

Latest News from ETHICON Women's Health & Urology

ETHICON Introduces Diagnostic Device for Female Incontinence *Portable, Simplified Tool Designed for In-Office Use Features New Urodynamic Test*

Somerville, NJ March 5, 2004 – ETHICON announces the availability of the GYNECARE MONITORR * Urodynamic Measurement System, a new advancement in urodynamics which aids in the diagnosis of female incontinence. Designed to be easily used in nearly any practice setting, the affordable, portable device provides objective measures of urethra and bladder function to help physicians diagnose and differentiate stress, urge or mixed forms of incontinence.

The GYNECARE MONITORR device features a new type of urethral pressure measurement for stress incontinence called Urethral Retro-resistance Pressure (URP). Results of an international, multi-center investigation published in the February issue of the *Journal of Neurourology and Urodynamics* substantiate the clinical utility of URP as a consistent and reproducible measure of urethral function – unique information that is not currently available as part of current multi-channel urodynamic testing.

“URP measurements are simple to obtain and reproducible,” said Patrick Culligan, MD, Director, Division of Urogynecology and Reconstructive Pelvic Surgery, University of Louisville, KY, and lead U.S. investigator for the study. “In the near future, URP values may be predictive of surgical success – allowing us to better counsel patients.”

In contrast to more complex diagnostics, GYNECARE MONITORR requires just one operator, taking only 20 to 30 minutes to perform a full clinical work-up. The menu-driven system is simple to use, and can be learned in a single in-service session. The device consists of a reusable, rechargeable electronics unit and two disposable

cartridges, and a printer station that allows documentation for patient files. The device performs the following three urodynamic tests:

- Single channel cystometrogram (CMG), for urge incontinence. CMG aids in identifying detrusor overactivity, or bladder contractions.
- Leak Point Pressure (LPP), a dynamic urethral measurement for stress incontinence (SUI).
- Urethral Retro-resistance Pressure (URP), the new type of urethral measurement for SUI that can be performed in 20 seconds.

Urethral Retro-resistance Pressure, Proprietary to GYNECARE MONITORR

Designed to minimize patient discomfort, URP measures urethral function without the use of a catheter. Filling is accomplished by placing a meatus plug into the urethra, about 5 mm, to achieve a seal. The device pumps sterile saline slowly into the urethra, building pressure against the urethral sphincter, and records the pressure required to achieve and maintain an open sphincter.

URP is the first test to make the previously explored concept of retrograde filling of the bladder clinically accessible. Because there is no catheter artifact, URP provides a consistent measure of urethral competency.

In the study published in the *Journal of Neurourology and Urodynamics*; 23 (2), URP measurement was shown to have a consistent relationship to incontinence severity. In addition, the study showed patients prefer URP testing with GYNECARE MONITORR two-to-one over traditional urodynamics. The clinical trial, involving 22 centers in the U.S. and Europe, represented one of the largest controlled urodynamic studies to date.

About Incontinence

Urinary incontinence (UI), or the unintentional loss of urine, is a problem for more than 13 million Americans—85 percent of them women. Although about half of the elderly have episodes of incontinence, bladder problems are not a natural consequence of aging, and they are not exclusively a problem of the elderly. In fact, one in four women ages 30-59 have experienced an episode of UI.

Incontinence has several causes. Women are most likely to develop incontinence either during pregnancy and childbirth, or after the hormonal changes of menopause, because of weakened pelvic muscles.

Common types of incontinence include:

- Stress incontinence happens when the bladder can't handle the increased compression during exercise, coughing, or sneezing.
- Urge incontinence is caused by a sudden, involuntary bladder contraction.
- Mixed incontinence is a combination of both stress and urge incontinence.

* Trademark of ETHICON