TECHNICAL NOTE



Device Explantation

It may be necessary to remove an implant intact, such as when it may be reused in another animal (following cleaning and re-sterilization), or if there have been any signal quality concerns and the implant is being sent back to DSI for analysis. The following guidelines should be followed to maintain the integrity of the implant and ensure proper cleaning and re-sterilization:

Implant

Careful dissection should be used to remove the implant and all tissue should be removed to allow for thorough sterilization. The implant should be handled with care. Avoid dropping it or suspending it from the biopotential leads or pressure catheter(s).

Biopotential Leads

The exposed biopotential wires may be cut near the insertion site, if needed (solid tip lead may not be cut for reuse). A suture should be tied at the end of the silicone tubing prior to enzymatic cleaning and sterilization to prevent fluid ingress up the lead. This distal portion including this suture and any exposed wire should be removed prior to re-implantation.

If there were any concerns with the biopotential signal(s), the placement of the exposed wires should be assessed prior to cutting to determine if all leads are in the correct position or if any post-operative migration may have occurred.

Catheter(s)

Explanting the catheter(s) intact requires careful dissection to remove it from the vessel/heart without accidentally cutting it. The use of fine-tipped [microsurgical] instruments may help to free the catheter from the surrounding tissue. A delicate scissors can be used to cut the suture knots very close to the catheter they are securing, allowing the knots to be unraveled so the catheter can be withdrawn. Alternatively, the catheter can be removed with the knots intact and the suture and associated tissue can be detached later.

If there were any concerns with the pressure signal(s), the placement of the pressure-sensing tip and quality of the surrounding tissue (e.g. vessel, heart chamber, etc.) should be assessed. The location where the catheter is placed should be carefully incised for observation *in situ*. Evidence of potential complications can include migration of the tip from the original intended insertion depth, fibrosis/thrombosis surrounding the pressure-sensing tip, discoloration or proliferation where the tip may be impacting the tissue, discoloration of the catheter tip, or organized blood/clot inside the catheter tip. The catheter should be carefully removed without creating excessive pressure

anywhere along the length, as this can damage the pressure sensor and/or disturb the catheter's meniscus. Once the catheter is removed, the tip may be rinsed with water to see if any blood that may be present rinses freely (normal post-mortem finding due to cooling) or if it appears organized which may indicate the presence of a clot that could negatively affect the pressure signal).

If the implant is being sent back for DSI Exchange and there are no concerns about signal quality that require analysis, it isn't necessary to remove it intact. In this case, the biopotential leads and catheter(s) may be cut to improve ease of explantation.

If cutting the catheter is necessary, use only a new scalpel blade to cut the catheter at a 45degree angle away from the device body and at least 3 cm from the device body. Do not use any instrument other than a scalpel blade to cut the catheter. Cutting the catheter with a pair of scissors or any other instrument could cause damage to the pressure sensor and void the warranty. If the catheter must be cut, the device can NOT be reused.

If present, an antenna may also be cut with a sharp instrument if needed for explantation; however, the device can NOT be reused after the antenna has been cut.

Glucose Sensor

Careful dissection should be used to remove the implant, connector board and reference lead and all tissue should be removed to allow for thorough sterilization. The implant should be handled with care. Avoid dropping it or suspending it from the sensor, connector board or reference lead. *Note:* The HD-XG implant is not reusable and must be sent to DSI for exchange after it is explanted.

If there were any concerns with the signal, the placement of the sensor tip, connector board, reference electrode and quality of the surrounding tissue (e.g. vessel) should be assessed. The vessel where the sensor is placed should be carefully incised for observation in situ. Evidence of potential complications can include migration of the tip from the original intended insertion depth (i.e. backing out of the sensor from the aorta, or perforation through the aorta), fibrosis/thrombosis surrounding the sensor tip, discoloration or proliferation where the tip may be impacting the tissue, kinking or bending of the sensor tip, or organized blood/clot over or around the sensor tip. The sensor should be carefully removed without creating excessive stress anywhere along the length, as this can damage the sensor. Once the sensor is removed, it may be rinsed with water to see if any blood or tissue that may be present rinses freely or if it appears organized which may indicate that the sensing capabilities were compromised. The entire length of the sensor and lead, including the connector board) should be carefully visualized under magnification, if possible, to check for any breaks or damage, fluid collection or other irregularities inside the tubing.

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Product Return Information

Explanted implants and contaminated equipment may constitute a biohazard. In order to protect anyone who may come in contact with the contaminated product and comply with national and international transportation regulations all implants and equipment that comes in contact with an animal must be cleaned and disinfected before it is returned to DSI.

Ensure that the devices are well packed, preferably in their original packaging and boxes, and return the devices via a traceable shipping method to prevent losses in transit.

A detailed procedure for properly returning telemetry devices to DSI is provided on our website: <u>http://www.datasci.com/policies/returning-products</u>

Contact DSI Technical Support with any concerns or comments regarding the performance of the devices, prior to returning them, to allow for proper handling and product analysis.

DSI Technical Support - U.S. and Canada

Email <u>support@datasci.com</u> Toll-free in U.S. and Canada Phone: 1-800-262-9687 Monday through Friday: 8 AM to 5 PM CST (except Holidays)

DSI Technical Support - Europe

Email: Europe-support@datasci.com Phone: +44 1359 259400 Monday through Friday: 8 AM to 5 PM CET (except Holidays)

DSI Technical Support - China

Email: <u>Apacsupport@datasci.com</u> Toll-free in U.S. and Canada Phone: +86-21-50793177 Monday through Friday: 9 AM to 5 PM CST (except Holidays)

DSI Technical Support – All Other Countries

Email: <u>support@datasci.com</u> Phone: +1-651-481-7400 Monday through Friday: 8 AM to 5 PM CST (except Holidays)

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