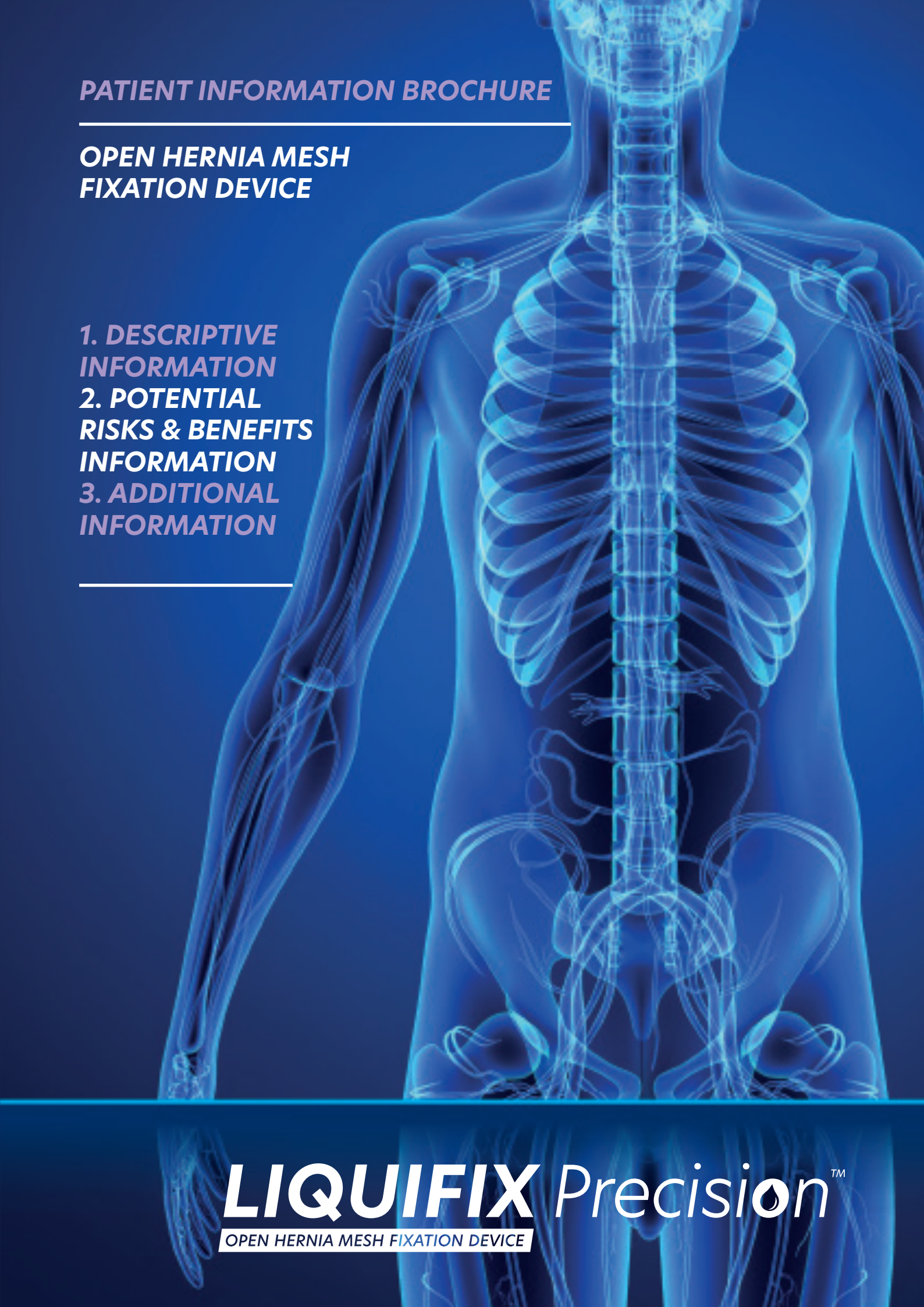

PATIENT INFORMATION BROCHURE

OPEN HERNIA MESH FIXATION DEVICE

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LIQUIFIX Precision™

OPEN HERNIA MESH FIXATION DEVICE

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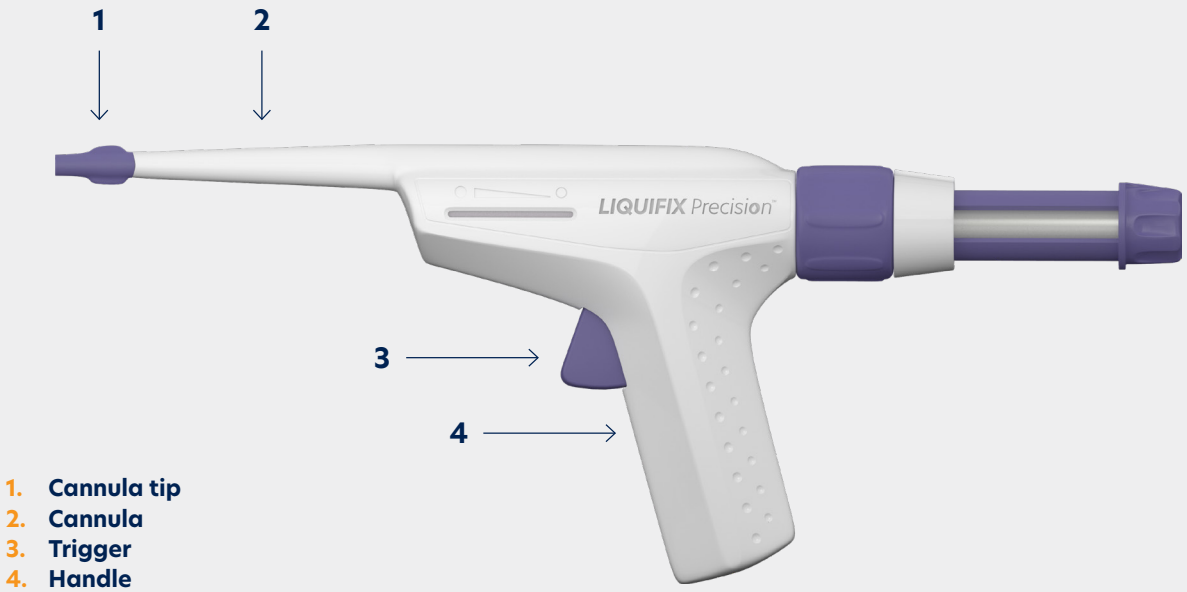
1. DESCRIPTIVE INFORMATION

What is the purpose of LIQUIFIX Precision™ Open?

LIQUIFIX Precision™ Open Hernia Mesh Fixation device is intended for use in open surgical repair of groin (inguinal and femoral) hernias in adults, achieved through the fixation of prosthetic polypropylene or polyester mesh to the abdominal wall.

A hernia is when an internal part of the body pushes through a weakness in the abdominal wall. To repair a hernia through surgery, the hernia contents or other protruding tissues are returned to their normal position and the weakness in the abdominal wall is repaired. Sometimes it is necessary to support the repair with a mesh which is fixed to the abdominal wall at the site of the hernia. The mesh is secured until it becomes integrated with the surrounding tissue. This is often done with the use of sutures (stitches) or small screw-like-tacks, which are designed to penetrate the tissue and hold the mesh in place. LIQUIFIX Precision™ Open, which is a medical grade tissue adhesive (glue), is another option.

About LIQUIFIX Precision™ Open



1. **Cannula tip**
2. **Cannula**
3. **Trigger**
4. **Handle**

The LIQUIFIX Precision™ Open Hernia Mesh Fixation device consists of adhesive (n-butyl-2-cyanoacrylate) supplied in a glass vial within a handheld, single-use, disposable applicator. After the surgeon has primed the device, the device releases a drop of adhesive (anchor) when the trigger is pulled and released. Each drop is 12.5 mg on average. The adhesive is applied to an implanted hernia repair mesh in order to fix the mesh to the abdominal wall. When the adhesive is applied to the mesh and tissue, it sets (forms a chemical bond) due to the moisture on the tissue surface within approximately 10 seconds and allows the mesh to remain in the correct position.

When should LIQUIFIX Precision™ Open not be used (contraindications)?

LIQUIFIX Precision™ Open should not be used in individuals with a hypersensitivity (allergy) to cyanoacrylate adhesives, formaldehyde, or D&C Violet No. 2 dye.

Your doctor will assess if your hernia defect is suitable for the hernia repair procedure with LIQUIFIX Precision™ Open and guide you on all relevant information related to the device.

2. POTENTIAL RISKS & BENEFITS INFORMATION

What are the potential benefits to the patient for the use of LIQUIFIX Precision™ Open?
LIQUIFIX Precision™ Open provides atraumatic/non-penetrative fixation. This may reduce the risk of mechanical tissue trauma and also allows for fixation over sensitive anatomical locations, when compared to traditional penetrative fixation devices such as tackers or sutures.

Outside US registry data conducted with LIQUIFIX™ in open inguinal repair (n=141) has shown the following results:

- **Recurrence at 1 year follow-up 1.4%**
- **Pain requiring treatment at 1 year follow-up 2.1%**
- **Serum at 1 year follow-up 2.8%**

What are the potential risks to the patient for the use of LIQUIFIX Precision™ Open?
The potential adverse effects (e.g. complications) associated with the use of the LIQUIFIX Precision™ Open device may include, but are not limited to, toxic reaction and allergic reaction. As with the majority of implanted devices, adverse reactions associated with the use of the device may include transient local irritation at the implant site (i.e. inflammation or discomfort at the site of surgery, caused by a reaction to an irritant substance, lasting for a short time only) and a transitory inflammatory foreign body response (i.e. a non-permanent reaction caused by an object that is not typically found in the body).

Your doctor can discuss with you the potential adverse events associated with open hernia repair surgery, as well as any alternatives available to you.

What should I expect throughout the surgical procedure?
Your doctor can discuss the procedure with you. A brief summary of what to expect is below:

Before the procedure, your doctor will confirm the presence of hernia and that you are appropriate for hernia repair surgery. The surgical procedure will be performed as a standard of care of open hernia repair procedure under sterile conditions in an operating room. The surgery is normally performed under local anaesthesia. Sometimes, a general anaesthetic is used. An incision (cut) is made in the groin over the hernia, and the hernia is pushed back into the abdomen. A mesh is placed in the abdominal wall at the weak spot where the hernia came through, to strengthen it, and is fixed using LIQUIFIX Precision™ Open. At the end of the surgery, the abdominal incisions are then closed with standard wound closure devices such as sutures. You should discuss all hernia repair options with your doctor to determine which approach is best for you.

Your doctor will let you know what to expect after your open hernia repair surgery. The majority of patients undergoing elective or non-emergent groin hernia repair go home the same day as the surgery. Your doctor can help you determine when you can resume physical activity once evaluated at your post-operative visit.

You do not need to perform any device maintenance after surgery in relation to the LIQUIFIX Precision™ Open adhesive.

General warnings and precautions
You should talk to your doctor about all potential risks and adverse events discussed in this brochure, as well as any other concerns you have. Non-clinical testing has demonstrated that LIQUIFIX Precision™ Open adhesive implant is Magnetic Resonance Imaging (MRI) safe; it can safely be used in a magnetic environment.

Expected failure time and mode and its effect on the patient
The in-use lifetime of the implanted adhesive is approximately 2 weeks. The adhesive is only required to temporarily hold the mesh in place until the mesh is integrated with the abdominal wall. The adhesive does not need to be removed after this time and, as it does not degrade, it will remain within the body. Should the LIQUIFIX Precision™ Open fail, i.e. does not maintain bond before tissue integration, then you may experience symptoms of hernia recurrence (e.g. groin lump, persistent groin pain) and you should contact your doctor for examination to diagnose the appropriate medical condition.

Any follow-up after the procedure should be as recommended by the operating clinician.

3. ADDITIONAL INFORMATION

Clinical Studies Experience with LIQUIFIX™ adhesive
A 284 patient US pivotal study was performed to support the clinical safety and effectiveness of LIQUIFIX FIX8™ in the US. The US pivotal clinical study has been performed with an equivalent device (LIQUIFIX FIX8™ Laparoscopic Hernia Mesh Fixation device) which is used in laparoscopic hernia repair as opposed to open hernia repair.

The adhesive is identical and both devices are intended for hernia mesh fixation. The study compared difference in pain from baseline (worst pain experienced within 1 month of screening) to 6 months post-hernia repair with a US-marketed tacker device. The results showed that the improvement in pain in LIQUIFIX FIX8™ was not inferior to AbsorbaTack™ (control device).

The rate of hernia recurrence at 6 months for LIQUIFIX FIX8™ was not inferior to the control device. Successful hernia mesh fixation was accomplished in all hernias for LIQUIFIX FIX8™ and control device. The rate of successful hernia mesh fixation for LIQUIFIX FIX8™ was not inferior to the control device. The Quality of Life (Carolinas Comfort Scale Total Score) had a decreasing trend (improvement to Quality of Life) from 1 week through 12 months follow-up in both LIQUIFIX FIX8™ and control.

The incidence of device-related adverse events by subject were comparable in the LIQUIFIX FIX8™ and control groups. There were no unanticipated adverse events. There were no increased safety risks with the use of LIQUIFIX FIX8™ than when a tacker device was used.

The following possibly device-related adverse events were observed with LIQUIFIX FIX8™ in a US clinical study of 284 patients. All these adverse events were either possibly or definitely related to the hernia repair procedure, and therefore not necessarily a direct result from the device.

- **Hernia recurrence: 0.7% of subjects had this effect**
- **Seroma: 13.4% of subjects had this effect**
- **Groin pain: 2.8% of subjects had this effect**
- **Neuralgia: 1.4% of subjects had this effect**
- **Hypoaesthesia: 0.7% of subjects had this effect**
- **Hematoma: 0.7% of subjects had this effect**
- **Intestinal obstruction: 0.7% of subjects had this effect**
- **Mesh infection: 0.7% of subjects had this effect**
- **Lymphadenitis: 0.7% of subjects had this effect**
- **Testicular pain: 1.4% of subjects had this effect**
- **Swelling: 0.7% of subjects had this effect**
- **Genital Hemorrhage: 0.7% of subjects had this effect**
- **Spermatic cord inflammation: 0.7% of subjects had this effect**
- **Orchitis: 0.7% of subjects had this effect**
- **Muscle Strain: 0.7% of subjects had this effect**

3. ADDITIONAL INFORMATION Cont.

A summary of additional Outside-US (OUS) studies that are supportive of the clinical safety and effectiveness of LIQUIFIX FIX8™ have briefly been summarized below. Although the laparoscopic version of the device was used, the studies support the clinical effectiveness of an identical adhesive for hernia mesh fixation.

- **In a 20 patient TAPP inguinal hernia repair prospective clinical study, no recurrence was reported up to 3-month post-operative follow-up[1].**
- **In a 34 patient TAPP inguinal and femoral hernia repair prospective clinical study, no recurrence was reported up to 12-month post-operative follow-up[2].**
- **In a 67 patient TAPP/TEP inguinal hernia repair prospective clinical study, one recurrence (1.5%) was reported at 1-day post-surgery. No other recurrence was reported up to 12-month post-operative follow-up[3].**
- **In a 196 patient TAPP inguinal and femoral hernia repair retrospective clinical study, one recurrence (0.5%) was reported up to 24-month post-operative follow-up[4].**
- **In a 152 patient TAPP/TEP inguinal hernia repair retrospective study using an iron-loaded mesh, there were no confirmed cases of recurrence at minimum 6-month follow-up[5].**
- **In a 10 patient TAPP inguinal hernia repair prospective study, there were no recurrent hernias, wound infections or hematomas reported up to 30-day post-operative follow-up[6].**

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GLOSSARY

Carolinas Comfort scale (CCS) - A specific questionnaire used to evaluate Quality of Life in patients who underwent abdominal hernia repair with mesh.
Hemorrhage - Loss of blood from damaged blood vessels.
Hernia - The bulging of an internal organ through a weak area or tear in the muscle or other tissue that holds it in place.
Hematoma - A pool of mostly clotted blood that forms in an organ, tissue, or body space.
Hypoaesthesia - Partial or total loss of sensation in a part of your body.
Intestinal Obstruction - A partial or complete block of the small or large intestine that keeps food, liquid, gas, and stool from moving through the intestines in a normal way.
Lymphadenitis - Enlargement in one or more lymph nodes, usually due to infection.
MRI - Magnetic Resonance Imaging is a non-invasive procedure in which radio waves and a powerful magnet linked to a computer are used to create detailed pictures of areas inside the body.
Neuralgia - Pain in a nerve pathway.
Orchitis - Inflammation of the testicles.
Seroma – A mass or lump caused by a build-up of clear fluid in a tissue, organ, or body cavity.
TAPP - Laparoscopic Inguinal Hernia Repair (TAPP) is keyhole surgery to repair a groin hernia. Transabdominal pre-peritoneal (TAPP) surgery is performed through the peritoneum lining of your abdominal cavity.
TEP - Laparoscopic Inguinal Hernia Repair (TEP) is keyhole surgery to repair a groin hernia. Totally extra peritoneal (TEP) surgery repairs your hernia without entering the perineal cavity.

Advanced Medical Solutions

Advanced Medical Solutions Ltd
Western Wood Way,
Langage Science Park,
Plymouth, Devon,
PL7 5BG, United Kingdom

T: +44 (0) 1752 209 955
E: info@liquiband.com

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