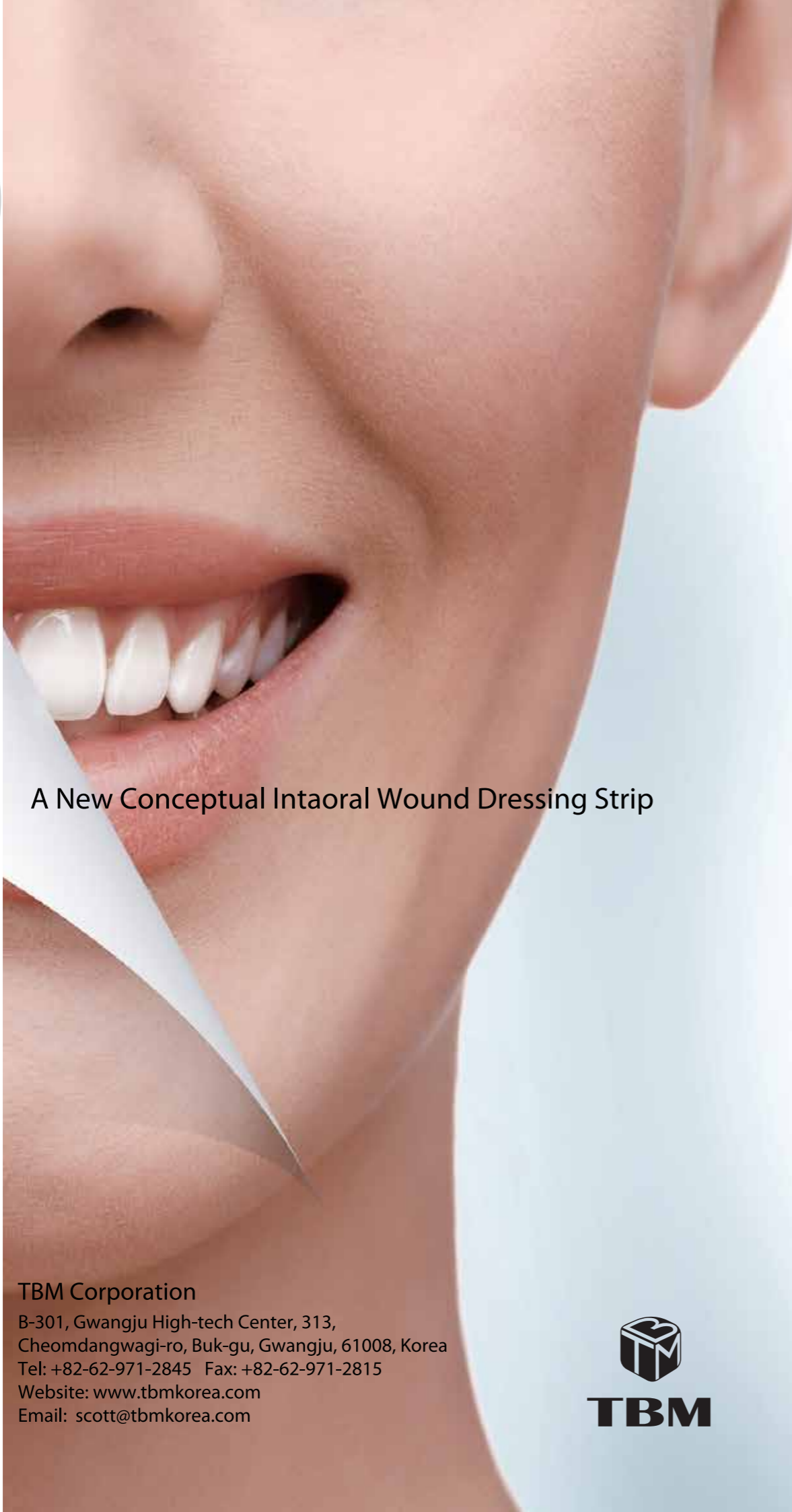


Ora-Aid



A New Conceptual Intraoral Wound Dressing Strip

TBM Corporation
B-301, Gwangju High-tech Center, 313,
Cheomdangwagi-ro, Buk-gu, Gwangju, 61008, Korea
Tel: +82-62-971-2845 Fax: +82-62-971-2815
Website: www.tbmkorea.com
Email: scott@tbmkorea.com



Ora-Aid



ISO
13485



"Ora-Aid Video"

Attachable Intraoral Wound Dressing



Implantion



Extraction



Bone graft



Periodontal
surgery



Free gingival graft



Braces &
Oral wonds



Ora-Aid

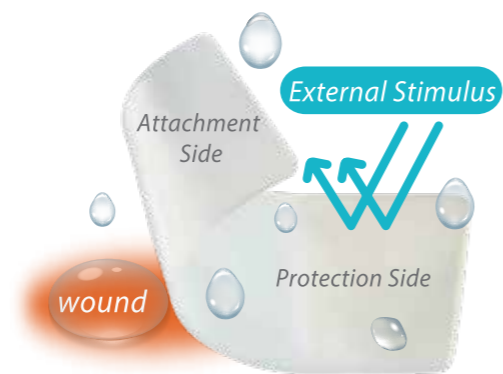
Safe, Easy, & Effective A New Paradigm
for Intraoral Healing

Features & Benefits	2
Principal of interaction	3
Instruction & Storage	4
Cautions & Product composition	5
Clinical data	6
Certificate	7
Clinical case	8
Q&A	16

Features & Benefits

This product is a non-eugenol protective dressing material applied to intraoral wounds.

- Advanced concept in intraoral dressing
- Protects intraoral wounds from food, bacteria and cigarette smoke
- Aids in hemostasis
- Protects suture thread from tongue irritation
- Strong adhesion using hydrophilic polymer
- Easy to cut into different shapes/sizes
- Self adhesive with saliva
- Reduces irritation sore in mouth
- Safe and easy to use
- Mint flavor reduces halitosis
- Contains vitamin E
- Aids in hemostasis

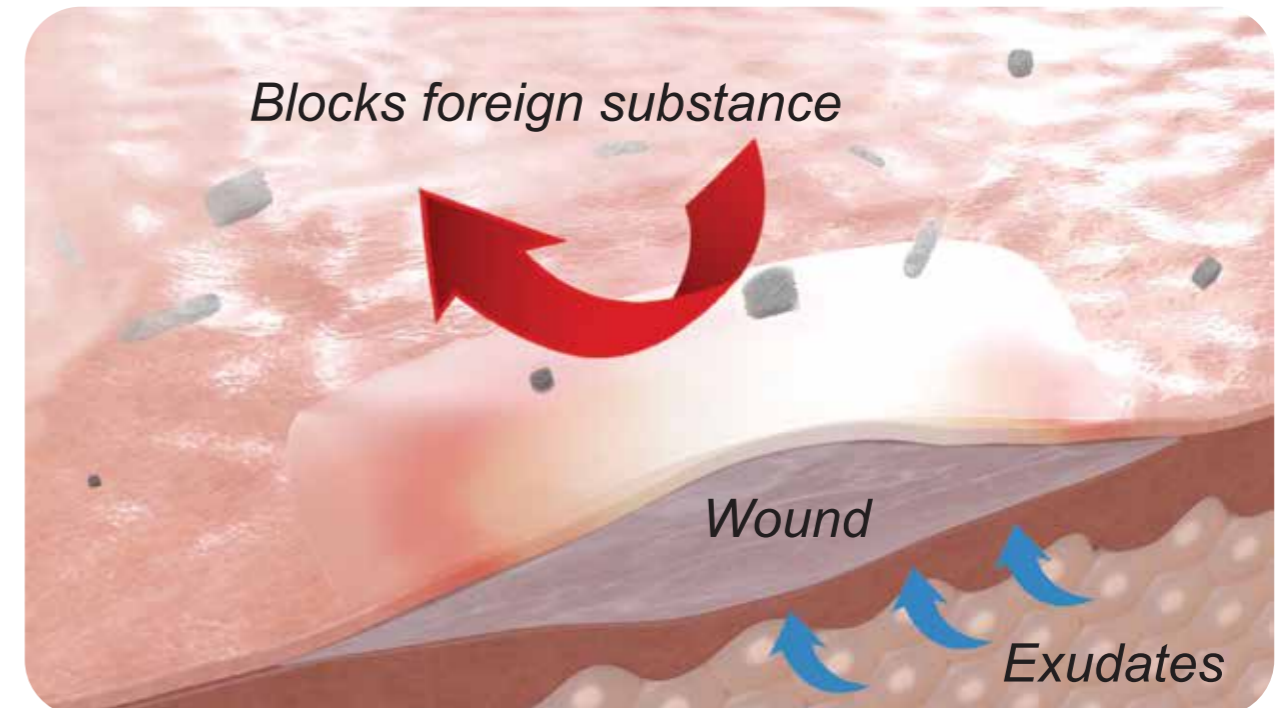


Indications for use

Intra-oral Wound Dressing is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery. Intra-oral Wound Dressing operates to relieve pain by adhering to and protecting affected tissues from further irritation, thereby allowing healing.



Principal of interaction



01

Absorption of excessive exudate

Too much secretion makes wounded area macerated

02

Remains Healing Growth Factors on the surface of the wound

White Blood Cell Macrophage Proteolytic Enzyme Cell Growth Factors

03

Protects Wound from temperature variation

Insulation improves blood supply and circulation, and makes cell move actively

04

Protects Wound from infection, external stimulus

Foods, smoke, infection factors

Instruction & Storage

• Instruction



- 1 Irrigate wound with sterile or saline solution
- 2 Cut Ora-Aid into a proper shape and size
- 3 Slightly remove moisture with gauze on the wound.
An excessive exudation may reduce its adhesive strength and attaching time
- 4 Remove transparent release paper and apply
- 5 Gently press Ora-Aid for 5 to 10 seconds while Ora-Aid adheres to wound
(Depends on circumstances, please press repeatedly)

• Storage

- 1 Store the product at room temperature(1°C~35°C), away from direct sun light and heating sources.
- 2 Follow storage condition to keep proper performance of product (adhesion, absorbability)

4

Incorrect usage case



At moving mucosa and tongue



Too much saliva and blood



At dry wound



Chronic ulcer which has not get better over 1 month, and severe inflammation



Space created due to incorrect attachment

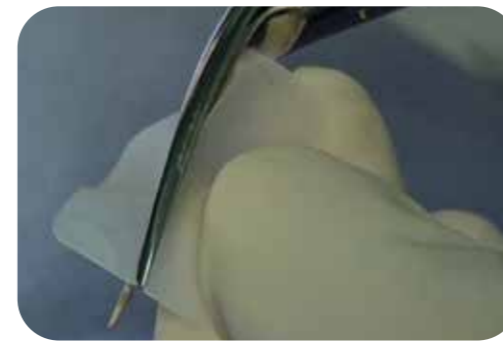
Recommendations

Compared to the movable mucosa, the attachment time is extended at the attached gingiva, upper jaw, and plate

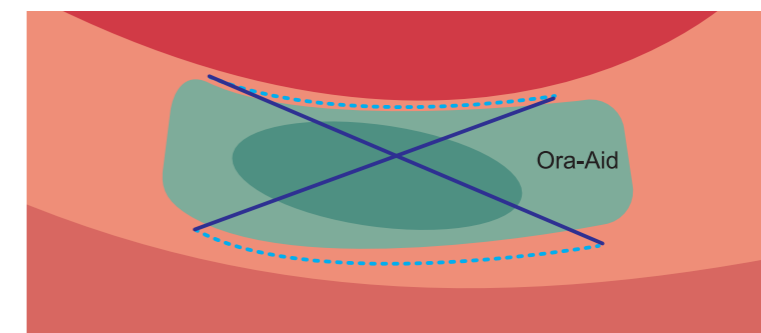


Suture Guide

Figure 8 suture



Ora-Aid
5



Caution

⚠ This medical device is for single use. If reused, the product may cause infection, cross infection, and inflammation. This product shall be disposed according to disposal regulation of each Competent Authorities.

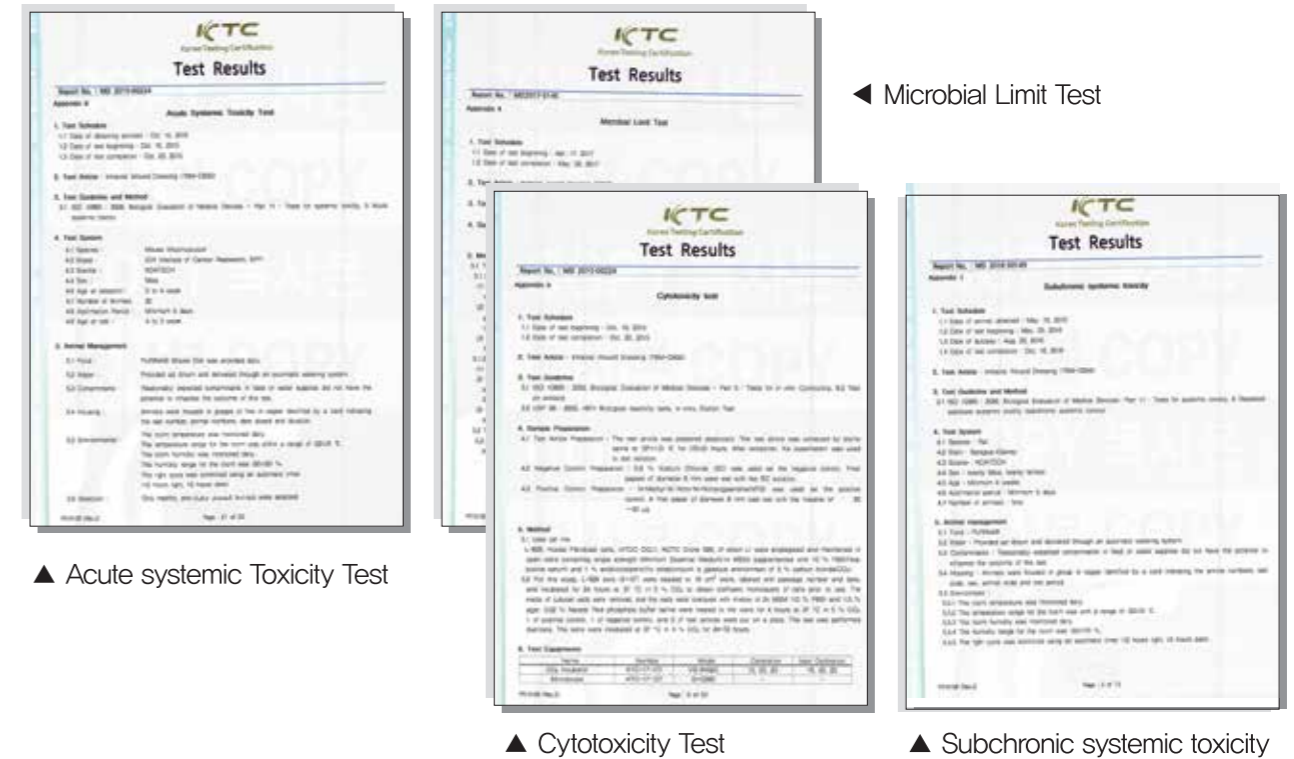
1. Please carefully read the instructions before use
 2. If you experience any swelling, allergic reaction, upset stomach or any signs of infection, consult with your doctor
 3. It is not recommended to remove the patch with force, the adhesive side will dissolve and fall off on its own.
 4. The protective side parted from the wound can be spit out
 5. The time of attachment may be reduced when stimulated by tongue or food
- A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;

Product composition



Quantity	20 ea	20 ea
Color	Red	Mint
Size	25x15mm	50x15mm
Code	AG-202A	AG-205A

Test Reports



▲ Acute systemic Toxicity Test

◀ Microbial Limit Test

▲ Cytotoxicity Test

▲ Subchronic systemic toxicity

Quality Certificates



▲ GMP

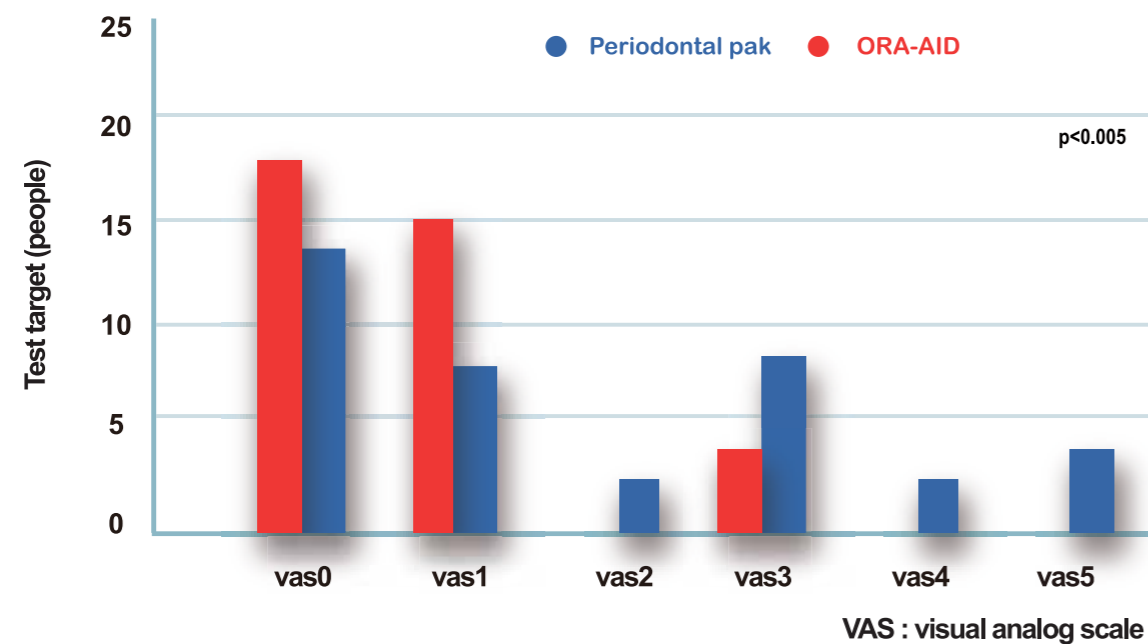
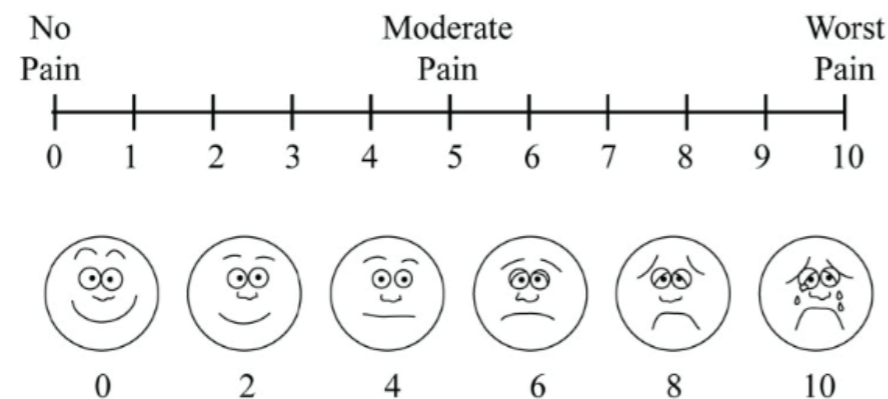
▲ ISO 13485

Clinical Data

Fig 1. Periodontal Pak(Left) and Ora-Aid(Right) were applied after modified Widman flap



Fig 2. Visual analogue scale for the assessment of postoperative pain

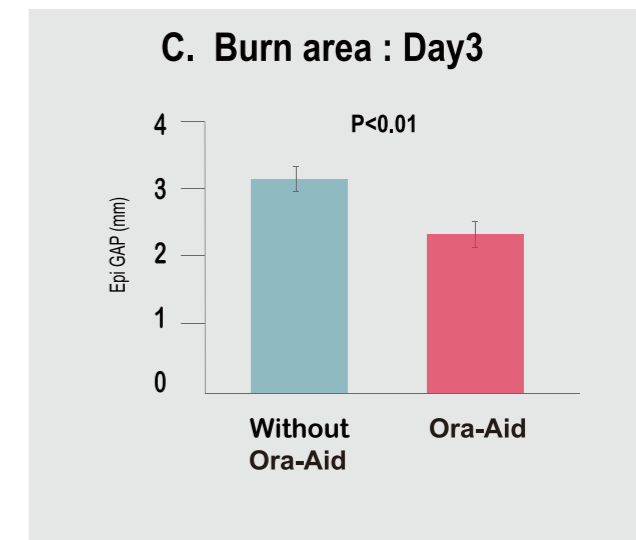
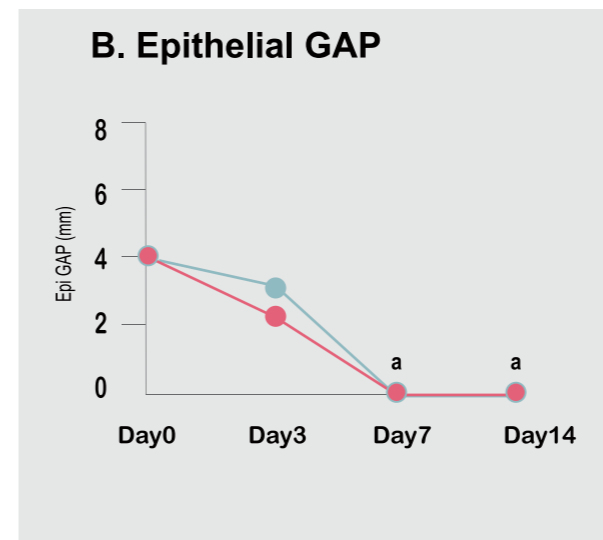
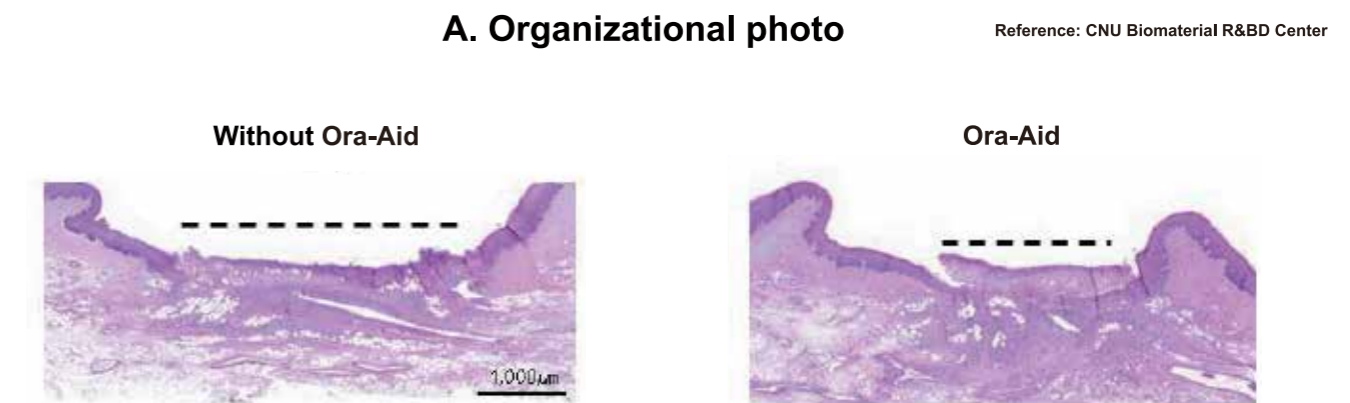


Healing effect

“ Ora-Aid has identified excellent wound healing and rapid collagen production at excision/inflammatory model in the oral cavity. ”

promotes excision healing in the mouth and preserves growth factors in the base of the wound surface for a long time.

Excision model 3rd day Epithelial GAP decreased



A. Organizational photos of the excision acquired on the 3rd day after surgery (H&E chromosome, Scale bar 1,000um) B. Graphs that measure and compared Epithelial gaps in each sample C. Comparative analysis graph of burn area

Increased collagen

Increase collagen levels means more tissue regeneration factors, faster healing of wounds.



10

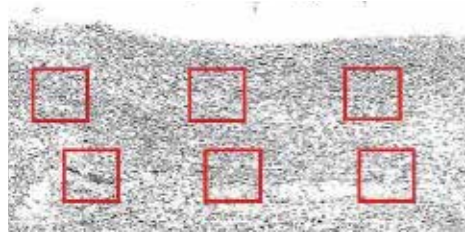
Clinical Cases

Ora-Aid

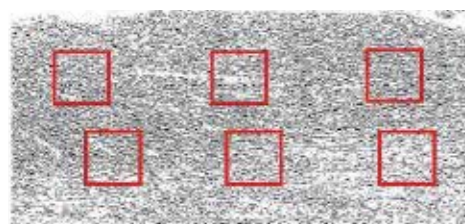
11

Excision model Collagen : 14th day, collagen level increased

A. Organizational photo

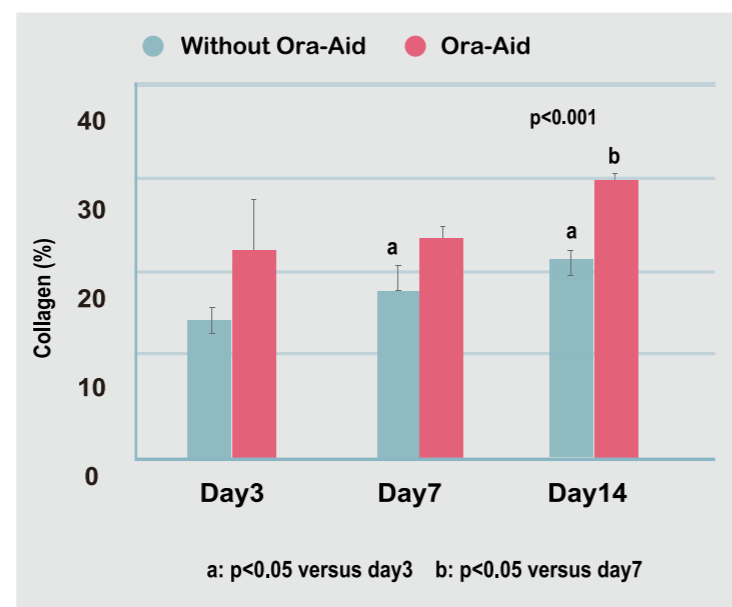


Without Ora-Aid



Ora-Aid

B. Collagen concentraion



A. Organizational photos of 3rd day after surgery(mt chromosome) B. Collagen(%) measured and analyzed for each sample

Clinical Case

Implantation 1



Exposed graft is protected by absorbable collagen sponge plug (Heliplug) secured in place above the graft



Ora-Aid is trimmed to fit the area



Ora-Aid placed on the wound



temporary Maryland bridge for aesthetic purpose



Soft tissue appearance 4 weeks post op



3 months post op

Socket Graft



Socket after extraction before grafting.



Socket grafting with Bond Apatite
A gap of 12 mm of exposed cement will be protected by Ora Aid until soft tissue proliferation will bridge the exposed gap.



Ora Aid sutured in place to protect the exposed Bond Apatite cement.



7 days post op excellent reaction between Ora Aid / Bond Apatite / soft tissue. The exposed gap is almost completely closed.

Clinical Case

Bone graft 1



Case by Dr. Amos Yahav
#24 extraction



apply Bond Apatite graft



Cut Ora-Aid into a proper shape and size



Placement of Ora-Aid patch on the exposed Bond Apatite



Fixation sutures to keep the Ora-Aid patch in place until soft tissue proliferation will bridge the exposed gap



10 days post op, complete closure of the exposed gap by soft tissue proliferation

Bone graft 2



Case by Dr. Amos Yahav
#36 Fractured with pain.



Extraction, and socket debridement



Socket grafting with Bone Apatite (Augma)



Sutures above Ora-Aid to maintain it in place for a long time until its absorption. Ora-Aid is quite effective to dress bleeding or oozing wounds and to protect the wound for longer time when it is sutured above the exposed Bond Apatite, enable soft tissue proliferation above the graft.



After 10 days



Suture removal. Uneventful healing with soft tissue proliferation above the graft can be seen.

Clinical Case

Immediate Implantation



Case by Dr. kim jaeyoon

Before implant

Surgery

After surgery & suture, dressing with Ora-Aid

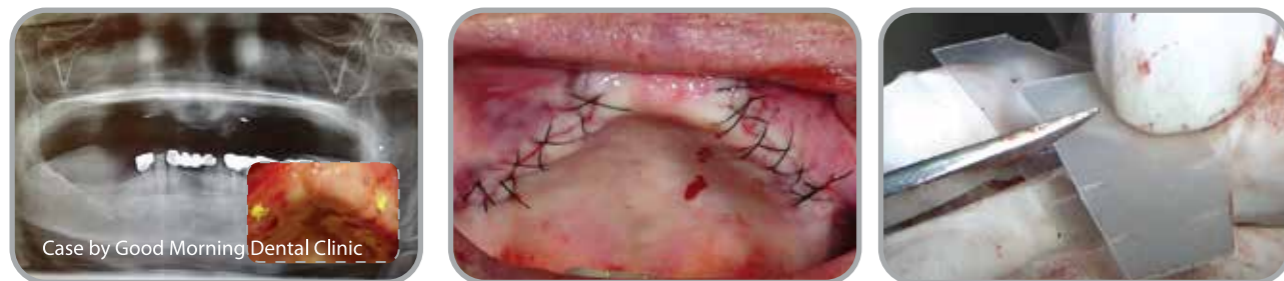


Excellent blood clot was formed on next day

After 2 weeks

After 1 month

Implantation 2



Case by Good Morning Dental Clinic

Panoramic shooting to check the location of the implant

Wiping the surgical site and blood control after implant placement.

Cutting the Ora-Aid to attach it on the wound suitably



Right side application (the retention time is depends on the attachment method)

Left side application

Postoperative panoramic imaging

Clinical Case

Implantation 3



Case by Central Dental Clinic

After surgery & suture

Dressing with Ora-Aid

After 7days

Implantation 4



Case by Dr. kim jaeyoon

After surgery & suture

Dressing with Ora-Aid

After 10 days

Two-step Implantation 1



Case by Yedameun Dental Clinic

After two-step implantation surgery & Ora-AID

Louis Button

After 10 days

two-step implantation 2



Case by Good Morning Dental Clinic

After surgery & suture

Cut Ora-Aid into a proper shape and size

Dressing with Ora-Aid

Clinical Case

Extraction 1



Case by Central Dental Clinic

palatal side impacted supernumerary tooth
After an incision of mucosa,
remove the supernumerary tooth.



palatal side After apply Ora-Aid



After 2 weeks

Extraction 2



Case by Central Dental Clinic

#12 After extraction, the blood clot
is formed and hemolysis presented
within 24 hours.



Apply Ora-Aid above on the open
socket to protect blood clot and help hemolysis.



After 7 days, you can see the growth
and formation of the graduation tissue.

Incision and drainage: I&D



Case by KimYooHwan Dental Clinic

#15 Visits by Pain Appeal Implementation
of I&D to remove inflammation



Apply Ora-Aid (25mm*15mm size)



Remove the drainage, and
apply Ora-Aid to prevent periodontitis

Mucous membrane traumatic damage



Case by Leeyoungseok Dental Clinic

oral ulcer occurred after surgery
(cuts by braces, self biting, etc)



Attach Ora-Aid to prevent secondary
infection. And it provides pain relaxation

Clinical Case

Temporary denture 1



Case by Dr. Carlos Adriano

#11, 13, 21, 22 Extraction



Bone graft



#21, 22 Apply bone graft



#21, 22 Attach Ora-Aid on
the surgical site after applied bone graft



#21, 22 Suture with Ora-Aid to
prevent loss of bone graft for a long time



#11, 13 Attach Ora-Aid on the surgical site
(protects socket, aids pain relaxation)



#11, 13 Apply Ora-Aid after suture



By using an Ora-Aid, it protects the area of
surgical site and eliminates pain caused by
temporary dentures.



Ora-Aid is thin and does not affect the
intersection between denture and gum.
And enable rapid recovery of patients
with cushioning(wall) roles during the
adaptation period.

Temporary denture 2



Case by Good Morning Dental Clinic

Suture



Dressing with Ora-Aid



Ora-Aid is Reducing irritation in
gum tissue formation

Clinical Case

Subepithelial connective tissue graft



Case by Leeyoungseok Dental Clinic

Obtain graft tissue



palatal side After apply Ora-Aid



After 1 week donor site



Gum Staining / Graft Insertion



After suture apply Ora-Aid



After 1 week recipient site

After 6 month

Free gingiva graft : FGG



Case by Dr. kim jaeyoon

Obtain subepithelial connective graft tissue of palatal side



Donor site dressing with Ora-Aid



After 1 week donor site



#45 #46 no attached gingiva / free gingival graft Insertion and Suturing



Recipient site dressing with Ora-Aid



After 3 week recipient site

Clinical Case

Crown lengthening procedure : CLP



Case by Leeyoungseok Dental Clinic

Before CLP



Preparation periodontal flap operation



Suturing



Dressing with Ora-Aid



After 1 week



After 3 week

Periodontal Flap Operation



Case by Rodem Dental Clinic

#14,15 Suturing after removed inflammatory tissue from the tooth cavity and mucosa



Apply Ora-Aid (25mm*15mm size)



Protect the donor site. Provide pain relaxation. Block external stimuli.

Frenectomy



Use laser to perform labial frenectomy



Apply Ora-Aid which is transparent and aesthetic, thin to minimize feeling of irritation

Clinical Case

Q & A

Ora-Aid and Periodontal Pak 1



Case by Seo jeong Dental Clinic

Before surgery



Apply the auto-tooth bone graft & membrane(absorbent) #16 Implant placement



Suture



Apply Ora-Aid for protection, pain relaxation, and blood control-> Apply Periodontal Pak aboveon the Ora-Aid



10 days later, remove Ora-Aid & Coe-pak



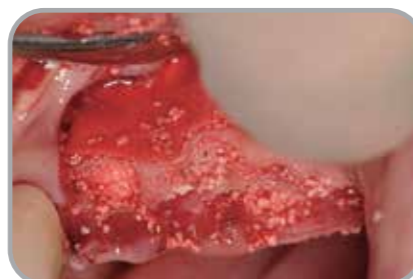
Through applying Ora-Aid under the Coe-pak, blocks plague formation and provides pain relaxation (When remove Periodontal Pak from the surgical sites, it usually causes pain because it adheres with silk)

Ora-Aid and Periodontal Pak 2



Case by Seo jeong Dental Clinic

#22,23,24,25 implantation. Check width and cool to 7mm to 10mm



Use bone grafting and synthetic bone to repair the broken parts and use absorbent shielding film.



Suture



Application of Ora-Aid for rapid Blood clot formation



Extend the attachment time using a Periodontal Pak over the Ora-Aid.



After 10 days. After removing the Ora-Aid and the Periodontal Pak

Q. Needs to remove protection layer?

Ora-Aid is composed of two layers, protection layer and attachment layer. When the attachment layer dissolved completely with moisture/saliva in mouth, the protection layer will fall off automatically. So, no need to remove protection layer by force

Q. Doesn't stick well? / Fall off too fast?

Usually it is caused by incorrect attachment on the surface of the wound and affected area. Cut Ora-Aid into a proper shape and size accordance with the wound. When attach Ora-Aid, it should be combined with some amount of moisture.

If there are too much moisture, slightly remove with gauze on the wound and gently press Ora-Aid 5~10 seconds to make high adhesion.

We also recommend customers to attach Ora-Aid to hard tissue.

If you attach to soft tissue, it may not last long due to the movement of soft tissue muscle.

Q. How long does the adhesion last?

In general, Ora-Aid stays more than 6 hours.

However, it depends on attaching cases because the circumstances are various.

Q. Ingredients?

It is made of polymeric materials, including hydroxy ethyl cellulose.

All raw materials are listed on KP&USP standards.

Q. Could be stay more than 2~3 days?

In general, Ora-Aid stays more than 6 hours.

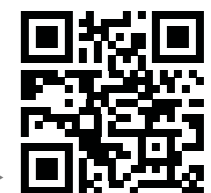
The main purpose of Ora-Aid is to increase natural healing effects of oral tissue with preserving growth factors through the absorption of exudate especially during prime time.

In addition, it provides protection to the wound area against secondary infection.

Through this early stage protection for several hours, it can help with the effect of initial wound healing. If it needs to extend attached time, please suture Ora-Aid on the wound according to provided protocol.



Suture Protocol Guide ▶



Q. Can use it on the open wound or can suture it inside of tissue?

We do not recommend it. Better to apply Ora-Aid after suturing.

Ora-Aid is not a membrane which can be used inside of oral tissue.