



Curatick

Oral Wound Home Care Solution

**Protect wounds
in your mouth**



TBM

An adhesive transparent medical device for cuts in your mouth, prevents cuts in your mouth from being contaminated and protecting such wound.



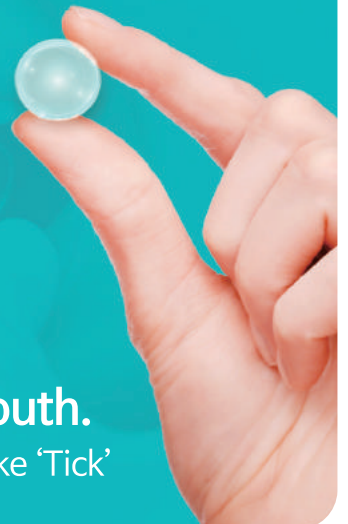
Curatick Oral Wound Home Care Solution



Attach it to an wound in your mouth.

‘Tick’

Attach this brand new wound protective patch in the mouths of children to adults.



Now, just **‘Tick!’** for an wound in your mouth.

There's no need sear, apply, or rinse. Just simply attach it. like ‘Tick’



A protective patch for an wound in your mouth which is applicable for a variety of wounds.



A protective patch for an wound in your mouth

It protects the wound by preventing it from coming in contact with anything else.



2~4 Hours

Attachable for 4 hours

It can be attached for 2 to 4 hours.
(The time may vary according to the oral conditions)



Wound

Low feeling of irritation/ rapid adhesion

Easy, fast adhesion and application
Easy to carry around thanks to the form of strip



Water-soluble adhesive patch

It is not adhesive in the ordinary times, but when it comes in contact with water/saliva, it becomes gel with adhesion.



The adhesive surface is naturally removed

When the adhesive surface melts thanks to reaction with saliva in your mouth, the protective surface is automatically removed.



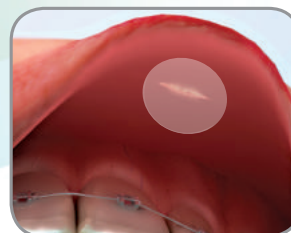
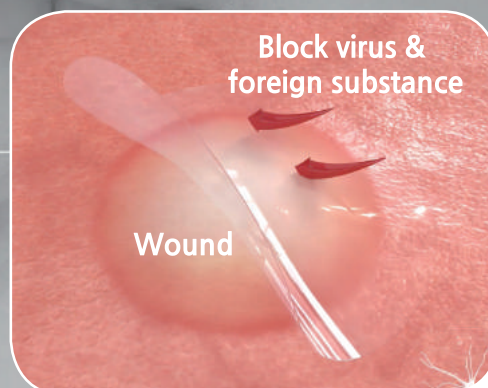
Raw materials that meet the specifications

Made by using raw materials that satisfy the specifications of KP and USP



Protects the wound in your mouth from foods, germs, tongue, and tobacco smoke.

- ✓ Protects the wound by preventing external irritants from coming in contact with the wound
- ✓ Easily attached to the wound!
- ✓ It sticks to the wound for up to four hours. (The time may vary according to your oral conditions.)
- ✓ Protects the wound and mucous membrane in your mouth
- ✓ Increased freshness thanks to mint flavor
- ✓ Containing vitamin E



Product Strong Point - 3N

No-Steroid

It does not contain steroid. Steroids are corticosteroid hormones that can cause serious side effects in infants and adults.

No-Pain

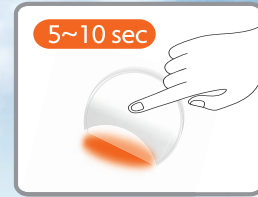
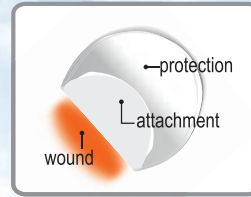
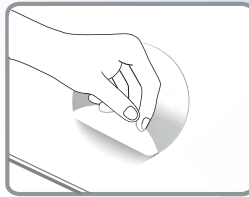
The flexible material protects the cuts and relieves pain in the mouth by forming physical protective film on the affected area.

Natural Cure

It improves the self-regeneration of oral mucosa by blocking the affected area from external stimuli for long time(2~4hrs).



Instructions



1. Clean the affected area and wipe off if there's a lot of saliva (too much saliva interferes with adhesion)
2. Pull off the product from the release liner
3. Apply adhesive layer on the wound
4. Press slightly for 5 seconds until adhesion occurs



Cautions



This medical product is for single use. If reused, the product may cause infection, cross infection, and inflammation.

1. Do not use products that have expired, damaged, or contaminated.
2. If you experience any swelling, allergic reaction, upset stomach or any signs of infection, consult with your doctor.
3. Do not use if an infection is suspected and if an infection occurs (a wound that appears to be abnormal, such as fever or edema.)
4. Do not use on deep wounds with excessive bleeding.
5. If the product is attached and removed forcibly, the wound may come off. Do not remove it.
6. Remove the dropped protection layer from a wound.
7. Sufficient care is required for sleeping or pediatric patients to remove the protection layer.
8. The time of attachment may be reduced when stimulated by tongue or food.



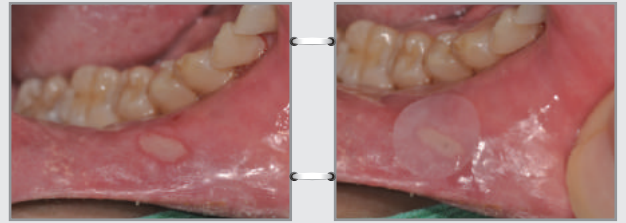
Curatick Application

Case#1,2

Contusion



Inside the Lip

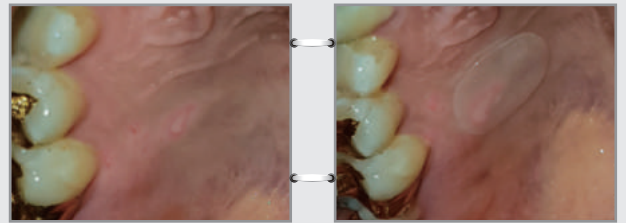


Case#3,4

Gum

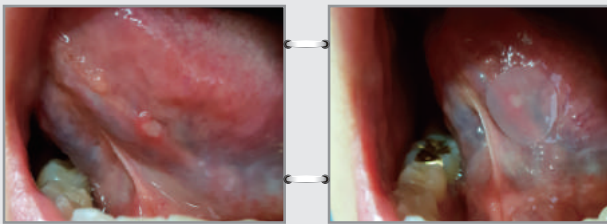


Palate

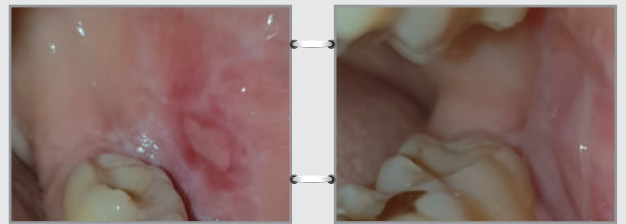


Case#5,6

Tongue



Buccal mucosa



Certified Biological Safety Test Report

KTC
Korea Testing Certification
Test Results

Report No.: KT-2019-0014
Appendix 8
Acute Systemic Toxicity Test

1. Test Schedule
1.1 Date of test beginning: Oct. 10, 2019
1.2 Date of test completion: Oct. 16, 2019
1.3 Date of test completion: May 10, 2019

2. Test Article: Ampicillin Sodium (TBM-0001)

3. Test Schedule and Method
3.1 Test Article: Ampicillin Sodium (TBM-0001) - Part 8: Tests for systemic toxicity, 2. Main systemic toxicity

4. Test System
4.1 Species: Mouse (Mus musculus)
4.2 Sex: C57BL/6J (Genetic Background: B6)
4.3 Strain: K12931
4.4 Age: 3 to 4 weeks
4.5 Age at start: 3 to 4 weeks
4.6 Age at end: 4 to 6 weeks

5. Animal Management
5.1 Food: Provided ad libitum and standard chow diet (standard laboratory chow)
5.2 Water: Provided ad libitum and standard chow diet (standard laboratory chow)
5.3 Environment: The room temperature was maintained at 20-25°C. The humidity was maintained at 30-70% RH. The light cycle was maintained with a 12-hour light/12-hour dark cycle. The light cycle was maintained with a 12-hour light/12-hour dark cycle.

▲ Acute systemic Toxicity Test

KTC
Korea Testing Certification
Test Results

Report No.: KT-2019-0014
Appendix 4
Microbial Limit Test

1. Test Schedule
1.1 Date of test beginning: May 17, 2019
1.2 Date of test completion: May 17, 2019

2. Test Article: Ampicillin Sodium (TBM-0001)

3. Test Schedule and Method
3.1 Test Article: Ampicillin Sodium (TBM-0001) - Part 8: Tests for systemic toxicity, 2. Main systemic toxicity

4. Test System
4.1 Species: Mouse (Mus musculus)
4.2 Sex: C57BL/6J (Genetic Background: B6)
4.3 Strain: K12931
4.4 Age: 3 to 4 weeks
4.5 Age at start: 3 to 4 weeks
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5. Animal Management
5.1 Food: Provided ad libitum and standard chow diet (standard laboratory chow)
5.2 Water: Provided ad libitum and standard chow diet (standard laboratory chow)
5.3 Environment: The room temperature was maintained at 20-25°C. The humidity was maintained at 30-70% RH. The light cycle was maintained with a 12-hour light/12-hour dark cycle. The light cycle was maintained with a 12-hour light/12-hour dark cycle.

▲ Microbial Limit Test

KTC
Korea Testing Certification
Test Results

Report No.: KT-2019-0014
Appendix 5
Cytotoxicity Test

1. Test Schedule
1.1 Date of test beginning: Oct. 10, 2019
1.2 Date of test completion: Oct. 16, 2019

2. Test Article: Ampicillin Sodium (TBM-0001)

3. Test Schedule and Method
3.1 Test Article: Ampicillin Sodium (TBM-0001) - Part 8: Tests for systemic toxicity, 2. Main systemic toxicity

4. Test System
4.1 Species: Mouse (Mus musculus)
4.2 Sex: C57BL/6J (Genetic Background: B6)
4.3 Strain: K12931
4.4 Age: 3 to 4 weeks
4.5 Age at start: 3 to 4 weeks
4.6 Age at end: 4 to 6 weeks

5. Animal Management
5.1 Food: Provided ad libitum and standard chow diet (standard laboratory chow)
5.2 Water: Provided ad libitum and standard chow diet (standard laboratory chow)
5.3 Environment: The room temperature was maintained at 20-25°C. The humidity was maintained at 30-70% RH. The light cycle was maintained with a 12-hour light/12-hour dark cycle. The light cycle was maintained with a 12-hour light/12-hour dark cycle.

▲ Cytotoxicity Test

KTC
Korea Testing Certification
Test Results

Report No.: KT-2019-0014
Appendix 1
Subchronic systemic toxicity

1. Test Schedule
1.1 Date of test beginning: May 10, 2019
1.2 Date of test completion: May 10, 2019
1.3 Date of test completion: May 10, 2019
1.4 Date of test completion: May 10, 2019

2. Test Article: Ampicillin Sodium (TBM-0001)

3. Test Schedule and Method
3.1 Test Article: Ampicillin Sodium (TBM-0001) - Part 8: Tests for systemic toxicity, 2. Main systemic toxicity

4. Test System
4.1 Species: Mouse (Mus musculus)
4.2 Sex: C57BL/6J (Genetic Background: B6)
4.3 Strain: K12931
4.4 Age: 3 to 4 weeks
4.5 Age at start: 3 to 4 weeks
4.6 Age at end: 4 to 6 weeks

5. Animal Management
5.1 Food: Provided ad libitum and standard chow diet (standard laboratory chow)
5.2 Water: Provided ad libitum and standard chow diet (standard laboratory chow)
5.3 Environment: The room temperature was maintained at 20-25°C. The humidity was maintained at 30-70% RH. The light cycle was maintained with a 12-hour light/12-hour dark cycle. The light cycle was maintained with a 12-hour light/12-hour dark cycle.

▲ Subchronic systemic toxicity

Quality Management Certificate (GMP / ISO 13485)

연장번호 (No.): KT-2019-0014

의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

■ 업체명/제조사명 (Company name of Applicant / Licensee No.)
다비엘(주) (DABIEL)
TBM Corporation

■ 대표자 (Representative)
장재홍 (Jangjaehong)

■ 업체 소재지 (Company address of Applicant)
광주광역시 북구 황간리길 313 광주하이테크센터 8동 301호
301-1, 313, Cheongdam-gil, Buk-gu, Gwangju, Korea

■ 제조소명 (Name of Manufacturer)
제조소명: 다비엘(주)
제조소명: (주)다비엘모데스트

■ 제조소 소재지 (Address of Manufacturer)
제조소소재지: 광주광역시 북구 황간리길 313 광주하이테크센터 8동 301호
제조소소재지: 광주광역시 북구 황간리길 313 광주하이테크센터 8동 301호

■ 품목명 (Category)
인대용 봉합사

의료기기 제조 및 품질관리기준에 적합함을 인정합니다.
(We hereby certify that the above manufacturer complies with the Korea Good Manufacturing Practices of Medical Devices for the production (listed above))

발행일자 (Date of Issue): 2019. 03. 17
유효기간 (Date of Expiration): 2019. 03. 16

광주지방식품의약품안전청
GWANGJU REGIONAL FOOD AND DRUG
ADMINISTRATION

한국기계전기전자시험연구원
Korea Testing Certification

▲ GMP

MTIC
INTERCERT
CERTIFICATE

CERTIFICATE No. SQ/014-2018

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

TBM Corporation
Registered office address:
B-301, Gwangju High-tech Center, 313, Cheongdam-gil, Buk-gu, Gwangju 61008 (REP. OF KOREA)

Certified operative unit address:
B-301, Gwangju High-tech Center, 313, Cheongdam-gil, Buk-gu, Gwangju 61008 (REP. OF KOREA)

IS IN COMPLIANCE WITH THE REQUIREMENTS OF STANDARD
UNI CEI EN ISO 13485:2016

THIS CERTIFICATE IS VALID FOR THE FOLLOWING ACTIVITIES
Design and distribution of attachable intraoral wound dressing

ACCREDITED TO
ISO 13485

MTIC INTERCERT S.p.A. Via Mazzini, 11 - 00197 Roma (RM) - ITALY
www.mtic.it

▲ ISO 13485

TBM Corporation

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www.curatick.com/en