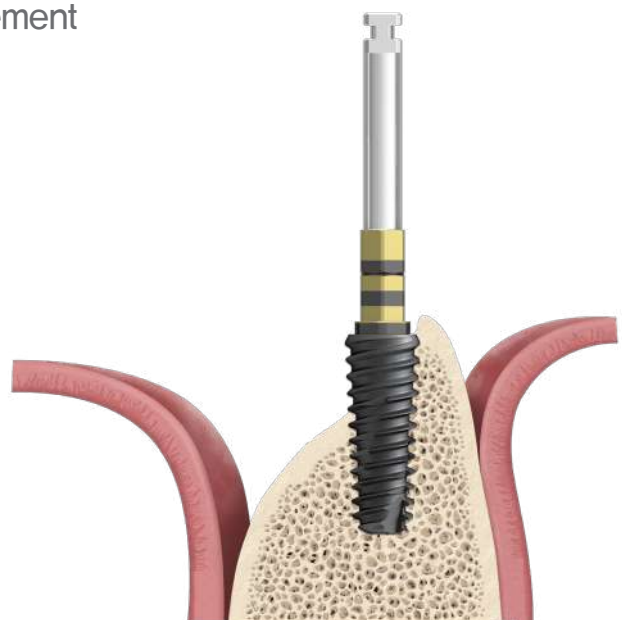
By connecting Ø 5.0 bone chip drill and stopper, autogenous bone is obtained with 300–600 rpm under copious amount of water irrigation.

3) Drilling

Surgical Drill

Perform drilling in accordance with the method recommended by the manufacture's fixture drilling sequence.

4) Implant placement



(Machined)
Mount Driver

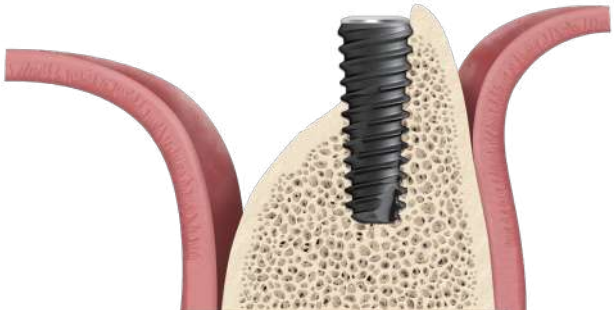
(Ratchet)
Mount Driver

Fixture

Fixture installation with fixture driver.

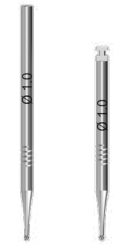
5) Connect Cover Screw

Cover Screw

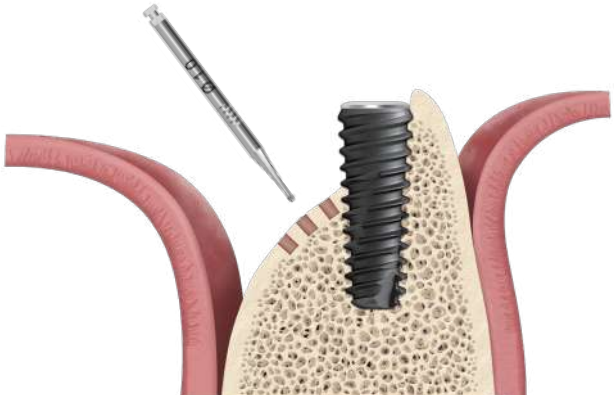


Connect cover screw.

6) Cortical bone perforation

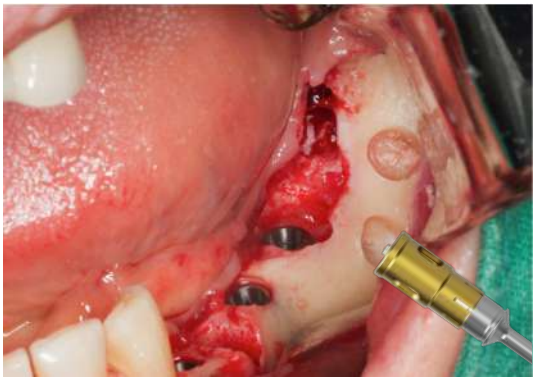


Low Speed High Speed



By using either low speed or high speed bur, cortical bone perforation is done for blood supply and osteogenic cell migration.

7) Harvest autogenous bone



Bone
Chip Drill

By connecting Ø 5.0 bone chip drill and stopper, autogenous bone is obtained with 300–600 rpm under copious amount of water irrigation.

Tip
- Check whether stopper is well connected to the bone chip drill before use. (No gap between the drill and stopper should exist.)
- Recommendation of the using for cortical bone

8) Choose non–resorbable membrane, Ovis TRM

Ovis TRM

PM1224A
12mmx24mm

PM1319A
13mmx19mm

PM3040A
30mmx40mm

PMB2325
25.16mmx23.56mm

PM1424A
14mmx24mm

PM1318A
13mmx18mm

PM2536A
36mmx25mm

PN2029(No Titanium)
29mmx19.82mm

PMB2029
29mmx19.82mm

PMB2028
20mmx28.4mm

PMB2830
30mmx28.4mm

PM1725A
17mmx25mm

PM2530A
25mmx30mm

PM3041A
41mmx30mm

PMB2127
27mmx21.44mm

PN2025(No Titanium)
20mmx25mm

PN2530(No Titanium)
25mmx30mm

PN3040(No Titanium)
30mmx40mm

PM2025A
20mmx25mm

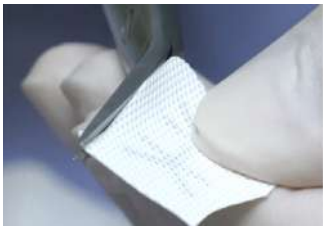
PM3040SA
30mmx40mm

PMB2021
20.71mmx19.8mm

PMB2530
30mmx24.9mm

PMB2025
20mmx24.9mm

9) Trim barrier membrane (Optional)



By using scissors, trim Ovis TRM in accordance with the surgery site.

Notice Titanium frame is trimmed so that it does not get cut.

10) Choose bone graft material, Ovis Bone Graft

Ovis Bone Graft

Ovis ALLO
Allogenic Material

- Osteoconduction and osteoinduction
- The used human anatomy with passed strict guidelines of FDA and KFDA
- Priority of domestic donor
- Production process by a single donor to prevent cross infection
- Ideal combination of cortical and cancellous bone powder
- Easy and simple syringe type

Ovis XENO-P
Xenogenic Material

- 100% cancellous swine bone that has been deproteinized.
- Safety from mad cow disease or Creutzfeldt–Jakob disease and so on.
- The most similar void fraction to that of human bone.
- Excellent hydrophilicity and transparency
- Biocompatible and excellent bone regeneration ability.
- Surface void form of natural bone is maintained due to special processing technique.

Ovis XENO
Xenogenic Material

- Bovine bone grafting material of natural mineral cancellous bone composed of double coated Ca–P
- Natural mineral bone obtained through strict manufacturing process
- No immunologic rejection
- Biocompatibility and great bioactivity
- Easy revascularization of the bone graft site
- Well–formed Macro/Micro porous similar to human's cancellous bone

Ovis Bone BCP
Alloplastic Material

- Osteoconductive synthetic bone graft with higher β–TCP content
- Excellent wettability
- Easy manipulation
- Biocompatibility and great bioactivity
- Well–formed Marco/Micro porous
- Porosity : 70%

11) Pilot drilling for hard bone (Optional)

It is used when cortical bone is thick while inserting the bone screw. Stopper is connected to the pilot drill, and drilling is done with 800~1,500 rpm on the site.


Pilot Drill


Stopper

Connect 3/5/7mm drill stopper to the Ø1.2mm pilot drill.

12) Bone graft application & membrane fixation

Fix the membrane by using at least 2 bone tacks or bone screws. After bone graft material is inserted, cover it again. If needed, fix it with additional bone tack or bone screw.

Choose Bone Tack, Bone Screw

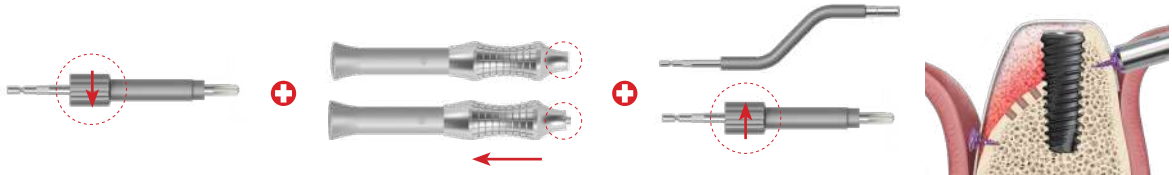
- **Fixation of regular membrane**
  Bone tack 3.5mm,
  Bone screw 3mm

- **Fixation in the case where it is thick and initial stability is poor**
  Bone tack 5mm,
  Bone screw 5mm

- **Vertical augmentation**
  Bone screw 7mm,
  Tenting screw (Coming Soon)

Membrane fixation Method

Connecting method of universal handle and driver



Bone screw driver is unscrewed in counter-clockwise rotation
(After use, it is loosened by unscrewing in the opposite direction.)

Pull the front part of universal handle backwards.

After connecting, rotate it again in clockwise direction for fastening.

Connecting method of driver with tack or screw

• **Connect bone tack & bone tack driver tip**

After connecting the straight or curved bone tack driver tip to universal handle, connect the bone tack and fix it by using mallet.

Curved bone tack driver tip is good for molar area

Bone Tack

Bone Tack Driver Tip

Universal Handle

• **Connect Bone Screw & Bone Screw Driver**

Bone screw driver is connected to the universal handle first and bone screw is connected.

Bone Screw

Bone Screw Driver

Universal Handle

• **Connect Bone Screw & Bone Screw Drive**

Bone screw drive tip is connected to the handpiece first and bone screw is connected.

Bone Screw

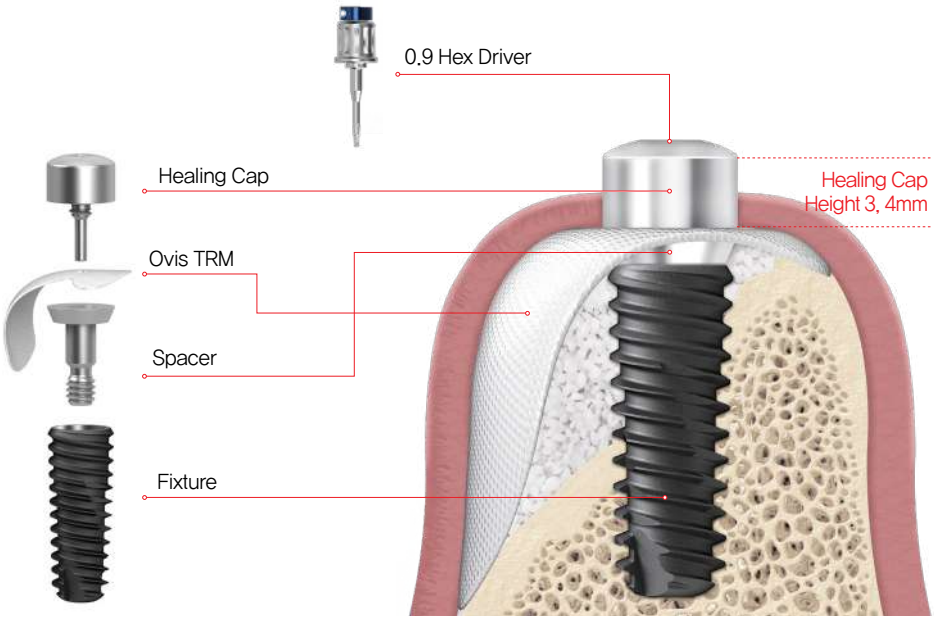
Bone Screw Driver Tip

Handpiece

13) Connect upper prophetic part (Optional)

If there is a hole in Ovis TRM, connect the healing cap and spacer in the SAVE GBR KIT by using Ø 0.9 hex driver.

Spacer　Haling Cap　Ø0.9 Hex Driver



Tip
- In terms of Ovis TRM, choosing a product with a hole will enable easy usage since forming a hole will be unnecessary.
- It is Non-submerged type GBR.

PMB2029
29mmx19.82mm

PMB2028
20mmx28.4mm

PMB2830
30mmx28.4mm

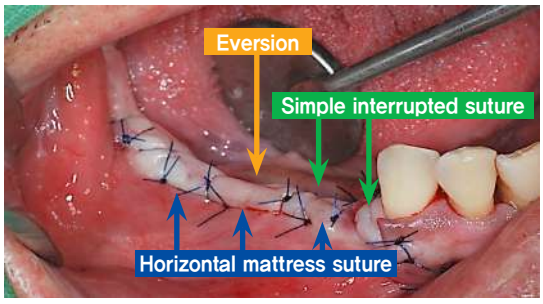
PMB2127
27mmx21.44mm

PMB2021
20.71mmx19.8mm

PMB2830
30mmx28.4mm

PMB2325
25.16mmx23.56mm

14) Suture



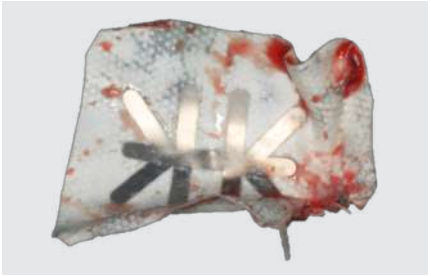
Suture using horizontal mattress suture and simple interrupted suture technique.

15) Removal Ovis TRM

Universal Handle

Bone Tack Removal Tip

Bone Screw Driver



When bone tack is used, remove it with bone tack removal tip, but when bone screw is used, remove it with bone screw driver. If there is no fixation of bone tack or bone screw, minimal flap design will be necessary, and remove them with pincette.

16) Connect healing abutment

Ø0.9
Hex Driver

Healing
Abutment

After completion of bone formation, cover screw is removed. When healing cap and spacer are used, remove them with Ø 0.9 hex driver and Ovis TRM. And healing abutment is connected.

2. Maintenance

1) Method for storage of the screw and bone tack

① Store the separately purchased screw, bone tack, healing cap are in the case.

② After relocating the component case in SAVE GBR KIT, 2) cleaning and sterilizing method for the KIT. Sterilize it according to ⑤~⑧.

③ During surgery, take out the component case and use it.

④ Do not reuse the screw bone tack that has been used.

2) Cleaning and disinfection of the KIT

① Thoroughly pre-rinse blood stain or foreign body on the instruments after using the kit by using a cleaning brush on the surface in distilled water or 30 ~ 40℃ running water for 20 seconds.

② In doing so, the blue part on the front of the bone tack driver tip is cleansed after being separated.

③ Pre-rinse it by immersing it in disinfectant liquid for 10 minutes.

④ Cleanse additionally by using ultrasonic cleanser.

⑤ After cleansing it by using detergent and cleaning brush, wash it in running water thoroughly.

⑥ Either 100% naturally dry the cleansed instruments or use a clean cloth to directly remove wetness.

⑦ Reposition the dried instruments in accordance with the mark of base plate of the kit.

⑧ Wrap the kit with sterilization wrap.

⑨ Mark the sterilization date after attaching sterilization tape on sterilization wrap.

⑩ Place the wrapped kit into the sterilization device and proceed sterilization.

3) Method for storage of the KIT

① Store it in room temperature on uncontaminated area.

② Check the marked sterilization date, and if it has not been used within 3 ~ 4 days, re-sterilize it before using it for surgery.

Ⅳ. Clinical Cases

Conventional GBR

Dr. Kim, Yongjin | Ilsan Apsun Dental Clinic

Patient Information

Placement Implant Area	5 6 7	**Sex / Age**	Female / 64
C.C.	Severe mobility of left upper bridge		
Treatment Plan	Implant placement and lateral sinus augmentation with Ovis TRM		
Materials and Methods	1. #24-27 extraction 2. Sinus grafty implant placement and lateral window approach with SAVE SINUS KIT 3. Ovis ALLO, Ovis Xeno-p 4. Ovis TRM fixed with bone tack from SAVE GBR KIT 5. Suture 6. 2nd op was done after 6 months 7. FGG was done after Ovis TRM removal		

Pre-operation

Fig.1 Pre-op panorama

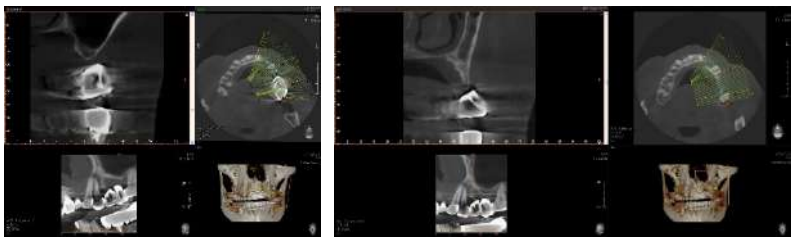


Fig.2a-b Pre-op CT. Severe horizontal bone deficiency and severe sinus pneumatization were seen

Fig.3a-b Pre-op clinical views

1st OP

Fig.4 Extraction was done

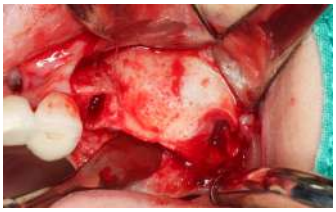


Fig.5 Incision and flap elevation

Fig.6 Bony window was prepared with a round bur from SAVE SINUS KIT

Fig.7 Removal of bony window

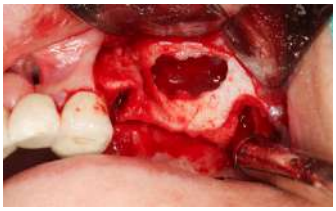


Fig.8 Sinus Membrane elevation with Sinus elevators from SAVE SINUS KIT

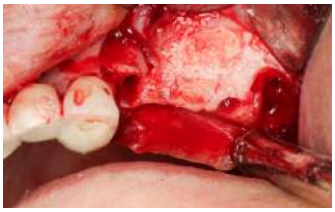


Fig.9 Ovis ALLO bone was grafted inside the sinus

Fig.10 Bony window was repositioned covering the bone graft material

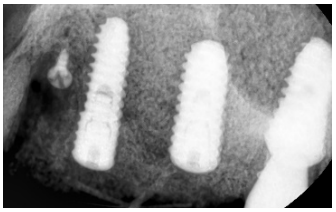
Fig.11 3 Implants were placed. Because of horizontal bone deficiency, 2nd premolar implant was exposed

Fig.12 Ovis Xeno-p was grafted covering the exposed implant and Ovis TRM was placed

Fig.13 Ovis TRM membrane was fixed with bone screws from SAVE GBR KIT

Fig.14 Tension free primary closure was done

Fig.15 Post-op panorama



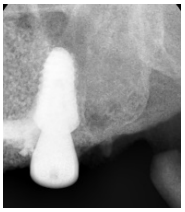


Fig.16a-b Post-op P.A.

2nd OP


Fig.17a-b Post-op 5months. Distal side of Ovis TRM membrane was exposed. However there was no infection or inflammation symptom

Fig.18 Post-op 24 weeks. 2nd stage surgery was done



Fig.18a-c Ovis TRM was removed

Fig.19 Apically positioned flap was done to increase vestibular depth


Fig.20a-b Free gingiva graft was done to increase keratinized gingiva

Fig.21 Free gingiva graft was secured with sutures and Louis buttons

Fig.22 After 1 week. Partial S/O was done

Fig.23 After 2 weeks, Louis Buttons were removed

Fig.24 After 3 weeks. Increased Keratinized gingiva were seen

Conclusion

Successful horizontal augmentation was possible by using Ovis TRM.
In this case, Ovis TRM was fixed with bone screws without drilling.
Because of poor bone quality. As shown in this case, bone screw might be better than bone tack In soft bone.

Ⅳ. Clinical Cases

Non-submerged GBR with spacer & healing cap

Dr. Kim, Yongjin | Ilsan Apsun Dental Clinic

Patient Information

Placement Implant Area	5	**Sex / Age**	Female / 45
C.C.	#45 pain and mobility		
Treatment Plan	#45 extraction and implant placement and GBR		
Materials and Methods	1. #45 extraction 2. Dentis OneQ-SL Ø4.0 X 10mm implant placement 3. Spacer was connected to the implant for non-submerged GBR 4. Bone graft material application 5. Ovis TRM was fixed with healing abutment & bone tacks 6. Suture 7. 4 months after Ovis TRM, healing cap, spacer removed 8. Connect healing abutment and suture		

Pre-operation

Fig.1 Pre-op panorama

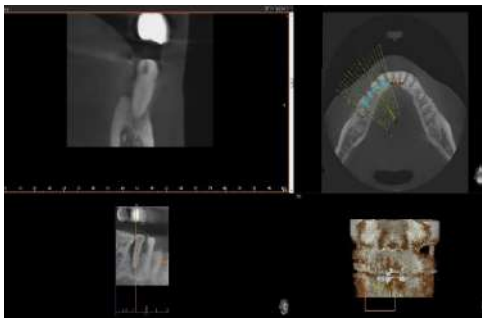


Fig.2 Pre-op CT

Fig.3 Pre-op clinical view

1st OP

Fig.4 #45 extraction

Fig.5 Flap elevation. Buccal bone defect was seen

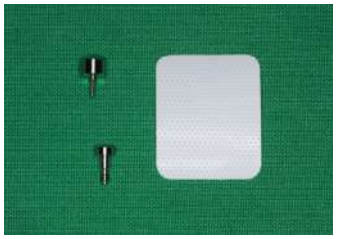


Fig.6 Ovis TRM, SAVE GBR KIT spacer and healing cap were prepared for non submerged GBR

Fig.7 Dentis OneQ-SL Ø4.0 X 10mm implant placement was done. Spacer was connected

Fig.8 Ovis TRM was trimmed and punched by Membrane punch®

Fig.9 Ovis TRM was fixed by healing cap

Fig.10 (ICB cortical) Bone graft material application

Fig.11 Ovis TRM was fixed with bone tack from SAVE GBR KIT

Fig.12 Suture around healing cap

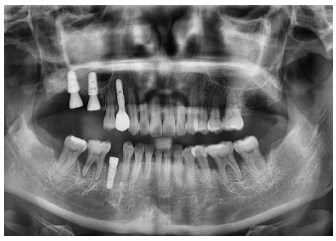


Fig.13 Post-op panorama

2nd OP


Fig.14a-b 4 months after GBR, soft tissue got healed very well

Fig.15 Flap elevation was done 4 months after GBR


Fig.16a-b Ovis TRM, healing cap and spacer were removed

Fig.17 Ovis TRM was fixed by healing cap

Fig.18 Ovis TRM was fixed by healing cap

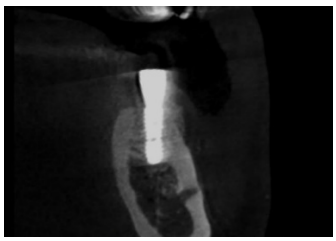
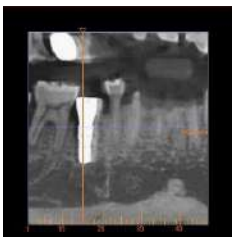



Fig.19 Post-op CT. Bucccal bone was regenerated with ideal contour

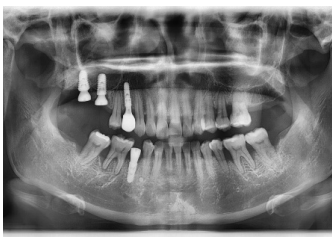


Fig.20 Post-op panorama

F/U

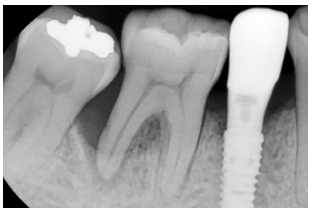


Fig.21 P.A. Final prosthesis was delivered 5 months after GBR

Fig.22 Final prosthesis delivery panorama


Fig.23a-b Post-op 11 months follow-up

Conclusion

By using spacer and healing cap from SAVE GBR KIT, easy and successful non-submerged GBR was possible.

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