

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

**September 14, 2020  
Date of Report (date of earliest event reported)**

**TransEnterix, Inc.**  
**(Exact name of Registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction of  
incorporation or organization)**

**0-19437**  
**(Commission  
File Number)**

**11-2962080**  
**(I.R.S. Employer  
Identification Number)**

**635 Davis Drive, Suite 300**  
**Morrisville, North Carolina 27560**  
**(Address of principal executive offices)**

**919-765-8400**  
**(Registrant's telephone number, including area code)**

**Not Applicable**  
**(Former name or former address, if changed since last report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of each class</b>	<b>Trading symbol</b>	<b>Name of each exchange on which registered</b>
<b>Common Stock</b> <b>\$0.001 par value per share</b>	<b>TRXC</b>	<b>NYSE American</b>

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure.**

On September 15, 2020, TransEnterix, Inc. (the “Company”) is making a corporate presentation to investors at an H.C. Wainwright conference that provides a current overview about the Company. The information provided during such corporate presentation is attached as Exhibit 99.1 to this Form 8-K.

*The information in this Item 7.01 this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.*

**Item 8.01 Other Events.**

The Company issued a press release on September 14, 2020, announcing the opening of its training center for surgeons in Japan. The full text of the press release is attached as Exhibit 99.2 hereto and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

**Exhibit No. Description**

99.1	<a href="#">TransEnterix, Inc. Corporate Presentation, September 2020.</a>
99.2	<a href="#">Press Release dated September 14, 2020.</a>
104	Cover Page Interactive Data File (formatted in inline XBRL).

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: September 15, 2020

**TRANSENERIX, INC.**

/s/ Shameze Rampertab

Shameze Rampertab

Executive Vice President and Chief Financial Officer



## **H.C. Wainwright 22nd Annual Global Investment Conference**

**Anthony Fernando, President & CEO  
September 15, 2020**



*This presentation includes statements relating to the Senhance Surgical System's market development and a general corporate update. These statements and other statements regarding our future plans and goals constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control, and which may cause results to differ materially from expectations. Factors that could cause our results to differ materially from those described include, but are not limited to, whether the market development activities related to the Senhance Surgical System will be successful, the pace of adoption of our products by surgeons, the success and market opportunity of our products, the impact on the ongoing pandemic on our business and our customers, our current cash reach, the effect on our business on existing and new regulatory requirements and other economic and competitive factors and whether we will be able to execute upon our corporate objectives. For a discussion of the risks and uncertainties associated with TransEnterix's business, please review our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 16, 2020 and our other filings we make with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which are based on our expectations as of the date of this presentation and speak only as of the origination date of this presentation. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.*

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## OUR STRATEGIC INTENT

At TransEnterix, we believe in digitizing the interface between the surgeon and patient in laparoscopy to increase control and reduce surgical variability for improved patient outcomes in today's value-based healthcare environment.

## COMPANY OVERVIEW

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# TRANSENERIX (NYSE American:TRXC)

EARLY-COMMERCIAL STAGE COMPANY USHERING IN A NEW ERA OF  
MINIMALLY INVASIVE SURGERY



Senhance®



- **Senhance Surgical Robotic System** – the first and only **Digital Laparoscopy** platform
- Significant and differentiated addressable market opportunity
- FDA Cleared, CE Marked and Japan PMDA approved
- Building awareness and ramping up clinical adoption
- Well positioned to bring Augmented Intelligence (AI) and Machine Vision to surgery



## COMPANY SNAPSHOT

FIRST NEW ENTRANT IN THE FIELD OF ABDOMINAL SURGICAL ROBOTICS IN NEARLY 20 YEARS

Active sites in the  
U.S., E.U. and Asia

3,400+ Surgeries  
Performed, to date

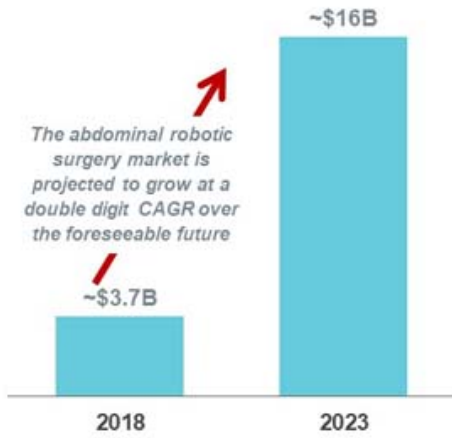
140 global employees  
with 30+ customer facing

100+  
Surgeon Users



# GLOBAL TRENDS IN ROBOTIC SURGERY

SURGICAL ROBOTICS IS A LARGE AND FAST GROWING MARKET AND LAPAROSCOPIC SURGERY IS A GREENFIELD OPPORTUNITY



**10mm**  
Annual Abdominal Surgical Procedures (EU & US)

### Current robotics market

Open Surgery  
**4mm**  
procedures  
(EU and US)

↓  
Current  
Robotic Penetration  
**25%**

### Laparoscopic greenfield opportunity

Laparoscopic Surgery  
**6mm**  
procedures  
(EU and US)

↓  
Limited  
Robotic Penetration



Source: Abdominal Surgical Robots Market Shares, Strategies, and Forecasts, Worldwide, 2017 to 2023 WinterGreen Research, June 2017, TRXC Estimates, Millennium Research Group 2020 and Intuitive Surgical

**VALUE-BASED HEALTHCARE IS FORCING HOSPITALS TO IMPROVE OUTCOMES, EFFICIENCIES, AND TALENT RETENTION**  
THE PRESSURE AND IMPACT ON SURGEONS ARE INCREASING UNDER THE CONSTRAINTS OF VALUE-BASED HEALTHCARE



OR  
Inefficiencies



Surgical  
Variability



Workforce  
Challenges



**Laparoscopy is the most widely performed surgical technique and carries limitations that compound these factors and can impact clinical outcomes**

*Digital laparoscopy seeks to address these limitations*

## The Senhance Surgical System

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# SENHANCE SYSTEM ADDRESSES KEY CHALLENGES FACING HOSPITALS AND LAPAROSCOPIC SURGEONS

## BUILDING THE BRIDGE FROM LAPAROSCOPY TO ROBOTICS

**First** robotic system with **Augmented Intelligence (AI) and Machine Vision Capabilities**

**First** robotic system to offer the security of **haptic feedback**

**First** robotic system to offer **simultaneous surgeon-controlled visualization**

**86** different types of procedure/technique surgeries performed

New standard in minimally invasive surgery with **3mm** instruments

Developed broad instrument portfolio with **70** instruments in the catalog



# WE ARE UNIQUELY FOCUSED ON DIGITAL LAPAROSCOPY



AN OPPORTUNITY AND NEED TO ADD TO THE WAYS SURGICAL ROBOTICS CREATES VALUE



## Senhance

INTUITIVE  
SURGICAL

## Da Vinci

	Digital Laparoscopy		Robotic Assisted Surgery	
	Feature	Implication	Feature	Implication
<b>Motion</b>	<ul style="list-style-type: none"> <li>Lap</li> </ul>	<ul style="list-style-type: none"> <li>Familiarity for laparoscopic surgeons</li> </ul>	<ul style="list-style-type: none"> <li>Open</li> </ul>	<ul style="list-style-type: none"> <li>More enabling for non-laparoscopists</li> </ul>
<b>Instruments</b>	<ul style="list-style-type: none"> <li>Fully reusable</li> </ul>	<ul style="list-style-type: none"> <li>Low cost per procedure</li> </ul>	<ul style="list-style-type: none"> <li>Limited Use (10x max)</li> </ul>	<ul style="list-style-type: none"> <li>High cost per procedure</li> </ul>
	<ul style="list-style-type: none"> <li>5mm and 3mm</li> </ul>	<ul style="list-style-type: none"> <li>Advances MIS benefit</li> </ul>	<ul style="list-style-type: none"> <li>8mm</li> </ul>	<ul style="list-style-type: none"> <li>Not improving invasiveness over laparoscopy</li> </ul>
<b>Additional Features</b>	<ul style="list-style-type: none"> <li>Haptic feedback</li> </ul>	<ul style="list-style-type: none"> <li>Restores significant sensory input</li> </ul>	<ul style="list-style-type: none"> <li>Wristed instruments</li> </ul>	<ul style="list-style-type: none"> <li>Enabling but higher cost per procedure</li> </ul>
	<ul style="list-style-type: none"> <li>Eye tracking camera control</li> </ul>	<ul style="list-style-type: none"> <li>Novel surgical vision control</li> </ul>		
	<ul style="list-style-type: none"> <li>Open vision system</li> </ul>	<ul style="list-style-type: none"> <li>Leverage best in class visualization technologies</li> </ul>		
	<ul style="list-style-type: none"> <li>Individual boom arms</li> </ul>	<ul style="list-style-type: none"> <li>Full patient access</li> </ul>		
	<ul style="list-style-type: none"> <li>Articulating instruments</li> </ul>	<ul style="list-style-type: none"> <li>Enabling where needed</li> </ul>		

*Standard Laparoscopic tools, digital information and decision support tools will be the primary driver of the added value through computer assistance*

*Competitors are following the Da Vinci model*

## Our Plan for 2020

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# 2020 – SENHANCE AND DIGITAL LAPAROSCOPY RECOGNIZED AS KEY COMPONENTS FOR ROBOTIC GROWTH

WE ARE FOCUSED ON:

## MARKET DEVELOPMENT

- Expand the number of sites using the Senhance System in key geographies
- Double the number of clinical cases
- Increase the number of speakers & advocates cascading our key messages

## CLINICAL EVIDENCE

- Publication of evidence supporting Senhance value propositions
  - Cost Effectiveness
  - Clinical Outcomes
  - O.R. Efficiency
  - Ergonomics

## PORTFOLIO EXPANSION

- Scene cognition and Augmented Intelligence technology launched in the US
- Full EU launch of 5mm Articulating instruments
- Indication expansion
  - Pediatrics in EU
  - General Surgery in US
  - Bariatric in US

**By End 2020 – Critical mass of advocacy, awareness, and credibility developed as a foundation to drive future growth**

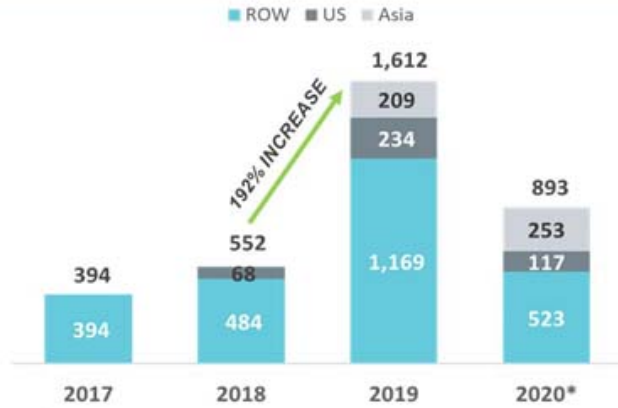


# STRONG, BROAD-BASED CLINICAL PERFORMANCE



SENHANCE DEMONSTRATING STRONG CLINICAL PERFORMANCE ACROSS THE THREE MAJOR GEOGRAPHIES

## GLOBAL CLINICAL CASE VOLUME TREND

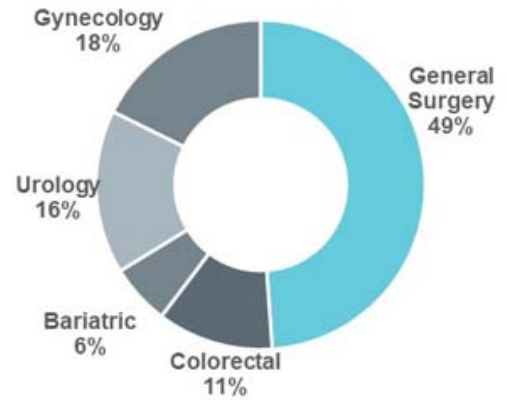


Active Sites	2017	2018	2019	2020*
Active Sites	6	15	24	30*

Strong clinical case performance in 2019  
Strong momentum in Q1 2020 dampened by COVID

\* TransEnterix Estimates and YTD Actual

## 2019/2020 CASE MIX



Adoption across multiple specialty areas,  
demonstrating broader applicability and adoption

# THE FIRST MACHINE VISION SYSTEM IN ROBOTIC SURGERY

LEADING THE WAY IN AUGMENTED INTELLIGENCE AND MACHINE VISION IN SURGERY

## SENHANCE INTELLIGENT SURGICAL UNIT (ISU)

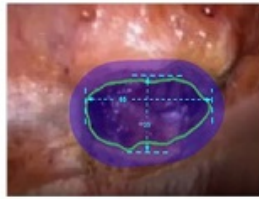


FDA 510(k) Approved  
in March 2020



In Clinical use in  
the US

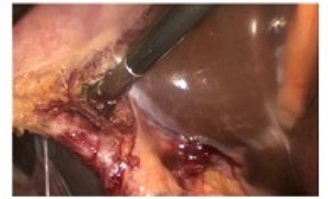
## DEFECT IDENTIFICATION AND SIZING



## 3D POINT TO POINT MEASUREMENT



## CRITICAL STRUCTURE IDENTIFICATION



FUTURE FEATURE  
ADDITIONS

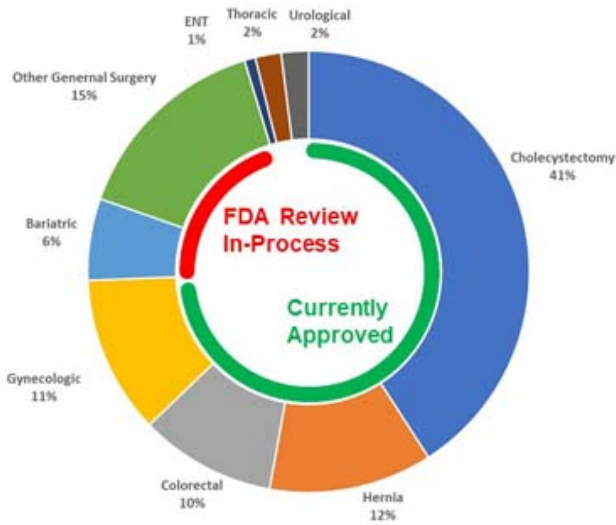
These Features are still in development and the safety or effectiveness of these products have not been established. This product/feature is not currently for sale in any market.

# GENERAL SURGERY OPPORTUNITY IN THE U.S.

GROWTH IN GENERAL SURGERY MUST COME FROM LAPAROSCOPIC MIS PROCEDURES



## US Laparoscopic Procedures by Type



- Based on current Senhance FDA 510(k) approval, 1.4M procedures are addressable in the US
- Approximately 800K additional procedure will be addressable with expected FDA 510(k) clearance

Source: Millennium Research Group, Inc. Laparoscopic Devices Report US 2020

## **Financial Overview & Key Operational Accomplishments**

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# 2020 OPERATIONAL HIGHLIGHTS

## SIGNIFICANT OPERATIONAL PROGRESS YEAR TO DATE

- Eight Senhance lease agreements signed, 6 clinical programs initiated and completed ~900 cases YTD
- Filed and received FDA clearance for Augmented Intelligence(AI) and machine vision system, Intelligent Surgical Unit (ISU)
- Received CE Mark for Pediatric use of Senhance in Europe
- Made FDA 510(k) submission for General Surgery indication expansion
- Established Asia Pacific Training Center at Saitama Medical University International Medical Center in Japan



# FINANCIAL HIGHLIGHTS

## PRUDENTLY MANAGING CASH TO FUND EXECUTION



- Pro-forma cash of \$29.9M<sup>1</sup>
- Debt-free, except for government promissory note
- Completed restructuring expected to reduce cash burn by 37% in FY2020 compared to FY2019
- Reduced operating expenses by 15% or \$2.4M in Q2 2020 compared to Q1 2020
- Cash sufficient for needs into Q2 2021

1. Includes Q2 2020 cash of \$16.2M and July 6, 2020 public offering net proceeds of \$13.7M



## TransEnterix Announces Establishment of Japanese Training Center for Senhance Surgical System

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--September 14, 2020-- TransEnterix, Inc. (NYSE American:TRXC), a medical device company that is digitizing the interface between the surgeon and the patient to improve minimally invasive surgery, today announced that it established the first training center for the Senhance® Surgical System in the Asia-Pacific region in Japan at the Saitama Medical University International Medical Center in the Greater Tokyo Area.

“The Asia-Pacific region has been a major contributor of new system placements and surgical cases utilizing Senhance, a trend that we would expect to continue into the future,” said Anthony Fernando, president and chief executive officer at TransEnterix. “We see the establishment of a dedicated surgical training center at Saitama as an important milestone in enabling faster adoption of Senhance in minimally invasive surgery throughout the region. Given the growth and opportunity in the Asia-Pacific region, we are pleased to provide local access to training for Asian surgical teams, which is particularly important in the current environment where travel to the US or EU is more difficult.”

“We were the first center in Japan to begin a clinical program utilizing the Senhance System to provide advanced digital surgical technology in treating our patients, and have grown our clinical expertise using the system in multiple surgical disciplines,” said Dr. Isamu Koyama, Senior Managing Director of Saitama Medical University. “This training center will allow surgeons from throughout Japan and the region to collaborate and develop their skills on the Senhance System as they begin utilizing this technology in their own institutions.”

The Asia-Pacific laparoscopy device market is expected to grow at a cumulative average growth rate of 8.2% from \$1.26 billion in 2019 to \$1.87 billion by 2024, according to Market Data Forecast, Inc. This expected growth, the significant benefits of digital laparoscopy, and the establishment of the Japanese Training Center is expected to drive increased utilization of our six system installations in the Asia-Pacific region and encourage further adoption of our technology in additional hospitals. In 2020, the number of clinical case procedures in this region utilizing the Senhance System has surpassed the number of procedures in all of 2019, despite the impact of the COVID-19 pandemic.

The Senhance System is the first and only digital laparoscopic surgical platform designed to maintain laparoscopic MIS standards while providing digital benefits such as haptic feedback, robotic precision, comfortable ergonomics, advanced instrumentation including, 3mm microlaparoscopic instruments, eye-sensing camera control and reusable standard instruments to help maintain per-procedure costs similar to traditional laparoscopy. The Senhance Surgical System was approved for use by the Japanese Ministry of Health, Labor and Welfare (MHLW) in 2019, and has the broadest procedural reimbursement of any abdominal robotic surgery platform in Japan, which applies to 98 benign and malignant laparoscopic procedures across general, colorectal, gynecologic, pediatric and urologic surgeries at reimbursement rates equivalent to traditional laparoscopy in Category A1.

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## **About Saitama Medical University International Medical Center**

Saitama Medical University International Medical Center was established in April 2007 with the objective of contributing to regional and Japanese medicine, aiming to create an internationally competitive world-class hospital. Their mission is to cover all areas of Saitama prefecture, to be dedicated in highly specialized medical service for cancer and heart disease, and to provide advanced critical and emergency medical care. The medical center is affiliated with Saitama Medical University Medical Hospital, and is one of the top ranked hospitals in Japan. Saitama Medical University International Medical Center is the first university hospital in Japan to be Joint Commission International (JCI) accredited.

## **About TransEnterix**

At TransEnterix, Inc., we are digitizing the interface between the surgeon and the patient to improve minimally invasive surgery (MIS) through a new category of care called Digital Laparoscopy. Digitizing the interface enables the use of advanced capabilities like augmented intelligence, connectivity and robotics in laparoscopy, and allows us to address the current clinical, cognitive and economic shortcomings in surgery. The system features the first machine vision system for use in robotic surgery which is powered by the new Intelligent Surgical Unit (ISU™) that enables augmented intelligence in surgery. The Senhance® Surgical System brings the benefits of Digital Laparoscopy to patients around the world while staying true to the principles of value-based healthcare. Learn more about Digital Laparoscopy with the Senhance Surgical System here: <https://Senhance.com/>. Now available for sale in the US, the EU, Japan, and select other countries. For a complete list of indications for use, please visit: <https://www.transenterix.com/indications-for-use/>.

## **Forward-Looking Statements**

This press release includes statements relating to the Senhance System and the Company's first training center in Japan. These statements and other statements regarding our future plans and goals constitute "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control and which may cause results to differ materially from expectations and include whether the Company's first training center in Japan at the Saitama Medical University International Medical Center will be an important milestone in enabling faster adoption of Senhance in minimally invasive surgery throughout the region, whether the training center will allow surgeons from throughout Japan and the region to collaborate and develop their skills on the Senhance System as they begin utilizing this technology in their own institutions and whether the expected growth, significant benefits of digital laparoscopy and the establishment of the Japanese Training Center will drive increased utilization of our installed systems in the Asia-Pacific region and encourage further adoption of our technology in hospitals. For a discussion of the risks and uncertainties associated with TransEnterix's business, please review our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 16, 2020 and our other filings we make with the SEC. You are cautioned not to place undue reliance on these forward looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Source: TransEnterix, Inc.

For TransEnterix, Inc.

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