



Palium Instrument

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Palium instrument instructions for use and sterilization



PALIUM Biopsy Instrument Reusable Indications for Use

Non-Sterile, Sterilize Before Use.

Description

Reusable gun for automatic core biopsy of the soft tissues, compatible only with MGK1 as single use needle (PALIUM NEEDLE). Non-Sterile.

The Palium is sold nonsterile and is to be decontaminated and cleaned prior to use by the final user.

Indications

Palium Automatic Reusable Biopsy Device is intended for use in obtaining core biopsies from soft tissues such as liver, kidney, prostate, breast, spleen, lymph nodes and various soft tissue tumors. The device is not intended for use in bone.

The extent of histological abnormality cannot be reliably determined from its mammographic appearance. Therefore the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histological abnormality (e.g. malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Contra-Indications

ATTENTION! Palium Biopsy Instrument is MR Unsafe.

The device is not intended for use in bone.

Warnings

Read all instructions before use.

The Palium Biopsy Instrument is NON-STERILE. Before use, clean and sterilize the biopsy instrument according to the Cleaning and Sterilization Instructions.

To be used only by specialized medical practitioners.

In case of patients who are receiving anticoagulant therapy or who have a bleeding disorder, good medical judgement should be applied in considering biopsy.



his Use Procedure has an informative purpose. The specialist physician is responsible for the proper aseptic procedure and biopsy techniques to be used with this device according to his familiarity with the use and limitations of this instrument. Any variations in the use of this device are the responsibility of the specialist physician.

Inspect the device every time before the use. If the device present signs of deterioration and/or damage (pitting, blistering, separation of coating, cracking) DO NOT USE. Verify the correct operation of safety before use.

Precautions

The user of the product should be a physician who is familiar with the indications, contra-indications, limitations, typical results and possible side effects core needle biopsy, in particular, those relating to the specific organ being biopsied.

The collection of multiple samples may help to ensure the detection of any cancer tissue. A “negative” biopsy in the presence of suspicious radiographic findings does not preclude the presence of carcinoma.

Do not test the device while the needle is in the instrument. This could result in needle damage and/or patient/user injury.

The introduction of the needle into the body should be carried out under imaging guidance.

Unusual force applied to the stylet or unusual resistance against the stylet, while extended out of the supportive cannula may cause the stylet to bend at the specimen notch. A bent specimen notch may interfere with needle function.

Used medical devices have a high contamination risk. Use extreme caution to avoid accidental puncture. Treat the medical devices as contaminated hospital waste.

Dispose in applicable laws and regulations.

Use

Palium Instrument can be used for 2000 shots (approximately one year of use) without incurring deterioration. At this point of use, it is recommended to carefully inspect the instrument for signs of damage and deterioration prior to use.

Equipment Necessary

Proper imaging modality accessories

Surgical gloves and drapes

Local Anesthetic

Scalpel

Sample collection container



Adverse Reactions

Potential complications may be associated with any percutaneous removal/biopsy technique for tissue collection. The adverse reactions associated with core biopsy procedures are site specific and may include but are not limited to: hematoma; hemorrhage; infection; adjacent tissue injury; pain; bleeding; hemoptysis; hemo-thorax; non-target tissue, organ or vessel perforation; pneumothorax; and air embolism. Air embolism is a rare but serious potential complication of lung biopsy procedures. Rapid deterioration of neurological status and/or cardiac arrhythmia may be indicative of air embolism. Prompt diagnosis and treatment must be considered if the patient exhibits signs or symptoms of air embolism.

Rx Only

Federal (USA) law restricts this device to sale by or on the order of a licensed physician. To be used only by specialized medical practitioners.

The specialist physician is responsible for the proper aseptic procedure and biopsy techniques used with this device; any variations in the use of this device are the responsibility of the specialist physician.

PALIUM Directions for Use

A. How to Prepare Palium Biopsy Instrument

Refer to the provided directions for reprocessing (cleaning, lubrication and sterilization) of the Palium Instrument. Once the reprocessing steps have been performed:

1. Remove the instrument from its sterilization package by using aseptic technique.
2. It is suggested to hold the instrument in the palm with the fingers on the white recessed part. **(See Figure 1)**

Apply a force on the trigger by using the fingers twice, pushing the white recessed part toward the palm of the hand, until both sleds are fully engaged. Palium is provided with two indicators, a change in the color of the distal indicator represents the cannula being loaded; the proximal indicator represents the stylet. **(See Figures 2A and 2B.)**



3. Test the functionality of the device by switching the safety lever from a horizontal position to a vertical position (hold instrument with the white recessed part on the bottom). Push the release button to activate the instrument. Once released, the safety lever will automatically return into the safe position.

4. Recharge the instrument by loading both sliders (cannula and stylet).

5. Select the appropriate penetration depth of 22mm or 15mm by moving the lever on the back of the instrument.

CAUTION: ONCE THE SAFETY LEVER HAS BEEN MOVED, THE INSTRUMENT IS READY TO SHOOT. BE CAREFUL NOT TO INADVERTENTLY PRESS THE SHOOTING BUTTON.

The gun is now ready for use.

B. Palium Biopsy Needle Preparation

1. The needle has centimeter markings for depth measurement and is packaged with a spacer. The spacer holds the stylet and cannula in the correct position while the operator insert it either into the patient or into the Palium Device.

2. Prior to use, determine the appropriate gauge and length of the needle re-quired for the specific biopsy to be performed.

Precautions

Make sure that packaging of the disposable Palium Biopsy Needle is not opened and/or damaged before using. Remove the needle from the package and from the protective sheath using aseptic technique. Inspect the needle components for damage.

DO NOT USE if the needle components are damaged.

Note: The tip is made with a slight back bend. This is not a defect.



C. Biopsy Procedure

The biopsy procedure must be performed using appropriate aseptic technique and appropriate preparation of the site.

1. The procedure must be performed following the proper preparation of the site.

Anesthesia should be utilized before the incision of the skin.

Recommendation: In order to ease the insertion of the needle, puncture the skin with a scalpel at the entry site.

2. Needle Loading and Positioning:

A) With the Palium Biopsy Instrument fully charged insert the selected Biopsy Needle: open the cover of the energized (cocked) instrument. Align the holes of the needle with the holders of the loading slides of the instrument. Partially close the cover to maintain the position of the needle hubs. Pull the spacer to remove it and close the cover. Introduce the needle, under imaging control where appropriate, through the incision until the needle point is proximal to the area to be biopsied.

B) With Palium biopsy needle and spacer only: introduce the needle with the spacer possibly under ultrasound guidance through the incision until the tip of the needle is near the site of biopsy. Once the position is confirmed, attach the loaded Palium gun. Taking care to maintain the orientation of the needle, align the holes of the needle with the holders of the loading slides of the instrument. Partially close the lid to keep the needle pins in place. Remove the spacer from the needle by holding the Palium device firmly. Close the lid.

3. While maintaining the instrument position and needle orientation, move the safety lever to get the instrument ready to actuate the biopsy and push the trigger button to release the cannula and the stylet.

4. Remove the instrument and needle from the patient.

Note: It is not necessary to take the needle out of the instrument to retrieve the core tissue specimen.

5. In order to expose the sample, pull back the white slide once. Doing this movement the cannula will be loaded and the indicators will be of two different colors. The notch located at the distal end of the needle will be exposed, together with the specimen. Remove the sample.

6. Fully load the instrument by pulling the white slide one more time. Both of the status indicators will be the same color now (see Figure 2.B). This movement will activate the device for a second biopsy.

After one biopsy, if it is necessary to collect more samples, always evaluate the integrity of the needle and inspect for damage before starting another biopsy. Do not use the needle if any imperfection is noted.



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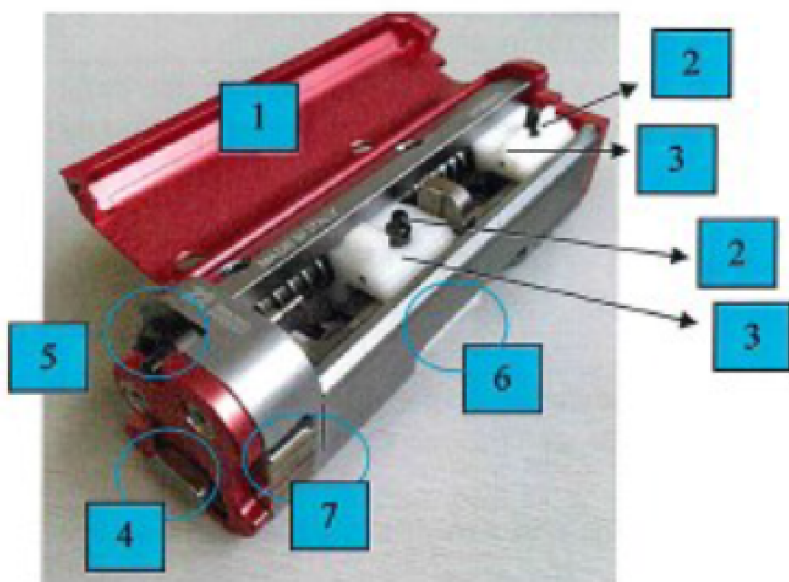
7. If additional biopsies are not needed, remove the needle by opening the instrument cover and re-inserting the spacer.

8. Remove the coaxial (if present) and discard the used needles in the appropriate biohazard container according to the specific hospital procedures

9. If the biopsy needle is equipped with NeedleVISE®, insert the tip into the NeedleVISE® and dispose in the appropriate container according to the specific hospital procedures.

10. Clean, lubricate and sterilize Palium™ Biopsy Instrument prior to every use according to the instructions.

Device illustration



- 1. Cover
- 2.. Needle hooking pins
- 3. Anchoring pin
- 4. Safety
- 5. Notch length lever
- 6. Loading carter
- 7. Shooting button



D. Warranty

The device is guaranteed for one year of use (comparable to a maximum of 2000 biopsies). At the end of the year, the doctor is required to provide the device to MDL to renew an additional year of warranty.

After the second year of warranty (refurbished), the responsibility for the integrity of the device and its proper functioning is charged for an assessment of the user.

Even after the two-year warranty, MDL still offers the availability for a review of the device and its possible repair. The assessment of the correct state of the de-vice before each biopsy remains with the user. The user is required to disclose to MDL eventual disposal of the device.



PALIUM Reusable Biopsy Device Cleaning and Sterilizing Instructions



1. PALIUM Reusable Biopsy Device Cleaning and Sterilizing Instructions

This document contains the instructions for the process of cleaning and sterilization of Palium Automatic Reusable Biopsy Device.

Palium Automatic Reusable Biopsy Device is a non-sterile, reusable device intended to be sterilized prior to each use. Palium Biopsy Device is for use in obtaining core biopsies from soft tissues such as liver, kidney, prostate, breast, spleen, lymph nodes and various soft tissue tumors.

2. The Palium Automatic Reusable Biopsy Instrument must be reprocessed according to the following instructions due to the potential for the Instrument to come in contact with tissue, blood, or bodily fluids during its use with biopsy needles.

REPROCESSING WARNINGS:

DO NOT use 2% glutaraldehyde or other bacterial solutions.

DO NOT use highly alkaline or highly acidic cleaners.

DO NOT clean with concentrated chlorhexidine gluconate or any other agent containing alcohol.

DO NOT sterilize by irradiation.

DO USE appropriate personal protective equipment as dictated by facility protocol during the cleaning steps.

3. MANUAL CLEANING METHOD

Re-Usable Biopsy Device (Instrument) Preparation

Remove and discard the Biopsy needle assembly. Further disassembly of the PALI-UM Biopsy Instrument is not recommended.

NOTE: To simplify reprocessing, set the PALIUM Biopsy Instrument in the 22mm position with the lid (cover) open. This setting will provide better access to the areas for cleaning.



4. Initial Cleaning:

Perform Initial Cleaning at Point of Use as follows:

Prepare a rinse bath with cool tap water to completely cover the instrument.

With the lid (cover) open, rinse the instrument by:

- a) agitating the instrument under the water level;
- b) bringing the instrument above the water level;
- c) re-immersing the instrument under the water level.

Repeat this process until there is no visible evidence of contamination and tissue debris in the rinse.

5. **Warning: The instrument should not be rinsed under running water as this may cause splashing and contamination of user.**

6. Enzymatic Pre-Soak Process:

Following the manufacturer's instructions prepare the enzymatic cleaner solution: using warm tap water, prepare sufficient volume of multi-tiered enzymatic at 0.3% (3 mL/L water) for Septozym EC (an aqueous alkaline surfactant and enzyme mixture), to completely cover the PALIUM Biopsy Instrument. Allow the PALIUM instrument with the lid (cover) open to soak in the cleaner for a minimum of 30 minutes at room temperature.

Use a sterile syringe to introduce and flush the cleaning solution to the hard-to-reach areas (e.g., crevices, threads) of the instrument interior and exterior surfaces.

Actuate the device while it is still in the solution to reach the most hidden areas of the instrument.

7. Manual Cleaning Procedure:

While holding the instrument under the solution level and using a soft-bristle brush, brush all accessible surfaces inside and out for a minimum of one (1) minute with the enzymatic solution to remove blood and/or debris. Pull and hold the white cocking slide back once and brush the inside of the device for one (1) additional minute to ensure the brush reaches all accessible areas inside the device.



8. Rinse Process:

Prepare a rinse bath with cool tap water to completely cover the instrument. With the device lid (cover) open, rinse the instrument by:

- a) agitating the instrument under the water level;
- b) bringing the instrument above the water level;
- c) re-immersing the instrument under the water level.

Repeat this process until there is no visible evidence of the cleaning solution. Actuate the instrument while in the rinse water to ensure the rinse water reaches the hidden areas of the instrument interior and exterior surfaces.

Alternately, the complete rinse procedure may be performed using demineralized (deionized) running water.

9. Warning: The instrument should not be rinsed under running water as this may cause splashing and contamination of user.

10. Device Drying

Position the Palium instrument on a soft sterile wipe to drain.

11. Visual Inspection:

After drying the Palium Instrument visually inspect the instrument in an area that is well lit. Visually verify all debris or contamination has been removed. Repeat the cleaning process steps if there is evidence of specimen stain or contamination on the interior or exterior of the instrument.

It is necessary to dispose of the instrument if damage or deterioration appearing as corrosion, discoloration, pitting or cracked seals is noted during the cleaning inspection.

12. Device Lubrication:

The manufacturer, MDL Srl, recommends the PALIUM Biopsy Instrument be cleaned and lubricated after every use to enhance the performance and longevity of the instrument. Silicone free, quality medical grade lubrication compatible with steam sterilization should be used to lubricate the PALIUM Biopsy Instrument (e.g. Aescu-lap® Sterilit® I Oilspray JG 600, Miltex® Spray Lube 3-700, Weck®-Lube Concentrate #850150).



Refer to appropriate manufacturer's instructions for the use of the selected lubricating agent. Ensure that all moving parts of the PALIUM Biopsy Instrument are lubricated.

STEAM STERILIZATION INSTRUCTIONS:

13. WARNINGS

Before the sterilization of PALIUM Biopsy Instrument, the device should be properly cleaned, lubricated and placed in single self-sealing pouches constructed of a multilayer material, medical grade paper – PE /PET plastic film for steam sterilization (Packed) in accordance with the pouch Instructions for Use.*

*FDA-cleared sterilization packaging materials per 21CFR880. Sterilization packaging should be cleared and labelled for the same sterilization parameters specified for Pali-um Instrument.

During sterilization PALIUM Biopsy Instrument must be in the 22mm position and not cocked, energized or actuated.

14. Biological Indicator and/or steam integrators should be used within the sterilizer load to ensure the proper sterilization conditions of time, temperature, and saturated steam have been met. To ensure effectiveness, sterilization process should be properly validated and monitored with the proper biological controls.

15. The following 'worse case' sterilization cycle using an autoclave vertical loading model ATV 80 (Medline Italia brand) was used in the cleaning validation of the Pali-um Re-usable Automatic Biopsy Device provided sterile devices.

16.

	Parameters for the process of sterilization:
Time	10 minutes
Temperature	134°C ± 3°C
Pressure	2 Bar
Dry-Time	30 minutes
Sterilization Typology	Gravity



17. NOTE: the parameters used are chosen as worst case between the different one normally adopted for steam sterilization processes in hospital environment.

The 'worse case' sterilization cycle performed using an autoclave vertical loading model ATV 80 (Medline Italia brand) used in the Sterilization and Cleaning validation of the Palium Re-usable Automatic Biopsy Device provided sterile devices.

Note: Verify the sterilization pouch selected for the Palium Instrument is approved and compatible with the specified sterilization cycle listed above.

18. Sterilization process steps:

Thoroughly clean, dry, and visually inspect the device.

Palium Instrument must not be assembled with any disposable biopsy needle during sterilization. Further disassembly of the instrument is not recommended.

Insert the device in the single self-sealing pouch constituted by multilayer material medical grade paper – PE /PET plastic film suitable for steam sterilization (sterilization packaging system that has been cleared by FDA).

Place the pouched Palium Instrument inside the autoclave.

Activate the autoclave setting the parameters listed in the above table.

The sterilization process will last for 10 minutes.

Once the sterilization is over, wait 30 minutes before taking the instrument out to let it dry. Wait 30 minutes to let the Palium Instrument cool down at room temperature.

Warning:

Before use, inspect the sterilization pouch for damage. Re-pouch and re-sterilize the instrument if the sterile barrier has been damaged.

Prior to use in the biopsy procedure, remove the Palium Instrument from the sterilization pouch. Inspect the Instrument for functionality and integrity before use. If the Palium Instrument fails to activate or load the biopsy needles, notify the manufacturer for technical assistance.



Note: The aforementioned reprocessing steps were validated and are recommended in accordance with applicable industry standards such as: EC1-2011 UNI EN ISO 11737 – 1, UNI EN ISO 11737 – 2, AAMI TIR 12, AAMI TIR 30, Guidance for Industry and FDA Staff, EN ISO 15883-1, ISO TS 15883-5 and ISO17664.

19. For additional information on cleaning, lubrication and sterilization, or technical assistance, contact MDL Srl +39 0342 682130 Fax +39 0342 691316 and visit www.mdlsrl.com

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