New Low Power Advanced Vessel Sealing Technology in Pediatric Applications

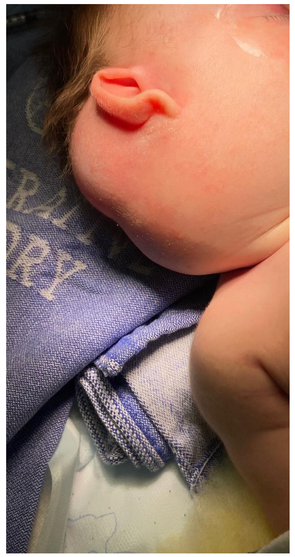
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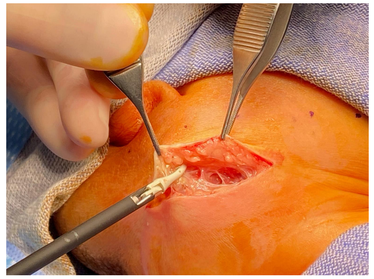
Background :
Energy-based vessel sealing has been used for many years as an effective way to seal blood vessels quickly without leaving behind any foreign material in the body. One drawback of energy-based vessel sealing is the inherent heat that is generated during sealing. This can be significant and may result in permanent thermal injury to adjacent structures, such as bowel. The CoolSeal Reveal Vessel Sealer was developed using a new low power energy output and a small well insulated profile. The goal of these changes was to minimize the total energy delivery through the instrument without compromising seal quality.

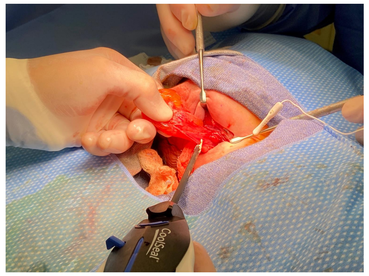
Technology Description:
Bolder Surgical (now Hologic) developed a low power 3mm sealer that has been used extensively in minimally invasive pediatric surgery since 2013. The small size of the device precluded the device having a cutter. The generator delivers only 25W compared to up to 350W for other systems. The energy delivery is optimized so that it is focused to the target tissue and delivered very quickly with average seal times of 1.7s. The optimized power and quick sealing times leads to minimized thermal damage. Seal strengths have been demonstrated to be equivalent to LigaSure™. This optimized energy delivery system including the 3mm sealer is termed CoolSeal™ technology.

The CoolSeal Reveal is a 5 mm diameter shafted device for open pediatric and adult surgery. The device incorporates a knife/cutter which was previously not possible on devices of this size. Additionally, the insulation has been improved further lowering the extent of thermal injury. The optimized energy delivery has further shortened seal times to an average of 0.67 seconds while still maintaining equivalent seal quality.
A small initial case series in pediatric patients has been completed using the Reveal device.









Excision of Giant Cystic Hygroma

Results: Thirty-five pediatric surgeries were completed by 30 surgeons at 22 hospitals across a wide range of procedures. Procedures included but were not limited to bowel resection, nephrectomy, mesenteric cyst removal, thyroidectomy, and excision of a giant cystic hygroma. Seal quality, seal time, and thermal injury were all rated to be above expectations with an overall average score of 4.2 on a 5 point scale. One case of note, the cystic hygroma, involved an extensive dissection of lymphatic malformations around structures of the carotid sheath, facial nerve, and parotid gland without injury to these structures. The device was used for dissection and hemostasis during the procedure.

Conclusions: The Reveal device allows good access and visualization in small spaces as are found in pediatric surgery. Seal quality is excellent and seal times are noticeably faster than other devices resulting in very low thermal effect adjacent to the seal.

