AS 3825:2020

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Procedures and devices for the removal, containment and disposal of scalpel blades from scalpel handles

This Australian Standard ® was prepared by HE-011, Safe Management of Sharps and Healthcare related Wastes. It was approved on behalf of the Council of Standards Australia on 7 December 2020.

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The following are represented on Committee HE-011:

Australasian College for Infection Prevention and Control
Australian College of Perioperative Nurses
Australian Dental Association
Australian Funeral Directors Association
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Australian Medical Association
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AS 3825:2020

Procedures and devices for the removal, containment and disposal of scalpel blades from scalpel handles

Originated as AS/NZS 3825:1998.
Revised and redesignated as AS 3825:2020.

Preface

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-011, Safe Management of Sharps and Healthcare Related Wastes, to supersede AS/NZS 3825—1998, *Procedures and devices for the removal and disposal of scalpel blades from scalpel handles*.

The objectives of this Standard are as follows, in order to reduce the incidence of injury or transmission of infection to the user and other personnel:

(a) Define the performance characteristics of devices which are used to remove and contain scalpel blades from scalpel handles.

(b) Recommend appropriate procedures for removal and containment of scalpel blades from scalpel handles.

(c) Recommend appropriate procedures for the disposal of scalpel blade removal devices and contained scalpel blades.

(d) Specify test methods for assessment of removal and containment.

The major changes in this edition are as follows:

(i) Expansion to include both multiple-use and single-use scalpel blade removal devices.

(ii) Removal of unsafe practices such as using artery forceps to remove used scalpel blades.

(iii) Specification of the immediate containment of removed scalpel blades to provide protection against injury to downstream staff.

This Standard is applicable to all clinical and non-clinical settings. Examples include, but are not limited to, hospitals, surgical settings, residential aged care facilities, doctors' surgeries, dental offices and podiatry clinics, and areas other than health facilities, e.g. schools, universities, laboratories, veterinary surgeries, aesthetic clinics, architects' offices, graphic design studios and any establishment where scalpels are used.

The terms "normative" and "informative" are used in Standards to define the application of the appendices to which they apply. A "normative" appendix is an integral part of a Standard, whereas an "informative" appendix is only for information and guidance.

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Australian Standard®

Procedures and devices for the removal, containment and disposal of scalpel blades from scalpel handles

1 Scope

This Standard sets out performance characteristics of devices used in, and procedures for, the removal, containment and disposal of scalpel blades from scalpel handles.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document:

NOTE Documents for informative purposes are listed in the Bibliography.

AS 4031, *Non-reusable containers for the collection of sharp medical items used in health care areas*

AS/NZS 4261, *Reusable containers for the collection of sharp items used in human and animal medical applications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
chamber
that part of the scalpel blade removal device which fully encloses the scalpel blade after its removal

3.2
container
receptacle intended for the collection and containment of scalpel blade removal devices

3.3
containment
complete enclosure of the scalpel blade within a chamber of the scalpel blade removal device following removal

3.4
loaded
physical state wherein a scalpel blade is attached to a scalpel handle, ready for use

3.5
may
indicates the existence of an option

3.6
removal
separation of the scalpel blade from the scalpel handle prior to containment

3.7
resheathing-type removal action
physical action whereby the user or other person holds a loaded scalpel handle with one hand and attempts to remove the scalpel blade with a device held in the other hand

3.8
scalpel blade
device which has a sharpened edge or edges designed for cutting, and which can be loaded onto a scalpel handle

3.9
scalpel blade removal device
any device designed for the safe removal and containment of a scalpel blade from a loaded scalpel handle

3.9.1
active scalpel blade removal device
scalpel blade removal device in which removal is manually performed by the user

3.9.2
multiple-use scalpel blade removal device
device consisting of one chamber which is designed to contain more than one blade

Note 1 to entry: A multi-use device can typically accommodate in the order of 100 or more blades.

3.9.3
passive scalpel blade removal device
scalpel blade removal device in which removal is automatically performed with no extra action being required by the user

3.9.4
single-use scalpel blade removal device
device consisting of one or more chambers, each chamber designed to contain a single blade

3.10
scalpel blade removal procedure
any procedure or series of procedures designed to separate a scalpel blade from a loaded scalpel handle

3.11
scalpel handle
handle, or other device of similar function, designed for holding a scalpel blade during use

3.12
shall
indicates that a statement is mandatory

3.13
should
indicates a recommendation

4 Design requirements for scalpel blade removal devices

The design of the scalpel blade removal device shall —

(a) allow for the safe removal of a scalpel blade with a single-handed operation, (test in accordance with Appendix A);

NOTE 1 This may require the fixing of the scalpel blade removal device to a surface with a bracket or suitable alternative fixation device, e.g. suction cup, reusable adhesive or hook-and-loop fastener.

(b) indicate that the used scalpel blade has been removed by —

(i) an audible sound; and/or

(ii) a visual cue;

(c) allow for the safe containment of the scalpel blade immediately after the scalpel blade is removed, (test in accordance with Appendix A);

(d) ensure that the scalpel blade remains completely contained within the device after removal (test in accordance with Appendix B);

(e) be such that during use the loaded scalpel handle is not directed towards the user's body; and

(f) if a single-use device, allow for accurate count of the contained scalpel blades.

The design of the scalpel blade removal device should also —

(i) permit the removal of the scalpel blade —

(A) with minimum droplet dispersal;

(B) without breakage or flip-back of the blade, and

(C) without damage to the scalpel blade handle;

(ii) not require excessive force to remove the scalpel blade;

(iii) if a single-use device, be capable of being sterilized, where claimed by the manufacturer; and

(iv) if a multiple-use device, allow for ease of cleaning of the external surfaces.

NOTE 2 Appendix C may be useful for reporting purposes.

5 Procedures for the removal of scalpel blades

5.1 Location of scalpel blade removal device

The scalpel blade removal device shall be situated as close as possible to the point of use.

5.2 Type of scalpel blade removal device

Where a scalpel blade removal device is loaded onto a reusable handle, removal of the scalpel blade from the handle shall be done with a passive scalpel blade removal device in preference to an active scalpel blade removal device.

5.3 Removal by hand

Scalpel blades shall not be removed by hand (see Figure 1).

Figure 1 — Do not remove scalpel blade by hand

5.4 Removal by needle holders, artery forceps or similar devices

Scalpel blades shall not be removed with needle holders, artery forceps or similar devices that are not designed for this purpose (see Figure 2).

Figure 2 — Do not remove the scalpel blade using needle holders, artery forceps or similar devices that are not designed for the removal of scalpel blades

5.5 Removal by a resheathing-type action

Scalpel blades shall not be removed by a resheathing-type removal action (see Figure 3).

Figure 3 — Do not remove the scalpel blade using a resheathing-type removal action involving the use of both hands

5.6 Disposal of scalpel blade removal device

Where a one-piece scalpel handle and blade is used, the intact unit shall be disposed of in accordance with Clause 6.

NOTE 1 The scalpel blade should be removed as soon as possible after use.

NOTE 2 See Appendix D for general training guidelines.

NOTE 3 See Appendix E for general audit guidelines

6 Procedures for the disposal of scalpel blade removal devices

Scalpel blade removal devices with their contained scalpel blades shall be disposed of into a sharps container which conforms to AS 4031 for single-use sharps containers, or AS/NZS 4261 for reusable sharps containers, with the following exceptions:

(a) If a counting device is provided on the scalpel blade removal device, the marking requirements for a fill line and capacity indicator need not apply.

(b) Where there is an automatic closure mechanism which comes into effect when the container is full, the requirement for a separate lid, cover or closure device need not apply.

NOTE Refer to AS 3816:2018 for disposal of the sharps container.

Appendix A
(normative)

Assessment of removal and containment by a single-handed action

A.1 Scope

This Appendix sets out the procedure for determining whether the scalpel blade removal device can be operated with a single-handed action, as required by Clause 4(a), and the removed scalpel blade is immediately contained, as required by Clause 4(c).

A.2 Principle

The scalpel blade removal device is tested in accordance with the manufacturer's instructions, including the use of a bracket or similar fixation device if specified, to ensure that a scalpel blade can be removed from a reusable scalpel handle by the operator using only one hand and that the scalpel blade is immediately contained within the device.

A.3 Apparatus

Use the following apparatus:

(a) Reusable scalpel blade handles, sizes 3 and 4.

NOTE 1 The number of reusable handles required is at the discretion of the test house.

(b) Where testing a single-use device, the following:

(i) Two devices.

NOTE 2 These devices can be reused for Appendix B if desired.

(ii) Bracket or fixation device, if specified by the manufacturer.

(iii) The number of size 15 scalpel blades equal to the number of chambers in one device.

(iv) The number of size 22 scalpel blades equal to the number of chambers in one device.

WARNING: The use of blunt scalpel blades or cut-resistant gloves is recommended in order to ensure operator safety.

(c) Where testing a multiple-use device, the following:

(i) One device.

NOTE 3 This device can be reused for Appendix B if desired.

(ii) Bracket or fixation device, if specified by the manufacturer.

(iii) Five size 15 scalpel blades.

(iv) Five size 22 scalpel blades.

WARNING: The use of blunt scalpel blades or cut-resistant gloves is recommended in order to ensure operator safety.

A.4 Procedure

A.4.1 General

Conduct the test at (21 ± 2) °C and at the normal working height of the device.

NOTE A height of approximately 1 m is considered appropriate.

A.4.2 Single-use scalpel blade removal device

A.4.2.1 Method

Proceed as follows:

(a) Assemble the device, including the bracket or fixation device if specified by the manufacturer, in accordance with the manufacturer's instructions.

(b) Load the size 3 scalpel handle with a size 15 scalpel blade. Using the dominant hand only, attempt to remove the scalpel blade with the removal device by following the manufacturer's instructions.

(c) Where the device has more than one chamber, repeat step (b) for each chamber.

(d) Using the second device, repeat steps (a) to (c) using a size 4 scalpel handle loaded with a size 22 scalpel blade.

A.4.2.2 Interpretation of results

The scalpel blade removal device meets the requirements of Clause 4(a) and 4(c) if all blades are successfully removed from the loaded scalpel handle and contained within the device.

A.4.2.3 Report

Report the following information:

(a) Whether the device passes or fails.

(b) The reasons for any failures.

(c) Reference to this test method i.e. AS 3825:2020 Appendix A.

A.4.3 Multiple-use scalpel blade removal device

A.4.3.1 Method

Proceed as follows:

(a) Assemble the device, including the bracket or fixation device if specified by the manufacturer, in accordance with the manufacturer's instructions.

(b) Load the size 3 scalpel handle with a size 15 scalpel blade. Using the dominant hand only, attempt to remove the scalpel blade with the scalpel blade removal device by following the manufacturer's instructions.

(c) Perform step (b) five times.

(d) Repeat steps (b) and (c) using a size 4 scalpel handle loaded with a size 22 scalpel blade.

A.4.3.2 Interpretation of results

The scalpel blade removal device meets the requirements of Clause 4(a) and 4(c) if all blades are successfully removed from the loaded scalpel handle and contained within the device.

A.4.3.3 Report

Report the following information:

(a) Whether the device passes or fails.

(b) The reasons for any failure.

(c) A reference to this test method, i.e. AS 3825:2020 Appendix A.

Appendix B
(normative)

Assessment of containment function

B.1 Scope

This Appendix sets out the procedure for determining whether the scalpel blade removal device meets the containment requirement of Clause 4(d).

B.2 Principle

The scalpel blade removal device is tested by a drop test to ensure that none of the scalpel blades become partially or completely dislodged from the device.

B.3 Apparatus

Use the following apparatus:

(a) Reusable scalpel blade handles, size 3.

NOTE 1 The number of reusable handles required is at the discretion of the test house.

(b) Suspension apparatus, capable of holding the device, with its opening facing downwards, at (1 ± 0.2) m above the impact surface.

NOTE 2 The device can be held by hand if necessary.

(c) Rigid, level, non-deformable impact surface.

NOTE 3 An uncovered concrete, steel or tiled floor is suitable.

(d) Where testing a single-use device, the following:

(i) Two devices.

(ii) Bracket or fixation device, if specified by the manufacturer.

NOTE 4 The same devices tested according to the procedure in Appendix A may be used.

(iii) The number of size 15 scalpel blades equal to the total number of chambers in the two devices.

WARNING: The use of blunt scalpel blades or cut-resistant gloves is recommended in order to ensure operator safety.

(e) Where testing a multiple-use device, the following:

(i) Two devices.

NOTE 5 The same devices tested according to the procedure in Appendix A may be used, with the addition of extra scalpel blades.

(ii) Bracket or fixation device, if specified by the manufacturer.

(iii) Approximately 250 size 15 scalpel blades.

WARNING: the use of blunt scalpel blades or cut-resistant gloves is recommended in order to ensure operator safety.

B.4 Procedure

B.4.1 Single-use scalpel blade removal device

B.4.1.1 Method

Proceed as follows:

(a) Assemble the device, including the bracket or fixation device where required, in accordance with the manufacturer's instructions.

(b) Load a size 3 scalpel handle with a size 15 scalpel blade.

(c) Remove the blade using the device according to the manufacturer's instructions.

(d) Where the device has more than one chamber, repeat steps (b) and (c) until all chambers are used.

(e) Secure the device in the suspension apparatus.

NOTE The device can be held by hand if necessary.

(f) Release the device, allowing it to freefall such that the opening of the device strikes the impact surface first.

(g) Leave the device where it has fallen and assess by visual inspection if any blades are partly or completely dislodged from the device.

(h) Repeat steps (a) to (g) using the second device.

B.4.1.2 Interpretation of results

The scalpel blade removal device meets the requirements of Clause 4(d) if none of the blades are partially or completely dislodged from the devices after being dropped.

B.4.1.3 Report

Report the following information:

(a) whether the device passes or fails.

(b) the reasons for any failures.

(c) a reference to this test method, i.e. AS 3825:2020 Appendix B.

B.4.2 Multiple-use scalpel blade removal device

B.4.2.1 Method

Proceed as follows:

(a) Assemble the scalpel blade removal device, including the bracket or fixation device where required, in accordance with the manufacturer's instructions.

(b) Load a size 3 scalpel handle with a size 15 scalpel blade.

(c) Remove the blade using the device according to the manufacturer's instructions.

(d) Repeat steps (b) and (c) until —

(i) either the device is at 90 % of the manufacturer's stated capacity; or

(ii) where the capacity is not stated, at an estimated 90 % of capacity.

(e) Secure the device in the suspension apparatus.

NOTE The device can be held by hand if necessary.

(f) Release the device, allowing it to freefall such that the opening of the device strikes the impact surface first.

(g) Leave the device where it has fallen and assess by visual inspection if any blades are partly or completely dislodged from the device.

(h) Using the second device, repeat steps (b) and (c) until —

(i) where the device has automatic shut-off, the automatic shut-off actuates; or

(ii) where the device does not have an automatic shut-off, the device is at an estimated 100 % capacity, at which point operate the manual shut-off.

(i) Repeat steps (e) to (g).

B.4.2.2 Interpretation of results

The scalpel blade removal device meets the requirements of Clause 4(d) if none of the blades are partially or completely dislodged from the devices after being dropped.

B.4.2.3 Report

Report the following information:

(a) Whether the device passes or fails.

(b) The reasons for any failures.

(c) A reference to this test method, i.e. AS 3825:2020 Appendix B.

Appendix C
(informative)

Example of reporting template for inspection

This Appendix sets out an example of an inspection sheet. It can be used as is or modified and incorporated into the standard report template of the test house. The form can be completed when the Appendix A Test Method is used.

Clause 4 item	Design requirements for Scalpel blade removal devices	Conforming Yes/No	Comments
(b)	Shall indicate that the used scalpel blade has been removed by — (i) an audible sound; and/or (ii) a visual cue.	Yes/No	
(e)	Shall be such that the loaded scalpel handle is not directed towards the user's body.	Yes/No	
(f)	If a single-use device, shall allow for accurate count of the contained scalpel blades.	Yes/No	

Appendix D
(informative)

Training protocol

Training should involve —

(a) initial training in a non-clinical setting on the use of the scalpel blade removal device in accordance with the manufacturer's instructions;

(b) a periodic review of competency to use the scalpel blade removal device at least annually;

(c) training on the recommended protocol for managing a sharps injury;

(d) awareness of the protocol for conducting a root cause analysis in the event of a sharps injury; and

(e) awareness of all relevant guidelines.

NOTE Refer to the Australian Immunization Handbook, the Safe Work Australia Model Code of Practice and the Australian Guidelines for the Prevention and Control of Infection in Healthcare, for further information on training (see Bibliography).

Appendix E
(informative)

Audit protocol

Periodic audit should involve, at least, the following annual assessment and reviews:

(a) Assessment of the compliance of safety devices in use with relevant legislation, regulations and safety policies and practices, including, but not limited to, those listed in Clause 4.

(b) Review of the number of compliant safety devices being used.

(c) Review of safety policies and practices against compliance with relevant legislation and regulations, including but not limited to those listed in Clause 5 and Clause 6.

(d) Review of staff adherence to these safety policies and practices.

Bibliography

AS/NZS 3816, *Management of clinical and related wastes*

AUSTRALIAN TECHNICAL ADVISORY GROUP ON IMMUNISATION (ATAGI). *Australian Immunisation Handbook*. Australian Government Department of Health, Canberra, 2018. Available from immunisationhandbook.health.gov.au/

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL. Australian Guidelines for the Prevention and Control of Infection in Healthcare. Canberra, 2019. Available from www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019

SAFE WORK AUSTRALIA. *Model Code of Practice: How to manage work health and safety risks*. Available from www.safeworkaustralia.gov.au/doc/model-code-practice-how-manage-work-health-and-safety-risks

NOTES

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