



Clip attachments – Frequently Asked Questions (FAQ)

How interchangeable is your clip?

The correct selection and safe use of a clip attachment-sling combination is essential to your client/patient and employee safety. This factsheet answers a number of Frequently Asked Questions relating to the safe use of clips.

1. What is the purpose of clip attachments?

Clip attachments are designed to safely attach slings to active and passive patient lifts and ceiling lifts using nipples. The clip attachments can be used in conjunction with generic slings, comfort slings, toilet slings and bariatric slings.

Slings are attached to a 2 to 8-point spreader bar fitted with nipples. The dimensions of these nipples determine whether the sling can be attached correctly and safely. These dimensions and other requirements for use must be included in the user manual for your sling.

Sources of clip manufacturer: QMS ISO 9001/13485, 'Intended Use' CE file, user instructions for clip

Whereby the requirement is that all load-bearing fasteners shall be either self-locking or fitted with a locking device to prevent inadvertent detachment. On purchasing the clip attachment-sling combination, it is recommended that you specifically state this in your specifications.

In 2002, the Health Care Inspectorate (IGZ) clearly stated that patient lifts must be constructed and designed such that human errors must be excluded as much as possible. This was highlighted once again in an IGZ report published in September 2004 entitled 'Tilliftgebruik is nog steeds niet zonder risico' ('Use of patient lifts still not free of risk').

Sources: NEN-EN-ISO 10535:2007 (Patient Lifts), IGZ (NL)

2. How do you guarantee that the clip is securely attached?

Securing the clip correctly is the responsibility of the health professional working with the patient lift.

In some cases errors are inevitable. For example, if the clip attachment is used non-intuitively, the safety and efficacy of the product will be compromised. The likelihood of user errors and incidents is reduced if the clip is designed in such a way that once it is attached to the nipple, detachment is not possible without an additional action or the use of force.

Both manufacturers and health organisations are required to identify the (potential) risks associated with the use of slings in conjunction with patient lifts, with the ultimate objective of improving patient and employee safety and managing risk. This includes factoring chain safety and transfers into the risk analyses.

Sources: Medical Devices Directive, FMEA and CE certificate provided by manufacturer, Stigah (NL); Quality Act (NL), NTA (NL), health organisation risk management

4. Can the clip attachment be used in conjunction with other brands of patient lifts, slings and frames?

Yes, you can use the clip-sling combination regardless of the type/brand of patient lift used.

Under the Medical Devices Directive 93/42/EEC, manufacturers are required to apply a CE mark to medical devices. The devices used in this situation are classified in risk category 1, which means that the patient lift and the clip-sling combination both have their own CE mark.

Source: Besluit medische hulpmiddelen, 22 February 2010 (NL)

5. Can I use a sling produced by manufacturer A in conjunction with a patient lift produced by manufacturer B?

Yes – there is no guideline prescribing that both the sling and the patient lift must originate from the same manufacturer. However, you must make sure that the clip attachment-sling combination and the patient lift is compatible.

Source: Stigah nieuws no. 2 2012 (NL)

3. Does the clip attachment-sling combination comply with the General Safety Requirements (GSR)?

Requirement 4.3.1.5 of the GSR: 'All load-bearing fasteners shall be either self-locking or fitted with a locking device to prevent inadvertent detachment.'

6. How do I inspect the clip attachment?

When inspecting patient slings featuring clip attachments, you must check if the clip operates properly and the sling's clip and lock are in order.

Stigah: "A key requirement for the safe operation of the clip attachment is that the clip's inadvertent detachment from the nipple, for example when the device is not used, must be prevented. One guideline for using clips is that, when attached or detaching a clip without an independent lock, you must pass a type of 'dead' point, which means you must use a little extra force to attach or detach the clip."

This guideline is based in part on the requirement contained in ISO 10535 (the standard for patient lifts) that states that all load-bearing fasteners shall be either self-locking or fitted with a locking device to prevent inadvertent detachment. Conclusion of requirement 4.3.1.5 (General safety requirements).

Sources: Stigah inspection requirement: patient slings, inspection of clips/ loops (NL), NEN-EN-ISO 10535:2007 (Patient Lifts)

7. Can our health organisation be held responsible or liable for using a patient sling produced by manufacturer A in conjunction with a patient lift produced by manufacturer B?

Health organisations (i.e. health professionals) have freedom of choice in using these devices and determine what combination they consider safe and reliable. In addition, health organisations are required to perform a risk analysis when purchasing medical devices. End users are recommended to request the CE file from the manufacturer.

Source: Public Liability Insurance 11-12

8. Is instruction required to secure the clip attachment correctly?

Under Dutch law, all slings must include a user manual/ instruction manual (in English).

It is recommended that you attach labels to the patient lift that remind health professionals to check that the clip is correctly secured. Depending on the design, the clip can support audible and tangible locking.

Sources: Besluit medische hulpmiddelen (NL), letter from Stigah dated 27 September 2012 (NL)

9. Where can I find more information about the clip attachments?

You can request information about the clips from the various sling manufacturers and resellers. Independent information is available from Stigah.

Stigah (NL)

Stichting Garantiekeur Hulpmiddelen (Stigah) guarantees the safe use of medical devices. The Stigah inspection procedures allow owners, managers and end users of these devices, independently and in accordance with the service and maintenance instructions, to check annually whether these devices can be used safely.

IGZ (NL)

The Health Care Inspectorate (IGZ) promotes public health by effectively maintaining the quality of care, prevention and medical products.

Besluit medische hulpmiddelen (NL)

Executive legislation of the Medical Devices Directive 93/42/EEC. European laws and regulations are based on European Directive 93/42/EEC relating to all medical devices.

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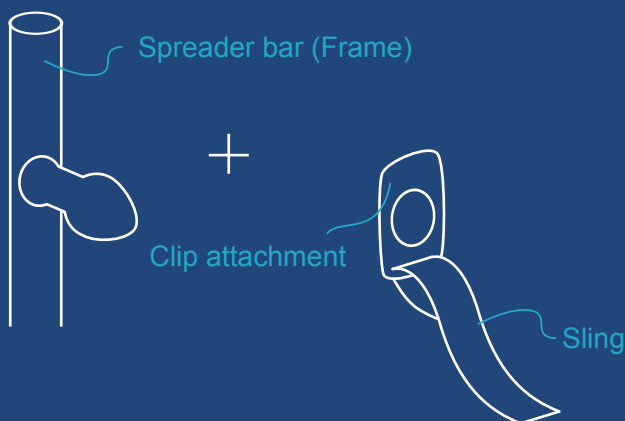


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From a safety perspective and as part of its safe-use policy, MEDD performed a baseline measurement of various clip attachment-spreader bar combinations. For more information, please see pages 3 and 4, 'Baseline measurement of clip-attachment safety'.

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Clip attachments – baseline measurement

How interchangeable is your clip?

From a safety perspective and as part of its safe-use policy, Dutch health organisation MEDD performed a baseline measurement of the clip attachment. This involved testing a variety of attachments in conjunction with different types of frames in a multidisciplinary setting, with test subjects ranging from end users to user-centered designers, for usability and quality/safety aspects.

These findings have been compiled and are shown in a diagram on page 4. The criteria used are detailed on this page, along with the different types of frames.



You can use our safety assessment as a basic document for your internal audits or safety checks, risk analyses, work meetings, training courses, instructions etc.

This document can also serve as a guideline in preparing your functional specifications when purchasing new slings.

Interchangeability

The clip's features, which can be exchanged or combined with a variety of frames without making any specific adjustments. In other words: can the clip attachment be used in combination with a variety of frames?

Inherent safety

An inherently safe clip is constructed from elements that automatically shift to a secure position after misuse or failure.

Lock fastening

The clip is correctly/securely locked if it cannot become detached from the nipple, for example when there is no load on the clip. The clip is safer to use if the user can hear/feel it being locked/secured.

Hygiene

Is the clip easy to clean?

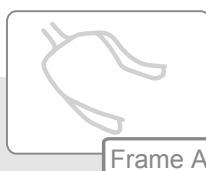
Design

The design can enhance the device's user-friendliness and safety.

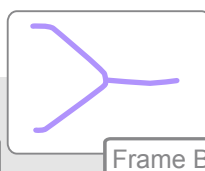
User-friendliness

The clip is user-friendly/user-friendlier if the intended end users can use it intuitively, effectively, efficiently and to their satisfaction.

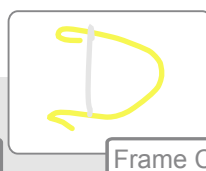
Frames shown in legend:



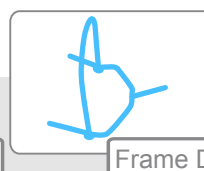
Frame A



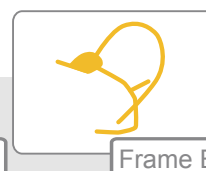
Frame B



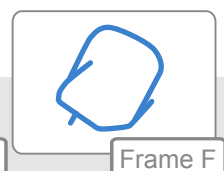
Frame C



Frame D



Frame E



Frame F

[illegible]

Legend for evaluating clip-frame combinations: ● Good ● Fair ● Poor

* The probability of the clip becoming detached when the user responds to unexpected movements that might occur for children or clients/patients suffering from spasms was the lowest by far for clip 4.

! Some users may regard the fit as inconvenient or less than ideal.

