

## **Smith+Nephew announces new study showing GRAFIX™ Membrane cut the rate of diabetic foot ulcer recurrence in half compared to leading competitors**

**31 March 2022**

Smith+Nephew (LSE: SN, NYSE: SNN), the global medical technology business, announces the publication of a peer-reviewed study in the *Advances in Wound Care Journal* reporting outcomes for Medicare patients with a diabetic foot ulcer (DFU) that shows GRAFIX Cryopreserved Placental Membrane cut DFU recurrence rates in half compared to leading cellular and tissue-based product (CTP) competitors.<sup>1</sup> ([Link to publication](#)).

DFUs affect 3 million people annually in the US, and Medicare spending for the treatment of DFUs has been estimated to be \$6-18 billion annually.<sup>2</sup> This study reviewed over 1.3 million Medicare patients with lower limb chronic ulcers, and analyzed 7,849 claims for patients treated between 2013 and 2017 in an outpatient setting who presented with a DFU and received a CTP. It compared ulcer recurrence rates, patient mortality, and other outcomes at 30-, 90-, 180-, and 365-days for GRAFIX Membrane vs. Cellular CTPs and vs. Acellular CTPs. Examples of leading competitors included in this study are Apligraf® (Organogenesis, a Cellular CTP) and EpiFix® (MiMedx, a devitalized Acellular CTP).<sup>1,3</sup>

The study found a statistically significant reduction in ulcer recurrence and/or new ulcer formation, for patients presenting with a DFU at all time periods for GRAFIX compared to either Cellular or Acellular CTP groups, ranging from 36.7% reduction at 30-days compared to Cellular CTPs, and 58.5% reduction at 365-days compared to Acellular CTPs ( $p < 0.001$ ). Mortality rates were also reviewed at each time point and differences noted were favorable. The cohorts were risk-adjusted to ensure appropriate comparisons.

A similar study of Medicare patient claims from 2015-2018 was recently published that found CTPs, including GRAFIX Membranes, performed better than standard of care where performance measures were reductions in major and minor amputations, emergency department use, and hospital readmission, and were estimated to lead to millions of dollars in healthcare cost savings in that time ( $n=12,676$  episodes per cohort).<sup>4</sup> The study announced here expands upon that analysis of the class of CTPs to demonstrate the enhanced value GRAFIX Membranes can offer patients with DFU compared to leading competitors.

Dr. Charles Ananian, DPM commented, "This new study cements what I have seen in my practice with the GRAFIX Membrane products. In conjunction with standard of care, GRAFIX has led to a higher percentage of closed wounds, faster wound closure, and

less ulcer recurrence than many competitors.<sup>5,6</sup> In indicated wounds, GRAFIX has proven itself as a high-performing therapy for difficult-to-treat wounds.”

“Smith+Nephew is committed to helping patients with chronic wounds live a Life Unlimited. Backed by evidence, GRAFIX delivers on this promise by helping patients with chronic wounds as an advanced therapy shown to be clinically superior to standard of care and leading competitors.<sup>5,6,7</sup> Because of the strong body of clinical evidence for GRAFIX, Medicare and all of the top 50 commercial payers now cover GRAFIX for DFU, including recent positive coverage by the largest payer in the US,<sup>7</sup>” said Simon Fraser, Smith+Nephew President of Global Advanced Wound Management.

## **About GRAFIX**

GRAFIX PL and GRAFIX Membranes are human placental tissue products composed of native living cells, growth factors and an intact extracellular matrix. All native components of the GRAFIX PL and GRAFIX Membranes are preserved, including mesenchymal stem cells. GRAFIX Membranes are regulated as Human Cells, Tissues, and Cellular Tissue Based Product (HCT/P) as defined in 21 CFR part 1271 and Section 361 of the Public Health Service Act, are limited to homologous use as wound covers, and may be used for acute and chronic wounds. For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product’s instructions for use prior to use.

To learn more about the GRAFIX Membrane portfolio of products and see the evidence, visit [www.grafixpl.com](http://www.grafixpl.com).

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## **Enquiries**

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## **References:**

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## About Smith+Nephew

Smith+Nephew is a portfolio medical technology business focused on the repair, regeneration and replacement of soft and hard tissue. We exist to restore people's bodies and their self-belief by using technology to take the limits off living. We call this purpose 'Life Unlimited'. Our 18,000 employees deliver this mission every day, making a difference to patients' lives through the excellence of our product portfolio, and the invention and application of new technologies across our three global franchises of Orthopaedics, Sports Medicine & ENT and Advanced Wound Management.

Founded in Hull, UK, in 1856, we now operate in more than 100 countries, and generated annual sales of \$5.2 billion in 2021. Smith+Nephew is a constituent of the FTSE100 (LSE:SN, NYSE:SNN). The terms 'Group' and 'Smith+Nephew' are used to refer to Smith & Nephew plc and its consolidated subsidiaries, unless the context requires otherwise.

For more information about Smith+Nephew, please visit [www.smithnephew.com](http://www.smithnephew.com) and follow us on [Twitter](#), [LinkedIn](#), [Instagram](#) or [Facebook](#).

### **Forward-looking Statements**

*This document may contain forward-looking statements that may or may not prove accurate. For example, statements regarding expected revenue growth and trading margins, market trends and our product pipeline are forward-looking statements. Phrases such as "aim", "plan", "intend", "anticipate", "well-placed", "believe", "estimate", "expect", "target", "consider" and similar expressions are generally intended to identify forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from what is expressed or implied by the statements. For Smith+Nephew, these factors include: risks related to the impact of COVID-19, such as the depth and longevity of its impact, government actions and other restrictive measures taken in response, material delays and cancellations of elective procedures, reduced procedure capacity at medical facilities, restricted access for sales representatives to medical facilities, or our ability to execute business continuity plans as a result of COVID-19; economic and financial conditions in the markets we serve, especially those affecting health care providers, payers and customers (including, without limitation, as a result of COVID-19); price levels for established and innovative medical devices; developments in medical technology; regulatory approvals, reimbursement decisions or other government actions; product defects or recalls or other problems with quality management systems or failure to comply with related regulations; litigation relating to patent or other claims; legal compliance risks and related investigative, remedial or enforcement actions; disruption to our supply chain or operations or those of our suppliers (including, without limitation, as a result of COVID-19); competition for qualified personnel; strategic actions, including acquisitions and dispositions, our success in performing due diligence, valuing and integrating acquired businesses; disruption that may result from transactions or other changes we make in our business plans or organisation to adapt to market developments; and numerous other matters that affect us or our markets, including those of a political, economic, business, competitive or reputational nature. Please refer to the documents that Smith+Nephew has filed with the U.S. Securities and Exchange Commission under the U.S. Securities Exchange Act of 1934, as amended, including Smith+Nephew's most recent annual report on Form 20-F, for a discussion of certain of these factors. Any forward-looking statement is based on information available to Smith+Nephew as of the date of the statement. All written or oral forward-looking statements attributable to Smith+Nephew are qualified by this caution. Smith+Nephew does not undertake any obligation to update or revise any forward-looking statement to reflect any change in circumstances or in Smith+Nephew's expectations.*

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