

**Medtronic Representative Confirmation Form / Unable to Obtain Customer Confirmation Form**

**URGENT: MEDICAL DEVICE RECALL**

**Octopus™ Tissue Stabilizer - Canister Incorrect Tubing Configuration**

Account/Hospital/Physician name: \_\_\_\_\_

Country: \_\_\_\_\_

This form is for use by Medtronic Representatives to document communication attempts, to consignees and/or complete additional actions, as applicable, for the field corrective action (e.g. software updates).

Please see important guidelines on how to fill out this form correctly at the bottom; non-compliant forms **will be rejected**.

Please tick only one (1) of the boxes below to indicate the status of communication with the account, customer or physician:

By signing this form, I confirm that:

- The customer listed above has received the Urgent Medical Device Correction letter/Urgent Field Safety Notice.

<input type="checkbox"/> verbally	<input type="checkbox"/> during a site visit (the FSN was hand delivered to the customer) <input type="checkbox"/> through a phone call Date acknowledged (dd-mmm-yyyy): _____ Name of acknowledging person: _____ Job title: _____
<input type="checkbox"/> via email	Provide copy of email acknowledgment (applicable per local requirements)

- Despite multiple attempts, Medtronic was unable locate or reach successfully the <account/physician> listed above / obtain a signed consignee confirmation.

Please document all confirmation attempts in the table below (and add communication evidence). These attempts must be made in accordance with regional requirements using various contact methods.

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Attempt	Date (DD/MMM/YYYY)	Communication method	Individual Contacted Name and Title	Include Proof (if applicable)
1		<input type="checkbox"/> Telephone <input type="checkbox"/> Site Visit <input type="checkbox"/> Email <input type="checkbox"/> Other_____	Name:  Title:	
2		<input type="checkbox"/> Telephone <input type="checkbox"/> Site Visit <input type="checkbox"/> Email <input type="checkbox"/> Other_____	Name:  Title:	
3		<input type="checkbox"/> Telephone <input type="checkbox"/> Site Visit <input type="checkbox"/> Email <input type="checkbox"/> Other_____	Name:  Title:	

I confirm that multiple attempts were not necessary because:  
*Tick this box if one of the following reasons applies. Then tick the appropriate sub-reason below.*

Account is no longer in business

Refused to sign

Physician is retired\*

Physician is deceased\*

Physician relocated (provide any known new location information) \* \_\_\_\_\_

*\*Please provide new physician name(s) for existing records on the following line if known (if a specific physician has not been assigned, please confirm following clinic/account)*

\_\_\_\_\_

Details: (if field is not applicable, please remove from form)

\_\_\_\_\_  
 \_\_\_\_\_

Please tick **one (1)** of the boxes below;

The customer has returned all unused affected devices. See the table below for details of returned devices.

The customer has no unused affected devices. Indicate "N/A" in the table below if no unused affected devices were located at the account.

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- No information is available about unused affected devices since I (Medtronic Rep) was not able to locate the customer.
- The customer/Medtronic Reps was unable to locate the affected devices/lost at the customer location/in-transit. Please indicate the details of the untraceable/ lost units in the table below.

Details:

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Product	Lot #	Quantity (in eaches)

As a Medtronic Representative, I certify that the information on this form is, to the best of my knowledge, complete and accurate.

Medtronic Representative Name (Print): \_\_\_\_\_

Medtronic Representative Title (Print): \_\_\_\_\_

Medtronic Representative Signature (Ink): \_\_\_\_\_

Date (DD/MMM/YYYY) \_\_\_\_\_

Please send this completed form (or questions) via email to Medtronic at [rs.seandfmplusca@medtronic.com](mailto:rs.seandfmplusca@medtronic.com).

## Important Guidelines:

Confirmation Forms are an FCA document and **MUST** be completed properly following good documentation practices for quality including:

- One form per Account/Physician.
- 2, 3, or 4 documented attempts (depending on country) using at least 2 different methods must be included if the account/physician was unable to be reached.
- Evidence for contacting the account via email / (phone)call / messaging apps such as copy of the email or screenshots of call logs or messages must be attached in this form (applicable per local requirements).
- There should be at least 7 calendar days from first attempt to the last attempt to conform to regulator expectation of good faith attempts
- All sections of the form must be completed
  - Account/Physician information (top of the form) must be fully completed including physician name, physician account and address (If available, as applicable per local requirements).
  - Box checked (where required/applicable).
  - Please provide as much detail as is available
  - Person completing the form must sign by hand in ink or via DocuSign/Adobe fill (depending on local requirement) and sign signature. **(Simply typing a name in the signature field is NOT ACCEPTABLE)**
- Errors must be corrected with a single line strike through, initials, date, and error explanation. **NO white out, completely blacking out text, etc.**
- Completed forms can be returned electronically. If submitting electronically, it is acceptable to scan using a smart phone or tablet. Image of the form must be good quality **(information cannot be cutoff, blurry, illegible).**