Please note: These studies may involve findings that exceed the claims currently cleared by the FDA for the product. Bravida Medical is not intending to make performance claims about its product. The intent is to disseminate the scientific literature on these products. We encourage you to read these studies to understand the strengths and limitations of the data. For some claims, Bravida is seeking to broaden the indications with the FDA in the future using data, such as these studies, to provide the substantiation.



Modified Sodium Hypochlorite Anti-microbial Skin and Wound Gel in Difficult to Heal Wounds

POSTER PRESENTATION AT THE SYMPOSIUM ON ADVANCED WOUND CARE, FALL 2021

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THREE CASE HISTORIES USING:

Anasept® Antimicrobial Skin & Wound Cleanser and Anasept® Antimicrobial Skin & Wound Gel



INTRODUCTION:

A chronic wound can be defined as having a physiologically impaired healing cycle secondary to disruption in one of the four stages of wound healing. Chronic wounds and their treatment continue to be a financial burden to the healthcare system, and present a social and psychological burden to affected patients, making timely and effective treatment of utmost importance. The treatment of chronic non-healing wounds are an ever-evolving field with new products and methods of treatment continually under investigation. Proper wound bed preparation, with cleansing of the wound bed and peri-wound to reduce microbial bioburden, is an important step in treatment, as heavy microbial bioburden can inhibit proper wound healing.

DISCUSSION:

Modified sodium hypochlorite anti-microbial skin and wound gel and cleanser (MSHAMSW gel and cleanser) is a cost effective, physiologically isotonic, and active against MRSA, VRE, fungi and viruses. MSHAMSW gel and cleanser has been shown in several studies to have superiority in removing Pseudomonas and other bacterial bioburden compared to other methods in wound bed preparation. Our case studies demonstrate the importance of microbial bioburden control with the use of MSHAMSW gel and cleanser in healing of chronic ulcerations of varying etiologies.

REFERENCES

Nussbaum SR, Carter MJ, Fife CE, DaVanzo J, Haught R, Nusgart M, Cartwright D. An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health. 2018 Jan;21(1):27-32. doi: 10.1016/j.jval.2017.07.007. Epub 2017 Sep 19. PMID: 29304937.

Sen CK. Human Wounds and Its Burden: An Updated Compendium of Estimates. Adv Wound Care (New Rochelle). 2019;8(2):39-48. doi:10.1089/wound.2019.0946

Case #1

R.S. is an 85yo male with past medical history of Type 2 Diabetes, Hypertension, Former Tobacco User, Osteoarthritis, Benign Prosthetic Hypertrophy and Atrial Flutter presenting on 5/18/2021 for evaluation of left lower extremity traumatic ulceration after a fall into a swimming pool leaving a hematoma.

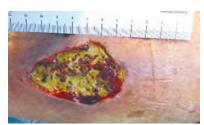
5/18/21: Debridement of necrotic tissue.



6/1/21: Collagenase recommended but too costly. Switch to MSHAMSW G&C.



6/16/21: Vascular evaluation, angiogram scheduled. Continues with MSHAMSW G&C.



7/6/21: Angiogram with no intervention. Single vessel Perineal runoff with total occlusion of Anterior Tibial and Posterior Tibial arteries.

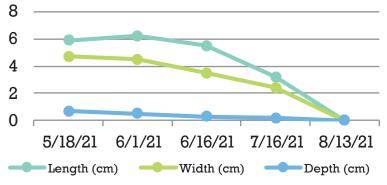


7/16/21: Wound continues to improve. Continues with MSHAMSW G&C.



8/13/21: Wound achieved 95% closure as of this date and was lost to follow up.





Case #2

C.W. is a 53yo female with past medical history of Ankylosing Spondylitis, Osteoarthritis, Fibromyalgia, OSA. Asthma and Morbid Obesity presenting on 5/6/2021 for evaluation of right lower extremity ulcerations after several bouts of cellulitis starting in December 2020, with multiple antibiotic courses.

5/6/21: Ddx includes Pyoderma Gangrenosum due to violaceous borders and pain; steroid course prescribed.

5/14/21: On Bactrim. Switch to MSHAMSW G&C.



5/20/21: Enbrel started by rheumatology.



6/7/21 through 7/29/21: Wound improving and less painful.

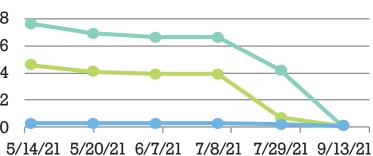


9/13/21: Wound closure achieved.

Length (cm)



Depth (cm)



Width (cm)

Case #3

C.G. is a 62yo male with past medical history of Pyoderma Gangrenosum, Venous Insufficiency and Obesity presenting on 5/6/2021 for evaluation of a right lower extremity ulceration after sustaining a fall resulting in hematoma formation and subsequent eschar on first evaluation.

5/20/21: Black eschar remains. Switch to MSHAMSW G&C.



6/20/21: Black Eschar is unstable and able to be deroofed at this visit.

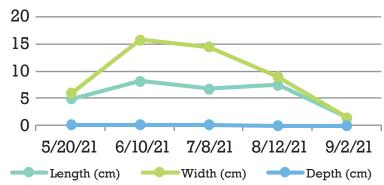


7/8/21: Ulceration continues to improve.



8/12/21: Ulceration with healthy granulation tissue. Switch to collagen dressing.









ordering information:

| Anasept® Antimicrobial Skin & Wound Cleanser | | | | | | | | |
|--|-------------------|--------------|-------|---------------|--|--|--|--|
| CATALOG NO. | | NDC NUMBER | SIZE | CASE QUANTITY | | | | |
| 4004C | (Dispensing Cap) | 67180-400-04 | 4 oz | 24 | | | | |
| 4008C | (Dispensing Cap) | 67180-400-08 | 8 oz | 12 | | | | |
| 4004SC | (Sprayer) | 67180-400-44 | 4 oz | 12 | | | | |
| 4008SC | (Sprayer) | 67180-400-88 | 8 oz | 12 | | | | |
| 4008TC | (Trigger Sprayer) | 67180-408-88 | 8 oz | 12 | | | | |
| 4012SC | (Trigger Sprayer) | 67180-400-12 | 12 oz | 12 | | | | |
| 4016C | (Dispensing Cap) | 67180-400-16 | 15 oz | 12 | | | | |
| Health Canada License #97043 | | | | | | | | |

| Anasept® Antimicrobial Skin & Wound Gel | | | | | | | | |
|--|--------|------------|-----------|---------------|--|--|--|--|
| CATALOG | NO. | NDC NUME | SER SIZE | CASE QUANTITY | | | | |
| 5015G | (Tube) | 67180-500- | -15 1.5 o | z 12 | | | | |
| 5003G | (Tube) | 67180-500- | 03 3 oz | 12 | | | | |
| Medicare Reimbursement HCPCS Code # A6248 Health Canada License #97167 | | | | | | | | |



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Anasept products are manufactured in the USA.