CIVCO
MEDICAL INSTRUMENTS

The Race For Efficiency-
How Do You Rate?

Needle Guides

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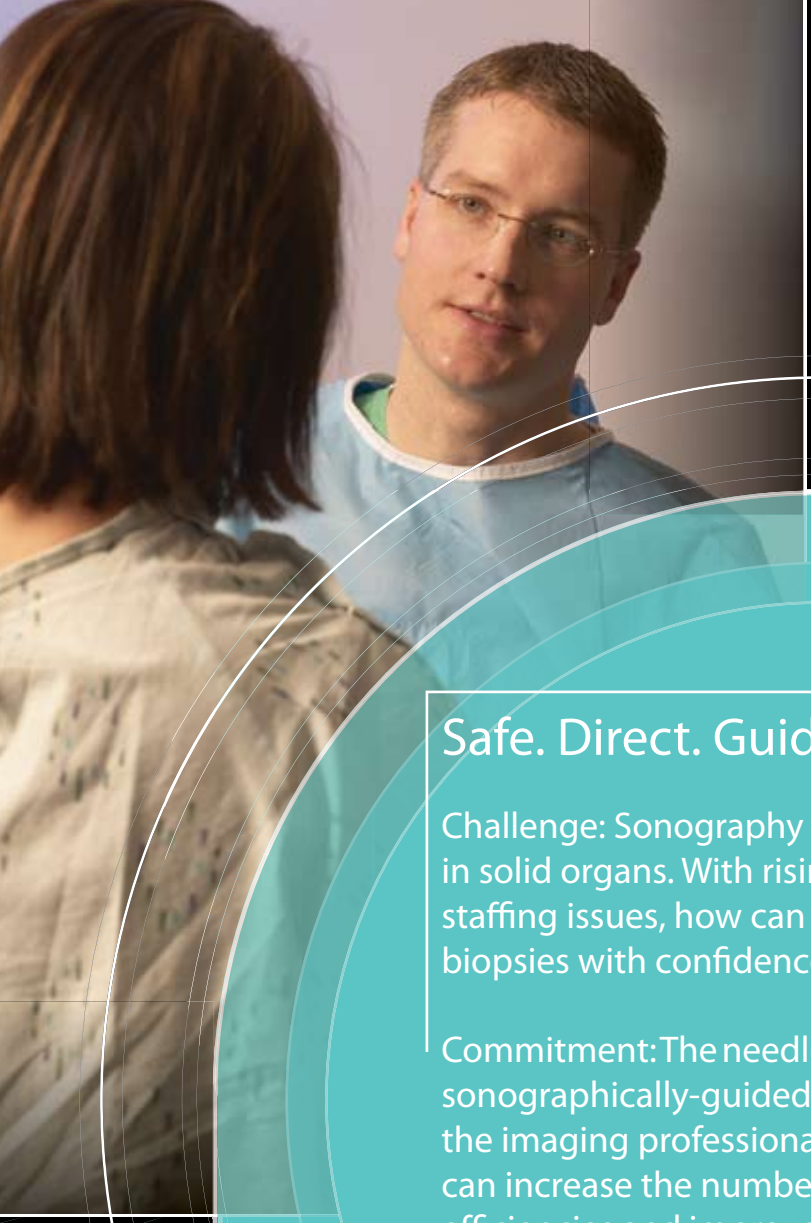

Safe. Direct. Guiding Patient Care.

Challenge: Sonography enables real-time targeting of focal lesions in solid organs. With rising healthcare costs, smaller budgets and staffing issues, how can you efficiently and accurately perform biopsies with confidence?

Commitment: The needle guide technique has been proven to make sonographically-guided biopsies easier and quicker while increasing the imaging professional's confidence. Using CIVCO needle guides can increase the number of patient cases, increase departmental efficiencies and improve staff confidence which ultimately leads to increased revenue.

Performance: Using quality CIVCO products and accessories provides added confidence for both staff and the patient. Overall, the performance of quality products will save healthcare professionals time, improve safety during procedures and provide greater patient and staff comfort.

Success: Taking the steps to invest in CIVCO needle guidance systems will improve the quality of care you can provide for your patients and the overall success of the department.

HIGH-PERFORMANCE PRODUCTS.

As the leading supplier of customized needle guides for ultrasound transducers, CIVCO is committed to providing cost-effective solutions to save imaging professionals time, improve safety during procedures and provide greater patient and staff comfort. CIVCO's complete line of needle guides provides healthcare professionals the assurance quality products are used in each and every procedure.

CIVCO's complete line of general purpose needle guides includes:

ULTRA-PRO 3™

- Offers advantages of needle guidance while maintaining the tactile feel of the freehand technique
- Easy-to-read gauge selector makes it simple to identify and alter gauge sizes in a darkened ultrasound suite
- Features zero needle resistance, offering smooth movement and navigation during puncture procedures
- Accepts 11-22 gauge instruments (19, 21 GA not available)
- Fits brackets customized for Aloka, Fukuda, GE Healthcare, Hitachi, Medison, Philips, Siemens, Shimadzu, SonoSite, Terason and Toshiba ultrasound systems

ULTRA-PRO II™

- Recognized worldwide as the number one general purpose needle guide
- Features enhanced ergonomics with easy-to-read gauge sizes and a large funnel for needle insertion
- Offers added functionality with a large quick-release tab, allowing for easy detachment of the needle from the transducer
- Accepts 8.5FR, 14-23 gauge instruments
- Fits brackets customized for Aloka, Fukuda, GE Healthcare, Hitachi, Medison, Philips, Siemens, Shimadzu, SonoSite, Terason and Toshiba ultrasound systems

MULTI-PRO 2000™

- Attaches to C & P (Clip and Pin) Needle Guidance Systems in the market
- Accepts 14, 16, 18, 20, 22 and 25 gauge instruments
- Fits brackets customized for Philips and Siemens ultrasound transducers

CIVCO's complete line of endocavity needle guides include custom transrectal and transvaginal guides for ultrasound transducers from leading system manufacturers. The endocavity line includes:

DISPOSABLE NEEDLE GUIDES

- Contoured design for patient comfort
- Disposable design reduces risks of cross-contamination
- Most accept 16-18 gauge instruments
- Conveniently packaged with cover, gel and bands for increased efficiencies

REUSABLE NEEDLE GUIDES

- Typically manufactured from stainless steel allowing autoclave sterilization
- Sleek design of guide provides added patient comfort
- Most accept 16-18 gauge instruments

The Race for Efficiency - Why Use Needle Guidance?

For over two decades, CIVCO's needle guides have been used to provide precise, targeted guidance in procedures around the world. Needle guidance is a critical element in providing accurate healthcare for your patients.

- Research has shown use of needle guides reduces technique variability leading to a shorter learning curve for biopsy/aspiration procedures; reduced procedure time; and consistent replicable procedures. 1
- Needle guides provide predetermined needle path boundaries which can be viewed on the system monitor. Patients and professionals can visualize needle trajectory on-screen for a safe and accurate procedure. 2
- Disposable design of select needle guides offers increased office efficiencies by reducing the risks of cross-contamination and increasing patient throughput.
- Proponents of the biopsy-guided technique suggest needle guides make the sonographically-guided biopsy easier and quicker, specifically for the less experienced imaging professional. 3-5
- Needle guides keep the needle within the plane of the sonographic image as it is advanced toward the biopsy target. 2
- General purpose multi-angle brackets offer improved visualization and more user flexibility and variability. 2
- Transrectal sonography has become the widespread, standard method of prostate imaging with most prostate cancers detected by ultrasound-guided biopsy. 6

1 Phal P, Brooks, D, Wolfe R. Sonographically Guided Biopsy of Focal Lesions: A Comparison of Freehand and Probe-Guided Techniques Using a Phantom. Am J Radiol 2005;184:1652-1656

2. CIVCO Product Validation/OEM Endorsements

3 Lindgren G, Andersson T. Invasive ultrasound. The NICER yearbook 1996 ultrasonography. Oslo, Norway: Isis Medical Medica, 1996-641-668

4 Esaola CC, Chopra S, Dodd GD. Sonographic guidance in biopsies and drainages: techniques and applications. Semin Interv Radiol 1997; 14:343-369

5 Cronan JJ. Percutaneous biopsy. Radiol Clin North Am 1996; 34:1207-1223

6. Papatheodorou, A, Tandeles, Savvas, Ellinas, P. Transrectal sonography clearly visualizes prostate anatomy. Diagnostic Imaging 2005;27(2):39-45.

DEFINITIONS:

Disposable- Single-use only

Endocavity Needle Guide- used in transrectal and transvaginal biopsy procedures

High-Level Disinfect- close cousin to sterilization and is sometimes considered an acceptable alternative to sterilization but only in some very specific circumstances

Locating Features- detentions/grooves/indicators manufactured on ultrasound transducer which provide a place for attaching reusable bracket or endocavity needle guide

Needle Guide- Attaches to an ultrasound transducer to direct instruments to targeted area following software guidelines

Reusable- packaged non-sterile, can be used multiple times; Requires proper sterilization/disinfection after each use

Reusable Bracket- non-sterile multi-angle or single-angle attachment which fits into locating features on an ultrasound transducer; Disposable needle guide attaches onto mount on reusable bracket

Soaking Cup- a lightweight cup used for soaking endocavity transducers in disinfecting liquid

Sterilization- the compete and absolute absence of any living thing, including spores; Normally accomplished in healthcare facility by subjecting devices to steam sterilization, ethylene oxide gas or to a liquid or vapor chemical sterilant

Surface Disinfect- a process that eliminates or reduces the number of microorganisms to a level appropriate for the use of a particular device

PROTOCOL

Research has shown there is a significant time benefit with the use of needle guides. Use of needle guides are recommended as a cost-effective solution for biopsy, tissue aspirations and catheter placement which can lead to improvements in the outcomes of procedures and the overall success of your department.

NEEDLE GUIDE PROTOCOL:

1. Apply bracket. Prior to a general purpose procedure, apply the reusable bracket onto the transducer. The bracket should snap into locating features on the transducer and fit securely. Note: Select endocavity needle guides include a reusable bracket- refer to User's Manual for details.

2. Cover transducer. Once the bracket is attached, apply a transducer cover onto the transducer. Extend the cover over as much of the transducer cord as possible. Ensure the cover is secured to the transducer.

   Note: Transducer covers provide a cost-effective protective barrier between the transducer, gel and the patient to prevent the transmission of bloodborne pathogens and the chances of cross-contamination. Use of a cover also provides added efficiencies for your department by reducing the time necessary to sterilize the transducer after each patient. Ultrasound equipment manufacturers recommend using covers to protect the integrity of the transducer and thus preserve the life of the transducer.

3. General Purpose: Attach disposable needle guide. Needle guides are custom designed to attach onto the reusable bracket. Select desired gauge size and lock onto bracket/cover assembly.

   Endocavity: Attach needle guide. Align the disposable needle guide onto the transducer and snap into position. If using a reusable guide, align the needle guide and tightening the thumbscrew securely into position.

   Note: Disposable needle guides are designed to reduce the risks of cross-contamination. Disposable needle guides are conveniently packaged in sterile procedure kits, providing added efficiencies for your department. Reusable guides require proper sterilization/disinfection after each use.

4. Clean transducer. After the examination and removal of the needle guide/cover, remove any residual gel and debris from the transducer by using an approved cleansing towelette or wipe. Additional use of liquid chemical germicides may be used to help ensure further reduction in microbial load.

   Note: When used as instructed, disinfecting wipes can provide protection against infection and biological contamination, efficiently killing most major bacteria, viruses (including HIV-1) and molds on first contact. A lightweight soaking cup provides a safe and efficient soaking system for endocavity transducers.

5. Aseptic Technique. For the protection of both the patient and the healthcare worker, examinations should be performed with the sonographer properly gloved throughout the procedure.

   Note: The above is only a suggested Infection Control Protocol. Healthcare professionals should follow protocols set by their facility and should consult their System User's Manual for product/solution compatibility with their ultrasound transducer.

Demo Videos are available online at www.civco.com.

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