SLOVENSKI STANDARD
SIST EN 13726-4:2003

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Neaktivni medicinski pripomoļ ki ï Preskusne metode za sanitetni material za primarno oskrbo rane - 4. del: Ustreznost

Non-active medical devices - Test methods for primary wound dressings - Part 4: Conformability

Nichtaktive Medizinprodukte - Prüfverfarhen für primäre Verbandstoffe (Wundauflagen) - Teil 4: Anpassungsfähigkeit

Dispositifs médicaux non-actifs - Méthodes d'essai pour les pansements en contact avec la plaie - Partie 4: Conformabilité

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Non-active medical devices - Test methods for primary wound dressings - Part 4: Conformability

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This European Standard was approved by CEN on 21 February 2003.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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Foreword

This document (EN 13726-4:2003) has been prepared by Technical Committee CEN /TC 205, "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2003, and conflicting national standards shall be withdrawn at the latest by October 2003.

EN 13726 consists of the following Parts under the general title *Non-active medical devices - Test methods for primary wound dressings:*

Part 1: Aspects of absorbency

Part 2: Moisture vapour transmission rate of permeable film dressings

Part 3: Waterproofness

Part 4: Conformability

Part 5: Bacterial barrier properties

Part 6: Odour control

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

EN 13726 gives a test method and does not contain performance requirements. EN 13726-4 describes test methods for measuring aspects of conformability of primary wound dressings.

Test methods for other aspects of primary wound dressings are described in other parts of EN 13726.

1 Scope

This European Standard describes a test method for measuring aspects of conformability of primary wound dressings.

2 Terms and definitions

For the purposes of this European Standard the following terms and definitions apply:

2.1
primary wound dressing
material or combination of materials, in any shape, form or size that is intended to remain in direct contact with a wound

NOTE They are used as mechanical barriers, for the absorption or transmission of exudates, to manage the micro-environment of the wound, and can enable the wound to heal by primary or secondary intent. Devices which have a metabolic, pharmacological or immunological interaction as their primary intent are excluded

2.2
conformability of a wound dressing
ability to adapt to the shape and movement of the body

2.3
extensibility
force required to stretch a wound dressing to known extension

2.4
permanent set
increase in the length of a sample after stretching and relaxing expressed as a percentage of the original length

3 Test method for conformability

3.1 Test conditions

Condition the sample for at least 16 h at (60 ± 15) % RH and a temperature of (21 ± 2) ºC and carry out the test in the same environment.

3.2 Extensibility and permanent set

3.2.1 Significance and use

This test is designed to assess the extensibility and permanent set conformability of a primary wound dressing by measuring its extensibility and permanent set.

NOTE 1 When a dressing is applied in a region of movement e.g. over a joint, it is important that it allows sufficient freedom of movement to avoid damage under the dressing. A dressing which is easily extended and which returns close to its original length after extension, will be more comfortable for the patient to wear. An adhesive product which extends sufficiently easily with the skin, helps to prevent subcutaneous shearing damage.

NOTE 2 The test is particularly suitable for adhesive dressings but can also be applied to other dressings which are required to move with the skin.

3.2.2 Equipment

3.2.2.1 A tensile testing machine fitted with a load cell suitable for the range being measured capable of measuring to ± 0,1 N.

3.2.2.2 A means of cutting a specimen (25,0 ± 0,5) mm wide.

3.2.2.3 Stopwatch.

3.2.3 Procedure

3.2.3.1 Cut out a (25,0 ± 0,5) mm wide specimen representative of the material under test.

3.2.3.2 After removing the specimen from the roll or backing paper, allow it to relax for a minimum of 300 s.

3.2.3.3 Place 2 parallel marks on the specimen, (100 ± 10) mm apart, such that the marks are at equal distances from the two ends. Measure the distance between the two marks to the nearest 0,5 mm *(L_1)*.

3.2.3.4 Clamp the specimen outside the marks into the jaws of the tensile testing machine and extend the specimen by 20 % using an extension rate of (300 ± 10) mm/min. Record the maximum load (*ML*) to the nearest 0,1 N.

3.2.3.5 Hold the specimen at this extension for (60 ± 1) s then remove the specimen from the jaws and allow it to relax for (300 ± 15) s.

3.2.3.6 Re-measure the distance between the two marks on the specimen (L_2).

3.2.3.7 Repeat 3.2.3.1 to 3.2.3.6 on a further two specimens.

3.2.3.8 Repeat 3.2.3.1 to 3.2.3.7 with a second set of specimens taken perpendicular to the first set.

3.2.4 Calculation of results

3.2.4.1 Calculate the extensibility using Formula 1:

$$\text{Extensibility } (\text{N}\cdot\text{cm}^{-1}) = \frac{ML}{2{,}5} \qquad (1)$$

where

ML = maximum load

Express the result to the nearest 0,1 $\text{N}\cdot\text{cm}^{-1}$ and calculate the average result of each set.

3.2.4.2 Calculate the permanent set using Formula 2:

$$\text{Permanent set } (\%) = \left(\frac{L_2 - L_1}{L_1}\right) \times 100 \qquad (2)$$

where

L_1= distance between two marks before elongation

L_2 = distance between two marks after elongation