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@vidanthealth.com

No Review

Record #:	**3619**
Date of Request:	July 22, 2021
Facility Name:	SurgiCenter of Eastern Carolina, LLC
FID #:	943478
Business Name:	SurgiCenter of Eastern Carolina, LLC
Business #:	1740
Project Description:	Acquire a ROSA Orthopedic Surgical System
County:	Pitt

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
Assistant Chief, Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR

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 SurgiCenter / Acquire a ROSA Orthopedic Surgical System / Pitt County / FID #943478 / License # AS0012

Dear Ms. Mitchell:

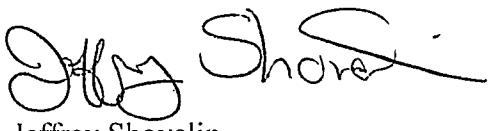
SurgiCenter of Eastern Carolina, LLC d/b/a Vidant SurgiCenter ("VSC") is planning to purchase a new ROSA orthopedic joint replacement surgical system ("ROSA"). A brochure detailing the capabilities of this system is attached. The proposed new ROSA would represent a new incremental increase in equipment and would not be considered replacement. VSC 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, VSC 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.

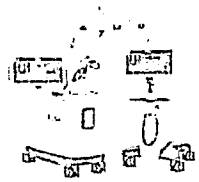
Since the total capital cost of the project is less than $750,000, the proposed project does not meet the definition of major medical equipment. Because the proposed project does not meet the definition of major medical equipment, VSC requests a determination that this project is exempt from CON review.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

Sincerely,



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

Zimmer Biomet Proposal



Account #	22832
Account Name	Vidant Surgi Center
Attention	Ken Shaw
Address	102 Bethesda Drive
City, State, Zip	Greenville, NC 27834
Phone Number	252-847-0702
Fax Number	
E-Mail	ken.shaw@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	

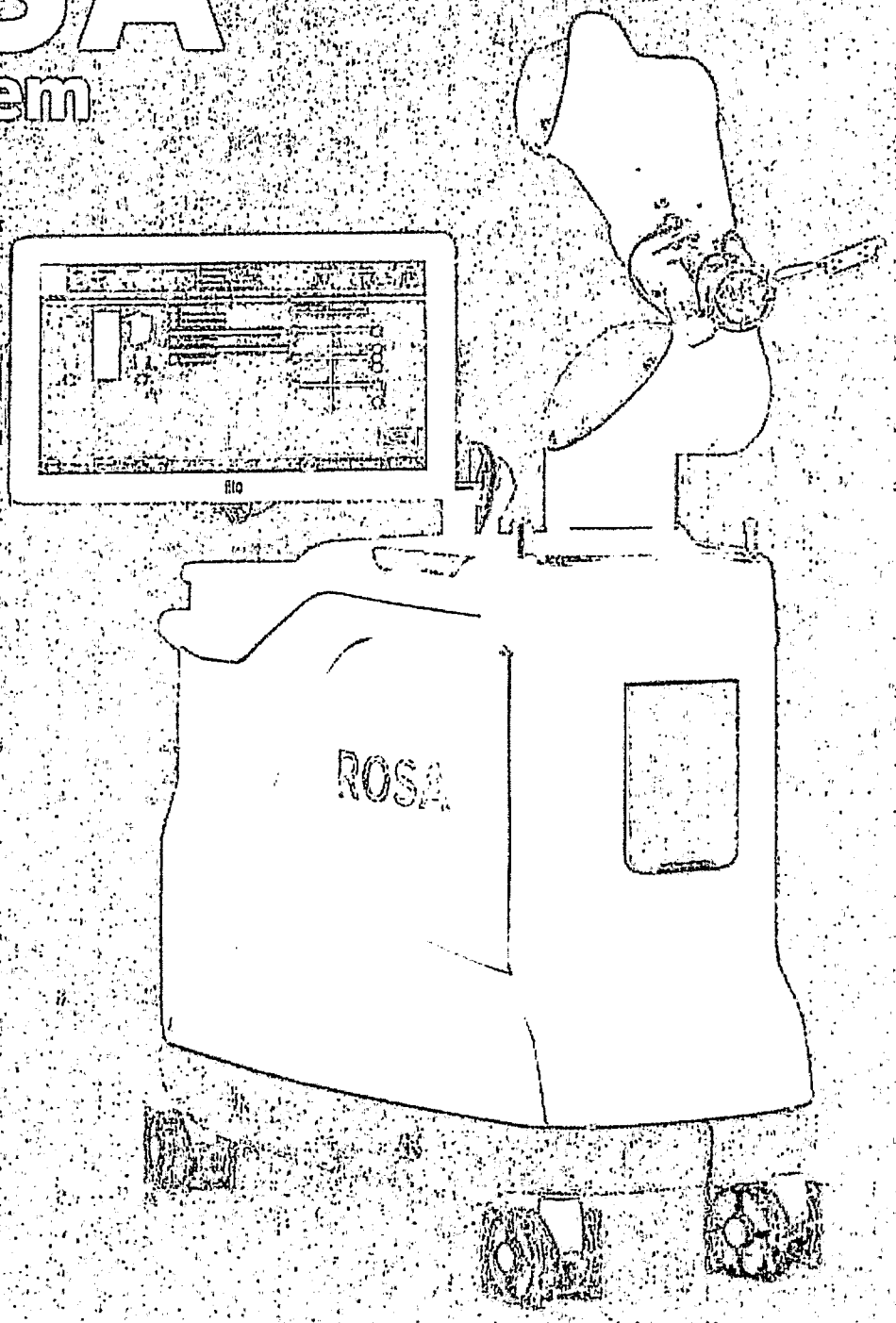
ITEM #	ITEM DESCRIPTION	UM	BOX QYT	ORDER QTY	LIST PRICE	UNIT PRICE	DISCOUNT	NET
ROSA Knee System								
20-8020-100-01	ROSA KNEE PLATFORM	1		1	$ 1,300,000.00	$ 739,350.00		$ 739,350.00
	ROSA KNEE OPTICAL UNIT					INCLUDED		INCLUDED
	ROSA KNEE SOFTWARE					INCLUDED		INCLUDED
	ROSA KNEE SOFTWARE UPGRADE					INCLUDED		INCLUDED
	CLINICAL PC					INCLUDED		INCLUDED
TOTAL Capital								$ 739,350.00
Instrument Kits								
KT-8020-060-00	Persona Implant Kit	1	1	2		Consigned		consigned
KT-8020-062-00	Vanguard Implant Kit	0	0	0				
X-PSI Calibration Kit								
20-8085-020-00	X-PSI Calibration Kit	1			$ 195.00	$ 195.00	0%	$ 195.00
Marketing								
Service								
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		
Shipping								
Shipping		1			$ 10,000.00	$ 10,000.00	0%	Invoiced Separately
							TOTAL	$ 739,545.00

Pay Terms Net 30

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

ROSA®

Knee System

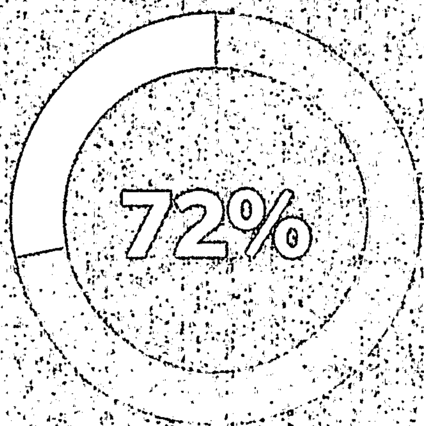


ZIMMER BIOMET

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 OFFERED BETTER RESULTS THAN MINIMALLY INVASIVE CONVENTIONAL SURGERY.[1]

SURGEON-CENTERED

ACCURATE[2]

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.[3-7]

Since its introduction in 2012, surgeons around the world have implanted over 1,000,000 Persona Total Knees[8]

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[3-7]
- Built on the heritage of the NexGen® Knee System, the most widely used and clinically proven total knee system in the world.[9]

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

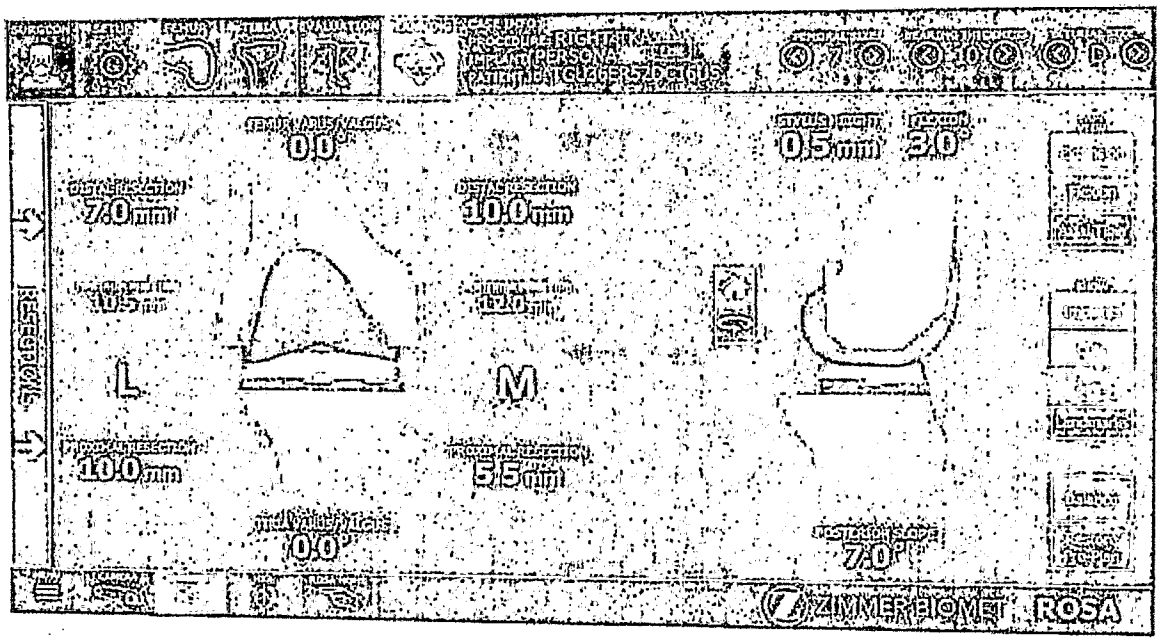
Perform a variety of approaches with ROSA Knee

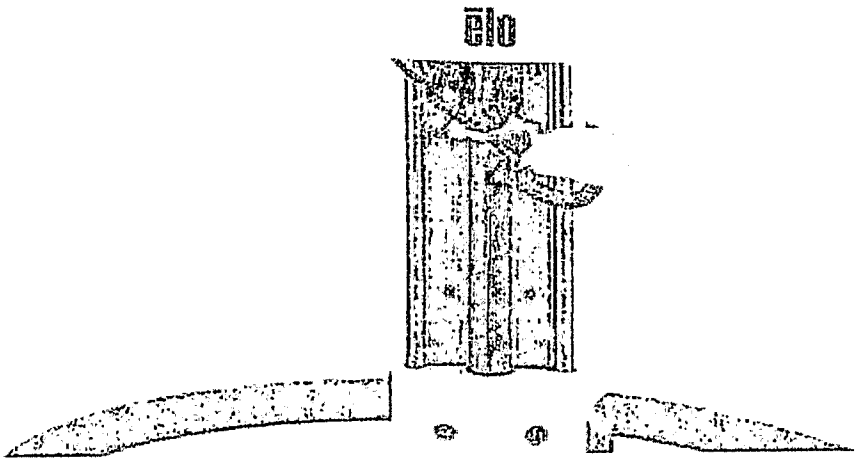
COLLABORATION DRIVEN BY YOU

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

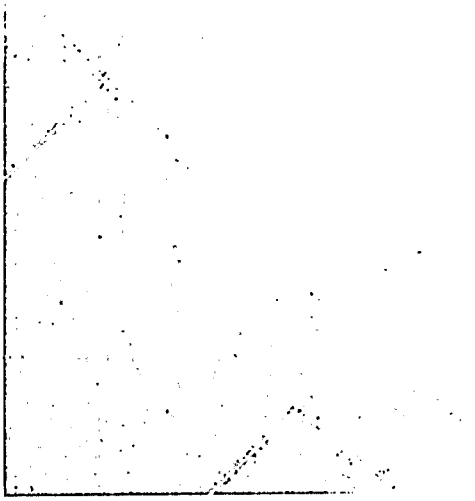
DELIVERING HIGHLY ACCURATE RESECTIONS AND LIMB ALIGNMENT[2,10]

Inaccurate implantation rates of up to 30 percent have been reported using the conventional technique in TKA, independent of the surgeon's experience.[11] 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.[10]

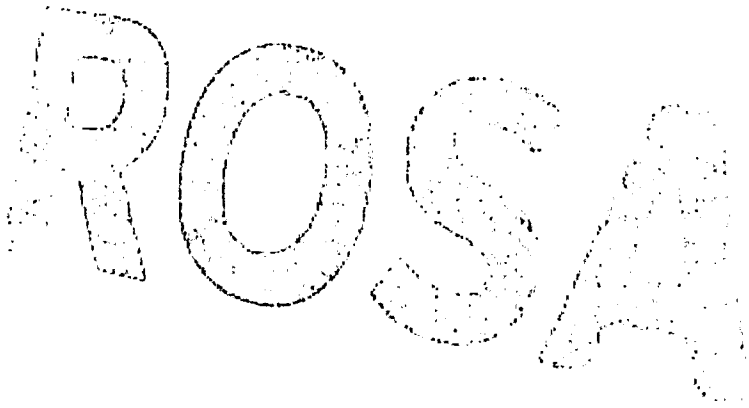
- Provides high levels of precision in regard to targeted angles and resection thickness.[2]
- Less outliers and 100% of cases within 3° of the targeted neutral alignment.[10]
- Validates all resection mean differences between the target resection and the measured resection were below 0.7 and had standard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

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.



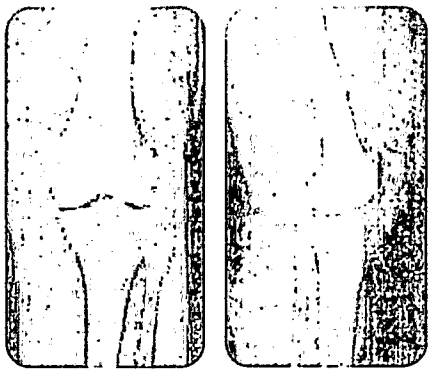
ROSA Knee is designed to offer surgeons precision and accuracy through the cut flow and validation feature, which is designed to ensure proper alignment in real time.



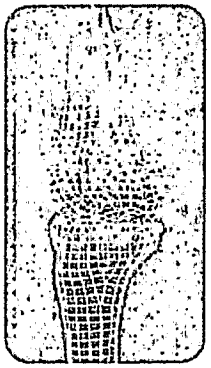
EFFICIENT

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.

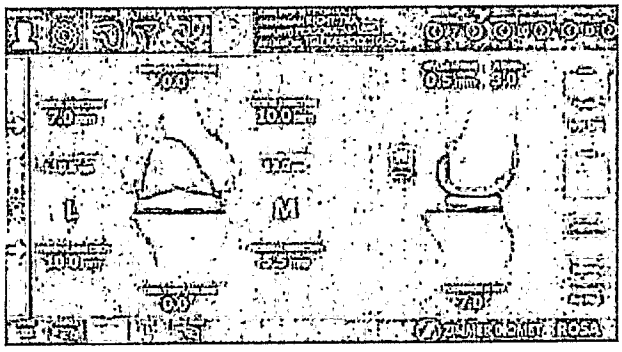


2D X-rays are submitted to your assigned Personalized Solutions Planning Expert



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

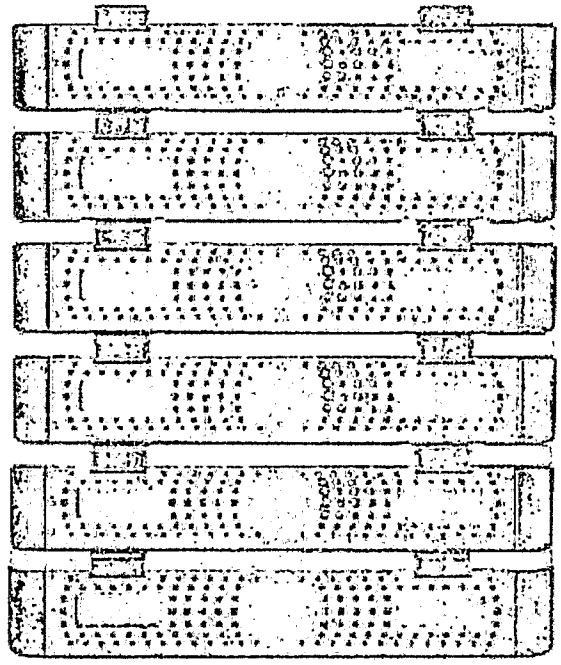


REDUCED INSTRUMENTATION

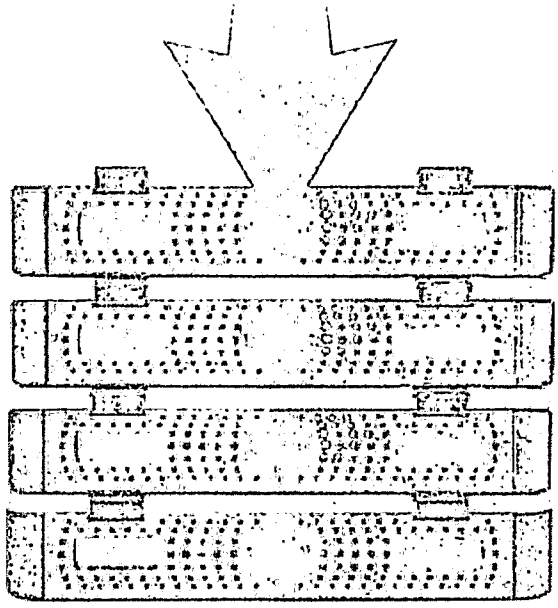
The Efficient Care program and X-Atlas technology lowers the cost to serve through experienced case planning and unique modular instrument trays that provide you with all the instrumentation you need – while eliminating the instruments you don't.

POTENTIAL SAVINGS[12]

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.

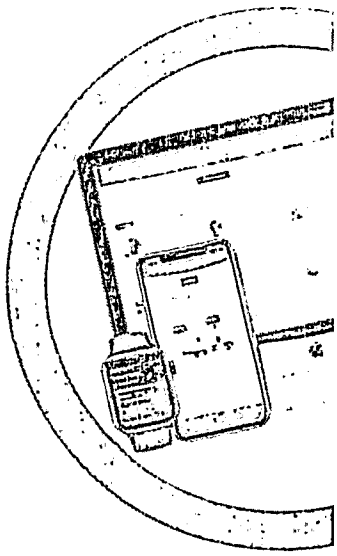
The following data metrics are currently captured on OrthoIntel Orthopedic Intelligence Platform ROSA Knee Reports:

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:

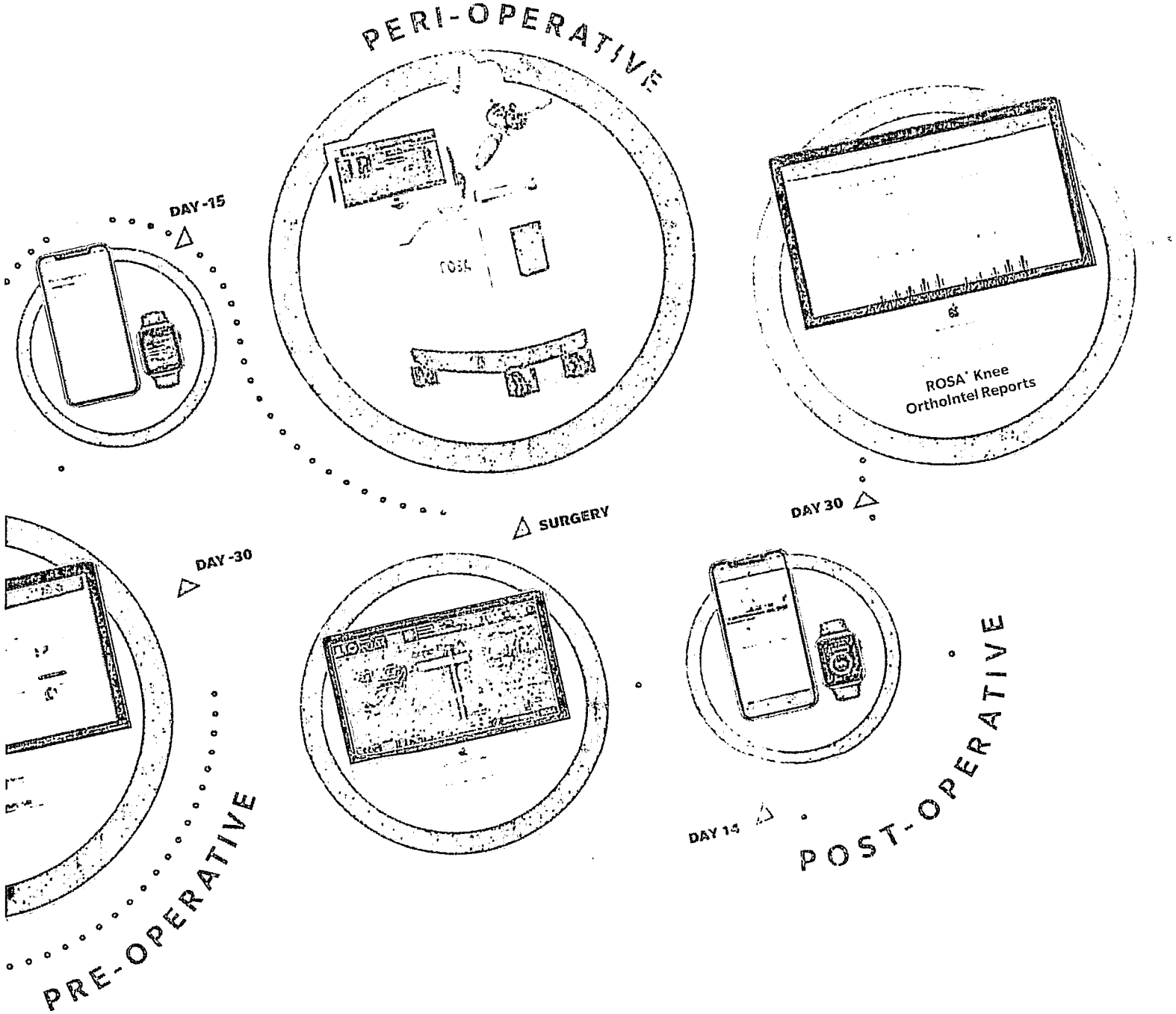
- Hip-Knee-Angle (HKA)
- Medial/Lateral Laxity at full extension
- Medial/Lateral Laxity at 90 degrees flexion
- Max Varus/Valgus at full extension
- Max Varus/Valgus at 90 degrees flexion



*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[9h] 300+ Publications[9i] 100% Survivorship at 17 Years[9a] Lowest revision rate[9b-e] Benchmark for PROMs[9f] 10A* ODEP rating for CR and PS knees both with and without patella[9g] Every 90 seconds a patient receives a NexGen knee[9h] 1 in 5 knees implanted globally is a NexGen Knee[9h]

    9a. Kim [illegible] patients younger than fifty five years [illegible] International Orthopaedics [illegible]

    9b. Australian Orthopaedic Association National Joint Replacement Registry Annual Report. Adelaide:AOA 2016 [illegible] Cumulative Percent Revision of Primary [illegible] with Cement Fixation

    9c. Australian Orthopaedic Association National Joint Replacement Registry Annual Report. Adelaide:AOA 2016 [illegible] Cumulative Percent Revision of Primary [illegible] with Cementless Fixation

    9d. Australian Orthopaedic Association National Joint Replacement Registry Annual Report. Adelaide: AOA 2016 [illegible] Cumulative Percent Revision of Primary [illegible] with Hybrid Fixation

    9e. [illegible] the 2016 Swedish National Registry [illegible]

    9f. [illegible] patient reported outcome measures (PROMs) following total knee [illegible] Bone Joint Surg Br [illegible] 61.

    9g. Latest ODEP rating [illegible] found at http://www.odep.org.uk

    9h. 2015 [illegible] available at Zimmer Biomet

    9i. [illegible] NexGen [illegible] 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.

ZIMMER BIOMET

Your progress. Our promise.®

3076.1-GLBL-en REV0720