

Lamination Anchors

1221, 1223T, 1257T, 1220A, 1220S, 1220T, 1230T, 1255S, 1221S, 1253S, 1253, 1254, 1254S

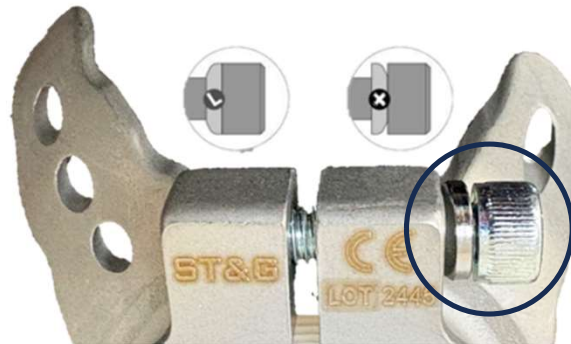
Lamination Dummy

1221-1, LD

Instructions for Use

Reference Diagrams

The following numbered figures illustrate the alignment, anchor variants, and dummy installation referenced throughout these instructions:



Note: Orient the Conical washer so flat side is facing the Screw Hex Head, not the adapter clamping surface



Note:
Pack the open slot, screw hex, and exposed threads with sealing putty to block resin.
(Optional) Coat the screw with petroleum jelly to make cleanup easier if resin seeps.

Fig. 1

1221-1



1221-1: short threaded lamination dummy

Fig. 2

1421-1



1421-1: taller threaded lamination dummy

Fig. 3

LD



LD : Pyramid Lamination Dummy

Fig. 4

1421



Fig. 5

1223T



Fig. 6

1257T



Fig. 7

1220A (Black)



Fig. 8

1220A



Fig. 9

1220S



Fig. 10

1220T



Fig. 11

1230T



Fig. 12

1255S



Fig. 13

1221S



Fig. 14

1253S



Fig. 15

1253



Fig. 16

1254



Fig. 17

1254S



Fig. 18

1 Product Description

INFORMATION

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- Please read this document carefully before using the product and observe the safety notices.
- Instruct the user in the safe use of the product.
- Please contact the manufacturer if you have questions about the product or in case of problems.
- Report each serious incident in connection with the product, in particular a worsening of the state of health, to the manufacturer and to the relevant authority in your country.
- Please keep this document for your records.

1.1 Construction and Function

Lamination anchors are laminated into a prosthetic socket. They serve to connect the prosthetic socket to the distal prosthetic components. This document applies to the following lamination anchors:

Lamination Anchor, 4-Prong

Reference Number	Distal Connection	Figure
1421	4-Prong AK rotating base	fig. 5
1223	4-Prong rotating base	fig. 6
1257T	4-Prong rotating base with receiver, Ti	fig. 7
1220A 1220A 1220S 1220T	4-Prong pyramid, Al, Black 4-Prong pyramid, Al 4-Prong pyramid, SS 4-Prong pyramid, Ti	fig. 8 fig. 9 Fig. 10 Fig. 11
LD	Fixed pyramid lamination dummy	fig. 4
1221-1	Rotating base lamination dummy	fig. 2

Lamination Anchor, 3-Prong

Reference Number	Distal Connection	Figure
1221	3-Prong rotating base	fig. 14
1253 / 1253S	3-Prong rotating base with receiver	fig. 16 Fig. 15
1254 / 1254S	3-Prong rotating base with pyramid	fig. 17 Fig. 18
LD	Fixed pyramid lamination dummy	fig. 4
1221-1	Rotating base lamination dummy	fig. 2

1.2 Combination Possibilities

This prosthetic component is compatible with ST&G system of modular connectors. Functionality with components of other manufacturers that have compatible modular connectors has not been tested.

2 Intended Use

2.1 Indications for Use

The product is intended exclusively for lower limb exoprosthetic fittings.

2.2 Area of Application

Product approved for max. body weight

- The maximum approved body weight is specified in the technical data (see page 6).

Additional constraints

- **1223, 1257, 1221, 1253, 1254, 1255:** Permissible in both **TT (transtibial)** and **TF (transfemoral)** prostheses.
- **1421:** Only permitted in **TF (transfemoral)** prostheses.
- **1220 series, 1230, 3230T, 5220T:** Only permitted in **TT (transtibial)** prostheses.

2.3 Environmental Conditions

Storage and Transport
• Temperature range -20°C to +60°C (-4°F to +140°F), relative humidity 20% to 90%, no mechanical vibrations or impacts.

Allowable environmental conditions
Temperature range: -10°C to +45°C
Moisture: relative humidity: 20% to 90%, non-condensing
Chemicals/Liquids: non-condensing; Fresh water as dripping water, occasional contact with salty air (e.g. near ocean)
Solids: dust

Prohibited environmental conditions
Chemicals/moisture: intensive contact with sand; Salt water, perspiration, urine, acids, continuous use in liquid media, soapsuds, chlorine water
Solids: dust in high concentrations such as construction sites, sand, highly hygroscopic particle (e.g. talcum)
Clean the product after contact with humidity/chemicals /solids in order to avoid increased wear and damage.

2.4 Service Life

All modular adapters are tested by the manufacturer, depending on the user's activity level, corresponds to a maximum service life of **3-5 years**. Component should not be used beyond the maximum life span.

3 Safety

3.1 Explanation of Warning Symbols

⚠ CAUTION Warning regarding possible risks of accident or injury.

3.2 General Safety Instructions

⚠ CAUTION

Excessive strain on the product

Risk of injury due to breakage of load-bearing components

- Use the product according to the specified area of application (See Page 3)

⚠ CAUTION

Unallowable combination of prosthetic components

Risk of injury due to breakage or deformation of the product

- Only combine the product with prosthetic components approved for that purpose.
- Based on the instructions for use of the prosthetic components, verify that they may be combined with each other.

⚠ CAUTION

Use under unallowable environmental conditions

Risk of injury due to damage to the product

- Do not expose the product to unallowable environmental conditions.
- If exposed, check it for damage.
- If damage is apparent or in case of doubt, do not continue using the product.
- Take suitable measures if required (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop).

⚠ CAUTION

Exceeding the service life

Risk of injury due to change in or loss of functionality and damage to the product

- Ensure that the approved service life is not exceeded

⚠ CAUTION

Mechanical damage to the product

Risk of injury due to change in or loss of functionality

- Use caution when working with the product.
- If damaged, check for proper function and readiness for use.
- In case of changes or loss of functionality, do not continue using the product.
- Take any necessary measures (e.g. repair, replacement, inspection by ST&G customer service, etc.).

Signs of changes in or loss of functionality during use

Changes in functionality can be indicated by an altered gait pattern, a change in the relative positioning of prosthetic components, or development of noise.

Advise your patient should any signs of changes or loss of functionality start or occur, they are to stop usage of the prosthesis and notify the Clinician immediately. Not following this step could result in bodily injury.

4 Corresponding Parts

3 Prong rotating or fixed base		
Quantity	Description	Part Number
1	Instructions for use	-
1	3 Prong Lamination Anchor	-
1	3 Prong rotating base lamination dummy	1221-1
1	Fixed pyramid lamination dummy	LD

4 Prong rotating or fixed base		
Quantity	Description	Part Number
1	Instructions for use	-
1	4 Prong Lamination Anchor	-
1	4 Prong rotating base lamination dummy	1421-1
1	Fixed pyramid lamination dummy	LD

Spare Parts	Part Number
Fixed pyramid lamination dummy	LD
3 Prong Lamination Anchor	1221-1
4 Prong rotating base lamination dummy	1421-1

5 Preparing the Product for Use

⚠ CAUTION

Incorrect alignment or assembly

Risk of injury due to damaged prosthetic components.

- Observe the alignment and assembly instructions.

⚠ CAUTION

Improper assembly of the screw connections

Risk of injury due to breakage or loosening of the screw connections.

- Clean threads prior to installation.
- Apply specified torque values.
- Follow screw length and thread-locking instructions.

⚠ CAUTION

Improper lamination anchor prong contouring

Risk of injury due to breakage of lamination anchor prongs

- Only bend anchor arms made of steel.
- Do not bend prongs too tightly or too frequently which can lead to fatigue failure or high stress points
- Use appropriate bending irons.
- Remove kinks caused from contouring .
- Do not deform or bend the base of lamination anchor.
- Do not contour Aluminum or Titanium lamination prongs.

INFORMATION

For waterproof models

Take care not to sand the coating on the pinch bolt or the alignment screws.

Do not sand down the coating on Aluminum lamination anchors, as this can lead to corrosion on the component.

5.1 Laminating a Transfemoral (TF) Socket

Required Materials: Torque wrench, bending irons, PVA bag, perlon stockinette, carbon fiber tape, Dacron felt, woven carbon fiber braid, Epoxy lamination resin is preferred for optimal outcomes.

Note: Lightly coat all threads, and the adapter clamp screw, with petroleum jelly, and wipe excess off to help prevent resin from sticking to those surfaces. Pack any open threaded area for the adapter clamp screw, and the open slot for the clamp. After applying and torquing the clamp screw, also pack the hex head area. In some cases, technicians tape off the hex head to reduce resin infiltration into the hex cavity. In some cases, technicians can putty in the adapter threaded cavity as needed when the 1221-1 or 1421-1 do not fit that particular application. Be sure if the LD is utilized, and the fixed pyramid has a through hole, drill out the LD to match the pyramid hole to allow resin to flow into the cavity if needed. If the adapter cavity was filled while bonding, no hole is necessary.

Note: This is a basic lay-up, and should be adjusted according to patient weight, and activity level.

1. **Threaded models:** Fully screw in the insert. Fixed pyramid models: Apply the LD lamination dummy on to the pyramid. (See Section 5.3)
2. Tighten the cap screw of the threaded clamp to **5 Nm** using the torque wrench for those threaded adapters.
3. Pull a soaked PVA bag over the model.
4. Apply 1 layer of Dacron felt; thin out fibers along edges.
5. Pull 2 layers of Perlon stockinette over the model.
6. Place 3 layers of woven carbon fiber (e.g. 15 cm × 15 cm) with offset fiber alignment on the distal end. If needed, add additional layers to prevent push through.
7. Pull 2 layers of Perlon stockinette over the model.
8. Pull a soaked PVA bag over the model.
9. Laminate as usual.
10. Remove the PVA bag once cured.
11. **When using the 1421 4 prong base**, align the flatter anchor arm in the **posterior direction**. Move the 3 prongs in the correct A/P/M/L position, but do not align the threaded clamping in the anterior or posterior. **When using the 1221, 1253, 1254, or 1255 3 prong base**, move the 3 prongs in the correct A/P/M/L position, but do not align the threaded clamping in the anterior or posterior.
12. Position the lamination anchor at the socket end.
13. Adapt the steel anchor arms to the model using bending irons taking care not to deform the threaded rotating base. Do not contour Aluminum or Titanium prongs.
14. Install the 1221-1 or 1421-1 lamination dummy (see Section 5.3).
15. Stabilize and permanently bond the anchor to the socket.
16. Pull 1 layer of Perlon stockinette over the model.
17. Place 2 layers of woven carbon fiber (15 cm × 15 cm) offset over the anchor arms. If needed, add additional layers.
18. Pull 1 layer of Perlon stockinette over the model.
19. Pull 2 layers of carbon braid over the model.
20. Pull 2 layers of Perlon stockinette over the model and **tie off below the threaded clamp screw**.
21. Pull a soaked PVA bag over the model.
22. Laminate as usual.

23. Remove the lamination dummy once the resin has fully cured.
24. Expose the adapter clamp hex head, remove screw, and clean out screw cavity carefully exposing the open end of the threaded area. Clean out the clamp slot, and smooth side of the clamp hole.

5.2 Laminating a Transtibial (TT) Socket

Required Materials: Torque wrench, bending irons, PVA bag, perlon stockinette, carbon fiber tape, Dacron felt, woven carbon fiber braid, NSP Braid, Epoxy lamination resin is preferred for optimal outcomes.

Note: Lightly coat all threads, and the adapter clamp screw, with petroleum jelly, and wipe excess off to help prevent resin from sticking to those surfaces. Pack any open threaded area for the adapter clamp screw, and the open slot for the clamp. After applying and torquing the clamp screw, also pack the hex head area. In some cases, technicians tape off the hex head to reduce resin infiltration into the hex cavity. In some cases, technicians can putty in the adapter threaded cavity as needed when the 1221-1 or 1421-1 do not fit that particular application. Be sure if the LD is utilized, and the fixed pyramid has a through hole, drill out the LD to match the pyramid hole to allow resin to flow into the cavity if needed. If the adapter cavity was filled while bonding, no hole is necessary.

Note: This is a basic lay-up, and should be adjusted according to patient weight, and activity level.

1. **Threaded models:** Fully screw in the insert. Fixed pyramid models: Apply the LD lamination dummy on to the pyramid. (See Section 5.3)
2. Tighten the cap screw of the threaded clamp to **5 Nm** using the torque wrench for those threaded adapters.
3. Pull a soaked PVA bag over the model (seal distal end).
4. Pull 2 layers of Perlon stockinette over the model.
5. Place 3 layers of woven carbon fiber (e.g. 15 cm × 15 cm) with offset fiber alignment on the distal end. If needed, add additional layers to prevent push through.
6. Pull 2 layers of Perlon stockinette over the model. Pull a soaked PVA bag over the model.
7. Laminate as usual.
8. Remove the PVA bag once cured.
9. **When using the 1421 4 prong base**, align the flatter anchor arm in the **posterior direction**. Move the prongs in the correct A/P/M/L position, but do not align the threaded clamping in the anterior or posterior. **When using the 1221, 1253, 1254, or 1255 3 prong base, or the 1220 series adapter, 1223T, 1257T, 1230T, 3230T, or 5220T** move the prongs in the correct A/P/M/L position, but do not align the threaded clamping in the anterior or posterior.
10. Position the lamination anchor at the socket end.
9. Adapt the steel anchor arms to the model using bending irons taking care not to deform the threaded rotating base. Do not contour Aluminum or Titanium prongs.
10. Install the 1221-1 or 1421-1 lamination dummy (see Section 5.3).
11. Stabilize and permanently bond the anchor to the socket.
12. Pull NSP roving through the arm holes and allow it to hang in a loop (if no holes are present, loop around the anchor arms).
13. Place 3 layers of carbon fiber cloth (15 cm × 15 cm) offset over the anchor arms. If needed, add additional layers.
14. Pull 1 layer of Perlon stockinette over the model.
15. Pull 2 layers of carbon braid over the model.
16. Pull 2 layers of Perlon stockinette over the model and **tie off below the threaded clamp screw**.
17. Pull a soaked PVA bag over the model.
18. Laminate as usual.

19. Remove the lamination dummy once the resin has fully cured.
20. Expose the adapter clamp hex head, remove screw, and clean out screw cavity carefully exposing the open end of the threaded area. Clean out the clamp slot, and smooth side of the clamp hole.

5.3 Installing the Lamination Dummy

INFORMATION

- Use dummy 1221-1 or 1421-1 when the anchor will be used with a screwed insert.

Anchor without threaded connector:

- Mount the LD dummy directly over the pyramid adapter (see Fig. 4).

Anchor with threaded connector:

- Tighten the cap screw of the clamp just enough that the insert can still be threaded in/out.
- Unscrew and remove the insert.
- Screw in **1421-1** or **1221-1*** lamination dummy (Fig. 2 or 3).

5.4 Assembling Distal Prosthetic Components

Installing the threaded component

Required Materials: torque wrench, Blue Loctite®.

Thread component (e.g. pyramid adapter) completely into the threaded adapter.

For alignment, unscrew by a **maximum of 1/4 turn**.

Apply Loctite® to the cap screw of the clamp and tighten to **10 Nm**.

Connecting Pyramid Adapter and Receiver:

Required Materials: Torque wrench, Blue Loctite® 241.

Trial Fitting: Screw in set screws and tighten to **10 Nm**.

Definitive Assembly: Secure set screws with Loctite® 241. Pre-tighten to **10 Nm**, then torque fully to **15 Nm**.

Over tightening will damage the pyramid adapter, and can lead to noise.

Replace any alignment screws that may not be set in the Receiver adapter properly. Set screws are material type specific.

P/N	Size	Coating	Metal Type Adapter
812SS-AZ	M8x12	Al Zinc	Ti
816SS-AZ	M8x16	Al Zinc	Ti
812SS-Z	M8x12	Zinc	Al / SS
816SS-Z	M8x16	Zinc	Al / SS

Alignment

Use set screws in the receiver to make static corrections during alignment, fitting, and post delivery.

Replacement / Disassembly

To preserve adjusted component alignment when removal is necessary, unscrew only the two adjacent set screws that are screwed in the deepest.

Cleaning

- Clean the product with a damp, soft cloth.
- Dry with a soft cloth.
- Allow to air dry to eliminate residual moisture.

7 Maintenance

CAUTION

Failure to follow maintenance instructions

Risk of injury due to changes in/loss of functionality or product damage.

- Observe the following maintenance instructions.

- Perform a visual inspection and functional test after the first **30 days** of use.
- Inspect the complete prosthesis for wear during regular consultations.
- Conduct **annual** safety inspections.

8 Disposal

Do not dispose of this product with unsorted household waste. Improper disposal can harm health and the environment. Adhere to local regulations regarding return, collection, and disposal.

9 Legal Information

9.1 Liability: The manufacturer assumes liability only if the product is used in accordance with the descriptions and instructions in this document. The manufacturer is not liable for damage caused by improper use or unauthorized modifications.

9.2 CE Conformity: Meets Regulation (EU) 2017/745 on medical devices. Declaration of conformity available from the manufacturer website.

9.3 Warranty: 2 Years - Valid from date of purchase covering proven material, production, or construction flaws.

10 Technical Data

Lamination Anchor, 3 prong



P/N	Height	Weight	Material	Max Weight
1255S	12 mm	127 g	SS	100 kg / 220 lbs
1221S	9 mm	116 g	SS	136 kg / 300 lbs
1253S	23 mm	184 g	SS / SS	136 kg / 300 lbs
1253	23 mm	164 g	SS / Ti	136 kg / 300 lbs
1254	14 mm	158 g	SS / SS	136 kg / 300 lbs
1254S	14 mm	168 g	SS / Ti	136 kg / 300 lbs

Lamination Anchor, 4 prong

P/N	Height	Weight	Material	Weight
1421S	11 mm	159 g	Stainless	170 kg / 375 lbs
1223T	9 mm	116 g	Titanium	170 kg / 375 lbs
1257T	29 mm	112 g	Titanium	170 kg / 375 lbs
1230T	13 mm	58 g	Titanium	170 kg / 375 lbs
1220A	18 mm	63 g	Aluminum	114 Kg / 250 lbs
1220A*	18 mm	63 g	Aluminum	158 kg / 350 lbs
1220S	18 mm	97 g	Stainless	136 kg / 300 lbs
1220T	18 mm	55 g	Titanium	170 kg / 375 lbs
1257T	29 mm	112 g	Titanium	170 kg / 375 lbs

* Black Aluminum

Socket Anchor - Lamination Dummy IFU REV. A (10-5-26)
Specifications subject to change