

Smith+Nephew

Patient data confidentiality and security overview



VISIONAIRE 
Adaptive Guides



VISIONAIRE[◇] data privacy and security

VISIONAIRE Cutting Guides are patient specific products that require MRI and X-Ray to produce. The images are used to create the cutting guides for knee arthroplasty designed for that specific patient.

Some benefits of VISIONAIRE include^{1,2}:

- Less invasive procedure for patients
- Potentially less blood loss
- Shortens surgery time
- Improves implant alignment
- Reduces instrumentation needed for surgery

The foundation of a VISIONAIRE case is the patient imaging data submitted to Smith+Nephew by approved imaging centers. The submitted imaging data contains patient information, the security of which is of the utmost importance to Smith & Nephew. As a result, Smith+Nephew is committed to keeping patient information private and protected from the point of submission through to data archival following shipment of the cutting guides.

Smith+Nephew maintains measures to ensure the security of submitted patient imaging data. The following process flow (Figure 1) and associated bullet points outline some of the key security points for data submitted for the purpose of the design and manufacture of VISIONAIRE Cutting Guides:

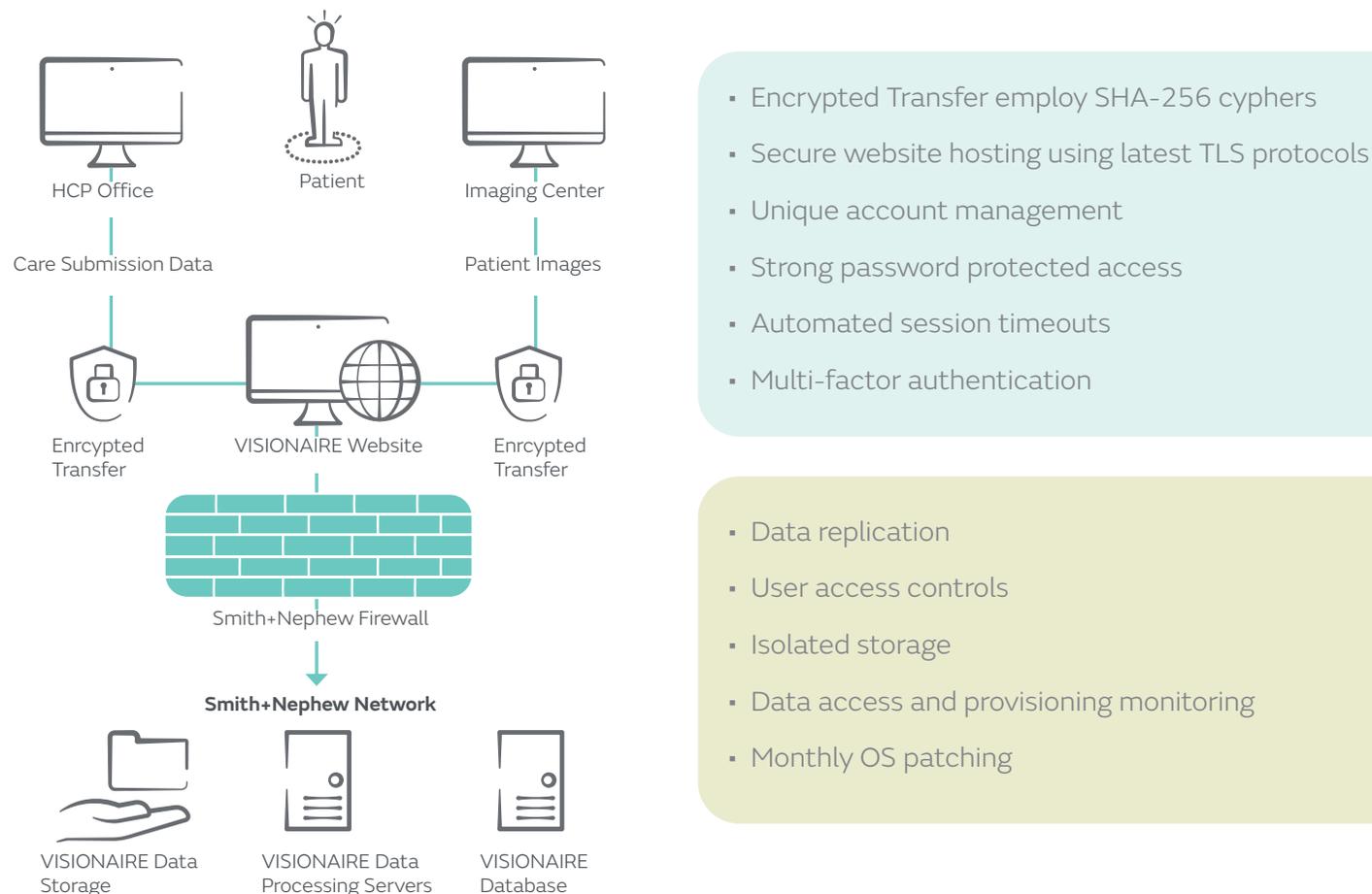
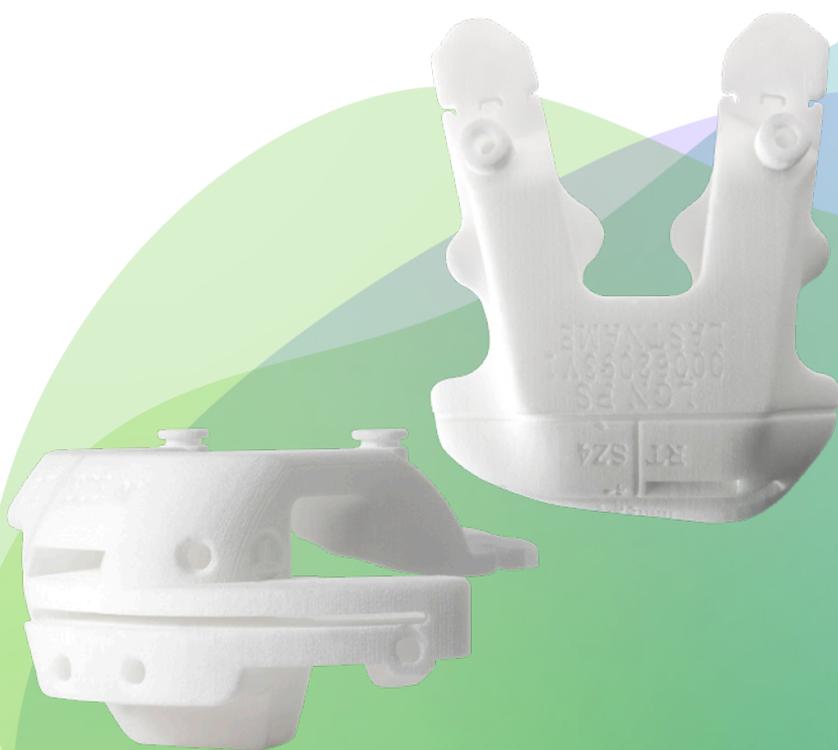
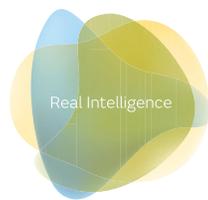


Figure 1 Graphical representation of patient imaging data flow for VISIONAIRE Cutting Guides

- Access to the VISIONAIRE[◇] website is password protected.
- Image data is submitted to the VISIONAIRE website by an approved imaging center via a secure encrypted upload.
- The website is hosted on secure Smith+Nephew servers protected by a firewall. Access to the stored data is password protected.
- Image data is stored in an access controlled storage device and the data is replicated for data reliability.
- Patient medical data is used to design, construct and deliver the VISIONAIRE Cutting Guides. Only individuals actively involved in this endeavor have access to this data via password-protected access to the Smith+Nephew network. De-identified/anonymized patient data may be used for analysis in product design and improvement for VISIONAIRE or other Smith+Nephew products
- Data used in the processing of VISIONAIRE Technology cases is stored indefinitely based on regulatory bodies.

Smith+Nephew strives to maintain a robust and secure infrastructure for the receiving, processing and storage of patient imaging data. Should you require more detailed information regarding security of data, please contact VISIONAIRE Support at 001-800-262-3536 option #1 (7am to 6pm CST), or email VISIONAIRESupport@smith-nephew.com for more information.





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References

1. Noble, J., Moore, C. A., & Liu, N. (2012). The value of patient-matched instrumentation in total knee arthroplasty. *The Journal of Arthroplasty*, 153-5.
2. Bali, K., Walker, P., & Bruce, W. (2012). Custom fit total arthroplasty: our initial experience in 32 knees. *The Journal of Arthroplasty*, 1149-54.