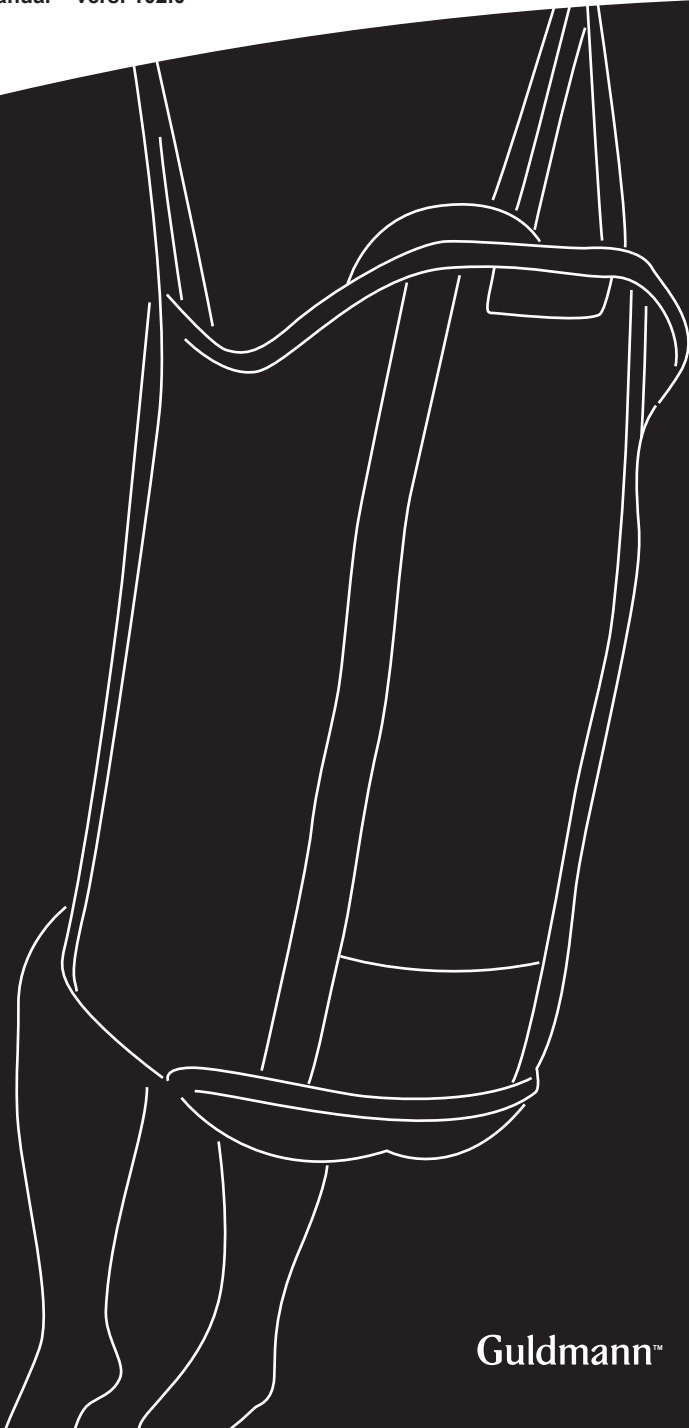




User manual – vers. 102.0

MD CE



Guldmann™

Vers. 102.0

Item nos:
 283672-1 (L/XL)
 283682-1 (XL/XXL)
 283692-1 (XXL/XXXL)

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1.00 Purpose and use

1.01 Manufacturer

V. Guldmann A/S

1.02 Intended purpose

The sling is intended for lifting or supporting a person or body parts of a person.

1.03 Area of use

The sling is suited for use in hospitals, nursing homes, institutions, and in rehabilitation centers.

As the sling is a disposable sling, it is suitable as a personal sling and in situations where a high degree of hygiene is required and for infection control program. The user's name can be written on the sling with the included pen. If necessary the sling can be discarded every time it has been used – or when the user is discharged.

1.04 Conditions of use

The sling is designed for use with both mobile lifters and ceiling hoist systems. It is ideal for lifting a person to and from beds and wheelchairs on seated or lying position as required.

The sling is designed for lifting or transferring a person with little control over head and body.

The use of the sling is subject to the following:

- The sling is used by trained staff or persons who have been instructed in the use of the sling in question.
- The correct size of sling is used.
- The maximum nominal load, 500 kg (1100 lbs) must not be exceeded.
- The sling is used for lifting a person in a seated or lying position.
- The helper pays attention to the well-being of the user when using the sling.
- The sling is used with the Guldmann lifting hanger.

Important!

Plan the move. Never leaving the user in the lifting sling unattended. Do not start to lift until it has been checked that the user cannot get trapped and that the sling does not catch on the bed, wheelchair or other obstacles. The user's head, arms, hands and feet must not be in danger of becoming trapped. Be careful with any tubes and wires that are attached to the user and/or equipment. Check that the hand control and hand control cable is free of hanger, patient and other object before the hoist is activated up or down moved.

Guldmann shall not be liable for faults or accidents due to incorrect use of the lifting sling, or for reasons of inadequate attention on the part of the carer or user. If the sling is used in combination with products that are not manufactured by Guldmann, a risk assessment must be made by qualified staff.

1.05 Important/Precautions

- Read the instructions carefully before using the sling.
- The slings maximum load must never be exceeded.
- The sling may only be used to lift a person.

- Disposable slings must not be used for bath and in swimming pools.
- Before a sling is used, it must be examined according to point 2.02.
- Never use a sling that is too big for the user.
- Possible repairs must only be made by the manufacturer.
- Any serious incident that occurred in relation to this device should be reported to the manufacturer and the local competent authority.

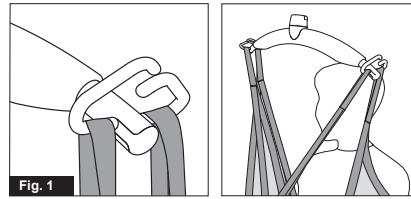


Fig. 1

Caution!

Be careful when attaching the lifting sling on the hooks. Check that the straps have been pulled completely through the rubber safety catch (A) and into place in the lifting hanger's hooks. When pressing the up button to lift the user, check again that all the straps remain correctly placed in the lifting hanger's hooks (fig. 1a and fig. 1b).

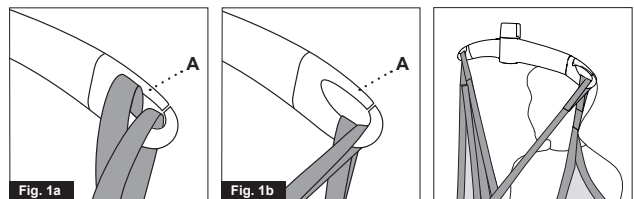


Fig. 1a Fig. 1b

1.06 Labels and Marking



CE marking



Medical Device Class I in accordance with EU MDR Regulation



Read the manual before use



Single Patient Multiple use

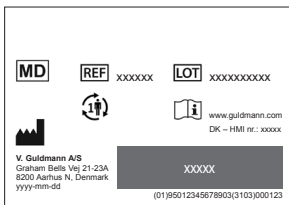


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Example of product label



LOT number label



1.07 Use

If there is any doubt about the selection or use of a lifting sling, please contact your supplier.

Lifting hanger, 4 attachment points

Caution!

Be careful when attaching the lifting sling's straps on the hooks. Check that the straps have been correctly placed in the lifting hanger's hooks. When pressing the up button on the hand control to lift the user, check again that all straps remain correctly placed in the lifting hanger's hooks (Fig. 1).

2.00 Maintenance

2.01 Cleaning

- Do not wash
- Do not use bleaching agent
- Do not tumble dry
- Do not iron

The sling is a disposable sling and if necessary it can be discarded every time it has been used – or when the user is discharged.

The label "Do not wash" will be changed to "Do not use" if the sling has been washed.

2.02 The owner's daily maintenance duty

Check the lifting sling for wear and damage before use according to the following checklist which is not intended to represent all potential inspection steps. Potential damage may vary. Judgment of inspector/site prevails.

Sling inspection checklist

Before using a Guldmann sling / accessory check the following:

Is the sling clean?

Follow facility specific infection control procedure.

Is the sling's label present, legible and complete?

Missing, illegible or incomplete sling label(s) could compromise identification of appropriate size of the sling, function of sling, and or weight limit capacity of the sling.

Are the lifting straps and stitches intact?

- Look for broken or worn stitches
- Look for knots in straps
- Look for tears or fraying of straps
- Look for snags or punctures or holes
- Look for any particles in fabric or straps

Is the fabric intact?

- Look for abnormal wear patterns, excessive wear, abrasive evidence
- Look for cuts or frayed fabric
- Look for unusual or significant discoloration
- Look for snags, punctures, tears, holes
- Look for frayed or insecure seams
- Look for any acid / caustic / thermal burns
- Look for changes in material consistency, e.g. increased stiffness
- Look for any imbedded particles

Has the shape of the sling been altered, made shorter or longer in relation to the original size using knots, needles, tape or other methods?

Conclusion

If the sling suffers from one or more of the above mentioned conditions then it must be taken out of service regardless of the weight of the person to be lifted.

2.03 Disposal of slings

Slings are disposed of by incineration.

By proper incineration polypropylene and polyester will be degraded to carbon dioxide and water.

3.00 Service and lifetime

3.01 Safety/service inspections

In accordance with international standard EN/ISO 10535 "Hoist for the transfer of disabled persons – Requirements and test methods" an inspection **must** be performed every 6-month according to the following instructions, which is not intended to represent all potential inspection steps. Potential damage may vary. Judgment of inspector/site prevails.

Safe Operating Practices with Slings

Considerations for damaged or defective slings and taking them out of service. Withdraw the sling from service if any of the following conditions exist:

- chemical or caustic burns
- melting or charring of any part of the sling
- snags, punctures, tears or cuts
- broken or worn stitches
- missing, illegible or incomplete sling tag
- knots in any part of the sling
- abrasion
- other visible damage that causes doubt as to the strength of the sling

Sling inspection is done for the protection of the user, the caregiver, and the overall hospital site safety. A sling inspection system has additional benefit. Systematic sling inspection will assist in the identification of damage trends, potentially leading to cost effective suggestions and results. The inspection process can also help to identify inventory duplicity in certain sling types and sizes.

Sling inspection system

Development of a specific procedure and program for the inspection of slings at your facility is your best safeguard. Consider employing a three part system of inspection. Slings that are removed from service and are not capable of repair should be disposed of so they are unfit for any future use and can not find a way back into active inventory.

1) Initial

This level of inspection is done at the time that the sling is received into your facility. The inspector should insure that no damage has occurred during transit, and also verify that the sling work

load limits match those contained in the manufacturer's catalogue. If your facility documents the sling inspection process through written inspection records, the paper trail should begin at this stage

2) Frequent

The frequent level of inspection should be done by the sling user before each use. The sling should be examined and removed from service if damage is detected. The sling user should also determine that the sling is proper for the user conditions, care task required and the required weight capacity.

3) Periodic

Your facility might want to consider implementing a program for a periodic level of inspection at regular intervals. The interval should be based upon the frequency of use, severity of the service cycle and information derived through the inspection process. Recommendations to prevent damage and enhance service life could be made by staff that perform the periodic inspections. If written inspection records are maintained, they should always reference the unique sling identification number, and be updated to record the condition of the sling. Not intended to represent all potential inspection steps or all potential aspects of product management program. Judgment of inspector/site prevails.

Sling inspection technique

The sling inspection procedure should be thorough, systematic and consistent; both visual and "hands on" inspection techniques are recommended. Certain forms of damage are far more discernable through hands-on inspection, than by visual inspection. For example, fabric stiffness, crushed webbing, as well as, thinning fabric can be identified through tactile inspection. Visual inspection alone may not reveal all forms of sling damage. Once signs of damage have been identified, do not downgrade the work load limit of the sling, with the intent of continuing to use it, but at limited capacity or frequency. This is sometimes done to get more service life out of a damaged sling. The operating rule and standard should be: intact = use; damage = do not use.

Consider the practice of documenting sling inspections through written inspection records. The documentation should include information such as: the name of manufacturer, the sling stock number, width and length, the unique sling identification number (important in differentiating similar slings), as well as the condition of the sling. Other important information might also include the date it was received or put into use at your facility and any special features (if applicable). A beneficial outcome of an inspection program would be the realization of repetitive forms of damage and the analysis that would lead to specific recommendations.

Sample visual examples of synthetic sling damage x)

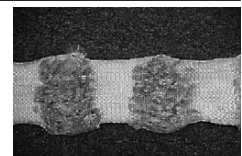
Chemical/caustic burns



Broken stitching



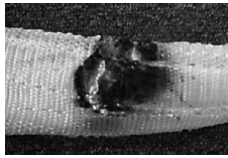
Crushed / Frayed webbing



Knots



Melting / Charring



x) sample visual images not intended to represent all types of potential damage

3.02 Lifetime

The sling is designed for short-term use by one particular user and is to be discarded when soiled or not longer needed.

4.00 Technical specifications

Lifting capacity, SWL 500 kg (1100 lbs)
Material, Disposable High Bariatric Polyester/cotton

5.00 EU-Declaration of conformity

CE The product is manufactured in compliance with regulation (EU) 2017/745 of the European parliament and of the Council of 5 April 2017, as medical device Class I.

6.00 Environmental policy statement – V. Guldmann A/S

Guldmann is continuously working towards ensuring that the company's impact on the environment, locally and globally, is reduced to a minimum.

It is Guldmann's goal to:

- Comply with the current environmental legislation (e.g. WEEE and REACH directives)
• Ensure that we, at the widest possible range, use RoHS compliant materials and components
• Ensure that our products do not have an unnecessary negative impact on the environment regarding use, recirculation or disposal
• Ensure that our products contribute to a positive working environment in the places they are utilised

Inspections are made annually by the Department for Nature and Environment from the Municipality of Aarhus using the Danish Environmental Protection Act, section 42 as a reference.

7.00 Warranty and service conditions

A. Warranty

Guldmann warrants its equipment is free from material defects under normal use, and will perform substantially in accordance with the specifications set forth in documentation provided with the equipment.

This express warranty shall be in effect for one year from the date of original purchase and installation (the "Warranty Period"). If a valid claim is made during the Warranty Period for malfunction or equipment defect, Guldmann will repair or replace the equipment at no additional cost to you. Guldmann retains sole discretion as to whether the equipment will be repaired or replaced.

The warranty does not cover any part of the equipment that has been subject to damage or abuse by the user or others. The warranty does not cover any part of the equipment that has been altered or changed in any way by the user or others. Guldmann does not warrant that the lifting device functions will meet your requirements, be uninterrupted or error free.

The warranty set forth is in lieu of all other express and implied warranties, whether oral, written or implied, and the remedies set

forth above are your sole and exclusive remedies. Only an authorized officer of Guldmann may make modifications to this warranty, or additional warranties binding on Guldmann. Accordingly, additional statements such as advertising or presentations, whether oral or written, do not constitute warranties by Guldmann.

This warranty shall be null and void if the equipment is operated and maintained in any manner inconsistent with its intended use or the instructions provided with the product. Further, in order for the warranty to remain in effect for the full Warranty Period, all service to the equipment must be provided by a Guldmann certified technician. Any parts or components repaired or replaced by a Guldmann certified technician will be guaranteed for the remainder of the Warranty Period.

Only for USA

This warranty shall be null and void if the equipment is operated and maintained in any manner inconsistent with its intended use or the instructions provided with the product. Further, in order for the warranty to remain in effect for the full Warranty Period, all service to the equipment must be provided by a Guldmann Certified Technician. A Guldmann Certified Technician is a technician who has successfully completed Guldmann Service Training, and who holds a valid Service Training Certificate from Guldmann, and is in possession of a valid password to access Guldmann's Service and Information Console (SIC). A Guldmann Service Training Certificate and SIC password are valid for three years (only USA) from the date the technician is first certified. Thereafter, the technician must undergo re-certification training to obtain a new valid certificate and password. Any parts or components repaired or replaced by a Guldmann Certified Technician will be guaranteed for the remainder of the Warranty Period. In the event the warranty is rendered null and void, the purchaser shall indemnify and hold Guldmann harmless of and from any and all claims or liability arising as a result of equipment malfunction or misuse.

B. Service or Repair

Contact Guldmann Repair for an authorization to return any defective item during the Warranty Period. You will be provided with a return authorization number and address for returning the item for warranty service or replacement. Do not return items to Guldmann under warranty without receiving a Return Authorization Number.

If mailing the item, pack it carefully in a sturdy carton to prevent damage. Include your Return Authorization Number, a brief description of the problem and your return address and phone number. Guldmann does not assume the risk of loss or damage while in transit, so it is recommended you insure the package.