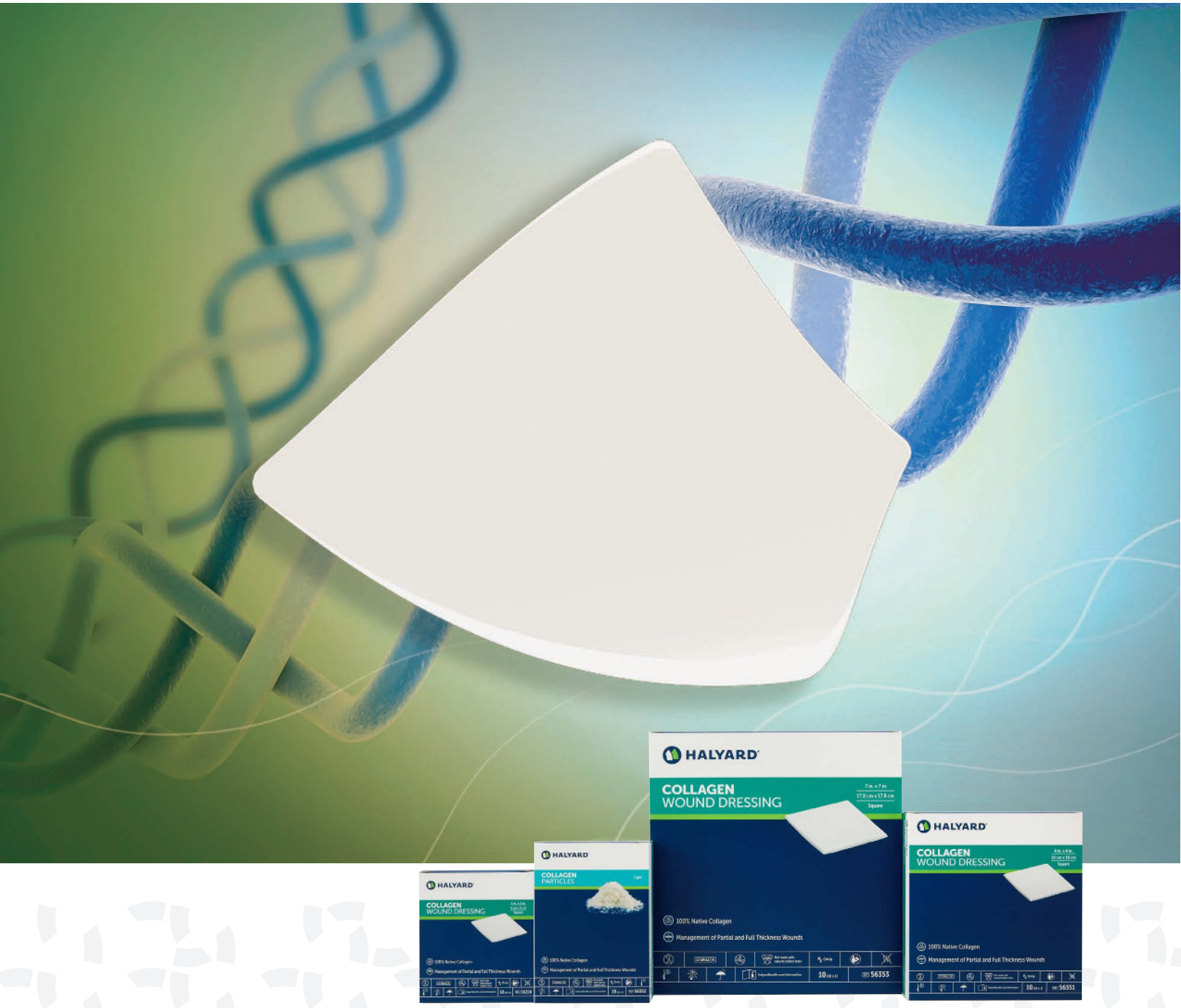
HALYARD*

Collagen Wound Dressing



HALYARD*

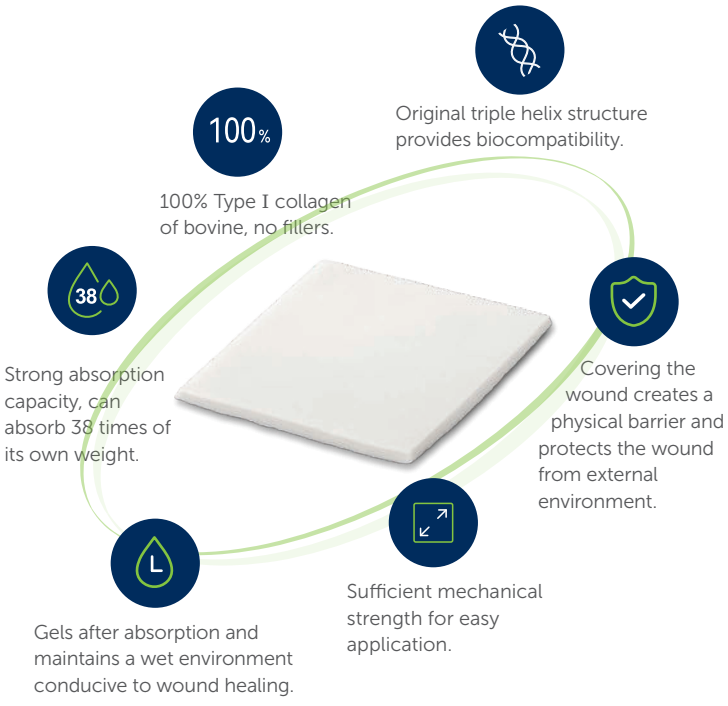
Collagen Wound Dressing

100% BOVINE COLLAGEN SUPPORTS WOUND HEALING WITH EXCELLENT BIOCOMPATIBILITY.

A porous matrix of cross-linked bovine collagen makes up HALYARD* Collagen Wound Dressing. The HALYARD* Collagen Wound Dressing is a sterile, single-use wound dressing that is white or off-white, pliable, absorbent and biodegradable.

When the wound dressing absorbs wound exudate or sterile water, HALYARD* Collagen Wound Dressing transforms into a soft, conformable gel sheet, maintaining a moist wound environment, to protect the wound and support the wound's natural healing.

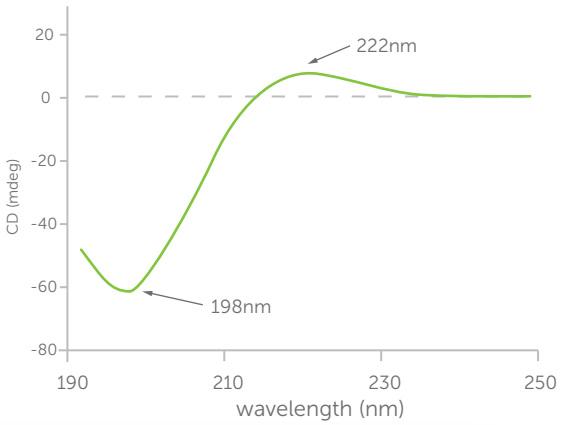
HALYARD* Collagen Wound Dressing may be applied directly to the wound as a primary dressing or may be used in conjunction with other acceptable secondary dressings. The dressing may be used in numerous layers and can be precisely trimmed to fit the size of the wound.

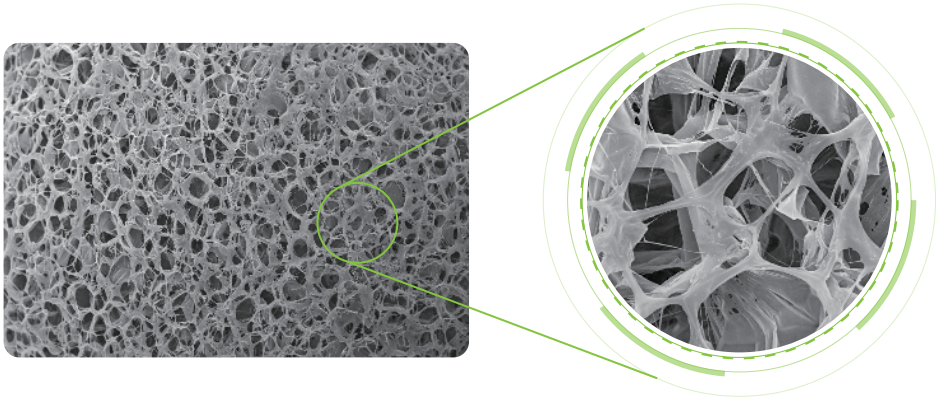


Advantages about HALYARD* Collagen Wound Dressing

- The dressing, which falls under the category of permanent contact device, is non-pyrogenic, super conforming, entirely absorbable, and simple to use.
- It serves as a porous scaffold for cell proliferation and migration and may be used as a hemostatic dressing for surface wounds.
- Dressings are suitable for use under compression with proper supervision by a healthcare professional.
- The product's strength and enzyme resistance are increased without the use of chemical additives and with the aid of safe cross-linking technology.

CD scanning of the collagen material





HALYARD* Collagen Wound Dressing has a homogeneous fiber network structure, which produces high biocompatibility and is helpful in supporting wound healing, as seen from the electron microscope image.

Indications

HALYARD* Collagen Wound Dressing is intended for the management of wounds including:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Partial thickness burns
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical incisions

Contraindications

Patients who are sensitive to bovine collagen, those with third-degree burns, or wounds that are infected actively should not use collagen wound dressing.

References:

[1] Rangaraj A , Harding K , Leaper D . Role of collagen in wound management[J]. Wounds Uk, 2011.

[2] Riccio M . Safety and Efficacy of Collagen-Based Biological Dressings in the Management of Chronic Superficial Skin Wounds in Non-Complex Trauma: A Post-Marketing Surveillance Study[J]. Trauma Care, 2021, 1.

Case

Efficacy of Type I Bovine Collagen Wound Dressing in the Management of Chronic Wounds

Type I Collagen is the most abundant extracellular matrix protein in the human body and it is clinically effective in the management of Acute & Chronic wounds. Collagen is produced by fibroblasts and it is intricately involved in the (3) phases of wound healing. Collagen primary function is to provide mechanical support and assist in regulating variety of processes, including cell migration, differentiation and proliferation. Use of Collagen dressing has shown to accelerate wound healing, granulation tissue formation, and supports neovascularization, and reduces bacterial infection in the chronic wounds.

Treatment

This prospective randomized controlled study was conducted at Pro Healthcare Clinic, Dallas, Texas U.S.A. from January to April, 2023. Patients' inclusion criteria:

Type of wound
Chronic,
Present for > 6 weeks

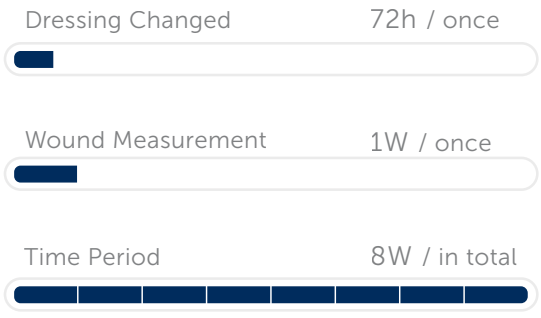
Extent of Tissue Damage
Full thickness Wound, tissue injury extended to the muscle

Pre-Albumin Levels
10 to 40 milligrams per deciliter (mg/dl)

A1c
5.7% to 8.0%

Patient Age
Between 55 to 90 years

All wounds were initially debrided utilizing 7mm dermal curette; swab cultures were collected using Levine's method and sent to lab for culture and sensitivity testing. Based on culture and sensitivity results; oral antibiotics were ordered for the duration of 10 days. Each wound was evaluated and size was measured on a weekly basis. HALYARD* Type-I Bovine Collagen dressing was applied to each wound after being moistened with sterile water, once every 72 hours. Wound square surface area and depth was measured and compared on a weekly basis for 8 weeks.



ITEM NUMBERS	DESCRIPTION	BOX UOM	HCPCS CODE
56350	HALYARD* Collagen Dressing, 2"x 2"	10	A6021
56351	HALYARD* Collagen Dressing, 4"x 4"	10	A6021
56353	HALYARD* Collagen Dressing, 7"x 7"	10	A6023
56352	HALYARD* Collagen Particles, 1G	10	A6010

Venous Stasis Ulcer (Right Leg)

CASE 01

Wound	Area (cm²)	Depth (cm)
Week 1	12.50	0.4
Week 2	12.00	0.4
Week 3	11.27	0.3
Week 4	10.34	0.3
Week 5	9.45	0.3
Week 6	7.56	0.3
Week 7	4.56	0.2
Week 8	3.15	0.2
Decrease	1.33cm² (10.7%)	0.02cm (5%)

Week 1

Week 8

Average Wound Contraction per Week: 10.7%
Average Wound Depth Reduction per Week: 5%

Venous Stasis Ulcer (Full Thickness-right Leg)

CASE 02

Wound	Area (cm²)	Depth (cm)
Week 1	4.48	0.6
Week 2	4.03	0.5
Week 3	3.60	0.5
Week 4	3.19	0.4
Week 5	2.80	0.4
Week 6	2.80	0.3
Week 7	2.34	0.3
Week 8	2.00	0.3
Decrease	0.35cm² (7.8%)	0.04cm (6.6%)

Week 1

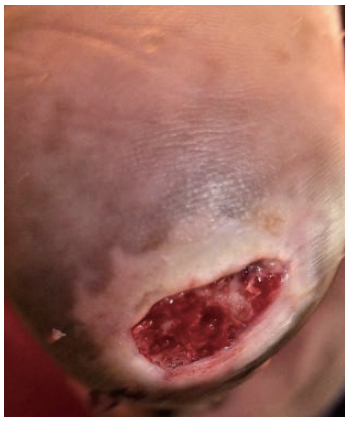
Week 8

Average Wound Contraction per Week: 7.8%
Average Wound Depth Reduction per Week: 6.6%

Venous Stasis Ulcer (Right Foot)

CASE 03

Wound	Area (cm²)	Depth (cm)
Week 1	3.64	0.5
Week 2	3.24	0.5
Week 3	2.40	0.4
Week 4	1.76	0.4
Week 5	1.60	0.3
Week 6	1.26	0.2
Week 7	0.98	0.2
Week 8	0.72	0.1
Decrease	0.41cm² (11.4%)	0.04cm (11.4%)



Week 1

Week 8

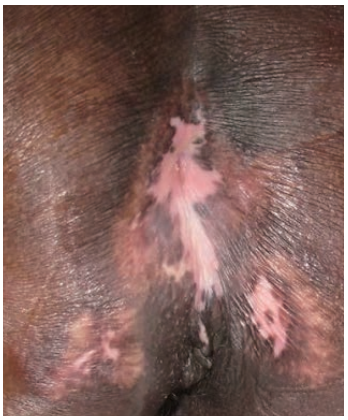
Average Wound Contraction per Week: 11.4%
Average Wound Depth Reduction per Week: 11.4%

Venous Stasis Ulcer (Sacro-Coccyx Region)

CASE 04

Wound	Area (cm²)	Depth (cm)
Week 1	0.90	0.8
Week 2	0.84	0.7
Week 3	0.60	0.6
Week 4	0.55	0.5
Week 5	0.40	0.4
Week 6	0.14	0.3
Week 7	0.08	0.2
Week 8	0.00	0.0
Decrease	0.12cm² (14.2%)	0.11cm (13.75%)

Week 1



Week 8

Average Wound Contraction per Week: 14.2%
Average Wound Depth Reduction per Week: 13.75%

Stage IV Pressure Ulcer (Sacro-Coccyx Region)

CASE 05

Wound	Area (cm²)	Depth (cm)
Week 1	195.90	4.6
Week 2	175.00	4.4
Week 3	156.00	4.1
Week 4	139.20	4.0
Week 5	121.00	4.0
Week 6	114.48	3.8
Week 7	92.00	3.3
Week 8	74.52	3.0
Decrease	2.94cm² ((5.3%)	0.15cm (6%)

Week 1

Week 8

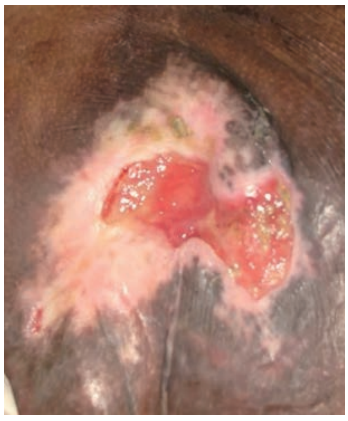
Average Wound Contraction per Week: 5.3%
Average Wound Depth Reduction per Week: 6%

Stage IV Pressure Ulcer (Sacro-Coccyx Region)

CASE 06

Wound	Area (cm²)	Depth (cm)
Week 1	45.08	0.8
Week 2	42.75	0.7
Week 3	39.56	0.7
Week 4	36.00	0.6
Week 5	32.30	0.5
Week 6	29.97	0.4
Week 7	26.25	0.3
Week 8	23.43	0.3
Decrease	3.09cm² (6.8%)	0.07cm (8.75%)

Week 1



Week 8

Average Wound Contraction per Week: 6.8%
Average Wound Depth Reduction per Week: 8.75%

Stage IV Pressure Ulcer (Sacro-Coccyx Region)

CASE 07

Wound	Area (cm²)	Depth (cm)
Week 1	3.84	1.5
Week 2	3.00	1.4
Week 3	2.52	1.2
Week 4	2.08	1.0
Week 5	1.50	0.8
Week 6	1.10	0.6
Week 7	0.80	0.4
Week 8	0.54	0.3
Decrease	0.47cm² (12.2%)	0.17cm (11.4%)

Week 1

Week 8

Average Wound Contraction per Week: 12.2%
Average Wound Depth Reduction per Week: 11.4%

Stage IV Pressure Ulcer (Sacro-Coccyx Region)

CASE 08

Wound	Area (cm²)	Depth (cm)
Week 1	55.04	2.6
Week 2	52.08	2.4
Week 3	48.00	2.4
Week 4	45.24	2.2
Week 5	42.75	2.0
Week 6	40.88	1.8
Week 7	38.50	1.6
Week 8	34.45	1.5
Decrease	2.9cm² (5.3%)	0.15cm (6%)

Week 1

Week 8

Average Wound Contraction per Week: 5.3%
Average Wound Depth Reduction per Week: 6%

Stage IV Pressure Ulcer (Right Foot Heel)

CASE 09

Wound	Area (cm²)	Depth (cm)
Week 1	2.52	1.5
Week 2	1.92	1.2
Week 3	1.80	1.0
Week 4	1.40	0.8
Week 5	0.96	0.7
Week 6	0.70	0.5
Week 7	0.48	0.4
Week 8	0.24	0.2
Decrease	0.32cm² (12.5%)	0.18cm ((12.3%)

Week 1

Week 8

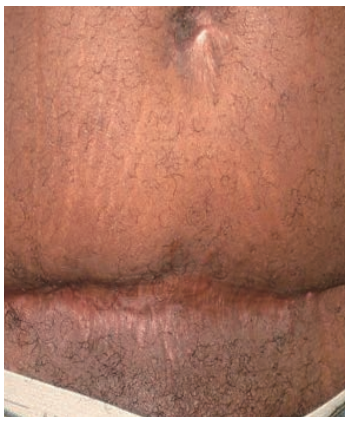
Average Wound Contraction per Week: 12.5%
Average Wound Depth Reduction per Week: 12.3%

Surgical Wound Dehiscence (Abdomen)

CASE 10

Wound	Area (cm²)	Depth (cm)
Week 1	14.80	0.5
Week 2	12.60	0.5
Week 3	10.24	0.4
Week 4	8.40	0.4
Week 5	6.00	0.3
Week 6	3.20	0.3
Week 7	1.20	0.2
Week 8	0.00	0.0
Decrease	2.11cm² (14.2%)	0.07cm (14.2%)

Week 1



Week 8

Average Wound Contraction per Week: 14.2%
Average Wound Depth Reduction per Week: 14.2%

Findings

The average reduction in wound surface area achieved was 1.4cm^2 per week.

The average reduction in depth of the wound was 0.1cm per week.

Conclusion

In managing chronic wounds, collagen dressings have shown to be an effective modality. Our evidence based clinical study shows that when a Bovine Type I collagen is utilized as a treatment for a full thickness wound; approximately 10% reduction in wound surface area and 9.5% in the depth of the wound may be achieved. The limited sample study showed clinical data is consistent with the positive effects of Type I collagen in the management of Chronic wounds.

-10 %
in wound surface area

-9.5 %
in the depth of the wound

References:

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2. De Francesco F, De Francesco M, Riccio M. Safety and Efficacy of Collagen-Based Biological Dressings in the Management of Chronic Superficial Skin Wounds in Non-Complex Trauma: A Post-Marketing Surveillance Study. Trauma Care. 2021; 1(3):195-205. https://doi.org/10.3390/traumacare1030017

3. Sen, C.K.; Gordillo, G.M.; Roy, S.; Kirsner, R.; Lambert, L.; Hunt, T.K.; Gottrup, F.; Gurtner, G.C.; Longaker, M.T. Human skin wounds: A major and snow balling threat to public health and the economy. Wound Repair Regen. 2009, 17, 763–771

4. Zhang M-X, Zhao W-Y, Fang Q-Q, et al. Effects of chitosan-collagen dressing on wound healing in vitro and in vivo assays. Journal of Applied Biomaterials & Functional Materials. 2021;19.

5. Li Zhang, Simei Wang, Meihua Tan, Hongwei Zhou, Ying Tang, Yan Zou, "Efficacy of Oxidized Regenerated Cellulose/Collagen Dressing for Management of Skin Wounds: A Systematic Review and Meta-Analysis", Evidence-Based Complementary and Alternative Medicine, vol. 2021, Article ID 1058671, 10 pages, 2021. https://-doi.org/10.1155/2021/1058671

Source: HALYARD* data on file