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FDA clears Invictus Medical's GELShield™ for market launch

San Antonio, TX – Invictus Medical, the San Antonio, Texas-based medical device company dedicated to providing newborns with healthy developmental milestones, has received Food and Drug Administration (FDA) clearance to begin marketing its GELShield™ extracranial pressure relief device.

The FDA cleared the GELShield with an indication to alleviate extracranial pressure due to prolonged immobility. The device has undergone a comprehensive safety validation study at the nationally recognized Baylor University Medical Center in Dallas. The center oversees approximately 4,200 births annually and operates an 83-bed, level III neonatal intensive care unit (NICU) providing the highest level of care for small and fragile newborn babies.

“Our mission is to secure healthy early development milestones in newborns by providing innovative products, services and solutions to the healthcare professional and consumer markets,” said Steve Dufilho, Chairman of Invictus Medical’s Board of Directors and Vice Chairman of Ascension Health. “FDA clearance of the GELShield is a major strategic milestone in that effort and we expect to begin seeing this breakthrough product in use in neonatal intensive care units in the very near future,” added Tom Roberts, Invictus Medical President and CEO.

“More than 100 hospitals so far have expressed significant interest in the GELShield,” Roberts said. “The company has built a robust sales and distribution network of highly accomplished medical device industry experts across the U.S.,” he added.

Long-term, Invictus Medical’s technology interest focuses on combating deformational plagiocephaly (DP), a cranial deformity exhibited in infants resulting from repeated external pressure to one area of the head. Studies have found a significant rise in the incidence of plagiocephaly since the early 1990s. In addition to being a cosmetic issue, DP has been associated with heightened risk for developmental delays in infants and toddlers, according to a study published in *Pediatrics* in 2013.

To date, Invictus Medical has successfully raised \$5 million. The company is in the process of securing an additional \$4.5 million in Series B funding to support the commercialization efforts of the GELShield.

About Invictus Medical

Invictus Medical is a San Antonio, Texas-based medical device company that aims to ensure that children are able to attain their developmental milestones. As evidenced by their award-winning innovations, Invictus Medical has been at the forefront of pediatric care since its founding in 2012. Invictus Medical is a privately held company. For more information about Invictus Medical, please see [www. Invictusmed.com](http://www.Invictusmed.com).

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