

Spirotome technology for the gynecologist



In applications for:

Introduction

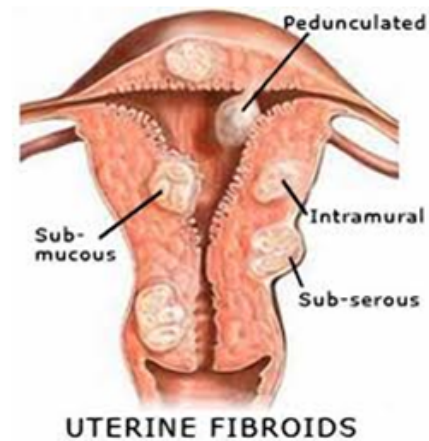
- Vulva
- Vagina & Cervix
- Endometrium
- Myometrium
- Ovary
- Lower Urinary Tract

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Introduction

In July 2014 the FDA expressed concern that morcellation of fibroids can disseminate an unsuspected sarcoma . This lethal complication, that occurs in about one out of 350 applications, has drawn attention to prior biopsy. With two general anesthesias the advantages of morcellation are again in balance of just surgery. Newer biopsy methods may offer a solution to this unexpected damper to less invasive means of treating fibroids. MedInvents likes to tell more about minimal invasive ways to comply with this FDA concern and about other tissue acquisition innovations in gynecology.

FDA monograph executive summary: Laparoscopic Power Morcellation during Uterine Surgery for Fibroids. 2014



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Offering innovative technology, such as various non-surgical ways of treating fibroids and biopsy methods, to the clinician frequently creates confusion: “If I need a new method, does it mean that older methods were not adequate?”. Of course not. But medicine changes in the adoption of appropriate interventions for new needs. Clinicians want to adapt to contemporary progress. In gynecology, these defies come also from different other angles. A few examples: **Oncology** has become a genomic discipline where molecular biology is now prominently present. **Reproduction** has learned much more about the ovarian follicle stem cells and the new opportunities for women that like to postpone pregnancy. **Regenerative medicine** offers brilliant alternatives to surgical interventions for urinary and fecal incontinence.

Harries R, Lawson S, Bruckers Liesbeth. Assessment of microcalcifications with limited number of high-precision macrobiopsies. [Eur J Cancer Prev](#) 2010; 19: 374-8.

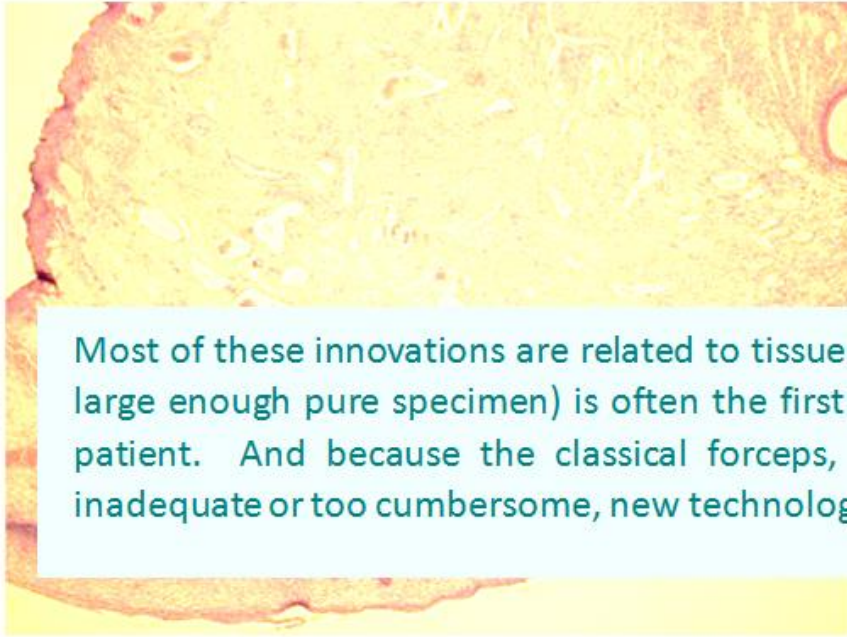
Jaak Ph. Janssens New Direct and Frontal Tissue Acquisition Tools for Gene Expression Analysis. [Current Pharmacogenomics & Personalized Medicine](#) 2010; 8: 37-48

Johnson J, Canning J, Kaneko T, Pru J, Tilly J. Germline stem cells and follicular renewal in the postnatal mammalian ovary. [Nature](#) 2004; 428, 145-150.

Carr, L.K.; Steele, D.; Steele, S.; Wagner, D.; Pruchnic, R.; Jankowski, R.; Erickson, J.; Huard, J.; Chancellor, M.B. 1-Year follow-up of autologous muscle-derived stem cell injection: pilot study to treat stress urinary incontinence. [Int. Urogynecol. J. Pelvic Floor Dysfunct.](#) 2008,19, 881–883.

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Most of these innovations are related to tissues. Harvest of high quality tissue (i.e. fresh large enough pure specimen) is often the first critical step in the health journey of the patient. And because the classical forceps, tru-cut and minimal surgery often are inadequate or too cumbersome, new technology has been developed.

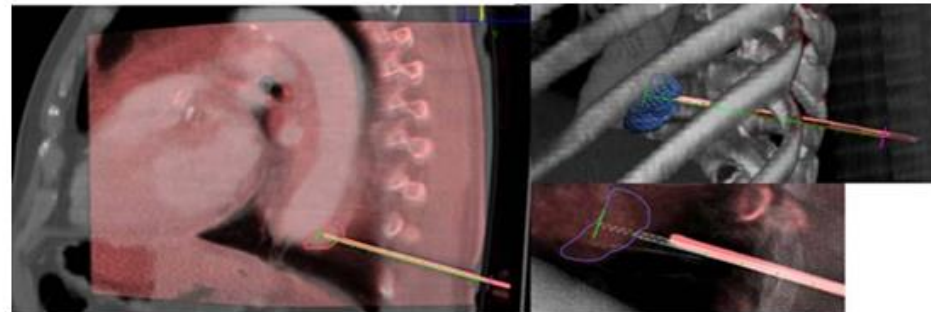
*Why should I, offering medical skills for over 20 years, change my biopsy method? Because:
Medicine has changed.*

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MedInvents has created novel proprietary instruments, based on the Spirotome technology. In recent years, many medical centers world-wide have evaluated this technology in several clinical applications. At the same time, much effort has been put in the safety of applications. One of the best examples of crucial safety has been observed in critical transdermal lung biopsies.

This is a summary of the latest developments and indications related to the Spirotome technology for the gynecologist.




[Lalji UC](#), [Wildberger JE](#), [Zur Hausen A](#), [Bendek M](#), [Dingemans AC](#), [Hochstenbag M](#), [Das M](#). CT-Guided Percutaneous Transthoracic Needle Biopsies Using 10G Large-Core Needles: Initial Experience. [Cardiovasc Intervent Radiol](#) 2014; DOI 10.1007/s00270-015-1098-z

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Vulva

With the Spirotome, type of lesion as well as depth of invasion are rather easy to assess for skin lesions.

Anatomical site	Indications	Tool
Skin	Cancer characterization	
Lymph Node	Staging of cancer Characterization of cancer	

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Vagina & Cervix

Submucosal lesions are tricky to assess with forceps. With the Spirotome, mucosa, submucosa and stroma are visible in the same biopsy.

Anatomical site	Indications	Tool
Ectocervix¹	Cancer risk assessment Identification of high risk women Premalignant lesions Cancer characterization Detection of residual disease Follow-up	


¹ J Janssens, P Cusumano, E Murta. Cervicore in the diagnosis of cervical lesions. Maturitas 63, S119, 2009

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Vagina & Cervix - 2

The role of stromal factors can't be overemphasized. In short, the table demonstrates that cancer risk assessment is not confined to the detection of HPV infection. The presence of stromal factors, together with HPV infection, identifies much closely the women at higher risk for (pre-) malignant lesions of the cervix.



Colposcopy	-	-	-	-	+	+
Pap-smear	-	+	+	+	+	+
HPV	-	-	+	+	+	+
Stroma	-	-	-	+	+	+
Cancer Risk	< 2%	<2%	<3-6%	30 - 85 %	70 - 95 %	100 %
Cervicore benefit	none	<ul style="list-style-type: none"> • Stromal diseases • Stromal extension of gynecological diseases 	<ul style="list-style-type: none"> • Stromal diseases • Stromal extension of gynecological diseases 	<ul style="list-style-type: none"> • Stromal carcinogenetic co-factors • Prognostic factors 	<ul style="list-style-type: none"> • Depth of invasion • Prognostic factors • Extension 	<ul style="list-style-type: none"> • Prognostic factors • Therapy outcome • Recurrent disease

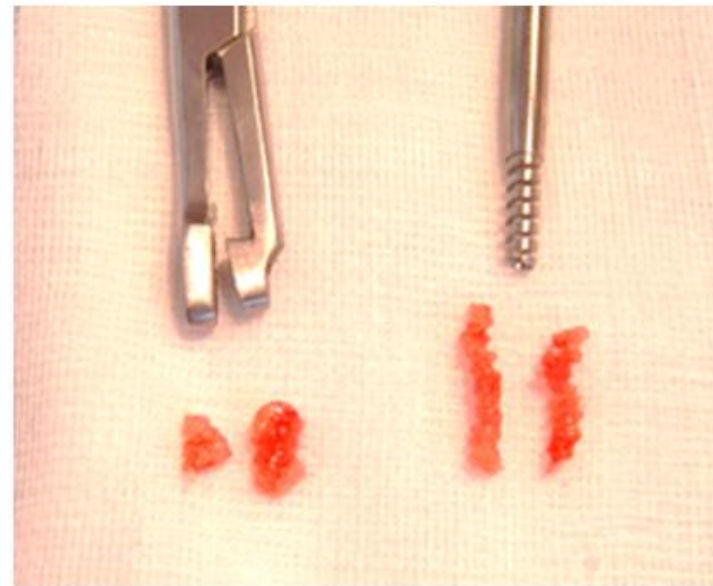
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Vagina & Cervix - 3

Comparison between size and direction of samples from forceps and Spirotome Cervicore.

The sample from the Spirotome Cervicore is perpendicular to the mucosa creating less collateral damage of the mucosa (less bleeding) and gives substantial information about the deeper layers (stroma) of the cervix.

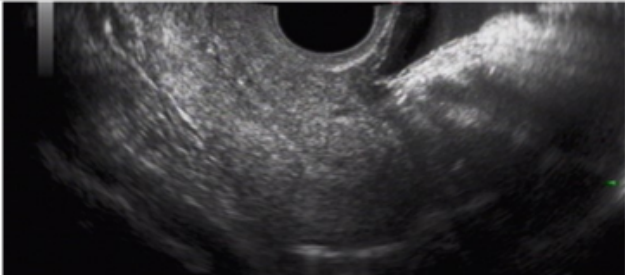


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Endometrium

The endometrium is often the seat of carcinogenesis but also the reason of infertility. In particular, the transition zone between endometrium and myometrium. For both, cancer and infertility, interventionists like to create minimal trauma to the tissues. Spirotome Cervicore gives no collateral damage.

Anatomical site	Indications	Tool
Transition zone	Diagnosis of infertility: Evaluation of transition zone between endo- and myometrium	



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Myometrium

The transition zone can be approached also from the outside, through the myometrium.

The myometrium is the structure where fibroids originate.

Anatomical site	Indications	Tool
Transition zone ¹	Diagnosis of infertility: Evaluation of transition zone between endo- and myometrium	
Fibroids	Prior to ablation, diagnosis of sarcoma presence is mandatory. The uterine cavity approach is useful for submucosal lesions, while the laparoscopic route is preferred for subserosal lesions. In both instances, care should be taken not to touch the opposite site of the uterine wall to prevent fistulation.	


¹S. Gordts, R. Campo, J.-P. Bogers, J. Janssen, P. Puttemans. Uterine junctional zone pathology: “the utero-spirotome” a new approach in diagnosis? 11th World Congress on Endometriosis FC#6-1, 2011

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Lower urinary tract

About half of women might experience temporary or permanent urinary incontinence. Non-surgical treatments seem to offer excellent alternatives.

Anatomical site	Indications	Tool
Sphincter	Lower urinary tract incontinence treated with muscle derived satellite cells	

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More info:

- www.Bioncise.com
- Bioncise
Klein Hilststraat 5
3500 Hasselt
Belgium
- info@Bioncise.com

