Customer Feedback Form

The inclusion of as many details as possible greatly aids the complaint investigation process as well as provides useful information for continuous improvement. Missing information will delay processing.

A. Customer Information

Date: _____
Account #: _____
Account Name: _____
Address: _____
City, Zip, Country: _____
Phone #: _____
E-mail: _____
Submitted By: _____

B. Product Information: One form should be used per patient or event.

Item #	*Lot#*

Are we replacing the same product? ☐ Yes ☐ No - Please provide length and diameter of the requested replacement product: _____ No credit will be issued.

C. Event Information

Implantation Date (dd/mm/yy): _____ Event Date (dd/mm/yy): _____ Removal Date (dd/mm/yy): _____

Description of the Event (check all that apply):
☐ No Primary Stability ☐ Loss or Failure of Integration ☐ Packaging or Labeling ☐ Fracture ☐ Malfunction
☐ Other (please describe) _____

Discovered:
☐ During Receiving ☐ Unpacking ☐ During Clinical Procedure ☐ During Laboratory Procedure
☐ Other: _____

Provide a detailed description of the reported problem (including procedure being performed, related products and settings used): _____

Was there any injury to the patient as a result of the event? ☐ ***Yes*** ☐ ***No***
If yes, please describe: _____

Describe what happened to the patient as a result of the event (check all that apply):
☐ No Patient Impact ☐ Allergic Reaction ☐ Aspiration ☐ Hemorrhage ☐ Nerve Damage ☐ Pain ☐ Bone Loss
☐ Dehiscence ☐ Delayed Healing ☐ Edema ☐ Hyperesthesia ☐ Hyperplasia ☐ Infection ☐ Inflammation ☐ Ingestion
☐ Other: _____

Other Relevant Patient History (check all that apply):

☐ Smoker/Tabacco use ☐ Poor Oral Hygiene ☐ Bruxism ☐ Osteoporosis ☐ Clenching ☐ Diabetes
☐ Other: _____

D. Patient Information

Gender: ☐ Male ☐ Female

Patient Age: _____

Implant Position: _____

Bone Density Type: ☐ I ☐ II ☐ III ☐ IV ☐ Unknown

Instructions:

When returning products, the following guidelines must be followed:

- Used product MUST be sterilized in pouches which show sterility with color change or other indications prior to shipping. Please refer to Implant Direct IFU-001 for sterilization requirements.
- Return only the complaint product.

According to legal requirements, please attach the present form to the returned items.
The product should be returned to the following address.

Nederland
Implant Direct Benelux
Jan Muschlaan 21a
3584 GV Utrecht

Telefoon: +31 (0) 30 25 998 25
E-mail: info@implantdirect.nu