After 30 years in wound care, we at Coloplast believe that absorption is the key to better healing. Our Biatain® portfolio brings superior absorption to daily wound care needs, making Biatain the simple choice for faster healing.

Biatain®



Diabetic foot ulcers – prevention and treatment

A Coloplast quick guide





Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare. Our business includes ostomy care, urology and continence care and wound and skin care. We operate globally and employ more than 7,000 people.

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Introduction

Diabetic foot ulcers have a considerable negative impact on patients lives, and are highly susceptible to infection that all too often leads to amputation. It is essential that diabetic foot ulcers receive the best possible wound management. Successfully treating a diabetic foot ulcer requires a comprehensive understanding of the wound: its cause, progression, risk, and treatment. However more than this, it takes a cross functional approach, where the patient also has an active role in the treatment process.

The information provided here is intended as a general guideline. Please consult diabetic foot ulcer guidelines applicable in your area. For further study, please refer to the International Consensus on the Diabetic Foot, 2011.²

We hope that this quick guide will help you diagnose, assess and treat diabetic foot ulcers in clinical practice, as well as identify opportunities for prevention and minimising the risk of infection and amputation.

Developed by

Faculty panel: Dr. Christian Münter, Germany; Professor Patricia Price, UK; Wilma Ruigrok van der Werven, MA, RN, Netherlands; Professor Gary Sibbald, Canada

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This Coloplast quick guide was updated in March 2012 in collaboration with Dr. Christian Münter.

"I marvel that society would pay a surgeon a fortune to remove a person's leg – but nothing to save it!"

George Bernard Shaw

The diabetic foot – a clinical challenge

Diabetes is a serious chronic disease that needs attention. Approximately 15% of all people with diabetes will be affected by a foot ulcer during their lifetime.¹

Diabetic foot ulcers (DFUs) often co-exist with vascular insufficiency and are the major cause of gangrene and amputation in people with diabetes. Risk of developing diabetic foot ulcers is greatly increased by reduced sensation and blood pressure.

Diabetic foot ulcers represent a huge risk to the patient's quality of life, escalating wound/infection management and costs and account for a large proportion of all national healthcare budgets.

- $\cdot\,$ Five-year recurrence rates of foot ulcers are 70% 2
- Up to 85% of all amputations in relation to people with diabetes are preceded by a foot ulcer¹⁻²
- $\cdot\,$ People with diabetes with one lower limb amputation have a 50% risk of developing a serious lesion in the second limb within 2 years^3 $\,$
- People with diabetes have a 50% mortality rate in the 5 years following the initial amputation⁴

It is possible to reduce amputation rates by 49-85% through a care strategy that combines prevention, the interprofessional diabetes care team, appropriate organisation, close monitoring and education.¹

Pathway to clinical care and clinical evidence



How to prevent DFUs

Prevention and education

"49-85% of all diabetic foot related problems are preventable." **Spraul, M., 2000.**⁶

"This can be achieved through a combination of good foot care, provided by an interprofessional diabetes care team and appropriate education for people with diabetes." Modified from Bakker, K. et al., 2005.¹

"Education of patients, carers and healthcare providers is an essential component of an effective, interprofessional team approach, ...but effective systems and structures for screening, provision of chiropody and footwear and prompt treatment when required must be in place."

Modified from Spraul, M., 2000.⁶

"The most important aspects, for example, danger signs which require prompt action by the patient, should be summarized and repeated."

Spraul, M., 2000.6

"Successful diagnosis and treatment of patients with chronic wounds involve holistic care and a team approach. The integration of the work of an interprofessional care team that includes doctors, nurses and allied health professionals with the patient, family and caregivers offers an optimal formula for achieving wound resolution."

Sibbald, R.G., et al, 2001.¹⁸

Prevention of ulcer formation

People with diabetes must inspect their feet regularly, or have a family member or care provider do it on their behalf. Daily inspection is the foundation of diabetic foot ulcer prevention. All wounds and sores should be taken seriously early on.

Regular, gentle cleansing with soapy water, followed by the application of topical moisturizers, helps to keep the skin healthy and better able to resist breakdown and injury.

Shoes should be checked to ensure that they fit properly and offer adequate support. Consider athletic/sports shoes and thick, padded socks. Diabetic socks (unrestrictive on circulation) are also available. In the case of foot deformities or special support needs, custom shoes should be considered.

Minor foot injuries and infections, such as cuts, scrapes, blisters and tinea pedis (athletes foot), can be unintentionally worsened by home treatments that impede healing. Patients should be reminded to avoid hot soaks, heating pads and harsh topical agents such as hydrogen peroxide, iodine and astringents. A moist wound environment will help prevent ulcer formation. Minor wounds should be gently cleansed and treated with topical antiseptics. In addition, a physician should inspect any minor wounds that do not heal quickly.

By reinforcing preventive advice and inspecting the patient's feet at routine follow-ups, the physician can help the patient develop and maintain good foot-care practices.

An interprofessional team approach

- Dietitian
- · Diabetologist
- · Pharmacist
- · Family doctor/General practitioner
- · Orthopaedic surgeon
- · Rehabilitation team:
- Occupational therapist
- Physiotherapist or
- Specialised physician
- · Interventional radiologist
- · Vascular surgeon
- · Community nurse
- · Dermatologist
- Orthotist
- · Footcare specialist: Podiatrist

Others

- · Diabetes educator
- Psychologist
- · Social worker
- Neurologist

The involvement of the patient as a member of the healthcare team improves patient care outcomes

The patient's role

Patient self-exam needs to be part of diabetic foot care and follow-up

Education of patient, family and healthcare providers, such as using an easy to understand patient leaflet for education, must be a priority.

- Any cut or open skin should be treated by a qualified healthcare
 provider immediately
- · Inspect and examine the feet and shoes on a daily basis
- · Appropriate footwear
- Nails should be cared for by a qualified foot specialist (podiatrist or related disciplines)
- Dry skin should be treated with appropriate moisturizing, such as (humectant) creams containing urea or lactic acid¹⁸
- Fungal infections, especially of the toe webs require topical antifungal agents

Patients should always remember to remove socks and shoes for regular inspection of both feet

Consider the whole patient to ensure effective care of the foot ulcer

Past history, medications and allergies	Check for medications that may inhibit healing (i.e. steroids, immunosuppressants)	
Check for other complications	Neurological, eye, heart, kidney, vascular	
Glycaemic* control	Hb (Haemoglobin) A1c < 7.5% (depending on the specific situation of the patient, e.g. medication, risk of hypoglycemia, body weight)	
Hypertension* control	< 140/90 mmHg	
Clinical obesity* control	BMI < 30 kg/m²	
Hyperlipidemia* control	Cholesterol < 5,2 mmol/L (200 mg/dL)	

*All 4 are associated with the metabolic syndrome and type 2 onset diabetes. Optimal control of diabetes will improve patient care outcomes.

Disclaimer

These are general guidelines. Please check local treatment recommendations applicable for your country or healthcare institution.

How to diagnose and assess a diabetic foot ulcer

"The VIPS"^{7,8} of diabetic foot management to ensure outcomes

- V Vascular supply is adequate
- Infection control is achieved
- P Pressure offloading/downloading
- S Sharp/surgical debridement has been considered

Diabetic foot ulcers typically have a thick rim of keratinised tissue surrounding the wound⁹



Blisters are associated with friction and shear



Callus is associated with increased pressure and haemorrhage

Local wound assessment¹⁰

History	· Previous ulcer(s), amputations	
Local skin assessment	· Oedema	
	· Colour	
	· Temperature	
	· Callus	
Vascular examination	 Check for peripheral arterial disease Symptoms are often not found, but the following signs may be present: cold feet, blanching on elevation, absent hair growth, dry, shiny and atrophic skin⁹ 	
	 Palpate and check for dorsalis pedis, posterior tibial, popliteal and femoral pulses⁹ 	
	 Measure the ankle brachial pressure index (ABPI) Toe pressure or transcutaneous oxygen may be assessed, because arterial calcification can cause falsely elevated ABPI results⁹ 	
Neuropathy 8,11	Sensory – loss of protective sensation	
	 Autonomic – lack of sweating that results in dry, cracked skin that bleeds and creates a portal of entry for bacteria 	
	 Muscular – loss of reflexes or atrophy of muscles that leads to foot deformities 	
Deformity and	Charcot foot	
lootwear	· Hammer toes, claw toes, bunions	
	 Check the deformity and address inappropriately fitted shoes 	

Types of neuropathy¹⁰

Etiology	Sensory neuropathy	Autonomic neuropathy	Motor neuropathy
Characteristics	 Loss of protective sensation No perception of shoes rubbing or temperature changes 	 Reduced sweating results in dry cracked skin Increased blood flow leads to a warm foot 	 Dysfunction of the motor nerves that control the movement of the foot. Limited joint mobility may increase plantar pressure Foot deformities develop Hammer toes
Clinical presentations	 Unaware of a foot ulcer or lack of discomfort when a wound is being probed 	 Dry skin with cracks and fissures Bounding pulses Dilated dorsal veins Warm feet 	 High medial longitudinal arch, leading to prominent metatarsal heads and pressure points over the plantar forefoot Clawed toes Altered gait
			0

10g monofilament testing

The 10g monofilament testing is recommended as a screening tool to determine the presence of protective sensation in people with diabetes.11-13

Places for testing

- Plantar surface of the metatarsal heads (min. 3 metatarsal heads)^{12,13}
- The great toe/first toe¹²
- · The medial and lateral sides of the plantar aspect of the midfoot¹³
- \cdot The plantar area of the heel¹³
- The dorsal aspect of the midfoot¹³



The pictures show testing sites

"There is no clear evidence on how many negative response sites equals an at-risk foot. Some literature shows that even one site with a negative response on each foot may indicate an at-risk foot."

Baker, N. et al., 2005.¹²

Areas at risk for neuropathic, ischaemic and neuro-ischaemic ulcers

In a cross-sectional, population-based study the proportion of the lesions were $\ensuremath{^{\ast_2}}$



Neuropathic ulcers 55% of total diabetic foot ulcers



Ischaemic ulcers 10% and neuro-ischaemic ulcers 34% of total diabetic foot ulcers

"Recent experience from our clinic indicates that the frequency of neuropathic ulcers has decreased and the incidence of ischaemic and neuro-ischaemic ulcers has increased, equaling 50-50%." Mike Edmonds, 2005.

Clinical symptoms of neuropathic and ischaemic foot ulcers¹⁴

Clinical signs	Neuropathic ulcer	Ischaemic ulcer
Foot deformities	Clawed toes, possible high arch, possible Charcot deformities	No specific deformities. Possible absent toes/forefoot from previous amputations
Foot temperature/ foot pulse	Warm, palpable pulse	Cold or decreased temperature, pulse may be absent or reduced
Skin colour	Normal or red	Pale/bluish. Pronounced redness when lowered (dependent rubor), blanching on elevation
Skin condition	Dry skin due to decreased sweating	Thin, fragile and dry
Ulcer location	On the plantar aspects (forefoot 80%) of the foot/toes	Distal/tips of the toes, heel, or margins of the foot
Callus present	Commonly seen on the weight-bearing areas and is generally thick	Not usually. If present, distal eschar or necrosis
Ulcer characteristics	Usually painless, with a "punched out" appearance (granulation or deeper base) surrounded by callus	Painful, especially with necrosis or slough
Sensation	Reduced or absent sensation to touch, vibration, pain, and pressure	Sensation may be present but decreased if there is associated neuropathy
Ankle reflexes	Usually not present	Usually present
Foot pulses	Present and often bounding. Dilated, prominent veins	Absent or markedly reduced

Ulcer assessment

Neuropathic pain	Burning, stinging, shooting and stabbing (non-stimulus dependent)	
Local pain	Deep infection or Charcot joint	
Size	Length, width, depth and location, preferably with clinical photograph	
Wound bed	Appearance • Black (necrosis) • • Yellow, red, pink • • Undermined •	
Infection signs	Odour Be aware that some signs (fever, pain, increased white blood count/ ESR) may be absent. Evaluate the ulcer for signs of infection, inflammation and oedema. For more information, please see page 20	
Exudate	Copious, moderate, mild, none	
Wound edge	Callus and scale, maceration, erythema, oedema	

Wound bed





Sloughy



Wound undermining, deep tissue infection



Maceration

Unhealthy wound edge



Superficial and deep infection symptoms^{10,15,16}

Superficial (local) - Treat topically

- · Non-healing
- · Exuberant friable granulation tissue
- · Bright red discoloration of granulation tissue
- Increased exudate



· New slough in wound base

Topical antimicrobial treatment may be considered for superficial/ local infection, dependent on the assessment that will direct the treatment. Superficial/local infection may, however, require systemic antibiotics. For further details and updates, please see the International Consensus on the Diabetic Foot, 2011.²

Deep – Treat systemically

- Pain
- Probes to bone (increased risk in the presence of osteomyelitis)
- · New areas of break-down
- Warmth
- · Erythema, oedema

Signs of local and deep infection are potentially limb and/or life threatening. These clinical signs and symptoms require urgent medical attention¹¹

Wagner classification

Grade		Ulcer appearance
Grade 0		No open lesions; may have deformity or cellulitis
Grade 1	(e)	Superficial diabetic ulcer (partial or full thickness)
Grade 2		Ulcer extension to ligament, tendon, joint capsule, or deep fascia without abscess or osteomyelitis
Grade 3		Deep ulcer with abscess, osteomyelitis or joint sepsis
Grade 4		Gangrene localised to portion of forefoot or heel
Grade 5	1	Extensive gangrenous involvement of the entire foot

Further reading:

International Consensus on the Diabetic Foot, The International Working Group on the Diabetic Foot, 2011², www.iwgdf.org

How to treat a diabetic foot ulcer

Treatment of diabetic foot ulcers

Vacaular	If inadequate circulation, refer to vegeular accomment and investigations		
vasculai	· In Induequate circulation, relef to vascular assessment and investigations		
	Consider angioplasty, bypass or amputation		
Infection	Bacterial swabs help to identify organisms and sensitivity but do not diagnose infection in isolation from clinical features		
	 Superficial/local – consider topical antimicrobial treatment (e.g. sustained silver releasing dressings). However, it may need systemic antibiotic therapy. The general treatment may also include debridement of devitalized tissue, pressure relief, optimising metabolic control and vascular intervention² 		
	 Deep – requires systemic antibiotic therapy to initially cover Gram-positive, Gram-negative and anaerobic organisms. Subsequently, systemic antibiotic therapy can be modified according to the results of the culture. In addition, it is essential to consider the need for surgical debridement, drainage of infection alongside pressure relief and optimising metabolic control 		
	 Topical antimicrobial (e.g. sustained silver-releasing dressings) may give added benefit together with systemic coverage for deep infection 		
Pressure	Appropriate offloading must be provided		
	Total contact cast or pneumatic walker		
	· Deep toed or special shoes and orthotics		

Frequent (dependent on the clinical situation) inspection of the diabetic foot ulcer is vital due to the increased risk of infection

Local wound treatment

Tissue	Sharp surgery preferred	
debridement	· Hydrogels, alginates and enzymes	
	· Biosurgery	
Infection	Dependent on the outcomes of the wound assessment:	
	· Topical antimicrobials (e.g. sustained silver releasing dressings)	
	Systemic antibiotic therapy	
Exudate management	· Foams, alginates	
Management	 The treatment of the edge depends on the outcomes of the assessment of the edge of the wound. In general, healthy wounds have a pink woundbed and an advancing wound margin, while un-healthy wounds have a dark and undermined wound margin¹¹ 	
Neuropathic pain	Occasionally, neuropathy can be associated with pain. For people with painful diabetic neuropathy, consider the following treatment:	
	Tricyclic antidepressants ^{7,17} (TCAs):	
	· Second generation TCA agents ¹⁷ e.g. duloxetine	
	First generation TCA agent ^{7,17} : amitriptyline	
	Anticonvulsants: pregabalin ¹⁷	

Application of moisture retentive dressings in the context of ischaemia and/or dry gangrene can result in a serious life-or-limb-threatening infection¹¹

Infection control is of paramount importance in DFU treatment because of its strong association with amputation. A study of 1,666 patients with diabetes found that foot infection increased the risk of amputation by 155 times¹⁹

Case study

Diabetic foot saved from amputation – 10 months treatment with Biatain[®] Ag Non-Adhesive foam dressing

Authors: Juan Miguel Aranda, Monica Alcaide, José Manuel Sanchez Primary health care nurses. CAP Sant Llátzer del Consorci Sanitari de Terrassa (Barcelona).

Introduction

A breach in the skin caused by an ulcer is a portal for the entry of germs. In diabetics, the diminished response of white blood cells in quantitative and qualitative terms fosters infection. Aggravation and loss of feeling means that the patient may walk on infected tissue without being aware of it. This may escalate to more serious levels, worsening the condition of the wound and the patient. 40-50% of diabetic patients develop ulceration of the foot in the course of their life and of those, 14-20% experience amputation.

An ulcerated diabetic foot is a foot with suppuration, malodour, local necrosis, associated with two or more signs of perilesional inflammation (reddening, heat, pain, induration, pain when pressed), or osteomielitis proved by imaging. Other causes of inflammation must be eliminated such as Charcot's neuro-arthropathy, breaks, thrombophlebitis, gout, lipoderm atosclerosis, etc.

A highly complex case of a diabetic foot calling constituting a major challenge for the nursing team is set out below. For all treatment, it is crucial to follow a personal care plan that coordinates the actions of all the members of the multidisciplinary medical history team. The success in this case was the result of perseverance by the team combined with the actions of family members and the effectiveness of the materials used.

Medical history

Suffering from heart failure, coronary heart disease, arterial hypertension and venous insufficiency in both lower limbs, as well as Alzheimer's. Not suffering from dislipemia or drug allergies. For four months, she had a very deep wound on the right foot with erythema, oedema, crepitation and heat in the surrounding tissues. It should be pointed out that the patient was not aware of the seriousness of the process since she was suffering from disorientation in space and time and was in a wheelchair. She was referred to the A&E department and after examination by Vascular Surgery, her family was informed that the immediate treatment would involved supracondylar amputation since she was suffering from a grade 4-5 diabetic foot (Figure 1) based on the Wagner scale. The family was opposed to this treatment and the patient was returned to her home for monitoring by her family doctor and out-patient care and dressing by home nursing.

Materials used

Biatain Ag foam dressings are highly absorbent, soft and conformable antibacterial polyurethane foam dressings that provide an optimal moist wound healing environment and effective exudate management.

Biatain Ag combines superior absorption with controlled and continuous silver release, at an effective rate. An antibacterial ionic silver complex is homogeneously dispersed within the foam and silver ions are released to the wound bed when wound exudate is absorbed into the dressing.



Figure 1. The ulcer at inclusion.

that are waterproof and provide bacterial barriers. Biatain Ag Non-Adhesive foam dressings are suitable for use on fragile

Biatain Ag foam dressings are protected with semi-permeable top films

Wound Progress

skin due to the absence of adhesive.

Once the diagnosis of grade 4-5 infected diabetic foot had been confirmed, systematic treatment with oral antibiotics monitored by the family doctor and strict temperature control, carried out by family members, was started to prevent the risk of generalised septicaemia. A daily home care plan for the nursing team was drawn up calling for a high degree of consistency, patience and dedication, and counting on the family's commitment to cooperation in the light of the risk of amputation. The care began with mechanical debridement and extraction of part of the necrotic, slough and suppurative skin and was then treated with enzymatic and autolytic debridements. The dressing used from the beginning was Biatain Ag due to the good exudate management properties and antimicrobial properties in one dressing.

Additionally Biatain Ag had the right density to alleviate pressure. When the treatment was first started, an alginate was used in the cavities to ensure effective management of the exudate and prevent maceration of the edges.

Conclusion

The objective set was to prevent amputation of the foot, ensure the wellbeing and comfort of the patient and of the family. The method used began to bear fruit already seven days after the treatment started, with visible changes in the development of the wound. Analytical and culture checks were carried out regularly to ensure exhaustive monitoring of the infection, glycaemia and other analytical values to ensure proper planning and performance of the ongoing care. The wound closed ten months after the treatment was started.



Figure 2. The ulcer after 5 weeks treatment.



Figure 3. The ulcer after 4 months treatment.



Figure 4. Closed ulcer after 10 months treatment

Coloplast solutions for diabetic foot ulcers

Biatain[®] Adhesive – superior absorption for faster wound healing

Biatain is a soft and conformable foam dressing that effectively absorbs and retains wound exudate.^{20,21} This ensures a moisture balance that is optimal for healing of exuding wounds.^{22,23}





Biatain Non-Adhesive – superior absorption for wounds with extra fragile skin

Biatain Non-Adhesive is a soft and flexible absorbent polyurethane foam dressing with bevelled edges



Biatain Silicone – superior absorption for general purposes

Biatain Silicone is a soft and flexible absorbent foam dressing with a gentle silicone adhesive only on the border leaving the foam free to absorb exudate and heal the wound



Biatain Soft-Hold – superior absorption for wounds that are difficult to bandage

Biatain Soft-Hold has a gentle adherent layer covering less than 50% of the foam surface, allowing both hands to be free during dressing application and removal



Biatain[®] Alginate – superior absorption for slough and cavity filling

Highly absorbent alginate dressing for moderately to heavily exuding wounds. Faster wound healing by conforming to any wound size/shape and by debridement of slough



Purilon[®] Gel – faster wound healing by effective and gentle debridement

- · Fast and effective debridement
- $\cdot\,$ High cohesion the gel stays in place

Coloplast antimicrobial dressings for infected diabetic foot ulcers and ulcers at risk of infection

Biatain® Ag Adhesive – superior absorption for infected wounds

Sustained release of silver during the entire wear time (up to 7 days)^{\rm 25}

- Optimal healing environment²⁶⁻²⁷
- Rapid killing of bacteria²⁸
- · Designed to prevent wound infection





Biatain Ag Non-Adhesive – superior absorption for infected wounds with extra fragile skin

Biatain Ag is a soft and conformable silver foam dressing that is proven to help infected wounds heal faster^{26,27}

Mode of action



Optimal healing environment 26,27

- · Unique 3D polymer foam
- · Superior absorption and high retention



Designed to prevent wound infection²⁶⁻²⁸

- · Patented silver profile
- Sustained release of silver into the wound (up to seven days)



Rapid killing of bacteria^{28,29,30}

- · Optimal concentration of silver
- Faster killing of bacteria in wound and dressing (e.g. MRSA, VRE, ESBL, Pseudomonas)

Biatain[®] – superior absorption for faster healing

Superior absorption for non-infected wounds*

Biatain Silicone

	Item no.
7.5x7.5	33434
10x10	33435
12.5x12.5	33436
15x15	33437
17.5x17.5	33438

Slatain So	π-Ηοία	Item no.
1.12-	10x10	3470
1.00	10x20	3472
-	15x15	3475

Item no.

3423

Biatain Non-Adhesive

		Item no.
State of the second	5x7	6105
10-11-11	10x10	3410
the loss	10x20	3412
The state of	15x15	3413
	20x20	3416

Biatain Adhesive		
	7.5x7.5	
	12.5x12.5	
	18x18	
	23x23 Sacral	
	19x20 Heel	
500052		

Superior absorption for infected wounds

Biatain Ag Non-Adhesive

Provide State		Item no.
Contraction of the	5x7	5105
230 28	10x10	9622
2000	15x15	9625
The second	5x8 Cavity	9628

Other Coloplast Products for diabetic foot ulcers

Biatain® Alginate

		Item no.
	5x5	3705
1000	10x10	3710
and see a	15x15	3715
	40cm/2g	3740

Biatain Ag Adhesive

ALC: NAME OF		Item no.
	7.5x7.5	9631
	12.5x12.5	9632

Purilon [®] Gel		
0.611		Item no.
69	8 g	3906
	15 g	3900
1		
1		

Superior absorption for painful wounds

Biatain Ibu Non-Adhesive

		Item no.
	10x10	34110
	10x20	34112
	15x15	34115
-	20x20	34120

* Can be used for all types of exuding wounds.

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Own notes

