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Our reference	LAF1000_LLA210-S_connection
Date	24 November 2025

Field Safety Notice

Subject	Potential severe injury due to unintended disconnection of LAF1000 transfer tube from LLA210-S needle during or after brachytherapy treatment
Reference	LAF1000_LLA210-S_connection
Date of notification	24 November 2025
Type of action	Field Safety Notice

Legal Manufacturer BEBIG Medical GmbH is issuing this Field Safety Notice (FSN) in coordination with Legal Manufacturer Eckert & Ziegler BEBIG GmbH, following the transfer of the HDR brachytherapy product line from Eckert & Ziegler BEBIG to BEBIG Medical. The content of this FSN has been jointly agreed upon by both manufacturers for their respective product variants (please note that there is no design and intended purpose difference between these product variants apart from the manufacturer name). BEBIG Medical is acting as the responsible contact point for communication and distribution of this notice to all affected customers.

1. Affected medical devices

Article number	Article variant	Article name	UDI-DI	Manufacturer (name and SRN)	Batch number
LAF1000	:05	Transfer Tube, D=3mm, L=1000mm	04049223103675	Eckert & Ziegler BEBIG GmbH DE-MF-000005760	Not restricted
LAF1000	:06	Transfer Tube, D=3mm, L=1000mm	04065983000986	BEBIG Medical GmbH DE-MF-000012644	Not restricted
LLA210-S	:02	Disposable Steel Needle, D=1.5mm/ 17G	04049223119126	Eckert & Ziegler BEBIG GmbH DE-MF-000005760	Not restricted
LLA210-S	:05	Disposable Steel Needle, D=1.5mm/ 17G	04065983000986	BEBIG Medical GmbH DE-MF-000012644	Not restricted

2. Description of problem

We have identified cases in which the LAF1000 transfer tube disconnects from the LLA210-S disposable steel needle during or after treatment. Such disconnection may occur if the transfer tube shows operational wear, if contamination is present on the mechanical coupling surfaces, or if functional checks prior to use are not performed according to the Instructions for Use (IFU). Since such disconnections cannot be detected after the dummy test has been completed, there is a risk of injury of the patient if the source leaves the treatment channel and contacts unintended parts of the body.

This notice applies to all customers who have received both LAF1000 transfer tubes and LLA210-S needles manufactured by Eckert & Ziegler BEBIG GmbH or BEBIG Medical GmbH.

3. Potential Risks

A disconnection during treatment can lead to:

- **Severe injury due to unwanted radiation of healthy tissue if the source leaves the open treatment channel and comes close or in direct contact with the patient on unintended parts of the body.**

- **Incomplete or interrupted treatment with possible need to repeat the clinical procedure,**

A disconnection after treatment will not poss any risk to the patient and user.

4. Risk mitigation measures

To prevent risks listed above from occurence, the user manual for the transfer tubes (BEBIG Medical IFU-12-009 revision 3 valid from 05.Mar.2025, attached to this field safety notice) shall be strickly followed in terms of important safety warnings and cautions. This IFU shall also apply to all users of the transfer tubes LAF1000 :05 manufactured by Eckert & Ziegler BEBIG.

Overview of risk mitigation measures:

- **Inspect the transfer tube for operational wear and maximum lifetime**
- **Perform a functionality check**
- **Perform the mandatory pull test to ensure the transfer tube is securely connected**
- **Ensure correct positioning**
- **Ensure cleanliness during handling and storage**
- **Use only LAF1000 in combination with LLA210-S**

Details of risk mitigation measurements:

a. Inspection of operational wear and maximum lifetime

Assure to inspect the transfer tubes prior to every treatment and discontinue use of any component that displays wear, corrosion, deformation, or any other damage. Do not use transfer tubes beyond the maximum life time of 3 years.

CAUTION C002-1

Inspect the individual components for breaks, cracks, bends, and proper function. Discontinue use of any component that displays wear, corrosion, deformation, or any other damage.

Lifetime The life expectancy of the Transfer Tubes and Connector is a maximum of 3 years after shipping date. The Transfer Tubes and Connector must be visually inspected prior to use. Any damaged component must immediately be replaced and disposed of in accordance with hospital/clinic guidelines.

b. Functionality check – mandatory pull test

Assure to perform the gentle pull test after connection of each transfer tube and each LLA210-S needle.

Warning W002-1
If the connection (coupling) between the Transfer Tubes / Connector and the applicator is released during treatment, the radioactive source may be advanced outside the device. This can cause unnecessary and uncontrolled radiation exposure to the patient and user.
Verify that Transfer Tubes / Connector are properly connected to the applicators by gently pulling on the couplings prior starting treatment. The couplings must remain secure and do not disengage.
Verify Transfer Tubes / Connector compatibility with the remote afterloader prior to use, i.e. SagiNova®, MultiSource.

c. Correct positioning

Assure a slight slag of the transfer tubes of approximately 20cm for 100cm length and avoid placing any testion on the tube.

CAUTION C002-2
Avoid placing any tension on the transfer tubes.

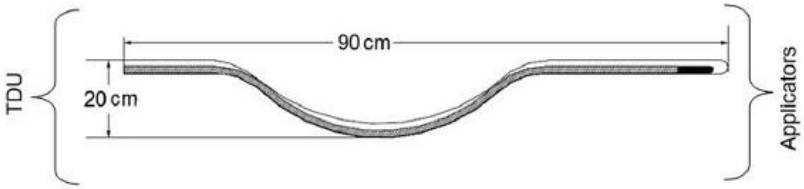

Figure 9 Positioning a Transfer Tubes with a length of 1 m

d. Video surveillance of connection

Use the video surveilance system to monitor any issues of the transfer tube and applicator connection during the treatment.

Warning W002-3
User must monitor the connection of the applicator Transfer Tube / Connector via the video system throughout the treatment process.

e. Cleanliness during handling and storage

Assure cleanliness of the transfer tubes during handling and storage by following the cleaning and disinfection procedure, avoiding any liquid penetration into the couplings, and use storage caps for additional protection against contamination.

CAUTION C002-5
Liquid or other kinds of contamination entering the Transfer Tube and Connector can lead to malfunction Transfer Tube and Connector of or damage to the BEBIG Medical afterloader.

CAUTION C003-1
To avoid damage, do not place the whole transfer guide tube in the disinfectant; only do a wipe disinfection. Remove Storage Caps (LLZ10-04 & LLZ10-05) prior starting wiping.

Visual Inspection Check	Check the Transfer Tube and Connector after cleaning and disinfection, respectively, for corrosion, damaged surfaces, and impurities. Please make sure that the coupling is dry before placing back the storage cap. Do not further use damaged or bent instruments. If the instruments are still dirty, repeat the cleaning and disinfection process again.
Storage	Store the Transfer Tubes and Connector in a clean, dry environment (relative humidity ≤ 85 %). Recommended optimal storage conditions are 25°C +/-10°C. It is important that no chemicals are in close proximity to the storage location. Use and place Storage Caps (LLZ10-04 & LLZ10-05) on coupling part (applicator side only) to prevent entering of any dirt to transfer tubes during storage. Please note that sliding the Storage Caps on coupling part up to 5mm would be enough (See Figure 10).

For further details please refer to the full text of the transfer tube user manual IFU-12-009 in the attachment.

Furthermore, please take into consideration that the disposable steel needles LLA210-S can only be used with LAF1000 transfer tubes as per the respective instruction for use – screenshot below.

1 Set components

Part No.	Item	In this manual	Ref. manual
LLA210-S	Disposable steel needle, D = 1.5 mm, single use	x	
LLH01-210	Obturator for disposable steel needles, L= 210 mm (à 5 pc)	x	

Required Accessories

Part No.	Item	In this manual	Ref. manual
LAF1000	Transfer Tube, D=3 mm, L=1000 mm		①

5. Actions to be taken by users

- Inform all employees in your clinic who work with the designated products about this problem and instruct emplyoees to re-read the transfer tube user manual IFU-12-009 revision 3 provided with this Field Safety Notice demanding strict adherence to all warnings and causions.
- Re-check transfer tubes on stock in your clinic for signs of operational wear, cleanliness and duration of use. If any transfer tube is older than 3 years from the shipment date an and/or shows signs of wear or contamination, remove it from service and order replacements from BEBIG Medical GmbH.
- If no video surveillance camera is installed for monitoring of the transfer tube and applicator connection, install one. You may contact our Customer Support for a quote.
- Confirm receipt of this Field Safety Notice in writing on the last page and return to BEBIG Medical GmbH contact by latest 5th of December 2025.

We trust that we have provided you with the sufficient information and sincerely apologize for any inconvenience caused. No follow up action from our side is to be expected.

Please also be informed that this Field Safety Corrective Action has been reported to the required EU competent authorities as per the medical device regulations.

Should you have any questions or require further information, please do not hesitate to contact us. Your cooperation and vigilance are greatly appreciated to ensure patient safety.

Yours sincerely

Natalia Khramova (Nov 21, 2025 16:12:33 GMT+1)

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Confirmation

Field Safety Notice from BEBIG Medical GmbH

This is to confirm that we have received and understood the Field Safety Notice.

It was forwarded inside our clinic to the respective personnel.

Reference	LAF1000_LLA210-S_connection

Name of clinic	
Country, city	
HDR System	☐ SagiNova, Serial number: _____ ☐ Multisource, Serial number: _____ ☐ Gynesource, Serial number: _____
Name	
Function	
Signature, Date	

Please send the copy of the signed form to quality@bebigmedical.com or your regiational sales manager.

BEBIG

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Instructions for Use

Transfer tubes and connector

CE

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Conformity assessment

The transfer tubes & connector comply with the requirements of the EU Medical Device Regulation (EU) 2017/745. The mentioned products bear the CE mark. They can be used in all the countries in the European Union as well as in countries that recognize the aforesaid directives.

Subject to technical changes

The manufacturer reserves the right to modify the appearance, graphics, and technical data of the product through continued development of its products.

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1 Instructions for Use Overview

Observing the IFU

This IFU provides necessary information required for the safe handling of the medical device. Non-observance of the IFU can lead to hazardous situations causing potential damage to the health of the user/patient.

- Read the IFU carefully before initial use and follow the specified instructions.
- Keep the IFU in a safe place and accessible to authorized users during the lifetime of the medical device.
- Follow any subsequently supplied information.
- Replace old versions of the IFU with the current version.
- If applicable, transfer the IFU to the next users.

Target Group /User Profile

The IFU is intended for authorized and qualified medical staff. It requires the user to be trained in the field of HDR brachytherapy and therefore does not contain information on performing clinical treatment.

Content

The IFU provides information on the following:

- Intended purpose
- Messages for possible hazards that cause damage to health or property
- Device description
- Proper handling and use

This IFU does not contain information or recommendation regarding the practice of clinical treatment.

Terms

Tab. 1: Terms

Notation	Meaning
Manufacturer	BEBIG Medical GmbH
IFU	Instructions for Use
User	See Target Group (this IFU)
MR, MRI	Magnetic Resonance Imaging
CT	Computed Tomography
X-Ray	Radiographic Imaging
HDPE	High Density Poly Ethylene
TDU	Treatment Delivery Unit (Afterloader)

Symbols

The words **WARNING**, **CAUTION**, and **NOTICE** carry special meanings. Sections marked with these words must be given special attention.

Safety messages provide information related to:

- Possible hazards that cause damage to health or property
- Possible consequences if warnings are ignored
- Measures for avoiding hazards

Tab. 2: Definitions of symbols/signal words

Symbol/Signal word	Definition
 **WARNING**	Indicates a potentially dangerous situation. Failure to observe this warning can cause severe damage to health, possibly resulting in death.
 **CAUTION**	Indicates a potentially hazardous situation. Failure to observe this warning can cause damage to health.
NOTICE	Indicates a potentially hazardous situation. Failure to observe this warning can cause damage to the product and the environment.

2 General Information

2.1 Intended Purpose

Intended Purpose

The transfer tubes & connector are intended for connecting HDR applicators and interstitials to the treatment delivery unit (TDU) but are not intended to come into contact with the patient.

2.2 Indications

Indications

The Transfer Tubes and Couplings are for HDR brachytherapy remote afterloading for the treatment of benign or malignant tumors.

2.3 Contraindications

Contra-indications

There is no contradiction as it is only an accessory for the brachytherapy remote afterloading system.

2.4 Duration of use

Duration of use

Not applicable as it is only an accessory for the brachytherapy remote afterloading system.

2.5 Side Effects

Side Effects

The device has no known side effects.

2.6 Device Description

WARNING

An unauthorized user can operate the system improperly. Under these conditions hazardous situations may result causing damage to the health of the user / patient / third party.

- **Define the responsibilities for operating the system and delegate them accordingly.**
- **Access to the system is for authorized individuals only.**
- **Operate the system only in accordance with its' intended use.**

CAUTION

Accessories approved by the manufacturer are compatible with each other and the system. Use of non-approved accessories can lead to hazardous situations causing damage to the health of the user / patient / third party.

- **Only use accessories approved by the manufacturer**

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

Device description

The transfer tubes & connector are used HDR remote brachytherapy in order to connect HDR applicators with HDR remote afterloading systems. The transfer tube & connector are reusable, and delivered non-sterile, clean and in sealed packaging.

Material Information

The device has components with the following materials:

Transfer tubes (non-color-coded):

- Aluminum Alloy (ALMGSi1)
- PEEK
- Stainless steel
- HDPE

Transfer tubes (color-coded):

- Aluminum Alloy (ALMGSi1)
- PEEK
- Stainless steel
- HDPE
- Titanium

Connector:

- Aluminum Alloy (ALMGSi1)
- PEEK
- Stainless Steel

2.7 Scope of Delivery

Item number	Product Name
	Transfer Tubes
LAF1000	Transfer Tube, D=3mm, L=1000mm
LAF1000-1	Transfer Tube, D=3mm, L=1000mm, Green, Channel 1
LAF1000-2	Transfer Tube, D=3mm, L=1000mm, Yellow, Channel 2
LAF1000-3	Transfer Tube, D=3mm, L=1000mm, Blue, Channel 3
LAF1000-T	Transfer Tube, D=3mm, L=1000mm, T-connector
LAF1000-1-T	Transfer Tube, D=3mm, L=1000mm, Green, Channel 1, T-connector
LAF1000-2-T	Transfer Tube, D=3mm, L=1000mm, Yellow, Channel 2, T-connector
LAF1000-3-T	Transfer Tube, D=3mm, L=1000mm, Blue, Channel 3, T-connector
LAG1000	Easy Click Transfer Tube, D=3mm, L=1000mm
LAG1000-6F	Easy Click Transfer Tube 6F, D=3mm, L=1000mm
	Connector
LLS50-6F	Connector for Universal Applicator, D=2.0mm (EasyClick 6F)

3 Related Devices and Accessories

Necessary Devices and Accessories

-

Optional Devices and Accessories

LAZ10-01 Wall Rack
LLZ10-04 Storage Cap for transfer tubes (LAFXXX & LAG1000)
LLZ10-05 Storage Cap for transfer tubes LAG1000-6F

4 Device Setup

CAUTION C001-1
Please refer to the relevant user manuals for the applicators not described in this manual.

4.1 Preparation for Initial Use

Warning W004-1
As these products do not come into contact with the patient, sterilization is not required. Do not sterilize Transfer Tubes and Connector. Sterilizing the Transfer Tubes and Connector can cause changes in material properties. The damaged transfer tube may affect source position accuracy within the applicator or may split or break causing unnecessary exposure to the patient / user.

CAUTION C002-1

Inspect the individual components for breaks, cracks, bends, and proper function. Discontinue use of any component that displays wear, corrosion, deformation, or any other damage.

Clean and disinfect

Cleaning and disinfection procedures and parameters are provided in the chapter 9.

4.2 Assembly Prior to Application

Assembly Prior to Application

All Transfer Tubes and Connector will be shipped assembled to the users. Each Transfer Tube / Connector is carefully packed. It is in a clean but non-sterile condition. Remove the components from the packaging in a clean environment. These reusable Transfer Tubes and Connector must be handled carefully to avoid damage. As the manufacturer cannot control the final use of these guide tubes, the manufacturer cannot be held responsible for damage resulting from mishandling.

5 Application

Warning W002-1
If the connection (coupling) between the Transfer Tubes / Connector and the applicator is released during treatment, the radioactive source may be advanced outside the device. This can cause unnecessary and uncontrolled radiation exposure to the patient and user.
Verify that Transfer Tubes / Connector are properly connected to the applicators by gently pulling on the couplings prior starting treatment. The couplings must remain secure and do not disengage.
Verify Transfer Tubes / Connector compatibility with the remote afterloader prior to use, i.e. SagiNova®, MultiSource.

Warning W002-2
Connect the Transfer Tubes / Connectors according to the treatment plan. Failure to do so could result in treatment errors.

Warning W002-3
User must monitor the connection of the applicator Transfer Tube / Connector via the video system throughout the treatment process.

Warning W002-4

Damage to Transfer Tubes and connector, such as bending or kinking, can obstruct the path of the radioactive source. This can result in the inability of the source to pass through the applicator or may affect the accuracy of the source positions causing errors in treatment delivery to the patient.

- Prior to each use, check the transfer tubes & connectors and applicator coupling for damage and cleanliness prior to use or compromised integrity.
- Perform a dummy source test prior to patient treatment.
- Discard damaged transfer tubes according to hospital guidelines.

CAUTION C002-2
Avoid placing any tension on the transfer tubes.

CAUTION C002-3
Before starting the treatment, as necessary, inform the patient about appropriate behavior during the treatment.

CAUTION C002-4
The user must check the blocking function of the transfer tubes before each use. For this check, the user should ensure that no applicator or catheter has been connected to the transfer tube. Please insert a dummy source wire into the transfer tube from the afterloader connector side and ensure the dummy source wire tip cannot pass through the transfer tube on the applicator connector side.

CAUTION C002-5
Liquid or other kinds of contamination entering the Transfer Tube and Connector can lead to malfunction Transfer Tube and Connector of or damage to the BEBIG Medical afterloader.

5.1 Connecting/Disconnecting the Transfer Tube (LAF1000, LAF1000-1, LAF1000-2, LAF1000-3) to the Applicator

Connection

Place the Transfer Tube's coupling on the end of the applicator until resistance is felt and the coupling clicks audibly into place.
You can verify that the applicator has been properly connected by checking the distance between both sleeves of the coupling (Figure 1 & 2).
If the applicator has been properly connected, the distance is visibly enlarged (Figure 2). If you use color-coded Transfer Tubes with color-coded applicators, ensure that the corresponding colors are correctly assigned to each.

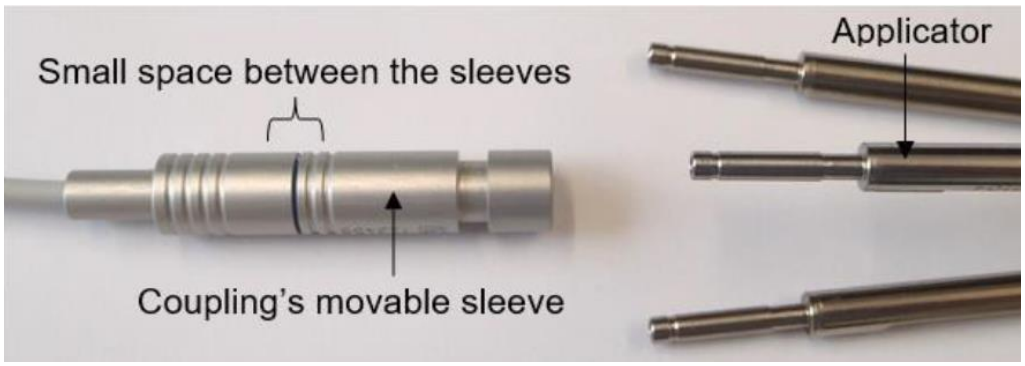


Figure 1 Transfer Tube NOT connected to applicator

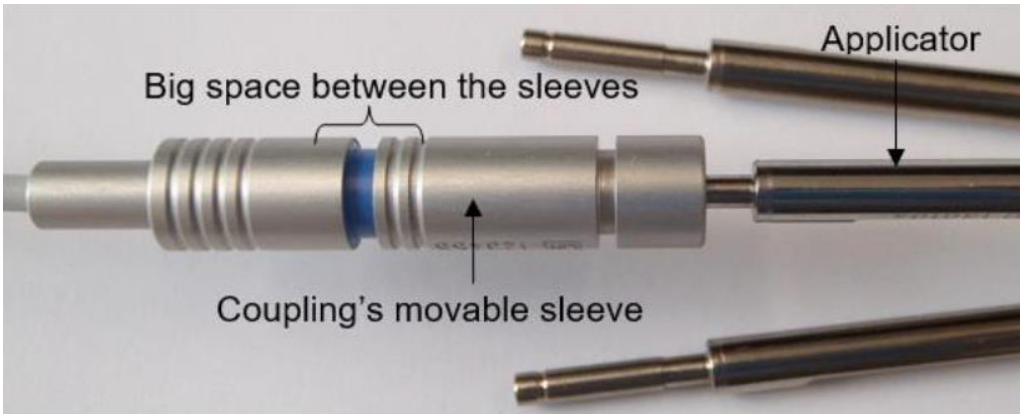


Figure 2 Transfer Tube connected to applicator

Disconnection

To disconnect the Transfer Tube from the applicator, push the movable sleeve of the coupling in the direction of the transfer tube.

5.2 Connecting/Disconnecting the Transfer Tube (LAF1000-T, LAF1000-1-T, LAF1000-2-T, LAF1000-3-T) to the Applicator

Connection

Place the Transfer Tube's coupling on the end of the applicator and push the movable sleeve in direction of the applicator until the coupling clicks into place.
You can verify that the applicator has been properly connected by checking the distance between both sleeves of the coupling (Figure 3 & 4).

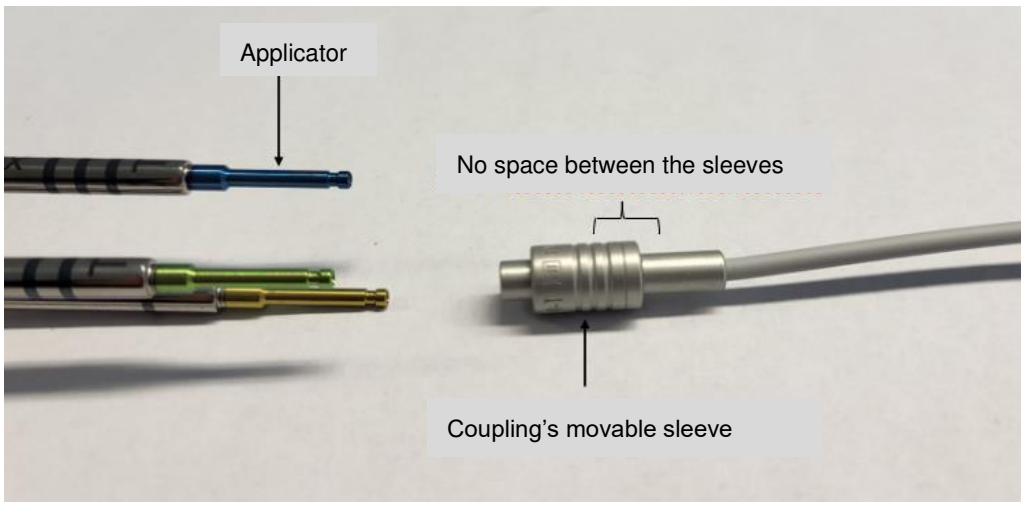


Figure 3 Transfer Tube NOT connected to applicator.

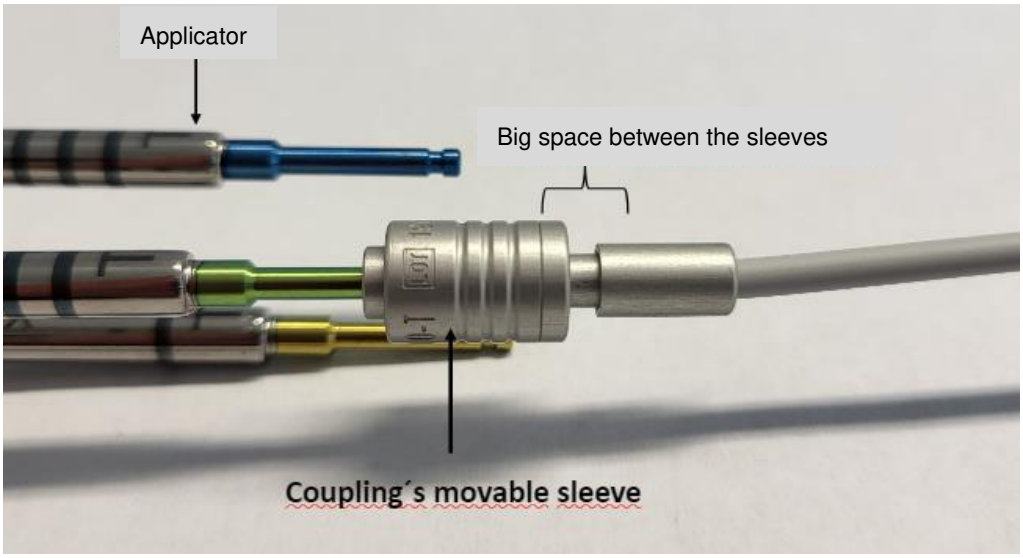


Figure 4 Transfer Tube connected to applicator

Disconnection

To disconnect the applicator, push the movable sleeve of the coupling in the direction of the applicator until the coupling releases.

5.3 Connecting/Disconnecting the Easy Click Transfer Tube (LAG1000, LAG1000-6F) to the Applicator

Connection

Insert the applicator into the Easy Click Transfer Tube coupling until resistance is felt and the coupling clicks audibly into place. The distance between both sleeves of the coupling is visibly enlarged.

Figure 5 Easy Click Transfer Tube connected to applicator

Disconnection

Push the movable sleeve of the coupling in the direction of the Easy Click Transfer Tube and remove the applicator from the transfer tube. The distance between both sleeves of the coupling is visibly reduced.

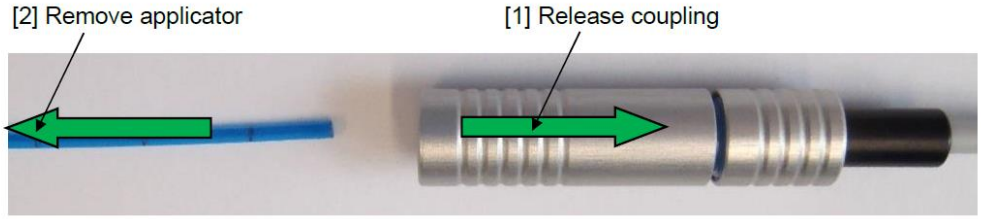


Figure 6 Easy Click Transfer Tube disconnected from applicator

5.4 Connecting/Disconnecting the connector (LLS50-6F) to the Applicator

Connection / Disconnection

Connecting / Disconnecting the Connector to the applicator is done in the same way as connecting / disconnecting the Easy Click Transfer Tube to the applicator (see chapter 5.3).

Figure 7 Connector LLS50-6F

5.5 Connecting / Disconnecting all Transfer Tubes and Connector from TDU

Connection

Connect the Transfer Tubes / Connector to the correct TDU channel in accordance with the treatment plan.

Disconnection

To disconnect the Transfer Tubes / Connector from the TDU, push the movable sleeve of the connector in the direction of the Transfer Tubes / Connector and pull the connector out of the TDU channel.

Figure 8 Disconnecting connector from the TDU

5.6 Clinical Performance and Benefits

Clinical Benefits & Performance

All Transfer Tubes and Connector are designed to be used with HDR remote brachytherapy in order to connect HDR applicators with HDR remote afterloading systems. It provides and unobstructed pathway for source to be placed inside the applicators onto or near the tumor site.

5.7 Instructions for Combined Use

Instructions for Combined use with other devices

All Transfer Tubes and Connector are accessories for connecting applicators to the TDU. Please refer to correspond applicators' instruction for use.

6 Removing and Disassembling

6.1 Removing

Removing

Transfer Tubes and connector must be disconnected from applicator and TDU according to chapter 5.

6.2 Disassembling

Disassembling

Transfer Tubes and connector don't need any disassembly. However, place Storage Cap (LLZ10-04 & LLZ10-05) on coupling part of transfer tubes (only applicator side) after disconnection from applicator and it is highly recommended to use wall rack (LAZ10-01) for storing them. Please hang Transfer Tubes and Connector in each of the two turn-table magazines of wall rack. It helps products stay straight, clean and dry until next use.

7 Imaging Methods

CT / X-ray

The Transfer Tubes and Connector can be used within X-Ray and CT environment.

Warning W006-1
The Transfer Tubes and Connector are MR unsafe. Performing MR imaging with the transfer tubes present may result in serious injury to the user, patient or third parties.
Connect the transfer tubes in the treatment room after MR imaging has been completed.

Magnetic Resonance Imaging

The Transfer Tubes and Connector are MR unsafe.

8 Source Position Accuracy & Treatment Planning Information

Color Coded Transfer Tubes

When using color-coded applicators, verify the treatment plan matches the Transfer Tube connection.
For instance, Fletcher and Henschke Applicator should be connected to the indexer of TDU in the following way:

- Right Ovoid tube (Green): **Channel 1** by using **LAF1000-1** / **LAF1000-1-T** Transfer Tube (Green).
- Central IU-tube (Yellow): **Channel 2** by using **LAF1000-2** / **LAF1000-2-T** Transfer Tube (Yellow).
- Left Ovoid tube (Blue): **Channel 3** by using **LAF1000-3** / **LAF1000-3-T** Transfer Tube (Blue).

Position Accuracy

Compared to a completely straight Transfer Tube, the system is optimized for a 10 cm shorter distance between the TDU and the applicator. To ensure accurate source positioning, the Transfer Tubes should be placed with a slight sag over the length of the tubing.

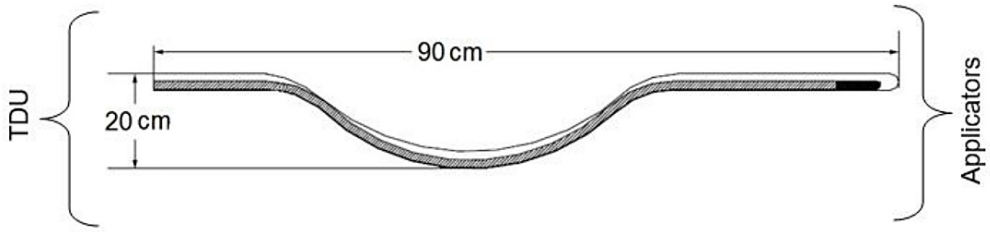


Figure 9 Positioning a Transfer Tubes with a length of 1 m

If the distance between the TDU and the application deviates by more than **± 5 cm** from the specified value, source positioning errors of **≥ 2 mm** can occur.

Compatibility

All Transfer Tubes and Connector are compatible with SagiNova afterloader. For the MultiSource / GyneSource afterloaders, it (all transfer tubes & connector except T models) can be used only with applicator database version **≥ 5.0.0.**

9 Reprocessing

Warning W004-1

As these products do not come into contact with the patient, sterilization is not required. Do not sterilize Transfer Tubes and Connector. Sterilizing the Transfer Tubes and Connector can cause changes in material properties. The damaged transfer tube may affect source position accuracy within the applicator or may split or break causing unnecessary exposure to the patient / user.

CAUTION C003-1

To avoid damage, do not place the whole transfer guide tube in the disinfectant; only do a wipe disinfection. Remove Storage Caps (LLZ10-04 & LLZ10-05) prior starting wiping.

Cleaning

Clean the Transfer Tubes / Connectors using a lint-free cloth with an alkaline cleaning solution (pH value < 11). Wipe at least five times, make sure to reach all the grooves and edges. You can use a little brush for better access of the grooves. Visible inspect the Transfer Tubes / Connector, if not clean, repeat the process. Dry the Transfer Tubes / Connectors at ambient temperatures. If a drying chamber is used, the maximum permissible temperature must not exceed 60 °C.

Disinfection

Disinfect the Transfer tubes / Connectors using a lint-free cloth with a commercially available disinfectant (pH value < 11), which is designated to be used for disinfecting medical instruments and which is preferably quick-drying (e.g. 70% Isopropanol). Wipe at least five times, make sure to reach all the grooves and edges.
Use distilled water to prepare the disinfectant solution. Refer to the disinfectant manufacturer's manual for further information regarding disinfection.

Visual Inspection Check

Check the Transfer Tube and Connector after cleaning and disinfection, respectively, for corrosion, damaged surfaces, and impurities. Please make sure that the coupling is dry before placing back the storage cap. Do not further use damaged or bent instruments. If the instruments are still dirty, repeat the cleaning and disinfection process again.

10 Storage and Transport

Storage

Store the Transfer Tubes and Connector in a clean, dry environment (relative humidity ≤ 85 %). Recommended optimal storage conditions are 25°C +/-10°C. It is important that no chemicals are in close proximity to the storage location. Use and place Storage Caps (LLZ10-04 & LLZ10-05) on coupling part (applicator side only) to prevent entering of any dirt to transfer tubes during storage. Please note that sliding the Storage Caps on coupling part up to 5mm would be enough (See Figure 10).

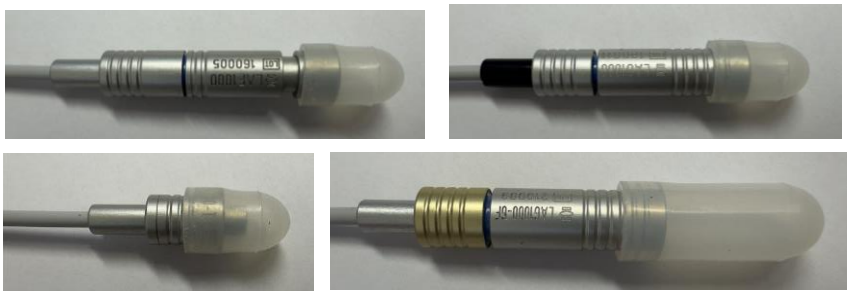


Figure 10 A) LAF1000 with LLZ10-04, B) LAG1000 with LLZ10-04, C) LAF1000-T with LLZ10-04, D) LAG1000-6F with LLZ10-05

Condition upon delivery

The Transfer Tubes and Connector are delivered unsterile. They should be cleaned and disinfected prior to initial use.

11 Incident Reporting

Incident Reporting Instructions

In case that any serious incident has occurred in relation with Transfer Tubes and Connector, the incident shall be reported to the manufacturer BEBIG Medical GmbH (service contact) and the competent authority of the Member State in which the user and/or patient is established.

12 Lifetime and Disposal

Warning W005-1

The Transfer Tubes and connector are reusable which may result in damage after multiple uses. Damage can result in the inability of the source to pass through the applicator or may affect the accuracy of the source positions causing errors in treatment delivery to the patient. Discontinue use of the transfer tubes if they show wear, corrosion, deformation or other damage.

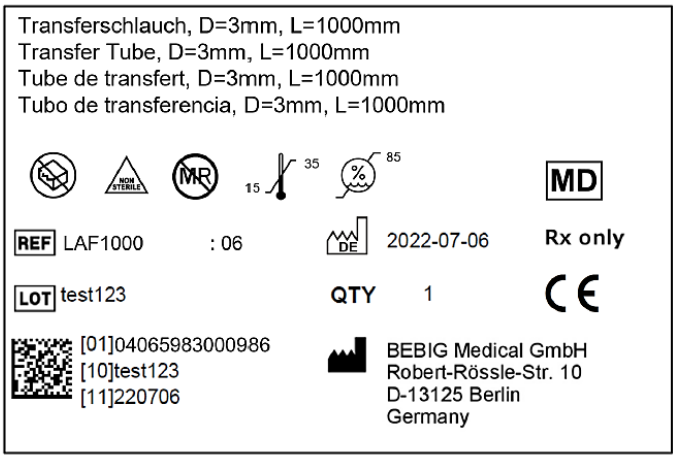
Lifetime

The life expectancy of the Transfer Tubes and Connector is a maximum of 3 years after shipping date. The Transfer Tubes and Connector must be visually inspected prior to use. Any damaged component must immediately be replaced and disposed of in accordance with hospital/clinic guidelines.

Disposal

The Transfer Tubes and Connector that require disposal should be considered a biohazard and disposed of in accordance with the hospital/clinic guidelines.

13 Example Label



14 Used Symbols

#	Symbol	Description
1		Manufacturer
2		Date of manufacture with Country of manufacture symbol (YYYY-MM-DD)
3	LOT	Batch code
4	REF	Catalogue number
5	NON STERILE	Non-sterile
6		Do not use if packaging is damaged
7		Temperature limit
8		Humidity limitation
9	MD	Medical Device
10	**Rx only**	Authorized for Sale or use by Physician only
11	**:**	Variant number
12	CE	CE Mark
13	MR	MR Unsafe
14		Refer to instruction manual