



Bedside Detection of Obstetric Anal Sphincter Injuries



OASIS Diagnostics S.A.

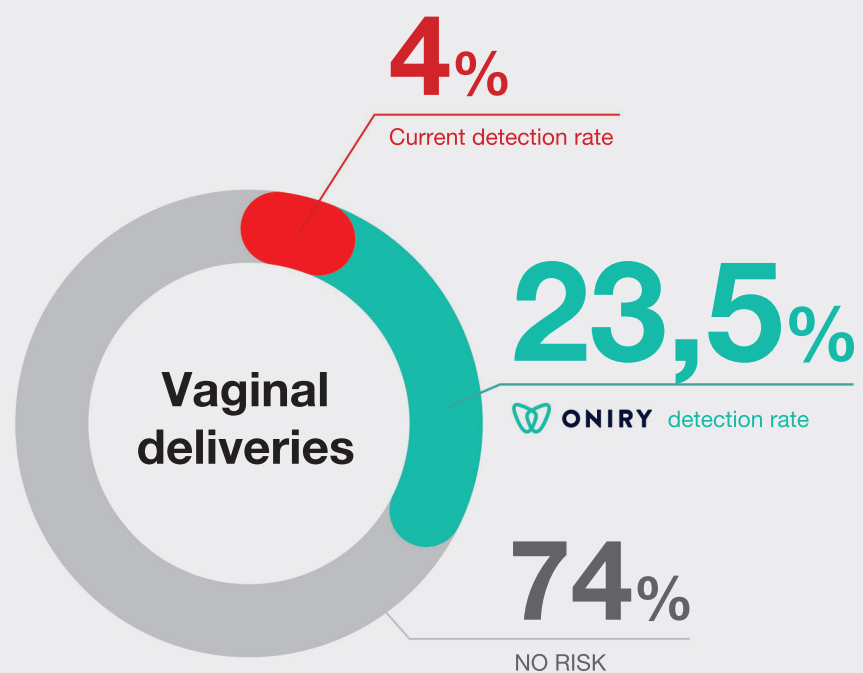
Obstetric anal sphincter injuries (OASI) are highly incident

Approximately **25%** of women giving vaginal childbirth suffer from any perineal injury affecting anal sphincters. Of them, as many as **4 out of 5** remain undetected.

Meanwhile, an untreated sphincter injury can lead to faecal and/or flatal incontinence, with the life-time risk of development of incontinence elevated almost **4-fold**. Incontinence symptoms may manifest right after childbirth or emerge several years down the line¹.

The timely detection of OASI postpartum is crucial for initiating optimal treatment. In case the primary surgical repair is the treatment option chosen, its therapeutic window spans no longer than **24-48 hours (max 72 hours)** after delivery. However, currently, OASI are detected in less than **4%** of women giving vaginal childbirth. The physical digital rectal examination often remains the only diagnostic option at bedside, if at all performed. However, its sensitivity is variable, usually low, and highly contingent on experience of the given obstetrician or midwife. Endoanal ultrasound (EAUS), the gold standard method for detection of OASI, is rarely available at bedside as a rule.

The use of ONIRY early postpartum markedly improves the detection rate of OASI. With its sensitivity and specificity of around 90%, ONIRY allows for precise identification of most injuries, including occult. Unlike traditional diagnostic strategies that are limited to symptomatic women, ONIRY can be administered to the entire population of women having given vaginal childbirth, thus enabling early intervention within the optimal time window.



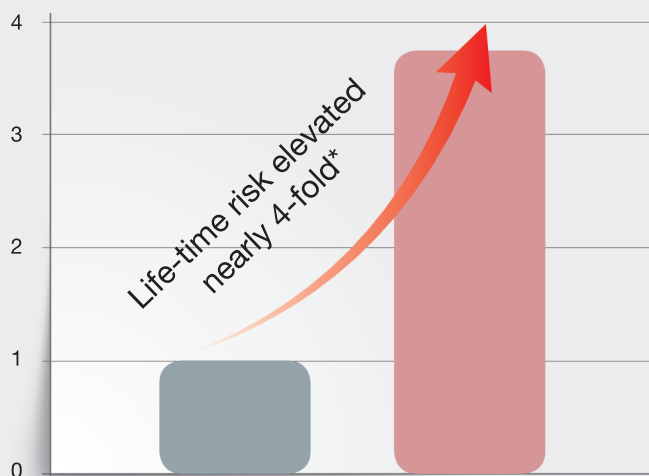
The use of ONIRY can translate to reduced incontinence rates and thereby improved overall quality of life of women having given vaginal childbirth. ONIRY represents an important progress in the field of obstetric care that could have far-reaching benefits for maternal health.

1. Sideris *et al.*, Eur J Obstet Gynecol Reprod Biol 2020 Sep;252:303-312

OASI highly increase the risk of incontinence

Relative risk of faecal incontinence in women experiencing OASI

versus women not experiencing OASI



scan to explore more information

* Relative Risk = 3.74 (95% Confidence Interval: 2.17 - 6.45, I²=80 %) as meta-analysed by Sideris M, *et al.* (Eur J Obstet Gynecol Reprod Biol 252 (2020) 303-312) from 2005 women in 19 clinical studies.



By increasing the detection rate of OASI and allowing for early intervention, ONIRY has the potential to significantly reduce incontinence rates and improve the overall quality of life for women who have experienced OASI. Women undergoing timely primary repair of external anal sphincter due to OASI can be reassured that the prognosis is good, with 60% to 80% of women being asymptomatic at 12 months². This, in turn, can reduce women's concerns and fears surrounding vaginal childbirth

2. Green-top Guideline No. 29 (2015) by the Royal College of Obstetricians and Gynaecologists. The management of third- and fourth-degree perineal tears.





ONIRY

meeting the unmet medical need

Bedside Detection of Obstetric Anal Sphincter Injuries (OASI)

We introduce ONIRY, the first clinically evaluated device specifically developed for bedside detection of OASI immediately after childbirth.

ONIRY is a game-changer in perinatal care empowering healthcare professionals with an immediate insight to the physical condition of anal sphincter.

ONIRY provides rapid and precise detection of OASI within an examination run of approximately 1 minute. The technology behind is machine-learning-assisted electric impedance spectroscopy. Examination results are promptly displayed on the screen enabling real time decision making.

The ONIRY system is composed of two portable medical devices: the ONIRY Probe and ONIRY Spectrometer.

ONIRY Probe

The ONIRY Probe is a disposable disinfected endoanal probe designed for detection of OASIs using impedance spectroscopy with the ONIRY Spectrometer.

The ONIRY probe applies and collects electric current, below the threshold of sensation, as to identify abnormalities within the sphincter complex. In addition, the location of an injury may be indicated.



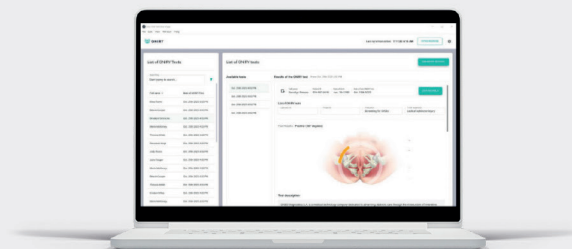
ONIRY Spectrometer

The ONIRY Spectrometer is an electric impedance spectrometer that conducts an automated examination process while connected with an ONIRY Probe. The ONIRY system has been tested for result repeatability.

With a 7 inch LCD touchscreen for intuitive navigation, a rechargeable battery for mobility, built in memory for data storage, built in machine learning model, without the need for connection to the cloud and a USB connector for seamless data transfer, it offers efficiency and precision in one device.

ONIRY App

The ONIRY App is a streamlined and efficient documentation software, designed to offer users a rapid and uncomplicated method for documenting their work, as well as for generating examination reports for medical records. This software aims to optimize the process, ultimately enhancing productivity.



ONIRY versus other methods for detection of Obstetric Anal Sphincter Injuries (OASI)

Digital Rectal (per rectum) Examination |ONIRY| Endoanal Ultrasound

Intended examination performed at the delivery room or within 6 weeks post-partum

	Digital rectal (per rectum) examination	ONIRY	Endoscopic ultrasound (EAUS)
Diagnostic SENSITIVITY¹	+ ¹	++/+++	+++
Diagnostic SPECIFICITY²	++ ²	++/+++	+++
Patient tolerability	+++	+++	++
Operation by novice user	++	+++	+
Examination time efficiency	+++	+++	+
Ease of use	+++	+++	+
Availability	+++	+++	+

1. Shlamovitz GZ, et al. Poor test characteristics for the digital rectal examination in trauma patients. *Ann Emerg Med* 2007; 50(1): 25-33, 33.e1.
2. Coura MMA, et al. Is digital rectal exam reliable in grading anal sphincter defects? *Arg Gastroenterol* 2016; 53(4): 240-245.





Key features of ONIRY



1-minute examination right after childbirth



High accuracy for precise problem recognition



Machine learning support



Tiny probe diameter comparable with a finger



Ease of use operable following a short training session



Availability in every delivery room



Fostering safety for women and healthcare professionals





We are a medical technology company dedicated to advancing maternity care through introducing novel diagnostic methods.

We are focusing on the implementation of innovative and clinically-assessed medical devices. Our solution overcomes challenges in obstetric standards and improves the quality of women's lives after giving birth.



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