



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Rapid HTA on the use of vesicostomy buttons in children: plain language summary

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About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with relevant government Ministers and departments, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children’s special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children’s social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children’s social services.
- **Health technology assessment** — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland’s health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

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Plain language summary

What did we look at?

Children with certain health conditions can have problems storing urine and emptying their bladder. One of these health conditions is known as neurogenic bladder. This is where the nerves which control the bladder are damaged, for example due to spina bifida. Spina bifida is a condition where the spine and spinal cord do not form properly in the baby in the mother's womb during pregnancy. It can cause mild to serious disabilities, including problems with the bowel and bladder.

If urine storage and bladder emptying problems are not managed early, children may be more likely to get infections and may develop damage to the bladder and kidneys. There are different ways of managing these bladder problems. These depend on factors like how severe the condition is, what a patient or caregiver prefers, and whether a particular option is possible for an individual patient.

The Minister for Health asked the Health Information and Quality Authority (HIQA) to carry out a review to see whether using a medical device known as a vesicostomy button for the management of urine storage and bladder emptying problems in children works well and is safe. Since 2018, between two and four vesicostomy buttons were placed into children each year in Children's Health Ireland (CHI) hospitals.

What is a vesicostomy button?

A vesicostomy is a surgical procedure, performed while the child is under anaesthetic, to create a small opening on the abdomen just below the belly button. Through this opening, a 'catheter' or tube is passed to allow urine to drain out of the bladder. This helps to reduce urine going back up to the kidneys and improves emptying of the bladder. This in turn helps to reduce the risk of infections and damage to the kidneys. A vesicostomy button is a medical device, made from medical-grade silicone, which is placed into the bladder, through the vesicostomy (opening) and used to drain urine out of the bladder. The material used in these devices (medical-grade silicone) is the same material used in 'standard' catheters. Compared to a 'standard' catheter, which has longer tubing on the outside of the body, the vesicostomy button is small and can easily be hidden under clothes. It allows children to participate more comfortably in everyday activities, including sports and swimming.

These button devices are manufactured and licensed to be used in the stomach, not the bladder. Therefore, when these devices are used to help with storing urine and emptying the bladder, their use is considered 'off-label'. This means they are being

used differently to how they were originally intended to be used. However, it is quite common and appropriate in some circumstances for medical devices to be used 'off-label', particularly in children. In many cases, 'off-label' use of a device is often supported within the clinical community, based on scientific literature and clinical guidelines. To help ensure that patients are kept safe, extra safeguards are needed, including clear discussion of risks and benefits with the child and their family, and following relevant clinical guidelines or hospital policies. Information about the devices and support on the safe use of the device should also be provided to the child and their family.

What did we find?

We found that there wasn't a lot of medical literature published about the use of vesicostomy buttons in children. The 14 research studies which we found included a total of 244 children between them and came from the United Kingdom, Italy, the United States, France, the Netherlands and Argentina. Children in these research studies ranged in age from newborn babies to 19 years, but most children were about five years old when they had the vesicostomy button inserted. In the majority of studies, one of two types of vesicostomy buttons were used, known as the MIC-KEY® and MiniONE® devices.

Due to the very small amount of research studies published, it is not possible to draw firm conclusions about how well vesicostomy buttons work, or how safe they are, compared with other ways of managing problems with storing urine and emptying the bladder. Complications such as leakage from the button site, infections, and skin reactions were noted in these research studies. It is not possible to know whether these complications occur more often when using vesicostomy buttons compared with 'standard' catheters. However, this review indicates that vesicostomy buttons have been used since 1996 without any serious safety concerns. Overall, healthcare professionals, patients and caregivers from the research studies seem to agree that vesicostomy buttons work well, for certain children, in specific circumstances. These circumstances include those with severe bladder problems where standard catheterisation through the urethra (the tube that carries urine out of the body) is difficult, painful or not possible. They can also provide a short-term option until a better long-term way of emptying the bladder can be set up.

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