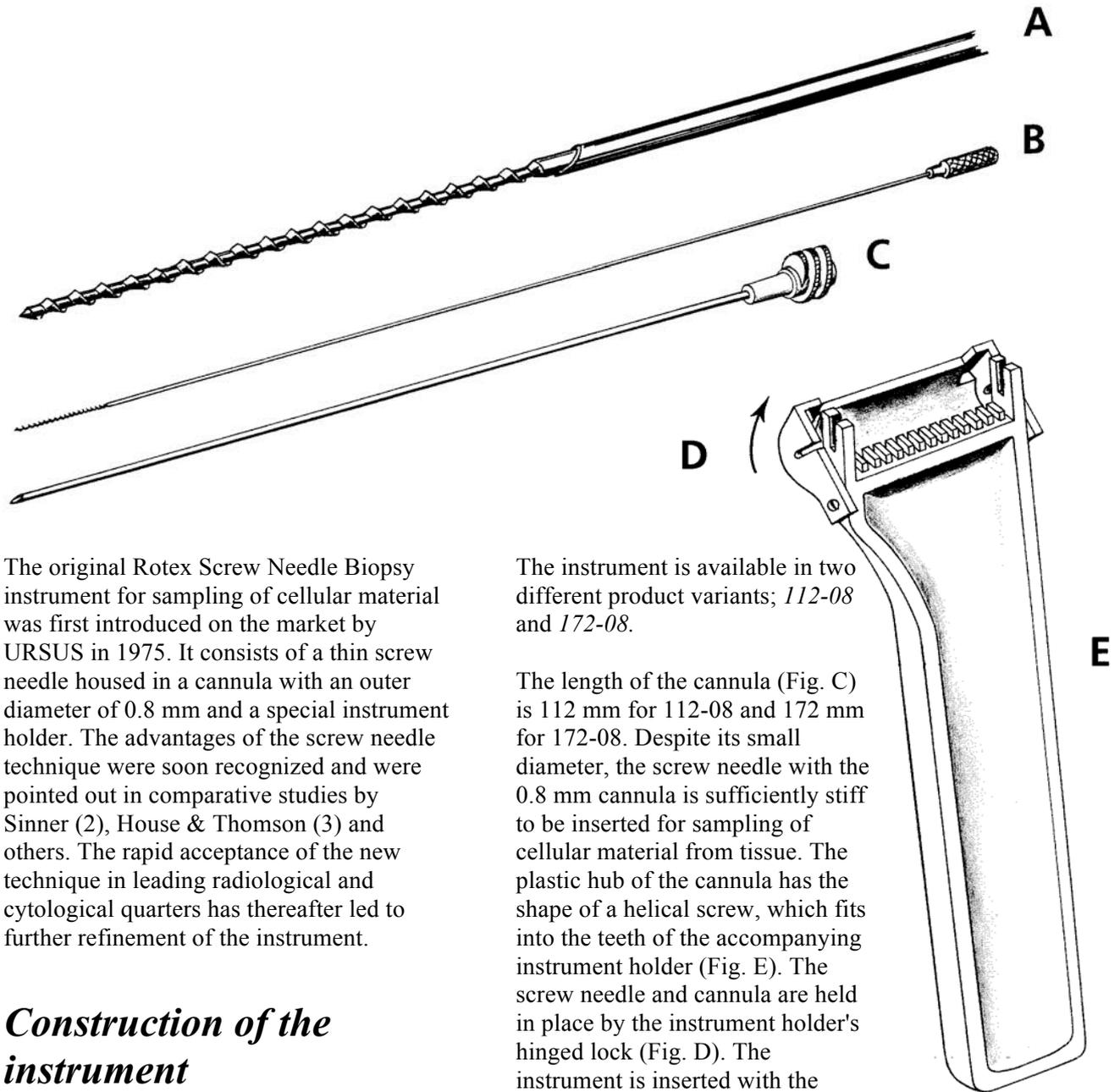


The Rotex Screw Needle Biopsy Instrument[®] CE 0413



The original Rotex Screw Needle Biopsy instrument for sampling of cellular material was first introduced on the market by URSUS in 1975. It consists of a thin screw needle housed in a cannula with an outer diameter of 0.8 mm and a special instrument holder. The advantages of the screw needle technique were soon recognized and were pointed out in comparative studies by Sinner (2), House & Thomson (3) and others. The rapid acceptance of the new technique in leading radiological and cytological quarters has thereafter led to further refinement of the instrument.

Construction of the instrument

screw with cutting ridge (Fig. A). The needle is housed in a steel cannula with an outer diameter of 0.8 mm, equivalent to 21 gauge needles.

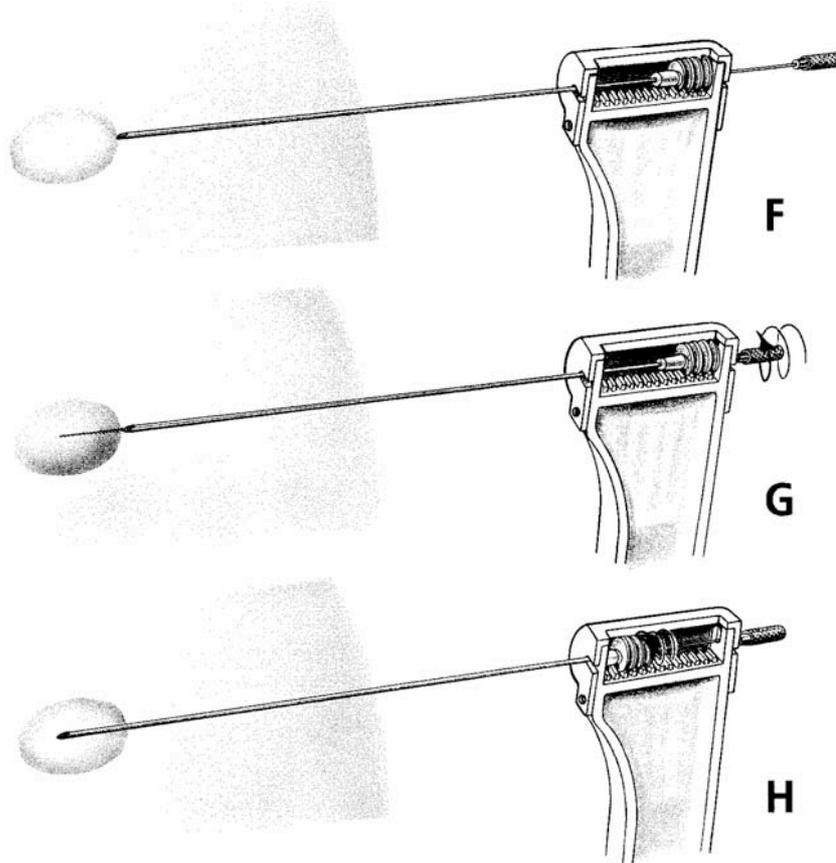
The instrument is available in two different product variants; 112-08 and 172-08.

The length of the cannula (Fig. C) is 112 mm for 112-08 and 172 mm for 172-08. Despite its small diameter, the screw needle with the 0.8 mm cannula is sufficiently stiff to be inserted for sampling of cellular material from tissue. The plastic hub of the cannula has the shape of a helical screw, which fits into the teeth of the accompanying instrument holder (Fig. E). The screw needle and cannula are held in place by the instrument holder's hinged lock (Fig. D). The instrument is inserted with the screw needle in a protected position in the cannula.

The screw needle is also positioned in the cannula at the withdrawal of the instrument. The risk of seeding surrounding tissues with cellular material from the screw needle during withdrawal of the instrument is thereby reduced to a minimum. The screw needle and cannula are delivered in standard packs of 20 instruments, each in individual protective packaging, sterilized using beta irradiation and ready for use. They are disposable and intended for single use to ensure efficient sampling, sterility and indisputable security against any kind of accidental inoculation. The instrument holder, which is made of polycarbonate, is intended for repeated use and is not sterile. The instrument holder is not intended to be sterilized by user, but recommend to be rinsed in alcohol between use. Each standard pack of 20 instruments includes two instrument holders. The instrument is available in other standard dimensions according to our price-list.

Assembly of the instrument

- 1) Open the hinged lock of the instrument holder.
- 2) Remove the screw needle together with its cannula housing from its protective packaging and place it in the two slots in the head of the instrument holder so that the cannula's helical hub assumes the position against the back wall of the instrument holder (Fig. D and F). Pull back the handle of the screw needle so that its screw is entirely withdrawn into the cannula.
- 3) Swing the hinged lock up to the locked position, thereby locking the cannula hub against the back wall of the instrument holder. The instrument is now ready for use.

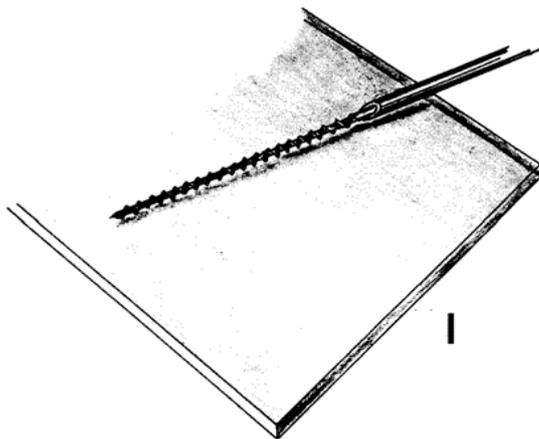


Preparation of the insertion site

- 1) After selecting an appropriate insertion site, clean and anaesthetize the skin in the underlying tissue.
- 2) An ordinary disposable 1.5 mm thick needle is then used to make a puncture canal through the skin.

Sampling cell material

- 1) Introduce the cannula of the assembled Rotex screw needle biopsy instrument into the puncture canal and guide it up to the edge of the tissue to be sampled (Fig. F), under guidance of biplane fluoroscopy, CT or ultrasound.
- 2) Rotate the handle of the screw needle clockwise, thereby driving the 16 mm long screwed part into the tissue to be sampled (Fig. G). In the event strong resistance is encountered, rotate the screw needle no more than 5 turns. This is done in order to prevent the screw needle from bending. Pull



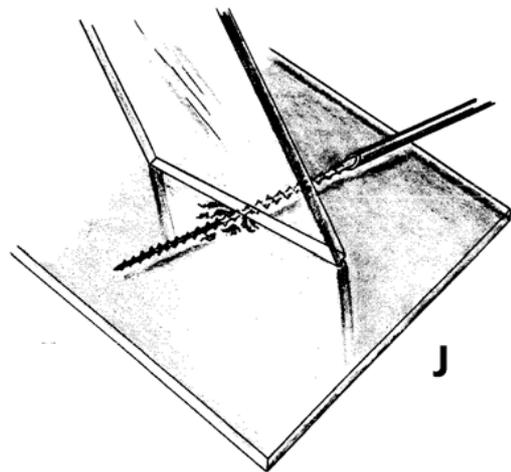
Retrieval of collected cell material

- 1) Push the screw needle out of the tip of the cannula. Place the screw against a glass slide

the needle back into the cannula, push it forward again, and rotate it another 5 turns into the tissue. Repeat this procedure until the full length of the screwed part of the needle has been introduced into the lesion. In lesions with soft material, the screw needle is pushed and pulled in and out of the tissue 2-3 times and then secured in its protected position in the cannula.

- 3) The helical hub screw of the cannula is, after the screwed part of the needle is driven into the tissue, rotated anti-clockwise until the screwed part is positioned in the protected position of the cannula (Fig. H). The cannula now holds the screw needle, which contains tissue and cell material from the sample in its grooves in a protected position. Increasing resistance to rotation of the helical hub may indicate that the screw needle tip is bent. Forcing rotation of the hub may then lead to further bending of the screw tip. When in doubt, the screw needle should simply be pulled back into the cannula.

- 4) When sampling has been completed, withdraw the instrument and release the cannula and screw needle from the instrument holder.



(Fig. I) and prepare smears from the material, which are then fixed and stained.

- 2) Material rolled up in the grooves of the screw is retrieved by rotating the screw needle anti-clockwise against the edge of a

sterile glass slide (Fig. J). The fragments are then fixed in formaline. Cell and tissue material thus obtained may be imbedded and treated as an ordinary histological specimen.

3) After removal of the screw needle from the cannula an ordinary syringe should be

Some advantages

- ◆ The Rotex Screw Needle Biopsy Instrument offers a safe, simple way of obtaining highly reliable samples. Since material is excised instead of being aspirated, complete cell clusters are obtained rather than single cells. As a result, at least 95% diagnostic accuracy has been obtained using the Rotex Screw Needle Biopsy Instrument for sampling lung tumors (3) and non palpable breast tumors (9). The diameter of the instrument cannula is 0.8 which explains the low incidence of reported complications (3).
- ◆ The echogenic Rotex Screw Needle Biopsy Instrument improves sampling accuracy. The tip of the screw needle is clearly visible during sonographic guidance.
- ◆ The instrument is easy to operate. It occupies a minimum of space under an image intensifier.
- ◆ Sampling is performed efficiently over a distance of 16 mm, corresponding to the spiral portion of the screw needle. This enhances the possibility of obtaining representative samples. The screw needle and cannula work together as a cutting instrument, and the screw needle stabilize the tissue when the cannula is rotated over it. In this way all tissue components are sampled before they are lifted out. Material from fibrous inflammatory lesions and highly organized tissue such as benign tumors can therefore also be obtained. The material is highly concentrated and is not diluted by tissue fluid and blood as in aspiration biopsy. This facilitates microscopic examination of the material. Rather large flakes of cells and connective tissue can often be obtained. The clumps of tissue which can be sampled from organized tissue may allow treatment of the material with histological techniques.

attached to the cannula and its contents blown out. This material may then be smeared on a glass slide for staining and microscopy or transferred to a bacteriological culture medium.

- ◆ Material from the screw needle can be inoculated directly on culture media for bacteriological examination.
- ◆ The dimensions of the instrument have been optimized with regard to minimizing trauma and maximizing stability. This latter factor is of importance in order to enable precision sampling. In this way unnecessary insertion of the cannula in several directions can be avoided.
- ◆ The screw needle is always in a protected position; i.e., withdrawn into the cannula, when the helical hub is positioned distally in the instrument holder. In this way the risk of tumor seeding to surrounding tissue is reduced to a minimum.

Fields of application

The Rotex instrument was originally constructed for the biopsy of lung lesions. It has also been proven to be equally suitable for the biopsy of other organs; liver, kidney, lymph nodes, mammary tissue and thyroid. The instrument is not for use in the central circulatory system or central nerve system

WARNING

Discard any damaged instrument in a sharps container, specially designed for safe disposal of sharps waste with potential biological hazards.



The Rotex Screw Needle Biopsy Instrument is for single-use only and must not be reused. Reusing arouses risks of infection, contamination, tumor seeding and failure in usability and it may transfer the legal responsibility to the user.



Do not use the instrument if the package has been damaged or the sterile barrier system or its packaging is compromised.

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