



## TERMS AND CONDITIONS OF CELLFINA® SYSTEM PURCHASE AND USE

**Agreement:** Customer's sales agreement cover page, these Terms and Conditions of Cellfina System Purchase and Use, and the Cellfina System Limited Warranty (collectively, this "Agreement") constitute the entire binding agreement by and between the customer set forth on the cover page hereof ("Customer") and Merz North America, Inc. ("Merz"; Customer and Merz, hereinafter, collectively, the "Parties") regarding Customer's purchase and use of the Cellfina System and/or related disposables (collectively, "Products"). This Agreement supersedes all other agreements and understandings, whether written or oral, between the Parties. Notwithstanding anything to the contrary, whether executing a purchase order, quotation, proposal, standing order, or letter of authorization, or by accepting delivery of the Products, Customer agrees to be bound by and accept the terms and conditions contained in this Agreement. No additions, conditions, amendments, alterations, or modifications by Customer or any other person, whether oral or contained in any other documents submitted from Customer to Merz will be binding on Merz, regardless of Merz's failure to object or Merz's shipment of Products, unless otherwise agreed to in writing and signed by Merz. These terms and conditions may be updated or amended from time to time by Merz without notice to Customer; a copy of such updated terms will be available for Customer's review at <http://www.merzusa.com/about-merz/terms-and-conditions-products/>. Customer agrees to be bound by the most recent terms. THIS AGREEMENT WILL APPLY UNLESS CUSTOMER HAS A SEPARATE WRITTEN AGREEMENT WITH MERZ THAT EXPRESSLY REPLACES THIS AGREEMENT.

**Prices and Payment Terms:** Applicable sales tax will be invoiced unless Customer supplies a valid tax-exempt certificate prior to delivery. Applicable shipping, handling, and other taxes will be added to the final invoice price for each order. A non-refundable \$10,000 deposit is required to secure purchase of *each* Cellfina System. Full payment of the balance due on the System(s) is due upon receipt of the System(s) unless the Parties have expressly agreed to a different payment schedule in writing. For disposable Products, full payment of the invoice is due within thirty (30) days of the order. If Customer's account is delinquent by more than thirty (30) days, it shall accrue interest at the rate of 1.5% per month on the balance due or, if less, the maximum rate permitted by law. Merz reserves the right to change Product prices and discontinue Products without prior notice. If Customer fails to fulfill the terms of payment or does not meet Merz's continuing credit requirements, Merz will have the option to do one or more of the following: (i) decline to accept orders or fulfill pending orders; (ii) require all pending and future orders to be on a prepaid basis; (iii) delay any shipment until payment is received by Merz or further assurances asked for by Merz are received; (iv) declare all outstanding sums immediately due and payable; or (v) require payment for all Products delivered hereunder to be made by irrevocable letter of credit in a form approved by Merz. Nothing contained herein will release Customer from any previous obligations. Customer will be liable to Merz for all costs incurred by Merz in its collection of any amounts owing by Customer which are not paid when due, including collection agencies' and attorneys' fees and expenses, regardless of whether a lawsuit is commenced. All orders are subject to current credit approval. From time to time, Merz may review Customer's creditworthiness. Customer agrees to provide Merz with all credit information reasonably requested, and Customer represents and warrants to Merz now, and each time Customer places an order, that all information Customer has provided is true and correct.

**Delivery and Risk of Loss; Lead Times:** Unless otherwise agreed in writing between the Parties, all orders within the United States will be delivered FOB Merz's facilities. Upon Merz's tender of the Products to a common carrier, title and risk of loss shall pass to Customer, and delivery shall be deemed completed. Quoted delivery dates are estimates only; however, Merz will make commercially reasonable efforts to fulfill each order by the quoted delivery date. In particular, Customer acknowledges that delivery lead time is currently approximately one hundred and twenty (120) days after receipt of the Product order and deposit, and Customer hereby consents to such delivery lead time. At times, Merz may ship partial orders as needed. All shipments are fully insured for the benefit, and at the expense, of Customer.

**Inspection and Acceptance; Returns:** Orders may not be cancelled after shipment, and delivered Products may not be returned without Merz's prior written consent (which consent may be withheld in its sole discretion). Customer must inspect delivered Products and report claims for defects, damages, shortages, or receipt of wrong Products which are discoverable on a visual inspection within 72 hours of delivery, or the Products will be deemed irrevocably accepted and such claims will be deemed waived. However, shipping damage claims must be made by Customer directly with the shipping company in accordance with such company's policies, which generally require such claims to be made prior to the time the carrier of the Products leaves the delivery destination. In the event of loss or damage in transit, Customer's payment obligations will not be affected, and Merz will act as Customer's agent in making any necessary insurance claim. The terms and conditions for returning any Products purchased from Merz will be those contained in Merz's Returned Material Authorization Policy ("RMA") in effect as of the date of shipment of the Products to Customer. Accepted returns are subject to the charges, terms and requirements provided in writing to Customer (which may include forfeit of deposit). No acts on the part of Merz, including but not limited to, Merz's receipt of returned Products from Customer, shall constitute Merz's approval and acceptance of the returned Products or cancelled order, unless Merz has provided its prior written consent to Customer.

**Changes to Products:** Merz may from time to time change the design or construction of the Products. In the event a significant change occurs after Customer's order but prior to shipment, Merz shall notify Customer, and Customer shall be entitled to accept the changed Product, or to cancel this Agreement as to that Product only and receive a refund of any monies paid for that Product only. The foregoing shall be Customer's sole and exclusive remedy for any Product changes prior to delivery, and Merz shall have no other liability whatsoever for any such changes.

**Cellfina Yearlong Assurance Guarantee:** Merz is confident that Customer's patients will be satisfied with the results of their Cellfina procedure. To that end, if, one year following her Cellfina treatment, any Cellfina patient of Customer, who resides in the United States, Puerto Rico or Guam, experiences the recurrence of cellulite dimples which were released in her initial Cellfina procedure, then Merz agrees to (1) remit to Customer up to \$2,500 for patient's use toward operating room costs, anesthesia costs, and other costs not covered by insurance and related to a second dimple removal procedure; and (2) provide one replacement Cellfina kit to Customer. In order to be eligible for such benefits:

- (A) Customer must have individually participated in the Merz Cellfina procedure training prior to the affected patient's procedure; and
- (B) Customer must have obtained the patient's written consent to share her protected health information regarding her Cellfina treatment with Merz to this Agreement and the Customer must provide, upon request, a copy of such signed consent to Merz along with the patient's Cellfina treatment record.
- (C) The patient must have registered her procedure online at [www.cellfinaguarantee.com](http://www.cellfinaguarantee.com) within thirty (30) days of the date of the original procedure. Such registration will require the following from patient: patient name, patient date of birth, patient contact information, date of original procedure, name of physician/practice where original procedure was performed, and Cellfina kit lot number.

In order to remit a claim, Customer must submit a claim request to Merz at [cellfinawarranty@merz.com](mailto:cellfinawarranty@merz.com) prior to performing the second treatment on the patient and within one (1) year following the patient's initial procedure, which request must include the patient's name, the patient's date of birth, the original procedure date, the reason(s) for the claim, properly photographed before and after photos of the patient's treated area, the original Cellfina kit lot number, and any other information reasonably requested by Merz. **Customer hereby represents and warrants that it will have obtained a written HIPAA/privacy consent and release from patient prior to transferring any of the aforementioned information to Merz, and Customer agrees to indemnify Merz for any claims or damages relating to Customer's failure to obtain such a consent. A sample consent is attached to these Terms and Conditions of Cellfina Purchase and Use.**

Upon receipt of the request from Customer, Merz will review its records in order to confirm that the eligibility prerequisites are met, and it will respond to Customer within sixty (60) days of receipt of Customer's request in order to accept the request, reject the request (in which case Merz shall provide the reason(s) for such rejection), or obtain further information. If Merz accepts Customer's request, then Merz shall provide the replacement kit to Customer within sixty (60) days of request acceptance, and Merz shall remit the monetary reimbursement to Customer within sixty (60) days of Merz's receipt of an invoice for such amount from Customer.

This Patient Satisfaction Warranty is only available beginning on October 1, 2017, and only for appropriately qualified, licensed physicians in the United States, Puerto Rico, and Guam.



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Customer acknowledges that Merz is required to report expenditures on health care providers to the federal government and in certain other jurisdictions, and that, accordingly, the value of the free Cellfina kit may be reported to any agency which mandates such reporting.

**Limited System Warranty:** Please refer to the Cellfina System Limited Warranty and (if applicable) Cellfina Service Contract.

**Use and Transfer of Products:** For regulatory compliance, medical oversight, and training purposes, Merz documents and tracks the Product(s) delivered to each Customer site. Products must be operated under the direction of a physician, in accordance with the Instructions for Use and Customer's applicable state medical regulations. Merz prohibits the re-sale or rental of Products by U.S. customers, regardless of whether such Products are new or used, or are sold within or outside the United States. Without limiting the foregoing, sale or transfer of Products to third parties for uses unauthorized by Merz (e.g., refurbishment, modification, etc.) is also prohibited. Customer acknowledges that refurbished Products are not FDA-cleared, do not meet the strict manufacturing and quality controls of Merz, and may result in patient safety concerns. If Customer uses refurbished Products, Customer assumes full liability for any adverse event that occurs. In addition, because it is unable to regulate the quality of refurbished Products, Merz is required to notify the FDA of any known violations, as well as any individuals suspected of being involved in these unlawful practices. Customer hereby further acknowledges and agrees that the Products are covered by valuable intellectual property owned by or licensed to Merz, including one or more valid United States patents. Neither this Agreement nor Customer's purchase of the Product shall be construed as a grant of any other rights in or to the intellectual property covering the Products. Customer acknowledges that Customer's unauthorized use or use of unauthorized products/components, or unauthorized transfer of the Product(s) would cause immediate, material, and irreparable harm to Merz. In the event of any violations of this section, then, in addition to any other remedies available to Merz, Merz may refuse to sell future Products to Customer or refuse to service Systems.

**Unauthorized Service Providers:** Merz is the only authorized service provider for the Products. Due to safety and quality concerns, Merz prohibits the repair of any Products by an unauthorized service provider. Use of an unauthorized service provider will immediately void any and all warranties or service contracts in effect.

**Reporting.** The Customer agrees to notify Merz within 24 hours of the occurrence of any event that reasonably suggests that a device has or may have caused or contributed to a death or serious injury, including events occurring as a result of a failure, malfunction, improper or inadequate design, manufacture, labeling, or user error. Customer will maintain adequate tracking for the Products to enable Merz to meet the FDA requirements applicable to the tracking of medical devices.

**Traceability.** Customer will create and maintain accurate records of all activities and events related to the Products to the extent necessary to ensure product traceability. The records will be constructed in such a manner that all significant activities or events will be traceable for a period of not less than 10 years past the date of manufacture. Such records must be clear, readily available, and include the following: (i) each order received and accepted; (ii) the serial or lot number and expiration date of the Product(s) and the address where Product(s) are delivered; (iii) the method of identifying the invoice issued to an end customer; and (iv) each end customer credit issued and the reason therefor.

**Customer Complaints.** Customer will cooperate fully with Merz in dealing with end customer complaints concerning the Products and will take such action to resolve such complaints as deemed necessary or appropriate by Customer or as may be otherwise reasonably requested by Merz. Customer agrees to report to Merz any complaint regarding a Product of which Customer becomes aware within 24 hours of becoming aware. Customer agrees to assist Merz to facilitate the resolution of complaints. For purposes of this Agreement, a complaint can be the occurrence of any of the following: (i) receipt of any Product(s) quality claims, medical claims, or complaints or other written claims or complaints; or (ii) receipt of any written communication from any applicable regulatory agency pertaining to a Product.

**Anti-Kickback Statute.** It is the intent of Customer and Merz to comply with the Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)) and the Discount Safe Harbor and Warranties Safe Harbor regulations set forth in 42 C.F.R. 1001.952(h) and (g), respectively. Customer's price may constitute a 'discount or other reduction in price' under the Anti-Kickback Statute. Merz will provide Customer with invoices that fully and accurately disclose the discounted price of all Products purchased under this Agreement to allow Customer to comply with this Section and the Discount Safe Harbor regulations, including sufficient information to enable it to accurately report its actual cost for all purchases of Products. Customer acknowledges that, if applicable, it will fully and accurately report all discounts or other price reductions, including warranty items, in the costs claimed or charges made under any Federal or State healthcare program and provide information upon request to third-party reimbursement programs. Customer will be solely responsible for determining whether any savings or discount or warranty item it receives must be reported or passed on to payors.

**Foreign Corrupt Practices Act.** Customer will comply with all applicable anti-corruption, anti-bribery, and anti-kickback laws, rules, and regulations, including, without limitation, the United States Foreign Corrupt Practices Act (15 U.S.C. §78dd-1, et seq.) and other laws, rules, and regulations applicable to where Customer conducts business.

**Limitation of Liabilities and Remedies.** UNDER NO CIRCUMSTANCES WILL EITHER PARTY HAVE ANY LIABILITY TO THE OTHER PARTY FOR, AND EACH PARTY HEREBY EXPRESSLY WAIVES, ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE DAMAGES OF ANY DESCRIPTION, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, WHETHER ARISING OUT OF WARRANTY OR CONTRACT, NEGLIGENCE OR OTHER TORT, OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, FORESEEABLE BUSINESS LOSSES, LOSS OF PROFITS, AND RELIANCE DAMAGES. CUSTOMER AGREES THAT UNDER NO CIRCUMSTANCES WILL MERZ'S LIABILITY RELATING TO ITS SALE OF PRODUCTS TO BUYER FOR ANY CAUSE EXCEED THE PURCHASE PRICE PAID BY CUSTOMER FOR THE PARTICULAR PRODUCTS INVOLVED. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, THE REMEDIES SET FORTH IN THIS AGREEMENT WILL APPLY EVEN IF SUCH REMEDIES FAIL THEIR ESSENTIAL PURPOSE.

**Indemnity.** To the fullest extent permitted by law, Customer will indemnify, defend, and hold harmless Merz, including Merz's affiliates and their officers, directors, agents, employees, successors, and assigns, from and against any claim, demand, cause of action, debt, liability, loss, fine, damage, or expense (including reasonable attorneys' or legal fees, expenses, and court costs) (collectively, "Liabilities") that relate to: (i) Customer's modification of or addition to any Product(s); (ii) Customer's breach of this Agreement; (iii) Customer's gross negligence or willful misconduct; or (iv) Customer's failure to abide by all applicable laws, rules, regulations, and orders that affect the Products. To the fullest extent permitted by law, Merz will indemnify, defend, and hold harmless Customer, including Customer's officers, directors, agents, employees, subsidiaries, affiliates, parents, successors, and permitted assigns, from and against any Liabilities arising out of a third party claim (i) for bodily injury to or property damage to the extent caused by a defect in a Product manufactured by Merz; (ii) to the extent caused by Merz's breach of this Agreement; or (iii) to the extent caused by Merz's gross negligence or willful misconduct. Merz is not required to indemnify Customer to the extent that any claim arises out of Customer's gross negligence or willful misconduct or use of a Product by any person or entity other than in accordance with this Agreement and Merz-approved Product labeling, and restrictions on transfer or re-use of Products.

**Essential Basis of the Bargain.** Customer acknowledges that Merz has set its Product prices and entered into the Agreement in reliance upon the limitations and exclusions of liability, the disclaimers of warranties, and Customer's indemnity obligations set forth herein, that the same form an essential basis of the bargain between the Parties, and THAT THE CONSIDERATION WOULD BE HIGHER IF MERZ WERE REQUIRED TO BEAR LIABILITY IN EXCESS OF THAT STATED HEREIN.

**Financing and Assignment:** This Agreement binds Customer, regardless of any financing arrangements, subrogations or assumptions. Customer may not assign its rights or delegate its obligations hereunder except with the prior written consent of Merz (which consent may be withheld in its sole discretion). Merz may subcontract the performance of any obligation of Merz under the Agreement, and Merz may assign any right or obligation under the Agreement, to an affiliated party of Merz.

**Independent Contractors.** No provision of this Agreement will be deemed to create a partnership, joint venture, or other combination between Merz and Customer. Customer and Merz are independent contractors. Neither Party will make any warranties or representations or assume any obligations on the other Party's behalf. Neither Party is or will claim to be a legal representative, partner, agent, or employee of the other Party. Each Party is responsible for the direction and compensation, and is liable



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for the actions of, its employees and subcontractors.

**Amendments:** The Agreement may not be amended, altered or modified except in writing by an authorized signatory of Merz. No other purported additions, amendments, alterations or modifications by Customer or any other person, whether oral or written, shall be binding on Merz, regardless of Merz's failure to object or Merz's shipment of products. In the event of a conflict between these terms and conditions and any other part of this Agreement, these terms and conditions shall govern.

**Governing Law:** This Agreement shall be construed in accordance with the laws of the State of North Carolina, USA without giving effect to its conflicts of laws rules. Customer hereby consents to the jurisdiction and venue of any North Carolina state or federal courts, and hereby waives any objections based on inconvenient forum or conflicts of laws principles. The provisions of this Agreement are divisible and the invalidity or unenforceability of any provision or provisions contained herein shall not in any way affect the validity of this Agreement without the invalid or unenforceable provision or provision.

**Severability:** If any provision of this Agreement shall be determined to be illegal or unenforceable by any court of law in any jurisdiction, the remaining provisions hereof and thereof shall be severable and enforceable in accordance with their terms, and all provisions shall remain enforceable in any other jurisdiction.

**Entire Agreement:** Customer and Merz acknowledge that there have been no warranties, representations, covenants or understandings made by either Party to the other, except such as are expressly set forth in the Agreement. **Without limiting the foregoing, Customer acknowledges and agrees on behalf of him/herself individually and on behalf of the Customer entity, that, in entering into this Agreement and this transaction: (1) it has relied solely on the terms and conditions of this Agreement; and (2) it has not relied on any oral or written statements by Merz sales representatives, other Merz personnel, or third parties (including, but not limited to, third-party financing companies), or on any statements included in any of Merz's written or electronic promotional materials (including its web sites). In particular, Customer acknowledges that Merz makes no representations or warranties regarding Customer's authority to utilize the Products in the state(s) in which Customer operates; on the contrary, Merz is relying on Customer's representation that Customer is properly licensed and authorized to utilize the Products.** This Agreement constitutes the entire understanding and obligation of Customer and Merz with respect to the subject matter of this Agreement and supersedes any prior agreements, writings, or understandings, whether oral or written.



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**PATIENT AUTHORIZATION TO DISCLOSE PROTECTED HEALTH INFORMATION**

This notice describes how private medical information about your Cellfina treatment may be used and disclosed. The manufacturer of the Cellfina system, Merz North America, Inc. (“Merz”) is so confident in the effectiveness of its medical device that it provides an optional guarantee to any Cellfina patient who chooses to participate in the Cellfina Yearlong Assurance Guarantee Program. To that end, if, within one year following your Cellfina treatment, you experience the recurrence of cellulite dimples that were released in your initial Cellfina procedure, Merz will reimburse your treating health care provider for up to \$2,500 toward operating room costs, anesthesia costs, and other costs not covered by insurance and related to a second dimple release procedure, and provide your health care provider one replacement Cellfina kit for use in a second dimple release procedure.

In order to participate in the program you agree that the health care provider who performed your Cellfina treatment may provide copies of private medical information related to your Cellfina treatment to Merz so that Merz may evaluate the effectiveness of the Cellfina procedure. This medical information will include “before and after” photos of your treatment area (which may include photographs of your bottom and thighs), your health care provider’s treatment notes, and any other medical information related to your Cellfina treatment.

This Patient Authorization to Disclose Protected Health Information will be valid for two (2) years of the date you signed it.

Signed, this the \_\_\_\_ day of \_\_\_\_\_, 20\_\_

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Print Patient Name