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# FDA has granted investigational Device Exemption approval (IDE) to BioProtect

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**BioProtect Launches a pivotal clinical study to examine the use of the ProSpace[TM] Balloon System to prevent cancer radiotherapy, following FDA investigational Device Exemption (IDE)**

BioProtect, the technology leader in biodegradable balloon spacers protecting normal tissue during radiation therapy, announced the launch of its clinical trial following Investigational Device Exemption (IDE) approval granted by the FDA in November 2017.

The trial is a prospective, randomized study to demonstrate the safety and efficacy of the ProSpace biodegradable spacer to protect the rectum and lower GI tract during radiation therapy for prostate cancer compared to patients without any spacers.

ProSpace is approved for sale in Europe under CE regulations.

The company believes it could be used to spare the rectum in hundreds of thousands of patients who are undergoing prostate cancer radiotherapy every year.

The potential global market for the ProSpace is estimated to exceed $1.2 Billion annually.