EXACT IMAGING

Care, Cleaning and Use Guide

for EV29L High Resolution Side-Fire Transducer

Part Number 6132
Revision 2.5

CE 2797

Preface

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Trademarks
Exact Imaging trademarks:
- ExactVu™
- Exact Imaging™

CIV-Flex™ is a trademark of Civco Medical Solutions.
CIVCO® is a registered trademark of Civco Medical Solutions.

Warranty information
The ExactVu micro-ultrasound system and its accessories, when supplied and delivered new, in the original shipping container to the original purchaser, are covered under a one-year warranty that covers damage due to defective materials and workmanship, and/or failure of the equipment to operate in accordance with information in the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*.

Version information
System: ExactVu™ High Resolution Micro-Ultrasound System
Care, Cleaning and Use Guide for EV29L High Resolution Side-Fire Transducer Revision 2.5, *original instructions*

Table of Contents

Chapter 1 Introduction

Care, Cleaning and Use Guide for EV29L High Resolution Side-Fire Transducer provides instructions to properly care for, clean and use the Exact Imaging EV29L transducer. EV29L is a 29 MHz high resolution transrectal side-fire transducer with 22.5 MHz center frequency.

The materials used in the construction of the EV29L transducer meet the applicable requirements of *ISO 10993-10 Biological evaluation of medical devices*.

It is important to use this *Care, Cleaning and Use Guide for EV29L High Resolution Side-Fire Transducer* in conjunction with other instructions for using the ExactVu system.

Document
Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System
Care, Cleaning and Use Guide for EV29L High Resolution Side-Fire Transducer (this document)
Service Manual for ExactVu™ High Resolution Micro-Ultrasound System
Approved Chemicals List for ExactVu Transducers

Table 1: ExactVu Labeling

Other documents that are provided with the ExactVu system include:

- Quick Reference Guide
- PRI-MUS™ Quick Reference Guide
- PRI-MUS™ Quick Reference Poster

Exact Imaging catalog references for configurations of the ExactVu micro-ultrasound system are:

- EV-SYS-220: ExactVu™ Micro-Ultrasound Imaging System (220V)
- EV-SYS-120: ExactVu™ Micro-Ultrasound Imaging System (120V)
- EV-SYS-100: ExactVu™ Micro-Ultrasound Imaging System (100V)

WARNING
EN-W1

Failure to follow safety instructions and/or using the equipment for purposes other than those described in ExactVu Labeling constitutes improper use.

WARNING
EN-W6

The use of this equipment is intended for qualified operators only.

Operators should be thoroughly familiar with the safe operation of this equipment, and should be knowledgeable in the use of urological ultrasound procedures in order to reduce discomfort and possible injury to the patient.

Read all *Labeling* provided with this equipment.

WARNING
EN-W2

Unauthorized modification of this equipment is not permitted and may compromise the safe operation of the equipment.

Chapter 2 General Information

1 Transducer Safety

The EV29L transducer meets FDA's *Track 3 Requirements*, per *Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* and the requirements of IEC 60601-2-37.

This section provides warnings and cautions that are specific to ExactVu transducers as well as the use of the ExactVu system and the EV29L transducer in conjunction with ExactVu-compatible steppers for transperineal procedures. For a complete list of warnings and cautions that apply to the ExactVu system, refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*.

1.1 General

WARNING
EN-W11

Service activities must only be performed by qualified Exact Imaging Technical Support technicians.

Opening an ExactVu transducer will void the terms of the warranty.

Only those maintenance activities specified in Chapter 5, section 2 on page 48 should be performed by operators.

WARNING
EN-W3

Only the components identified in this guide may be connected to the ExactVu system.

If components other than those specified in this guide are connected to the system, the ExactVu software may fail and cause injury to the patient or operator.

WARNING
EN-W88

In the event of a serious incident using ExactVu or any Exact Imaging medical device, contact Technical Support using the contract information in Appendix C as well as the authority governing medical device regulation in the locale.

A serious incident is an incident that directly or indirectly led or may have led to any of the following:

- The death of a patient, user or other person
- The temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- A serious public health threat

For the transperineal stepper, refer to the manufacturer's information for warnings and precautions related to general and mechanical safety, as well as a description of symbols found on its label.

1.2 Electrical Safety

WARNING
EN-W12

Inspect transducers often for cracks or openings in the transducer housing and connector, for scratches, and for holes in and around the acoustic lens or other damage that could allow liquid entry.

If the transducer housing or connector shows any cracking or sign of damage, do not use the transducer. Contact Technical Support using the contact information in Appendix C.

Inspect the transducer cable for damage.

1.3 Interference

1.3.1 Electromagnetic (EMC)

WARNING
EN-W17

Do not activate the EV29L transducer outside the patient's body if it would not comply with electromagnetic compliance requirements. It may cause harmful interference with other nearby equipment.

1.4 Acoustic Safety

Safety information for the ExactVu micro-ultrasound system is provided in the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*. Acoustic output data and the display of onscreen indicators and accuracy for these values are also provided, along with a recommendation to follow the *ALARA* (As Low as Reasonably Achievable) principle for the prudent use of ultrasound.

1.5 Bio-safety

ExactVu operators have an obligation and responsibility to provide the highest possible degree of infection control to patients, co-workers and themselves. It is the responsibility of the operator to verify and maintain the effectiveness of the infection control procedures in use. Adequate reprocessing is necessary to prevent disease transmission.

High-level disinfection is required for semi-critical devices, defined by the *Centers for Disease Control and Prevention* as "a reusable medical device that comes in contact with mucus membranes or non-intact skin". This definition is applicable to ultrasound transducers used in transrectal ultrasound (TRUS) procedures, as well as applicable accessories.

1.5.1 Precautions Regarding TRUS (Transrectal Ultrasound) Procedures

WARNING
EN-W35

To prevent possible infection or contamination, the transducer must be reprocessed following the complete procedure in Chapter 4 prior to using it in another procedure.

Always use a sterile sheath during the procedure.

CAUTION
EN-C13

It is important to prevent air bubbles from forming inside the sheath near the imaging surface of the transducer to avoid interfering with image quality.

CAUTION
EN-C15

Use only the needle guides identified in Chapter 2, section 2.2 in this *Care, Cleaning and Use Guide for EV29L High Resolution Side-Fire Transducer*. Do not use any other needle guides with the EV29L transducer.

WARNING
EN-W4

Do not use a single-use needle guide or any component of a needle guide package or kit if its packaging indicates its expiry date has passed.

Operators are responsible for adhering to internal clinical procedures regarding checking for and disposing of expired consumables.

WARNING
EN-W5

Do not use a single-use needle guide if the packaging appears to be compromised.

Discard it and its packaging according to internal clinical procedures for safe disposal.

WARNING
EN-W69

Do not attach the EV29L reusable transrectal needle guide to the EV29L transducer if either of its parts has not been reprocessed.

Perform the reprocessing procedure in Chapter 2, section 2.2.2.4 on page 15 before its first use and prior to attaching it to the EV29L transducer.

1.5.2 Precautions Regarding Transperineal Procedures

WARNING
EN-W63

To prevent possible infection or contamination, the transperineal stepper must be reprocessed following the complete procedure referenced in Chapter 2, section 2.5.4 before its first use and prior to using it in another procedure.

WARNING
EN-W59

Some components of the transperineal stepper must be disinfected or sterilized before first use.

Refer to the manufacturer's instructions for the transperineal stepper to determine whether it must be disinfected or sterilized before its first use.

WARNING
EN-W58

Refer to the manufacturer's instructions for the transperineal stepper to determine which of its components must be disinfected or sterilized before and after each use.

WARNING
EN-W60

Do not store a reprocessed transducer on the transperineal stepper unless the stepper has been reprocessed following the procedure referenced in Chapter 2, section 2.5.4.

1.5.3 Precautions Regarding Biopsy Procedures

WARNING
EN-W31

The use of damaged transducers can result in injury or increased risk of infection. Inspect transducers often for sharp, pointed, or rough surface damage that could cause injury to the patient or increased risk of infection.

WARNING
EN-W29

If air bubbles or wrinkles occur near the point where the needle exits the needle guide, the sheath may be punctured by the needle during biopsy, and may increase the risk of infection.

If the sheath is punctured by the needle, discard it and re-prepare the transducer as described in Chapter 3, section 2 on page 22.

WARNING
EN-W72

Do not use the reusable transrectal needle guide to perform a biopsy for a patient diagnosed with variant Creutzfeldt-Jakob disease (*vCJD*).

For transrectal procedures, use only the single-use needle guide, or alternatively, follow a transperineal protocol to perform the biopsy for a patient with this disease.

2 Transducer Parts, Accessories, Consumables

NOTE
EN-N4

Biopsy, anesthesia and puncture needles are not available from Exact Imaging.

NOTE
EN-N5

Operators are responsible for selection of biopsy, anesthesia and puncture needles, and for adhering to internal clinical procedures regarding checking for and disposing of expired needles.

2.1 Parts of the EV29L Transducer

Figure 1 identifies parts of the EV29L transducer (Exact Imaging Catalog Reference EV-29L).

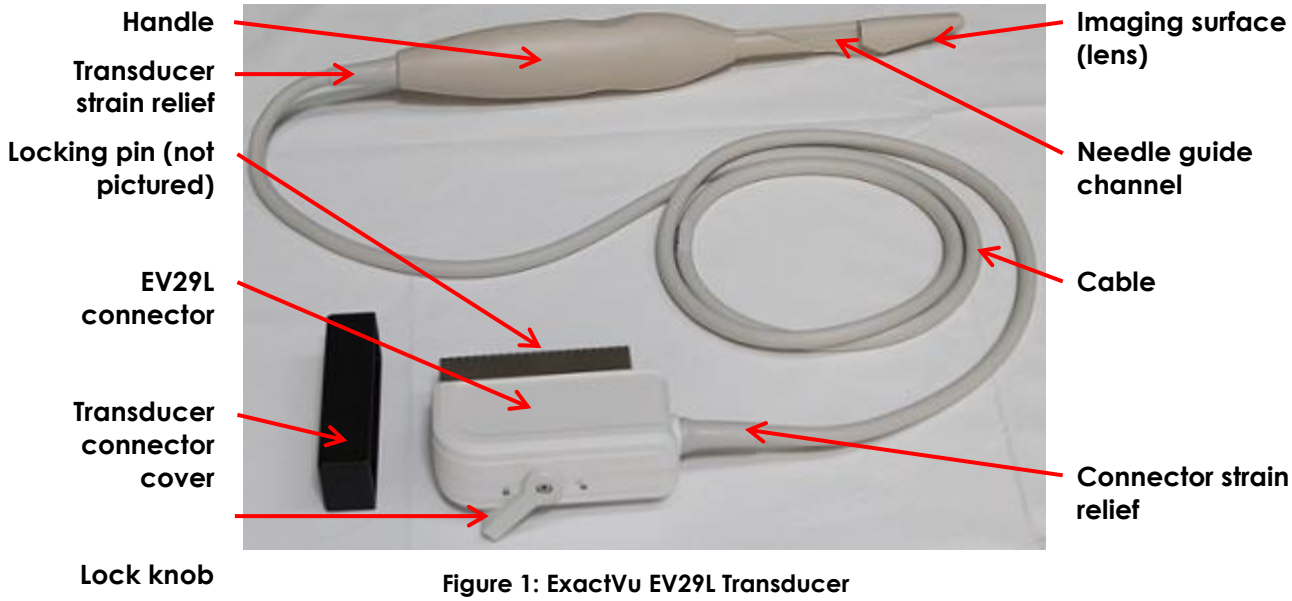

Figure 1: ExactVu EV29L Transducer

2.2 Needle Guides for Transrectal Procedures

For transrectal biopsy procedures using the EV29L transducer, Exact Imaging supports two needle guides designed for use with the EV29L transducer:

- EV29L Sterile Transrectal Needle Guide
- EV29L Reusable Transrectal Needle Guide

2.2.1 EV29L Sterile Transrectal Needle Guide for Procedures using the EV29L Transducer

2.2.1.1 Specifications

The *EV29L Sterile Transrectal Needle Guide* is available in the following packaging configurations, depending on the geographic region in which it will be used:

- Exact Imaging catalog reference **EV-29L-TRK-24**: Complete Transrectal Needle Guide Kit for EV29L (24-Pack), 24 units of single-use sterile, transrectal needle guides, gel packets and latex-free sheaths.
- Exact Imaging catalog reference **EV-29L-TR-S-24**: Sterile transrectal needle guide for use with Exact Imaging EV29L transducer, 24-pack (EV-BIOG-24) and CIV-Flex™ sterile transducer cover (10.1 tapered to 2.5 x 30.5 cm), 24-pack (670-038).

All configurations include the document *Transrectal Needle Guide Reference Guide for Use with Exact Imaging EV29L Transducer*. Replacement needle guides and sheaths may be ordered from your local distributor. Refer to Appendix C for contact information.

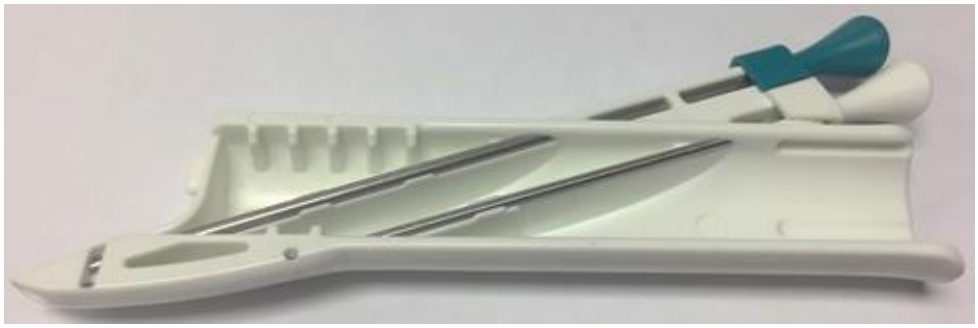

Figure 2: EV29L Sterile Transrectal Needle Guide

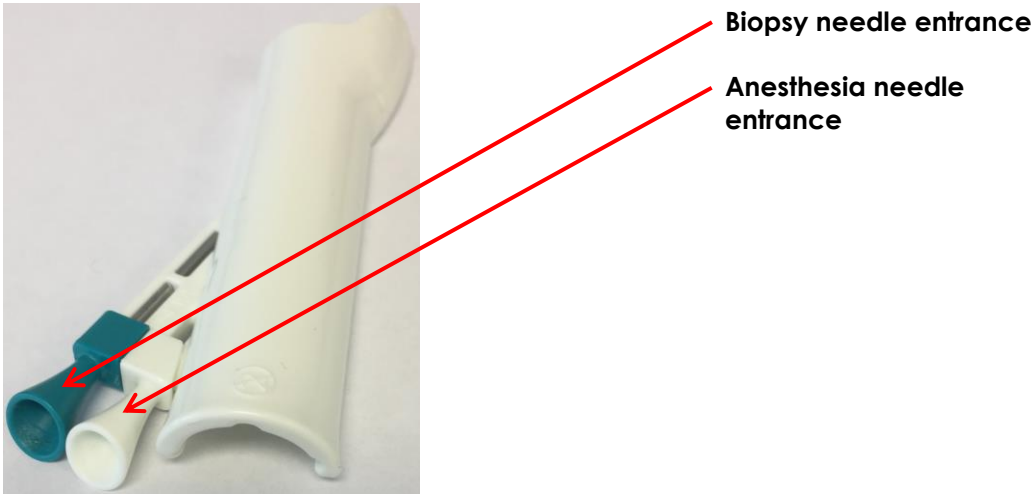

Figure 3: EV29L Sterile Transrectal Needle Guide

2.2.1.2 Biopsy Needle

The *EV29L Sterile Transrectal Needle Guide* supports two needles: one for anesthesia delivery and the other for biopsy. Each needle fits into the needle guide at an angle appropriate for its function (15 degrees for anesthesia delivery and 35 degrees for biopsy). The needle gauge sizes for each function are as follows:

- Anesthesia needle: 22-gauge
- Biopsy needle: 18-gauge

2.2.1.3 Working Life

The *EV29L Sterile Transrectal Needle Guide* is intended for single-use only and is provided in sterile packaging. It has a limited shelf life and its package indicates its expiry date.

WARNING
EN-W4

Do not use a single-use needle guide or any component of a needle guide package or kit if its packaging indicates its expiry date has passed.

Operators are responsible for adhering to internal clinical procedures regarding checking for and disposing of expired consumables.

2.2.2 EV29L Non-Sterile Reusable Transrectal Needle Guide

2.2.2.1 Specifications

The *EV29L Non-Sterile Reusable Transrectal Needle Guide* provides the means to guide a needle through a stainless-steel *needle cannula*.

There are two variants available for this needle guide:

- 18 GA EV29L Reusable Transrectal Needle Guide (Exact Imaging catalog reference EV-BIOGR)
- 16 GA EV29L Reusable Transrectal Needle Guide (Exact Imaging catalog reference EV-BIOG-R16)

The device identifier of the needle guide is laser-etched on the side of the plastic enclosure.

Replacement needle guides and sheaths may be ordered from your local distributor. Refer to Appendix C for contact information.

The EV29L reusable transrectal needle guide consists of two parts as shown in Figure 4 and Figure 5:

- Plastic enclosure
- Needle cannula

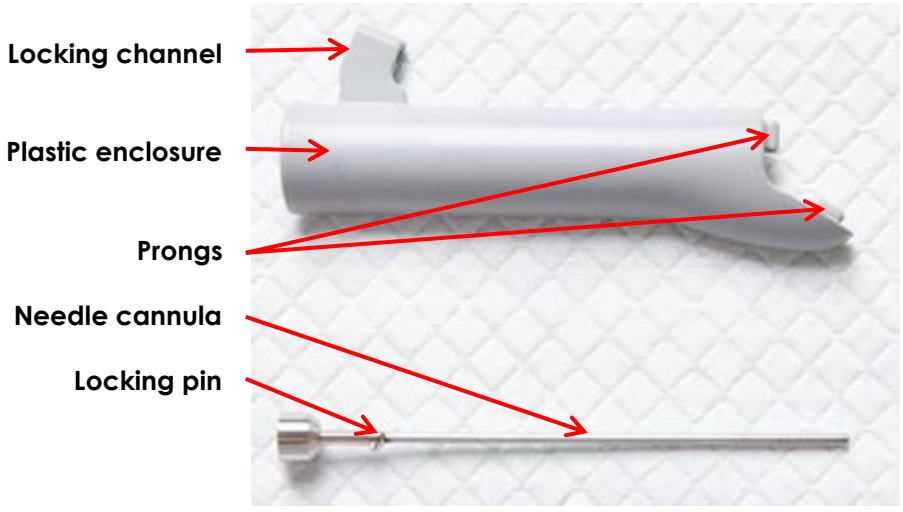

Figure 4: EV29L Reusable Transrectal Needle Guide

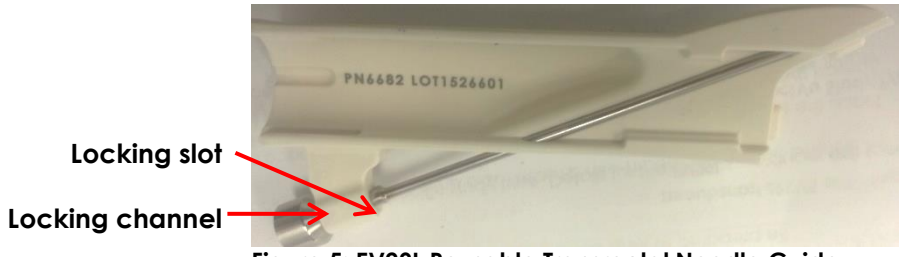

Figure 5: EV29L Reusable Transrectal Needle Guide

The EV29L reusable transrectal needle guide is packaged with a quick reference guide.

2.2.2.2 Biopsy Needle

Exact Imaging recommends using an 18-gauge or 16-gauge biopsy needle with the EV29L reusable transrectal needle guide, depending on the variant in use. Anesthesia needles may also be used with the needle guide.

Needles fit into the EV29L reusable transrectal needle guide at an angle of 35 degrees.

2.2.2.3 Preparing the Needle Guide for Use

NOTE
EN-N136

Both biopsy procedures and imaging-only procedures (i.e., imaging procedures without biopsy) using the EV29L transducer require the use of a needle guide. The EV29L reusable transrectal needle guide may be used without the needle cannula for imaging-only procedures.

For imaging-only procedures, attach the needle guide to the transducer prior to covering it with the sheath to reduce the risk of infection due to cross-contamination.

To prepare the EV29L reusable transrectal needle guide:

1. Insert the *needle cannula* into the *plastic enclosure* (refer to Figure 6).

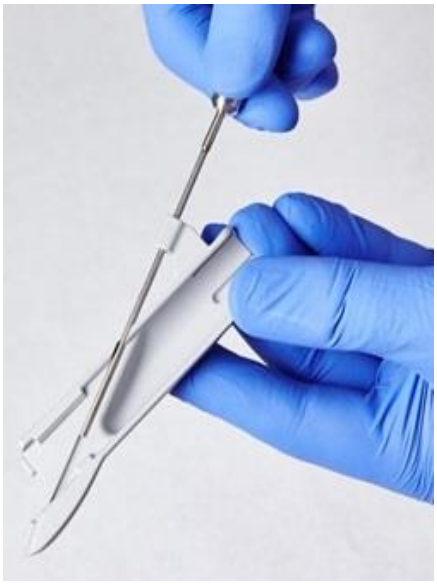

Figure 6: Insert the Needle Cannula into the Plastic Enclosure

2. Align the locking pin with the *locking slot* on the *plastic enclosure* and slide it through the entire *locking slot* (refer to Figure 7).

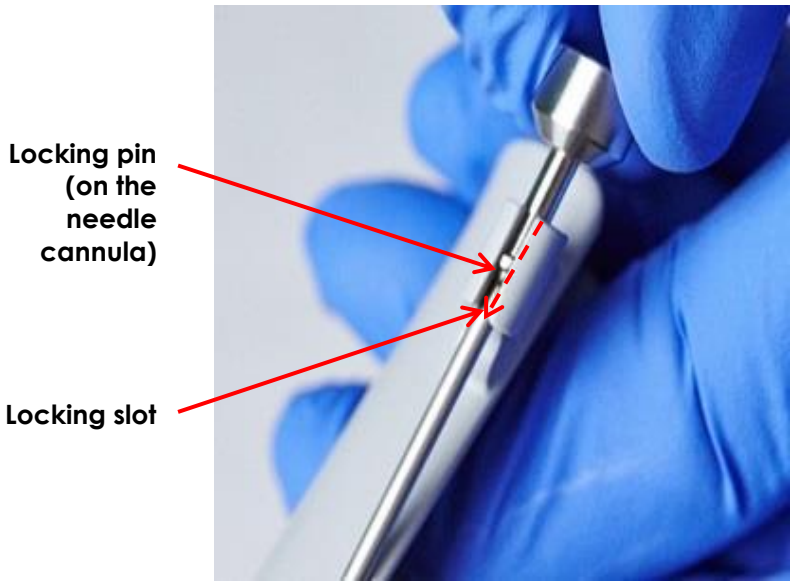

Figure 7: Lock the Needle Cannula

3. Rotate the *needle cannula* clockwise until the locking pin turns a minimum of 120° and feels tight and secure (refer to Figure 8).

Figure 8: Rotate the Needle Cannula

WARNING
EN-W67

To prevent injury during procedures using the EV29L reusable transrectal needle guide, ensure the needle cannula is securely twisted to a locked position, to avoid accidental dislodgement.

4. When the *needle cannula* is securely attached to the *plastic enclosure*, the *needle guide* is ready to be attached to the EV29L transducer.

WARNING
EN-W69

Do not attach the EV29L reusable transrectal needle guide to the EV29L transducer if either of its parts has not been reprocessed.

Perform the reprocessing procedure in section 2.2.2.4 on page 15 before its first use and prior to attaching the needle guide to the EV29L transducer.

2.2.2.4 Reprocessing the EV29L Reusable Transrectal Needle Guide

Refer to Chapter 4 section 3 on page 42 for reprocessing instructions for the EV29L Reusable Transrectal Needle Guide.

2.2.2.5 Maintaining the EV29L Reusable Transrectal Needle Guide

The EV29L reusable transrectal needle guide must be checked regularly to maintain a high level of safety and performance. Exact Imaging recommends an inspection procedure that consists of two parts:

- Visual inspection
- Check the needle guide alignment as described in Chapter 5, section 2.1.2 on page 49

If you observe mechanical damage while performing maintenance activities for the needle guide, contact Technical Support using the contact information in Appendix C.

2.2.2.5.1 Visual Inspection

Perform a visual inspection of the EV29L reusable transrectal needle guide before each use.

What to look for	Where to look
There should be no cracking	Plastic enclosure
Prongs and locking channel are not damaged or broken	Plastic enclosure
Snug fit in the plastic enclosure	Needle cannula
Ease of attaching the plastic enclosure to the EV29L transducer	

Table 2: EV29L Reusable Transrectal Needle Guide Inspection

2.2.2.5.2 Needle Guide Alignment Check

Perform the needle guide alignment check procedure in Chapter 5, section 2.1.2 on page 49. Exact Imaging recommends checking the needle guide alignment every six months or when improper alignment is suspected.

The needle should be visible in this procedure.

2.2.2.6 Working Life

When used with proper care, the EV29L reusable transrectal needle guide is designed for a working lifetime of whichever occurs first of 2 years or 1000 reprocessing cycles.

2.3 Needle Guides for Transperineal Procedures

For transperineal biopsy procedures using the EV29L transducer, Exact Imaging supports the following needle guide designed for use with the EV29L transducer:

- EV29L Sterile Transperineal Needle Guide (Exact Imaging catalog reference, EV-29L-TRK-24)

The *template grid* described in section 2.5 on page 17 may also be used for transperineal procedures with the EV29L transducer.

2.3.1 EV29L Sterile Transperineal Needle Guide

2.3.1.1 Specifications

The EV29L *Sterile Transperineal Needle Guide* consists of two parts as shown in Figure 9:

- *Needle guide tower*: provides ten needle entrances and attaches to the *guide plug*
- *Guide plug*: attaches to the neck of the EV29L transducer and is secured in place by a latch

These parts are separated in the image below, but are assembled in their packaged configuration.

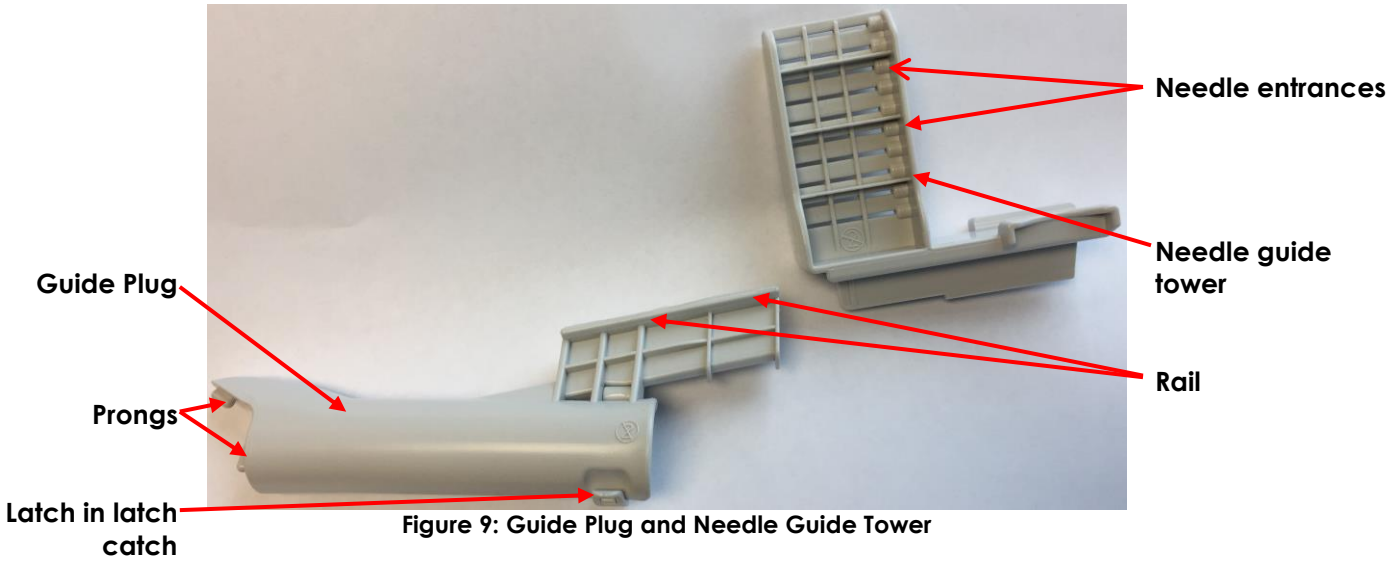

Figure 9: Guide Plug and Needle Guide Tower

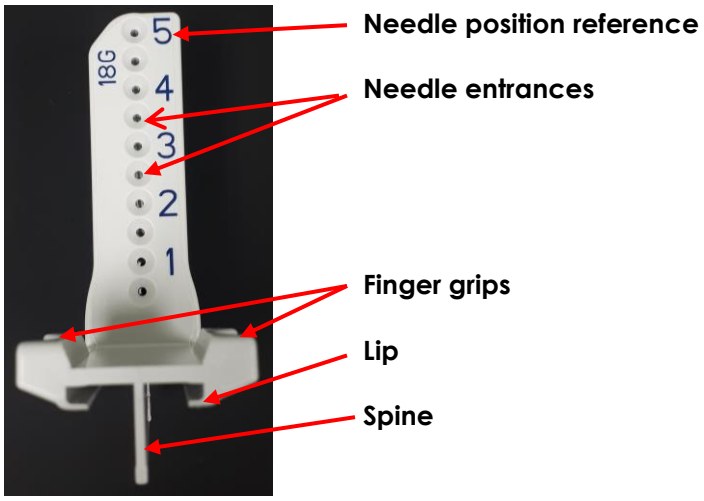

Figure 10: Needle Guide Tower

The *EV29L Sterile Transperineal Needle Guide* is available in the following packaging configurations, depending on the geographic region in which it will be used:

- **EV-29L-TPK-24**: Complete Transperineal Needle Guide Kit for EV29L (24-Pack), 24 units of single-use sterile, transperineal needle guides, gel packets and latex-free sheaths.

- **EV-29L-TP-S-24**: Sterile transperineal needle guide for use with Exact Imaging EV29L transducer, 24-pack (EV-29L-TP-24) and CIV-Flex™ sterile transducer cover (10.1 tapered to 2.5 x 30.5 cm), 24-pack (670-038).

These configurations include the document *Transperineal Needle Guide Reference Guide for Use with Exact Imaging EV29L Transducer*.

Replacement needle guides and sheaths may be ordered from your local distributor. Refer to Appendix C for contact information.

2.3.1.2 Biopsy Needle

Exact Imaging recommends using an 18-gauge biopsy needle with the *EV29L Sterile Transperineal Needle Guide*.

Needles fit into the *EV29L Sterile Transperineal Needle Guide* at an angle of 13 degrees relative to the transducer neck at a distance from the center of the transducer lens of 11 cm. It allows the *needle guide tower* to slide along the *guide plug* to a distance of 8 cm the center of the transducer lens.

2.3.1.3 Working Life

The *EV29L Sterile Transperineal Needle Guide* is intended for single-use only and is provided in sterile packaging. It has a limited shelf life and its package indicates its expiry date.

WARNING
EN-W4

Do not use a single-use needle guide or any component of a needle guide package or kit if its packaging indicates its expiry date has passed.

Operators are responsible for adhering to internal clinical procedures regarding checking for and disposing of expired consumables.

2.4 Sterile Transducer Sheath

Exact Imaging recommends *CIV-Flex™ Transducer Cover* manufactured by CIVCO® Medical Solutions (latex-free transducer sheath, 10.1 cm (4"), tapered to 2.5 x 30 cm (1" x 12") 24-pack, catalog reference 670-038).

The EV29L transducer is also compatible with *Sterile Transducer Sheaths* manufactured by Sheathing Technologies (latex-free transducer sheath, 2.2 cm (7/8"), tapered to 7.4 x 30 cm (2.9" x 11.8") 24-pack, catalog reference 26840).

WARNING
EN-W49

To ensure optimal performance of the ExactVu™ High Resolution Micro-Ultrasound system, use only the consumables listed in this document and other ExactVu instructions for use listed in Table 1 on page 5.

2.5 MTT Universal Stepper (Optional Accessory)

The complete configuration for the *MTT Universal Stepper* (i.e., the *transperineal stepper*) consists of the following components:

- Universal Stepper for Transperineal Applications
- Template Holder for Universal Stepper

- Articulating Arm Complete for high lithotomy position in one of two options:
    - Universal rail adapter
    - Side rail adapter
- Transperineal Transducer Cradle for securing the EV29L Transducer
- Template grid, available in one of two options:
    - Stainless steel G18 reusable template grid
    - Single-use, sterile G18 template grid, available from Exact Imaging in a 5-pack configuration

The complete configuration is available from Exact Imaging either as a package or as individual components. In addition to these components, the following accessories are also available from Exact Imaging:

- Floor Stand for Transperineal Stepper Package, for convenient floor mounting of the complete transperineal stepper package
- Transperineal Transducer Cradle for securing the EV29L Transducer

The manufacturer's information for the transperineal stepper is found in the document provided with in the stepper packaging.

Refer to the manufacturer's information for images and the identification of the components of the transperineal stepper.

Contact your local distributor using the contact information in Appendix C for ordering information.

2.5.1 Biopsy Needle

Exact Imaging recommends using an 18-gauge biopsy needle with the G18 template grid.

2.5.2 Stepper Specifications

Refer to the manufacturer's information for the operating and storage environment for the transperineal stepper.

2.5.3 Setup and Installation

The transperineal stepper comes pre-configured so that the EV29L transducer sits at the correct height for use with the ExactVu system.

Prior to the initial use of the transperineal stepper, perform the following checks to ensure the configuration is correct:

- Perform the procedure to check the *template grid holder vertical height* provided in Appendix A.
- Perform the procedure to check the *needle path alignment* provided in Appendix B.
- Refer to the manufacturer's information for instructions to connect and disconnect the EV29L transducer to the stepper.

2.5.4 Cleaning, Disinfection and Sterilization

Equipment must be cleaned as appropriate for the procedure prior to each use. After every use, follow proper procedures for cleaning and waste disposal. Figure 11 identifies parts of the transperineal stepper that require cleaning, disinfection and sterilization.

Refer to the appropriate section of the manufacturer's information for the following:

- Instructions to disassemble parts of the transperineal stepper for cleaning, disinfection and sterilization
- Required items and instructions to clean, disinfect and sterilize parts of the transperineal stepper
- Instructions to clean, disinfect and sterilize the tracking stepper rail, reusable template grid, template grid holder, transducer cradle (refer to Figure 11)

WARNING
EN-W65

Never reuse the EV29L sterile transperineal needle guide or a single-use template grid. Re-use of a single-use device carries a risk of infection to patients, due to residual microbial contamination.

After procedures using the EV29L sterile transperineal needle guide or a single-use template grid, discard the device according to internal clinical procedures for safe disposal.

- Instructions to clean the articulating arm
- Instructions for inspecting the transperineal stepper parts after cleaning, disinfection and sterilization
- Instructions to reassemble parts of the transperineal stepper after cleaning, disinfection and sterilization
- Instructions for storing the transperineal stepper parts after cleaning, disinfection and sterilization

WARNING
EN-W58

Refer to the manufacturer's instructions for the transperineal stepper to determine which of its components must be disinfected or sterilized before and after each use.

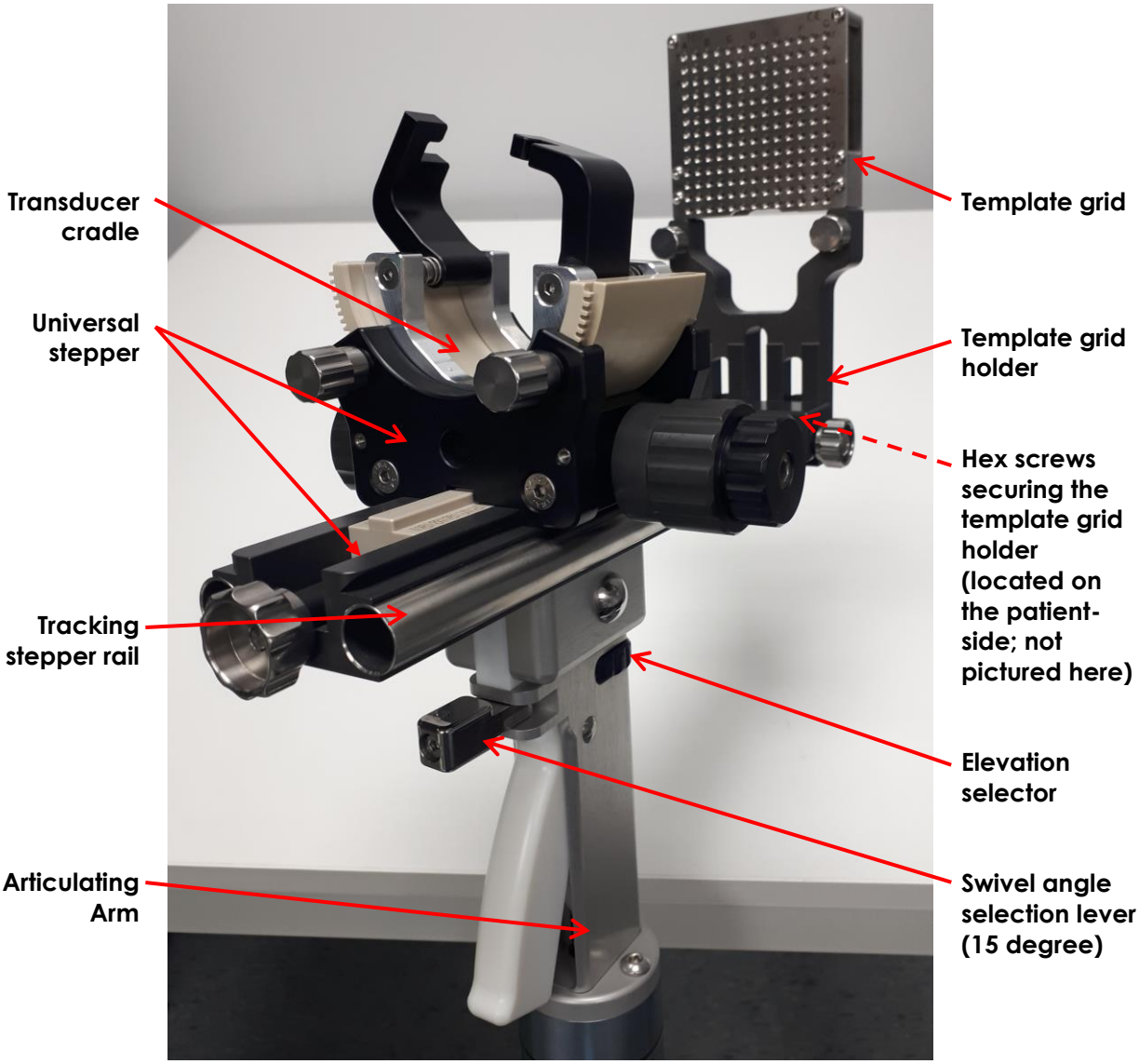

Figure 11: Transperineal Stepper Parts Requiring Disinfection

2.5.5 Caring for the Stepper

Refer to the manufacturer's information for information regarding:

- Careful handling of the transperineal stepper
- Maintenance and inspection of the transperineal stepper
- Cleaning, disinfection and sterilization of the transperineal stepper
- Storing the transperineal stepper

In addition to those procedures referenced, Exact Imaging recommends performing the following checks annually:

- Check the *template grid holder vertical height* using the procedure provided in Appendix A.

- Check the *needle path alignment* using the procedure provided in Appendix B.

If you notice mechanical damage to the transperineal stepper, contact Technical Support using the contact information in Appendix C.

2.5.6 Working Life of the Stepper

Refer to the manufacturer's information for information regarding the working lifetime of the transperineal stepper.

3 Transducer Specifications

Refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* for the operating and storage environment for the EV29L transducer.

Chapter 3 Preparing for Imaging

1 Preparing the ExactVu System

1.1 Exam Type

Each transducer is associated with a specific exam type. Details for the EV29L transducer are specified in the table below:

Transducer Name	General Description	Broadband Frequency	ExactVu Exam Types
EV29L	29 MHz High Resolution Side-Fire Transducer (Linear)	29 MHz	Prostate TRUS Biopsy (default) Fusion Prostate TRUS Biopsy

Table 3: ExactVu Transducers and Exam Types

WARNING
EN-W27

Always use the specific transducer for the intended exam type.

1.2 Presets

The *image preset* settings for each transducer/exam type combination have been optimized on the ExactVu system to give the best compromise between producing low acoustic output and sufficient power to view features on the structure being imaged as quickly as possible. The default imaging settings for all transducers are intended to ensure the lowest acoustic output during imaging. The default imaging settings for all transducers are displayed on the imaging screen when a transducer, exam type and image preset are selected.

2 Preparing the Transducer

The ExactVu system is designed to optimize the workflow of a standard TRUS procedure. It is designed based on the assumption that its operators will wish to begin imaging as quickly as possible. Once the ExactVu system is turned on, it initializes, the software launches, and it may be used for imaging immediately.

NOTE
EN-N12

Connect the transducer to the ExactVu system according to internal clinical protocols for biopsy.

This procedure assumes the transducer will be connected to the ExactVu system after it has been prepared for the procedure in which it will be used.

The following items are needed to prepare the transducer:

- Ultrasound gel
- Surgical (or similar) gloves

Depending on the type of procedure being performed, the following items may also be required:

- Needle guide (Use one of the needle guides identified in Chapter 2, section 2.2 for transrectal procedures or in section 2.3 for transperineal procedures.)
- Sterile transducer sheaths (refer to section 2.4 on page 17)
- Biopsy needle or anesthesia needle
- Sterilized reusable template grid or single-use template grid

WARNING
EN-W28

Always wear gloves when handling sterile items.

WARNING
EN-W31

The use of damaged transducers can result in injury or increased risk of infection. Inspect transducers often for sharp, pointed, or rough surface damage that could cause injury to the patient or increased risk of infection.

WARNING
EN-W47

Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some patients.

Exact Imaging recommends using a latex-free sheath for patients identified as latex-sensitive or talc-sensitive.

Be prepared to treat allergic reactions promptly.

2.1 Preparing the EV29L Transducer for a TRUS Imaging or Biopsy Procedure

These instructions are applicable to:

- Preparing the EV29L transducer for transrectal biopsy procedures
- Preparing the EV29L transducer for imaging-only procedures

To prepare the EV29L transducer:

1. Fill a sterile transducer sheath with a reasonable amount of sterile gel.

NOTE
EN-N68

Always use an adequate amount of sterile gel on the transducer imaging surface.

2. Place the sheath over the transducer leaving a small amount of space at the tip.
3. Spread the gel onto the imaging surface of the transducer (using a gloved finger) so that it is well covered. Ensure no bubbles are covering the imaging surface of the transducer.

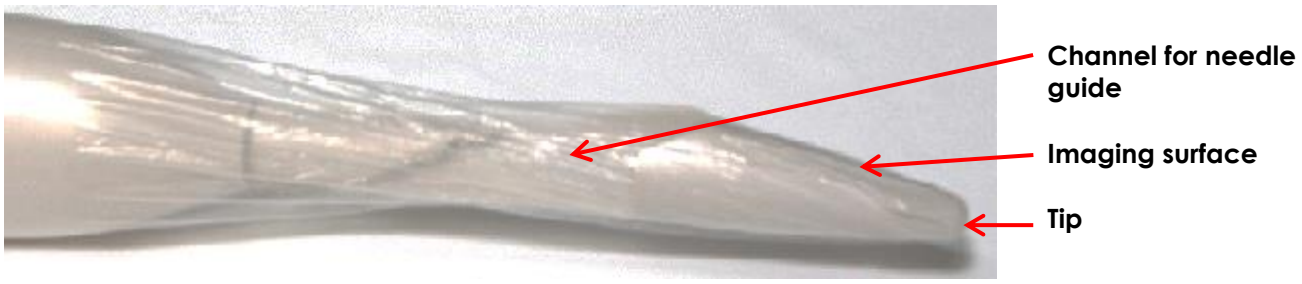

Figure 12: EV29L Transducer with Gel-filled Sheath

CAUTION
EN-C13

It is important to prevent air bubbles from forming inside the sheath near the imaging surface of the transducer to avoid interfering with image quality.

4. Working away from the imaging surface, gently twist the sheath to keep the gel in place at the imaging surface of the transducer.
5. After removing air from the sheath, attach the appropriate needle guide using the instructions in one of the following subsections.

WARNING
EN-W30

Only attach a needle guide to the EV29L transducer if the transducer has been prepared as described above.

6. Pull the sheath as far over the transducer handle as possible.

WARNING
EN-W29

If air bubbles or wrinkles occur near the point where the needle exits the needle guide, the sheath may be punctured by the needle during biopsy, and may increase the risk of infection.

If the sheath is punctured by the needle, discard it and re-prepare the transducer as described in this section.

2.1.1 Attaching the Transrectal Needle Guide

This procedure is applicable to either of the needle guides identified in Chapter 2, section 2.2 on page 10, and includes images of both needle guides.

NOTE
EN-N136

Both biopsy procedures and imaging-only procedures (i.e., imaging procedures without biopsy) using the EV29L transducer require the use of a needle guide. The EV29L reusable transrectal needle guide may be used without the needle cannula for imaging-only procedures.

For imaging-only procedures, attach the needle guide to the transducer prior to covering it with the sheath to reduce the risk of infection due to cross-contamination.

To attach the EV29L transrectal needle guide to the EV29L transducer:

1. With the sheath filled with gel covering the transducer (as per section 2.1), identify the small indentation on the EV29L needle guide and the ridge at the side of the channel on the EV29L transducer.

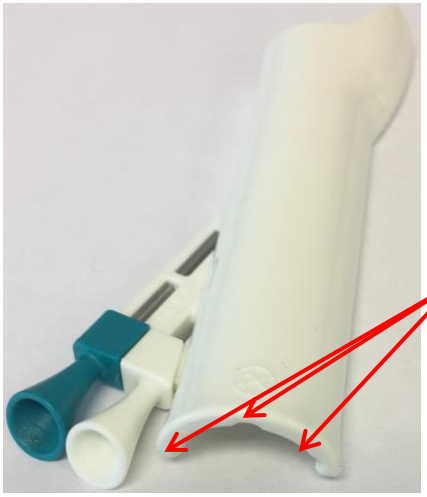

Figure 13: EV29L Sterile Transrectal Needle Guide

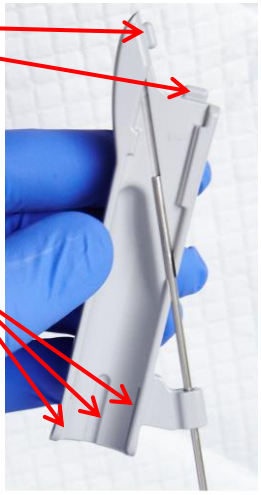

Figure 14: EV29L Reusable Transrectal Needle Guide

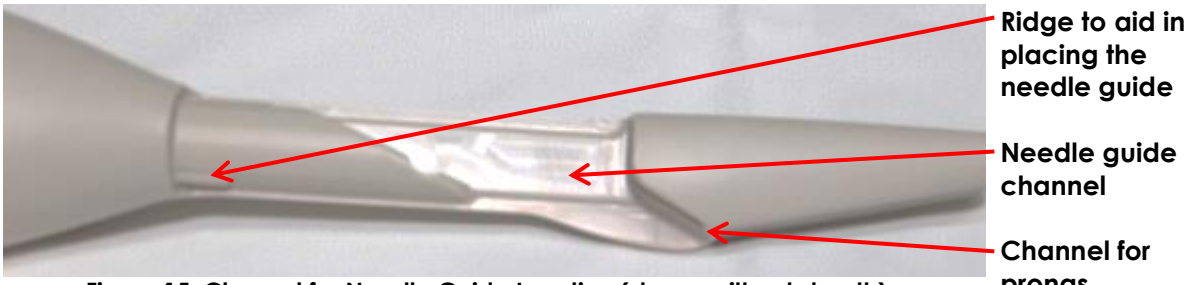

Figure 15: Channel for Needle Guide Insertion (shown without sheath)

2. Insert the needle guide into the *needle guide channel* by first inserting the *prongs* into the channel so that the indentation on the needle guide is aligned with the *ridge* on the channel.

Figure 16: Reusable Transrectal Needle Guide Insertion

3. Firmly press the needle guide onto the transducer so that it clicks into position. When doing this, avoid pressing the needle entrances. Instead, press on the body of the needle guide.

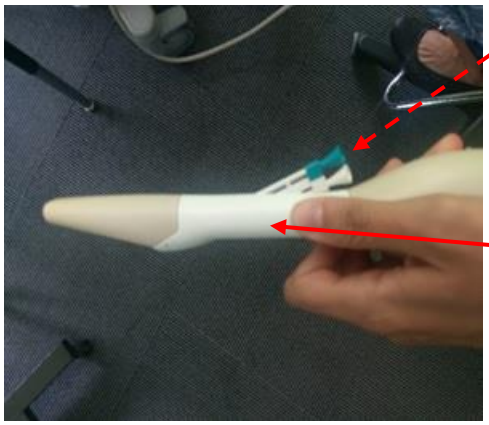

Figure 17: EV29L Sterile Transrectal Needle Guide Insertion

The needle guide is now securely attached to the EV29L transducer, and a biopsy needle or anesthesia needle can be inserted into it.

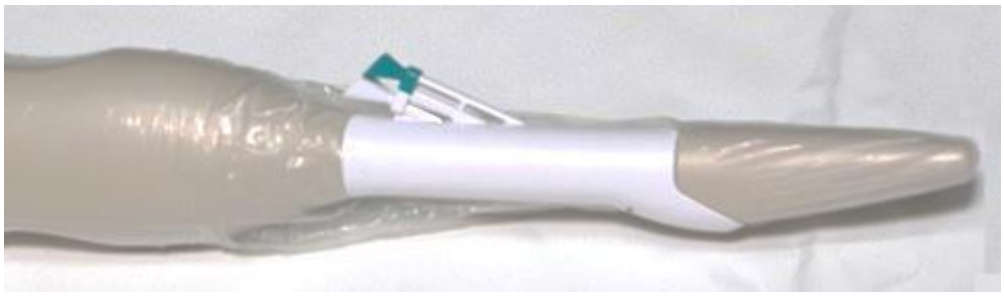

Figure 18: EV29L with Inserted EV29L Sterile Transrectal Needle Guide

WARNING
EN-W81

Do not use an EV29L single-use needle guide if it does not attach securely and correctly to the transducer.

WARNING
EN-W83

Do not use any needle guide if it appears to be damaged.

If a needle guide shows any sign of damage, contact Technical Support using the contact information in Appendix C.

CAUTION
EN-C13

It is important to prevent air bubbles from forming inside the sheath near the imaging surface of the transducer to avoid interfering with image quality.

2.1.2 Attaching the EV29L Sterile Transperineal Needle Guide

This procedure is applicable to the needle guide identified in Chapter 2, section 2.3 on page 15.

To attach the EV29L sterile transperineal needle guide to the EV29L transducer:

1. With the sheath filled with gel covering the transducer (as per section 2.1), identify the small indentation on the needle guide and the ridge at the side of the channel on the EV29L transducer.

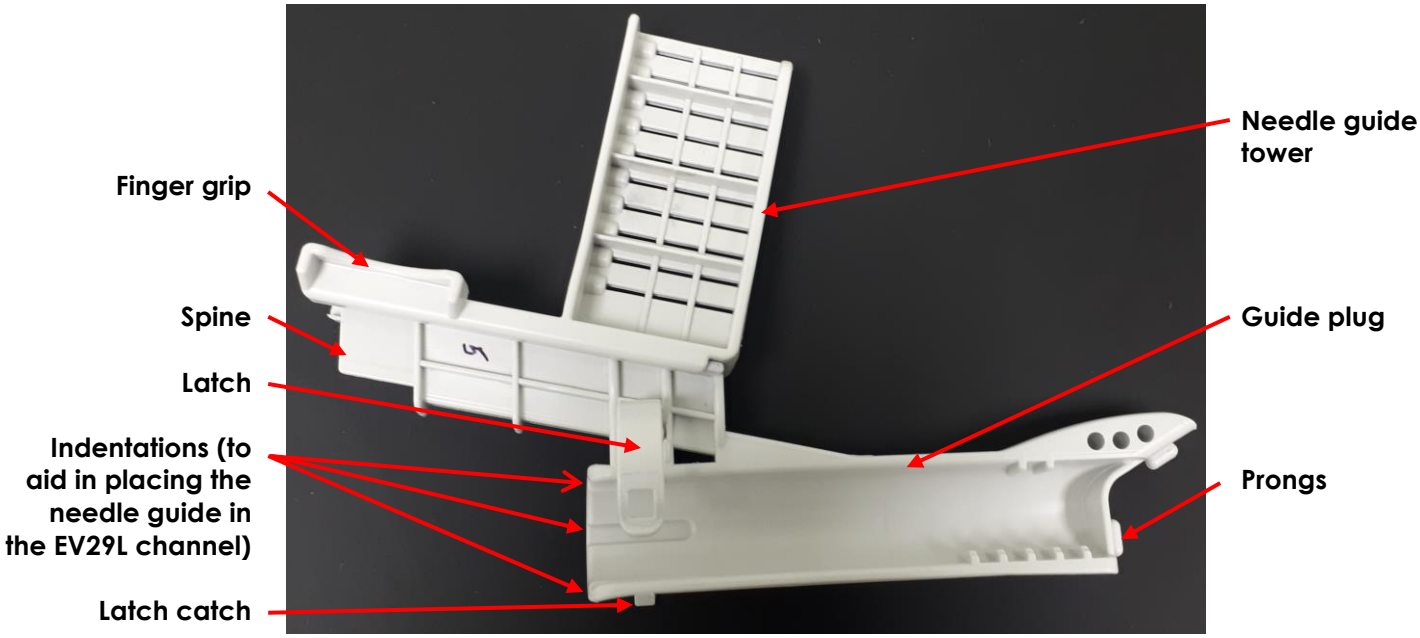

Figure 19: Indentations in the Guide Plug

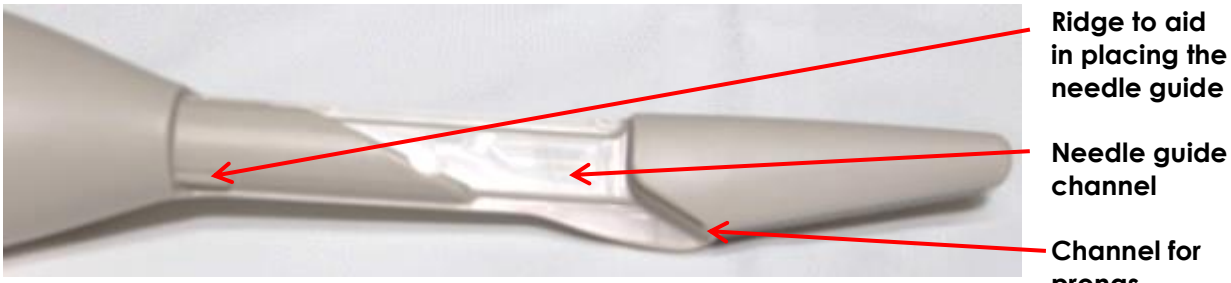

Figure 20: Channel for Needle Guide Insertion (shown without sheath)

2. Ensure the latch is open (i.e., not clipped to the latch catch).
3. With the latch open, insert the EV29L sterile transperineal needle guide into the *needle guide channel* by first inserting the *prongs* into the channel so that the indentation on the needle guide is aligned with the *ridge* on the channel.
4. Firmly press the needle guide onto the transducer so that it clicks into position. When doing this, avoid pressing any part of the *needle guide tower*. Instead, press on the body of the *guide plug*.

   The needle guide is now securely attached to the EV29L transducer.
5. Secure the latch by pulling it across the EV29L transducer and attaching it to the latch catch so that it clicks into position. Avoid letting the sheath get between the latch and the latch catch. Pull the sheath under the latch.

Figure 21: EV29L with Inserted EV29L sterile Transperineal Needle Guide (shown without sheath)

WARNING
EN-W81

Do not use the EV29L sterile transperineal needle guide if it does not attach securely and correctly to the transducer or if the latch does not securely attach to the latch catch.

WARNING
EN-W83

Do not use any needle guide if it appears to be damaged.

If a needle guide shows any sign of damage, contact Technical Support using the contact information in Appendix C.

CAUTION
EN-C13

It is important to prevent air bubbles from forming inside the sheath near the imaging surface of the transducer to avoid interfering with image quality.

2.1.2.1 Removing the Needle Guide Tower or Adjusting its Position

The operator may wish to remove the *needle guide tower* from the *guide plug* in order to have full access to the perineum (for example, to perform imaging-only procedures, perirectal spacing procedures, or to administer anesthesia) without the *needle guide tower* being in the way.

To remove the needle guide tower from the guide plug:

1. Gently squeeze together both *finger grips* on the needle guide.
2. Continue squeezing the finger grips while pulling the *needle guide tower* away from the *guide plug*.

   The *needle guide tower* slides off the *guide plug*.

   The *needle guide tower* may be left attached to the *guide plug* and used at any position along the *rail*.

To reinsert the needle guide tower in the guide plug:

1. Align the *spine* of the *needle guide tower* with the groove in the *guide plug*.
2. Align the *lip* of the *needle guide tower* with the *rail* in the *guide plug*.
3. Squeeze together both *finger grips* on the needle guide tower, and while squeezing, slide the *spine* of the *needle guide tower* through the *groove* in the *guide plug* such that the rail of the *guide plug* is under the lip of the needle guide tower.
4. Push the *needle guide tower* to the desired position along the rail.
5. Release the finger grips when the *needle guide tower* reaches the desired position.

   The orientation of the needle guide tower should be as shown in Figure 22, with the numbers labeling the *needle entrances* facing the operator.

2.2 Connecting and Disconnecting the EV29L Transducer to the Stepper (Applicable when Performing Transperineal Procedures)

Refer to the manufacturer's information for instructions to connect and disconnect the EV29L transducer to the stepper.

Figure 23 shows the EV29L transducer sitting in the *transducer cradle* of the transperineal stepper with the EV29L sterile transperineal needle guide attached to the transducer. Biopsy needles enter the perineum through the *needle entrances* on the needle guide.

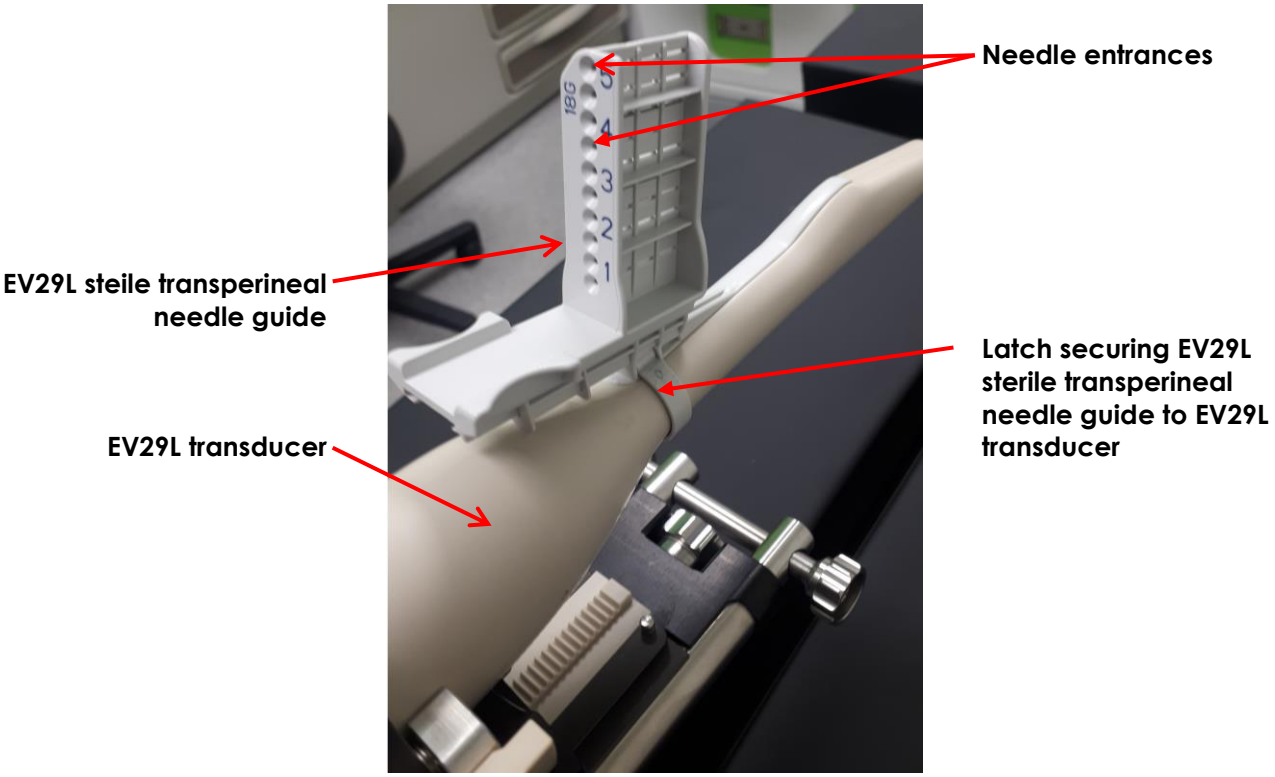

Figure 22: EV29L Transducer Connected to the Transperineal Stepper with the EV29L Sterile Transperineal Needle Guide (pictured without sheath)

Figure 23 shows the EV29L transducer sitting in the *transducer cradle* of the transperineal stepper. Biopsy needles enter the perineum through the *template grid*.

NOTE
EN-N170

Transperineal procedures using the template grid also require the use of a needle guide.

Exact Imaging recommends using the EV29L Non-Sterile Reusable Transrectal Needle Guide or the EV29L Sterile Transrectal Needle Guide.

Do not use the EV29L Sterile Transperineal Needle Guide for transperineal procedures that use the template grid.

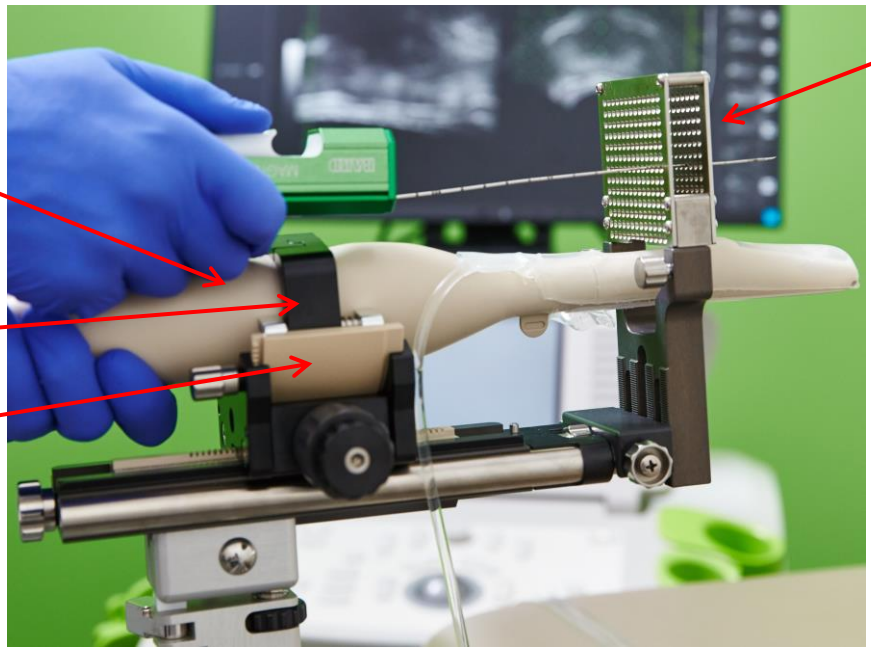

Figure 23: EV29L Transducer Connected to the Transperineal Stepper

NOTE
EN-N129

The term *transducer* is referred to as *probe* in the manufacturer's information.

3 Connecting the Transducer to the ExactVu System

NOTE
EN-N12

Connect the transducer to the ExactVu system according to internal clinical protocols for biopsy.

This procedure assumes the transducer will be connected to the ExactVu system after it has been prepared for the procedure in which it will be used.

To connect the transducer to the ExactVu system:

1. On the transducer connector, turn the *lock knob* to its *unlocked* position (refer to the *unlocked icon* in Figure 25).
2. Line up the locking pin (see Figure 26) on the transducer connector with the lock notch on the transducer connector slot on the ExactVu system (see Figure 27) so that the transducer connector is oriented as indicated in Figure 28.
3. Push in the connector and then turn the *lock knob* to the *locked* position (see Figure 28).

Figure 24: Transducer Locked Icon

Figure 25: Transducer Unlocked Icon

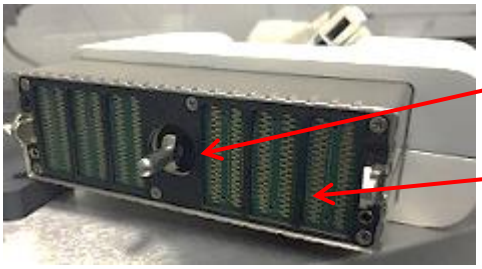

Figure 26: Locking Pin

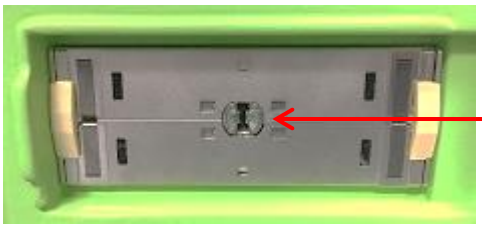

Figure 27: Lock Notch on the Transducer Connector Slot

Figure 28: Transducer Connector Orientation

4 Performing a Biopsy Procedure

Perform the transrectal or transperineal biopsy procedure according to internal clinical protocols for prostate biopsy. Observe all cautions and warnings related to performing transrectal and transperineal procedures using the ExactVu system.

NOTE
EN-N82

Refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* for information about set-up and operation for the ExactVu system.

WARNING
EN-W8

Do not unfreeze imaging and hold the transducer in mid-air without there being ultrasound gel applied to the transducer's imaging surface. Doing so may cause the temperature on the imaging surface to heat, and possibly cause injury to the patient.

WARNING
EN-W34

The *needle guide overlay* is intended to assist the operator to visualize the approximate needle path. However, the actual needle movement may deviate from the *needle guide overlay*. Always monitor the relative positions of the biopsy needle and the tissue target during the procedure.

WARNING
EN-W57

The transperineal *needle guide overlays* are intended to assist the operator to visualize the approximate needle path. However, the actual needle movement may deviate from the *overlay*. Always monitor the relative positions of the biopsy needle and the tissue target during the procedure.

For transperineal procedures, ensure there is alignment between the position on the needle guide overlay and the needle entrance position on the physical EV29L sterile transperineal needle guide or template grid.

The use of a small preset may prevent visualization of needles inserted through the deepest needle entrances (i.e., the highest numbered needle entrances). If the needle is not visible, changing the image depth may help to ensure the needle is displayed.

WARNING
EN-W67

To prevent injury during procedures using the EV29L reusable transrectal needle guide, ensure the needle cannula is securely twisted to a locked position, to avoid accidental dislodgement. Refer to Chapter 2, section 2.2.2.3 on page 13 for details about preparing the needle guide for a procedure.

4.1 Removing the Needle Guide from the Transducer

After a TRUS (transrectal ultrasound) procedure, remove the needle guide.

To remove the needle guide from the EV29L transducer:

1. Firmly press on the white plastic area at the needle entrance. Avoid pressing either needle entrance.
2. Pull the needle guide away from the transducer.
3. Perform the applicable action with the needle guide:
    - For procedures using the EV29L reusable transrectal needle guide, clean, disinfect and sterilize it according to the procedure in Chapter 2, section 2.2.2.4 on page 15
    - For procedures using the EV29L sterile transrectal needle guide, discard it according to internal clinical procedures for safe disposal

WARNING
EN-W36

Never reuse a single-use needle guide. Re-use of a single-use needle guide carries a risk of infection to patients, due to residual microbial contamination.

After use, discard the needle guide according to internal clinical procedures for safe disposal.

4.2 Disconnecting the EV29L Transducer from the Transperineal Stepper

(If applicable), after completing a transperineal procedure, refer to section 2.2 for instructions on disconnecting the EV29L transducer from the stepper.

After removing the EV29L transducer from the stepper, reprocess the stepper according to the instructions referenced in Chapter 3, section 2.5.4.

If deterioration of the performance of the transperineal stepper is observed, contact Technical Support using the contact information in Appendix C.

WARNING
EN-W58

Refer to the manufacturer's instructions for the transperineal stepper to determine which of its components must be disinfected or sterilized before and after each use.

4.3 Removing and Discarding Other Consumables

To remove and discard other consumables:

1. Remove the sheath from the transducer and discard it according to internal clinical procedures for safe disposal.
2. Discard surgical gloves used during the procedure according to internal clinical procedures for safe disposal.
3. Wipe off any material or gel from the EV29L transducer using a damp, soft cloth.

CAUTION
EN-C24

Use caution to prevent damaging the transducer during cleaning and to avoid scratching the transducer's *imaging surface* (i.e., the lens). This will damage the transducer.

WARNING
EN-W20

To avoid cross-contamination, follow all internal clinical procedures for infection control for personnel and equipment.

WARNING
EN-W49

To ensure optimal performance of the ExactVu™ High Resolution Micro-Ultrasound system, use only the consumables listed in this document and other ExactVu instructions for use listed in Table 1 on page 5.

Verify that the supply of consumables for upcoming procedures is adequate. Replacement needle guides and sheaths may be ordered from your local distributor. Refer to Appendix C for contact information.

5 Disconnecting the Transducer

To disconnect the transducer from the ExactVu system:

1. On the connected transducer connector, turn the lock knob to its *unlocked* position.
2. Grip the connector firmly and pull it out of the transducer connector slot.
3. Line up the locking pin on the transducer connector with the notch on the *transducer connector cover*.
4. Attach the *transducer connector cover* to the connector (to protect the contact pads).

Figure 29: Unlocked Transducer Connector Lock Knob

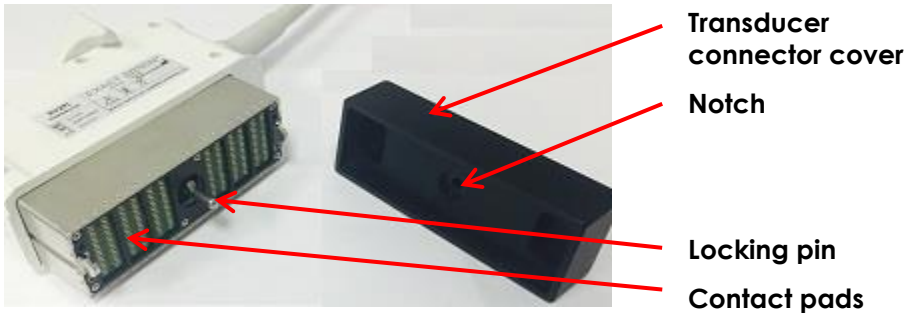

Figure 30: Transducer Connector Cover

CAUTION
EN-C23

Do not transport or clean the transducer without attaching the *transducer connector cover*. Do not allow debris or moisture to come in contact with the contact pads on the connector. Failure to use the *transducer connector cover* can cause damage to the transducer.

Chapter 4 Reprocessing

Always use sterile, legally marketed transducer sheaths for transrectal procedures.

These reprocessing procedures apply only to Exact Imaging transducers and the EV29L Reusable Transrectal Needle Guide. Discard single-use devices (including the *EV29L Sterile Transrectal Needle Guide*, the *EV29L Sterile Transperineal Needle Guide* and biopsy needle), sheaths and gloves according to internal clinical procedures. If applicable, refer to Chapter 2, section 2.2.2.4 on page 15 for instructions to clean, disinfect and sterilize the EV29L reusable transrectal needle guide.

NOTE
EN-N71

For the parts of the transducer that are not in contact with the sheath, cleaning with a low-alcohol surface disinfecting wipe is sufficient. Refer to *Approved Chemicals List for ExactVu Transducers*.

Equipment must be cleaned as appropriate for the procedure prior to each use.

- After every use, follow proper procedures for cleaning and waste disposal.
- Follow the procedure in this section for cleaning and disinfecting the EV29L transducer, and observe all warnings, cautions and notes.

WARNING
EN-W80

The use of damaged transducers may cause the reprocessing procedure in this chapter to be ineffective.

If the transducer shows any sign of damage, do not use the transducer. Contact Technical Support using the contact information in Appendix C.

1 General

In typical TRUS procedures, the use of a sterile gel and a transducer sheath are recommended. This procedure dictates that the parts of the transducer that are in contact with the sheath are to be cleaned following guidelines for semi-critical devices, i.e., using high-level disinfection.

WARNING
EN-W21

Failure to properly clean transducers and applicable accessories carries a risk of infection to patients, due to residual microbial contamination.

WARNING
EN-W40

Reprocess transrectal transducers as soon as possible after use to prevent biological materials from drying on them.

CAUTION
EN-C60

The EV29L transducer and the EV29L Reusable Transrectal Needle Guide are not designed and validated to withstand a reprocessing method that uses an automated reprocessor, with the exception of those identified on the Material Compatibility List.

2 Reprocessing the EV29L Transducer

2.1 Preparation for Transducer Reprocessing

2.1.1 Required items

Several items are required to perform the reprocessing procedure for the EV29L transducer:

- Cleaner and disinfectant (For a list of cleaning agents and disinfectants approved by Exact Imaging for use in this procedure, refer to *Approved Chemicals List for ExactVu Transducers*)
- Soft cloths and a soft-bristled brush (such as a nail brush)
- A cleaning station, including a cleaner container, a high-level disinfection container, and a rinse container for using cleaning and disinfection solutions
- Transducer connector cover (to protect the contact pads on the EV29L connector from moisture)
- Personal protective equipment (sterile gloves, surgical mask) as recommended by the manufacturer of the cleaning agent or disinfectant

NOTE
EN-N81

Cleaning and disinfecting chemicals are not available from Exact Imaging.

2.1.2 EV29L Transducer Parts Requiring Reprocessing

This procedure calls for washing, soaking and rinsing the transducer in various solutions. In all cases, the transducer should be exposed to solution levels that are approximately half-way up the handle (refer to *soak level* in Figure 31).

Contact should not be made between the solution and the electrical components of the transducer.

CAUTION
EN-C22

At no time should the transducer connector, the cable, or transducer strain relief be washed, rinsed or soaked in any solution.

Exposure of these parts to excessive moisture can cause damage to the transducer.

CAUTION
EN-C50

Proper handling conditions during reprocessing means:

- the transducer lens is protected
- the transducer cable is not twisted
- the transducer connector cover is attached to the transducer connector

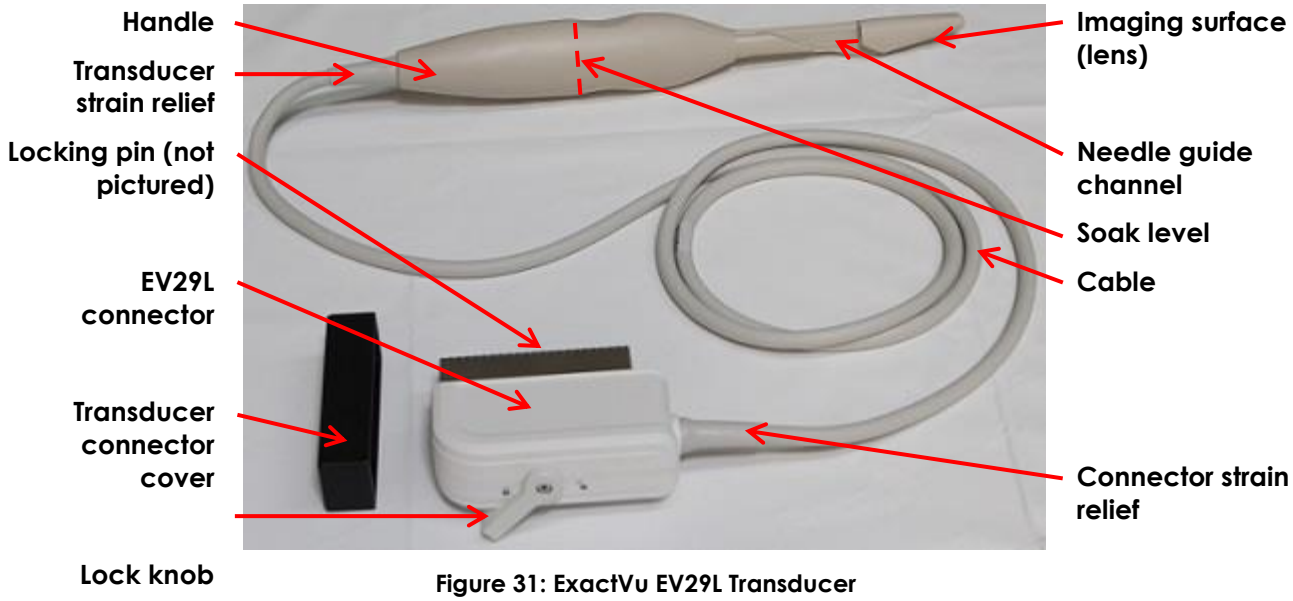

Figure 31: ExactVu EV29L Transducer

2.2 Surface Cleaning for the EV29L Transducer

Surface cleaning is required for non-critical devices, defined by *Centers for Disease Control and Prevention* as "a reusable medical device that comes in contact with unbroken skin and does not penetrate it".

This part of the procedure consists of:

- Cleaning non-critical parts of the EV29L transducer using a cleaner, and is to be performed after every study and before first use

It is applicable to:

- The parts of the EV29L transducer that do not come into contact with the sheath during a TRUS procedure, or in other words, the part of the transducer that is above the *soak level* (refer to Figure 31).

NOTE
EN-N83

In this procedure, *above* the soak level means the direction *away* from the imaging surface (refer to Figure 31).

To surface clean parts of the EV29L transducer that are above the soak level:

1. With a low-alcohol surface disinfecting wipe, wipe the outside of the *EV29L connector*.
2. With a low-alcohol surface disinfecting wipe, wipe the *cable* in a direction towards the transducer handle.
3. With a low-alcohol surface disinfecting wipe, thoroughly wipe the area from the *transducer strain relief* to the *soak level.*

NOTE
EN-N148

Over time, minor scratches may develop on the transducer handle. These areas should be wiped using a low-alcohol wipe.

4. Dispose of used cleaning materials as per internal clinical procedures for safe disposal.

2.3 Reprocessing the EV29L Transducer

This part of the procedure consists of:

- Cleaning and high-level disinfecting applicable parts of the EV29L transducer, and is to be performed after every study

It is applicable to:

- The parts of the EV29L transducer that come into contact with the sheath during a TRUS procedure, or in other words, the part of the transducer that is on or below the *soak level* (refer to Figure 31). For parts above the *soak level* (including the cable), refer to section 2.2.

2.3.1 Cleaning the EV29L Transducer

NOTE
EN-N73

Ensure that the cleaner has not passed its expiry date.

CAUTION
EN-C23

Do not transport or clean the transducer without attaching the *transducer connector cover*. Do not allow debris or moisture to come in contact with the contact pads on the connector. Failure to use the *transducer connector cover* can cause damage to the transducer.

1. Rinse the transducer in warm running water to remove excess debris. Thoroughly rinse the channel where the needle guide attaches to the transducer.

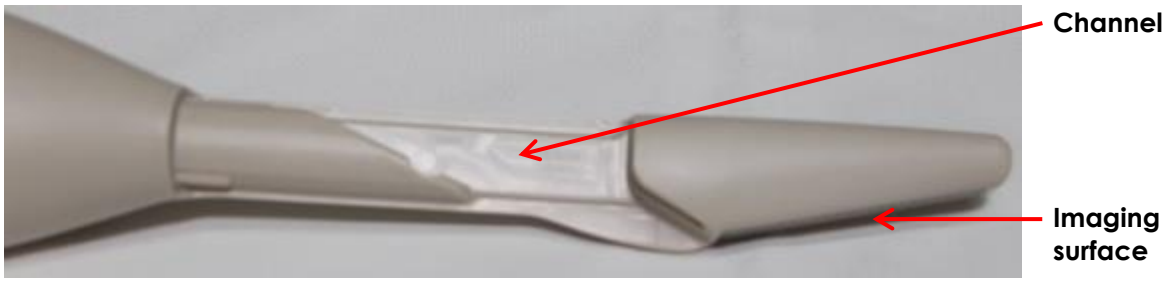

Figure 32: EV29L Needle Guide Channel

2. Use a soft cloth to wipe the transducer in water or the cleaner to remove all visible residue before soaking.
    - If any residue has dried on the transducer, gently rub it with moist gauze, sponge or a soft-bristled brush (such as a nail brush) to completely remove the residue.

NOTE
EN-N148

Over time, minor scratches may develop on the transducer handle. These areas should be brushed using a soft-bristled brush during cleaning of the transducer.

CAUTION
EN-C24

Use caution to prevent damaging the transducer during cleaning and to avoid scratching the transducer's *imaging surface* (i.e., the lens). This will damage the transducer.

3. Use a soft-bristled brush to thoroughly clean the needle guide *channel* including all grooves and any minor scratches below the *soak level* of the handle.
4. When using a cleaning solution:
    - Prepare the cleaning solution according to the manufacturer's instructions for the selected cleaner using the dilution ratio specified. Refer to *Approved Chemicals List for ExactVu Transducers*.

NOTE
EN-N76

The cleaning solution may be prepared in advance of cleaning the transducer.

- Fill the *cleaner container* with a sufficient volume of cleaning solution for the EV29L transducer to be immersed to the *soak level* indicated in Figure 31.
- Immerse the EV29L transducer in the cleaning solution to the *soak level* indicated in Figure 31.

CAUTION
EN-C25

Do not immerse the EV29L transducer beyond its soak level.

5. Expose the EV29L transducer according to the instructions provided by the manufacturer of the cleaner in the *Approved Chemicals List for ExactVu Transducers*.
    - If any residue remains, gently rub the transducer with moist gauze, sponge or a soft-bristled brush (such as a nail brush) to completely remove the residue.

NOTE
EN-N148

Over time, minor scratches may develop on the transducer handle. These areas should be brushed using a soft-bristled brush during cleaning of the transducer.

6. Rinse the EV29L transducer in running water, following the rinsing instructions provided by the manufacturer of the cleaner.
    - Thoroughly flush the channel.
7. Dispose of the water used for rinsing.
8. Using a soft cloth, rough-dry the transducer.

9. Dispose of the used cleaning solution/wipe.

2.3.2 High-level Disinfecting the EV29L Transducer

NOTE
EN-N74

Ensure the high-level disinfectant to be used has not passed any of its expiry dates. Check (as applicable):

- The manufacturer's expiry date marked on the container
- The maximum allowable time after opening the container
- The maximum allowable reuse time

NOTE
EN-N75

Follow any manufacturer's instructions regarding verification of minimum effective concentrations.

1. When using a solution:
    - Prepare the high-level disinfectant according to the concentrations recommended by the manufacturer.
    - Fill the *high-level disinfection container* with a sufficient volume of high-level disinfectant for the EV29L transducer to be immersed to the *soak level* indicated in Figure 31.
    - Immerse the EV29L transducer in the high-level disinfectant to the *soak level* indicated in Figure 31.

CAUTION
EN-C25

Do not immerse the EV29L transducer beyond its soak level.

2. Expose the EV29L transducer according to the instructions for use provided by the manufacturer of the high-level disinfectant in the *Approved Chemicals List for ExactVu Transducers*.

CAUTION
EN-C46

Do not exceed the duration of exposure recommended in the instructions for use provided by the manufacturer of the high-level disinfectant.

3. Fill the rinse container with a sufficient volume of sterile water or tap water for the EV29L transducer to be immersed to its *soak level*.
4. Rinse the EV29L transducer with sterile water or tap water, unless otherwise indicated by the manufacturer's instructions.
5. Rinse the transducer in large volumes of fresh water, following the manufacturer's rinsing instructions for the high-level disinfectant that was used.

WARNING
EN-W39

Ensure no residual disinfectant remains on the transducer after disinfection. This could cause serious side effects for the patient.

Three separate large volume rinses are required.

6. Check the entire EV29L transducer for any residual organic material.
    - If any is present below the *soak line*, repeat all steps for cleaning and disinfecting the transducer.
    - If any is present above the *soak line* including the cable, repeat all steps for surface cleaning the transducer.
    - If it is not possible to reprocess the EV29L transducer for any reason, contact Technical Support using the contact information in Appendix C.
7. Gently dry the EV29L transducer with a soft, clean cloth.

2.4 Inspecting the EV29L Transducer after Reprocessing

Inspect the EV29L transducer for signs of deterioration due to cleaning and disinfection after every application of the cleaning and disinfecting procedure.

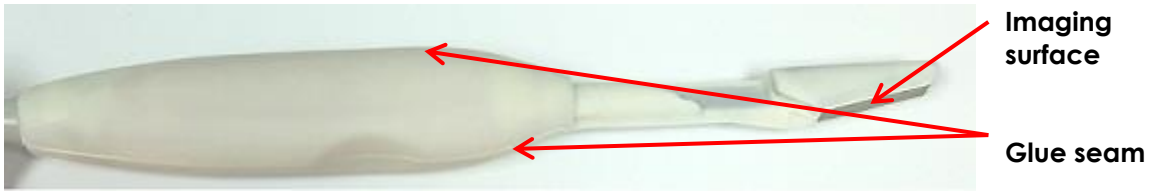

Figure 33: EV29L Transducer

There should be:

- No scratches on the *imaging surface*
- No scratches on the transducer
- No gap in any *glue seam*
- No cracks in the handle
- No cracks in the connector

Over time, cleaning and disinfecting the EV29L transducer may cause discoloration. Discoloration does not affect the performance of the EV29L transducer; however, if considerable discoloration is observed over a period of approximately six months, contact Technical Support using the contact information in Appendix C.

NOTE
EN-N69

If you notice any deterioration in the performance of any ExactVu transducer, contact Technical Support using the contact information in Appendix C.

2.5 Storing the EV29L Transducer after Reprocessing

Store the transducer in a transducer holder on the ExactVu system cart as described in Chapter 5, section 2.2 on page 50.

WARNING
EN-W22

Before putting a reprocessed transducer into the transducer holder on the ExactVu system cart, ensure the holder is clean to avoid the risk of cross-contamination.

WARNING
EN-W79

To avoid the risk of cross-contamination, never store a transducer in the transducer holder on the ExactVu system cart unless the transducer has been reprocessed as described in Chapter 4.

3 Reprocessing the EV29L Reusable Transrectal Needle Guide

In typical TRUS procedures, the use of a sterile gel and a transducer sheath are recommended. This procedure dictates that the accessories that are in contact with the sheath are to be cleaned following guidelines for semi-critical devices.

WARNING
EN-W21

Failure to properly clean transducers and applicable accessories carries a risk of infection to patients, due to residual microbial contamination.

The EV29L reusable transrectal needle guide must be reprocessed following every use and before first use, using one of the following methods:

- Cleaning and sterilizing:
    - Follow the procedures in both section 3.2 and section 3.3
- Cleaning and disinfection:
    - Follow the procedures in both section 3.2 and section 3.4

NOTE
EN-N167

Exact Imaging recommends following the cleaning and sterilization procedure unless there is no possible access to an autoclave system.

Type of Chemical	Chemical Name	Validated Contact Time	Manufacturer
Cleaner	Cidezyme / Enzol	5 min	Advanced Sterilization Products
High-level Disinfectant	Cidex OPA	12 min	Advanced Sterilization Products

Table 4: Approved Chemicals List

Sterilizer	Class	Validated Cycle

Autoclave (Steam sterilizer)	B	• 4 vacuum cycles • Sterilization cycle: 134°C for 3 min OR 132°C for 4 min • Dry time: 30 min

Table 5: Steam Sterilizer for EV29L Reusable Transrectal Needle Guide

NOTE
EN-N81

Cleaning and disinfecting chemicals are not available from Exact Imaging.

3.1 Prepare the Needle Guide

Before performing the cleaning and sterilization procedure, separate the parts of the needle guide. For procedures performed without the *needle cannula*, perform the cleaning, disinfection and sterilization instructions with the *plastic enclosure*.

To separate the parts of the EV29L reusable transrectal needle guide:

1. Rotate the *needle cannula* counter-clockwise until the locking pin is aligned with the *locking slot* on the *plastic enclosure*.
2. Pull the *needle cannula* out of the *plastic enclosure*.

WARNING
EN-W70

Always disassemble the EV29L reusable transrectal needle guide before reprocessing.

3.2 Cleaning the Needle Guide

Required items:

- Cleaner and disinfectant (For a list of cleaning agents and disinfectants approved by Exact Imaging for use in this procedure, refer to Table 4)
- Soft cloths and a soft-bristled brush (such as a nail brush)
- Biopsy guide cleaning brush
- Cleaning station, including a cleaner container and a rinse container for using cleaning and solutions
- Personal protective equipment (sterile gloves, surgical mask) as recommended by the manufacturer of the cleaning agent or disinfectant

To clean the needle guide:

1. Rinse both the *needle cannula* and the *plastic enclosure* in warm running water to remove excess debris. Thoroughly rinse the back of the *plastic enclosure*, the *locking slot*, and the *needle cannula*.
2. Use a suitable brush to brush the *needle cannula* and the *plastic enclosure* in water to remove all visible residue before soaking.
3. If any residue has dried on the *plastic enclosure*, gently rub it with moist gauze, sponge or a soft-bristled brush (such as a nail brush) to completely remove the residue.

4. Use a biopsy guide cleaning brush to brush:
    - the *locking channel* where the *needle cannula* is inserted
    - the *needle cannula*
5. Prepare the cleaning solution according to the manufacturer's instructions for the selected cleaner using the dilution ratio specified. Refer to Table 4 for a list of approved cleaners.

NOTE
EN-N76

The cleaning solution may be prepared in advance of cleaning the transducer.

6. Fill the container used to clean *needle cannula* and the *plastic enclosure*, and immerse both pieces in the cleaner.
7. Expose the *needle cannula* and the *plastic enclosure* for the contact time indicated in Table 4 for the selected cleaner.
8. Thoroughly flush the *locking channel* and the *needle cannula* with the cleaner.
9. If any residue has dried on the *plastic enclosure*, gently rub it with moist gauze, sponge or a soft-bristled brush (such as a nail brush) to completely remove the residue.
10. Use a biopsy guide cleaning brush to brush:
    - the channel where the *needle cannula* is inserted
    - the *needle cannula*
11. Rinse the *needle cannula* and the *plastic enclosure* in running water following the rinsing instructions provided by the manufacturer of the cleaner.
12. Thoroughly flush the *locking channel* and the *needle cannula* with running water (refer to Figure 34 and Figure 35).

Figure 34: Locking Channel on the Plastic Enclosure

Figure 35: Needle Cannula

13. Dispose of the water used for rinsing.
14. Using a soft cloth, rough-dry the *needle cannula* and the *plastic enclosure*.
15. Dispose of the used cleaning solution.

3.3 Sterilizing the Needle Guide

Required items:

- Class B Autoclave (Steam sterilizer)

To sterilize the needle guide:

WARNING
EN-W68

Do not perform this sterilization procedure unless the cleaning procedure in section 3.2 has been performed first.

1. Refer to Table 5 to choose a validated cycle duration for a Class B autoclave.
2. Prepare the *needle cannula* and the *plastic enclosure* for sterilization according to internal clinical procedures. Wrap the *needle cannula* and the *plastic enclosure* if required for the sterilization method chosen.
3. Place the *needle cannula* and the *plastic enclosure* into the autoclave.
4. Follow autoclave manufacturer's instructions for use.
5. Remove the *needle cannula* and the *plastic enclosure*, and store both pieces according to internal clinical procedures.

3.4 Disinfecting the Needle Guide

Required items:

- Cleaner and disinfectant (For a list of cleaning agents and disinfectants approved by Exact Imaging for use in this procedure, refer to Table 4)
- Cleaning station, including a disinfectant container and a rinse container for using cleaning and solutions

NOTE
EN-N74

Ensure the high-level disinfectant to be used has not passed any of its expiry dates. Check (as applicable):

- The manufacturer's expiry date marked on the container
- The maximum allowable time after opening the container
- The maximum allowable reuse time

NOTE
EN-N75

Follow any manufacturer's instructions regarding verification of minimum effective concentrations.

To high-level disinfect the biopsy needle guide:

WARNING
EN-W68

Do not perform this sterilization procedure unless the cleaning procedure in section 3.2 has been performed first.

1. Prepare the high-level disinfectant according to the concentrations recommended by the manufacturer. Refer to Table 4 for a list of approved disinfectants.
2. Fill the container used to disinfect the *needle cannula* and the *plastic enclosure*, and immerse both pieces in the high-level disinfectant.
3. Expose the *needle cannula* and the *plastic enclosure* according to the instructions for use provided by the manufacturer of the high-level disinfectant listed in Table 2.
4. Thoroughly flush the *locking channel* and the *needle cannula* with the high-level disinfectant.
5. Fill the rinse container with a sufficient volume of sterile water or tap water to immerse the *needle cannula* and the *plastic enclosure*.
6. Rinse the *needle cannula* and the *plastic enclosure* with sterile water or tap water, unless otherwise indicated by the manufacturer's instructions.
7. Rinse the *needle cannula* and the *plastic enclosure* in large volumes of fresh water, following the manufacturer's rinsing instructions for the high-level disinfectant that was used.

WARNING
EN-W39

Ensure no residual disinfectant remains on the needle cannula and the plastic enclosure after disinfection. This could cause serious side effects for the patient.

Three separate large volume rinses are required.

8. Thoroughly flush the *locking channel* and the *needle cannula* with running water (refer to Figure 34 and Figure 35).

9. Check the *locking channel*, the *needle cannula* and the *plastic enclosure* for any residual organic material.

   If any is present, repeat all steps for cleaning and disinfecting *needle cannula* and the *plastic enclosure*.

3.5 Inspecting the Needle Guide after Reprocessing

Inspect the EV29L reusable transrectal needle guide for signs of deterioration after every application of the reprocessing procedure.

Look for:

- Cracks in the *plastic enclosure* (there should be none)
- *Needle cannula* should fit snugly in the locking channel/plastic enclosure after turning the locking pin (it should not be loose)
- There should be no difficulty attaching the EV29L reusable transrectal needle guide to the EV29L transducer
- The needle should be visible when performing the needle guide alignment check procedure in Chapter 5, section 2.1.2

Over time cleaning and disinfecting the needle guide may cause discoloration. Discoloration does not affect the performance of the needle guide; however, if considerable discoloration is observed over a period of approximately six months, contact Technical Support using the contact information in Appendix C.

4 Disposing of Consumed Cleaning and Disinfection Materials

Dispose of used cleaning materials as per internal clinical procedures for safe disposal. Do not exceed the maximum reuse period or expiry dates for any cleaning or disinfecting chemicals. Dispose of cleaning and disinfecting chemicals after the reuse period indicated by the manufacturer.

Chapter 5 Caring for the EV29L Transducer

Caring for ExactVu transducers includes careful handling, maintenance, reprocessing (as described in Chapter 4).

1 Careful Handling of the EV29L Transducer

In order to prevent damage, the EV29L transducer must be handled carefully at all times. This includes:

- During use
- While performing the reprocessing procedure
- While performing maintenance activities
- During storage

Follow these guidelines when handling the EV29L transducer:

- Keep the transducer cable away from the system's *castors* when the ExactVu system is being moved
- Do not kink or acutely bend the cable
- Handle the transducer connector with care and always use the *transducer connector cover* when it is not connected to the ExactVu system
- Do not let any part of the transducer impact or drop onto a hard surface

2 Maintenance of ExactVu Transducers

2.1 Inspecting the Transducer

The EV29L transducer must be checked regularly to maintain a high level of safety and performance. Exact Imaging recommends an inspection procedure that consists of two parts:

- Visual inspection
- Check the needle guide alignment

2.1.1 Visual Inspection of the EV29L Transducer

Perform a visual inspection of the EV29L transducer every three months.

What to look for	Where to look
Cracking (there should be none)	Transducer handle
Scratches (there should be none)	• Imaging surface (lens) • Transducer handle
Bulging (there should be none)	Imaging surface (lens)

What to look for	Where to look
Cracking or gap opening (there should be none)	• Transducer strain relief • Connector strain relief (at connection to cable) • Connector strain relief (at connection to connector) • Entire length of transducer cable
Gap (there should be none)	Top of the connector, near the lock knob
Scratches on the contact pads (there should be none)	EV29L connector, at the interface to the ExactVu system cart (near the locking pin)
Cracking or scratches	Needle guide channel

Table 6: EV29L Transducer Inspection

If you observe mechanical damage during the visual inspection, contact Technical Support using the contact information in Appendix C.

WARNING
EN-W80

The use of damaged transducers may cause the reprocessing procedure in Chapter 4 to be ineffective.

If the transducer shows any sign of damage, do not use the transducer. Contact Technical Support using the contact information in Appendix C.

2.1.2 Checking the Needle Guide Alignment for the EV29L Transducer

The procedure to check the alignment of the needle guide consists of comparing the alignment of the biopsy needle in the *needle guide* with the *needle guide overlay* displayed on the ExactVu system's *imaging screen*. Exact Imaging recommends checking the needle guide alignment when improper alignment is suspected.

Required equipment:

- Tank of water
- Biopsy needle
- Needle guide for use with the EV29L transducer

To check the needle guide alignment:

1. Fill a suitable tank with water.
2. Attach the needle guide to the EV29L transducer using the procedure on page 25.
3. Turn on the ExactVu system and connect the EV29L transducer.
4. Immerse the EV29L transducer's *imaging surface* into the water.

CAUTION
EN-C25

Do not immerse the EV29L transducer beyond its soak level.

5. Start imaging to produce an image on the monitor.
    - Use the *Gain* knob to adjust the gain as required.

6. Using the ExactVu system's *Workflow* touch screen, enable *Biopsy sub-mode*. Press **OFF** to toggle *Needle Enhancement* off.

NOTE
EN-N82

Refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* for information about set-up and operation for the ExactVu system.

7. Insert the biopsy needle into the needle guide. Align the markings on the needle to the needle guide entrance, and observe the *needle guide overlay* on the image.

   The needle tip on the image should align with the corresponding marking on the *needle guide overlay*.

If the alignment is not acceptable, contact Technical Support using the contact information in Appendix C.

WARNING
EN-W48

The *needle guide overlay* provides an indication of the expected needle path. The needle tip echo should be monitored at all times to identify any deviation from the desired path.

WARNING
EN-W41

After checking the EV29L needle guide alignment, the reprocessing procedure in Chapter 4 must be performed prior to using the transducer in a procedure. If applicable, the reprocessing procedure in Chapter 2, section 2.2.2.4 on page 15 must be performed prior to using the reusable transrectal needle guide in a procedure.

2.2 Storing the EV29L Transducer

EV29L transducers may be stored in the transducer holders on the front of the ExactVu system cart.

WARNING
EN-W22

Before putting a reprocessed transducer into the transducer holder on the ExactVu system cart, ensure the holder is clean to avoid the risk of cross-contamination.

WARNING
EN-W79

To avoid the risk of cross-contamination, never store a transducer in the transducer holder on the ExactVu system cart unless the transducer has been reprocessed as described in Chapter 4.

CAUTION
EN-C36

When storing a transducer in the transducer holder, ensure the cable does not get twisted.

To store the EV29L transducer on the ExactVu system cart:

1. Place the clean and dry transducer in one of the transducer holders.
2. Guide the slack part of the cable through the cable guide.

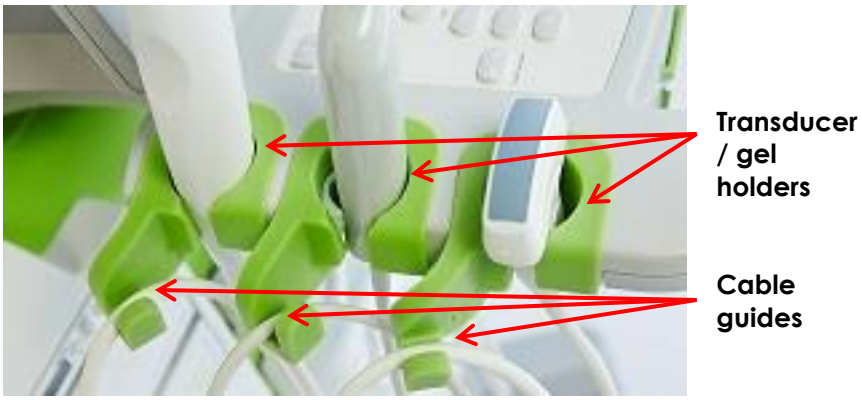

Figure 36: Transducer / Gel Holders and Cable Guides

To store the EV29L transducer in its shipping package:

1. Connect the *transducer connector cover* to the *transducer connector*.
2. Place the *transducer connector* inside the shipping package.
3. Straighten the transducer cable, and then place the transducer in the shipping package.
4. Place the transducer cable inside the shipping package, ensuring that no part of the cable is twisted.

To package the EV29L transducer for returning to Exact Imaging:

1. Follow the complete procedure for cleaning and disinfecting the EV29L transducer provided in provided in Chapter 4.
2. Follow the instructions provided above for storing the EV29L transducer in its shipping package.
3. Seal the shipping package with packing tape.
4. Contact Technical Support using the contact information in Appendix C to obtain an RMA (Return Material Authorization) number. The RMA number must appear on the shipping label.

Follow these guidelines when storing the EV29L transducer:

- Make sure that the transducer is clean and dry before storing it
- Refer to *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* for environmental conditions for storage
- Store the transducer separately from other instruments so it won't get damaged accidentally

CAUTION
EN-C38

To prevent damage during storage and transportation, keep the transducer within the temperature range specified in the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*.

Follow these guidelines when transporting the EV29L transducer:

- Do not transport the transducer without the *transducer connector cover* attached
- Do not allow debris or moisture come in contact with the contact pads on the *transducer connector*

CAUTION
EN-C37

To prevent damage, Exact Imaging recommends securely packaging transducers during transportation.

Chapter 6 Service and Repair

1 Working Life of ExactVu Transducers

The EV29L transducer, when used with proper care, is designed for a working lifetime of whichever comes first of 5 years or 2500 reprocessing cycles. The working lifetime for Exact Imaging transducers is based on their ability to withstand the effects of cycles of the reprocessing procedure without degrading functionality or compromising safety. Therefore, the lifetime is determined beginning when the transducer is first reprocessed.

Where internal clinical procedures are not already in place for tracking the number of reprocessing cycles performed on a device, Exact Imaging recommends the use of a tally marking system for the EV29L transducer.

2 Technical Support

If problems arise with the EV29L transducer or other ExactVu accessory and it does not perform as expected, contact Technical Support using the contact information in Appendix C.

3 Disposal of the EV29L Transducer

When the EV29L transducer reaches the end of its working life, national rules for discarding/recycling the relevant material in each individual country must be followed.

If further information is required regarding disposal of the ExactVu system and its accessories, contact Technical Support using the contact information in Appendix C.

4 Disposal of the Transperineal Stepper

When the transperineal stepper reaches the end of its working life, national rules for discarding/recycling the relevant material in each individual country must be followed.

If further information is required regarding disposal of the transperineal stepper, contact Technical Support using the contact information in Appendix C.

Appendix A Template Grid Holder Height Check

In order to maintain the expected performance of the *MTT Universal Stepper* in transperineal procedures, Exact Imaging recommends checking the vertical height setting of the template grid holder annually, or when improper alignment (due to needle misalignment with the *Transperineal Grid*) is suspected, or when the stepper parts are fully disassembled.

To verify the template grid holder height:

1. Perform a visual inspection to check if the *template grid holder* is set to the height corresponding to the 8th pin (refer to Figure 37), and centered (refer to Figure 38).
2. If adjustment is needed proceed to step 3, otherwise proceed to Appendix B, and perform the *needle path alignment check*.
3. Refer to the manufacturer's instructions for information about making basic adjustments to the transperineal stepper.
4. Using the appropriate hex driver, loosen the screws securing the *template grid holder* (refer to Figure 11).
5. Shift the *template grid holder* upwards until it is set to the height corresponding to the 8th pin (refer to Figure 37).
6. Adjust the horizontal position of the *template grid holder* until it is centered between the arms of the *template grid holder* (refer to Figure 38).

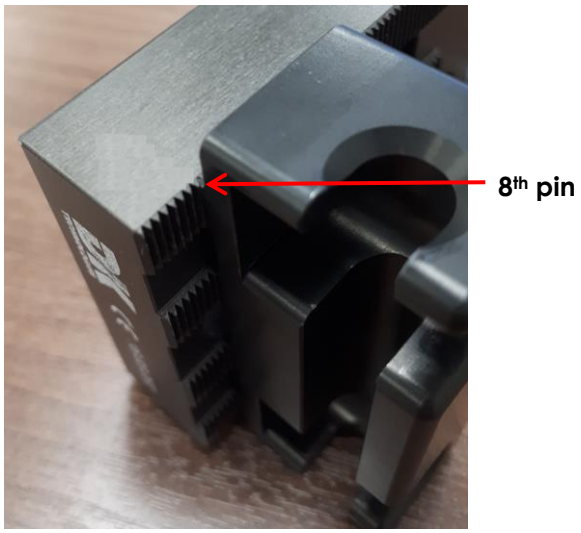

Figure 37: Template Grid Holder at 8th Pin Position

Figure 38: Centered Template Grid Holder

WARNING
EN-W64

After checking the vertical height of the template grid holder, the reprocessing procedure referenced in Chapter 3, section 2.5.4 on page 19 must be performed prior to using the stepper in a procedure.

Appendix B Needle Path Alignment Check for the Transperineal Stepper

In order to maintain the expected performance of the *DK Technologies Universal Stepper* in transperineal procedures, Exact Imaging recommends verifying that the path of the needle through the template grid holder is accurate compared to the on-screen *Transperineal Grid*. Exact Imaging recommends checking the needle path alignment annually, when improper alignment (due to needle misalignment with the Transperineal Grid) is suspected, or when the stepper parts are fully disassembled.

The procedure to check the needle path alignment consists of the following actions:

- Verifying in the sagittal view that the *template grid holder* is set to the correct vertical height and is centered correctly
- Verifying in the transverse view that the *template grid holder* is set to the correct vertical height and is centered correctly

Refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System* for details about using the controls on the ExactVu system.

To check the needle path alignment:

1. After performing the template grid holder height check described in Appendix A, clamp the transducer into *transducer cradle*.
2. Create a water bath as follows:
    - Fill a 33 cm x 19 cm (13" x 7.5") container with distilled water
    - If required, a piece of rubber or similar material that is the same width as the container may be placed at the front of the container (to secure the needle tip)

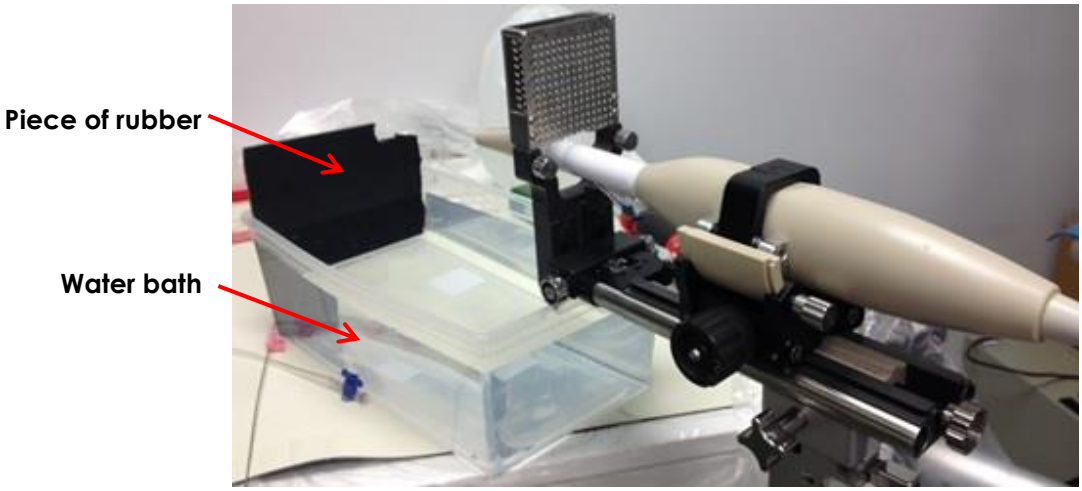

Figure 39: Water Bath Configuration

3. Advance the transducer along the *tracking stepper rail* to the point shown in Figure 40.

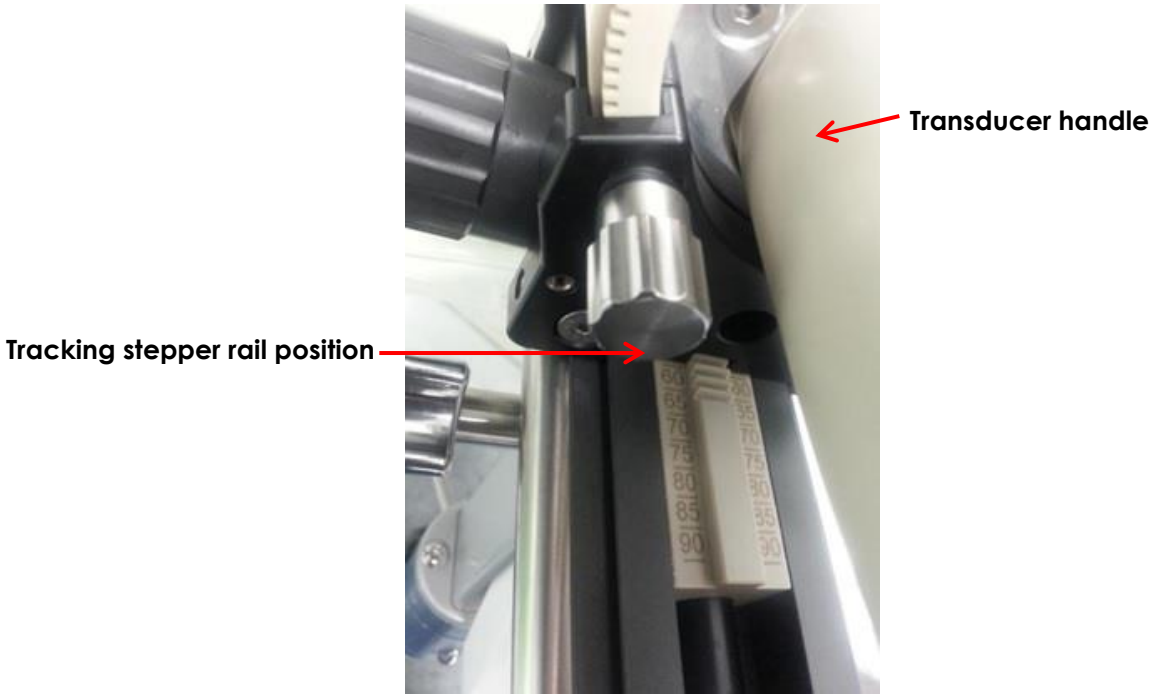

Figure 40: Tracking Stepper Rail Position

4. Tilt the transducer and place it in the water bath as shown in Figure 41.

Figure 41: Transducer and Transperineal Stepper in Water Bath

5. Begin imaging in 2D Mode and observe the *Angle* in the status panel. Adjust the tilt of the transducer as required until the *Angle* is in the range 87 – 93 degrees.

To check the vertical height of the transperineal stepper in 2D Mode:

1. Set up a test patient using the Medium *image preset*.
2. In 2D Mode, enable the *Transperineal Grid* (refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*).

3. Rotate the transducer in the transducer receptacle such that it sits in the *zero notch*.
4. Advance a needle through location D2.5 on the *template grid*. (If required, secure the tip of the needle in the piece of rubber for increased measurement accuracy.)

WARNING
EN-W82

For transperineal procedures, always point the bevel of the needle (i.e., the sharpest point) away from the transducer.

If the needle is pointed toward the transducer and is inserted through the shallower needle entrances (i.e., the lowest numbered needle entrances) of the EV29L sterile transperineal needle guide, it is possible for the needle to injure the patient's rectum as well as to scratch or cause other damage to the transducer lens.

When using the shallower needle entrances take extra caution to track the full path of the needle to ensure any needle deflection is away from the rectum as well as from the transducer lens.

5. Using the *Distance* measurement tool, measure the distance between the center of the needle (i.e., the bright area in the image) and the center of the *Transperineal Grid* needle guides representing the expected trajectory for the needle in the D2.5 location.

   A measurement of 0.3 cm or less is an acceptable result.

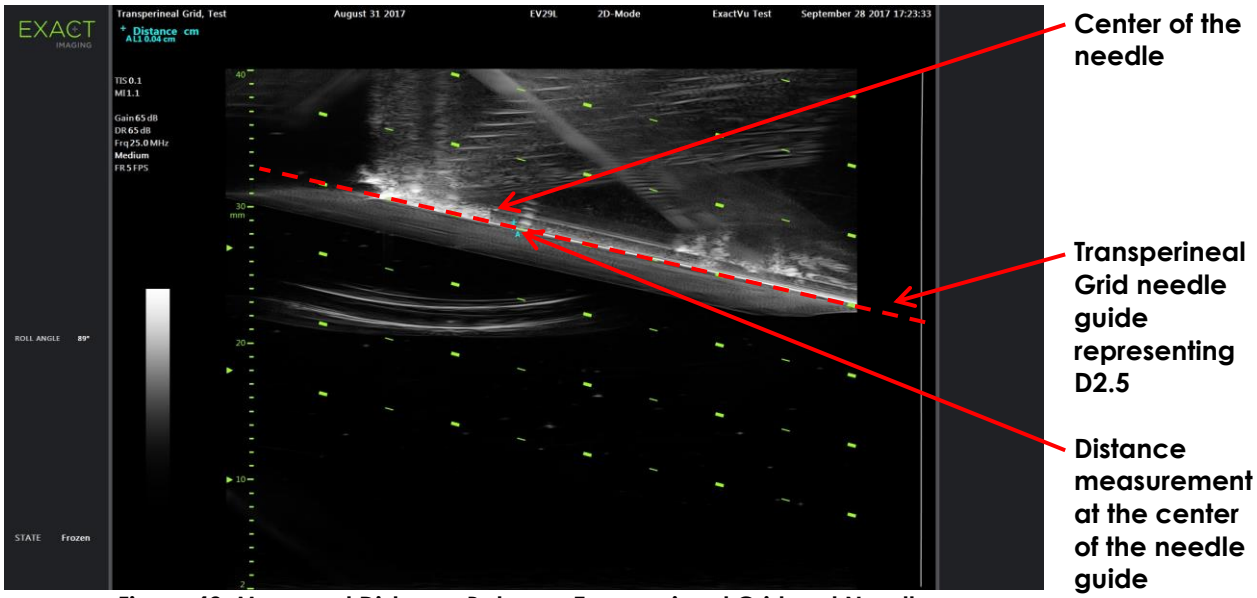

Figure 42: Measured Distance Between Transperineal Grid and Needle

To check the vertical height of the transperineal stepper in Transverse Mode:

1. Set up a test patient using the Medium *image preset*.
2. In 2D Mode, enable the *Transperineal Grid* (refer to the *Operation and Safety Manual for ExactVu™ High Resolution Micro-Ultrasound System*).
3. Rotate the transducer in the transducer receptacle such that it sits in the *zero notch*.
4. Advance needles through locations e1.5 and b1.5 on the *template grid*. (If required secure the tip of the needle in the piece of rubber for increased measurement accuracy.)

WARNING
EN-W82

For transperineal procedures, always point the bevel of the needle (i.e., the sharpest point) away from the transducer.

If the needle is pointed toward the transducer and is inserted through the shallower needle entrances (i.e., the lowest numbered needle entrances) of the EV29L sterile transperineal needle guide, it is possible for the needle to injure the patient's rectum as well as to scratch or cause other damage to the transducer lens.

When using the shallower needle entrances take extra caution to track the full path of the needle to ensure any needle deflection is away from the rectum as well as from the transducer lens.

5. Press **Dual/Transverse** on the *control panel*.
6. Construct a transverse image for the needle in the e1.5 location as follows:
    - Rotate the transducer to the expected location of the needle (i.e., on or near the e1.5 location on the image).
    - Gently hold the cradle only with one hand and rotate slowly.
    - Observe the needle in the image as the transverse image is constructed from right to left. (Due to motion sensor accuracy, it may be necessary to construct the image several times to get the required image.)
7. Using the *Distance* measurement tool, measure the distance between the e1.5 location on the Transperineal Grid and the brightest spot in the needle image.

    A measurement of 0.3 cm or less is an acceptable result.

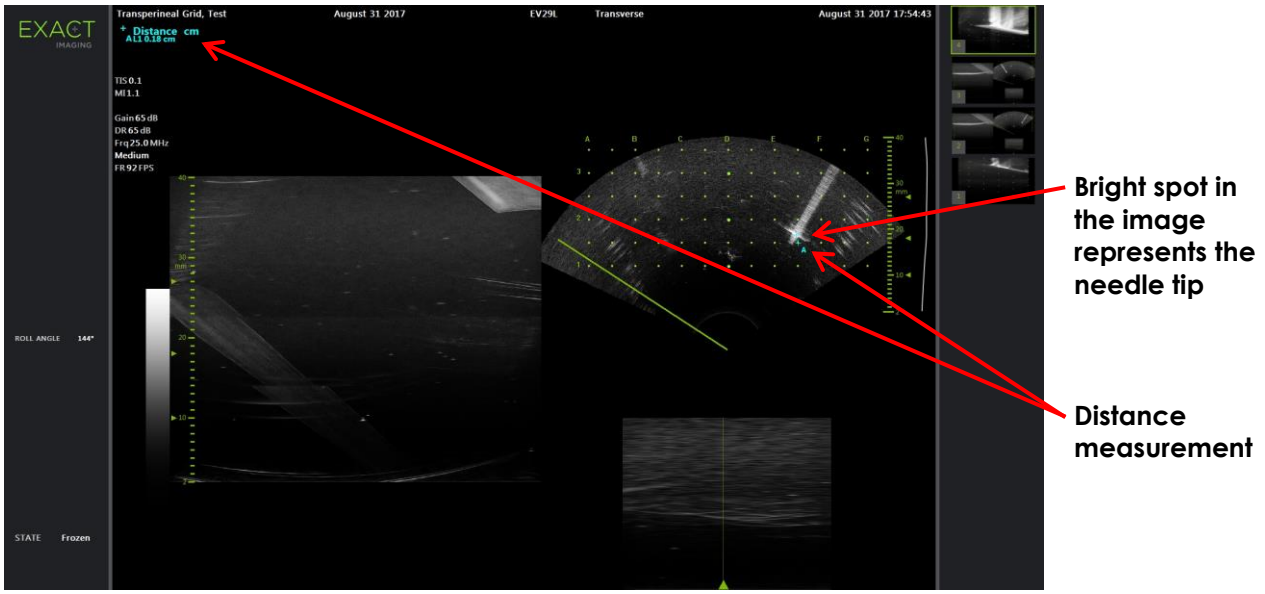

Figure 43: Measured Distance Between Transperineal Grid and Needle in Location e1.5

8. Construct a transverse image for the needle in the b1.5 location as follows:
    - Rotate the transducer to the expected location of the needle (i.e., on or near the b1.5 location on the image).
    - Gently hold the cradle only with one hand and rotate slowly.

- Observe the needle in the image as the transverse image is constructed from left to right. (Due to motion sensor accuracy, it may be necessary to construct the image several times to get the required image.)

9. Using the *Distance* measurement tool, measure the distance between the b1.5 location on the Transperineal Grid and the brightest spot in the needle image.

   A measurement of 0.3 cm or less is an acceptable result.

If the measured values are outside an acceptable range, contact Technical Support using the contact information in Appendix C.

WARNING
EN-W66

After checking the needle path alignment of the transperineal stepper, the cleaning, disinfection and sterilization procedure referenced in Chapter 3, section 2.5.4 on page 19 must be performed prior to using the stepper in a procedure.

Appendix C Contact Information

For Technical Support

Region	Phone number	Email address
All regions except North America – contact EDAP TMS	+33(0)472 153 150	ccc@edap-tms.com
North America (US, CA, MX) – contact EDAP USA	+1 (512) 852-9685	service@edap-usa.com

For ordering consumables and other accessories and parts

Region	Phone number	Email address
France (FR), Belgium (BE) - contact EDAP TMS	+33(0)472 153 150	order@edap-tms.com
Germany (DE), Austria (AT), Switzerland (CH) - contact EDAP TMS GmbH	+49 461 80 72 590	order@edap-tms.de
North America (US, CA, MX) - contact EDAP USA	+1 (512) 832-7956	order@edap-usa.com
All other regions - contact EDAP TMS	+33(0)472 153 150	order@edap-tms.com