WINDOME BANKING PARTNERS

Diabetic Foot and Digital Ulcer Market Overview

January 2025 – WINDOME BANKING PARTNERS

Disclaimer

This document, reflecting estimates as of December January, is based on WINDOME BANKING PARTNERS SAS' intelligence, which leverages a number of independent sources:

1. **Prevalence, risk level and risk factors of diabetic foot ulcer among adult individuals with diabetes in the Southeastern Anatolia Region of Turkiye**, Journal of Tissue Viability Volume 34, Issue 1, February 2025, 100839
2. IDF Diabetes Atlas Diabetes reports 2022
3. IDF Diabetes Atlas Diabetes reports 2023
4. **Etiology, Epidemiology, and Disparities in the Burden of Diabetic Foot Ulcers,** 2022 Dec 22;46(1):209–221. doi: 10.2337/dci22-0043
5. **International Diabetes Federation .** The Diabetic Foot. Brussels, Belgium, International Diabetes Federation, 2020. Accessed 1 August 2022.
6. Armstrong DG, Boulton AJM, Bus SA. **Diabetic foot ulcers and their recurrence**. N Engl J Med 2017;376:2367–2375
7. Hoffstad O, Mitra N, Walsh J, Margolis DJ. **Diabetes, lower-extremity amputation,** and death. Diabetes Care 2015;38:1852–1857
8. van Netten JJ, Bus SA, Apelqvist J, et al. .; **International Working Group on the Diabetic Foot . Definitions and criteria for diabetic foot disease.** Diabetes Metab Res Rev 2020;36(Suppl. 1):e3268.
9. Boulton AJM. **The pathway to foot ulceration in diabetes**. Med Clin North Am 2013;97:775–790 – PubMed
10. Yotsu RR, Pham NM, Oe M, et al. . **Comparison of characteristics and healing course of diabetic foot ulcers by etiological classification: neuropathic, ischemic, and neuro-ischemic type.** J Diabetes Complications 2014;28:528–535

Although we have taken great care prior to producing this presentation, it represents WINDOME BANKING PARTNERS SAS' view at a particular point in time.

We cautiously advise our customers to make their own assessment as to the appropriate course of action to take, use this presentation as guidance. Please carefully consider local laws and guidance in your area, particularly the most recent advice issued by your local (and national) health authorities, before making any decision.

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Introduction on Diabetic Foot Ulceration

A diabetic foot ulcer is an open sore or wound that occurs in approximately 15 percent of patients with diabetes

Diabetic foot ulceration is a devastating complication of diabetes that is associated with infection, amputation, and death, and is affecting increasing numbers of patients with diabetes mellitus. DFU pathogenesis is multifactorial. The refractory nature of foot ulcer is reflected in that even after healing there is still a high recurrence rate and amputation rate, which means that management and nursing plans need to be considered carefully. Establishment of measures for prevention and management of DFU have to be implemented to prevent its degeneration

A validated and appropriate DFU classification matching the progression is necessary for clinical diagnosis and management. In the first part of this review,
Focusing on the relationship between the risk factors and DFU progression may facilitate prevention and timely management, the treatment including glycemic control, exercise, offloading, and infection control, and call for taking into account and weighing the quality of life during the formulation of treatment plans.

Multidisciplinary intervention and management of DFUs, based on the effective and systematic combination of these three components contribute to the prevention and treatment of DFUs, and improve their prognosis.

Sources: *Management of diabetic foot ulcers and the challenging points: An endocrine view. Diabetic Foot Ulcer Management and Treatment: An Overview of Published*

Other complications of DFU

Mismanaged diabetes can also lead to heart disease, stroke, nerve damage, and decreased blood flow, which could cause amputation

Healing and Recurrence

The strongest clinical predictor of developing a DFU is a prior DFU or amputation. Recurrence is the occurrence of an ulcer, either at the site of a prior ulcer or at another site, after complete healing. Prospective cohort studies demonstrate [redacted]

Infection

Diabetic foot infection affects approximately [redacted] of DFU and confers a substantial risk of morbidity. Infection is a primary driver of emergency department visits and hospitalization in patients with diabetes and with DFU specifically

Lower-Extremity Amputation

Diabetes is the leading risk factor for lower-extremity amputation in U.S. adults, with an estimated [redacted] diabetes-related major or minor amputations per year. Lifetime risk of any lower-extremity amputation among people with DFU is at least [redacted] Overall diabetes-related amputations decreased steadily over the [redacted] despite rising diabetes prevalence.

Mortality

Survival in people with incident DFU is significantly worse compared with that of similar people with diabetes without foot complications. Although DFU is a marker of more severe microvascular disease and/or otherwise poor health status, both DFU and any lower-extremity amputation are independent predictors of mortality. A recent meta-analysis comprising almost [redacted] reported mortality rates of [redacted], and [redacted] following incident DFU, with cardiovascular disease and infection representing the leading causes of death

Sources:

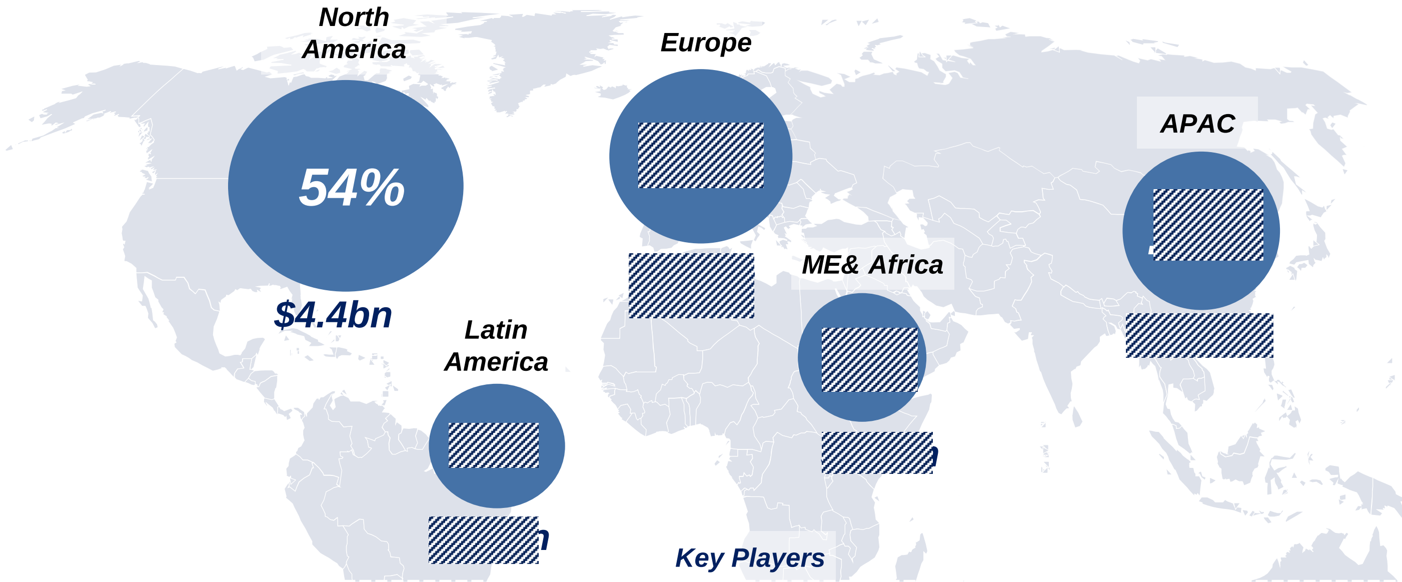
Diabetic Foot Ulcer Market Overview - Key Takeaways

A Continuous Growth Trajectory Of The Global Diabetic Foot Ulcer Market With An Expected 5.9% CAGR From 2022-2032

$8.2bn
2022

[redacted]
2032

[redacted]
CAGR 2022-2032

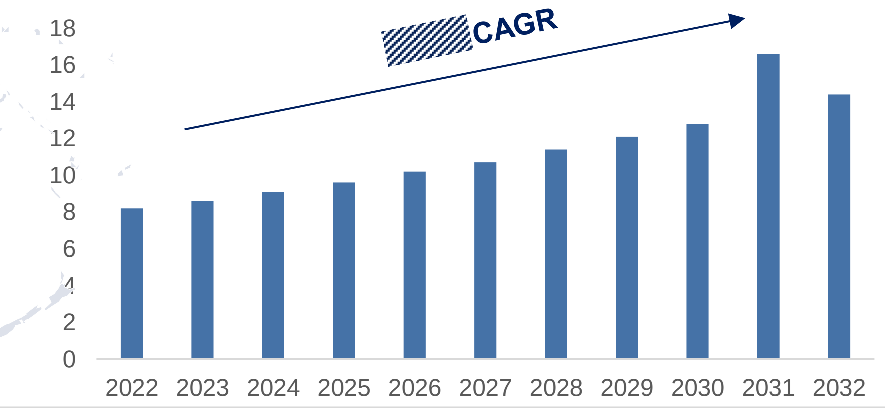


Key Players

MIMEDX, convatec, 3M, CardinalHealth, MEDLINE, Organogenesis inc., URGO Healthcare, Mölnlycke, Coloplast, smith&nephew, B|BRAUN, Kerecis

- *The global diabetic foot ulcer treatment market size was valued by Grandview Research at [redacted] and projected to reach around [redacted]2, poised to grow at a compounded annual growth rate **(CAGR) of ca. 6% from 2023 to 2032.***
- [redacted]
- *It is an increasing trend due to urbanization, exposure to oxidative stress, sedentary lifestyle and lack of physical exercise and mobility, smoking pollution and unhealthy eating habits with the westernization of nutrition as well as the imbalances in food intake globally disrupting people's metabolism.*
- [redacted]

Global Diabetic Foot Ulcer Treatment Market (2022-2032) (in $Bn)

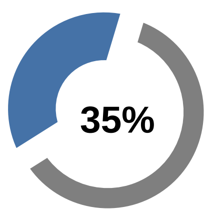


Sources: *Precedence Research, Grandview Research (Diabetic Foot Ulcer report)*

Diabetic Foot Ulcer Etiology – Key Disease Factors

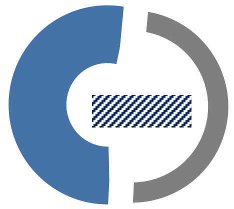
The underlying etiology of DFU is classified into purely purely neuropathic (35%), purely ischemic (15%), and mixed neuroischemic (50%)

The underlying etiology of DFU



purely neuropathic

purely ischemic



mixed neuroischemic

These classifications are based on the presence or absence of peripheral neuropathy (PN) and associated sensory loss (neuropathic), peripheral artery disease (PAD) (ischemic), or both (neuroischemic)

1. Peripheral Neuropathy

- **Sensory neuropathy:** Loss of sensation in the feet prevents patients from noticing injuries or pressure sores.
- **Motor neuropathy:** Weakness in foot muscles leads to deformities (e.g., claw toes), altering pressure distribution during walking.
- **Autonomic neuropathy:** Reduced sweat production causes dry, cracked skin, which is more prone to injury and infection.

2. Peripheral Arterial Disease (PAD)

- **Diabetes accelerates atherosclerosis**, reducing blood flow to the lower extremities.
- **Impaired circulation** compromises wound healing and increases the risk of tissue necrosis.

3. Hyperglycemia

- **Chronic elevated blood** glucose impairs immune function, leading to delayed wound healing.
- It also promotes oxidative stress and inflammation, further damaging tissues.

4. Foot Deformities

Structural changes, such as bunions or Charcot foot, create areas of high pressure, leading to skin breakdown and ulceration.

5. Infection

Diabetic ulcers are highly susceptible to bacterial infections, which can further deteriorate the wound and lead to complications like osteomyelitis or gangrene.

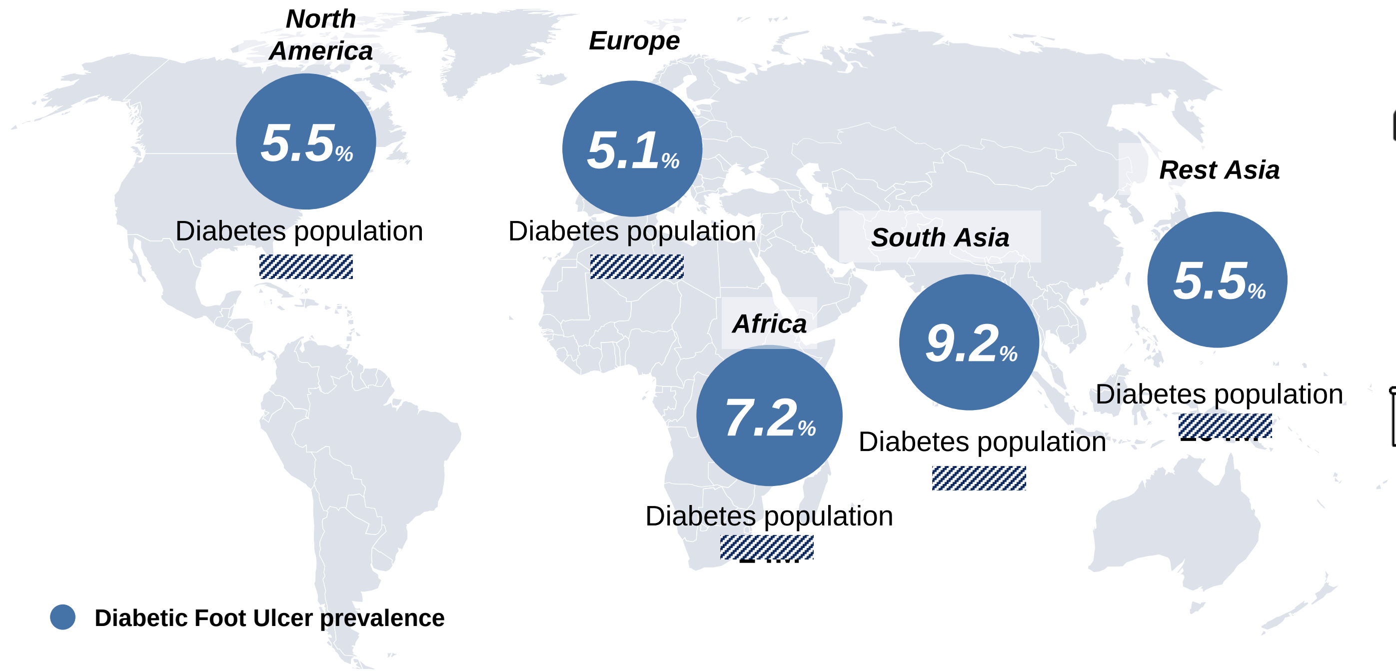
Sources: *Global Data, Precedence Research, Grandview Research (Diabetic Foot Ulcer report)*

Diabetic Foot Ulcer Epidemiology

0.2% to 11% of diabetes population develops DFU

- Reported incidence of DFU varies widely depending on the study design, the population, and the area. In series since 2010, annual incidence generally ranges from [redacted]n diabetes-specific clinical settings or from less than [redacted] community- and population-based cohorts. The International Diabetes Foundation estimates that [redacted]people globally are affected by DFU, A recent meta-analysis found a [redacted] global prevalence of DFU among adults with diabetes, which equates to approximately [redacted] people affected by DFU.
- While DFU has historically been reported at the highest rates in the more regularly diagnosed North America modern cohort studies find rates upwards of [redacted] in populations of people with diabetes in Africa and South America.

Diabetic Foot Ulcer prevalence and Diabetes population (2022) by region (based on Diabetes population)



Prevalence by ethnicity

Black, Hispanic, and other non-White groups experience a much higher burden of diabetes than White adults, including a higher burden of DFU

Socioeconomic and geographic disparities overlap heavily with racial and ethnic disparities in DFU, and the independent effects of these factors are difficult to separate

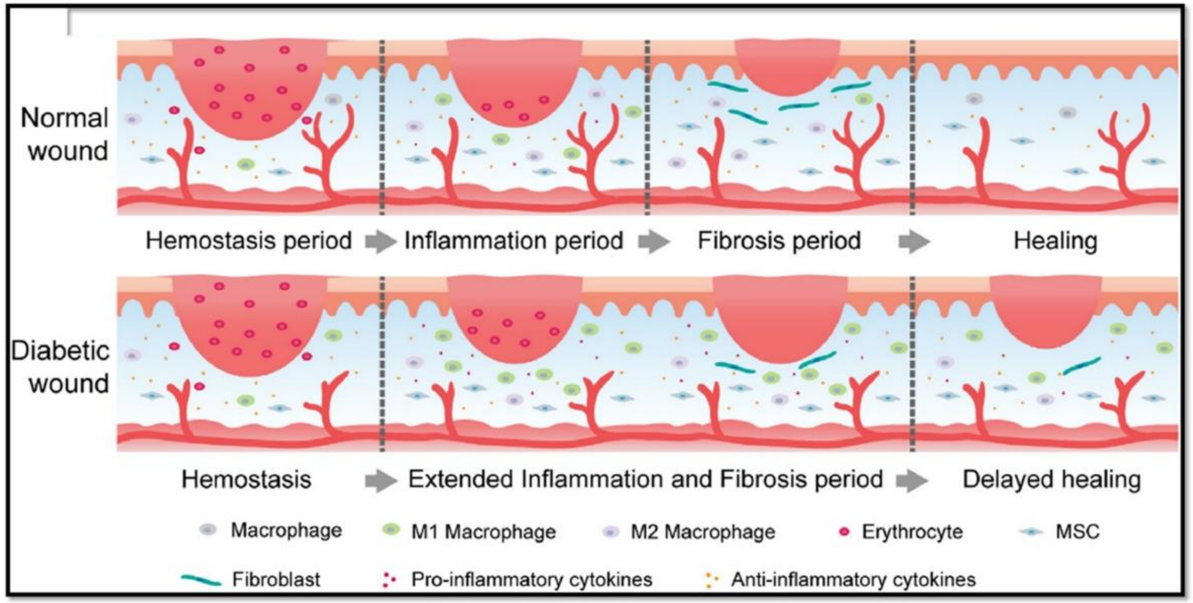
Likelihood of advanced-stage ulcer at diagnosis and risk of hospitalization for DFU are higher among Black and Hispanic adults

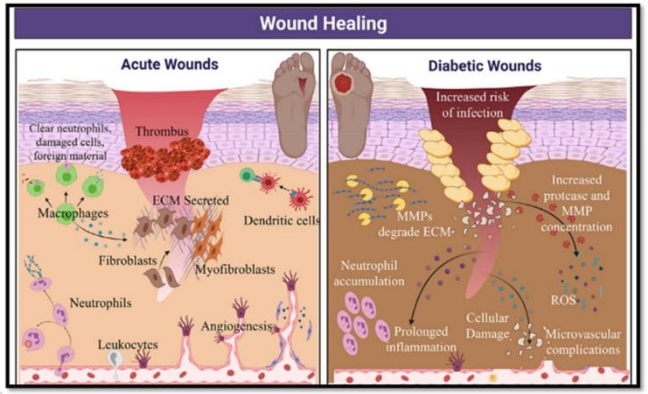
individuals in the lowest-income categories, those with less comprehensive (or no) insurance, malnutrition habits, exposure to alcoholic addictions, oxidative stress and pollutions often correlated with lower education levels, and those who live in socioeconomically deprived neighborhoods.

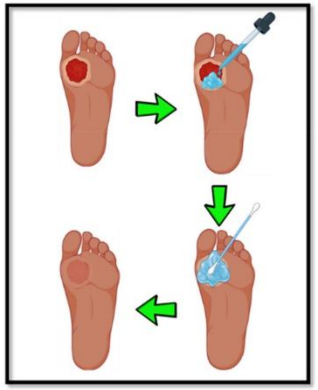
Sources: *Global Data, Precedence Research, Grandview Research (Diabetic Foot Ulcer report*), Diabetes care, Journal of Tissue Viability,

Diabetic Foot Ulcer Segmental Overview

Biologics Treatments Dominated The Industry With 36% Of Total Market Share Respectively







The biologics segment dominated the industry with [redacted] **2023**. Biologics include growth factors, such as vascular endothelial growth factor (VEGF) and platelet-derived growth factor (PDGF).

Key Drugs Treatments

[redacted]

Key Medical Devices Treatments

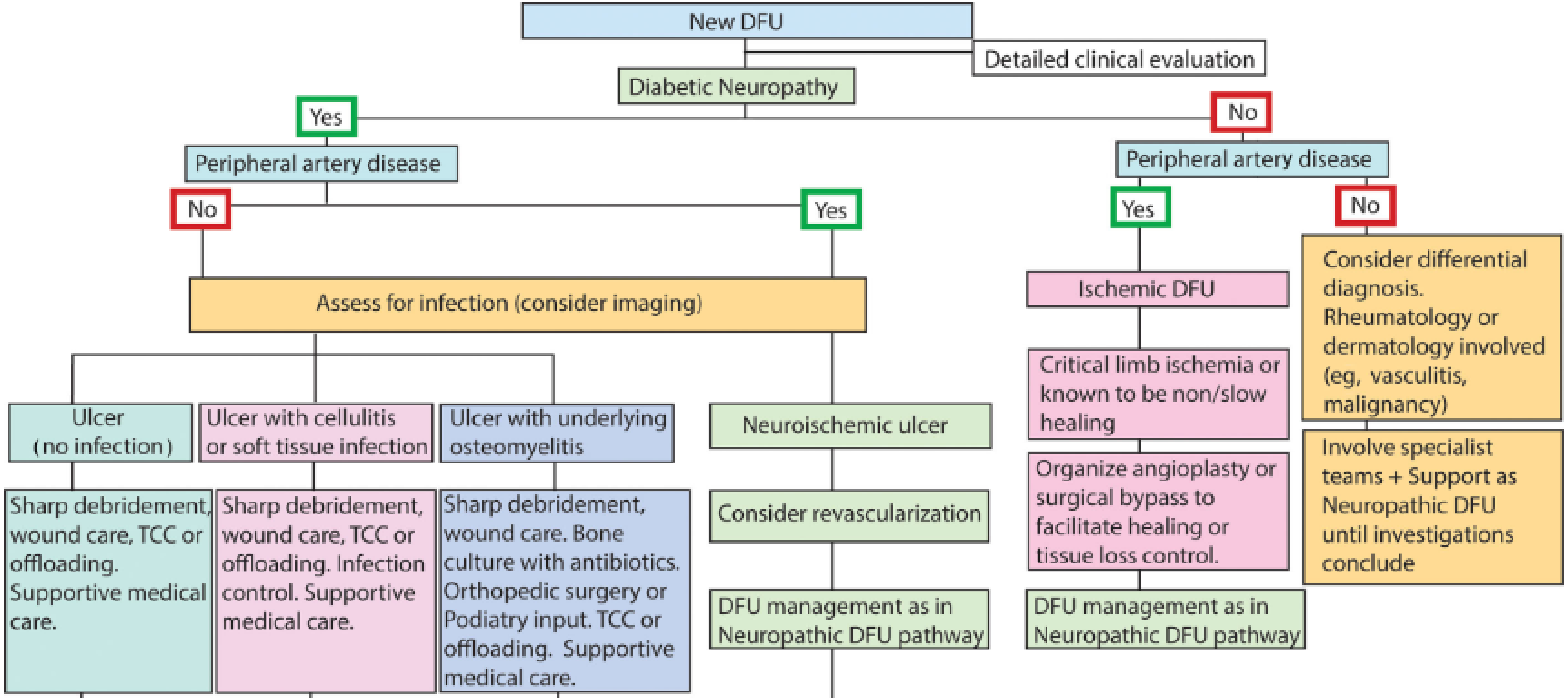
- *Negative Pressure Wound Therapy (NPWT)- such as V.A.C*
- *Total Contact Cast (TCC)*
- *Offloading Devices (Removable Cast Walkers, Postoperative Shoes, Orthopedic Shoes and Inserts*
- *Compression Therapy (Compression Stockings or Wraps)*
- *Biofeedback Systems (Smart Insoles or Socks)*
- *Electrical Stimulation Devices:Hyperbaric Oxygen Therapy (HBOT)*
- *Debridement Devices (Sharp Debridement Tools, Enzymatic Debriding Agents)*

Sources: *Global Data, Precedence Research, Grandview Research (Diabetic Foot Ulcer report*), Current Therapeutic Strategies in Diabetic Foot Ulcers

Therapeutic Strategies in Diabetic Foot Ulcers

Current therapeutic strategies for DFUs include conventional (surgical debridement, antibiotics, vascular assessment, offloading, and amputation) and adjuvant practices

MANAGEMENT BASED ON DFU CLASSIFICATION



Sources: *Global Data, Precedence Research, Grandview Research (Diabetic Foot Ulcer report*), Current Therapeutic Strategies in Diabetic Foot Ulcers

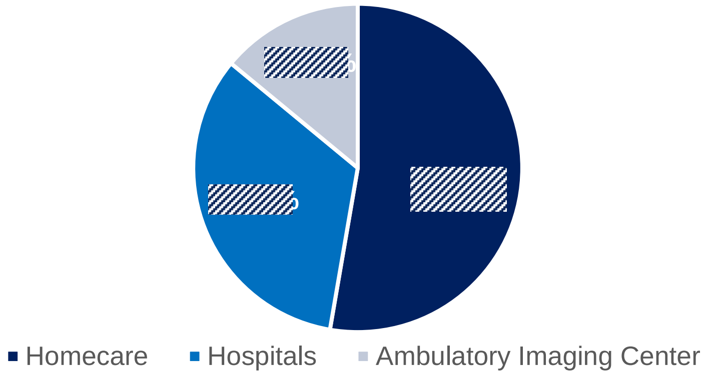
Diabetic Foot Ulcer Regional And Users Overview

Homecare Segment And North America Dominated End-users And Geographical Segments By 53% And 54% Respectively

End-User Insights

- The **hospital segment accounted for a share of** [redacted] The segment growth is attributed to factors, such as widespread adoption of treatments, presence of skilled staff, and favourable reimbursement policies.
- **The homecare settings segment accounted for the largest share of** [redacted]. It is projected to expand further at the fastest CAGR from 2024 to 2030 due to the growing geriatric patient population, a shift toward home-based care, and increased adoption of telemedicine.
- **The COVID-19 pandemic played a pivotal role in shaping this trend**, with most clinics embracing telemedicine, telediagnostication for DFU treatment. Utilizing digital photography for monitoring foot ulcers proved to be a valid, reliable, and feasible method for telehealth purposes. The use of audio, video, and online communication, particularly for foot ulcer monitoring, further propelled segment growth.

Global Diabetic Foot Ulcer Treatment Market (2023)



Geographical Insights

- **The North America** diabetic foot ulcer treatment market size was valued at [redacted]
- **In Europe**, in 2019, nearly [redacted] suffered from diabetes. (any more recent statistics)
- Prevalence **rate of** [redacted] An increased risk of obesity, chronic diabetic conditions, peripheral artery diseases, poor glycemic control, underlying neuropathy, or poor foot care are expected to increase the risk of DFU, eventually decreasing mobility and leading to amputation of lower extremities.

- **In the U.S., nearly 14% to 24% of the diabetic population with foot ulcers undergo foot amputation.**
- **About 60% of diabetes leads to neuropathy, causing foot ulcers**. Hence, it is also the leading cause of non-traumatic lower extremity amputations in the U.S.
- **In the U.S. the annual cost of DFU treatment has reached approximately USD 1 billion and is on the rise.**
- Studies indicate a notable surge in DFU cases, leading to an 11-fold increase in admissions and contributing to over 80% of amputations. **This surge has also resulted in a 10-fold rise in hospital costs over a span of 5 years**.

- **Germany accounted for the largest share of ~10.5%** of the diabetic population in Europe, **followed by Portugal (~9.5%) and Cyprus (~9.0%).**
- **The annual cost of treating DFU is approximately USD 780m in the UK** and around **USD 10.21 billion across Europe**, emphasizing the economic impact of DFU management.

Sources: *Precedence Research, Grandview Research (Diabetic Foot Ulcer report)*

Adjacent Co-morbidity : Scleroderma

Scleroderma is an autoimmune disease that causes inflammation and fibrosis (thickening) in the skin and other areas of the body. When an immune response tricks tissues into thinking they are injured, it causes inflammation, and the body makes too much collagen, leading to scleroderma. Too much collagen in your skin and other tissues causes areas of tight, hard skin. Scleroderma may involve many systems in your body.

There are two major types of scleroderma:
- Localized scleroderma only affects the skin and the structures directly under the skin.
- Systemic scleroderma, also called systemic sclerosis, affects many systems in the body. This is the more serious type of scleroderma and can damage your blood vessels and internal organs, such as the heart, lungs, and kidneys. This subset is also divided into two additional categories called "limited" and "diffuse" which represents how much skin involvement there is in the body.

Population with high morbidity:
- **Sex.** Scleroderma is more common in women than in men.
- **Age.** The disease usually appears between the ages of 30 and 50 and is more common in adults than children.
- **Race.** Scleroderma can affect people of all races and ethnic groups, but the disease can affect African Americans more severely. For example:
  - The disease is more common in African Americans than European Americans.
  - African Americans with scleroderma develop the disease earlier when compared with other groups.
  - African Americans are more likely to have more skin involvement and lung disease when compared with other groups.

Treatments:
- **Dilate blood vessels.** Blood pressure medicines that dilate blood vessels may help treat Raynaud's phenomenon.
- **Suppress the immune system**. Medicines that suppress the immune system, such as those taken after organ transplants
- **Reduce digestive symptoms.** Pills to reduce stomach acid can help relieve heartburn.

Sources: *Scleroderma from NHI*

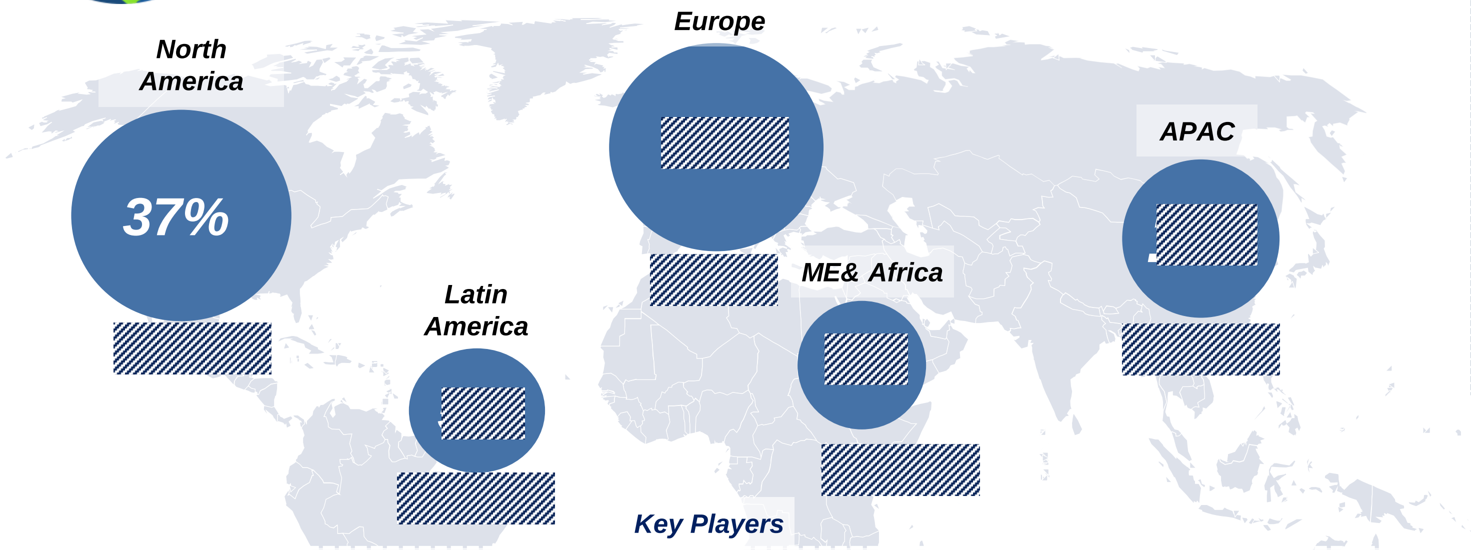
Scleroderma Market Overview

An Expanded Growth Trajectory Of The Scleroderma Market With An Expected 6.4% CAGR From 2021-2030

$2.9bn
2021

[redacted]

[redacted]



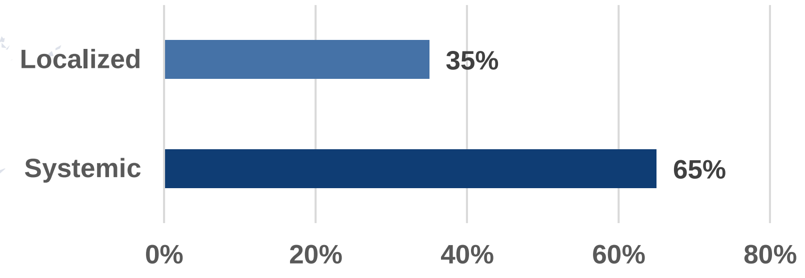
Key Players

Bayer, Active Biotech, Daval International Ltd, BiolineRx, Boehringer Ingelheim, GSK, angion, Fibrocell, Novartis, Gilead

Key Takeaways

- ***Global scleroderma therapeutics market** revenue is expected to expand by* [redacted]
- ***North America** scleroderma therapeutics market share accounting for around* [redacted]*he total market in 2021*
- *According to research, systemic sclerosis affects approximately* [redacted]
- *According to Scleroderma & Raynaud's UK, approximately* [redacted]
- *Among drug class, **immunosuppressors segment will account for more than 60% of overall market share in 2021***
- [redacted]

Global Scleroderma Therapeutics Market by Indication (2021)



Sources: *Acumenresearch, verified market research*