BK Medical

Laparoscopic Transducer
User Guide

Types 8666 and 8666-RF

English
BB0532-I
November 2010

CE 0543

we specialize because you do

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Laparoscopic Transducer Types 8666 and 8666-RF

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Introduction

This is the user guide for Laparoscopic Transducer Types 8666 and 8666-RF and must be used together with *Care, Cleaning & Safety* which contains important safety information.

8666 and 8666-RF are intraoperative transducers for laparoscopic ultrasound.

Note: It is important that users read the user guide in its entirety and familiarize themselves with the operations of Laparoscopic Transducer Types 8666 and 8666-RF and their biopsy system before use.

WARNING

Do not use the transducer for applications where it may come in direct conductive contact with the patient's heart.

FDA WARNING for the United States of America

Types 8666 and 8666-RF should **not** be used for fetal examinations.

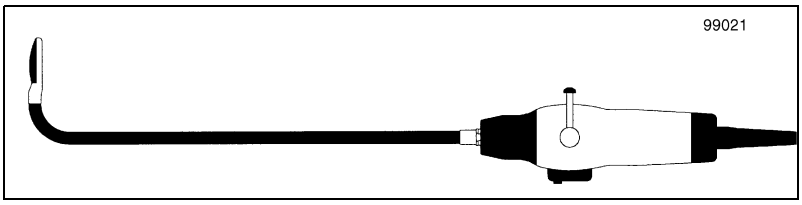

Fig. 1. Laparoscopic Transducer Types 8666 and 8666-RF

Scanning Plane

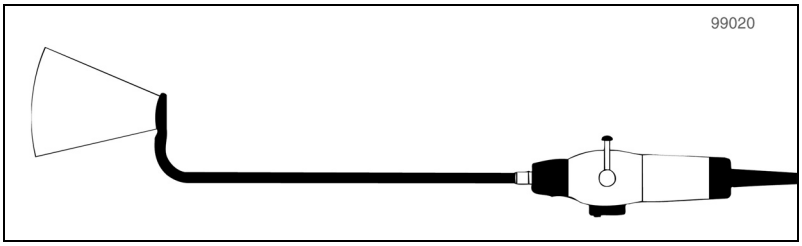

Fig. 2. Scanning plane of the transducer Types 8666 and 8666-RF

General Information

Product specifications for this transducer can be found in the Product Data sheet that accompanies this user guide.

WARNING

If at any time the scanner malfunctions, or the image is severely distorted or degraded, or you suspect in any way that the scanner is not functioning correctly:

- *Remove all transducers from contact with the patient.*
- *Turn off the scanner. Unplug the scanner from the wall and make sure it cannot be used until it has been checked.*
- *Do not remove the scanner cover.*
- *Contact your BK Medical representative or hospital technician.*

WARNING

Always keep the exposure level (the acoustic output level and the exposure time) as low as possible.

Service and Repair

WARNING

Service and repair of BK Medical electromedical equipment must be carried out only by the manufacturer or its authorized representatives. BK Medical reserves the right to disclaim all responsibility, including but not limited to responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties. After service or repairs have been carried out, a qualified electrical engineer or hospital technician should verify the safety of all equipment.

Caring for the Transducer

The transducer may be damaged during use or processing, so it must be checked before use for cracks or irregularities in the surface. It is important to check the black rubber cover over the 2 rocker switches on the transducer handle and the articulation joint on the flexible tip of the transducer to make sure that there are no defects in these areas. It should also be checked thoroughly once a month following the procedure in *Care, Cleaning & Safety.*

Cleaning and Disinfection

To ensure the best results when using BK Medical equipment, it is important to maintain a strict regular cleaning routine.

Full details of cleaning and disinfection procedures can be found in the *Care, Cleaning & Safety* booklet that accompanies this user guide. A list of disinfectants and disinfection methods that the transducer can withstand are listed in the Product Data sheet.

Sterile covers are available. See the Product Data sheet for more details.

WARNING

Users of this equipment have an obligation and responsibility to provide the highest degree of infection control possible to patients, co-workers and themselves. To avoid cross contamination, follow all infection control policies for personnel and equipment established for your office, department or hospital.

Caution

Keep all plugs and sockets absolutely dry at all times.

Starting Scanning

All equipment must be cleaned and disinfected before use.

Connecting the Transducer

WARNING
Keep all plugs and sockets absolutely dry at all times.

The transducer is connected to the scanner using the array Transducer Socket on the scanner. To connect, the transducer plug's locking lever should first be in a horizontal position. Align the plug to the scanner socket and insert securely. Turn the locking lever clockwise to lock in place.

When connected the transducer complies with Type BF requirements of EN60601-1 (IEC 60601-1).

Changing Frequency

The Multi-Frequency Imaging (MFI) facility enables you to select the scanning frequency. See the applicable scanner user guide for instructions. The selected frequency is displayed at the top of the screen.

Using a Transducer Cover

If the transducer is not sterile, it must be enclosed in a sterile disposable transducer cover for intraoperative use. See the Product Data sheet for a list of available transducer covers.

Note: These sterile disposable sheaths are only for use with the transducer without its biopsy system. They cannot be used when the biopsy system is attached to the transducer.

Note: In the United States of America, it is recommended that probe sheaths have been market-cleared. In Canada, use only licensed probe sheaths.

WARNING
Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), FDA is advising health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly.

Apply sterile gel to the tip of the transducer (to cover the black scanning array) or fill the transducer cover with 1 to 2ml of sterile water. This improves the screen images by preventing image artifacts caused by air bubbles.

Pull the transducer cover over the transducer. Use a sterile lubricant to make sure the transducer does not stick in the trocar.

WARNING
Use only water-soluble agents or gels. Petroleum or mineral oil-based materials may harm the cover material.

Changing Orientation

To change the orientation of the image on the monitor, refer to the applicable scanner user guide for instructions.

Operation of Types 8666 and 8666-RF

Operation of the Flexible Tip

Transducer Controls

The flexible tip is controlled by:

- 2 levers for the orientation of the flexible tip, one on either side of the transducer handle.
- 2 rocker switches to control the action of the adjustment levers. These 2 switches are located under a black rubber cover on the underside of the transducer handle.

The Upright Position

All of the following instructions for the use of this transducer are based on it being in the upright position. This is where the 2 levers are uppermost and the 2 rocker switches are underneath, see Fig. 3.

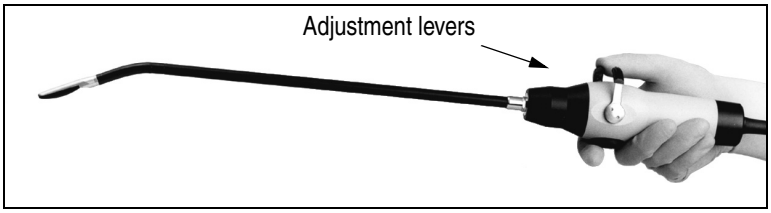

Fig. 3. Transducer Types 8666 and 8666-RF when held in the upright position

Adjustment of the Flexible Tip

The transducer is equipped with a flexible tip. This tip can be adjusted through an angle of up to 90° in 4 planes, with reference to the handle in its upright position; up, down, left and right, see Fig. 4. and Fig. 5.

The position of the tip is adjusted by 2 levers, one on either side of the transducer handle. As an extra guide, there are direction arrows on the handle, beside each lever. These give an indication of the direction of movement of the flexible tip when the corresponding lever is adjusted.

Up and Down Movement

The up and down movement of the tranducer's tip is controlled by the lever on the right-hand side of the transducer handle. Moving the lever forwards moves the tip downwards. Moving the lever backwards moves the tip upwards. See Fig. 4.

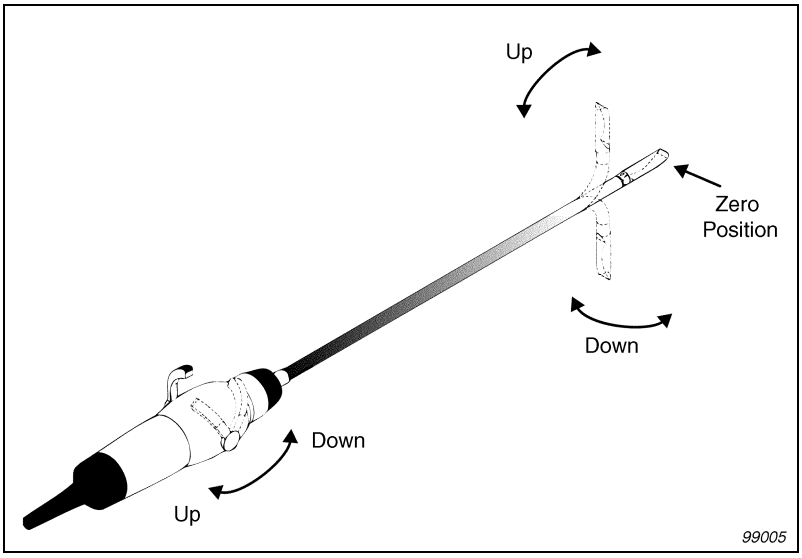

Fig. 4. Movement of the Types 8666 and 8666-RF's flexible tip. Up and down

Left and Right Movement

The left and right movement of the transducer's tip is controlled by the lever on the left-hand side of the transducer handle. Moving the lever forwards moves the tip to the left. Moving the lever backwards moves the tip to the right. See Fig. 5.

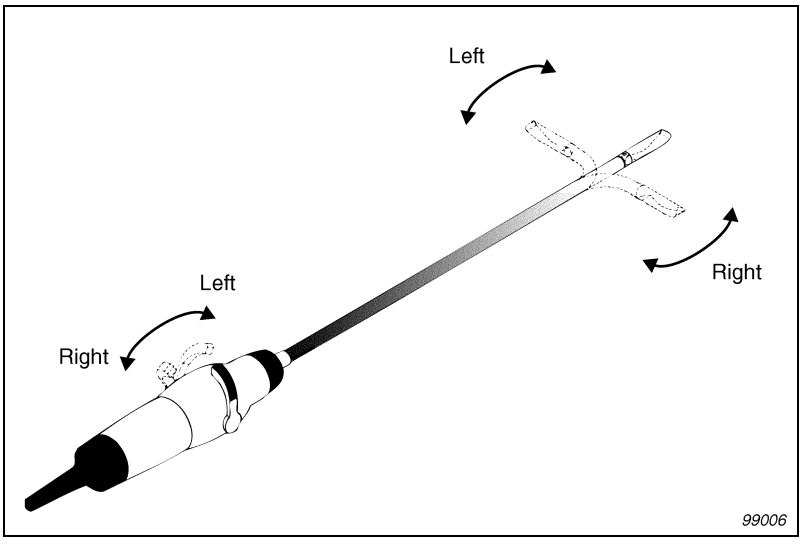

Fig. 5. Movement of the Types 8666 and 8666-RF's flexible tip. Right and left

Zero Position

Both levers have a zero position. This position is indicated by a line on the transducer's handle, between the 2 levers. When **both** the levers are adjusted to the zero position then the tip of the transducer will be in the straight, non-adjusted, zero position. See Fig. 4.

Lever Action

The action of the levers, when they are being adjusted can be switched between a ratchet action, and a smooth continuous action. Each lever has a separate rocker switch that controls its action, these switches can be used independently. They are located on the underside of the handle. The left-hand side switch controls the left-hand side lever. The right-hand side switch controls the right-hand side lever.

When a switch is pressed at the proximal end, the corresponding lever will move with a ratchet action, and the tip of the transducer will be locked between movements of the lever. When a switch is pressed at the distal end, the corresponding lever will move with a smooth action, and the tip of the transducer will not be locked between movements of the lever.

Intraoperative Scanning with Types 8666 and 8666-RF

Note: See important information about transducer covers on page 3.

WARNING

Because of the length of the transducer shaft it is possible to apply large forces to the tip of Types 8666 and 8666-RF by very small movements of the handle – if these forces are excessive they may injure the patient or cause the transducer to break.

Note: The trocar used with Types 8666 and 8666-RF when the biopsy system is NOT attached must have a minimum inner diameter of 10mm. The trocar used with Types 8666 and 8666-RF when the biopsy system IS attached must have a minimum inner diameter of 12mm.

Caution:

Metal trocars with sharp edges are not suitable for use with Types 8666 and 8666-RF as they may damage the transducer.

Prepare the patient and insert the trocar. Make sure that the flexible tip is in the zero position before starting to insert the transducer into the trocar. Hold the transducer by the handle and guide the transducer carefully into the entrance of the trocar with your other hand. Push the transducer slowly down the trocar until it is seen, using the video monitor, to touch the site of interest.

WARNING

The transducer must be in the zero position when it is removed from the trocar. Failure to do this may result in damage to the transducer's flexible sleeve.

Avoiding Damage from the Trocar Edge

The probe is typically moved back and forth and around within the trocar, and the tip of the probe is flexed. If the flexible region is too close to the trocar edge, the trocar can damage the rubber cover when the probe is flexed.

Caution

The rubber cover over the articulation joint on the flexible tip of the transducer can be damaged by the trocar if the articulation joint is too close to the edge of the trocar. The lower edge of the trocar, which is not within the surgeon's field of view, can damage the rubber cover. The trocar edge should be placed as far as possible from the area of ultrasound interest so that the straight part of the laparoscopic probe, not the flexible region, is in the open edge of the trocar. Make sure that the flexible part does not get near the sharp trocar edge.

Plastic Trocar

We recommend using a disposable plastic trocar to minimize the risk of damaging the transducer's flexible tip. If you use a metal trocar, you must be extremely careful to avoid damaging the transducer with the edges of the trocar, which are often very sharp.

Biopsy Facilities

The biopsy system is designed for intraoperative biopsy with Types 8666 and 8666-RF and two types of biopsy are possible: **cytological** and **histological**.

The system is illustrated below for 8666 and for 8666-RF.

WARNING

The biopsy hole in the flexible tip of 8666-RF is larger than in 8666. The diameter is 2.5mm in 8666-RF and 2.1mm in 8666. The biopsy kits UA0033, UA0034 and UA0035 are intended for use only with 8666, and must not be used with 8666-RF.

Biopsy System Components for 8666

For **cytological** biopsy, the biopsy system consists of:

- the biopsy attachment UA1249, see Fig. 6.
- and the single-use flexible biopsy kits UA0033 and UA0038.

For **histological** biopsy, the biopsy system consists of:

- the biopsy attachment UA1249, see Fig. 6.
- and the single-use flexible biopsy kits UA0034 and UA0039.

Biopsy System Components for 8666-RF

For **cytological** biopsy, the biopsy system consists of:

- the biopsy attachment UA1249, see Fig. 6.
- and the single-use flexible biopsy kit UA0038.

For **histological** biopsy, the biopsy system consists of:

- the biopsy attachment UA1249, see Fig. 6.

and the single-use flexible biopsy kits UA0039.

UA1249 can be autoclaved and or disinfected by immersion in a suitable solution.

The flexible biopsy kits UA0033, UA0034, UA0038 and UA0039 are single-use disposable kits that are sterile as supplied. Reuse can result in cross-contamination or can compromise the function of the product.

Note: Do not use the kits if the packaging is damaged in any way or if the expiry date has been exceeded.

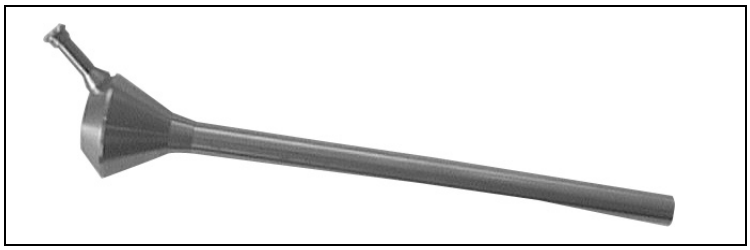

Fig. 6. Biopsy attachment UA1249

WARNING
It is essential for the patient's safety that only the correct biopsy attachment is used with Types 8666 and 8666-RF. Never use unauthorized combinations of transducers and biopsy attachments or other manufacturers' biopsy attachments.

WARNING
Only use the special needles as specified in this user guide.

WARNING
*Sterile disposable sheaths cannot be used when the biopsy system is attached to the transducer. Therefore Types 8666 and 8666-RF **must** be sterilized before intraoperative use.*

WARNING
All components of the biopsy system must be sterile before use.

External Assembly of the Biopsy System

WARNING
Before beginning a puncture or biopsy procedure always check that the transducer type number as displayed on the scanner monitor corresponds exactly to the type number on the transducer itself.

Preparation

1. Ensure that all of the components are sterile and undamaged before beginning assembly of the system.
2. Make sure that the transducer tip is in the straight, non-adjusted zero position, by setting both of the levers to the zero position. This position is indicated by a line on the transducer handle, between the 2 levers.

Securing the Biopsy Attachment UA1249

1. Slide the biopsy attachment gently over the transducer shaft until it is approximately 1 to 2 cm from the proximal end of the transducer shaft where the shaft is connected to the transducer handle.

The biopsy attachment is locked onto the shaft by means of a 2-way locator ring.

2. Rotate the biopsy attachment until the needle insertion point is on either the right or left-hand side of the transducer handle, in this position the sleeve is ready to be locked in place.

3. To do this push the attachment firmly into position until it "clicks" into place. The biopsy attachment is now locked onto the transducer shaft and ready to host the flexible biopsy kit. (See Fig. 7.)

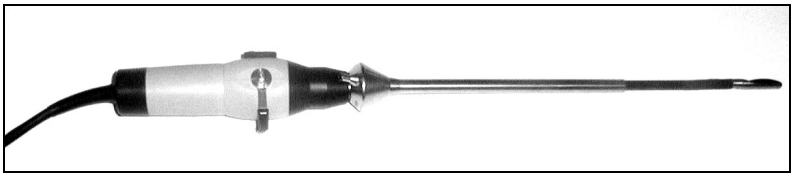

Fig. 7. Type 8666 with biopsy attachment UA1249 attached

Attaching the Flexible Biopsy Kit

The biopsy system supports two types of single-use flexible biopsy kits: the aspirated flexible needle kit (UA0033) and the flexible needle kit (UA0034). Details of their assembly and operation are provided below.

Intraoperative Biopsy with UA0033 (8666 only)

Components of the UA0033

The single-use UA 0033 is designed for **cytological** biopsy and consists of:

- an aspirated flexible stainless steel needle, item A in Fig. 8., 626mm in length, composed of a cannula and a stylet. The proximal end of the needle is marked in black for 110mm along its length.
- a mechanical stop (metal cylinder) mounted on the needle, item B in Fig. 8.
- a flexible stainless steel spiral needle guide, item C in Fig. 8., with a sealing tube at the proximal end, and a threaded interface at the distal end.
- a medial sealing tube, mounted on the flexible needle guide, item D in Fig. 8.

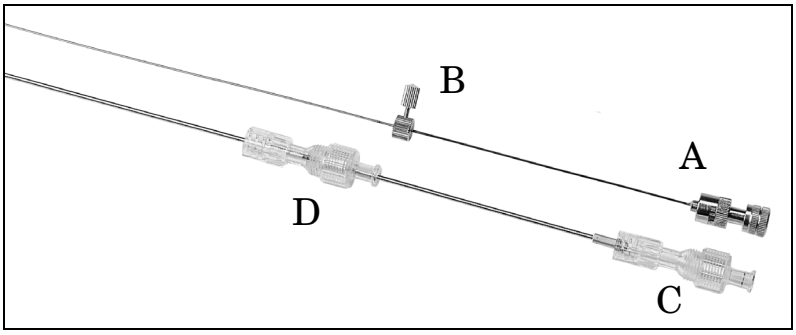

Fig. 8. The components of UA0033

Attaching the UA0033

Note: The kit is delivered with the needle placed inside the flexible needle guide; carefully remove the needle from the flexible needle guide before commencing assembly.

1. Insert the flexible needle guide into the biopsy attachment through the needle insertion point.

The tip of the flexible needle guide will soon appear at the distal end of the biopsy attachment.

2. Continue to push the flexible needle guide through until its tip is approximately level with the tip of the transducer.

3. There is a threaded hole in the top of the transducer tip. Insert the tip of the flexible needle guide and secure by gently turning the needle guide itself in a clockwise direction until all of the threaded interface is out of sight.
4. Secure the flexible needle guide to the biopsy attachment by inserting the medial sealing tube on the flexible needle guide (item D in Fig. 8.) into the needle insertion point. Tighten by turning in a clockwise direction.

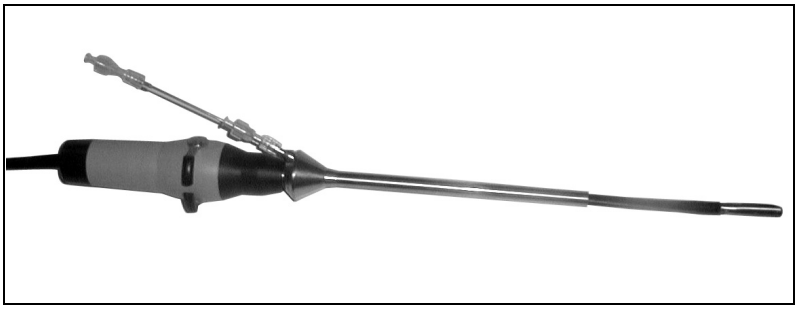

Fig. 9. Type 8666 with UA0033 flexible biopsy system: flexible needle guide is secured at the tip and ready for insertion into the trocar

Insertion of the Flexible Biopsy System

Note: The trocar used with Types 8666 when the biopsy system is attached must have a minimum inner diameter of 12mm.

1. Ensure that the tip of the transducer is still in the zero, non adjusted position (see Fig. 4.).
2. Carefully pull the flexible needle guide backwards through the biopsy attachment in the direction of the transducer handle until there is sufficient tension on the flexible needle guide to hold it flat against the transducer shaft.
3. Close the medial sealing tube on the flexible needle guide by turning the proximal screw clockwise to the point where you can feel a clear resistance to further movement of the needle guide.
4. Ensure that the sealing tube at the proximal end of the flexible needle guide is also closed to avoid leakage of gases.

The transducer is now ready for insertion into the trocar, see Fig. 9.

5. With the transducer fully inserted into the trocar, open the medial sealing tube and insert the flexible needle guide further into the biopsy attachment.
6. Using the levers on the transducer handle, ensure that the transducer tip is free to move as needed before tightening the sealing tube again, see Fig. 4. and Fig. 5.

The system is now ready for operation.

Insertion of the Needle

1. The flexible needle should now be inserted into the flexible needle guide. To facilitate insertion of the needle, the tip of the transducer should be flexed slightly, to an angle of approximately 30º, see Fig. 10.

Fig. 10. Type 8666 with the UA0033 biopsy system: flexible needle is inserted into the flexible needle guide

2. Ensure that the mechanical stop is secured to the needle shaft at the point where the color marking ends, 110mm from the proximal end of the needle; this will protect the patient before the biopsy is taken.
3. Open the sealing tube at the proximal end of the flexible needle guide. Then straighten the flexible needle guide by pulling it gently towards the proximal end of the biopsy attachment.
4. Insert the flexible needle into the flexible needle guide and continue gently pushing it into the guide up to the "locking point" where the mechanical stop on the needle meets the medial sealing tube on the needle guide.
5. Close the sealing tube at the proximal end of the flexible needle guide in order to prevent leakage of gases. The needle tip now lies approximately 5mm from its exit point at the tip of the transducer.

Intraoperative Use of UA0033

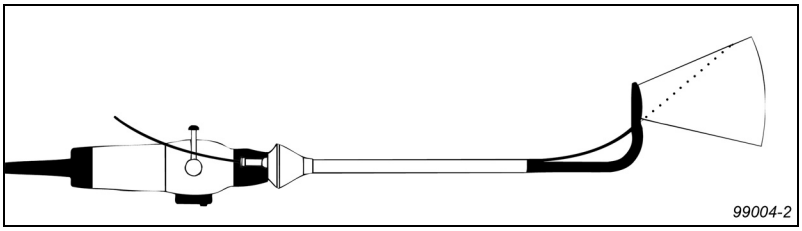

Fig. 11. Biopsy system and puncture line

1. Press the scanner's **Puncture** control to superimpose a puncture line on the scan image.
2. Move the transducer until the puncture line (see Fig. 11.) transects the target.

WARNING

Before beginning a puncture or biopsy procedure always check that the transducer type number as displayed on the scanner monitor corresponds exactly to the type number on the transducer itself.

WARNING

The puncture line on the scan image is an indication of the expected needle path. The needle tip echo should be monitored at all times so any deviation from the desired path can be corrected.

WARNING
The flexible biopsy needle is by design more flexible than other biopsy needles and therefore will have a higher tendency to deviate from the puncture line. Therefore very careful monitoring is recommended.

WARNING
The tip of the transducer shaft should be constantly monitored on the video monitor to ensure that the tip of the flexible biopsy needle is not exposed beyond the end of the transducer. If the tip of the needle is seen to be exposed then it should be withdrawn immediately to avoid the risk of damaging any organs or tissues.

3. Find the site from where the biopsy is to be obtained.
4. When the site has been found and a satisfactory image has been obtained, lock the position of both adjustment levers, so as to keep the transducer in place while taking the biopsy.
5. Ensure that the flexible needle guide has a suitable curvature. If the curvature is too acute, the flexible needle will not move freely within the needle guide (the ideal curvature is dependent on the amount of upwards or downwards adjustment of the transducer tip).
6. Take a firm hold of the transducer handle and position your fingers to hold the adjustment levers to prevent them from moving (this is an extra precaution to ensure that the position of the tip of the transducer does not change during the biopsy procedure).

WARNING
Because of the length of the transducer shaft it is possible to apply large forces to the tip of Type 8666 by very small movements of the handle – if these forces are excessive they may injure the patient or cause the transducer to break.

7. In order to set the desired penetration depth for the biopsy, loosen the mechanical stop on the flexible needle by turning the screw counter-clockwise.
8. Push the flexible needle into the organ, using the scanner image to monitor the location of the needle tip, see Fig. 12. The needle tip echo will be seen as a bright dot on the screen.

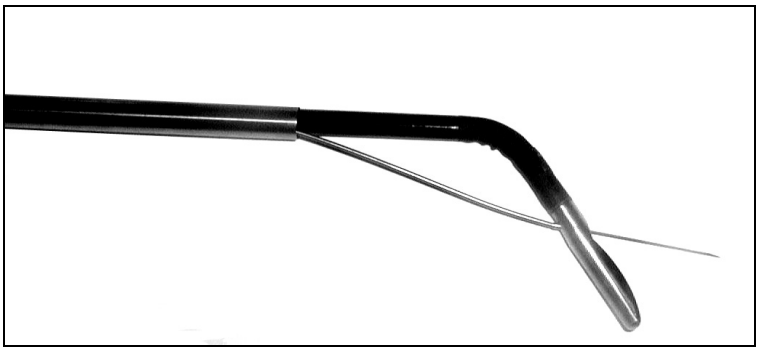

Fig. 12. Type 8666 with flexible needle UA0033 ready for aspiration

9. Insert the flexible needle to a point where the tip is in the middle of the biopsy target. Tighten the mechanical stop again to secure the needle.

WARNING
Do not move the transducer or its tip whilst a biopsy needle is inserted beyond the mechanical stop.

10. Slowly remove the needle stylet entirely whilst holding the needle connector. Simultaneously pull the stylet connector towards the transducer handle.
11. Attach a sterile syringe to the needle connector, see Fig. 13.

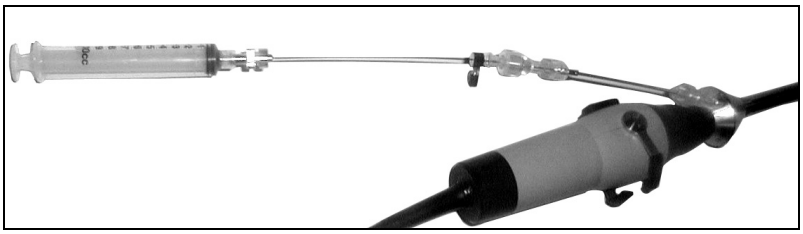

Fig. 13. UA0033 flexible biopsy system with syringe attached

12. To take the biopsy, aspirate by withdrawing the syringe piston. Once the aspiration is complete, remove the flexible needle from the target area.
13. To extract the biopsy sample, remove the flexible needle from the flexible needle guide and slowly push the sample out of the needle by depressing the syringe piston.

The flexible biopsy needle can be re-used (if this is appropriate) to take further biopsies during the same operation. You should however, carefully inspect the needle before re-use. You should also ensure that the mechanical stop is secured at the “locking point” on the needle shaft (where the color marking ends), in order to avoid patient injury.

Note: If wish to move the position of the transducer within the patient in order to take further biopsy samples, then you must repeat the steps above for use of the biopsy system beginning with the section "Intraoperative use of UA0033".

Removal and Disassembly of UA0033

When the biopsy procedure has been completed, the transducer and biopsy system can be removed from the patient.

Before removing the transducer:

1. Remove the flexible needle, if you have not already done so.
2. Set both levers to the zero position, to ensure that the transducer tip is in the zero, non-adjusted position.
3. Deselect both rocker switches so that the transducer tip is free to move.

WARNING
Before withdrawing the transducer ensure that the flexible needle guide is lying flat against the side of the transducer shaft.

4. Check that the transducer is still in the zero position.
5. Withdraw the transducer from the trocar.

To disassemble the flexible biopsy system, proceed as follows:

1. Unscrew the flexible needle guide and withdraw it from the biopsy attachment.

2. Ensure that the tip of the transducer is in the zero, non-adjusted position, and gently remove the biopsy attachment, taking care to avoid damage to the transducer shaft.

Intraoperative Biopsy with UA0034 (8666 only)

Components of the UA0034

The single-use UA0034 is designed for histological biopsy using a 19 gauge needle. It consists of:

- a flexible stainless steel needle, item A in Fig. 14., 600mm in length, composed of a cannula, a stylet, and a handle with two finger grips and a plunger. The proximal end of the needle is marked with a black striped pattern for 90mm along its length;
- a mechanical stop (plastic sheath) attached to the needle handle, item B in Fig. 14.;
- a flexible black Pebax needle guide, item C in Fig. 14., with a sealing tube at the proximal end;
- a medial sealing tube mounted on the flexible needle guide, item D in Fig. 14.

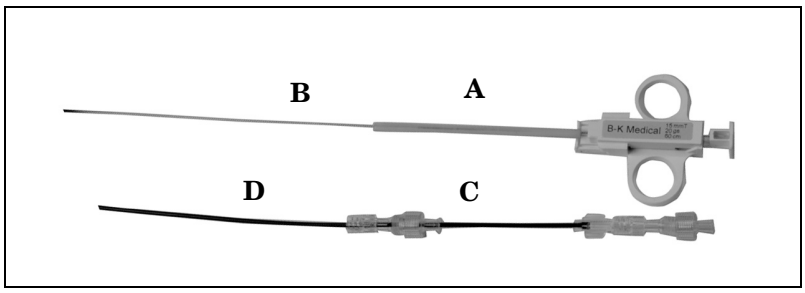

Fig. 14. The components of UA0034

Attaching the UA0034

1. Attach the **biopsy attachment** UA1249 to the transducer, see “External Assembly of the Biopsy System” on page 8.

Note: The flexible needle kit is delivered with the needle placed inside plastic protective covering; carefully remove the needle from this protective covering before commencing assembly.

2. Insert the flexible needle guide into the biopsy attachment through the needle insertion point. The tip of the flexible needle guide will soon appear at the distal end of the biopsy attachment.
3. Continue to push the flexible needle guide through until its tip is approximately level with the tip of the transducer.
4. There is a threaded hole in the top of the transducer tip. Adjust the tip of the transducer using the levers on the handle to an angle of approximately 90°.
5. Press the distal end of the flexible needle guide into this hole and secure by gently turning the adaptor screw on the medial sealing tube in a clockwise direction.
6. Secure the flexible needle guide to the biopsy attachment by inserting the medial sealing tube on the flexible needle guide (item D in Fig. 14.) into the needle insertion point, and turning in a clockwise direction.
7. Movement of the flexible needle guide can be controlled by regulating the proximal screw of the sealing tube. To tighten, turn clockwise, to loosen, turn counterclockwise. Prior to the insertion of the needle, some freedom of movement of the guide should be allowed.

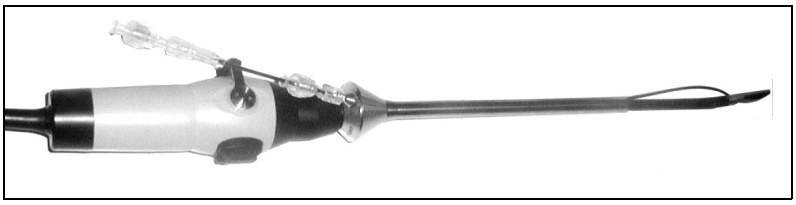

Fig. 15. Type 8666 with UA0034 flexible biopsy system: flexible needle guide secured at the tip and ready for insertion into trocar

Insertion of the Flexible Biopsy System

Note: The trocar used with Type 8666 when the biopsy system is attached must have a minimum inner diameter of 12mm.

1. Ensure that the tip of the transducer is still in the zero, non-adjusted position (see Fig. 4.).
2. Carefully pull the needle guide backwards through the biopsy attachment in the direction of the transducer handle until there is sufficient tension on the guide to hold it flat against the transducer shaft, see Fig. 16.

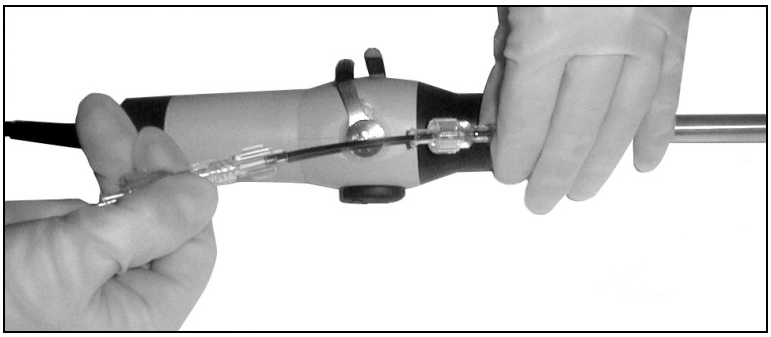

Fig. 16. Pulling the UA0034 in the direction of the handle of Type 8666 prior to insertion into the trocar

3. Close the medial sealing tube on the flexible needle guide by turning the proximal screw clockwise to the point where you can feel a clear resistance to further movement of the needle guide.

The transducer is now ready for insertion into the trocar.

4. Maintain the tension on the needle guide as it is being introduced into the trocar and ensure that the transducer tip is kept in the zero, non-adjusted position by locking the levers on the transducer handle.
5. With the transducer fully inserted into the trocar, loosen the medial sealing tube on the needle guide and using the levers on the transducer handle, ensure that the necessary freedom of movement exists in the transducer tip. The system is now ready for operation.

Insertion of the Needle

The biopsy needle should now be inserted into the needle guide.

1. Ensure that the mechanical stop (plastic sheath) is on the needle shaft; this will ensure that the patient is protected before the biopsy is taken.
2. Open the sealing tube at the proximal end of the flexible needle guide and insert the needle into the flexible needle guide. Continue gently pushing the needle into the guide until you feel resistance.

3. Take hold of both the flexible needle guide and the needle itself, and push both towards the biopsy attachment for approximately 4 cm; this will enable you to insert the needle further into the needle guide.
4. Straighten the needle guide by pulling it back in the direction of the transducer handle and insert the needle to the “locking point” where the mechanical stop on the needle meets the sealing tube at the proximal end of the needle guide.

Intraoperative Use of UA0034

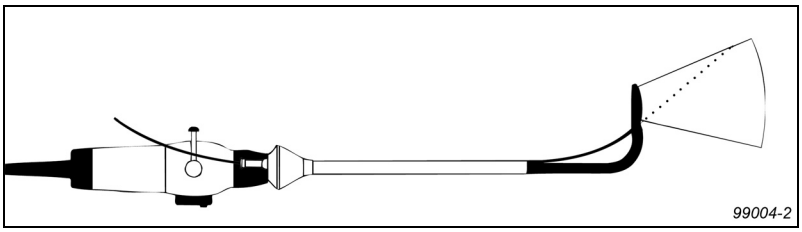

Fig. 17. Biopsy system and puncture line

1. Press the scanner’s **Puncture** control to superimpose a puncture line on the scan image.

WARNING
Because of the length of the transducer shaft it is possible to apply large forces to the tip of Type 8666 by very small movements of the handle – if these forces are excessive they may injure the patient or damage the transducer.

WARNING
The puncture line on the scan image is an indication of the expected needle path. The needle tip echo should be monitored at all times so any deviation from the desired path can be corrected.

WARNING
The flexible biopsy needle is by design more flexible than other biopsy needles and therefore will have a higher tendency to deviate from the puncture line. Therefore very careful monitoring is recommended.

WARNING
The tip of the transducer shaft should be constantly monitored on the video monitor to ensure that the tip of the flexible biopsy needle is not exposed beyond the end of the transducer. If the tip of the needle is seen to be exposed then it should be withdrawn immediately to avoid the risk of damaging any organs or tissues.

2. Find the site from where the biopsy is to be taken.
3. When the site has been found and a satisfactory image has been obtained, lock the position of both adjustment levers on the transducer handle; this is necessary to keep the transducer in place while taking the biopsy.
4. Before taking the biopsy, the flexible needle guide has to be adjusted so that it has a suitable curvature (the ideal curvature is dependent on the amount of upwards or downwards adjustment of the transducer tip). If the curvature is too acute, the flexible needle will not move freely within the needle guide, see Fig. 18.
5. **Note:** the best results are obtained with the transducer tip at an angle of between 60° and 90° from the zero, non-adjusted position.

Fig. 18. Type 8666 with the UA0034 biopsy system; flexible needle is inserted in the flexible needle guide

6. "Cock" the flexible needle: this is done by drawing the needle plunger all the way back until it has "clicked", see Fig. 19. The spring within the handle is now compressed and ready to fire when the biopsy is taken.

WARNING
The needle is now ready to fire. Be careful not to fire it accidentally.

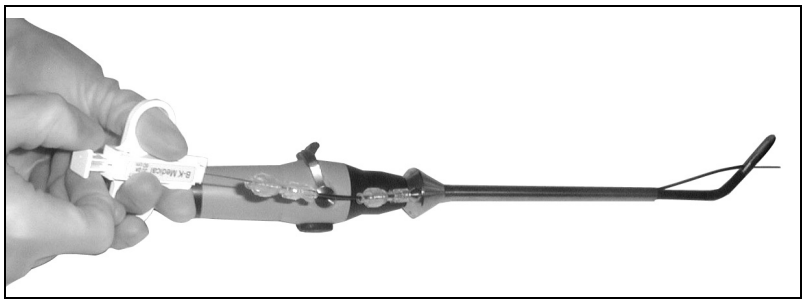

Fig. 19. Preparing the UA0034 flexible biopsy system for firing

7. Take a firm hold of the transducer handle and position your fingers to hold the adjustment levers (this is an extra precaution to ensure that the position of the tip of the transducer does not change during the biopsy procedure).

WARNING
Because of the length of the transducer shaft it is possible to apply large forces to the tip of Type 8666 by very small movements of the handle – if these forces are excessive they may injure the patient or cause the transducer to break.

8. In order to set the desired penetration depth for the biopsy, remove the mechanical stop on the needle, see Fig. 20. The flexible biopsy needle is now free to move.

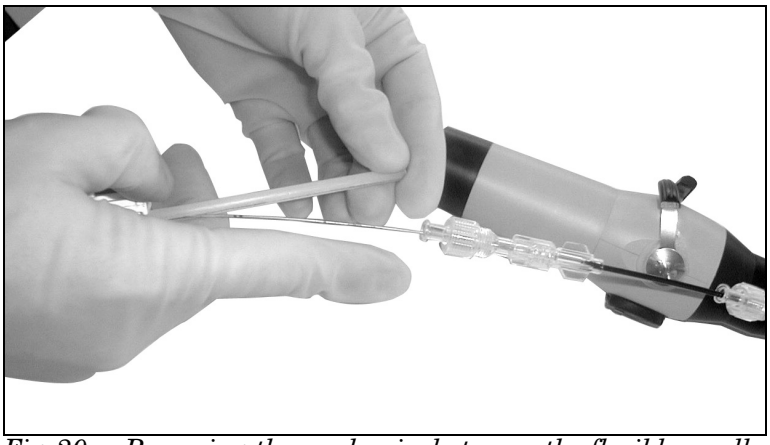

Fig. 20. Removing the mechanical stop on the flexible needle of the UA0034 flexible biopsy system

9. Use the needle handle to push the flexible needle into the organ, using the scanner image to monitor the position of the needle. The needle tip echo will be seen as a bright dot on the screen.
10. Insert the flexible needle to a point where its tip is just in front of the biopsy target, see Fig. 21. Close the sealing tube on the proximal end of the flexible needle guide to secure the needle.

WARNING

Do not move the transducer or its tip while a biopsy needle is inserted beyond the mechanical stop.

11. Advance the flexible needle stylet into the biopsy target by pushing on the plunger whilst holding the rest of the needle handle steady.
12. When the flexible needle stylet is inside the target area the biopsy can then be taken by "firing" the needle handle.

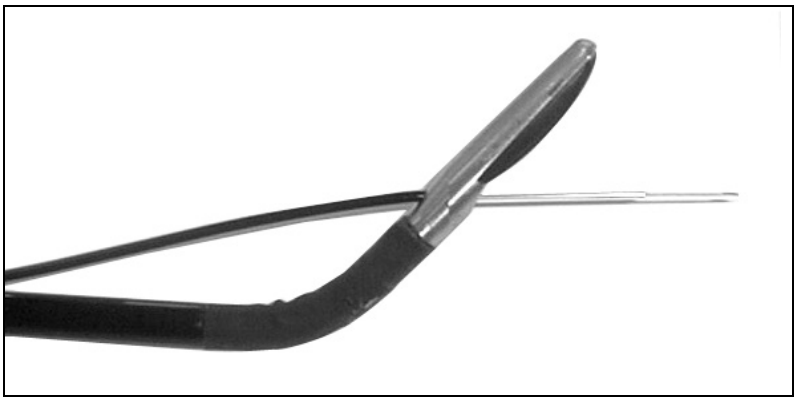

Fig. 21. Needle tip of the flexible biopsy system UA0034 ready for firing

13. Before firing, exert pressure on the tip of the transducer and take a firm hold of the end of the needle handle.
14. Maintain this position until after the flexible needle has been fired. These are precautions to prevent excessive backward movement of the transducer tip or the needle which could occur as a recoil action when the needle is fired.

The flexible needle can now be fired.

15. Push the needle handle plunger all the way down, beyond the point of resistance.

The flexible needle can now be withdrawn and the biopsy sample removed.

16. Pull the needle handle plunger until it "clicks". Push the stylet forward using the needle handle plunger until firm resistance is felt; the biopsy sample can now be removed.

WARNING
Do not continue to press on the biopsy handle plunger whilst the biopsy is being removed as this will fire the cannula which could result in injury to the operator.

17. If you wish to re-use the flexible needle to take further biopsy samples during the same operation, you must fire the needle outside the patient (dry-firing), provided you take the necessary precautions to avoid damage to the needle.

WARNING
Before firing the flexible needle outside the patient (dry firing) place the tip of the stylet against a flat solid surface and hold on to the needle shaft. This will prevent damage to the cannula tip.

18. The flexible needle can be re-used (if this is appropriate) to take further biopsies during the same operation. You should however make a careful inspection of the needle before re-use.

Note: If you move the position of the transducer then you must repeat all the steps for use of the flexible biopsy system beginning from the section “Intraoperative Use of UA0034” on page 16.

Removal and Disassembly of UA0034

When the biopsy procedure has been completed, the transducer and the biopsy system can be removed from the patient.

Before removing the transducer:

1. Remove the flexible needle.
2. Set both levers to the zero position, to ensure that the transducer tip is in the zero position.
3. Deselect both rocker switches so that the transducer tip is free to move.

WARNING
Before withdrawing the transducer ensure that the flexible needle guide is lying flat against the side of the transducer shaft.

4. Check that the transducer is still in the zero, non-adjusted position.
5. Withdraw the transducer from the trocar.

To disassemble the flexible biopsy guide proceed as follows:

1. Detach the distal end of the needle guide from the tip of the transducer by gently turning the adaptor screw on the medial sealing tube in a counterclockwise direction. Withdraw the needle guide from the biopsy attachment.
2. Ensure that the tip of the transducer is in the zero, non-adjusted position, and gently remove the biopsy attachment, taking care to avoid damage to the transducer shaft.

Cleaning After Use

If biological materials are allowed to dry on the transducer or puncture attachments, disinfection and sterilization processes may not be effective. Therefore, you must clean puncture attachments and transducers immediately after use.

Use a suitable brush to make sure that biological material and gel are removed from all needle guides and other channels and grooves. See *Care, Cleaning & Safety* for cleaning instructions.

Using Needles Other Than Those Sold by BK Medical

Large-diameter needles that are stiff (for example, some RF needles) can seem to "stick" when you retract them. This is especially true if the needle is coated. The needle is not really stuck, but if it is not perfectly aligned with the axis of the biopsy hole, there can be friction between the needle and the edges of the hole. The friction can make the needle "stick" and it can also pull the transducer tip back slightly when you pull on the needle.

Therefore, you should practice inserting and retracting the needle before you use it to perform a procedure on a patient.

Special Considerations for RF Ablation

WARNING

If you use the 8666-RF transducer for RF (radio-frequency) or other ablation, you must follow the instructions of the ablation equipment manufacturer.

In particular, be sure to burn off tissue that might stick to the needle and retract the tines fully (while flushing with water as the manufacturer recommends) before you retract an RF needle.

Caution

Avoid possibly overheating the transducer when you burn a tumor close to the surface of an organ: pull the transducer back from the organ surface while you burn.

3D Ultrasound

Types 8666 and 8666-RF uses the untracked fan method for acquisition of images.

Acquiring a 3D Data Set

- Before attempting to acquire a 3D data set, you must first identify the center of the sector that is to be scanned. The default sector acquisition size is 120°.
- Using the untracked fan technique, turn the transducer to one side to prepare for an acquisition over the full sector. Start the acquisition by rotating the transducer around its longitudinal axis.
- The count down clock in the right-hand corner of the monitor will time the length of the acquisition. An acquisition time of between 4 and 10 seconds is normal, depending on the maximum frame rate of the application settings that you select.

Caution

If you are not sure of the absolute contour of the surface over which you intend to acquire a 3D data set, make sure that the two rocker handles are set to the unlocked position. This allows the transducer to follow surfaces more smoothly.

WARNING

Before attempting to acquire a 3D data set, always ensure that the laparoscopic transducer is set completely straight and level.

WARNING

Never position the transducer or start a 3D acquisition without a clear laparoscopic camera view of the transducer tip. During the 3D acquisition the camera should always be positioned for monitoring the entire movement of the transducer.

An untracked fan scan with type 8666 and 8666-RF transducers provides a 3D data set quickly and simply. However, it is important to remember that you cannot make accurate measurements on a 3D data set acquired using the untracked freehand method.

Please refer to the appropriate scanner user guide for more information.

Maintenance of Types 8666 and 8666-RF

Checking the Transducer

At least once a month check the transducer for the following signs of damage:

- Cracks in any part of the transducer
- Deep scratches on any of the transducer's surfaces
- Splitting or peeling of the sealant around the acoustic window
- Damage to the joint filler on the body of the transducer
- Damage to, or evidence of contamination on the pins of the transducer connector
- Damage to the cable bonding around the cable flex relief

WARNING

For Types 8666 and 8666-RF, before disinfection by immersion, and before each use, you must check the black rubber cover over the 2 rocker switches on the transducer handle and the articulation joint on the flexible tip of the transducer to ensure that there are no defects in these areas.

Adjustment of the Flexible Tip

After a period of time, it may be necessary for a small readjustment or tightening of the flexible tip of the transducer. BK Medical can carry out the readjustment and you should contact your local service center for details about this service.

Disposal

When the transducer is scrapped at the end of its life, national rules for the relevant material in each individual land must be followed. Within the EU, when you discard the trans-

ducer, you must send it to appropriate facilities for recovery and recycling. See the applicable scanner user guide for further details.

WARNING

For contaminated disposals such as transducer covers or needle guides, follow disposal control policies established for your office, department or hospital.