ONIRY

Rapid detection of obstetric anal spincter injuries

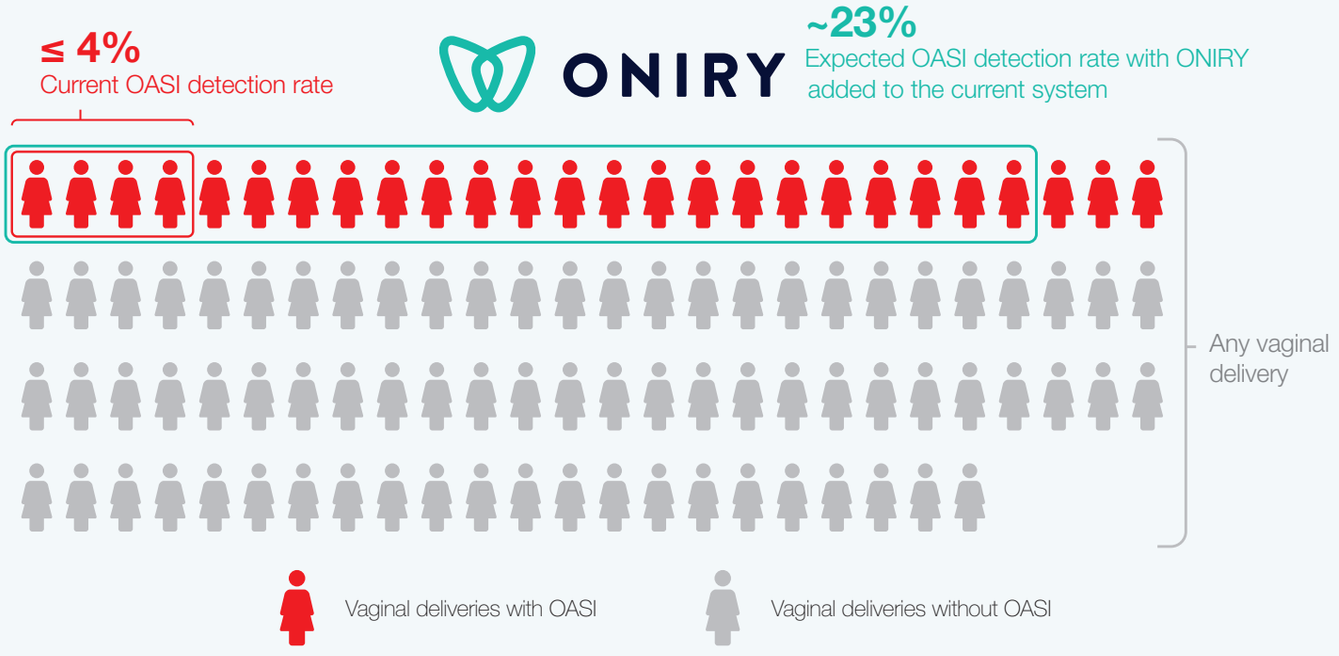


OASIS Diagnostics S.A.

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Obstetric anal sphincter injuries (OASI) are highly incident

Did you know that approximately **26%**[1] of women who give vaginal childbirth experience perineal injuries affecting the anal sphincter complex? What is more, up to **4 out of 5** of these cases go undetected[2].



Currently, obstetric anal sphincter injuries (OASI) are identified in **less than 4%** of women who give vaginal childbirth. This demonstrates the unmet need for improved methods and standards for OASI detection. The currently available methods, i.e., primarily the digital rectal examination (palpation), is often the only option available in the labour ward. However, its sensitivity varies, is generally low, and markedly contingent on the obstetrician's or midwife's experience. Endoanal ultrasound (EAUS), which is considered the gold standard for detecting OASI, is hardly available at the bedside in labour wards within the standard obstetrics practice.

1. Sideris, Michail, et al. "Risk of obstetric anal sphincter injuries (OASIS) and anal incontinence: a meta-analysis." European Journal of Obstetrics & Gynecology and Reproductive Biology 252 (2020): 303-312.
2. Nilsson, Ida EK, et al. "Symptoms of fecal incontinence two decades after no, one, or two obstetrical anal sphincter injuries." American journal of obstetrics and gynecology 224.3 (2021): 276-e1.

OASI frequently lead to faecal/anal incontinence

Overall, OASI count as the major cause of faecal/anal incontinence (FI) in women: a vaginal childbirth with any OASI increases the **FI risk as much as nearly 4-fold.** Research suggests that as many as 44% of women who experience OASI during childbirth will develop FI later in life[3].

Leaving an OASI untreated significantly increases the lifetime risk of developing FI. Incontinence symptoms may appear soon after childbirth or manifest years later. Knowing these potential risks and seeking appropriate care and support is essential.

Faecal/anal incontinence severely impacts quality of life

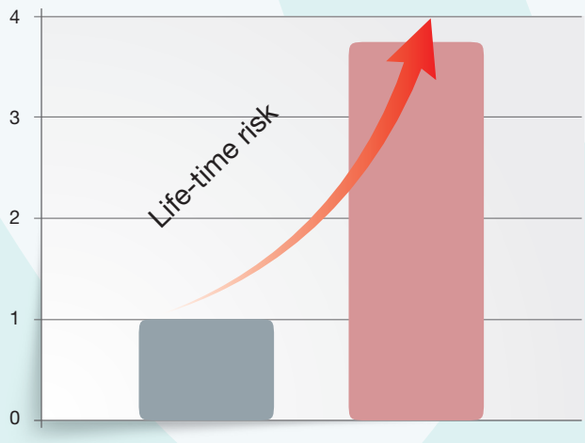
FI is a highly intimate and challenging problem that is not infrequent in women. While more and more health issues are no longer a taboo, FI is still considered embarrassing. Symptoms of FI can range from mild to severe.

Loss of control over defecation or uncontrolled expulsion of gas are at the severe end. However, even women with less severe FI often hide their symptoms for years, and ultimately withdraw from active life. Such symptoms can result in avoidance of social interactions and significantly interfere with daily personal and occupational activities. As a result, this can lead to significant disability.

As a result, FI is not only a medical but also a social problem, affecting the quality of life of those affected.

Relative risk of faecal incontincence in women experiencing OASI

versus women not experiencing OASI



* Relative risk = 3.74 (95% CI Siddiqui et al. Eur J Obstet Gynecol Reprod Biol 2020;252: 303-312) from 2005 women in 19 clinical studies.

3. O'Leary, B. D., et al. "Underdiagnosis of internal anal sphincter trauma following vaginal delivery." Ultrasound in Obstetrics & Gynecology 61.2 (2023): 251-256.

ONIRY

The solution: ONIRY®

The ONIRY® system, a machine learning-assisted impedance spectroscopy-based medical device, has been developed to fill the critical gap of early, bedside detection of OASI. This system offers a rapid and minimally invasive complement to the digital rectal examination (manual check) that brings detection of OASI to the next level in labour wards.

The early postpartum use of ONIRY® can significantly improve the detection rate of OASI. **With a sensitivity and specificity of approximately 90%,** ONIRY® allows for detection of most injuries, including occult ones.

Early detection of OASI is fundamental for FI prevention

Not all women who experience OASI will develop FI. Many could fully recover as long as adequate diagnostics and management is in place. It is crucial to detect OASI shortly after delivery as to ensure timely and effective treatment. If primary surgical repair is the chosen option, its optimal therapeutic windows falls within the first 8-12 hours postpartum.

Early detection of OASI is cost-effective

Data support that primary surgical repair offers a higher quality of life and is more cost-effective over 10 years[4]. The prognosis for women undergoing a **timely primary repair of external anal sphincter is good, with 60% to 80% chance of being asymptomatic at 12 months.** Implementing ONIRY enables far higher detection rates of OASI detection within the therapeutic window optimal for the primary repair.

ONIRY represents the progress in obstetric care translating to far-reaching benefits for maternal health

By increasing the detection rate of OASI, thus enabling early intervention, ONIRY® has the potential to significantly reduce FI rates and improve the overall quality of life of women giving vaginal childbirth. **This, in turn, can reduce women's concerns and fears surrounding vaginal childbirth.**

4. Tan, E. K., *et al.* "A cost-effectiveness analysis of delayed sphincteroplasty for anal sphincter injury." Colorectal Disease 10.7 (2008): 653-662.

Methods for Obstetric Anal Sphincter Injuries detection



	Digital rectal *(per rectum)* examination	Endoscopic ultrasound (EAUS)	ONIRY
Diagnostic SENSITIVITY[5]	+[5]	+++	++/+++
Diagnostic SPECIFICITY[6]	++ [6]	+++	++/+++
Patient tolerability	+++	++	+++
Operation by novice user	++	+	+++
Examination time efficiency	+++	+	+++
Ease of use	+++	+	+++
Availability	+++	+	+++

ONIRY

5. Shlamovitz, Gil Z., *et al.* "Poor test characteristics for the digital rectal examination in trauma patients." Annals of emergency medicine 50.1 (2007): 25-33.
6. Coura, Marcelo de Melo Andrade, *et al.* "Is digital rectal exam reliable in grading anal sphincter defects?." Arquivos de gastroenterologia 53.4 (2016): 240-245.

ONIRY

meeting the unmet medical need

Rapid detection of obstetric anal sphincter

**Examination performed at the delivery room or up to 6 weeks post-partum*

We introduce ONIRY®, the first medical device intended for rapid detection of Obstetric Anal Sphincter Injuries immediately after vaginal childbirth.

ONIRY® is a game-changer in obstetric diagnostics, filling the gap in post-partum care, intended for use by healthcare professionals.

ONIRY® provides for rapid, precise detection of OASI within 1 minute using electrical impedance spectroscopy and advanced Machine Learning algorithms, empowering healthcare professionals with immediate insights into the patient's condition.

ONIRY® test results are promptly displayed on the screen following the examination, fostering real-time decision-making.





Key features of ONIRY

1-minute examination right after vaginal childbirth

High accuracy for precise problem recognition

Machine Learning algorithm support

Tiny probe diameter comparable with a finger

Ease of use: operable following a short training session

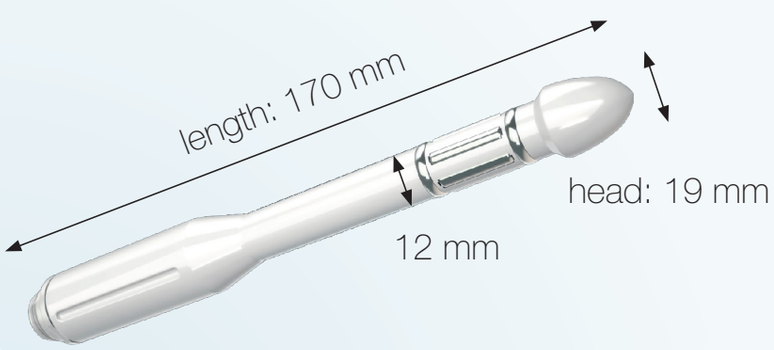
Additional functionality of locating the injury

ONIRY® consists of two medical devices: ONIRY® Probe and ONIRY® Spectrometer

ONIRY Probe

The ONIRY® Probe is an endoanal probe that facilitates the diagnosis of OASIs using electrical impedance spectroscopy with the ONIRY® Spectrometer.

The ONIRY® Probe uses electrodes to measure impedance, phase shift, resistance, and reactance of the anal sphincter structures. During the examination, the electrodes are being activated to cover the full 360-degree circumference as to detect the presence of trauma and its location.



Prioritize patient comfort

The ONIRY® Probe has been thoughtfully designed to prioritise patient comfort. It is no wider than a finger, and the measurement process takes less than a minute. The measurement low-voltage current is below the sensation threshold.

The examination process involves delicately inserting the ONIRY® Probe into the anal canal and activating the electrodes.

ONIRY

ONIRY Spectrometer

Thanks to the built-in machine learning model, the spectrometer provides quick results with 90% accuracy in distinguishing pathologies.

Easy to operate and navigate:

- The user-friendly 7-inch LCD touchscreen interface is intuitive and allows for effortless navigation.
- This highly portable device with a rechargeable battery has a built-in memory for data storage, and its USB connector facilitates seamless data transfer to ONIRY® App, rendering it highly efficient and easy to use.
- ONIRY® Spectrometer can be used with or without the ONIRY® Stand, a convenient transport trolley.

The ONIRY can optionally be equipped with accessories to facilitate usage and transport:

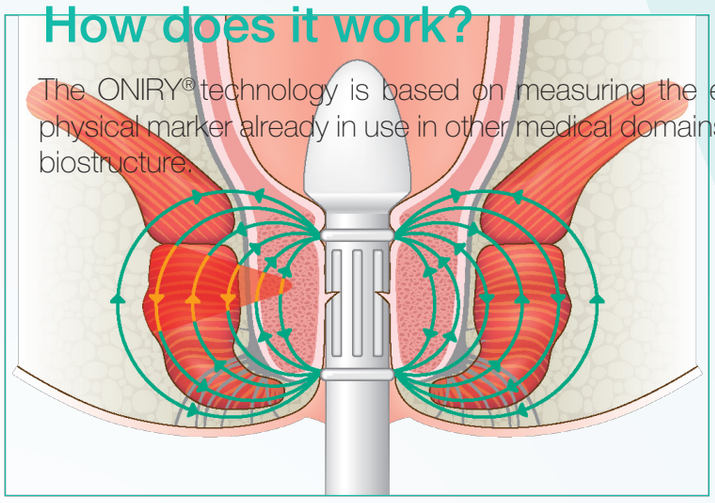


- ONIRY Stand
- ONIRY Bag
- ONIRY Cable Cover

* For more details, please visit www.oasis-diagnostics.com

How does it work?

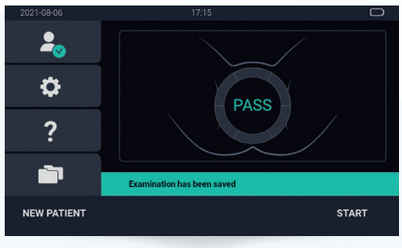
The ONIRY® technology is based on measuring the electrical impedance of tissues – a well-known physical marker already in use in other medical domains, capable of distinguishing normal and abnormal biostructure.

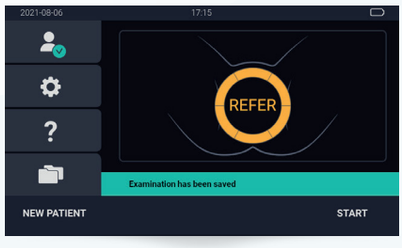


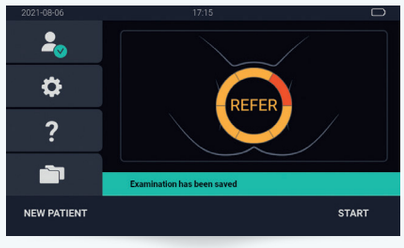
In case of OASI, as the differences between normal and abnormal impedance patterns are subtle, a Machine Learning model is implemented as to achieve sufficient accuracy and precision.

Analysis steps:

- Impedance data measurement
- Impedance data parameterisation
- Launching Machine Learning models (trained on clinical data)
- Presenting the result as **“PASS”** (no OASI) or **“REFER”** (OASI detected) and suggesting the location of the injury.







The **“PASS”** result indicates no OASI detected.

You can assure your patient that there is no injury, so she can safely embrace motherhood.

The **“REFER”** result suggests potential OASIs.

You may decide to repair the sphincter or include specialist (EAUS) diagnostics. ONIRY ML-model precisely indicates the location of the OASI to facilitate repair or further diagnosis.

NOTE: *If no specific location is suggested, the entire anal canal circumference will be depicted in the form of an orange ring. If data collected by ONIRY indicate a specific location of OASI, a corresponding section of the anal canal circumference will be further highlighted in red.*

ONIRY

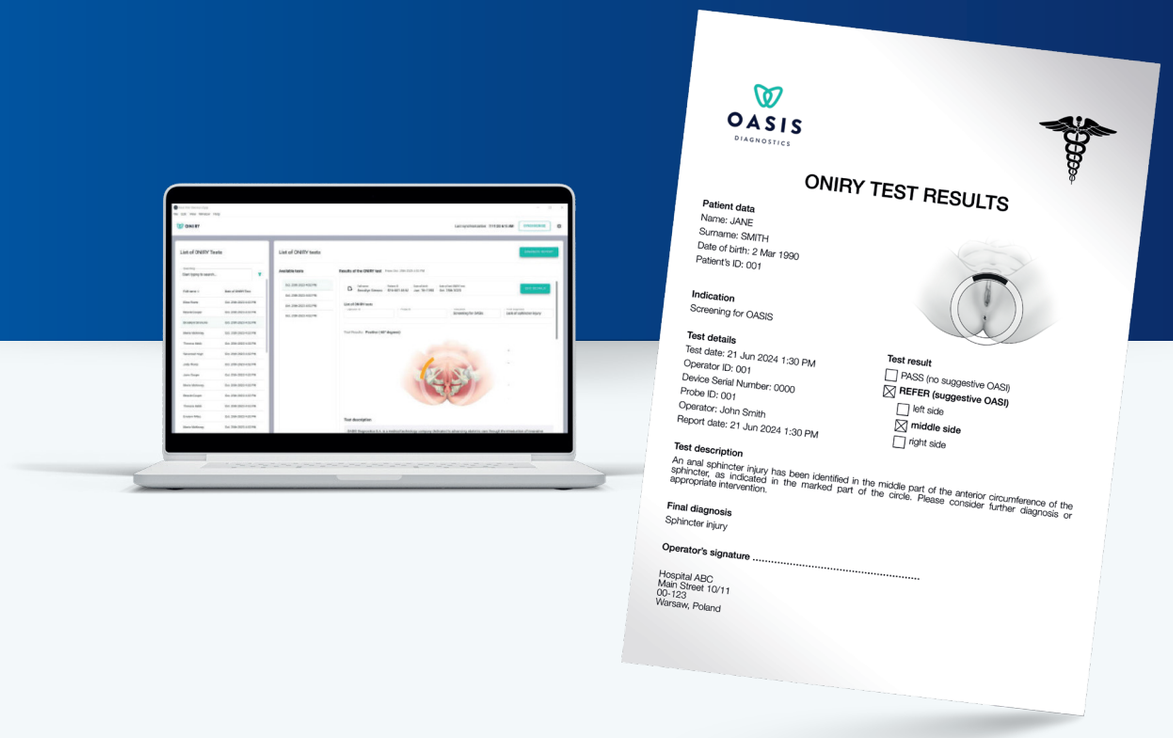
ONIRY App

Quickly generate examination reports

The ONIRY® App is a straightforward and rapid documentation software designed for simplicity and efficiency. It offers users a quick and efficient way to record the results of ONIRY® tests at the labour wards, streamlining the process for enhanced productivity.

Print the test result for your Patient's

The ONIRY App is a comprehensive desktop application with a web-based component. It has been designed specifically to manage patient data and generate **ready-to-print reports of patient results from ONIRY®.** There is a functionality to edit the data as well as customise the ONIRY® result layout for your institution as to show its address and the hospital logo.



OASIS
DIAGNOSTICS

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.

Scan & Explore more!

Only for healthcare professionals

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