



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor  
MANDY COHEN, MD, MPH • Secretary  
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

July 30, 2021

Jeffery Shovelin  
[jshoveli@vidanthhealth.com](mailto:jshoveli@vidanthhealth.com)

**No Review**

**Record #:** 3620  
**Date of Request:** July 22, 2021  
**Facility Name:** Eastern Carolina Health-Beaufort, Inc.  
**FID #:** 932963  
**Business Name:** Beaufort County Hospital Association, Inc.  
**Business #:** 145  
**Project Description:** Acquire a ROSA Orthopedic Surgical System  
**County:** Beaufort

Dear Mr. Shovelin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Gregory F. Yakaboski  
Project Analyst

Lisa Pittman  
Acting Chief, Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR  
NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION  
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603  
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704  
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



## VIDANT HEALTH™

July 22, 2021

Ms. Micheala Mitchell, Chief,  
Healthcare Planning and Certificate of Need,  
Division of Health Service Regulation  
NC Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, NC 27699-2704

**RE: Request for “No Review” / Vidant Beaufort Hospital / Acquire a ROSA Orthopedic Surgical System / Beaufort County / FID #932963 / License #H0188**

Dear Ms. Mitchell:

East Carolina Health-Beaufort, Inc. d/b/a Vidant Beaufort Hospital (“VBEA”) is planning to purchase a new ROSA orthopedic joint replacement surgical system (“ROSA”). A brochure detailing the capabilities of this system is attached. The proposed new ROSA would represent a new incremental increase in equipment and would not be considered replacement. VBEA believes the proposed project is not subject to review under North Carolina’s Certificate of Need laws. The only definition of a new institutional health service that could possibly apply to this equipment in “major medical equipment”. Pursuant to N.C.G.S. 131E-176(14o), the proposed project does not meet the definition of “major medical equipment” as defined below.

*“Major medical equipment” means A single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.*

As the attached vendor quote states, the estimated cost to add the ROSA is \$749,545 (including shipping). Since the ROSA is portable and plugs into a standard outlet, no construction, renovation, or any other activities are essential to acquiring and making the ROSA operational. In addition, VBEA believes the proposed quote for the equipment represents the fair market value for the equipment based on other medical equipment projects Vidant Health (parent company) has completed over the years.

Since the total capital cost of the project is less than \$750,000, the proposed project does not meet the definition of major medical equipment. Because the proposed project does not meet the definition of major medical equipment, VBEA requests a determination that this project is exempt from CON review. If you need additional information or clarification, please do not hesitate to contact me at (252) 847-3631.

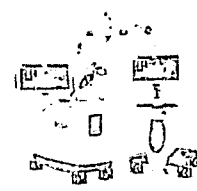
Sincerely,

A handwritten signature in black ink, appearing to read 'Jeffrey Shovelin', with a long horizontal flourish extending to the right.

Jeffrey Shovelin  
VP – Business Planning and Strategy  
Vidant Health  
PO Box 6028  
Greenville, NC 27835-6028  
Phone: (252)-847-3631  
Email: [jshoveli@vidanthealth.com](mailto:jshoveli@vidanthealth.com)



# Zimmer Biomet Proposal



Account # 4905  
 Account Name Vidant Beaufort Hospital  
 Attention Ken Shaw  
 Address 628 EAST 12th Street  
 City, State, Zip Washington, NC 27889  
 Phone Number 252-847-0702  
 Fax Number  
 E-Mail kenshaw@vidanthealth.com

Date July 8, 2021  
 Quote # RK VIDANT052021-01  
 Quote Valid Until 9/6/2021  
 Regional Sales Manager Tanner Forster  
 Phone Number 913-231-0855  
 E-Mail tanner.forster@zimmerbiomet.com

Customer Signature  
 Printed Name  
 Date

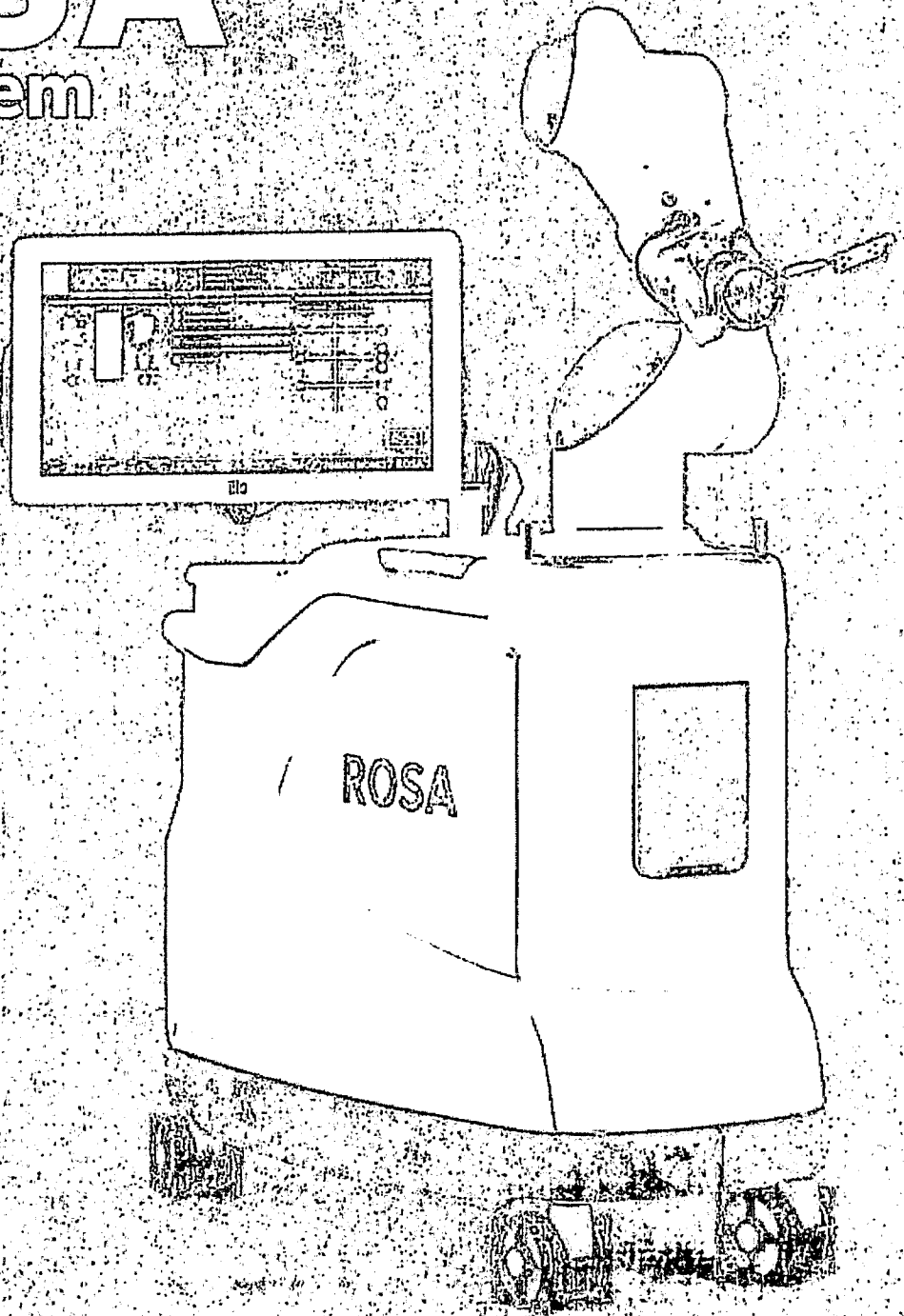
ITEM #	ITEM DESCRIPTION	UM	BOX QTY	ORDER QTY	LIST PRICE	UNIT PRICE	DISCOUNT	NET
<b><u>ROSA Knee System</u></b>								
20-8020-100-01	ROSA KNEE PLATFORM	1	1	1	\$ 1,300,000.00	\$ 739,350.00		\$ 739,350.00
	ROSA KNEE OPTICAL UNIT					INCLUDED		INCLUDED
	ROSA KNEE SOFTWARE					INCLUDED		INCLUDED
	ROSA KNEE SOFTWARE UPGRADE					INCLUDED		INCLUDED
	CLINICAL PC					INCLUDED		INCLUDED
<b>TOTAL Capital</b>								\$ 739,350.00
<b><u>Instrument Kits</u></b>								
KT-8020-060-00	Persona Implant Kit	1	1	2		Consigned		consigned
KT-8020-062-00	Vanguard Implant Kit	0	0	0				
<b><u>X-PSI Calibration Kit</u></b>								
20-8085-020-00	X-PSI Calibration Kit	1			\$ 195.00	\$ 195.00	0%	\$ 195.00
<b><u>Marketing</u></b>								
<b><u>Service</u></b>								
MANUFWARRK1	Standard Warranty + Preventative Maintenance, ROSA Knee Year-1	1			\$ 10,000.00			INCLUDED WITH PURCHASE
	Years 2 -5 quoted separately at \$98,500/yr				\$ 130,000.00	\$ 98,500.00		
<b><u>Shipping</u></b>								
Shipping		1			\$ 10,000.00	\$ 10,000.00	0%	Invoiced Separately
<b>TOTAL</b>								<b>\$ 739,545.00</b>

Pay Terms Net 30

Proposal Prepared By:  
 Zimmer U.S., Inc.  
 P.O. Box 708  
 Warsaw, IN 46581-0708

# ROSA<sup>®</sup>

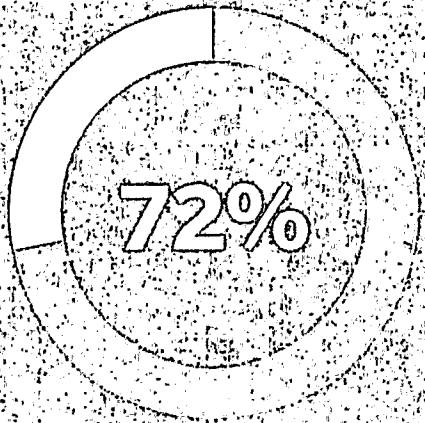
## Knee System



# ROSA KNEE

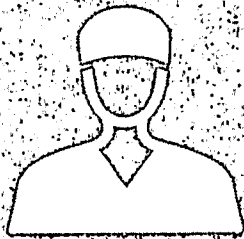
Patients are becoming increasingly aware of their healthcare options, especially when it comes to robotic-assisted surgery and the inherent value it brings. Meanwhile, healthcare providers are expected to continually increase patient volume, deliver patient quality and increase efficiency. To help address these critical concerns, Zimmer Biomet offers solutions to modernize your practice through efficient, easy-to-integrate technology.

ROSA Knee was designed by surgeons for surgeons as an accurate and efficient surgical assistant that also produces data. We keep you in the driver's seat by letting you maintain your current technique, approach and philosophy so you can focus on achieving the optimal outcome for your patients.

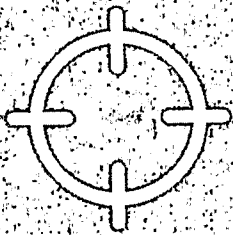


IN A 2016 GLOBAL SURVEY ASSESSING PUBLIC PERCEPTIONS ABOUT ROBOTIC-ASSISTED SURGERY, 72% OF RESPONDENTS INDICATED ROBOTIC-ASSISTED SURGERY WAS

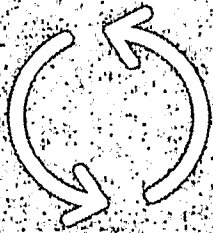
SAFER, FASTER AND LESS PAINFUL (OR CAUSED) BETTER RESULTS THAN MINIMALLY INVASIVE CONVENTIONAL SURGERY.



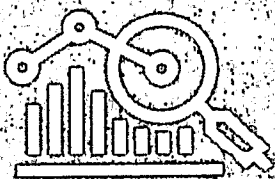
**SURGEON-CENTERED**



**ACCURATE<sup>2</sup>**



**EFFICIENT**



**DATA DRIVEN**

# SURGEON-CENTERED

## IMPLANTS DESIGNED TO IMPROVE OUTCOMES

Technologies are only as good as the implants they are used with. ROSA knee provides you the flexibility to utilize our leading knee brand: Persona™ The Personalized Knee™. The Persona Knee system is Zimmer Biomet's most comprehensive primary knee system, incorporating personalized implants, precise instrumentation and proven technology.<sup>3-7</sup>

Since its introduction in 2012, surgeons around the world have implanted over 1,000,000 Persona Total Knees<sup>8</sup>

### PERSONALIZED IMPLANTS

- Anatomic implants in standard and narrow sizes developed to more closely match the shape and size of various patient ethnicities, genders and statures.

### PRECISE INSTRUMENTATION

- Ergonomic instruments designed for precision with greater ease of use.

### PROVEN TECHNOLOGY

- Trabecular Metal™ Technology and Vivacit-E® HXPLE Material provide clinically proven solutions to help improve efficiency and implant longevity.<sup>1,7</sup>
- Built on the heritage of the NexGen® Knee System, the most widely used and clinically proven total knee system in the world.<sup>9</sup>

- ROSA Knee offers a simple and intuitive user interface operated solely by you and your staff adapting to your current approach, philosophy and workflow

Perform a variety of approaches with ROSA Knee

Measured  
Resection

Gap  
Balancing

Hybrid  
Approach

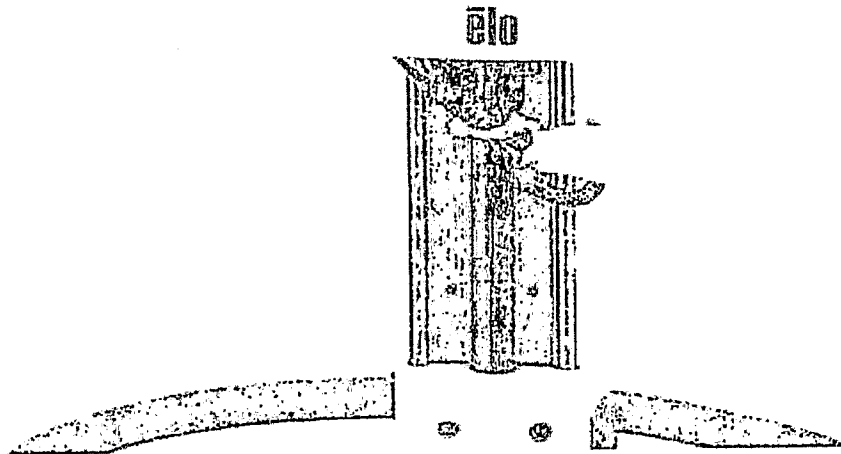
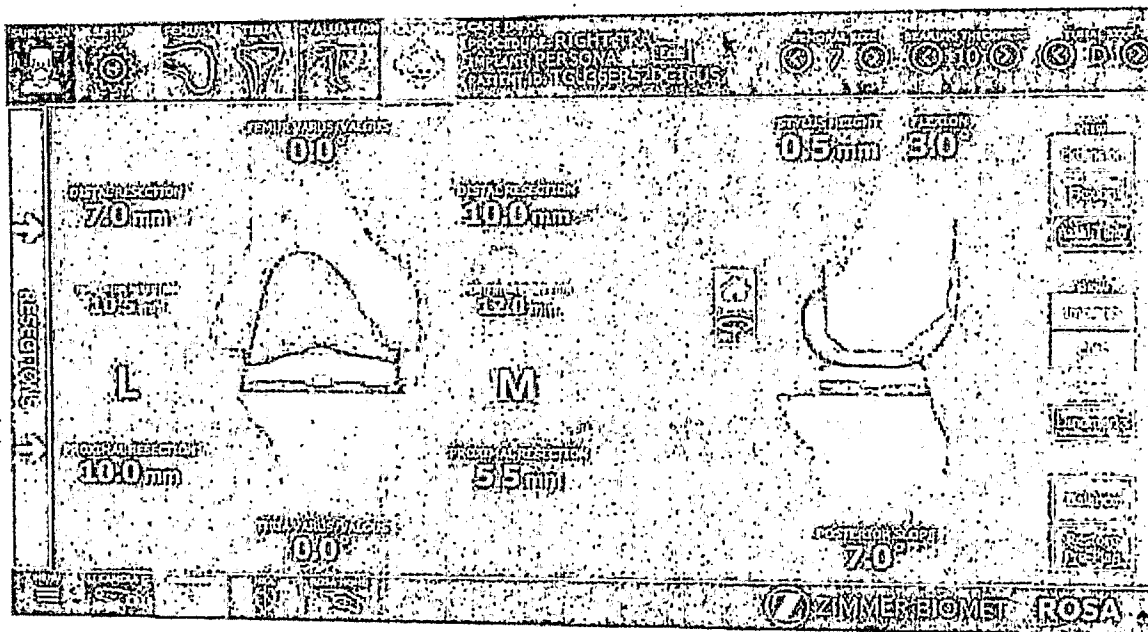


## COLLABORATION DRIVEN BY YOU

Factoring in soft tissue balance is not a new concept in knee replacement, but finding the right soft tissue balance with static, traditional instruments is highly subjective.

With ROSA Knee, surgeons are able to objectively measure soft tissue feedback and virtually conduct a knee replacement before performing any resections.

- In the Planning screen, surgeons receive live feedback of soft tissues, femoral rotation and ligament tension.
- Dynamic patient data throughout the range of motion.
- Live cut values ensure resections remain on plane.



# ACCURATE

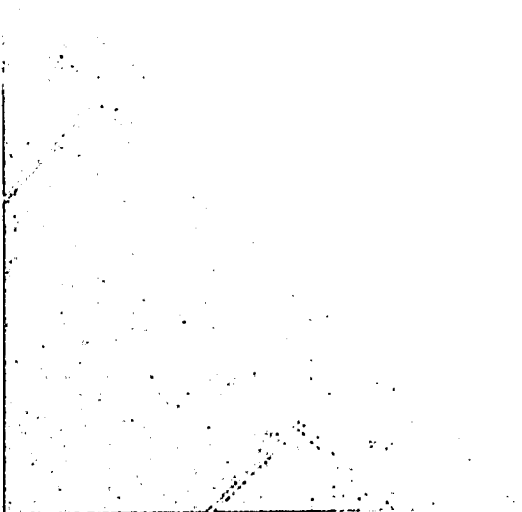
## DELIVERING HIGHLY ACCURATE RESECTIONS AND LIMB ALIGNMENT<sup>2,10</sup>

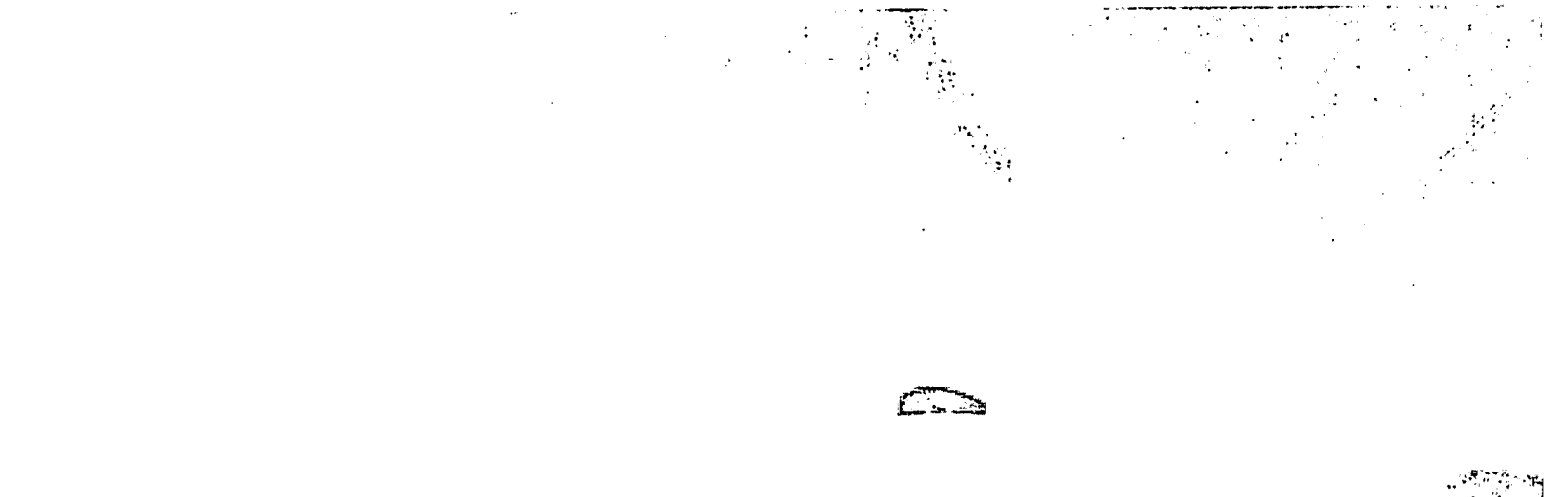
Inaccurate implantation rates of up to 30 percent have been reported using the conventional technique in TKA, independent of the surgeon's experience.<sup>11</sup> ROSA Knee offers surgeons precision and accuracy through the cut flow and validation feature, which is designed to ensure proper alignment in real time. A recent study shows ROSA Knee more accurate and more reproducible resections than conventional instrumentation.<sup>10</sup>

- Provides high levels of precision in regard to targeted angles and resection thickness.<sup>2</sup>
- Less outliers and 100% of cases within 3° of the targeted neutral alignment.<sup>10</sup>
- Validates all resection mean differences between the target resection and the measured resection were below 0.7 and had standard deviations below 1.1 mm.<sup>2</sup>
- Fewer outliers for ROSA Knee cases for all bone resection angles.<sup>10</sup>

## SOFT TISSUE MANAGEMENT

With ROSA Knee real-time soft-tissue balancing, surgeons can determine resections based on each patient's soft tissue as well as bony anatomy. This also allows the surgeon to personalize rotation of the femoral component based on ligament tension. Other robotic systems on the market collect soft tissue information by taking snapshots of the knee in two positions (flexion and extension), so the surgeon cannot collect data about how the knee is responding as it is being manipulated in the procedure.





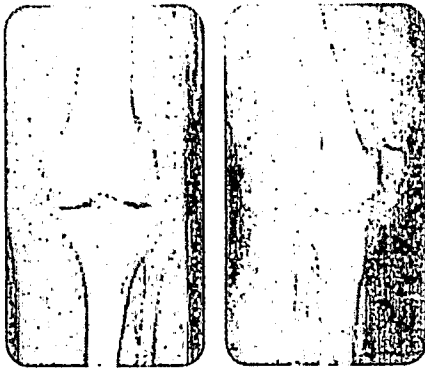
ROSA Knee is designed to offer surgeons precision and accuracy through the cut flow and validation feature, which is designed to ensure proper alignment in real time.

ROSA

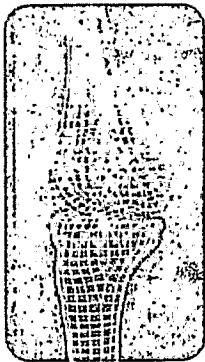
# EFFICIENT

## FLEXIBLE IMAGING OPTIONS

Based on surgeon preference, ROSA Knee offers both image-based and image-free options for greater flexibility. This reduces the time between image acquisition and preoperative planning, addresses reimbursement concerns, limits patient's exposure to radiation and minimizes scheduling requirements.

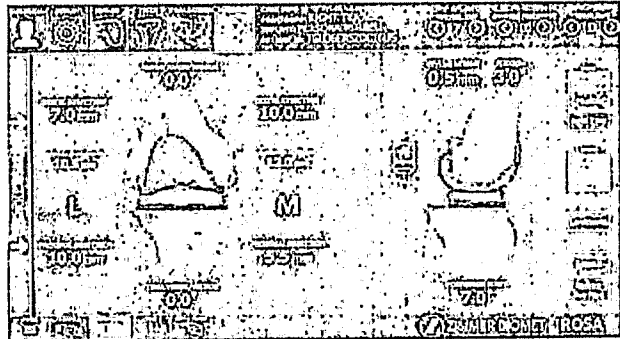


2D X-rays are submitted to your assigned Personalized Solutions Planning Expert



X-rays are transformed into a digital, 3D replication of the patient's anatomy

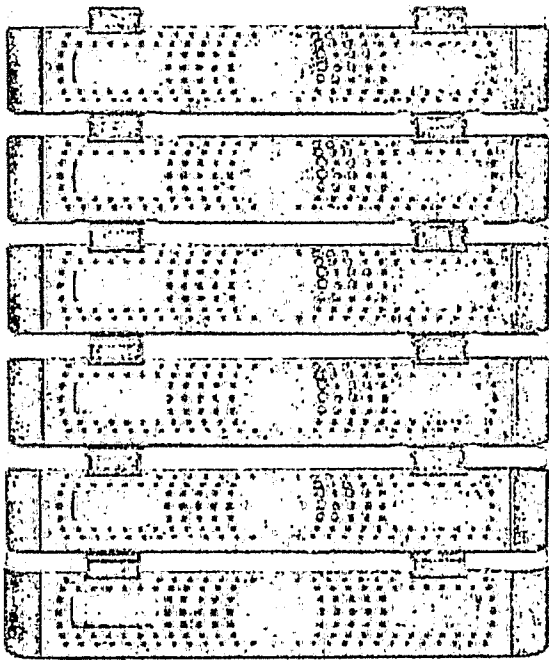
A plan is created and displayed on the user interface based on the patient's unique anatomy



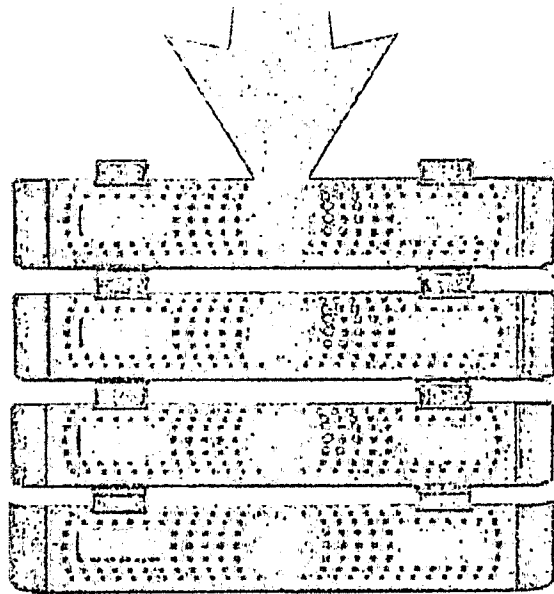
## REDUCED INSTRUMENTATION

The Efficient Care program and X-Atlas technology lowers the cost to serve through experienced case planning and unique modular instrument trays that provide you with all the instrumentation you need - while eliminating the instruments you don't.

## POTENTIAL SAVINGS<sup>12</sup> FOR EACH CASE



Six Trays



Four Trays

# DATA-DRIVEN

The data collected through ROSA Knee, is utilized to generate ROSA Knee Reports on the **OrthoIntel Orthopedic Intelligence Platform**. The OrthoIntel Orthopedic Intelligence Platform is a care management system that connects the **pre-, intra and post-operative data** gathered through the mymobility™ application\* as well as ROSA Knee to help uncover clinical insights throughout the episode of care. These insights are intended to help surgeons and care teams optimize care.

## HELP SURGEONS VISUALIZE THE CONNECTIONS BETWEEN INTRAOPERATIVE CARE AND POST-OPERATIVE RECOVERY.

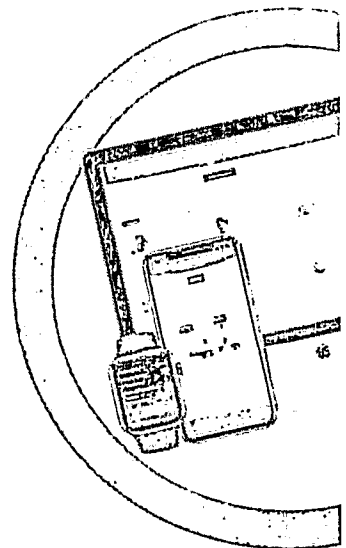
The following data metrics are currently captured on OrthoIntel Orthopedic Intelligence Platform ROSA Knee Reports:

### Pre and post-operative metrics:

- Steps
- PROMs (KOOS Jr.)
- Stand Time
- Demographics (age and gender)

### Intraoperative outcome comparisons for final knee state soft tissue balancing and change knee state pre-surgical measurements:

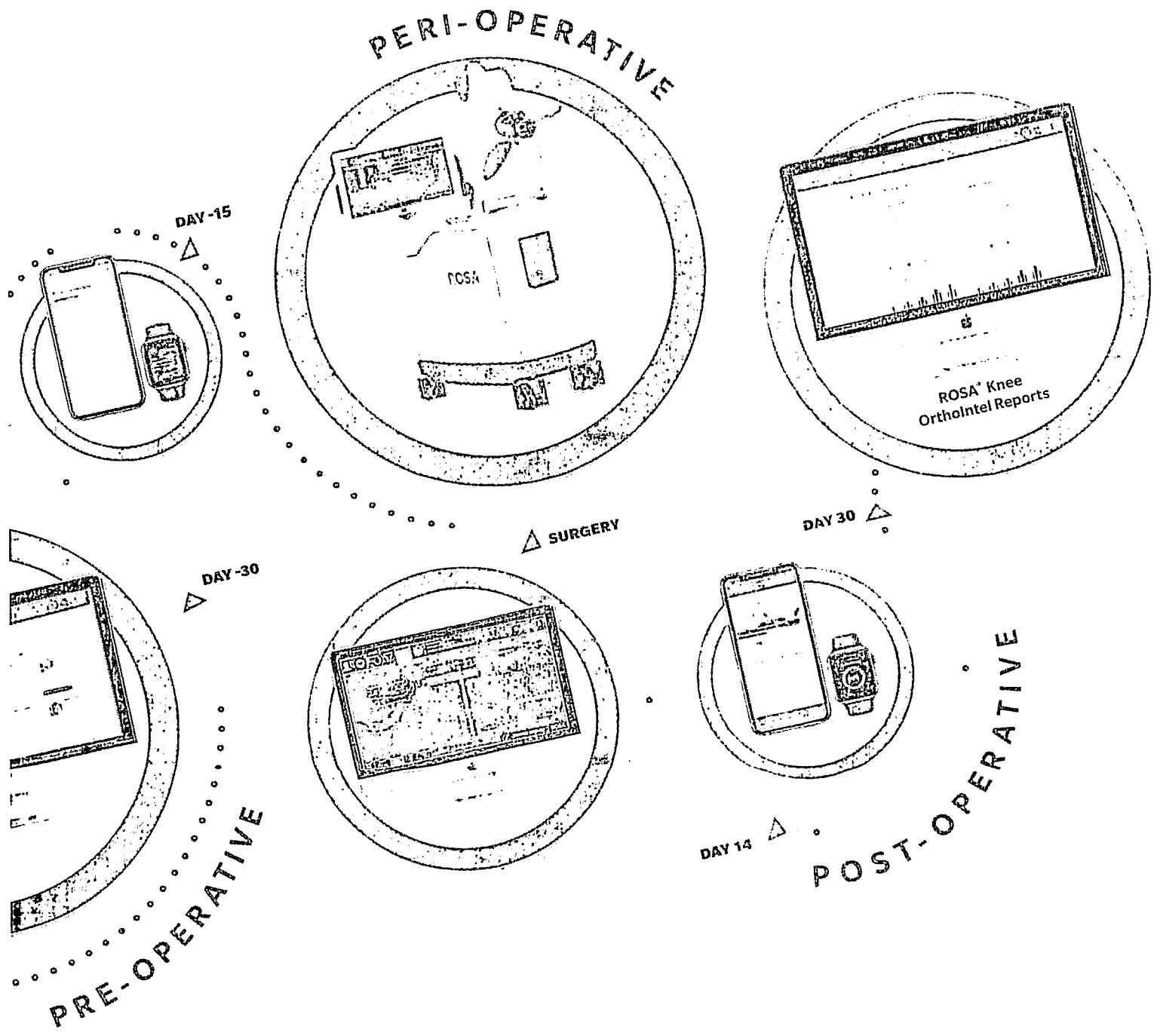
- Hip-Knee-Angle (HKA)
- Medial/Lateral Laxity at full extension
- Medial/Lateral Laxity at 90 degrees flexion
- Max Varus/Valgus at full extension
- Max Varus/Valgus at 90 degrees flexion



\*mymobility is a patient management dashboard that delivers passively collected data that can be used to track patient progression throughout the episode of care. Additionally, it can provide information to identify patients who aren't engaged or as active as you would like. Patients must have a compatible smart phone to use mymobility

**DAY -45**  
Surgery Scheduled ▲

# SEE THE CONNECTION



**References**

1. Boys, J. A., Alicuben, E. T., DeMeester, M. J., Worrell, S. G., Oh, D. S., Hagen, J. A., & DeMeester, S. R. (2016). Public perceptions on robotic surgery, hospitals with robots, and surgeons that use them. *Surgical endoscopy*, 30(4), 1310–1316. 2016. <https://doi.org/10.1007/s00464-015-4368-6>
2. Parratte, S., et al. Instability After Total Knee Arthroplasty. *Journal of Bone Joint Surgery (America)*. 90(1): 184, 2008. Cadaveric testing is not necessarily indicative of clinical performance.
3. Zhang, Y., et al. Interfacial Frictional Behavior Cancellous Bone, Cortical Bone, and a Novel Porous Tantalum Biomaterial. *Journal of Musculoskeletal Research*. 3(4): 245-251, 1999.
4. Bobyn, J.D., et al. Characteristics of Bone In-growth and Interface Mechanics of a New Porous Tantalum Biomaterial. *Journal of Bone and Joint Surgery (British)*. 81-B(5): 907, 1999.
5. Shirazi-Adl, A., et al. Experimental Determination of Friction Characteristics at the Trabecular Bone / Porous-coated Metal Interface in Cementless Implants. *The Journal of Biomedical Research*. 27: 167- 175, 1993.
6. Levine, B. et al. Experimental and Clinical Performance of Porous Metal Tantalum in Orthopedic Surgery. *Biomaterials*. 27: 4671-81, 2006.
7. Zimmer ZRR\_WA\_2537\_12.
8. Internal Persona Knee Cumulative Sales Report - Sales Globally as of May 2019.
9. Statement based on: 5 million implantations<sup>9h</sup> 300+ Publications<sup>9a</sup> 100% Survivorship at 17 Years<sup>9a</sup> Lowest revision rate<sup>9b,c</sup> Benchmark for PROMs<sup>9d</sup> 10A\* ODEP rating for CR and PS knees both with and without patella<sup>9e</sup> Every 90 seconds a patient receives a NexGen knee<sup>9f</sup> 1 in 5 knees implanted globally is a NexGen Knee<sup>9g</sup>
  - 9a. Kim, J.H., et al. Cementless and cemented total knee arthroplasty in patients younger than fifty-five years: Which is better? *International Orthopaedics*. 35(01): 127-131, 2011.
  - 9b. Australian Orthopaedic Association National Joint Replacement Registry. Annual Report, Adelaide, AOA 2018. Table 1.11 Cumulative Percent Revision of Primary Total Knee Replacement with Cement Fixation.
  - 9c. Australian Orthopaedic Association National Joint Replacement Registry. Annual Report, Adelaide, AOA 2018. Table 1.11 Cumulative Percent Revision of Primary Total Knee Replacement with Cementless Fixation.
  - 9d. Australian Orthopaedic Association National Joint Replacement Registry. Annual Report, Adelaide, AOA 2018. Table 1.11 Cumulative Percent Revision of Primary Total Knee Replacement with Hybrid Fixation.
  - 9e. Swedish Knee Register. The 2016 Swedish National Quality Evaluation of Total Knee Replacement. (p. 12-13)
  - 9f. Naket, J. et al. The effect of surgical factors on early patient-reported outcome measures (PROMs) following total knee replacement. *J Bone Joint Surg Br*. 94(10): 2012.
  - 9g. The 2019 PROMs data can be found at <http://www.odep.org.uk>
  - 9h. 2019 Sales data available at Zimmer Biomet
  - 9i. EMBASE (pubmed) NexGen® All-in-One® Knee

10. Seidenstein A, Birmingham M, Foran J, Ogden S. Better accuracy and reproducibility of a new robotically-assisted system for total knee arthroplasty compared to conventional instrumentation: a cadaveric study. *Knee Surg Sports Traumatol Arthrosc*. 2020 May 24. doi: 1007/s00167-020-06038-w. Epub ahead of print. PMID: 32448945 Cadaveric testing is not necessarily indicative of clinical performance.
11. Daniilidis, K., & Tibesku, C. O. (2014). A comparison of conventional and patient-specific instruments in total knee arthroplasty. *International Orthopaedics*, 38(3), 503–508. 2014 <https://doi.org/10.1007/s00264-013-2028-9>.
12. Persona® Instrument Tray Reduction. November 2018.

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For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert or contact your local representative; visit [www.zimmerbiomet.com](http://www.zimmerbiomet.com) for additional product information.

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