

1.1 Clinical

The efficacy and safety of dextranomer, in the form of both beads and paste, has been demonstrated in scientific literature¹¹. A summary table supporting the equivalence of the device to predicate devices, along with the scientific literature reference can be found in **Attachment 7**.

The following sections will provide an overview of data, in chronological order, conveying the efficacy and safety of Exudex[®], thereby supporting the safe and effective use of this Exudex[®] in its intended use.

Ljungberg et al.¹² compared the effectiveness dextranomer paste versus saline dressing (no debridement) in grade II to IV ulcers (Ljungberg, 1998). Results showed a significant improvement in drainage and decrease in necrosis in those treated with dextranomer.

Two studies compared dextranomer with autolytic debridement using topical amorphous hydrogel. In the first study, Colin et al.¹³ compared dextranomer paste with an amorphous hydrogel in the debridement of 64 sloughy grade II to IV pressure ulcers (Colin, 1996). After 3 weeks, both treatments were found to be equally efficacious in reducing the area of nonviable tissues (74% for amorphous hydrogel vs. 62% for dextranomer, $P = .20$). The proportion of ulcers with complete debridement was similar (14/68 in dextranomer vs. 13/67 in hydrogel).

The second study¹⁴ compared 20 pressure ulcers debrided using dextranomer to 19 ulcers debrided using an amorphous hydrogel (Thomas, 1993). The proportion of ulcers with complete debridement was not significantly different between the 2 groups.

A pooled analysis of the two aforementioned studies showed that both hydrogel and dextranomer paste were equally effective in achieving complete debridement; more patients reported leakage through the dressing in the group treated with hydrogel.

In a prospective randomized study involving 92 patients and 92 grade III to IV established pressure ulcers in a high-risk population (with immobilization, poor metal status, poor health status, and a high proportion of urinary and fecal incontinence), Sayag et al.¹⁵ compared 47 ulcers treated with calcium alginate dressing with 45 ulcers treated with dextranomer paste (Sayag, 1996). The authors reported that after 8 weeks of treatment, both treatments resulted in a reduction in wound size (74% vs. 42% respectively) and rate of wound healing (3.55 cm²/week vs. 2.15 cm²/week, respectively). It was noted that certain adverse events associated with dextranomer paste debridement (e.g. pain upon application, local infection, slight bleeding on removal, and hypergranulation) generally did not require termination of treatment.

¹¹ Health Quality Ontario. Management of Chronic Pressure Ulcers: An Evidence-Based Analysis. Ontario Health Technology Assessment Series. 2009;9(3):1-203.

¹² Ljungberg S. Comparison of dextranomer paste and saline dressings for management of decubital ulcers. Clin Ther. 1998;20(4):737-43.

¹³ Colin D, Kurring PA, Yvon C. Managing sloughy pressure sores. J Wound Care. 1996;5(10):444-6.

¹⁴ Thomas S. Comparing two dressings for wound debridement. J Wound Care. 1993;2(5):272-4.

¹⁵ Sayag J, Meaume S, Bohbot S. Healing properties of calcium alginate dressings. J Wound Care. 1996;5(8):357-62.

An RCT¹² (n = 40) compared the application of a dextranomer paste to the wound with the application of a gauze dressing soaked with polyvinylpyrrolidone 10% (Michiels, 1990). Time to clean wound bed (i.e. disappearance or resolution of edema, pus and debris, erythema, and necrotic tissue, and the presence of granulation tissue) were similar between the two groups; however, it was reported that dextranomer paste was more effective in cleansing those wounds with higher levels of pus and debris. No side effects were observed in the dextranomer paste group; however, one patient in the control group suffered an allergic reaction (edema and erythema) from polyvinylpyrrolidone, leading to their withdrawal from the study.

In a controlled study, fifteen patients with infected wounds and cutaneous ulcers were admitted to the K.E.M. Hospital, Bombay, where they received a thorough medical assessment and treated with local application of dextranomer (Parulkar, 1985)¹³. Results showed that, of the 15 lesions treated in the series, 12 healed completely; 2 others who responded to the treatment satisfactorily were lost to follow-up; and one, a case of diathermy burns, was taken off the trial because the patient complained of increased pain. The control of infection and the promotion of healing was seen in all cases. From these results, the authors concluded that dextranomer was effective as a wound healing agent.

Debrisan (dextranomer) was used for the treatment of purulent wounds in 125 patients with post injection and paraossal phlegmons, postoperative suppurations and tropic ulcers (Gostichev, 1983)¹⁴. The authors concluded that Debrisan (dextranomer) was shown to be an effective agent for physical antiseptics which can shorten the time of wound debridement.

An RCT¹⁵ (n = 50 participants) compared dextranomer beads with a silicone foam elastomer dressing in the treatment of post-surgical opened wounds (Young, 1982). Results showed that the mean time taken to complete healing in the dextranomer group was 41 ± 4 days and in the elastomer dressing group 37 ± 3 days.

Another study compared dextranomer (n=9) to a Eusol and paraffin dressing (n=9 controls) (Nasar and Morley, 1982)²⁰. The mean time to reach the primary endpoint (a clean and granulating wound less than 25% of the original size) was shorter for dextranomer compared with Eusol (39.3 days vs. 62 days). Three ulcers in the Eusol group were switched to dextranomer during the course of this study.

¹² Michiels I, Christiaens MR. Dextranomer (Debrisan) paste in post-operative wounds. A controlled study. *Clinical Trials Journal*. 1990;27:283–90.

¹³ Parulkar B G, Solti M K, Pardanani D S. Dextranomer dressing in the treatment of infected wounds and cutaneous ulcers. *J Postgrad Med* 1985;31:28-33

¹⁴ Gostishchev VK, Vasil'kova ZF, Khanin AG, Vavilova GS, Lebedskoĭ AG. [Debrisan in the treatment of purulent wounds]. *Vestn Khir Im I I Grek*. 1983 Sep;131(9):56-9. Russian. PubMed PMID: 6196903.

¹⁵ Young HL, Wheeler MH. Report of a prospective trial of dextranomer beads (Debrisan) and silicone foam elastomer (Silastic) dressings in surgical wounds. *British Journal of Surgery*. 1982;69:33–4.

²⁰ Nasar MA, Morley R. Cost effectiveness in treating deep pressure sores and ulcers. *Practitioner*. 1982;226(1364):307–10.

In a placebo-controlled study involving 17 nursing home residents (total of 34 pressure ulcers), the effects of collagenase and dextranomer as a debriding agent was evaluated compared to treatment with a placebo (sugar and egg white) (Parish and Collins, 1979)²¹. After wound cleansing with saline, 11 of the pressure ulcers were treated a daily application of a collagenase enzyme (Santyle®) and covered with a dry dressing while 14 of the ulcers were treated with dextranomer polysaccharide beads applied 1 to 3 times and covered with a dry dressing. Nine other ulcers were treated with the mixture of sugar and egg whites. After 4 weeks, the ulcers treated with dextranomer showed better healing than those treated with collagenase; none of the wounds treated with the placebo healed.

In an RCT involving 50 patients, Debrisan (dextranomer) treatment resulted in the rapid healing of cutaneous ulcers, measured by the rate of healing, dehydration, sterilization, loss of symptoms, and improvement in physiology (Sawyer, 1979)²².

An RCT⁶(n = 20) compared dextranomer with Eusol gauze in the healing process of postoperative wounds (Goode, 1979)²³. The primary outcome measure was time to a clean wound bed ready for secondary wound closure. The authors reported that the mean time to wound closure was significantly shorter for the dextranomer group when compared with the control group (8.1 days vs. 11.6 days).

Dextran polymer particles (Debrisan/dextranomer) was used in the treatment of 25 patients with non-venereal penile ulcers (Lassus, 1977)²⁴. Fourteen (14) of the ulcer cases were caused by herpes infection, 3 patients had dequalinum-induced necrosis. The etiology of ulceration was unknown in 8 of the cases. Results showed that ulcers healed in most cases during the first week of treatment, and in all cases within 4 weeks. Furthermore, the authors noted that most patients reported an almost immediate relief of pain upon use of Debrisan (dextranomer).

²¹Parish LC, Collins E. Decubitus ulcers: a comparative study. *Cutis*. 1979 Jan;23(1):106-10. PubMed PMID: 215386.

²² Sawyer PN, Dowbak G, Sophie Z, Feller J, Cohen L. A preliminary report of the efficacy of Debrisan (dextranomer) in the debridement of cutaneous ulcers. *Surgery*. 1979 Feb;85(2):201-4. PubMed PMID: 419460.

²³Goode AW, Glazer G, Ellis BW. The cost effectiveness of dextranomer and eusol in the treatment of infected surgical wounds. *British Journal of Clinical Practice*. 1979; 33:325-8.

²⁴Lassus A, Karvonen J, Juvakoski T. Dextran polymer particles (Debrisan) in the treatment of penile ulcers. *Acta Derm Venereol*. 1977;57(4):361-3. PubMed PMID: 70932.

Treatment with Debrisan (dextranomer) was evaluated in 15 patients (donor site on one thigh) was compared with donor sites on the contralateral thigh, subjected to open treatment (Jacobsson, 1976)²⁵. Results showed that the inflammation was less pronounced and more superficial in the Debrisan-treated wound compared to the control wounds, which were left open. The authors noted that no unfavorable influence of Debrisan treatment was observed on the process of repair.

A study involving thirteen patients with 17 burned hands evaluated the effects of Debrisan (dextranomer) on hand burns (Paavolainen, 1976)²⁶. Results showed clinically meaningful results with respect to decreases in pain, healing time and improved hand function (all hands treated recovered full mobility). The authors noted that no infection appeared as exudate and bacteria were continuously removed from the treated area. No side reactions or formation of crust were observed.

²⁵Jacobsson S, Jonsson L, Rank F, Rothman U. Studies on healing of Debrisan-treated wounds. *Scand J Plast Reconstr Surg.* 1976;10(2):97-101. PubMed PMID: 1019590.

²⁶Paavolainen P, Sundell B. The effect of dextranomer (Debrisan) on hand burns. A preliminary report on a new method in the treatment of hand burns. *Ann Chir Gynaecol.* 1976;65(5):313-17. PubMed PMID: 1008464.

Attachment 7

Summary Table Supporting the Equivalence of the Device to Predicate Devices

Equivalence Item	Scientific Article	Citation	Applicable Predicate Device
Absorbs wound exudate, aid to wound and ulcer management	Dextranomer: a review of its general properties and therapeutic efficacy.	Heel RC, Morton P, Brogden RN, Speight TM, Avery GS. Dextranomer: a review of its general properties and therapeutic efficacy. <i>Drugs</i> . 1979 Aug;18(2):89-102. Review. PubMed PMID: 385281.	KA01 Chitosan Wound Dressing, K143124
No side effects observed in Dextranomer paste applied to post-operative wound for clinical group. No allergic reaction.	Dextranomer (Debrisan) paste in post-operative wounds. A controlled study.	Michiels I, Christiaens MR. Dextranomer (Debrisan) paste in post-operative wounds. A controlled study. <i>Clinical Trials Journal</i> . 1990;27:283-90.	Bionect Clear Hydrogel, K984264
Dextranomer treated wounds and healing	Studies of healing of Debrisan-treated wounds	Jacobsson S, Jonsson L, Rank F, Rothman U. Studies on healing of Debrisan-treated wounds. <i>Scand. J Plast. Reconstr. Surg</i> . 1976;10(2):97-101. PubMed PMID: 1019590	KA01 Chitosan Wound Dressing, K143124
Effects of Dextranomer on burns	The effect of dextranomer (Debrisan) on hand burns. A preliminary report on a new method in the treatment of hand burns.	Paavolainen P, Sundell B. The effect of dextranomer (Debrisan) on hand burns. A preliminary report on a new method in the treatment of hand burns. <i>Ann Chir Gynaecol</i> . 1976;65(5):313-17. PubMed PMID: 1008464.	Bionect Clear Hydrogel, K984264

Equivalence Item	Scientific Article	Citation	Applicable Predicate Device
Sensitization, Toxicity	Testing of potential allergic contact sensitization of debrisan in guinea pigs	Jonsson, G., 1978: Testing of potential allergic contact sensitization of debrisan in guinea pigs. <i>Clinical Therapeutics</i> 1(4): 260-262	KA01 Chitosan Wound Dressing, K143124, Bionect Clear Hydrogel, K984264
Allergic Irritation	Application of dextranomer beads (debrisan®) in the treatment of exudating skin lesions: Results of a cooperative study	Romasz, R. S., Barnhart, M. D., & Schinagl, E. F. (1978). Application of dextranomer beads (debrisan®) in the treatment of exudating skin lesions: Results of a cooperative study. <i>Angiology</i> , 29(9), 675-682	KA01 Chitosan Wound Dressing, K143124, Bionect Clear Hydrogel, K984264
Irritation (contact dermatitis)	Dextranomer in dermatologic conditions	Parish, L. C., & Witkowski, J. A. (1979). Dextranomer in dermatologic conditions. <i>International Journal of Dermatology</i> , 18(6), 480-484	KA01 Chitosan Wound Dressing, K143124, Bionect Clear Hydrogel, K984264
Dextranomer without risk of contact allergy	Allergy to various components of topical preparations in stasis dermatitis and leg ulcer	Fräki, J. E., Peltonen, L., & Hopsu-Havu, V. K. (1979). Allergy to various components of topical preparations in stasis dermatitis and leg ulcer. <i>Contact Dermatitis</i> , 5(2), 97-100. doi:10.1111/j.1600-0536.1979.tb04806.x	KA01 Chitosan Wound Dressing, K143124, Bionect Clear Hydrogel, K984264
Dextranomer use effective for treatment of decubital ulcer	Comparison of Dextranomer Paste and Saline Dressings for Management of Decubital Ulcers	Ljungberg, S. (1998). Comparison of dextranomer paste and saline dressings for management of decubital ulcers. <i>Clinical Therapeutics</i> , 20(4), 737-743. doi:10.1016/S0149-2918(98)80136-7	KA01 Chitosan Wound Dressing, K143124, Bionect Clear Hydrogel, K984264

Equivalence Item	Scientific Article	Citation	Applicable Predicate Device
Application of Dextranomer powder on ulcers	Use and Limitations of Dextranomer Cutaneous Ulcerations	Lewis, V. L., Gavron, J., Yao, J. S. T., Lim, L. T., & Bergan, J. J. (1979). Use and limitations of dextranomer in cutaneous ulcerations. <i>Vascular and Endovascular Surgery</i> , 13(4), 265-272. doi:10.1177/153857447901300407	KA01 Chitosan Wound Dressing, K143124, Bionect Clear Hydrogel, K984264
Dextranomer beads a useful treatment (clinical studies)	Beads of a Dextran Polymer for the Local Treatment of Cutaneous Ulcers	Pace, W. E. (1978). Beads of a dextran polymer for the local treatment of cutaneous ulcers. <i>The Journal of Dermatologic Surgery and Oncology</i> , 4(9), 678-682. doi:10.1111/j.1524-4725.1978.tb00525.x	KA01 Chitosan Wound Dressing, K143124, Bionect Clear Hydrogel, K984264
Dextranomer clinical studies, no allergic or irritant contact dermatitis found	Dextranomer in Dermatologic Conditions	Parish, L. C., & Witkowski, J. A. (1979). Dextranomer in dermatologic conditions. <i>International Journal of Dermatology</i> , 18(6), 480-484. doi:10.1111/j.1365-4362.1979.tb01954.x	KA01 Chitosan Wound Dressing, K143124, Bionect Clear Hydrogel, K984264
Dextranomer clinical studies and effectiveness of ulcer treatment with dextranomer	New Approaches in the Therapy of the Peripheral Vascular Ulcer	Sawyer, P. N., Sophie, Z., Dowbak, G., Cohen, L., & Feller, J. (1978). New approaches in the therapy of the peripheral vascular ulcer. <i>Angiology</i> , 29(9), 666-674.	KA01 Chitosan Wound Dressing, K143124, Bionect Clear Hydrogel, K984264
Use of Dextranomer in preparation for skin grafting	Bacterial Studies of Leg Ulcers	Dagher, F. J., Alongi, S. V., & Smith, A. (1978). Bacterial studies of leg ulcers. <i>Angiology</i> , 29(9), 641-653. doi:10.1177/000331977802900901	KA01 Chitosan Wound Dressing, K143124, Bionect Clear Hydrogel, K984264