

英国 360度毛歯ブラシ マーケット情報

口腔ケアブラシ（スポンジ使い捨てモデル）使用禁止と
代替品360度毛歯ブラシ推奨について

口腔ケアブラシ（スポンジ使い捨てモデル）使用禁止に至る経緯、内容について



英国政府通達より2008年以降、注意喚起がなされています。

- 口腔用綿棒（口腔ケアブラシ）は、不適切に使用すると、重大な健康リスクを引き起こします。使用中にスポンジの端が外れて吸引される可能性がある為、窒息の危険があります。
- イングランド保険教育委員会より2015年9月のデータ公表では、「口腔用綿棒（口腔ケアブラシ）の使用に関連した800件の安全事故が発生、1件は死亡事故となり、病院、長期介護施設での口腔用綿棒（口腔ケアブラシ）使用を禁止した」とあります。
- 歯科医療コンサルティング --KnowledgeOralHealthcare-- サイトより
- マウスケアスワブ（口腔用綿棒）は医療機器警告（MDA/2012/020）に指定され、患者の口腔内でスポンジヘッドが外れて死亡事故が発生したため、ウェールズでは使用が禁止された。



Medical Device Alert
Ref: MDA2012020 Issued: 13 April 2012 at 12:00

Device
Oral swabs with a foam head.
All manufacturers.



Problem
Foam heads of oral swabs may detach from the stick during use. This may present a choking hazard for patients.

Action
Follow the manufacturer's instructions for use (where available).
Check that the foam head is firmly attached to the stick before use.
Do not leave the swabs soaking in liquid prior to use as this may affect the strength of the foam head attachment.

Action by
All those involved in the use and supply of these devices including those who advise patients and carers.

CAS deadlines
Action underway: 27 April 2012
Action complete: 14 May 2012

Additional Action
If required maintain the swab immediately before use.
If the patient is likely to bite down on the swab consider using an alternative such as a small headed toothbrush with soft bristles.
Ensure that all users, including unsupervised patients and carers, are aware of this advice and the manufacturer's instructions for use.
Discard oral swabs after use.
This advice supersedes the advice given in MDA2008017.

口腔ケアブラシ（スポンジ使い捨てモデル） 効能について

Royal College of Nursing（英国看護大学）発行資料より

- 口腔用綿棒（口腔ケアブラシ）は、歯の清掃、歯垢の除去には効果がありません。
- 歯科医療コンサルティング --KnowledgeOralHealthcare-- サイトより
- マウスケアスワブ（口腔用綿棒）は口腔内を湿らせ、粘着性のある粘液分泌物や食べ物のカス（残渣）、濃くなった唾液をほぐすためのものです。歯や歯茎の歯垢を取り除く効果は無く、歯ブラシの代わりにはなりません。

口腔ケアブラシ（スポンジ使い捨てモデル）代替品について ①

Royal College of Nursing（英国看護大学）発行資料より

- 口腔用綿棒（口腔ケアブラシ）を使用禁止と記載され、それに代わるものとして「360度毛歯ブラシ」を紹介されています。
- 「口腔内の痛みが強い場合、歯の根元の歯茎から出血している場合、又は終末期に安らぎを与える場合は、水分補給と口腔内の湿潤を保つため、柔らかい歯ブラシ、360度毛歯ブラシ、口腔洗浄器を使用することが望ましい」との記述があります。

MOUTH CARE DURING END OF LIFE CARE

Things You Should Not Use

Foam sponge mouth swabs

It is strongly recommended not to use foam sponge swabs of any type for mouth care. Their use is banned in Wales and in many organisations across the rest of the UK.

They are not effective in cleaning teeth or removing dental plaque, and there is a risk that the foam head could become detached. This is a serious choking hazard.

A mouth cleanser is a safe replacement for the foam sponge swabs.



Lemon and glycerine swabs

The use of lemon and glycerine swabs is not recommended.

They can worsen a dry mouth.

For people with severe mouth pain / bleeding from the gums at the base of the teeth, or to provide comfort at end of life, a soft toothbrush, circular brush or mouth cleanser is preferable to provide hydration and to keep the mouth moist.

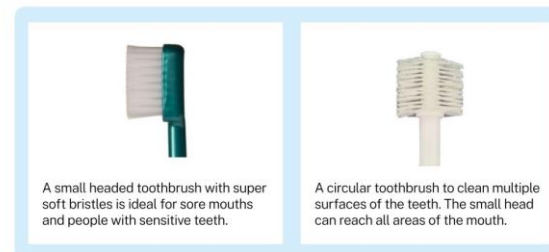
Tap water or water-based gel can be used to keep the mouth moist.

MOUTH CARE DURING END OF LIFE CARE

Products used to assist mouth care

Toothbrush

You can continue to use the person's preferred toothbrush; whether it's manual or an electric toothbrush. You can also decide which you feel more comfortable using. For both brushes it is important that the head of the brush is small and that the bristles are soft (see photo below). A toothbrush with a circular head is a good option (see photo below).



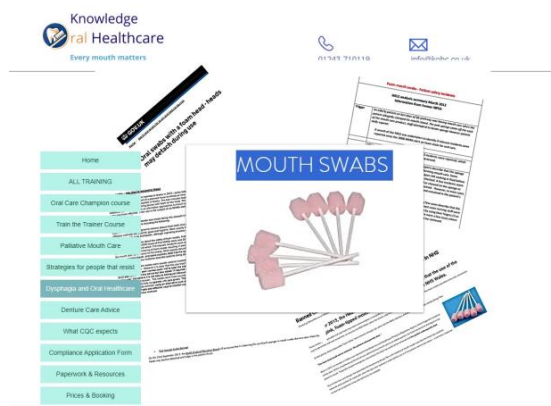
Toothpaste

Continue to use the person's preferred toothpaste. For some people at the end of life, the strong mint flavour and foaming nature of many toothpastes caused by an ingredient called sodium lauryl sulphate (SLS) can cause discomfort. Using fluoride toothpaste that is mild mint flavoured, or flavour free, and free of SLS would be a good alternative.

口腔ケアブラシ（スポンジ使い捨てモデル）代替品について ②

歯科医療コンサルティング --KnowledgeOralHealthcare--サイトより

- 360度毛歯ブラシは毛先が柔らかいため、口腔スポンジの代替品として適しています。
- 歯や舌、口蓋、頬などの口腔軟組織のバイオフィルム除去に使用できます。
- 又、水や保湿ジェルで口腔内を潤すためにも使用できる。
- スポンジ綿棒の代替品として急速に人気が高まっており、Oralieve（英国販売代理店）で購入できます



There are a range of oral swabs on the market in a variety of colours, the most common and recognised colours are pink and green. Sponge swabs are meant to moisten the oral cavity, help loosen sticky mucus secretions, food debris and thickened saliva. They are not effective at removing plaque from the teeth and gums and should not be a substitute for a toothbrush.

Since 2012 Mouth Care Swabs are on a Medical Device Alert (MDA/2012/020) and their use are banned in Wales following a fatality when the sponge head became detached and dislodge in a patients mouth. There have been over 800 safety incidents reported since April 2008 whereby the sponge head has come off either because it has become loose or because the resident/patient has bitten down on the sponge.

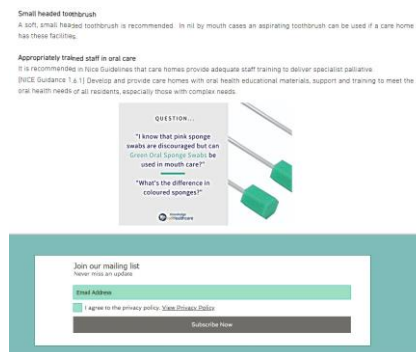
RECOMMENDED ALTERNATIVES

360 Degree Toothbrushes

The soft bristles make this product a suitable replacement to the mouth sponges. The can be used to remove biofilm from the teeth and soft tissues of the oral cavity such as the tongue, palate and cheeks. It can also be used to hydrate the mouth with water or hydrating gel. It is a fast growing popular alternative to the Sponge swabs and can be purchased at Oralieve click here

Gauze

An alternative to mouth sponge swabs is non-fraying gauze. Gauze squares are ideal for removing debris, plaque and dry mucus from the lips and oral cavity. Damp the gauze in water and wrap it around an index finger to remove plaque and food debris from the sulcus areas and outer teeth surfaces (buccal surfaces). A pea-sized amount of non-foaming toothpaste may be applied to the gauze when removing plaque from the teeth. The importance of plaque removal from the mouth and teeth is to lower the bacteria levels in the oral cavity it is important to also remember the sense of well being a clean mouth has as it is sometimes forgotten.



口腔ケアブラシ（スポンジ使い捨てモデル）使用警告について

MHRA

Medical Device Alert

Ref: MDA/2012/020 Issued: 13 April 2012 at 12:00

Device

Oral swabs with a foam head.

All manufacturers.



Problem

Foam heads of oral swabs may detach from the stick during use. This may present a choking hazard for patients.

Action

Follow the manufacturer's instructions for use (where available).

Check that the foam head is firmly attached to the stick before use.

Do not leave the swabs soaking in liquid prior to use as this may affect the strength of the foam head attachment.

Action by

All those involved in the use and supply of these devices including those who advise patients and carers.

If required moisten the swab immediately before use.

If the patient is likely to bite down on the swab consider using an alternative such as a small headed toothbrush with soft bristles.

Ensure that all users, including unsupervised patients and carers, are aware of this advice and the manufacturer's instructions for use.

Discard oral swabs after use.

CAS deadlines

Action underway: 27 April 2012

Action complete: 14 May 2012

This advice supersedes the advice given in MDA/2008/017.

Issued: 13 April 2012 at 12:00

Ref: MDA/2012/020

Problem

The MHRA is aware of a recent incident in Wales where the foam head detached from the stick of an oral swab while a carer was providing mouth care to an elderly patient. The foam head could not be retrieved. The patient subsequently died.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- OFSTED (Directors of Children's Services) for information
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All clinical departments
- All nursing staff
- All wards
- Clinical governance leads
- Dental departments
- Dental nurses
- ENT departments
- ENT medical staff
- ENT services, directors of
- Health and safety managers
- Intensive care medical staff/anaesthetists
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Nursing executive directors
- Oral and maxillofacial surgeons
- Risk managers

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Community children's nurses
- Community dental services
- Community hospitals
- Community nurses
- District nurses
- General dental practice
- Palliative care teams

Social services

- Care at home staff
- Community care staff
- Day centres (older people, hearing disabilities, mental health, physical disabilities, multiple care, autistic services)
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes

Medicines and Healthcare products Regulatory Agency

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Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies

Establishments registered with OFSTED

This alert should be read by:

- Children's services
- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gov.uk and requesting this facility.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/020** or **2012/003/001/481/005**

Technical aspects

Mojisola Agency / Sally Moulder
Medicines & Healthcare products Regulatory Agency
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151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 727/17168
Fax: 020 8754 3965
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Sally.moulder@mhra.gsi.gov.uk

Clinical aspects

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London SW1W 9SZ
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Fax: 020 8754 3965
Email: nicola.lennard@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>
Further information about CAS can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Medicines and Healthcare products Regulatory Agency

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Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system. Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ
Tel: 02890 523 704
Fax: 02890 523 900
Email: NIACC@dhspnri.gov.uk
<http://www.dhspnri.gov.uk/index/hea/niacc.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIACC. Further information can be found on our website <http://www.dhspnri.gov.uk/niacc>.
Further information about SABS can be found at <http://sabs.dhspnri.gov.uk/>

Scotland

This alert supersedes Hazard Notice HAZ/SC/08/06, issued by Scottish Healthcare Supplies on 19 March 2008.

Enquiries and adverse incident reports in Scotland should be addressed to:
Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH15 8EB
Tel: 0131 275 7575
Fax: 0131 314 0722
Email: ira.sc@nhs.net
<http://www.nhs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Chris Jones
Medical Director
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ
Tel: 029 2062 3922
Email: HAz-Act@wales.gsi.gov.uk

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