

VISIONAIRE[◇]

Cutting Guides

 A technology from **smith&nephew**



Simplified surgery.
Personalized performance.



VISIONAIRE[◊] Patient Matched Technology



Accuracy
.....
Advanced surgical precision,
resulting in reproducible outcomes

Efficiency
.....
Simplifying surgery, reducing costs,
and improving performance

Confidence
.....
Personalized, reliable solutions,
leading to increased satisfaction



What is the VISIONAIRE[◊] Cutting Guide Process?

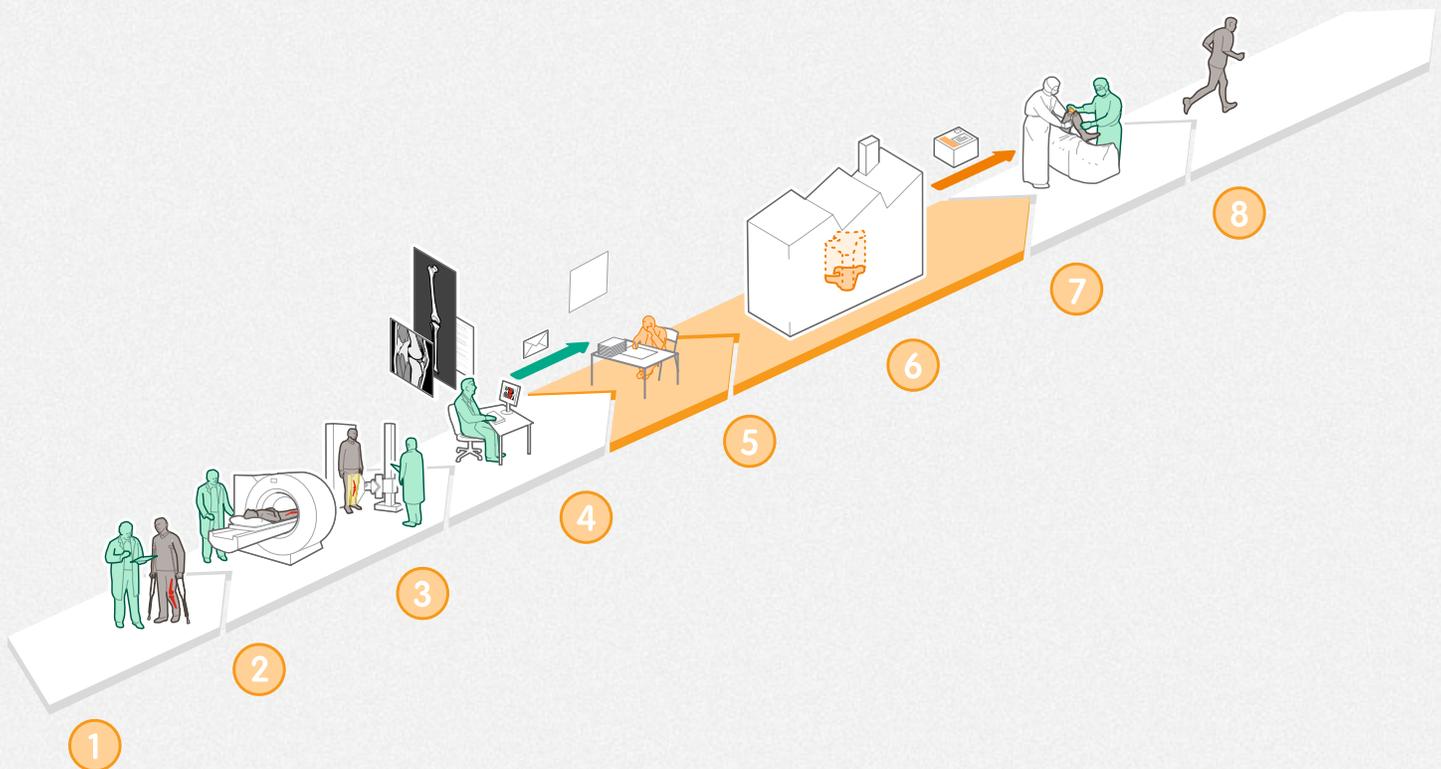


VISIONAIRE Patient Matched Technology is simplified surgery with personalized performance. The VISIONAIRE process allows Smith & Nephew to design and produce a set of cutting guides based on your patient's unique anatomy. The VISIONAIRE set of customized cutting guides reduces the number of steps and surgical instruments required for surgery creating a simplified surgical environment. The guides are designed from surgeon specific preferences, then developed by a dedicated engineer, allowing for personalized performance.

The inner shape of the cutting guide matches the outer shape of your patient's distal femur and proximal tibia. This hand-in-glove fit allows surgeons to make the precise bone cuts needed to position the knee implant in the optimal alignment.

VISIONAIRE Cutting Guide Process

1. Diagnostics
2. MRI
3. X-Ray
4. Upload Data
5. Preop Planning
6. Manufacturing
7. Surgery
8. Recovery



Implant Choice



VISIONAIRE® Cutting Guides are available for JOURNEY® II Knee System, GENESIS® II Knee System, LEGION® PRIMARY and TC-PLUS® PRIMARY Knee System in cruciate retaining and posterior stabilized options.



JOURNEY II BCS



JOURNEY II CR



GENESIS II



LEGION PS



LEGION CR



TC-PLUS PRIMARY

TC-PLUS PRIMARY is not available in Australia, New Zealand or the US.

Accuracy



Accuracy is the condition or quality of being true, correct or exact. VISIONAIRE® Cutting Guides achieve accuracy in alignment, rotation and sizing by incorporating actual images of patients to understand their specific alignment needs.

Alignment

VISIONAIRE Cutting Guides use mechanical axis alignment, the gold standard in orthopedics, which is based off of a patient's weight-bearing AP X-Ray.

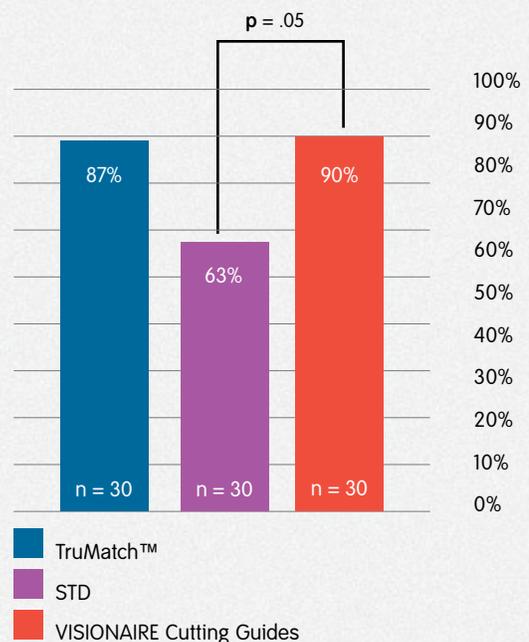
- This technology focuses on achieving accurate rotational and A-P position.
- A tibial component with more than 3.0° of varus has increased incidence of failure.⁸
- Components placed in varus alignment have a higher rate of loosening and revision when compared with components placed in neutral alignment.⁸

Utilizing common anatomical landmarks from patient images, an engineer creates a precise surgical plan based on each surgeon's preference.

Coronal Plane Alignment



Posterior Tibial Slope Inliers (+/-3°)



Daniilidis K, Tibesku C. Frontal plane alignment after total knee arthroplasty using patient-specific instruments. Int Orthop. 2012 Dec 12.

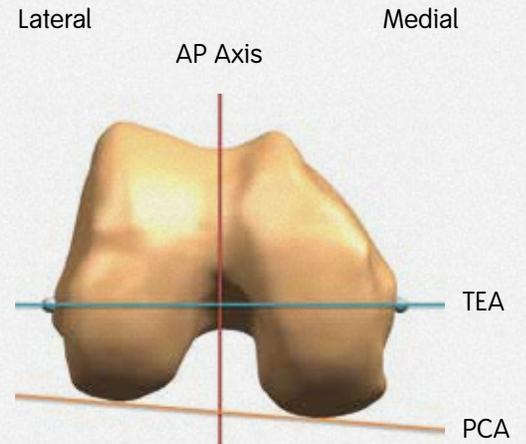
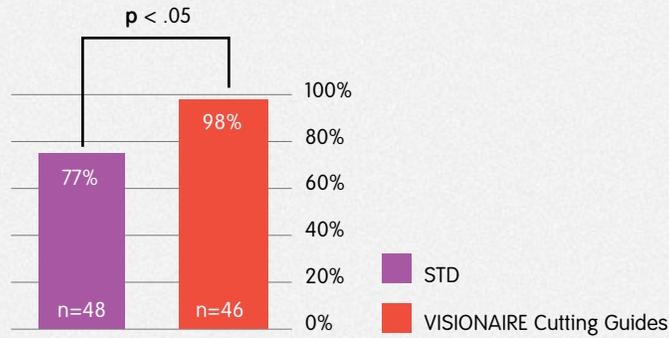
Pfutzner T, Abdel MP, et. al Small Improvements in Mechanical Axis Alignment Achieved with MRI versus CT-based Patient-specific Instruments in TKA. A Randomized Clinical Trial 2014.



Rotation

From the patient's MRI, engineers are able to create 3-D models representing the patient's actual bone. This allows for traditional landmarks such as the AP Axis, Surgical Epicondylar Axis, and the Posterior Condylar Axis to be easily identified and prioritized by surgeon preference.

Femoral Rotation



Heyse J. Improved femoral component rotation in TKA using patient-specific instrumentation; The Knee; 2012.

Sizing

The bone model created from the patient's MRI also allows the engineer to determine the most accurate Smith & Nephew implant size combination for your patient. VISIONAIRE[®] Cutting Guide sizing has demonstrated accuracy, as high as 94% in published reports.²

With VISIONAIRE Cutting Guides, a surgeon can be reassured that they are implanting components in accordance with the proven standards of total knee arthroplasty.

With VISIONAIRE Cutting Guides, we gather the required information pre-operatively for total knee arthroplasty with the potential to reduce coronal outliers and improve rotational alignment.





Advanced surgical precision, resulting in reproducible outcomes



Simplifying surgery, reducing costs and improving performance

Efficiency



Efficiency is the ability to accomplish a job with minimal expenditure of time and effort. VISIONAIRE[®] Cutting Guides help achieve efficiency and reduced cost in the OR by eliminating multiple steps and requiring less instrumentation for surgery.

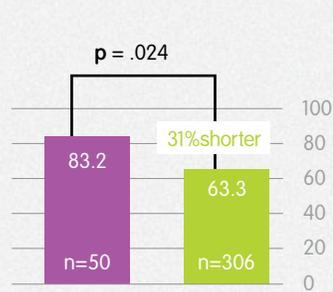
Reduced surgical steps

With VISIONAIRE Cutting Guides, up to 21 steps can be eliminated from surgery. This includes all the steps associated with alignment, rotation and sizing. These steps are built into the cutting guides and based on the surgeon preferences.

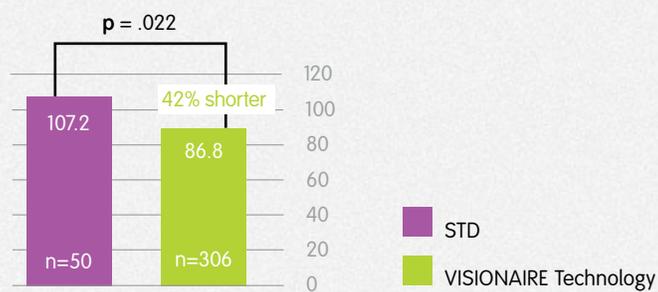
Reduced instruments and trays

By reducing the number of steps required for surgery, this also reduces the number of instruments and sterile trays required. With conventional instrumentation, seven to eight sterile trays may be required for surgery. With VISIONAIRE Cutting Guides, the number of trays required for surgery can be reduced to four or less.

Avg. Tourniquet Time (min)



OR Time (min)



DeHaan AM, Huff, TW; Patient-Specific Versus Conventional Instrumentation for Total Knee Arthroplasty: Peri-Operative and Cost Differences; J Arthroplasty; 2014

Reduced cost

With VISIONAIRE Cutting Guides, there are multiple opportunities to trim costs. By eliminating >40% of trays and instruments required for surgery, there is potential to reduce the sterilization cost.¹¹ Also, with less steps required for surgery, there is potential for shortened surgical time and lower costs related to surgical staff.¹¹

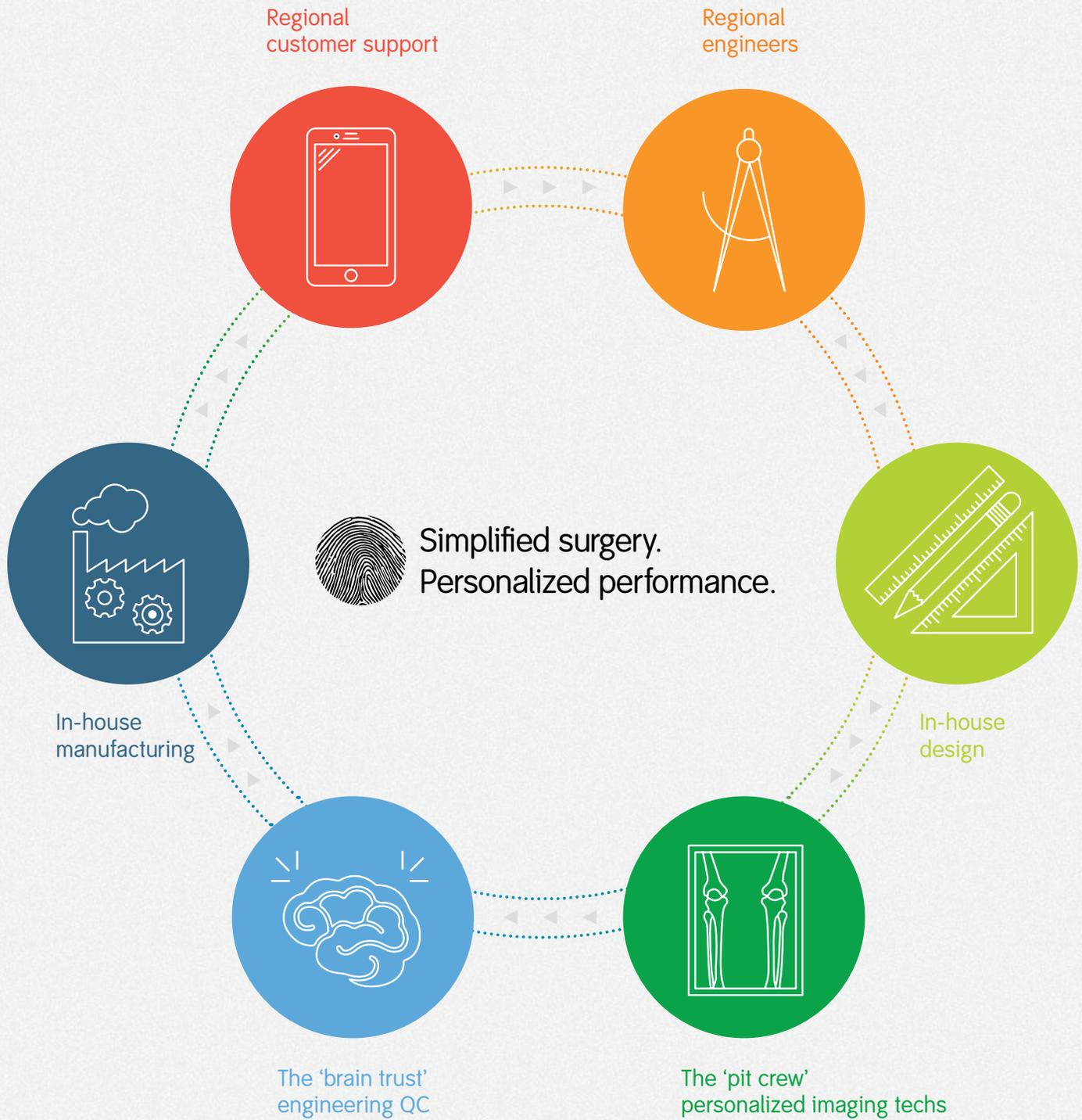
Reduced lead time

We know that meeting surgery dates for your patient is essential. Due to our proprietary in-house manufacturing process, we offer a “best in class” delivery time. Our VISIONAIRE Cutting Guides are shipped sterile for every case; however, a non-sterile option is also available for even faster delivery.



VISIONAIRE[◇]

Cutting Guides





Confidence is having trust or reliability in something. VISIONAIRE® Patient Matched Technology builds this confidence through providing a personalized team for every surgeon – a team that develops an understanding of each surgeon's surgical goals and preferences to ensure optimal patient outcomes.

Personalized service

An engineer is assigned to every surgeon that uses VISIONAIRE Cutting Guides. They work on all of the surgeon's cases and gain a true understanding of what the surgeon is expecting for their patient. As a part of this personalized service, each engineer works to develop and understand the surgical preferences of each surgeon and generate a surgical preop plan detailing exactly what to expect in surgery.

The entire VISIONAIRE Patient Matched Technology support team has been regionalized to support your VISIONAIRE Cutting Guide cases. We do this to ensure your staff and imaging centers are working with the same Smith & Nephew support staff throughout the entire process.

Knowing what to expect

VISIONAIRE Cutting Guides allow the surgeon to know exactly what to expect with surgery. A preop plan is created for every case and identifies the implant sizes that will be used and all the resections that will be made, including how much bone will be removed. This plan is sent to the surgeon before the blocks are even made, giving the surgeon the opportunity to make any changes to the plan.

Surgeon involvement

Surgeon involvement is key to the success of VISIONAIRE Cutting Guides. For every surgeon, we capture what we call surgeon preferences. Surgeon preferences are unique to every surgeon and determines how your engineer aligns your cases based on the patient's specific alignment and the surgeon's specific instructions, giving the surgeon ultimate control of the cutting guide design.





Patient outcomes

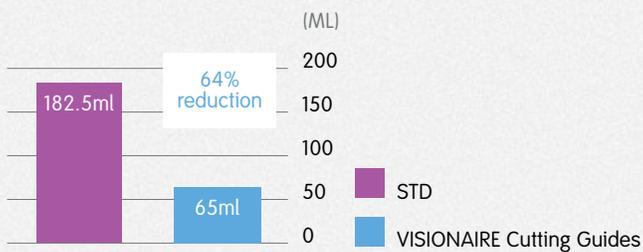
With VISIONAIRE[®] Cutting Guides, there are several benefits to your patients as well, when compared to traditional methods.

- Less invasive procedure (due to not drilling the IM canal)¹⁰
- Faster surgery, which leads to less blood loss²
- Earlier return to activities³

VISIONAIRE Cutting Guides vs. Standard Instrumentation (STD)

Mean Blood Loss

(six patients with contralateral knee replacements with STD)



Kamali Bali, MBBS, MS, DNB, Peter Walker, FRACS, and Warwick Bruce, FRACSJ Arthroplasty. 2012 Jun;27(6):1149-54. Epub 2012 Jan 27.

Safety

- VISIONAIRE Cutting Guides are made from biocompatible medical grade nylon.
- VISIONAIRE Cutting Guides have the option to be flashed up to 3 times.
- VISIONAIRE Cutting Guides match standard instrumentation for easy intraoperative changes.

Block design

VISIONAIRE Cutting Guide designs are based on an MRI of the knee and a full leg AP X-ray. Smith & Nephew has researched several other imaging modalities and determined that the combination of MRI and X-Ray provides the best possible fit and alignment. Our specific proprietary imaging protocol is able to capture the bone and cartilage of each patient, which consistently provides a “glove like” fit for the guide on the bone.





Personalized, reliable solutions, leading to improved satisfaction



Accuracy, efficiency and confidence – simplified



Image validation

Every imaging center that provides patient images for VISIONAIRE[®] Cutting Guides is required to complete a validation process. Smith & Nephew has developed a unique MRI protocol that provides exactly what we need to create VISIONAIRE Cutting Guides. As a part of this validation process, Smith & Nephew requires each center to perform a “phantom” scan, which ensures the images that Smith & Nephew receive are an exact replication of the patient’s anatomy.

Smith & Nephew also has a regionalized MRI technologist that will help set up your center and be the central point of contact for any questions or issues with patient images.

Why is the MRI so important?

- MRI is used to create a 3-D model of the patient’s anatomy
- The 3-D models allow for virtual surgery to plan the patient’s actual surgery
- The plan identifies the implant size for the patient and how much bone will be removed with each resection

Basic requirements of the Smith & Nephew protocol

- The MRI machine must be 1.5 Tesla or greater
- The radiology center must have a knee coil to perform the MRI
- Digital recording of images must be available
- Email account and Internet access to the Smith & Nephew website are required
- A unique Smith and Nephew protocol is required
- The protocol is specific for each MRI machine

Our process



Segment bone and cartilage



Create 3D bone model



Align implant on bone model



Cutting Guides created for surgery



Actual postop X-Ray showing implanted components



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